

European Observatory on Health Systems and Policies

Paying for Health

Learning from International Experience
in Health Financing

Edited by Jonathan Cylus,
Rebecca Forman, Nathan Shuftan,
Elias Mossialos and Peter C. Smith

CAMBRIDGE





Paying for Health

Health care financing is key in defining interactions between providers and the general population. It determines who is required to pay for care, how much they pay, and what types of services patients can receive. It also helps shape markets for health service providers and innovations in service delivery, pharmaceuticals and medical devices. *Paying for Health* brings together insights from over 50 global experts to provide a vital analysis of health care financing around the world, explaining issues related to funding both health and social care. It explores key aspects of health financing, delving into critical policy questions and examining strategies that shape sustainable, effective health systems. Offering real-world examples and evidence-based insights, this essential volume equips policymakers, researchers, and health leaders with the tools to design financing systems that drive progress now and in the future towards universal health coverage.

This title is also available as Open Access on Cambridge Core.

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European Observatory on Health Systems and Policies

The volumes in this series focus on topical issues around the transformation of health systems in Europe, a process being driven by a changing environment, increasing pressures and evolving needs.

Drawing on available evidence, existing experience and conceptual thinking, these studies aim to provide both practical and policy-relevant information and lessons on how to implement change to make health systems more equitable, effective and efficient. They are designed to promote and support evidence-informed policy-making in the health sector and will be a valuable resource for all those involved in developing, assessing or analyzing health systems and policies.

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The European Observatory on Health Systems and Policies supports and promotes evidence-based health policy-making through comprehensive and rigorous analysis of health systems in Europe. It brings together a wide range of policy-makers, academics and practitioners to analyse trends in health reform, drawing on experience from across Europe to illuminate policy issues.

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Contents

<i>List of Figures</i>	page xii
<i>List of Tables</i>	xvi
<i>List of Boxes</i>	xviii
<i>List of Contributors</i>	xx
<i>List of Abbreviations</i>	xxiii
<i>Foreword</i>	xxvii
<i>Reference Series Foreword</i>	xxx
<i>Acknowledgements</i>	xxxii
<i>Executive summary</i>	xxxiii
Introduction	1
<i>Jonathan Cylus, Rebecca Forman, Nathan Shuftan, Elias Mossialos, Peter C. Smith</i>	
Section 1: Revenue raising	27
1.1 General taxation and social health insurance	29
<i>Ajay Tandon, Christoph Kurowski, David B. Evans</i>	
1.2 Community-based health insurance	63
<i>Lucy Kanya, Manuela De Allegri, Valéry Ridde</i>	
1.3 Voluntary health insurance	91
<i>Anna Sagan, Sarah Thomson</i>	
1.4 Official development assistance for health	116
<i>Azusa Sato</i>	

Section 2: Pooling resources and defining benefits	135
2.1 Approaches to risk pooling <i>Sophie Witter, Joseph Kutzin, Susan Sparkes</i>	137
2.2 Setting a health benefits package <i>Michael Drummond, Aleksandra Torbica, Jonas Schreyögg</i>	165
2.3 Decommissioning/disinvestment: reducing the provision of low-value care <i>Michael Anderson, Humza Malik, Elias Mossialos</i>	196
2.4 User charges <i>Jonathan Cylus, Riya Doshi, Sarah Thomson, Tamás Evetovits</i>	224
2.5 Long-term care: its financing and provision <i>Tiago Cravo Oliveira Hashiguchi, Ana Llena-Nozal, Michael Mueller, José Carlos Ortega Regalado, Eileen Rocard, Francesca Colombo</i>	245
Section 3: Commissioning and purchasing	283
3.1 Paying for primary care <i>Anne Sophie Oxholm, Anthony Scott</i>	285
3.2 Methods for paying hospitals <i>Stephen Duckett, Andrew Street, Chris Walters</i>	320
3.3 Informal payments in health care <i>Sara Allin, Ilias Kyriopoulos, Iva Parvanova</i>	360
3.4 Paying for medicines <i>Nicole Mauer, Daniela Moye Holz, Sabine Vogler, Dimitra Panteli</i>	405
3.5 Paying for integrated care <i>Søren Rud Kristensen, Ewout van Ginneken, Matthew Sutton</i>	452

3.6	Balancing incentives to promote quality of care and improve long-term care <i>Ruth Waitzberg, Sharona Tsadok Rosenbluth</i>	478
3.7	From vertical to horizontal priority-setting: funding and procurement mechanisms <i>Ranjeeta Thomas, Kalipso Chalkidou</i>	515
3.8	Financing pandemic preparedness <i>Susan Sparkes, Andrew Mirelman, Alexandra Earle, Ankur Rakesh, Jonathan Abrahams</i>	540
3.9	Antibiotics as global public goods <i>Matthew Renwick</i>	572
3.10	Financing innovation for neglected diseases <i>Marisa Miraldo, Mujaheed Shaikh, Mohamed Gad</i>	611
	<i>Index</i>	674

Figures

0.2.1	How does money flow through the health system? The health financing functions	<i>page 2</i>
0.2.2	Average share of health spending by financing agent, by country income grouping, 2021	8
1.1.1	Public financing is a much bigger share of health spending in richer countries	40
1.1.2	OOP falls as public spending grows: the inverse relationship between public versus OOP spending on health, 2019	41
1.1.3	Spending has increased across the board but patterns of spending have evolved differently in low-, middle- and high-income countries	42
1.1.4	General government revenues are a small proportion of GDP in lower-income countries	45
1.1.5	Old-age dependency ratios are projected to increase in many (middle- to higher-income) countries	54
1.3.1	In 2021, the number of countries in which VHI accounted for at least 10% of current spending on health was very small	97
1.3.2	In 2021, the VHI share of current spending on health was highest in UMICs	97
1.3.3	In 2021 the VHI share of current spending on health was higher in the Americas than in other parts of the world	98
1.3.4	Not many countries saw substantial changes in the VHI share of current spending on health between 2000 and 2021	99
1.3.5	Public spending on health is more likely to reduce OOPs than VHI	104
2.1.1	Pooling arrangement classifications	144

2.2.1	A benefits package involves consideration of coverage in terms of cost, service and population	167
2.2.2	A framework can be used to help identify “best buys” and priorities for the health system given different budget thresholds	185
2.2.3	A generic framework for setting a benefits package will require context-specific interpretation	189
2.3.1	Conceptual framework for disinvestment from low-value care	198
2.4.1	OOP spending disproportionately finances pharmacies as compared to hospitals	228
2.4.2	Households in the poorest quintile have the highest level of catastrophic spending due to OOP payments	232
2.4.3	OOP spending can push households below or further below the poverty line	233
2.4.4	Low-income individuals are particularly vulnerable to experiencing unmet needs for health care due to cost	235
2.5.1	On average, OECD countries have five formal LTC workers per 100 people aged 65 years and over	249
2.5.2	Across 18 OECD countries, more than 1 in 10 people aged 50 years and older report providing informal care at least weekly	251
2.5.3	Women are most likely to take on the role of informal carer	251
2.5.4	A majority of OECD countries are moving LTC from residential facilities into the community	253
2.5.6	The largest share of total LTC spending in OECD countries is on nursing homes	261
2.5.7	Without public social protection, the majority of older individuals would not be able to afford LTC from their incomes alone	263
2.5.8	Instruments and procedures used to assess LTC needs vary widely	266
2.5.9	Nearly a third of people 65 years and older in the EU report at least one ADL/IADL limitation	271
2.5.10	The majority of LTC users are women and those aged 80 years and above	273

2.5.11	Just over half of older people reporting a need for help also report receiving help for it	274
3.2.1	Schema of payment flows in England	347
3.3.1	Prevalence of informal payments in selected countries, 2019–2021	385
3.3.2	Prevalence of informal payments in the EU, 2021	385
3.3.3	Prevalence of informal payments in the Asia–Pacific region, 2020	387
3.3.4	Share of GDP spent on health care versus percentage of patients who paid informally in the past 12 months, 2019–2021	388
3.3.5	OOP payments as share of total health spending versus percentage of patients who have paid informally in the past 12 months, 2019–2021	389
3.3.6	Physician density versus percentage of patients who have paid informally in the past 12 months, 2014–2021	390
3.4.1	Pharmaceutical expenditures are composed of the volume of medicines consumed times their prices	426
3.5.1	Three bundled payment schemes and how they vary on key dimensions	462
3.6.1	Framework to analyse financial flows in LTC and payments for providers	481
3.9.1	Number of new classes of antibiotics discovered or patented each decade	575
3.9.2	Antibiotic value chain and the barriers to R&D progression	577
3.9.3	Framework for developing a holistic incentive package for antibiotic development	581
3.9.4	Antibiotic drugs and alternative antibacterial therapies in clinical development	593
3.9.5	Types of alternative antibacterial therapies in development	595
3.9.6	Continuum of incentivization across the antibiotic value chain	596
3.10.1	Neglected diseases disproportionately affect LMICs	613
3.10.2	Neglected diseases have declined in richer countries but remain constant in LMICs	614

3.10.3	Top five neglected diseases: diarrhoeal diseases, HIV/AIDS, malaria, TB, and typhoid and paratyphoid	614
3.10.4	Global pharmaceutical companies are underinvesting in neglected disease R&D, 2019	617
3.10.5	Most money is spent on vaccines, drugs and basic research	617
3.10.6	Most R&D spending to address neglected disease challenges goes on just two stages	618
3.10.7	Academics and research institutions receive the biggest proportion of investment	619
3.10.8	Low-burden diseases receive more than their fair share of R&D	620
3.10.9	LMICs receive few market launches for new pharmaceutical products	621
3.10.10	HIV/AIDS, malaria and TB receive most investment	622
3.10.11	Low-burden diseases received more than their fair share of funding	623

Tables

0.2.1	User charges “cheat sheet”	<i>page 6</i>
0.2.2	Payment mechanisms “cheat sheet”	16
1.1.1	Private OOP spending is the largest source of funding for health among LICs and LMICS	39
1.1.2	Share of government expenditure for health, education, military and debt interest payments, 2019	50
1.3.1	VHI plays a supplementary role in most countries	95
2.2.1	Value-based formulary tiers, incremental cost-effectiveness ratio thresholds and co-payment levels	178
2.2.2	Current 69 priority health problems in the AUGÉ benefits package	181
2.3.1	Evidence on demand- and supply-side disinvesting interventions	203
2.3.2	Surgical procedures under the remit of phase one of the NHS England EBI programme	212
2.5.1	Higher-income countries tend to favour a mix of public, non-profit and for-profit provision of LTC	255
2.5.2	Overview of the use of means-testing in public support for LTC	264
3.1.1	The impact of different primary care payment models on health care system objectives	289
3.2.1	Key types of hospital payment method	329
3.3.1	List of cross-sectional surveys on informal payments	373
3.3.2	Countries in the EU by highest/lowest prevalence of informal payments, 2021	386
3.3.3	Countries in Asia by highest/lowest prevalence of informal payments, 2020	388
3.5.1	Payment methods to support coordinated and integrated care	461
3.6.1	Risk adjusters used in needs-based formulae for allocating pooled funds, 2018	493

3.6.2	Types of payment for nursing/care homes used in different countries	496
3.7.1	Key policy recommendations for donors and countries	534
3.8.1	International guiding instruments to frame public health threats and events and establish preparedness capacities	544
3.9.1	A selection of push and pull mechanisms available or proposed for incentivizing antibiotic R&D	580
3.9.2	Summary of initiatives incentivizing R&D	583
3.9.3	WHO priority pathogens list	592
3.10.1	Neglected diseases affect more than 1 billion people globally	612
3.10.2	Advantages and disadvantages of incentive mechanisms for innovation and access to innovation	628
3.10.3	PDPs have increased overall investment in R&D and innovation for neglected diseases	631
3.10.4	Selected examples of grants intermediaries	639
3.10.5	Fiscal incentives' effectiveness in stimulating neglected disease research is unclear	642
3.10.6	PRVs' impact on R&D is unclear because of a lack of data	648
3.10.7	Selected example of advanced market commitments	650
3.10.8	Selected examples of prizes	654

Boxes

0.1.1	Key challenges for the future in financing health systems for UHC	page li
0.2.1	What is UHC?	1
0.2.2	Defining efficiency, equity and quality in health care and systems	3
1.1.1	Parallel tax and SHI systems: India	36
1.1.2	Strengthening the tax system: Georgia	46
1.3.1	Medical savings accounts are inefficient, inequitable and do not provide sufficient financial protection	93
1.3.2	France demonstrates how difficult it is to achieve high levels of population coverage for complementary VHI covering user charges	107
1.3.3	VHI distorts the use of health system resources	108
2.1.1	Retrospective risk adjustment	150
2.2.1	Benefits of setting an explicit benefits package	169
2.5.1	Personal budgets in the Netherlands	257
3.1.1	The role of information technology and digital health infrastructure for primary care payment models	292
3.1.2	Payment methods for community pharmacists as their role expands to a first-contact point with the health system	296
3.1.3	Case study: the Quality and Outcomes Framework (QOF)	300
3.3.1	Adverse effects of informal payments on health systems	364
3.4.1	Definition: intellectual property rights	409
3.4.2	The role of public funding: COVID-19 vaccines and therapeutics	411
3.4.3	Industry spending on lobbying, marketing and consolidation	413

3.4.4	How do push and pull mechanisms work? Examples in the area of antimicrobial resistance (AMR)	414
3.4.5	Addressing R&D shortages: repurposing of medicines	418
3.4.6	What shapes manufacturers' prices?	428
3.4.7	Zolgensma® – worth the high price tag?	429
3.5.1	Common payment mechanisms in health care systems	455
3.6.1	Fragmentation within LTC financing systems	486
3.6.2	Summary of potential market failures in LTC and possible policy tools to mitigate them	489
3.6.3	Day care	496
3.6.4	Other tools to incentivize quality of LTC	499
3.7.1	Thailand's UHC scheme	525
3.7.2	Ghana's National Health Insurance Scheme	526
3.8.1	One Health approach	542
3.8.2	Programme budgeting: Australia	556
3.8.3	Pandemic Emergency Finance Facility (PEF)	561
3.10.1	PDP case study: Medicines for Malaria Venture and Coartem	635

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Abbreviations

ACO	accountable care organization
ADL	activities of daily living
AMC	advance market commitment
AMI	acute myocardial infarction
AMR	antimicrobial resistance
APVAX	Asia Pacific Vaccine Access Facility
ART	antiretroviral therapy
ATMP	advanced therapy medicinal product
AUGE	<i>Acceso Universal con Garantías Explicitas</i>
BARDA	Biomedical Advanced Research and Development Authority
BMGF	Bill & Melinda Gates Foundation
CARB-X	Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator
CBHI	community-based health insurance
CHE	current health expenditure
COPD	chronic obstructive pulmonary disease
COVID-19	coronavirus disease
CPRO	COVID-19 Pandemic Response Option
CSMBS	Civil Servant Medical Benefit Scheme (Thailand)
DAC	Development Assistance Committee
DALY	disability-adjusted life-year
DG-RTD	Directorate-General for Research and Innovation
DNDi	Drugs for Neglected Diseases initiative
DRG	diagnosis-related group
EBI	Evidence-Based Interventions (programme)
ECO	Economic Cooperation Organization
EDCTP	European and Developing Countries Clinical Trial Partnership
EIB	European Investment Bank
EMA	European Medicines Agency

EU	European Union
FFS	Fee-for-service
FDA	Food & Drug Administration
GAMRIF	Global Antimicrobial Resistance Innovation Fund
GARDP	Global Antibiotic Research and Development Partnership
G-BA	Federal Joint Committee (Germany)
GDP	gross domestic product
GNI	gross national income
GHS	global health security
GP	general practitioner
HBP	health benefits package
HERA	Health Preparedness and Response Authority
HNP	health, nutrition and population
HICs	high-income countries
HSFA	Health Security Financing Assessment
HTA	health technology assessment
IADL	instrumental activities of daily living
ICER	incremental cost–effectiveness ratio
IMF	International Monetary Fund
IMI	Innovative Medicines Initiative
INHS	Italian National Health Service
INN	international nonproprietary name
IPR	intellectual property rights
JPIAMR	Joint Programming Initiative on Antimicrobial Resistance
LICs	low-income countries
LMICs	low- and middle-income countries
LTC	long-term care
MDB	Multilateral Development Bank
MMV	Medicines for Malaria Venture
MRC	Medical Research Council
MSF	Médecins sans Frontières
NAPHS	National Action Plan for Health Security
NCD	noncommunicable disease
ND4BB	New Drugs for Bad Bugs
NGO	nongovernmental organization
NHA	National Health Accounts

NHS	National Health Service (United Kingdom)
NHIS	National Health Insurance Scheme
NIAID	National Institute for Allergy and Infectious Diseases (USA)
NICE	National Institute for Health and Care Excellence (United Kingdom)
NIHR	National Institute for Health Research (United Kingdom)
ODA	official development assistance
OECD	Organisation for Economic Co-operation and Development
OOP	out-of-pocket
P4C	pay for coordination
P4P	pay for performance
P4Q	pay for quality
PCO	primary care organization
PCP	primary care physician
PCV	pneumococcal conjugate vaccine
PDP	product development partnership
PEF	Pandemic Emergency Finance Facility
PPL	priority pathogens list
PRV	priority review voucher
QOF	Quality and Outcomes Framework
QuODA	Quality of Official Development Assistance
R&D	research and development
REDISSE	Regional Disease Surveillance Systems Enhancement (initiative)
SAP	structural adjustment programme
SDG	Sustainable Development Goal
SHA	System of Health Accounts
SHARE	Survey of Health, Ageing and Retirement in Europe
SHI	social health insurance
SME	small and medium-sized enterprise
SSNIT	Social Security and National Insurance Trust
TATFAR	Transatlantic Task Force on Antimicrobial Resistance
TB	tuberculosis
TIPR	transferable intellectual property rights
TPEs	transferable patent extensions
UCS	Universal Coverage Scheme (Thailand)
UHC	universal health coverage

UMICs	upper-middle-income countries
UNDP	United Nations Development Programme
USA	United States of America
VAT	value-added tax
VHI	voluntary health insurance
WHO	World Health Organization

Foreword

Navigating how to finance individual and public health services to enable progress towards universal health coverage remains a key issue for governments around the world as health systems are confronted with new pressures and demands. These challenges are complex and difficult and include the following examples: climate change has direct health consequences and is a cause of migration and conflict, which in turn have health implications; the health and socioeconomic effects of COVID-19 slowed growth, widened inequality and increased poverty, and the protective responses by governments in 2020 and 2021, while laudable, were funded mainly through deficit spending, which brings increases in debt service obligations; violent conflicts have directly harmful impacts on people's physical and mental health, and health facilities and health workers have also been explicitly targeted; redressing the chronic underinvestment in the training and employment of health workers remains a major challenge in much of the world; novel technologies for health, in addition to the promise they hold, pose many social and ethical implications, given the need to prioritize within finite resources; and the rise of antimicrobial resistance is not only a health threat but also a financial challenge.

In one sense, these challenges are not new; the need for both individual and public health services is growing faster than the available financial resources, and thus health systems face difficult trade-offs, even as they advocate for much-needed increases in spending. Reforms to improve efficiency can lessen the severity of these trade-offs, but they will always be with us.

However, the specific manifestations of the current challenges are new, and so too are the aspects of the global context noted above, plus the pressures arising from the approach of 2030 and the desire for quick fixes to reach the Sustainable Development Goals targets. From the perspective of health financing, and of health systems more

generally, we need to be vigilant and not let the urgency of the moment lead countries to act out of desperation. The calls, even if well-intentioned, for what might be deemed “zombie policies” – those bad ideas which keep coming back even though they have been shown not to work – may actually divert systems away from rather than towards universal health coverage.

This is why this book comes at such a crucial time. A multiyear effort by leading health policy analysts, this volume serves as a response to the need for evidence on how to organize and adapt health finance mechanisms to enable affordable, accessible and high-quality health services, even in the face of tight fiscal constraints. While publications on health financing exist, this is a unique and comprehensive resource that systematically examines each health financing function and investigates what the main issues are, why these arise, what the literature says about them and what country experience can tell us. This book takes a pedagogical approach that can serve policy-makers, practitioners and students alike. By unravelling the intricacies of why certain financing mechanisms persist while others waver, and highlighting country examples along the way, the book equips readers with the essential tools to comprehend, analyse and identify realistic and practical health financing reforms to support progress towards universal health coverage.

This endeavour has been undertaken under the auspices of the European Observatory on Health Systems and Policies, with which I have had the privilege to cooperate with for nearly 30 years, even before it was formally established. As with all Observatory products, it is deeply rooted in the ethos of evidence-based practice and knowledge brokering. The European Observatory was established late in the 20th century to support health policy-makers and advisors in Europe with the evidence needed to design and implement the best policies for their countries. In 2002, the Observatory published a seminal volume entitled, *Funding health care: options for Europe*. More than 20 years later, this new book provides an updated analysis of recent experiences with health financing reforms enriched by global, and not merely European, evidence. Its organization reflects the core functions and policies of health financing: revenue raising; pooling of funds and policies on benefits and their rationing; and commissioning and purchasing of services. The book takes the reader into next-generation issues – that in fact must be addressed now – such as paying for

integrated care, financing pandemic preparedness and the funding of global public goods. It is sure to remain relevant and influential for years to come, as was the case with its predecessor.

In essence, this textbook epitomizes a convergence of theory and practice, equipping readers with knowledge tools to push for good policy-making practice, while concurrently arming them against the rise of zombie ideas. We hope that scholars, practitioners, decision-makers and their advisors can take the lessons from the text back to their contexts and continue to improve their health financing systems to better meet the challenges of tomorrow.

Joseph Kutzin

Former Head, Health Financing Unit, WHO headquarters (Retired)

Reference Series Foreword

Using evidence to inform decisions is not a new idea or one that is lost on policy-makers. The politicians and civil servants shaping health systems want the changes they make to work so, although they have to juggle multiple considerations (including what they believe in, what the public find acceptable and what is feasible in their context), they want to know what has been shown to work and why. Convincing policy-makers that evidence matters is not the issue. Making authoritative evidence readily available is.

The Observatory's Reference Series is an attempt to bring together the relevant evidence on each of a set of core health system issues and to organize it so that the key messages and their implications are clear.

The issues or topics (funding, governance, primary health care etc.) are chosen because they underpin so much of health system reform; contributors because they have a track-record of high-quality research and credibility in the field (at European and global levels). Each volume sets out to:

- define terms clearly and explain core concepts;
- address key dimensions of the issue and how they interact with functions like finance, regulation or delivery and with the wider (governmental and sectoral) context;
- explore levers for (and systemic blocks to) change; and
- analyze the lessons of practical experience and why reforms work in practice or do not.

The series is aimed at a broad audience who will use the materials very differently. Each volume is, in effect, a collection of source material. Signposting allows policy-makers to find what they need, whether that is a conceptual framework to help shape policy directions or the granular evidence required to draft the detail of government plans. Every chapter has a set of key points and every volume has an overarching summary. Otherwise, the volumes are tailored to the specifics of the issue.

The series is a work in progress and will grow and change to fit needs over time, but it is built on a clear goal: to collect in one place the information policy-makers should have access to as they think about and develop plans for the future of their health systems.

The European Observatory on Health Systems and Policies is an evidence-generator, a knowledge broker and a partnership shaped by policy-makers. It aims to bridge the gap between evidence and policy. The hope is that the Reference Series and the evidence syntheses it offers will help to do this.

The Secretariat and Partners

European Observatory on Health Systems and Policies

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Executive summary

What is health financing, and why does it matter?

Health financing is a core component of a well-functioning health system and key to countries' progress towards universal health coverage (UHC). Furthermore, it plays a central role in shaping the health system and influencing its performance. It is therefore a critical topic for study by health policy-makers, especially those seeking to introduce and enhance UHC in their country.

Health financing encompasses the flow of money through the health system: from the collection and pooling of prepaid funds, to the allocation of money to health care providers. And yet there is more to health financing than simply raising and spending money. The aim of health financing is to ensure that resources are allocated effectively such that individuals and communities can receive the health care services they need. It is a key determinant of the supply of health services and the performance of the health system, profoundly influencing the extent to which a health system protects people from financial hardship when using health services, as well as the overall effectiveness, safety, people-centredness and quality of health care services.

How is this volume structured?

This volume brings together insights from more than 50 contributors worldwide, exploring various aspects of health and long-term care financing. Beyond just serving as an update to the seminal 2002 volume on health financing, *Funding health care: options for Europe*,¹ the book covers a broader array of topics than its predecessor and includes case studies from around the world. The content is organized

¹ Mossialos E et al. (2002). *Funding health care: options for Europe*. Buckingham/Philadelphia: Open University Press (<https://eurohealthobservatory.who.int/publications/m/funding-health-care-options-for-europe>).

into three sections, aligned with the fundamental functions of health financing: revenue raising, pooling resources and defining benefits, and commissioning and purchasing goods and services. Within each of these broad sections, individual chapters scrutinize specific policy relevant topics. Below we provide key learnings from each chapter.

What is covered in this volume: Revenue raising

The focus of this first section is on the ways that funds are generated for the health system. Revenue raising is a crucial component of health financing as it determines how much budget is available to pay for health care and how stable or predictable these funds are. This section explores the various sources of funding, and how the mix of funding influences progress towards UHC in terms of financial protection, equity, accessibility and quality. The section comprises four chapters, with the first concentrating on compulsory contributions through taxation and social health insurance (SHI), widely recognized as essential for progress towards UHC. It discusses common challenges when trying to raise funds from public sources, such as having a large informal economy, weak governance mechanisms and the impacts of an ageing population. The subsequent chapters delve into voluntary health insurance (VHI), with the first discussing community-based health insurance (CBHI) – used in some low- and middle-income country settings. The following chapter covers VHI more broadly, acknowledging its positive attributes, like prepayment and risk pooling but highlighting affordability and other challenges that inhibit universal uptake. The final chapter in this section explores official development assistance (ODA) as a revenue source for health systems, making a case for its importance, especially in the context of low- and middle-income countries during the coronavirus disease (COVID-19) pandemic. It examines the workings of ODA and historical involvement by key actors in this area. Key messages from the chapters in this section include:

Chapter 1.1 General taxation and social health insurance

A key objective of health financing is to redistribute financial resources from the healthy to the sick and from the well-off to the poor. This can

be best achieved through compulsory prepayment mechanisms like taxes and social contributions. Key learning includes that:

- A high reliance on public revenue-raising instruments (general taxes and/or SHI) is essential to progress towards UHC.
- Large informal economies and poor governance can make collecting public revenues difficult in low- and middle-income countries.
- Health financing systems have to be able to adapt to:
 - offset challenges to the revenue base such as economic decline, low levels of economic development or a preponderance of informal employment or economic activity; and
 - meet increasing health care demands which grow with rising expectations and population ageing.
- The traditional distinction between health systems that rely on general taxation (Beveridge or National Health System (NHS) systems) and social insurance contributions (Bismarck or SHI systems) has blurred with time.
- Health systems increasingly rely on a diverse mix of revenue-raising instruments to finance health care.
- There is a growing focus on delinking employment from entitlement to services in historically SHI-based systems and on emphasizing general taxation as a complementary source of revenues.

Chapter 1.2 Community-based health insurance

CBHI is a voluntary, self-organized approach to financing health care for groups of individuals in the absence of other forms of health care coverage. CBHI scheme members organize themselves, collect and pool their insurance premiums, and use them to purchase health services for members. Key learning includes that:

- CBHI is not a miracle solution to affordable access to health care:
 - the very poor often do not enrol, and when they do, they tend to use fewer health services;
 - out-of-pocket (OOP) payments are not necessarily reduced.
- Low uptake, poor delivery of promised benefits and challenges around governance undermine the impact of CBHI.
- CBHI does not overcome broader issues, such as a lack of financial resources.

- CBHI might serve as a transitional mechanism towards UHC and offer some financial protection for the most vulnerable provided that:
 - policy-makers create a supportive political and economic environment;
 - social capital can be mobilized;
 - schemes are institutionalized within the health sector.

Chapter 1.3 Voluntary health insurance

VHI is paid for privately by or on behalf of individuals and most often provides people with faster access to treatment and greater choice of health care provider. Premiums are not typically based on the policyholder's income but are likely to vary depending on their risk of ill health. Key learning includes that:

- Despite prepayment and risk pooling, VHI has limitations and does not align well with progress towards UHC because:
 - risk pools in VHI schemes are typically much smaller than pools established through statutory schemes, which means there are fewer people to share risk;
 - inequities are created because of the cost of premiums, which may not be affordable or accessible to everyone, including those most in need of financial protection.
- VHI has wider equity implications because it offers those who can afford to pay faster access to, or greater choice of, services (supplementary insurance) or coverage of excluded services or user charges for statutory care (complementary insurance).
- Governments seeking to use VHI to expand coverage typically have to make significant interventions, including through tax subsidies to make premiums more affordable, but this creates market distortions and is inefficient.
- Policy-makers can secure better health system performance by improving access to publicly financed health care than by promoting VHI.

Chapter 1.4 Official development assistance for health

ODA is provided by governments or multilateral development banks to support economic development in other countries. Key learning includes that:

- ODA is critical to achieving the Sustainable Development Goals in the world's poorest countries.
- Lower-middle and middle-income countries tend to receive more ODA than lower-income countries due to a number of factors, including precedence and project continuity, differences in the ability to borrow and attract higher volumes and extenuating circumstances and differences in capacity to absorb additional funds.
- Multilateral development bank funds are best utilized when they are invested in under resourced areas, such as global or regional public goods, and when they are well-aligned with domestic policies and national goals.
- ODA success (i.e. resources having a meaningful impact on development outcomes) depends on:
 - prioritizing the right long-term development challenges;
 - effective domestic governance and an active role for national-level stakeholders;
 - transparency around ODA activities;
 - continuous assessment, evaluation, learning and improvement.
- ODA and financing institutions must adjust to new challenges such as climate change – moving away from a sector-by-sector approach, addressing trends and emerging themes and delivering innovative and agile financing mechanisms.

What is covered in this volume: Pooling resources and defining benefits

Pooling involves aggregating prepaid health revenues to be used to purchase services for a defined population, with the primary goal of spreading financial risk. If the ultimate aim of the health system is UHC, a key objective of pooling is to ensure that an individual's financial contribution to the health system is not linked to medical need. Risk pooling exists to different extents globally and is a crucial determinant of the efficiency, effectiveness and equity of the health system, yet it has received less academic and policy attention compared to other functions in health financing.

Policy decisions on population coverage, services included in a benefits package, and the degree of reliance on user charges are fundamentally linked to pooling. Through five chapters, this section explores variations

and elements in risk pool design, such as consolidating pools, addressing funding disparities and the challenges in setting benefits packages. Chapters in this section also discuss the complex issues of disinvestment from certain treatments and designing pooling arrangements for long-term care in the context of changing demographics and family structures. Key messages from the chapters in this section include:

Chapter 2.1 Approaches to risk pooling

Risk pooling refers to the way prepaid funds are combined and then used to provide care for a covered population. Pooling is an often-underappreciated aspect of health financing which shapes the overall health system. Key learning includes that:

- Pooling prepaid funds is central to progressing towards UHC. It bolsters health system efficiency and equitable access to services.
- Pooling maximizes redistributive capacity and allows the health system to align funding with needs and social priorities.
- Having multiple risk pools can be problematic, particularly if:
 - pools have too few people;
 - if everyone in the pool has similar risks; and
 - if there is no redistribution of resources across pools.
- Structuring and managing risk pools well can offset problems associated with fragmentation by:
 - reducing duplication or overlap, making purchasing and service delivery more effective;
 - avoiding disproportionately large financial burdens falling on particular pools; and
 - minimizing risk selection and “cream-skimming”, whereby pools try to exclude high-risk (and therefore high-cost) individuals.
- Policy-makers can use a range of pooling strategies to enhance efficiency, equity and access but path dependencies, politics and context matter. Options include:
 - encouraging the integration (i.e. consolidation or merger) or coordination of pooling schemes;
 - boosting funding for less endowed pools;
 - equalization through risk adjustment across pools via direct transfers between schemes;
 - making membership compulsory; or

- aligning data systems, benefit packages and payment infrastructure across pools.

Chapter 2.2 Setting a health benefits package

A benefits package is the range of health care goods and services that people covered by a system or scheme are entitled to or should be able to access. Key learning includes that:

- All health systems have budgetary constraints and set some limits to entitlement, and therefore have some kind of benefits package.
- Benefits packages may be explicitly defined or implicit only, with the latter more common in high-income countries and the former more common in low- and middle-income countries.
- What is included or excluded, and the ways these decisions are made, vary widely but well-designed benefits packages should address population health needs and ensure the efficient use of health system resources.
- Defining a package of care is complex and often highly sensitive – using evidence and economic evaluation to determine what to include (or exclude) supports efficiency and equity and allows policy-makers to explain and defend their choices.
- There are a range of evidence-led instruments that can support policy choices such as health technology assessment, which incorporates economic evaluation.
- Any decision-making process should:
 - gain agreement and buy-in from key stakeholders on the ultimate goals of the benefits package and the level of explicitness;
 - take into account the specific characteristics of the setting where the benefits package will be implemented, including its cultural values, market configuration, political system and wealth.

Chapter 2.3 Decommissioning/disinvestment: reducing the provision of low-value care

Decommissioning or disinvesting from low-value care means taking money away from health care services that give poor value for money. Key learning includes that:

- Ending investment in health technologies or treatments that are ineffective releases resources for more effective high-value care, increases efficiency and quality and contributes to sustainability.
- Disinvesting from or decommissioning low-value care often faces institutional barriers.
- Health technology assessment and the continuous monitoring of peer-reviewed evidence and administrative health care data are key in identifying low-value care and prioritizing what should be decommissioned.
- Combining financial and nonfinancial mechanisms can help influence both the supply of and demand for low-value care and stop its provision.
- Broad stakeholder consultation and engagement is a key part of ending the use of low-value care because patients, clinicians, health-related organizations and health system norms and structures can all create barriers to change.
- Decision-makers need to address how resources released by disinvestment can best be reinvested to strengthen efficiency, quality and access.

Chapter 2.4 User charges

User charges are OOP payments made at the point of use for health services. Nearly all countries have some user charges, most commonly for medicines. They are intended to raise revenue and also to reduce the use of unnecessary health services and products. Key learning includes that:

- User charges can generate revenues but have many unintended negative consequences – creating barriers to access, contributing to inequities and increasing the risk of financial hardship for households.
- Health systems can reduce unnecessary or wasteful use of care without user charges by:
 - strengthening prescribing and referral systems to make sure care is appropriate;
 - offering information to steer patients and providers towards more cost-effective care.
- Supply-side mechanisms that guide providers' behaviour are more equitable and effective than demand-side mechanisms, such as user

charges, and have fewer negative impacts on patients – especially those with chronic or severe conditions or the economically disadvantaged.

- User charges are a suboptimal policy but – if they are to be used – health systems can mitigate the harm they cause and protect health care users through mechanisms such as exemptions, reduced co-payments, income-related co-payment caps and, to a lesser extent, price control and regulation.

Chapter 2.5 Long-term care: its financing and provision

Long-term care (LTC) refers to a broad package of personal, social and medical services provided over extended periods of time which may be delivered by care professionals or by informal care givers. Key learning includes that:

- Population ageing, particularly in advanced economies, creates growing demands for LTC.
- There are inequities in the need for and access to LTC. Older people, women, those with lower incomes and lower levels of education are all more likely to need care, but less likely to have access to it.
- Funding arrangements for LTC are problematic in many countries:
 - voluntary insurance and OOP payments commonly fill public coverage gaps but create inequities;
 - asset-tests for eligibility for publicly funded care are essentially regressive wealth taxes due to the unequal distribution of LTC needs;
 - encouraging for-profit provision theoretically fosters competition, availability and responsiveness but the pressures to generate profits can jeopardize quality and safety.
- Countries face urgent pressures on LTC and could usefully consider:
 - increasing public expenditure and broadening the funding mix for LTC;
 - better, fairer pooling of resources across generations;
 - revenue sources independent of payroll contributions since labour markets as a revenue base will shrink at the same time that demand for ageing-related LTC increases;

- better data and indicators to assess access, quality and value for money;
- patient-centred and coordinated approaches to LTC.

What is covered in this volume: Commissioning and purchasing

Purchasing is the final stage in the flow of health care funds, where pooled resources are used by a purchaser to remunerate health care providers. The primary goal is to ensure efficient and equitable resource utilization, aligning with the purchaser's objectives. Purchasing should guarantee the delivery of appropriate, high-quality care, minimizing waste and inefficiencies. Strategic purchasing, characterized by evidence-based decisions on provider selection, service procurement, payment methods and amounts, is an ideal but seldom fully realized concept. Performance monitoring, holding providers accountable through explicit or implicit criteria, is integral to the purchasing function, ensuring adherence to expectations and fair pricing. Various payment mechanisms, such as fee-for-service (FFS), capitation and case-based payments, have distinct effects on provider incentives and financial risk distribution, profoundly shaping health system behaviour.

This section of the volume encompasses 10 chapters. The initial chapters cover paying for primary and hospital care, exploring the potential of diverse payment models to address policy challenges and their effects on achieving health system objectives. The complexity of payment mechanisms, including user payments and informal payments, is discussed, emphasizing the importance of understanding their role in provider reimbursement. These chapters also tackle the financing of medicines, challenges in coordinating care across different providers and LTC, recognizing the unique challenges posed by the integration of social and health care. The section concludes by shedding light on often overlooked areas such as pandemic preparedness, financing antibiotic research and development (R&D) to combat antimicrobial resistance and incentivizing research for neglected diseases, underlining the importance of global collaboration and innovative financing mechanisms to address these critical issues. Key messages from the chapters in this section include:

Chapter 3.1 Paying for primary care

Primary care delivers first-contact access to health services and seeks to coordinate care. It is paid for in different ways in different settings: through salary, capitation (a fixed payment per enlisted patient), FFS, pay for performance (P4P) or through blended payments that combine two or more of these methods. Key learning includes that:

- The way health systems pay for primary care can incentivize treatment that supports wider health systems' goals, such as:
 - reducing avoidable referrals to secondary care, improving efficiency and reducing waste; and
 - encouraging adherence to evidence-based clinical guidelines, enhancing quality.
- P4P is often used to improve quality but the evidence on how effective it is, is mixed. If performance measures are not carefully designed to be context specific and adjusted for risk appropriately, they can create unintended barriers to and inequalities in access.
- The design of primary care payment models needs to be “holistic”, to consider the goals of the health system and to underpin quality, access and efficiency.

Chapter 3.2 Methods for paying hospitals

Methods for paying hospitals vary across countries and include FFS, block contracts, line-item budgeting (where purchasers specify exactly what funds are used for) and activity-based funding (with a fixed rate for each episode of care independent of the hospital's costs of care). Increasingly, P4P elements are also used. Key learning includes that:

- Third-party purchasers: government agencies, SHI funds or insurance companies provide the bulk of hospital revenue giving them levers to shape provision.
- Purchasers and hospitals have distinct objectives that are not always aligned – purchasers will pursue the best quality of care at the lowest price for their covered population while hospitals seek stable revenue streams to cover their costs.
- Information asymmetries give hospitals advantages over purchasers.

- Purchasers use payment methods and financial rewards to incentivize the volume and quality of care, patient-mix and management effort they want. There are complex challenges around:
 - specifying the details;
 - negotiating effective contracts; and
 - managing payment systems.
- Monitoring outputs and safeguarding quality requires structures and systems which are costly.
- Reforming funding or transitioning from one payment model to another is often a long process that demands sophisticated design and careful implementation.

Chapter 3.3 Informal payments in health care

Informal payments are unsanctioned, unregulated OOP payments made by patients directly to their health care provider for services that are covered by third-party purchasers. They are not recorded in routine administrative databases but can be captured in surveys, although they are usually underreported. Key learning includes that:

- Informal payments reduce access to health care and financial protection. They can undermine population health and reduce trust in providers and governments in the long run.
- Informal payments often stem from unmet desire for safe, timely or high-quality care and imply a mismatch between supply, demand and pricing in the formal health care payment system. When formal system payments are felt to be inadequate, informal payments may also be used to express gratitude to providers.
- Settings with low physician density, and/or where the share of gross domestic product spent on health care is low, tend to have higher levels of informal payments.
- Informal payments are also associated with settings with high reliance on formal OOP payments (user charges).
- Reducing or ending informal payments is difficult and requires a combination of specific, targeted measures and broad health systems reforms that address underlying causes.
- The policy measures that may reduce informal payments include:

- formalizing OOP payments, with exemptions to protect vulnerable populations;
- making clear and explicit what the health care benefits package covers;
- better monitoring and enforcement of rules and penalties;
- maintaining and expanding publicly financed statutory coverage.

Chapter 3.4 Paying for medicines

Paying for medicines includes how the end-purchase of existing medicines is managed but also the way investment in R&D is handled. Key learning includes that:

- Pharmaceutical innovation draws on substantial public and private resources.
- The public sector primarily supports early-stage research, regulates the industry and incentivizes development.
- The private sector is typically central to development, commercialization, manufacture and marketing. It seeks high profit margins and is not always transparent or responsive to public policy priorities.
- Novel and specialized therapeutics as well as population ageing are likely to accelerate medicine expenditure. This requires careful management of pricing and reimbursement.
- Policy-makers can leverage a mix of push and pull strategies to align industry efforts with societal need.
- To optimize pharmaceutical policy policy-makers must consider:
 - clear communication of health system priorities;
 - transparent incentive and pricing systems and measures to enhance R&D efficiency;
 - payment mechanisms that foster equity and sustainability;
 - cross-country collaboration including on preparedness, procurement and pricing transparency.

Chapter 3.5 Paying for integrated care

Integrated care is about better management of the care patients receive in different settings (primary, secondary) and from different specialists and teams. It is particularly important for patients with multimorbidity

and chronic long-term needs, and as populations age. Key learning includes that:

- Health systems' payment models can play an important role in incentivizing integrated care.
- Purchasers are now testing innovative payment models (e.g. pay for coordination) which explore how to foster better coordination. These models include:
 - bundling payments to single providers so that the multiple services a patient uses are better linked; and
 - bundling payments for patients being treated by multiple providers, creating joint budget responsibility and a need to work together and avoid duplication.
- Policy-makers would do well to focus on careful design of information systems to underpin payment schemes because:
 - information sharing supports clinical effectiveness;
 - quality indicators allow purchasers to tie bonuses or penalties to integration;
 - monitoring activity and health outcomes helps assess value for money;
 - tracking the distributional consequences of incentive schemes is crucial in protecting equity;
 - robust evaluation alongside payment reform allow immediate lessons to be shared and will capture changes over time and across the health care system.
- Health systems need to embed financial incentives as part of a broader system approach. Critical elements include:
 - committed leadership;
 - effective communication among providers;
 - structural integration, either through coordinating mechanisms that link provider roles or by the formation of new entities with single management teams.

Chapter 3.6 Balancing incentives to promote quality and improve long-term care

As populations continue to age with multimorbidity and the supply of informal care declines, expenditures in LTC are expected to increase significantly. However, better value for money can be achieved in LTC.

Resource allocation mechanisms for LTC and payments to providers are distinct from those for health care for a number of reasons. Key learning includes that:

- LTC is particularly prone to poor quality or inadequate care, under provision, overmedicalization and to delivery in suboptimal settings.
- The challenges for LTC reflect its differences from health care markets, including that:
 - in health care the focus is on improving health whereas, once an individual needs LTC, that need for care is permanent and the emphasis shifts to maintaining quality of life;
 - LTC is often provided by low-paid or informal (often unpaid) caregivers rather than highly-trained professionals;
 - LTC markets are generally fragmented, with a multitude of funding sources and payers involved;
 - collecting data on LTC quality, defining indicators and setting targets are difficult and make value-based payments particularly challenging.
- Payments for formal LTC provision should be adjusted based on risk and inevitable cost variation between patients, and then combined with other payment types that incentivize additional aspects, including quality of care and cost containment.
- Informal caregivers may be compensated either with cash or non-monetary benefits. Although these do not normally cover the full costs of providing care, they acknowledge carers' contributions and to some extent address issues such as working hours lost.

Chapter 3.7 From vertical to horizontal priority-setting: funding and procurement mechanisms

Priority-setting is about taking explicit decisions on where limited public resources should be allocated. Vertical priority-setting focuses on choices for particular sets of health conditions or population groups whereas horizontal priority-setting looks more broadly across types of care, such as primary or secondary care, and broader investments. Key learning includes that:

- Defining a health benefits package that is affordable and accessible by all implies a horizontal approach to priority-setting.

- Countries cannot progress towards UHC without horizontal priority-setting and without some form of collective funding and procurement mechanisms.
- Horizontal priority-setting is highly context specific. Countries may need to reorganize financing and procurement mechanisms to overcome barriers to progress.
- Increasing the total resources for health benefits packages can help with the introduction of more horizontal approaches.
- Improving procurement can also support the move towards horizontal priority-setting whether through national efforts (such as better data gathering and use) or international initiatives (i.e. harmonizing regulation across countries or global investment in health security).
- Local capacity is key in supporting the pooling mechanisms, health benefits package design and regulation which enable horizontal priority-setting. Donors can usefully support health systems strengthening by investing in capacity-building and information sharing.
- Strong political will and cooperation between stakeholders is critical in progressing towards appropriate priority-setting for UHC and in designing, financing and implementing a comprehensive health benefits package.

Chapter 3.8 Funding pandemic preparedness

A pandemic can wreak health, societal and economic havoc. Prioritizing common and global public goods for health and specifically for pandemic planning is complex and requires financing mechanisms at the national, regional and supranational levels. Key learning, including from COVID-19, is that:

- Pandemic preparedness is subject to inherent market and collective action failures and is often underfunded.
- Governments need clear strategies for financing preparedness.
- Preparedness depends on strong health system foundations and contingency funding mechanisms that go beyond simply setting funds aside. It is crucial that funds can be mobilized quickly and in a coordinated fashion.
- Key steps for planning responses include:
 - assessing existing activities and mapping value for money;

- agreeing on the need for public financing for population-based functions (i.e. common goods for health);
 - identifying appropriate types of financing that reflect the complexity of determining resource needs and allow for nuanced cost estimation;
 - developing context-specific financing tools that include flexible funds and address accountability;
 - holding transparent discussions about trade-offs;
 - improving budget transfer mechanisms;
 - integrating domestic finance into multiyear budgets; and
 - managing and strengthening international collaboration.
- International guidance and learning from COVID-19 can help inform preparations. Organizations including the World Health Organization and the World Bank offer tools to help decision-makers. It is crucial that these are assessed for suitability to context and customized to the national and local setting.

Chapter 3.9 Antibiotics as global public goods

Global public goods are goods and services whose benefits are universal in scope. Antimicrobial resistance poses a major health and economic threat worldwide, making novel antibiotics a global public good. Payment mechanisms have an important part to play in encouraging crucial R&D. Key learning includes that:

- Antibiotics are essential global public goods, but rising antimicrobial resistance is rapidly undermining their effectiveness worldwide.
- The antibiotic development pipeline has collapsed, as traditional patent-based market incentives fail to generate sufficient returns for industry.
- Antibiotic R&D faces high scientific risk, long timelines, high costs, and weak commercial viability, particularly at clinical and market-entry stages.
- Numerous global and national incentive programmes have been established to support, fund, and coordinate antibiotic R&D.
- Existing efforts rely mainly on push incentives, such as grants, which support early research but do not ensure successful commercialization.

- Pull incentives, such as market entry rewards and subscription payment models, are essential to correct market failure by delinking revenues from sales volume while supporting antimicrobial stewardship and patient access.
- Sustainable solutions require coordinated global action integrating push–pull incentives, regulatory harmonization, and One Health principles.

Chapter 3.10 Financing innovation for neglected diseases

Neglected diseases account for about a fifth of the global burden of disease and affect over a billion people. They are neglected because the pharmaceutical sector does not consider it profitable to develop treatments for them. This reflects the fact that neglected diseases are most prevalent in low- and middle-income countries with relatively low purchasing potential. Key learning includes that:

- Global pharmaceutical R&D invests a disproportionate share of innovation and activity in diseases that affect high income countries, something which fosters significant inequities.
- A range of push and pull incentive mechanisms have been developed to delink the cost of research from market profitability and promote innovation in areas of need. These include measures to:
 - reduce the upfront costs by subsidizing R&D pre-discovery (push incentives); and
 - offer a reward post-discovery (pull incentives).
- The evidence on the effectiveness and reach of incentive schemes is scant and more needs to be done to understand the relative cost–effectiveness of the different incentive mechanisms and the extent to which they mitigate inequalities in innovation and access to new medicines.
- A global, unified governance framework for needs assessment and resource allocation could usefully:
 - carry out systematic comparisons of the relative needs associated with neglected diseases globally;
 - assess the costs and benefits of addressing these;
 - set priorities for the coordinated global allocation of funding and targeted incentive mechanisms; and

- consider payment mechanisms that will translate research into market launches.

What are the lessons?

This volume presents health financing experience and case studies from diverse countries across income levels and regions to understand the options for addressing challenges across the three main functions of health financing (Box 0.1.1). Looking ahead, challenges in revenue raising involve selecting appropriate funding sources that generate adequate and stable resources, as well as ensuring equity in financing, particularly for lower-income groups who should pay only as much as they can afford. Pooling challenges encompass the inclusion of diverse population groups in risk pools with uniform financial contributions and health benefits, implementing necessary financial transfers between pools, and defining realistic benefit packages that adapt to emerging medical innovations. Purchasing health care necessitates payment mechanisms that are aligned with purchaser objectives, incentivizing high-quality care and promoting continuity of care in cases involving multiple providers. The COVID-19 pandemic underscored the imperative of global cooperation in financing public goods such as pandemic preparedness. There is no “best” way to finance a health system; each health system has its own needs, constraints, preferences and contexts that will influence

Box 0.1.1 Key challenges for the future in financing health systems for UHC

Revenue raising

- Securing reliable revenue sources of adequate size to fund the desired health system, especially as populations age and informal work sectors grow in many places.
- Reducing user fees and OOP payments, especially for lower-income groups and those in poorer health, by increasing the reliance on public sources of funding.
- Assuring that revenues are raised equitably, with the largest financial burden borne by those who can most afford it rather than those who need the most health care.

Box 0.1.1 (cont.)**Pooling and defining benefits**

- Assuring that all population groups are included in risk pools that promote equity and require similar financial contributions and offer similar packages.
- Where necessary, establishing and refining financial transfers between risk pools to promote equity between different population groups.
- Setting realistic, explicit benefits packages that maximize health benefits and adapt nimbly to the emergence of new treatments and technologies.

Paying providers

- Establishing and strengthening institutions that can make strategic purchasing decisions.
- Designing payment mechanisms that offer incentives aligned with purchaser objectives.
- Incentivizing the provision of mandated health services, especially for disadvantaged groups.
- Strengthening the monitoring and assessment of provider performance.
- Incentivizing continuity of an individual's care across multiple providers and across life stages.
- Securing global cooperation to finance global public goods (e.g. pandemic preparedness, challenging AMR).

what the optimal revenue raising, pooling and purchasing strategies are. However, health financing systems that successfully push towards UHC typically share some common traits of good governance such as: clear priorities, robust financial regulations, effective monitoring mechanisms, transparent decision-making processes that involve and engage stakeholders and a commitment to equity and fairness in resource distribution and procurement. These features can prove crucial in developing strategies to address the challenges listed above and move towards the ultimate goal of ensuring that people have access to high-quality, affordable, accessible, efficient and equitable health services that they need.

Introduction

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Trends and key challenges in health care financing

Health financing is a key component of any health system, but its role is more complex than simply raising and spending money on health. It is a crucial determinant of the overall performance of the health system, defining, among other things, how much money is available to be spent on health and who pays for it, who gets to benefit from those financial resources, what services that money can purchase and who ultimately receives resources from the health system as income. Without careful attention to the way health financing systems are designed, incentives for providers or patients can be misaligned with policy goals, leading to poor health outcomes, financial hardship for users of health care, wasted resources, failure to address inequalities and disruption of countries' progress towards universal health coverage (UHC) (Box 0.2.1).

In 2002, the European Observatory on Health Systems and Policies published a volume on health financing entitled *Funding health care: options for Europe* (Mossialos et al., 2002). Despite being more than 20 years old, that book remains one of the most downloaded and referenced

Box 0.2.1 What is UHC?

UHC refers to the concept that all individuals and communities receive the quality health services they need without suffering financial hardship (WHO, 2023). It is widely seen as a goal of societies to ensure that everyone has access to essential health services, including prevention, promotion, treatment, rehabilitation and palliative care, without facing financial barriers. UHC as a policy objective is enshrined in numerous international and regional agreements, including the Sustainable Development Goals (United Nations, 2024).

books in the Observatory's study series. Since its release, there have been important global shifts in health financing, including the ways revenues for health are generated and pooled, and advances in topics such as priority-setting, approaches to purchasing and provider payment methods.

In this book, our aim is to go beyond simply producing an update of that 2002 volume, which focused primarily on the ways revenues for the health system are generated but devoted less attention to other aspects of health financing. We have assembled a team of distinguished authors from around the world with expertise in theory and practice to provide an up-to-date analysis of recent experience in different topics of health and long-term care (LTC) financing. The following chapters are organized systematically around the three key health financing functions: revenue raising, pooling resources and defining benefits, and purchasing services. This structure follows the well-established framework first published by Kutzin (2001) and later adapted elsewhere (Papanicolas et al., 2022). These functions describe the way money flows through any health system, from collection to payment, in distinct stages (Fig. 0.2.1). Each of the chapters within these three broad sections of the book examines a particular aspect of the

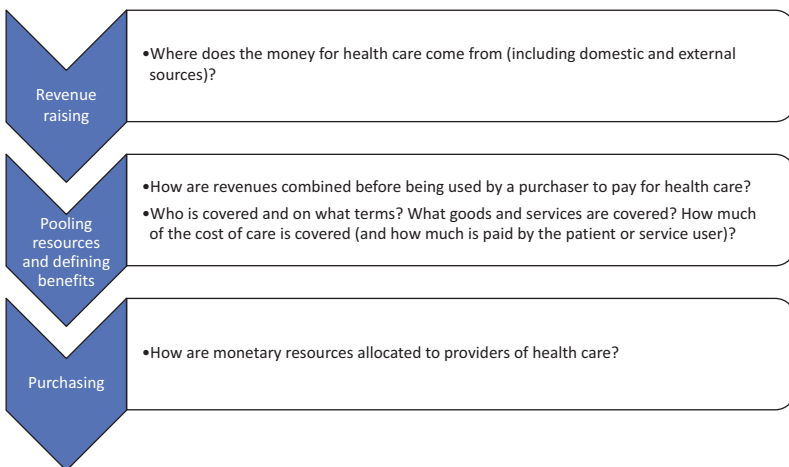


Fig. 0.2.1 How does money flow through the health system? The health financing functions

Source: Adapted from Kutzin (2001).

corresponding financing function. For each chapter, the authors begin by discussing the relevance of the topic, followed by an exploration of relevant academic theory. Finally, authors survey recent literature and global country experiences to provide insights into the current state-of-the-art of health financing.

By expanding the geographical coverage beyond Europe, this volume addresses key health financing issues relevant around the world, including topics which have historically received less attention such as community-based health insurance (CBHI), official development assistance (ODA) and pandemic preparedness, among others. Our goal is to provide a key resource for policy advisors at national and international levels, as well as a textbook for postgraduate students and others with interest in health financing.

In the following sections we provide a brief introduction to each of the financing functions for readers to better understand what each function includes, why it is relevant and how it can impact wider health system objectives, including efficiency, equity and quality of health care services (see Box 0.2.2). The aim here is not to provide a summary of the ensuing chapters, but rather, to provide motivation to read the material to come.

Box 0.2.2 Defining efficiency, equity and quality in health care and systems

Throughout this book, references are made to concepts such as efficiency, equity and quality. We use the following definitions for these:

Efficiency: “Health system efficiency seeks to capture the extent to which inputs to the health system, in the form of expenditures and other resources, are used to secure valued health system goals” (EOHSP, 2024).

Equity: “... the absence of unfair, unavoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically or by other dimensions of inequality (e.g. sex, gender, ethnicity, disability, or sexual orientation)” (WHO, 2024a).

Quality: “Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes. It is based on evidence-based professional knowledge and is critical for achieving universal health coverage” (WHO, 2024b).

Revenue raising

Revenue raising is the way that funding is generated for the health system and includes a description of the sources that fund the health system. In this first section of this book, our focus is on the funding mechanisms of entities (e.g. insurance schemes) that pool resources to purchase health goods and services on behalf of individuals. Historically, analysts have often distinguished between public sources of financing collected by governments or quasi-governmental entities (e.g. in the form of taxes), and private sources of financing such as voluntary insurance premiums or user charges paid at the point of service use. While the public versus private funding dichotomy is relevant, some analysts have begun to take a different approach after realizing that in some countries private sources of funding share a lot of characteristics with public sources of funding. For example, where payment of private insurance premiums is mandatory, it can be difficult to argue that it differs from a tax from the perspective of a household making payments (although there may be differences from the perspective of the fairness of financing as well as pooling (see below)). In this case, the degree of compulsion (i.e. if prepayment is mandatory or voluntary) may be more relevant than a distinction between public versus private.

Moreover, the public versus private funding distinction alone may not reveal much about the reliability or stability of a funding source, or the fairness of financing. For example, there are important differences between different types of revenue raising-mechanisms that are collected by the public sector, such as various forms of taxation. As an illustration, income taxes, sales taxes, excise taxes and social health insurance (SHI) might vary in their ability to generate revenues depending on the objectives of the tax system, the state of the economy and labour market participation levels in a country. Furthermore, the various sources may differ in terms of their progressivity or regressivity (that is, who ultimately bears the financial burden of an employment tax?). And even when taxes are intended to be progressive, they have the potential to become regressive if there is a cap on the amount paid through general or local taxes or SHI contributions. This can all lead to important variations in the equity implications of different forms of compulsory health contributions.

While compulsory revenue raising-mechanisms can therefore be either public or private, voluntary health insurance (VHI) mechanisms

are distinctly private. There are still differences across various forms of VHI, such as between medical savings accounts (MSAs) which allow individuals to save their own money for medical expenses, typically in a tax-advantaged manner, and which as a result pool risk within an individual or household; CBHI which pools resources within a local community in contexts where formal health insurance coverage is otherwise limited; and mechanisms which pool across a wider scheme, namely complementary insurance (which provides additional coverage for services which are already part of a statutory benefits package, such as compensation to households to cover the cost of user charges), or supplementary insurance (which provides increased choice of provider and offers expedited access to health care providers and enhanced amenities in hospitals, such as single-room accommodations).

MSAs are not the predominant source of funding in any health system and feature only as a minor portion of revenue in a few countries (China, Singapore, South Africa and the United States of America (USA)). In all countries, a key characteristic of VHI is that the decision to participate in these revenue raising-mechanisms is optional. This has important implications, as individuals with a lower perceived risk of needing health care may opt out of participation in a VHI scheme. Spending on voluntary insurance is typically a small portion of total expenditure, and in many countries VHI acts as a fringe benefit for employees or is purchased by wealthier people to obtain preferred access to care or, in a few countries, is used to mainly cover statutory co-payments for publicly funded services.

Another important source of funding for the health system is out-of-pocket (OOP) payments. These are payments made by households at the point of accessing health care goods and services. They do not typically serve as revenues per se from the perspective of this book because they are not necessarily pooled or redistributed across users of health services unless they are transferred from providers to ministries of health or finance, which oftentimes is not the case. However, they do serve as a major source of health financing, albeit one which we address more substantively elsewhere in this book (e.g. in Chapter 2.4 on user charges and Chapter 3.3 on informal payments). There are two broad types of OOP payments: those which are paid for covered (i.e. statutory) services and those which are paid for non-covered services. The former includes user charges (see Table 0.2.1 and Chapter 2.4) whereas the latter includes OOP payments for items such as over-the-counter medicines and services that are not part of a statutory benefits package.

Table 0.2.1 *User charges “cheat sheet”*

Type of user charge		Definition
Direct user charges	Co-payment	Fixed fee (flat rate) charged to the user for each item or service, regardless of that item or service’s underlying cost
	Co-insurance	Fixed percentage of the total cost of the item or service charged to the user (with the purchasing agent paying the remaining percentage)
	Deductible	A fixed maximum amount that the individual needs to pay over a certain period of time before coverage (either full or partial) will “kick in”
Indirect user charges	Extra/balance billing	When a provider is allowed to charge some amount above the reimbursed price, for example for a nicer hospital room, the user pays the price difference
	Reference pricing	A reference price is the maximum reimbursement level set by the purchaser for a group of equal or similar items, oftentimes medicines; if the individual receives a medicine that costs more than the reference price, the individual must pay the difference
	Coverage exclusions	Services which are not covered by purchaser; if the user chooses to receive one of these services, they must cover the costs themselves
	Benefit maximums	A defined amount the purchaser will reimburse over a period of time; if the user receives care which exceeds this amount, they will need to pay the difference

Importantly, while households are primarily responsible for paying taxes, social insurance contributions, private insurance premiums and OOP payments, it is only the first two which are traditionally considered as public spending, while the latter two are considered as private.

Ultimately, whichever revenue raising-mechanisms are used, they must generate sufficient resources for the health system so that it is properly resourced. To this end, there will naturally be differences

across countries in terms of the most efficient and sustainable revenue bases. In settings with large informal economies, generating adequate resources for the health system through compulsory financing mechanisms can be challenging, often resulting in a heavy reliance on user charges.

Most commentators would argue that revenues should be generated fairly and equitably so that those who pay the most for health do so because they can afford to do so, not because they are less healthy and need more services. When considering equity, one can think of different financing sources as regressive – where the poor end up paying a higher percentage of their income than the rich – or progressive – where the rich pay a higher percentage of their income than the poor. While it is uncontroversial to assert that OOP payments at the point of use are regressive because poor households are likely to have higher health needs and in many instances face the same prices for services as wealthier people, different forms of prepayment (e.g. taxes or insurance contributions) which are paid in advance of care provision irrespective of an individual's eventual use of goods and services may have different equity implications depending on their design. For example, sales and value-added taxes (VAT) are typically somewhat regressive as they usually charge a fixed percentage on a good or service regardless of the income of the person purchasing it. However, if these taxes are structured with tiered rates, particularly with significantly higher VAT taxes imposed on luxury goods, their regressivity can be alleviated to some degree.

There are also external sources of financing, such as charitable donations, bilateral and multinational development assistance for health and philanthropic donor funds, to consider. These sources often come with important conditions of how the funds can be used, implicitly shaping some aspects of the health system. They are most common in developing country settings (though they still account for less than 10% of total revenue in low- and middle-income countries (LMICs)) although some high-income countries (HICs) also do benefit from some external financing sources (see Fig. 0.2.2). For example, there are a range of mechanisms that provide some European Union (EU) funding to EU countries' health systems, although this is in a fairly limited capacity. Furthermore, external assistance can often come in the form of technical assistance or infrastructure projects and does not always entail direct subsidies for operational health services.

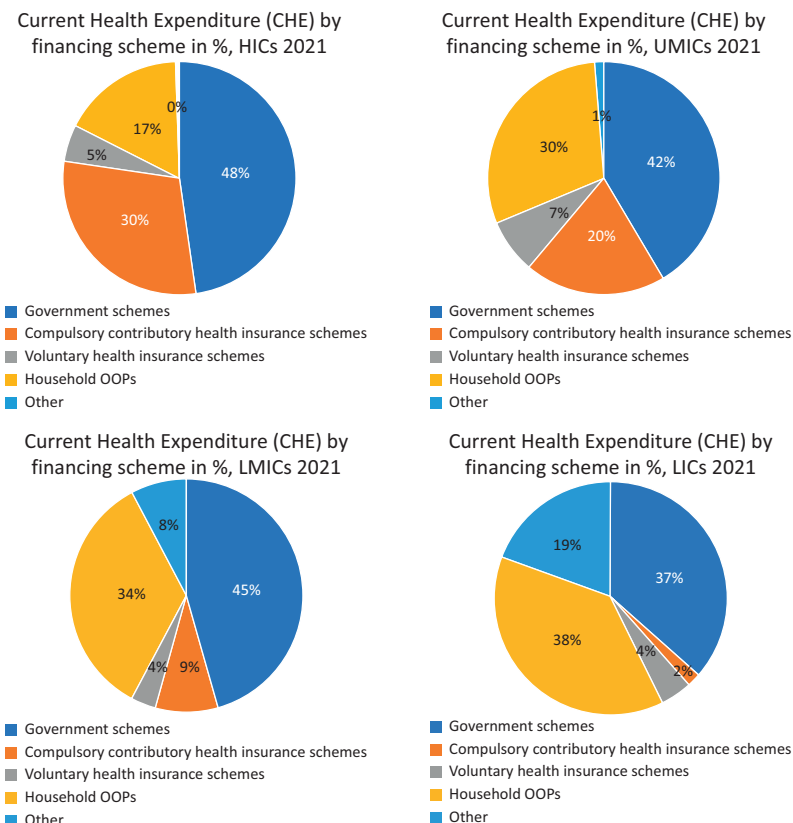


Fig. 0.2.2 Average share of health spending by financing agent, by country income grouping, 2021.

CHE: current health expenditure; HIC: high-income country; LIC: low-income country; OOP: out-of-pocket; UMIC: upper-middle-income country.

Notes: Unweighted average. Democratic People's Republic of Korea, Libya, Somalia (no data available for 2000–2021), Syrian Arab Republic and Yemen (no data were available for later years and not included in 2020–2021 data) were excluded from average calculation. The “Other” category subsumes a variety of other financing schemes including foreign aid in-kind (e.g. provided by nongovernmental organizations). Government, and other compulsory, schemes may include revenues from foreign transfers.

Source: WHO (2024c). Global Health Expenditure Database.

What is in the chapters?

This section of the book includes four chapters. The first focuses on revenues generated through compulsory contributions in the form of taxation and SHI. As mentioned, these public sources of financing are widely recognized as a key prerequisite for countries to progress towards UHC. The chapter discusses the complexities governments encounter in raising public revenue, examining challenges such as low levels of economic development, weak governance, narrow and unstable tax bases, high levels of informal economic activity, an ageing population exiting the labour force en masse and the growing incidence of noncommunicable diseases and comorbidities. Through various examples, the chapter provides insights into the efficiency and equity of relying on different forms of public financing to pay for health care in different countries and proposes solutions to some of the main challenges.

Next, are two chapters on VHI. Chapter 1.2 is on CBHI, a form of voluntary insurance used in some low-income settings to expand access to care. Various forms of CBHI acted as a precursor to more formal health systems in many HICs and can be viewed as stepping stones towards more mandatory arrangements. However, as the authors describe, CBHI is insufficient on its own to serve as a mechanism for progressing towards UHC. Some of the distinguishing characteristics of CBHI schemes are its community ownership and participatory management of the schemes, as well as being non-profit. Chapter 1.3 covers VHI more generally, considering the ways voluntary insurance can and cannot improve access to care. While prepayment and risk pooling are positive attributes of VHI schemes, they cannot serve as a legitimate basis for progress towards UHC due to their inherent feature that not everyone will participate in them, and may in some cases prove inimical to that objective. Countries will always find it challenging to achieve UHC solely through VHI, as economic theory and country experiences demonstrate that those who are poor or in ill health are most likely to be excluded from coverage. Indeed, many VHI systems use risk-adjusted premiums based on health status, and as a result cannot efficiently cover the poor (and even the middle classes). Making VHI compatible with UHC requires political commitment, careful policy design, strong regulatory capacity and efforts to ensure that publicly

financed coverage meets the needs of individuals with lower incomes or chronic conditions.

Lastly in the *Revenue raising* section of the book is a chapter on ODA as a source of revenues for health systems. The chapter uses the coronavirus disease (COVID-19) pandemic to argue the case for development assistance for health. It considers why ODA is important, how it works and which key actors have been involved historically.

Pooling resources and defining benefits

Pooling is the health system function whereby prepaid health revenues are aggregated and transferred to organizations that plan and purchase health services for a defined population. The primary purpose of pooling is to spread financial risk across the specified population so that no individual carries the full burden of paying for health care. The intention is, so far as possible, to make an individual's financial contributions to the health system independent of their medical needs.

Risk pooling exists, to different extents, in all countries and is in effect a health insurance function for the covered population. However, there are numerous possible pooling modalities. There may be single or multiple pools, competing or non-competing pools, territorially distinct or overlapping coverage, and insurance options tailored for specific population groups or designed to cover the entire population. The pooling arrangements found in particular countries are often the result of historical path dependencies and political decisions in the development of their health system. These decisions may have been influenced by factors such as previous reliance on employer-based health insurers, the role of local governments to organize health services, or the establishment of discrete health insurance schemes for civil servants.

Among the three fundamental functions in health system finance – raising revenue, pooling and purchasing of services – it is risk pooling that has received least academic and policy attention. Yet the design of pooling arrangements is a crucial determinant of the efficiency and equity of the health system.

The nature of a country's pooling choices can be examined using the coverage “cube” first conceptualized by Busse, Schreyögg & Gericke in 2007 and further developed by the World Health Organization and others since to illustrate progress towards UHC (WHO, 2021).

The three dimensions along which policy choices must be made for UHC are:

1. Population: which population groups are covered?
2. Services: which services are covered, and of what quality?
3. Direct costs: what proportion of the costs of access must be covered by the beneficiary?

These choices mirror the fundamental aspects of design that must be addressed when creating pooling arrangements.

A fundamental decision is the nature of the population group covered by each risk pool. In many health systems, early forms of risk pooling covered only workers in formal employment (and in some cases their dependants). For example, early forms of SHI used separate risk pools for different industrial groups. The financial capacity and medical needs of these pools could vary considerably, leading to variations in insurance premiums and the medical services covered, giving rise to manifest inequalities and administrative complexity.

While many health systems still only cover a portion of the population through risk pools, defined by factors such as employment status, age or deprivation status, there is growing recognition that risk pools should be structured to provide coverage to the entire population, irrespective of medical or economic status. This concept underpins the idea of “universal” health coverage. This does not necessarily rule out the creation of separate or supplementary risk pools to cover specific services, such as LTC or mental health services, if such “carve outs” are deemed to be favourable for either medical quality, administrative efficiency or even political reasons.

The services covered by a risk pool are commonly referred to as the health benefits package (HBP), which should in principle specify both the services covered and the circumstances in which they can be received. The benefits package can be explicitly defined, but, in a surprisingly large number of systems, is either undefined, or defined only partially or in very loose terms. In a health system with fragmented risk pools, citizens may have access to very different packages, depending on the resources available to the risk pool of which they are a member. However, under UHC there is a policy intention to mandate a nationally uniform HBP, defined in terms of its contents, the quality of services and the population groups entitled to secure access to specific treatments.

User charges are the third aspect of risk pooling design. They can be defined in terms of how the amount charged is determined, the type of service being used and the circumstances of the service user (see Table 0.2.1). For example, many systems waive some user charges for lower-income users. As for the benefits package, insurance premiums and user charges can vary considerably between pools in a fragmented system. However, under UHC they should be nationally mandated. In combination, the nature of the benefits package and the system of user charges are fundamental determinants of the level of financial protection offered to individuals by the pooling arrangements.

There are some commonly used variations from the simple design of risk pools described above. For example, some services (especially for high cost, low frequency treatments) might be transferred from local risk pools to a national risk pool in order to mitigate the financial risk to the lower-level pool arising from such services. It is also sometimes the case that certain services, such as LTC or public health, are carved out of the benefits package to create separate risk pools administered by separate institutions.

A well-established principle of health insurance, known as adverse selection, is that – if membership of an insurance scheme is voluntary – healthier individuals may opt out of the scheme, leaving the scheme with an increasingly unhealthy population base, increasing levels of premiums, and the eventual breakdown of the insurance arrangements (referred to as the “death spiral”). For this reason, it is generally considered essential that membership of statutory risk pools should be compulsory to assure the financial stability of the health system. In some countries there may nevertheless be additional VHI provision, which enables people with adequate resources to purchase insurance beyond the standard risk pool. The effect of such provision depends on whether it is a complement to or replacement for coverage offered by the standard risk pools, and whether it enables purchasers of private insurance to opt out of premiums for the standard risk pool, as is the case in Germany or Chile.

What is in the chapters?

This section of the book includes five chapters. The first examines principles and practices of risk pooling in modern health systems. It considers the merits of consolidating or merging pools, boosting

funding for less well-endowed pools in a fragmented system, implementing and improving risk adjustment across separate pools via direct transfers between pools, making membership compulsory and aligning benefit packages and payment systems across pools. The second chapter examines the setting of benefits packages. Although it highlights the important role of economic analysis in this task, it refers to the wider political, administrative and ethical context within which benefits package choices must be made. In principle, setting a benefits package requires the specification of services to be excluded from statutory provision as well as those to be included. In particular, with rapid technological developments, there are often treatments that have historically been provided by the health system that no longer offer value for money. The next chapter, Chapter 2.3, discusses the challenging task of identifying and disinvesting from such treatments.

Chapter 2.4 discusses the two main forms of direct user charges for goods and services that are included in the benefits package: fixed co-payments, which are a fixed amount of money that are not linked to the cost of the good or service, and percentage-based co-payments, based on a proportion of the price of the good or service. Such user charges are introduced in the belief that they will generate revenue for the health system, or moderate demand for services. However, research consistently finds that user charges have unintended consequences: they cause patients to skip necessary as well as unnecessary health care resulting in financial hardship (and potentially higher health care costs borne by the purchasing agency in the future if patients end up requiring more expensive hospital services), particularly for people with low incomes and people with chronic conditions. Unless direct user charges exempt high users of health care, they essentially become a tax on people in poor health.

The final chapter examines the especially challenging issue of designing pooling arrangements for LTC, a policy issue of rapidly increasing importance given population ageing and older peoples' care needs, and the changing structure of families who might hitherto have offered informal care.

Purchasing health care

Purchasing is the final stage in the flow of funds. Pooled resources are used by a purchaser (the entity responsible for spending pooled funds) to pay providers for goods and services, often on the basis of some

predetermined contract. The overarching aim of purchasing is to ensure that monetary resources are used efficiently and equitably and that resources are allocated according to the purchaser's objectives. In the context of UHC, the purchasing function should ensure that appropriate, high-quality care is delivered to patients who need it in a way that minimizes waste and other forms of inefficiency (e.g. prices which do not reflect actual costs or value, or over- or underprovision of services). An intrinsic element of the purchasing function is to provide appropriate incentives to service providers beforehand (*ex ante*), and that the performance of the provider is monitored afterwards (*ex post*).

Purchasing is often described in terms of being either strategic (alternatively, active) or passive. In essence, strategic purchasing refers to the deliberate ability to make key evidence-based decisions regarding the utilization of pooled resources. This means that purchasers are able to decide which providers to purchase from (selective contracting), which services to purchase from those providers, how to pay providers and how much to pay. Strategic purchasing is the concept that emphasizes active deliberation by purchasers to determine how money is spent within health systems. And yet, while this may be an ideal objective, purchasing is rarely, if ever, done in a fully strategic manner, even in well-developed health systems (Klasa, Greer & van Ginneken, 2018). In many instances, health care providers are reimbursed regardless of the appropriateness of services provided or even when the quality of those providers has not been evaluated.

Providers should be held accountable based on explicit or implicit criteria, which ideally specify the expected performance standards. Therefore, a key and often-neglected component of purchasing is performance monitoring. Monitoring is necessary to ensure that services are delivered in line with patient and purchaser expectations, and that fair prices are paid for goods and services. Monitoring is also essential for comparing the performance of different providers, establishing benchmarks for future performance and informing decisions regarding provider selection in the future.

There are different payment mechanisms used for different types of care and across different care settings, which can be either prospective or retrospective (i.e. before or after care is delivered, respectively). These include line-item budgets, per diem, fee-for-service (FFS), case-based payments, global budgets, capitation and blended payments which combine different payment mechanisms (Table 0.2.2).

Different payment mechanisms vary in the financial incentives they offer providers, and the extent to which they put the bulk of the financial risk on the provider or the purchaser (see Table 0.2.2). They therefore have a profound effect on provider behaviour, and ultimately patient care. For example, FFS, where a provider is paid a specific amount for each specific service they offer, puts the financial risk on a purchaser because the purchaser is effectively reimbursing the services delivered by the provider retrospectively. FFS is also typically used to financially incentivize providers to deliver greater volumes of care, since the more they do, the more they are paid. In contrast, capitation, where a provider is paid a lump sum to cover the treatment costs of a particular patient over a period of time, puts more of the financial risk on the provider; there can be important differences in how capitation is applied. If there is a fixed amount paid on behalf of each patient (i.e. ex-post capitation), providers may take on more volumes of patients to earn greater revenues but they may skimp on the volume or quality of care provided because the provider bears financial risk if use and costs are too high. As a result, they may be incentivized to take on low-complexity patients. If providers are paid based on a block (global) budget determined by the expected number of patients (i.e. ex-ante capitation) then providers are incentivized to reduce patient volumes and care use in an effort to be profitable. However, the financial incentive to ration services may be mitigated if the capitated payments are risk adjusted. In some systems, expensive cases (outliers) or certain treatments may be excluded from the capitated budget, and this may lead providers to increase the number of referrals to other providers if referrals are not capped.

What is in the chapters?

The *Commissioning and purchasing* section of the book includes 10 chapters, a reflection of the complexity of the purchasing function. The first two consider paying for primary care and hospital care, respectively, by purchasers. In the case of primary care, the chapter explores the potential of diverse payment methods in primary care to tackle policy challenges faced by health care systems, specifically addressing the issues of avoidable referrals to secondary care and the misalignment between actual care in primary settings and evidence-based clinical guidelines. The chapter emphasizes how various payment models create incentives and outlines their intermediate and long-term effects on achieving health systems' objectives. The next chapter on paying for

Note: This “cheat sheet” provides simplified information around how different provider payment mechanisms typically work and incentivize financially. However, it is essential to note that there are exceptions and nuances in reality that cannot be reflected with binary labels. Some of these are listed in the notes below. Further, a payment structure may create financial incentives but does not necessarily dictate provider behaviours as there are other nonfinancial incentives that will play a role in decision-making.

^a Under line-item payments, whether providers lack incentives to increase enrolment or amplify the severity of reported illnesses hinges heavily upon how the line-item budget is structured and what expenses are deemed justifiable. However, generally, line-item budgeting can lead to strong cost control and risk of under provision of services.

^b Generally, under per diem payment structures providers are incentivized to increase admissions/enrolment and patients' length of stay. If there is a fixed payment per day and it remains consistent for all days of hospitalizations, providers might be incentivized to exaggerate the severity of a patient's condition to justify an extended length of stay, and they may lack the incentive to increase the number of patients. Under this scenario of a fixed, consistent payment per day per patient providers may also opt to select healthier patients who will require less services during the days that they are hospitalized.

^c Generally, under FFS payment systems, the provider may be financially incentivized to overprescribe/overprovide costly services/care.

^d Under case-based payments, the purchaser faces risk depending on the number of cases and the case severity classification, but the provider faces the risk of cost of treatment for a given case. Generally, however, most of the risk falls on the purchaser unless the number of cases to be delivered is contractually specified. Therefore, it is important to consider how providers will be compensated if they exceed the contractually specified cases, such as reimbursement of variable costs only. Typically, case-based payments can incentivize higher volumes (of patients, care episodes), efficiency improvements, shifts to ambulatory care strategies and selection of low-cost patients.

^e Global budgets/salary payments typically incentivize cost control and may risk under provision and/or low productivity.

^f Under capitated payment systems, providers are typically incentivized to enrol more patients and control costs. There is a risk of under provision of care, patient selection and cost shifting.

Sources: Adapted from Roberts et al. (2004) and Saleh, Couttolenc & Barroy (2014).

hospital care covers four approaches to payment – line-item budgeting, FFS, block contracts and activity-based funding – and considers practical issues and the reasons for favouring one mechanism over another depending on context. Mixed payments methods which combine different payment approaches with different incentives are often preferable to try and strike a balance between competing incentives. For example, primary care providers may receive a capitation fee that provides adequate upfront resources for patient care without incentivizing overprovision of services. Additionally, they may also receive some FFS to encourage particular services, such as preventive activities, that may not be provided otherwise.

User payments are a fundamental element of provider reimbursement in many health systems. Chapter 2.4 has already given a general treatment of user charges. However, Chapter 3.3 specifically considers informal payments – direct payments by patients to providers, which are not sanctioned officially – and why they are used, particularly in low-resource settings. It explores some potential ways to try to limit their use, noting the complexities and that informal payments often emerge due to low levels of public spending on health care. Chapter 3.4 discusses the financing of medicines, aiming to encourage investment in research and development (R&D) by manufacturers, particularly in areas with high unmet need. It also covers pricing and reimbursement models for medicines already on the market.

The subsequent chapter focuses on the challenges and strategies for paying for care that requires the coordination of different types of providers. Integrated or coordinated care is particularly important for frequent users of the health system, such as those with chronic conditions. Therefore, mechanisms that bundle payment or which pool resources to be shared across providers may help to encourage better care coordination and ultimately, quality. LTC faces similar challenges given the need for a spectrum of providers to work collaboratively to deliver services. To this end, Chapter 3.6 discusses approaches both to resource allocation and payment in LTC. LTC differs from other types or providers in several ways, including the need to integrate social care services that support people with activity limitations and health care services, as well as the typically longer duration of care. LTC therefore poses specific challenges for payment mechanisms. The chapter explores the different factors which may need to be taken into account when implementing risk adjustment to ensure that LTC is adequately resourced based on population needs. Chapter 3.7 discusses the challenges associated with transitioning

from vertical priority-setting which focuses on specific conditions or populations to horizontal priority-setting which emphasizes affordable access to care more generally. It also delves into the role of financing arrangements in facilitating this transition.

The final three chapters address areas that often do not receive adequate attention despite their collective and global implications. Chapter 3.8 considers financing of pandemic preparedness, an issue which has become more salient since the COVID-19 pandemic but nevertheless was relevant before. The authors discuss mechanisms at the global, national and regional levels and conclude that effective planning requires more than just attention to resource allocation. Rather, preparedness is dependent on public financial management mechanisms, incentive structures and international collaboration. The next chapter looks at issues related to financing investments in antibiotic R&D and incentives for research to combat antimicrobial resistance. This is an important area because antibiotics are increasingly becoming less effective, in part due to overuse and more drug-resistant infections. The final chapter discusses financing mechanisms aimed at developing medicines to treat neglected diseases. Despite accounting for a large share of disease burden, there is often a perception that these medicines are not profitable, leading to a lack of resources dedicated to R&D. The chapter discusses incentives to address this historic mismatch.

Monitoring health financing globally: National Health Accounts

To monitor and compare health financing across countries, most countries produce National Health Accounts (NHA). These serve as a systematic and comprehensive approach towards capturing all financial transactions related to health care within a country over a specific period. NHA are designed to track and analyse the flow of funds within the health sector, offering insights into how resources are raised, allocated and utilized in health-related activities. They consist of information on financing sources including both public and private sources of funding for health care (both compulsory and voluntary), the distribution of spending among providers and health spending by type of services (or alternatively, function).

By compiling and analysing this information, NHA contribute to a better understanding of a country's health financing landscape.

Policy-makers, researchers and international organizations use NHA data to assess the efficiency, equity and sustainability of health financing systems to the extent possible with aggregated country-level data, enabling evidence-based decision-making and policy development in the health sector. For example, although NHA do not allow for stratification of health spending by socioeconomic class, the mix between OOP, VHI and compulsory health financing sheds some (limited) light on the redistributive nature of the health system.

While it is challenging to draw conclusions on health spending trends globally, we briefly attempt to give a sense of some of the overarching patterns in health financing. Across 186 countries, the average country health expenditure overall as a share of gross domestic product (GDP) increased from 5.5% in 2000 to 6.6% in 2019. This increased further during the COVID-19 pandemic to 7.4% of GDP by 2021, but much of this increase can be attributed to slower growth in GDP as well as one-time additional spending on health in response to the pandemic. Over the same time period, government spending as a share of current health spending remained relatively stable in the average country, increasing slightly from 51.2% in 2000 to 52.9% in 2019. OOP spending as a share of current health spending declined from 36.9% in the average country in 2000 to 30.9% in 2019, falling further to 28.2% in 2021. VHI remained fairly stable at just under 5.0% of current health expenditure. The role of external sources of financing showed the most variability, increasing from 6.2% of health spending in 2000, to around 11% between 2006 to 2015, and then falling to 9.4% in the average country by 2019. In the case of external sources of funding, just over one third of countries had more than 5% of their health spending coming from external sources in 2019. Likewise, government spending as a share of current expenditure varied in 2019 from under 10% in Afghanistan and Guinea-Bissau to over 90% in Kiribati, Cook Islands and Brunei.

The mix of funding sources varies substantially across countries as well as across-country income groups (Fig. 0.2.2). For example, government and compulsory insurance schemes comprised nearly 80% of health spending in 2021 in the average high-income country, whereas in the average low- or middle-income country these sources accounted for just over half of health spending. This speaks to the fact that it is difficult to raise such sources of financing in countries with large informal sectors. Moreover, the reliance on OOP spending on average is

highest in LMICs (35%) which is approximately half the level observed in HICs. Importantly, VHI schemes are among the least utilized sources of financing globally, although on average they pay for a slightly greater share of health care in upper-middle-income countries (UMICs) than they do in HICs. Of course, these averages mask significant heterogeneity, which is beyond the scope of this introductory chapter.

Future challenges

As detailed extensively throughout this volume, the methods used to collect and distribute funds directly influence the overall shape and performance of the health system. Aiming to capture the changes in the global landscape of health financing since the 2002 book, this updated text brings in real-world and recent evidence from countries of varying income levels and regions to discuss the policy areas relevant to health financing in the pursuit of UHC. Not only does the wide geographical coverage in this book provide contemporary insights into topics ranging from developmental assistance to integrated care to pandemic preparedness, but it also gives readers the opportunity to understand what has been achieved in recent years and what still needs to be done. It is in that context that we wrap up this introduction by briefly touching on the major challenges for each of the financing functions (revenue raising, pooling resources and defining benefits, purchasing) that demarcate the sections of this book.

Revenue raising

To secure necessary financing for the health system, countries have to ensure that they are drawing on the appropriate sources of funds given their own national contexts. For example, revenues generated via taxation or compulsory SHI contributions are the dominant public funding mechanisms used in HICs to promote equity and efficiency. In lower-income contexts, however, although countries do make some use of taxation or SHI systems, their use tends to be more limited in scope. Their systems therefore also feature a larger role for other financing sources, especially OOP payments, but also VHI (including CBHI in some countries), or external sources of financing (such as charitable donations or developmental assistance for health). The differences in

how the revenue raising function is organized reflect historical factors and path dependencies, as well as constraints on the use of some sources of finance, and are not necessarily an indication of policy failure, though it should be noted that a high reliance on voluntary funding sources can inhibit affordable access. Indeed, across all country income settings, securing reliable and sustainable revenue sources of adequate size to fund the desired health system is a major challenge, especially given the increasing prevalence of informal economy work, population ageing, conflict and migration. Furthermore, the inexorable rise of new technologies and changes in the epidemiology of disease can have a profound impact on the demand for finances. The continued use of user charges to pay for services is a challenge with often inequitable impacts – the most disadvantaged (lower-income, the least healthy, the most geographically remote) are often subject to the most catastrophic expenditure risks. Countries of all types therefore have a major challenge to ensure that sufficient and stable revenues are raised equitably, with the largest financial burden borne by those who can most afford it.

Pooling

Risk pooling entails bringing together different sources of revenue and transferring them to the organizations that commission and pay for health services for defined populations. This tool spreads financial risk across a population so that individuals' abilities to pay for health care is not linked to their medical need, and can be seen around the world at different levels and in different formats. A future focus area for policy-makers pursuing UHC is to ensure that all population groups are included in risk pools that require equitable financial contributions (either by them themselves or paid on their behalf by governments) and offer similar HBPs. This challenge becomes more acute in countries with more fragmented pooling (single versus multiple pools, pools overlapping geographies, pools competing against one another), especially where there are entrenched interests and limited resources. It will often be necessary to implement financial transfers from better endowed, healthier risk pools to poorer, less healthy risk pools in order to promote the chosen concepts of equity. Setting a realistic benefits package to maximize health benefits is another challenge for countries, and requires stakeholders to work together on an ongoing basis to decide what to define explicitly and what to leave adaptable to local circumstances.

Purchasing health care

As the final of the three functions, purchasing from the raised and pooled resources is typically based on a contract between the purchaser and the provider. The first requirement related to this function is therefore to establish or strengthen the institutions that make such strategic purchasing decisions, i.e. the conscious, evidence-based approach of deciding which services to buy from which providers, at what cost and how to pay for them. Payment mechanisms should be designed to offer providers incentives that align with the purchaser's objectives, which often focus on maintaining and/or improving access to health services that provide value for money, especially for disadvantaged groups. To ensure that the care is high-quality, performance monitoring is necessary for benchmarking and informing contracting choices in the future. In situations where an individual's care takes place across multiple providers (especially common in cases of those with long-term and chronic care needs), contracts and care collaborations between providers need to be designed to promote continuity and coordination of care. Finally, the COVID-19 pandemic and other global crises, like growing antibiotic resistance, have demonstrated the need to secure global cooperation in financing global public goods.

How to read this book?

Despite the aforementioned challenges, there has been immense progress in health financing in recent decades. We believe the policy lessons and insights set out in this volume can help researchers and policy-makers to continue to make further progress towards UHC in the years to come. Each chapter of this book has been written as a standalone piece allowing the book to reflect the diverse voices and expertise of its contributors. However, efforts have been made to highlight and cross-reference areas where readers would benefit from broader understanding of topics covered in other chapters. As such, the arrangement of the chapters in this volume allows readers to read the text sequentially from front-to-back, or to navigate freely between chapters based on their specific interests. Each chapter contains (i) a set of key messages at the start of each chapter, and (ii) a list of key resources (such as other books, journal articles, websites) where the reader can go to examine the topic area in further depth (in addition to the full list of references)

at the end of the chapter. These are intended to serve as easily digestible resources to aid the reader in understanding the most important points of each chapter.

It must be emphasized that the book does not provide specific how-to guides or endorse particular models. Instead, it conducts a thorough examination of the expanding body of evidence related to these various health financing elements to highlight ongoing debates and stimulate further discussion. Each chapter presents both theoretical frameworks as well as empirical findings from around the world. Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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SECTION I

Revenue raising

1.1

General taxation and social health insurance

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Key messages

Chapter 1.1 discusses the use of taxes and social health insurance (SHI) contributions. A key objective of health financing is to redistribute financial resources from the healthy to the sick and from the well-off to the poor. This can be best achieved through compulsory prepayment mechanisms like general taxes and social contributions. Key learning includes that:

- A high reliance on public revenue-raising instruments (general taxes and/or SHI) is essential to progress towards universal health coverage (UHC).
- Large informal economies and poor governance can make collecting public revenues difficult in low- and middle-income countries.
- Health financing systems have to be able to adapt to:
 - offset challenges to the revenue base such as economic decline, low levels of economic development or a preponderance of informal employment or economic activity; and
 - meet increasing health care demands which grow with rising expectations and population ageing.
- The traditional distinction between health systems that rely on general taxation (Beveridge or National Health Service (NHS) systems) and social insurance contributions (Bismarck or SHI systems) has blurred with time.
- Health systems increasingly rely on a diverse mix of revenue-raising instruments to finance health care.
- There is a growing focus on delinking employment from entitlement to services in historically SHI-based systems and on emphasizing general taxation as a complementary source of revenues.

Introduction

The objectives of this chapter are to describe global trends in countries' use of general taxation and SHI to finance health care and, by taking relevant country examples, to highlight some of the key challenges that governments face in raising public revenues for health as well as some of the solutions.

General taxation and SHI

Public funding of health systems is crucial to promote financial protection and improve access to services. The two dominant styles of publicly financing health care are general taxation and SHI – collectively referred to as public revenue-raising modalities – which enable health systems to move away from reliance on private out-of-pocket (OOP) spending at the time and place of seeking care. Financing health systems from OOP spending is both inefficient and inequitable, exposing individuals and households to financial risk when seeking care, including the risk of deeper impoverishment, as well as contributing to foregone care. Under general taxation, revenue comes from the share of overall government resources apportioned to the provision of health care. Under SHI, on the other hand, revenues are raised in the form of contributions from mandatory earmarked payroll taxes. The nature of health services – the presence of externalities, information asymmetries between providers and patients, the need for protection from the financial burden of unanticipated health spending, common public good elements, lack of competition in the hospital sector, information failures, etc. – is such that overdependence on unregulated private financing inevitably leads to suboptimal outcomes, including from the perspective of equity (Arrow, 1963).

Compulsion and redistribution

Well-designed health financing systems ensure that there is some form of mandatory prepayment combined with redistribution for funding health. Compulsion and redistribution are key elements of public financing for countries to make progress towards UHC, i.e. where everyone can access the essential health services they need without facing undue financial hardship in the process of doing so (Fuchs,

1996; WHO, 2010; Kutzin, Yip & Cashin, 2016; Tandon & Reddy, 2021). Critically, this involves risk pooling from the healthy to the sick as well as from the well-off to the poor via progressivity in prepayments. Although some countries implement this by mandating the purchase of private health insurance with targeted subsidies for those who cannot afford premiums, most countries have made progress towards UHC using public financing, i.e. via general taxation and SHI (Kutzin, 2012). Voluntary health insurance (VHI) plays a complementary or supplementary role but is not the primary mechanism for financing UHC globally, while funding from external sources including development assistance plays a role, particularly in lower-income settings (see chapters 1.3 and 1.4).

The health financing transition

In general, as countries grow and develop, overall levels of funding for health increase along with the share that comes from public sources, thus decreasing reliance on OOP and external financing. Across low- and middle-income countries (LMICs), this empirical trend – dubbed “the health financing transition” – brings with it the challenges of raising obligatory contributions for health care, whether as general taxes or mandatory SHI contributions (Fan & Savedoff, 2014). These challenges include low levels of economic development, high levels of poverty and informal economic activity, difficulties in collection of taxes, institutional and governance-related weaknesses and a low priority ascribed to, and poor absorption of, allocations for health in government budgets (World Bank, 2016). In high-income countries (HICs), on the other hand, governments are contending with the problems of an ageing population: rates of participation in the labour force are declining, so necessitating general tax infusions for SHI systems as contribution bases shrink, while at the same time the demand for and costs of health care are rising, thus raising issues of the existing systems’ long-term sustainability (Stadhouders et al., 2019; OECD, 2015).

The rest of the chapter is laid out as follows. First, we elaborate on the definitions of public financing for health, general taxation and SHI in particular, and examine how each relates to principles of equity and efficiency and where their boundaries have blurred. Next, we summarize the global landscape and trends in public financing for health across countries. Then, we outline key challenges

facing public financing for health across the different income groupings of countries and some of the solutions.

General taxation and SHI: how countries use them to raise revenues

High-performing health financing models for UHC can be characterized as those where financing levels are adequate, prepaid funds are pooled in order to spread the financial risks of ill health and spending is efficient and equitable. These characteristics ensure the desired levels of effective service coverage and financial risk protection for all people, and provide a system that is both resilient and sustainable (World Bank, 2019a). In general, the overall objectives of public financing are considered to be the provision of public goods as well as to address market failure, redistribute resources and stabilize the impact of business cycles. In the case of the health sector, expansion of public financing constitutes the means by which most countries have made progress towards UHC, including the elements of compulsion and redistribution that are inherent in such a financing modality, though – in a few cases – countries have instead implemented mandates and subsidies for purchasing private health insurance.

General taxation: definition

Under general taxation, revenues for health come from apportioning a share of overall government resources to the provision of health care, either for the entire population or for specific population subgroups such as the poor and vulnerable (Gottret & Schieber, 2006). This type of general tax-financed public delivery system is often referred to as the Beveridge model, named after William Beveridge, the economist whose ideas underpinned the introduction of the United Kingdom's NHS in 1948. Even earlier than this, in the 1920s, a similar, though more centralized and hospital-focused system of universal coverage had been introduced in the Soviet Union, known as the Semashko model, after health care commissar, Nikolai Semashko.

The term general taxation is often used interchangeably with general government revenue financing, although in fact the latter is more accurate since government funding typically comprises both tax and non-tax sources. For example, general taxation financing also includes

both general and sector-specific borrowing by the government. Tax revenues are defined as “compulsory, unrequited” payments to the government; unrequited because the benefits received from government spending are usually not proportional to the amount paid in taxes (OECD, 2021). Tax revenues are further classified into two broad categories, direct and indirect. Direct taxes – for example, taxes on income, profit, wealth and property – can be adjusted based on the characteristics of the payer, but cannot be shifted to another taxpayer. Indirect taxes, in contrast, are paid on transactions that are independent of the characteristics of the payer – for example, taxes on consumption, including sales taxes, value-added tax (VAT), excise taxes and import tariffs; these can, at least in part, be shifted to other taxpayers. Non-tax revenues typically comprise sources of funds other than from taxation: for example, from external grants, rents or royalties from natural resources such as oil, gas and other commodities, as well as profits from state-owned enterprises.

SHI: definition

Under SHI, revenues for health are raised in the form of contributions from a mandatory earmarked payroll tax (Wagstaff, 2010; Yazbeck et al., 2020). Payment of this mandatory contribution secures entitlement to health care, and it is this quid pro quo payment-for-entitlement that is one of the key differences between SHI and general taxation modalities for raising revenues for health. SHI contributions are generally imposed on wages and are paid by both employers and employees of firms as well as by those who are self-employed. Hence, due to the way revenues are collected, there is typically a link between employment status and entitlement. Under SHI financing, funds are pooled, and service providers are paid prospectively or retroactively on behalf of contributors for utilization of health care services; in some countries; for example, in Costa Rica, the SHI agency that collects and pools contributions also owns and manages service delivery via its own network of providers (OECD, 2017a). Contribution rates are usually set based on actuarial analysis of estimated costs and projected utilization rates. An SHI system is also sometimes referred to as the Bismarck model, named after Otto von Bismarck, Chancellor of Germany, who introduced it there in 1883.

Overlapping approaches to public financing in health

General taxation and SHI contributions are often collectively referred to as public sources of health financing given that they both constitute mandatory prepayments for health care and the fact that management and administration of these funds is usually undertaken by government or quasi-public agencies. Some countries – including the Netherlands (Kingdom of the)¹ and Switzerland – mandate that citizens purchase private health insurance; despite the presence of this mandate, revenues raised thus are managed and administered by private entities and, hence, are not considered to be public sources of financing. The latest System of Health Accounts (jointly produced by the Organisation for Economic Co-operation and Development (OECD), Eurostat and the World Health Organization (WHO)) eschews categorizing revenue-raising modalities for health in terms of public versus private; instead, the distinctions are based on whether revenues are: (i) compulsory or voluntary; (ii) domestic or external; and (iii) prepaid or OOP (Jowett & Kutzin, 2015; OECD, 2017b). For the remainder of this chapter, we follow others in the literature and take health's share of general government expenditure – financed by domestic revenues, borrowing, external grants and mandatory SHI contributions, but excluding resources raised via compulsory private insurance prepayments – to represent the overall public financing envelope for health (WHO, 2020).

General taxation and SHI versus principles of equity and efficiency

A key issue is who contributes to and who benefits from a publicly financed health system. One policy objective for such a system is that it should be equitable, with those most able to pay shouldering the heaviest burden of the costs (so in effect redistributing resources from the well-off to the poor). However, obligatory contributions to public funds such as general taxes and SHI can be either progressive or regressive. While progressive payments are defined as those where the well-off pay a generally higher share of their income, a regressive payment is one where the poor pay a higher share of their income

¹ The Kingdom of the Netherlands comprises six overseas countries and territories and the European mainland area. As data for this text refer only to the European territory, the text refers to it as the Netherlands throughout.

relative to the well-off. Generally, direct taxes – on income, property, wealth – are progressive. Indirect taxes – for example, taxes on consumption – are generally regressive. However, governments need to consider not just equity in payments linked to any instrument, but also the possible yield in terms of revenue generation, as well as the cost of collection. They also have the option to compensate for regressivity in any given instrument in two ways: making another instrument more progressive or compensating the poor using transfers in cash or kind from the revenue that is raised. In that sense, progressivity in terms of revenue generation of any particular instrument is not greatly relevant: the equity of the financing system needs to be assessed in terms of the distribution across individuals of *net* benefits, i.e. the payments into the system overall, including for health, net of what they receive as benefits in cash or kind (and not just health benefits) (Kaiser, Bredenkamp & Iglesias, 2016; Jellema, Wai-Poi & Afkar, 2017; World Bank, 2018).

Efficiency in how government revenues are raised is another key consideration in public finance, including for health. All taxes introduce distortions to economic activity by creating a gap between what a buyer pays and what a seller receives. Not only does this cause welfare losses, if not offset or balanced by externalities, but it can also adversely impact resource allocation decisions. In addition, some forms of tax collection themselves can be costlier to administer than others. Well-designed tax systems typically aim to reduce the economic inefficiencies that are inherent in any form of taxation, be progressive and broad-based in their incidence (ideally with minimal exemptions and loopholes) – and be relatively easy and cost-effective to administer.²

Several countries, mostly high income, that originally financed their health provision by means of SHI systems subsequently abolished them – usually out of concerns for equity or as part of more general political reforms – and replaced them with tax-financed systems (Saltman & Dubois, 2004). For instance, the United Kingdom absorbed its existing system of SHI when it transitioned to general

² Although policy choices around taxation and redistribution are largely outside the domain of the health sector, one area of taxation where the health sector has been actively involved is in raising taxes to deter consumption and use of “harmful” products – e.g. tobacco, alcohol, products with added sugar and salt, and polluting fuels – that can also help raise additional resource (even if revenues are not earmarked for health) while at the same time reducing the burden of disease.

Box 1.1.1 Parallel tax and SHI systems: India

India's tax-financed public delivery health system is universal, accessible to all and loosely modelled on the United Kingdom's NHS. It also has several supplementary noncontributory and contributory SHI schemes.

Pradhan Mantri Jan Arogya Yojana (PM-JAY): Noncontributory tax-financed hospitalization coverage scheme for the poor and near-poor which was introduced in 2018 and targets the bottom 500 million of India's population.

Central Government Health Scheme: This covers current and retired central government employees and their dependants, giving them access to public and designated private facilities.

Employees' State Insurance Scheme: For lower-income workers of private firms with 10 or more employees.

Source: Commonwealth Fund (2023).

tax financing in 1948. Norway abandoned its SHI system in 1967, followed by Denmark in 1973. Political transitions furthermore resulted in the removal of SHI and replacement by tax financing for health in Greece, Italy, Portugal and Spain. Conversely, many countries that started out with solely tax-financed health systems later introduced SHI, sometimes as a way to reduce financial pressure on existing tax-financed public delivery systems, but without dismantling them – in particular, in eastern and central Europe. In many countries – for example, in India (see Box 1.1.1), Nigeria, Myanmar and others – both general taxation and SHI financing systems coexist in parallel, but covering different population subgroups.

One advantage of general taxation over SHI is that the former is more broad-based and, hence, assumed to be more resilient and less volatile as a source of public financing. However, this is not always the case. This purported advantage of general taxation as a source of financing can be lost during economic downturns when public revenues decline significantly, especially in the absence of automatic stabilizers and countercyclical policy responses (Maresso et al., 2015). General taxation financing is also subject to political vicissitudes and competition for resources from other sectors, which can add to elements of unpredictability (Wagstaff, 2010). Although SHI revenues are also not immune to economic crises, in some countries – for example, Estonia

during the 2008/2009 economic downturn – SHI reserves can help stabilize volatility and other challenges to short-term revenue-raising pressures. In general, a move towards a diversified revenue base appears to offer the best prospects for mitigating some of these challenges.

Over time, distinctions between the SHI versus the general taxation public financing models have blurred, so much so that they have lost several core characteristics that initially differentiated them (Yazbeck et al., 2020; Mathauer, Saksena & Kutzin, 2019). Included under the umbrella of general taxation financing modalities are situations in which governments impose additional taxes on income or consumption specifically for health, whether or not these are earmarked at source or for use (or both), although payment of these earmarked taxes is usually not a prerequisite for entitlement to health care. At the same time, SHI systems are increasingly dependent on cofinancing via general taxation, either due to prevalence of informal economic activity or the impact of an ageing population. Where governments subsidize contributions – for example, if SHI contributions are fully or partially subsidized for the unemployed, the poor and pensioners – these are classified and analysed as cofinancing via general taxation even if they are paid out by SHI schemes. Several general tax-financed health funding models now include elements that were previously considered to be hallmarks of SHI-financed systems, such as having a clear separation between purchasers and providers, explicit and well-defined benefits packages, use of non-traditional provider payment mechanisms, as well as the purchasing of services from both public and private providers.

It is important to note that the way revenues are raised in health systems can have significant implications for the pooling function of health financing; for example, if resources are raised and pooled separately by geographical areas or – as is sometimes the case under SHI – by industrial affiliation. This is addressed elsewhere in the book (see Chapter 2.1); for the remainder of the chapter, we focus primarily on issues and challenges related to revenue generation via public financing.

Amount and modality of health funding versus country income level

Globally in 2019, the latest year for which data from WHO's Global Health Expenditure database were available at the time of writing, levels of per capita health spending – from all sources of financing,

not just public – ranged from lows of <US\$ 25 in Burundi, the Democratic Republic of the Congo, Madagascar and South Sudan to highs of >US\$ 8000 in Norway, Switzerland and the USA. Although these differences are not adjusted for variations in purchasing power of currencies across countries – for example, US\$ 1 buys more in low-income countries (LICs) than it does in HICs due to cheaper labour and other costs – the contrast in absolute levels of health spending across countries is nevertheless staggering. Differences are less stark when comparing health spending as share of gross domestic product (GDP). In 2019, health spending among LICs averaged 5.2% of GDP (US\$ 35 in per capita terms), compared with 11.4% (US\$ 5644 per capita) among HICs (Table 1.1.1).³ Average levels of health spending vary significantly across income classifications, but the way health is financed also differs significantly. Public financing for health predominates among upper-middle-income countries (UMICs) and HICs. Among HICs, 67% of spending on health in 2019 came from public funding (34% of the latter, on average, from SHI contributions). Among LICs, on the other hand, only 37% (US\$ 12) of funding for health came from public sources (with only 2% of the latter from SHI contributions); this number reduces to 22% if external financing that is channelled via government budgets is excluded (see Chapter 1.4). Private OOP spending is the largest source of funding for health among LICs and LMICs, accounting for 40–52% of health spending. Globally, VHI is not a significant source of financing, contributing only 6% of resources for health. Other private sources – for example, from faith-based organizations, other nongovernmental organizations (NGOs), external financing not channelled via government – are included in the “Other” category in Table 1.1.1.

General taxation is the main source of financing for health in several countries including Australia, Canada, Denmark, Italy, Norway and the United Kingdom (Fig. 1.1.1). SHI contributions, on the other hand, are predominant in Costa Rica, Croatia, France, Germany and Japan, among others. Blended public financing – a combination of financing via general taxation and SHI – is the largest source of health care funding in countries such as Belgium, China, the Republic of

³ We follow the World Bank’s country classification based on income. LICs are countries with a per capita GNI of less than or equal to US\$ 1045; LMICs have a per capita GNI of US\$ 1046–4095; UMICs have a per capita GNI of US\$ 4096–12 695; and HICs have a per capita GNI of US\$ 12 696 or higher.

Table 1.1.1 *Private OOP spending is the largest source of funding for health among LICs and LMICS*

Indicators	Low-income countries	Lower-middle-income countries	Upper-middle-income countries	High-income countries	All countries
Current health spending per capita (US\$)	35	97	555	5 644	1 138
Share of GDP (%)	5.2	3.6	5.9	11.4	5.8
Public share of current health spending (%)	37	36	55	67	47
Per capita (US\$)	12	39	304	3 487	681
Share from general taxation (%)	64	83	60	66	72
Share from SHI contributions (%)	2	11	40	34	24
Share from external sources (%)	33	5	0	0	5
OOP share of current health spending (%)	40	52	33	16	39
VHI share of current health spending (%)	2	5	9	3	6
Other (NGOs, etc.) (%)	21	7	3	14	8

GDP: gross domestic product; OOP: out-of-pocket; NGO: nongovernmental organization; SHI: social health insurance; VHI: voluntary health insurance.

Note: Averages are population weighted.

Source: Authors' estimates based on WHO (2022).

Korea and the Russian Federation. General taxation and SHI contributions account for less than half of current health expenditures in most LMICs including; for example, in Bangladesh, Brazil, Egypt, Ethiopia, India, Pakistan, the Philippines and Nigeria.

There is an inverse correlation between public spending on health as share of GDP and the OOP spending share in current health

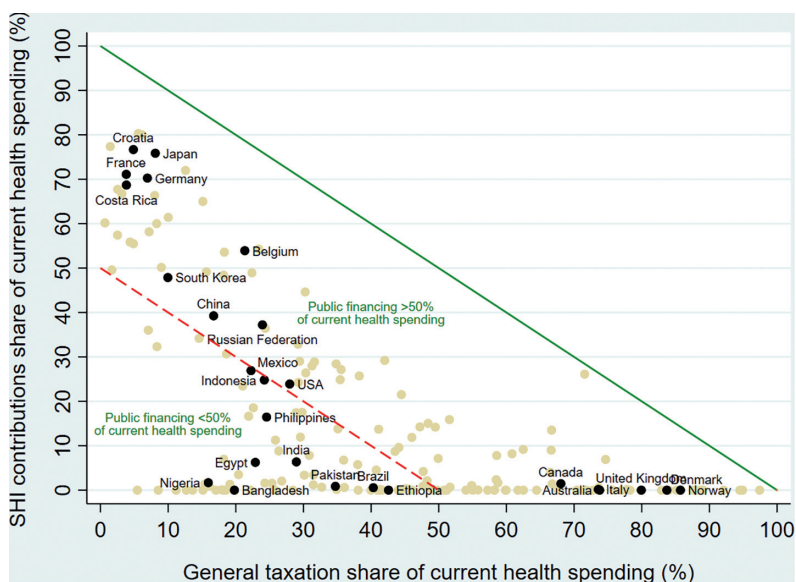


Fig. 1.1.1 Public financing is a much bigger share of health spending in richer countries

SHI: social health insurance; UK: United Kingdom; USA: United States of America.

Source: WHO (2022).

expenditures across countries (Fig. 1.1.2). Low public spending on health often manifests as poor supply-side readiness and responsiveness at public facilities, resulting in the population having to supplement public financing with private OOP payments for medicines and diagnostics or to seek self-financed care at private facilities. Countries that have made the most progress towards UHC generally have OOP spending levels that are less than 15–20% of current health spending, a threshold benchmark recommended by WHO and met or exceeded in HICs within the Organisation for Economic Co-operation and Development (OECD). In the case of countries that have made progress towards UHC despite their OOP spending being higher than the 15–20% threshold, their OOP outlay largely occurs among well-off segments of the population and therefore is no longer a significant risk factor for impoverishment; for example, in Malaysia and Sri Lanka (WHO, 2010). OOP spending shares are particularly high – exceeding two thirds of all spending on health – in sub-Saharan African countries such as in Cameroon, Nigeria and Sudan, as well as in several central

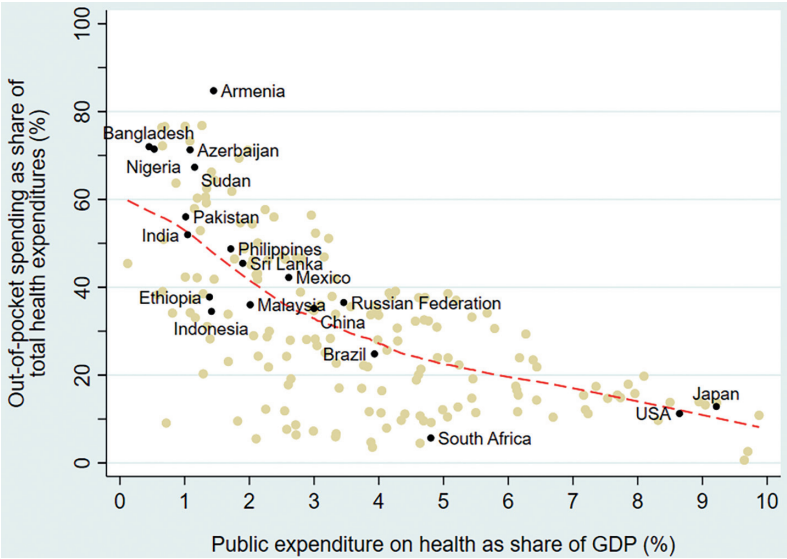


Fig. 1.1.2 OOP falls as public spending grows: the inverse relationship between public versus OOP spending on health, 2019

GDP: gross domestic product; USA: United States of America.

Source: WHO (2022).

Asian and south Asian countries such as Armenia, Azerbaijan, Bangladesh, Tajikistan and Turkmenistan.

Over time, health expenditures have typically risen faster than rates of economic growth, i.e. the unconditional income elasticity of health spending has exceeded unity. Between 2000 and 2019, for instance, there was a secular (long-term) increase in spending on health, both in levels and as share of GDP: for example, per capita spending levels on health increased globally from US\$ 713 (5.1% of GDP) in 2000 to US\$ 1138 in 2018 (5.8% of GDP). Higher levels of current health spending – and a changing composition of financing away from OOP and external sources towards a greater share coming from public sources – is also notable over time (Fig. 1.1.3). These empirical trends – dubbed the health financing transition – are driven by a range of factors (Fan & Savedoff, 2014). Some influence the overall quantum of health spending, while others impact the way in which health systems are financed. The faster growth in health expenditure is partly because people demand more and better services as they get richer. Other influences are population ageing and the associated changes in disease

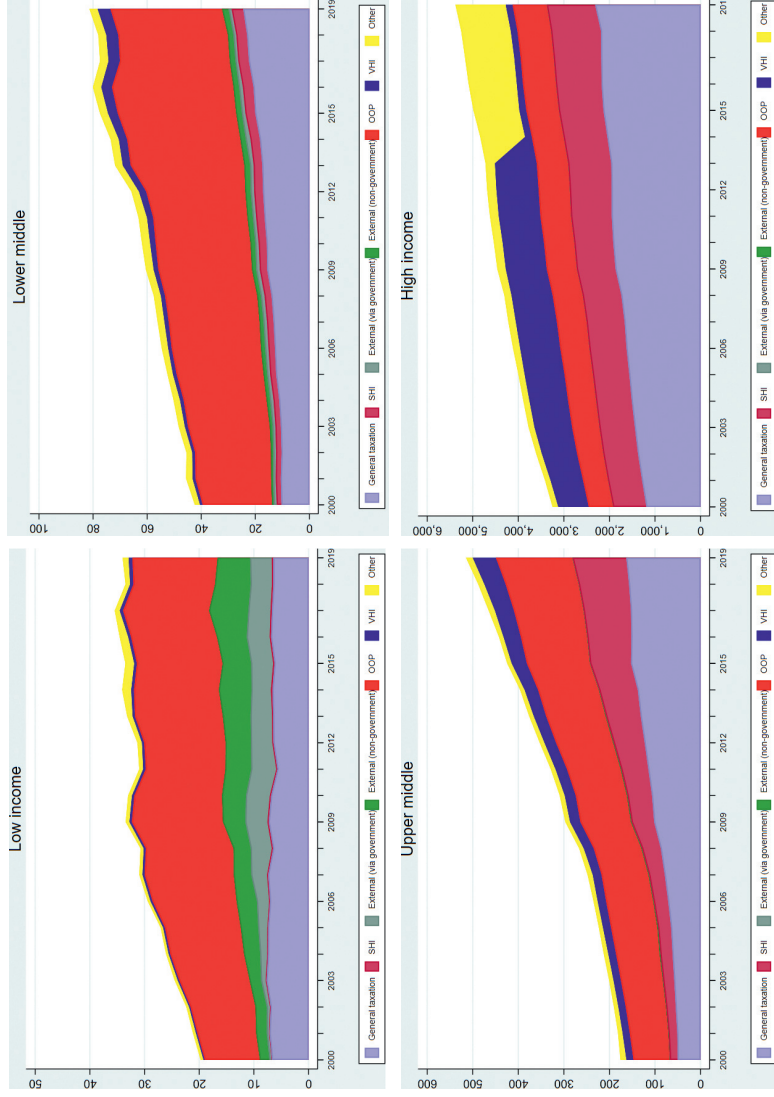


Fig. 1.1.3 Spending has increased across the board but patterns of spending have evolved differently in low-, middle- and high-income countries

OOP: out-of-pocket; SHI: social health insurance; VHI: voluntary health insurance.

Source: WHO (2022).

patterns to costlier chronic conditions; the continuous availability of new and often more expensive medicines and health technologies; and a range of public or private choices made around revenue generation, pooling and purchasing of health care.⁴

The health financing transition reflects what happens on average as countries move up the income ladder. There are important differences, though, across countries and many factors can shape the timing and magnitude of the transition and the extent to which it poses a policy challenge, especially in LMICs. For example, despite rapid economic growth and its transition from LIC to LMIC status in 2015, external financing in Myanmar subsequently increased (not decreased, as might be expected) as a share of health spending (Teo & Cain, 2018). Several countries in the Pacific – including the Solomon Islands, Kiribati and Vanuatu – have relatively low OOP shares in health spending, in contrast to other countries at similar levels of income. In UMICs such as Armenia, the OOP spending share has remained stubbornly high and has been increasing over time despite economic growth (Dudu et al., 2021).

General taxation and SHI: key challenges and country responses

In this section, we examine the challenges posed to the public financing of health, in particular: countries' levels of growth and poverty; countries' often weak overall generation of revenue; high rates of informal economic activity; popular resistance to making SHI contributions; conflicting budgetary priorities; and ageing populations. We also

⁴ Studies published from the 1970s to the 1990s, using cross-sectional data mostly from OECD countries, found income elasticities of health expenditure near or above one, suggesting that health is a luxury good. These studies also found that income differences explained over 90% of the variation in health expenditures across countries, implying that factors other than income were of marginal significance (Gerdtham & Jönsson, 2000). More recently, the dynamic and time series properties of health and GDP data have been taken into account, resulting in elasticities below unity, and classifying health care as a necessity rather than a luxury (Baltagi & Moscone, 2010; Samadi & Rad, 2013; Lv & Zhu, 2014; Fan & Savedoff, 2014). The fact that health spending is still observed to rise more rapidly than national income, despite an income elasticity below unity, is because of the importance of the other determinants described here, including choices made in revenue generation, pooling and purchasing.

include current responses to these challenges: reform of the tax system, blurring and diversifying revenue bases, earmarking new revenues and raising the pension age.

Challenge: Levels of economic growth and poverty

In most countries the overall size of the economy in per capita terms is a key constraint in terms of public financing, including for health. Economic activity is the basis of most forms of taxation, whether taxes are imposed with or without a quid pro quo intent. Countries that have experienced high levels of economic growth generally see levels of public financing for health also increasing at faster rates. India is a case in point: although levels of public financing for health remain far below those expected for its income level, relatively high economic growth rates have resulted in almost a tripling in real public financing for health in India in per capita terms since 2000 (Tandon et al., 2020). Conversely, countries on a lower growth trajectory – for example, Brazil, Mexico, Nigeria, and the Russian Federation – have faced a more constrained environment for public financing for health. Beyond the effects of economic growth, public spending for health is also a function of government revenues as well as the share of government budgets that flow to health (Tandon & Cashin, 2010). Lower levels of economic development are also associated with high rates of absolute poverty; hence, even if institutional mechanisms for collecting taxes exist (which often they do not), the ability of the poor to pay such taxes remains a constraint. In addition, ageing not only causes an increase in demand for health but also lowers the tax base as people retire. (We discuss both ageing and the tax system in more detail in the *Challenge: Governments' conflicting budget priorities* and the *Challenge: Ageing populations* sections).

Weak revenue generation

Weaknesses in revenue generation overall are a key challenge facing public financing of health, especially in LMICs. Lower-income countries tend to have lower levels of government revenue as a share of their economies. In 2019, whereas in HICs average general government revenues, both from taxes and non-tax sources, were 38% of GDP, in LICs this number was only 19%, even when external grants are included

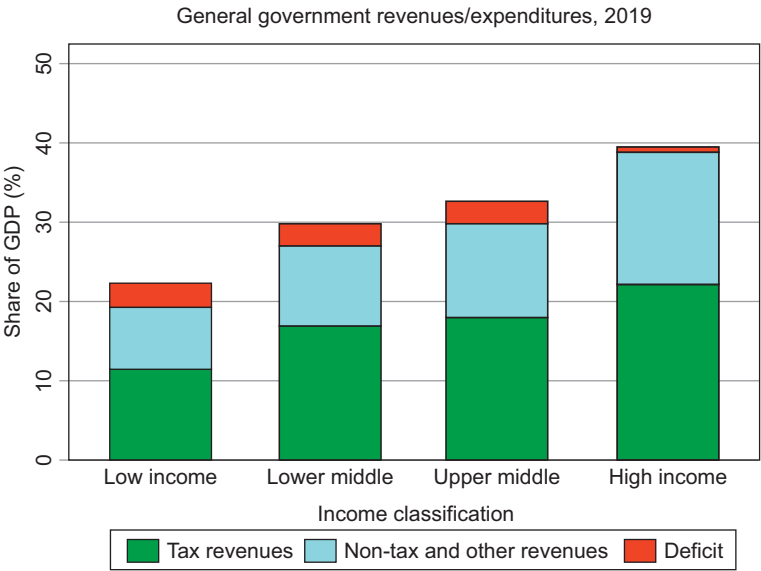


Fig. 1.1.4 General government revenues are a small proportion of GDP in lower-income countries

GDP: gross domestic product.

Source: IMF (2022).

(Fig. 1.1.4).⁵ Although countries can to some extent borrow to increase spending beyond the revenues received, repayment of debt can constrain future expenditure, especially if nominal economic growth rates are lower than the cost of borrowing (Blanchard, 2019). Even within country income groups, there are some countries that lag behind in terms of government revenue collection: for example, in 2019, the general government revenue share of GDP was <10% of GDP in countries such as Bangladesh and Nigeria and only between 10 and 15% of GDP in Democratic Republic of the Congo, Ethiopia, Indonesia and Pakistan, therefore constraining the ability of their governments to publicly finance spending across all sectors, including health.

Response: reform of the tax system

International Monetary Fund (IMF) research has recently suggested a benchmark of at least 15% for the tax revenue share of GDP if

⁵ These are estimates from 2019, i.e. pre-COVID-19.

Box 1.1.2 Strengthening the tax system: Georgia

At the time of its so-called Rose Revolution in 2003, Georgia's tax revenues as a share of GDP were only 12% due to evasion and corruption. Tax reforms – including simplification of the system, curbing exemptions, introduction of flat income taxes for individuals and corporations, a small reduction in the VAT rate and electronic reforms that made it easier to pay taxes – resulted in a sustained increase in tax revenues. In 2008, within just five years of implementing its reforms, Georgia's tax revenue share of GDP had doubled to 24% (Akitoby, 2018). As a result, public spending on health expanded from 1.2% to 1.6% of GDP during the period 2003–2008, despite a decline in health's share of overall government spending over the same period.

Similar reforms led to an increase in tax revenue collection and public spending on health in several other countries including Cambodia, Guyana, Liberia and Ukraine.

countries are to make sustained and inclusive progress on development outcomes (Gaspar, Jaramillo & Wingender, 2016). But how can countries that have low rates improve tax revenues? A systematic assessment across LMICs found 55 episodes of tax revenue increases during the period 2000–2015 that resulted in an annual increase of at least 0.5% of GDP and that lasted a minimum of three years. In most cases, a combination of tax policy and revenue administration reforms were employed. Increases in rates of indirect taxes and broadening the base for both direct and indirect taxes – in addition to simplification, increasing compliance and elimination of tax exemptions – were found to be key in most cases (see Box 1.1.2) (Akitoby et al., 2020).

Challenge: Informal economic activity

In LICs and LMICs, large and persistent levels of informality in the labour market and in the economy more generally makes collection of taxes – especially direct taxes on income, wealth and property – particularly challenging (e.g. tax revenues as a share of GDP are only 8% in the Democratic Republic of the Congo and 10% in Ethiopia). Recent estimates indicate that whereas one third of GDP on average across LMICs is informal activity output – i.e. market based and legal but unobserved or hidden from public authorities for monetary, regulatory or institutional

reasons – more than two thirds of all employment tends to be informal (Ohnsorge & Yu, 2022; Schneider, Buehn & Montenegro, 2010). Informality is often a consequence of poor government enforcement capacity as well as evasive strategies by firms and labourers to avoid (possibly burdensome) taxation and regulation.⁶ There are wide variations underlying these averages: in some lower-income countries with large agricultural sectors and widespread subsistence farming, estimated informal employment exceeds 80%. In addition to its association with agriculture and farming, informal employment is also prevalent among the self-employed or those employed in small firms with relatively few employees. By definition, informal employment occurs without contracts and without formal payroll arrangements.

The challenge of pervasive informality also makes SHI an impractical and ineffective revenue-raising modality for LMICs aiming to make rapid progress towards UHC (Yazbeck et al., 2020). When workers lack formal contracts, labour income cannot be taxed directly. This helps explain the relatively tiny share of SHI contributions in financing health in LICs and LMICs (see Table 1.1.1).

Challenge: Resistance to SHI contributions

Many LICs and LMICs have SHI schemes but they tend to cover a small proportion of the labour force: usually civil servants and those employed in the formal private sector. Even for the latter, imposing the mandate for payment of SHI contributions has often been difficult. For example, Nigeria's SHI programme for the formal sector covers approximately 1.5% of the population, the majority of whom are civil servants. The almost exclusive source of revenue is the employer contribution from the federal government for the civil servants (3.25% of the consolidated salary), while the collection of employee contributions has proven to be politically impossible (World Bank, 2019b). HICs have also faced challenges in maintaining their SHI systems when stakeholders are opposed to contributing because of concerns about rising labour costs and implications for competitiveness.

⁶ Although informality remains widespread in LMICs, there is some evidence that it has been declining – albeit slowly and unevenly – over the past few decades. However, preliminary estimates suggest that informality (and poverty) has risen as a result of the economic fallout from the COVID-19 pandemic (World Bank, 2020; Kurowskiet et al., 2021).

Response: blurring and diversifying revenue bases

Reluctance on the part of stakeholders to contribute to SHI schemes has led many countries to subsidize and co-finance SHI programmes with revenues from general taxation, notably Belgium and France. In the context of high levels of informality, concerns about competitiveness and an ageing population, many countries are moving towards delinking income-related contributions from entitlements and diversifying sources of earmarked taxation away from income (Kutzin, Yip & Cashin, 2016).

France and Hungary have diversified revenue bases for their SHI systems, for example. The United Kingdom collects earmarked National Insurance contributions on income from employers, employees and self-employed individuals and part of these revenues are used to provide about one fifth of NHS's financing; the remainder comes from general taxation (Cylus et al., 2015). Given its significant levels of informal economic activity, Ghana co-finances its SHI fund using earmarked revenues that are levied on consumption – as part of its VAT – in addition to SHI contributions levied on formal sector income (Government of Ghana, 2015). The introduction of India's tax-financed noncontributory health insurance programme for the poor and near-poor in 2018 that covers almost 500 million individuals was used as a means for the central government to raise a cess – basically, an additional 1% tax on all income taxes paid – although the funds are not strictly earmarked for the programme and most of the beneficiaries of the scheme are not the ones that pay income taxes since almost all of them are poor and in the informal sector (Government of India, 2018).

In some countries, the health sector has been actively involved in lobbying for taxes on “harmful” products such as tobacco, alcohol and products with added sugar, in order to deter their consumption and reduce the subsequent burden of disease on the sector, while also expanding the overall public resource envelope (even if the revenues thus raised are not earmarked for health). Given the growing ill health burden resulting from air pollution, carbon taxes are another possible area where the health sector can seek to raise revenues and reduce the risk of disease, as demonstrated by the experiences of some HICs (World Bank, 2019a). The challenge from a fiscal-space-for-health perspective – as opposed to a fiscal-policy-for-health perspective – is the amount of resources generated by adopting such a strategy and whether they can be earmarked and, if so, whether over time such

resources are truly additional. As discussed further below, the Philippines is a recent example of a country that has used earmarked tobacco and alcohol taxes to finance health care contributions on behalf of the indigent and thus create a fiscal space for health (Kaiser, Bredenkamp & Iglesias, 2016).

Challenge: Governments' conflicting budget priorities

A key challenge – especially in LMICs – is that health is accorded a relatively low priority in government budgets, for a variety of reasons: other sectors' demands for financing, perceptions that the health sector is inefficient or is unable to absorb allocated funds, or ideologically driven political narratives that favour private over public versus private financing for health. Globally, health's share in overall public spending stands at about 9% (WHO, 2022). However, there are very large variations across countries: on the one end, health accounts for less than 3% of public expenditure in countries such as Cameroon and South Sudan; on the other hand, health exceeds 20% of public expenditures in other countries such as Costa Rica, Japan, Panama, Uruguay and the USA. Despite large country-specific variations, health's share of government budgets is, on average, higher in HICs (Table 1.1.2). Health care costs tend to be higher in richer countries, driven by relative price differences as well as the availability of higher-technology care. Richer countries also tend to have more educated and ageing populations with preference structures that expect higher levels of public financing for health. Education tends to receive a higher share of government budgets across LICs, LMICs and UMICs; only in HICs does health's share end up being higher than education's, on average. Although both interest payments on debt and military spending represent the same or lower share than health on average, there are notable country-specific exceptions such as Armenia, Bangladesh, India, Morocco, Pakistan, Sri Lanka and Uganda where health receives a lower share vis-à-vis both interest payments and military spending.

Response: earmarking new revenues

Earmarking of new revenues is often implemented to increase health's share of the overall public financing envelope. Earmarking is when revenues are assigned through constitutional or statutory law from certain sources to specific expenditures (McCleary, 1991; Bird & Jun,

Table 1.1.2 *Share of government expenditure for health, education, military and debt interest payments, 2019^a*

Classification	Share of government expenditure			
	Health (%)	Education (%)	Military (%)	Interest payments (%)
Low-income country	9	16	7	5
Lower-middle-income country	6	15	8	15
Upper-middle-income country	10	13	5	5
High-income country	18	13	6	4
All countries	9	14	7	9

^a Share of government expenditure for education is for latest available year in 2014–2019.

Sources: WHO (2022); World Bank (2022).

2005). Apart from the standard case of SHI, different types of earmarks for health have emerged or gained popularity over the past two decades. Earmarks take different forms, with various attempts to categorize them based on the rationale, source of revenue, expenditure category and the revenue–expenditure link. The revenue–expenditure link may be tight, i.e. the amount spent is restricted to the amount raised through the earmark, or soft, i.e. the amount spent is loosely related, if at all, to the amount raised. In practice, many earmarks fall between these two extremes of strength of link. From a sector perspective, two classes of earmarks are of special interest as in both the earmarked revenues are substantial, i.e. they are a prominent source of funding.

Increased rates or new indirect taxes

The first class comprises cases of increased rates or the introduction of entirely new indirect taxes to finance the expansion of health care coverage beyond formal workers and their dependants. The most notable examples include Ghana (a 2.5% increase in VAT in 2004) and the Philippines (additional revenue generated from a

comprehensive reform of tobacco and alcohol taxes in 2012). Other countries are emulating the approach. For example, Egypt, as part of a comprehensive overhaul of its SHI system, introduced earmarks on additional revenue from tobacco tax reforms and new levies on toll roads, drivers and car licenses to complement compulsory, individual contributions (Government of Egypt, 2018). Lessons from Ghana and the Philippines highlight the potential advantages of a soft revenue–expenditure link (Cashin, Sparkes & Bloom, 2017). In both instances, tax reforms generated substantial amounts of funding for the extension of SHI: more than 0.5% of GDP. However, in the Philippines, even in the medium term, additional revenues exceeded the funds that the SHI agency managed to absorb (Ulep, Pargas & Alcantara, 2021). In contrast, in Ghana, from year three onwards, additional revenues fell far short of operational expenditures (Kurowski & Iglesias, in press).

Designated fixed shares for health in budget allocation

The second class of earmarked revenues comprises fixed shares for health in the allocation of general funds. Such fixed shares have been reported by more than a dozen countries. In decentralized systems, fixed shares for health have not only been established at the central level, but also in transfers from central to subnational governments, as well as for lower levels of government, to ensure the overall level of expenditure is adequate but also to reduce spending inequalities. Some countries use this type of earmark for specific expenditure categories – for example, Nigeria does so for its basic health care provision fund and South Africa for its HIV/AIDS programme. The fixed shares typically reflect only a minimum level of spending. As they fall short of actual spending needs, countries have combined them with other types of earmark.

But do these substantial earmarks affect spending levels in the targeted expenditure categories and ultimately in the health sector? In the absence of a counterfactual, this question is difficult to resolve. Country experiences suggest that there may be a short-term effect on government expenditures. For example, in Ghana, the size of the earmark correlated in the early years after its introduction with increases in the level of government spending on health (Kurowski & Iglesias, in press). With time, however, the likelihood increases that allocations from general taxes are reduced. These cuts

may lead to a shift in expenditure priorities with potential consequences for the efficiency of spending. In Ghana, for example, concerns have been raised that priority services outside SHI benefits – for example, immunization services – took a hit.

More generally, empirical work on prioritization has been sparse: the limited cross-country econometric analyses that exist suggest that factors such as democratization, lower levels of corruption, ethnolinguistic homogeneity and more women in public office are correlated with higher shares of public spending on health; however, these findings are not robust and are sensitive to model specification (Lebovic, 2001; Meltzer & Richard, 1981; Keefer & Khemani, 2005; Tandon et al., 2014). A range of factors – political changes, disease outbreaks/pandemics, macroeconomic shocks – are common triggers that can sometimes lead to a sustained increase in health's share of a government's budget. The use of budgetary or numeric financing targets (e.g. the Abuja Declaration target that health's share of the government budget be at least 15%) generally has not resulted in a higher priority for health. Evidence to date suggests that country-specific political economy considerations are key and that results-focused reform efforts – in particular efforts to explicitly expand the breadth and depth of health coverage as opposed to efforts focused only on government budgetary and numerical targets – are more likely to result in a sustained and politically feasible prioritization of health.

Challenge: Ageing populations

Another key policy challenge – particularly among UMICs and HICs – is that of an ageing population. With higher life expectancies and declining fertility has come a growing proportion of the population that is elderly with greater needs for health spending and long-term care. Some UMICs are seeing higher median ages resulting from declining fertility alone, even without registering significant improvements in life expectancy. United Nations estimates place the total number of people aged 65 years and above at 727 million in 2020, about 9% of the global population; this number is expected to more than double – to 1.5 billion, 16% of the global population – by 2050. In 2020, several countries such as Brazil, China and Mexico were already classified as “ageing”, i.e. with a population share of people aged more than 65

years over 7%; the Russian Federation and the USA counted among “aged” countries – with a population share of people aged more than 65 years exceeding 14% – and Japan was already “super-aged” with a share of the population aged more than 65 years of more than 21% of its total population (United Nations, 2020).

From a revenue generation perspective, the immediate risks from ageing are rising old-age dependency ratios – i.e. increasing numbers of those aged over 65 years relative to those in the working age population group aged 15–64 years – such that even if the size of the working age population is growing, it is having to provide a resource base for public financing for health and other services for a dependent population of people aged more than 65 years that is growing at an even faster rate. Elderly populations tend to have greater rates of multi-morbidity from noncommunicable diseases (NCDs) than younger, working populations and need integrated care, which currently is provided in a fragmented manner across most countries. This rise in old-age dependency is already occurring in nearly all countries – albeit at different rates – and the trend is expected to accelerate in coming decades, especially in HIC. According to the United Nations’ projections, by 2050, the proportion of those people aged more than 65 years will be almost three quarters the proportion of those in the working age population group in Japan; this same old-age dependency ratio will exceed 35% in China, Brazil, the Russian Federation and the USA.

Although rising over time, the old-age dependency ratio in 2050 is expected to remain 10% or below in lower-income countries such as Ethiopia and Nigeria (Fig. 1.1.5). In some countries such as China, Japan and the Russian Federation, the rise in old-age dependency is occurring on top of an ongoing decline in the working age population of 15–64 years old. With ageing comes the potential for declining labour productivity and, when combined with a shrinking labour force, the possibility of reductions in investments and economic output. These trends can have adverse knock-on effects on public financing including for health, increasing the need for additional public spending while at the same time reducing the ability of governments to raise revenues as (generally lower) pension incomes replace (generally higher) labour incomes. Tax revenues tend to be highly correlated with the size of the employed population rather than with the size of the total population (Rouzet et al., 2019). For lower-income countries, the challenge of ageing is that it is likely to occur at a rate that is faster

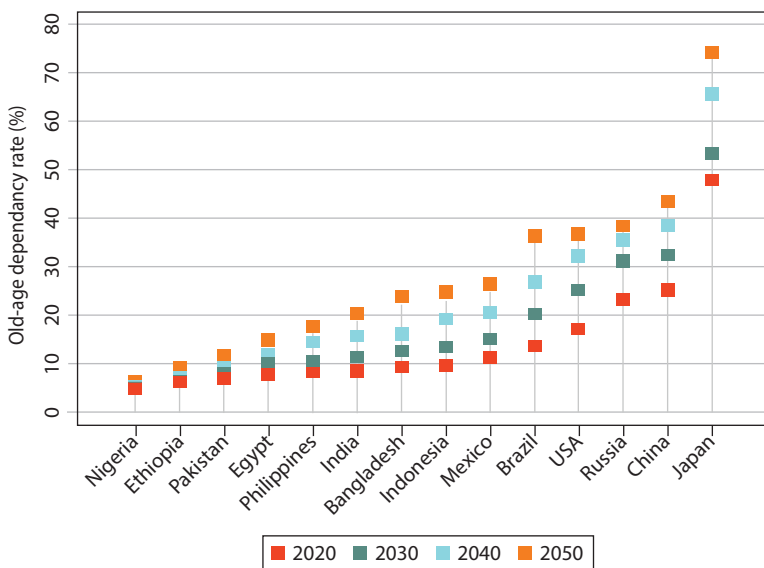


Fig. 1.1.5 Old-age dependency ratios are projected to increase in many (middle- to higher-income) countries

USA: United States of America.

Source: United Nations (2020).

than underlying rates of economic development, i.e. many of these countries will become old before they become rich.

Response: strategies to offset the impacts of ageing on revenues

There is growing empirical evidence that suggests the impact of ageing on health spending might not be as high as expected. Although ageing is associated with higher prevalence of multimorbidities and greater rates of utilization of health care, the impact is not as dramatic as that of other drivers of health spending such as technological innovations (Greer et al., 2021). Moreover, countries could cope with some of the challenges of reduced revenue generation due to ageing by implementing corrective policies. Many HICs have raised the mandatory retirement age in line with rising life expectancies to increase the potential labour force while at the same time decreasing old-age dependency ratios. In Portugal, for example, the mandatory retirement age now automatically increases by two thirds of any increase in life expectancy.

Similar approaches have been adopted in Denmark, Finland, Italy, the Netherlands and elsewhere. Simply raising the mandatory retirement age, however, may not be sufficient to induce older people to work: such policies would need to be combined with other incentives including flexible working arrangements and designing older people-friendly workplaces. A recent systematic review of the literature did find evidence, though, that raising the mandatory retirement age increased labour force participation rates among older people (Patrick, Groot & Pavlova, 2021).

As outlined above, other options include diversification of the revenue base by increasing taxes on consumption and wealth rather than relying on wage-based income alone. For example, although France's SHI system was initially almost entirely funded from wage-based payroll contributions, these now account for only about half of the system's revenues. The remainder is financed by an earmarked income tax – levied on all sources of income – along with taxes on tobacco and alcohol, the pharmaceutical industry – and VHI (Commonwealth Fund, 2020). The shift to a broader definition of taxable income in France has also decreased inequities in revenue generation as richer individuals not only tend to be older but they also have higher wealth-related income (World Bank, 2019a). Similarly, Hungary's SHI system is now a hybrid: transfers from general taxation are just as important a revenue source as payroll-based contributions, potentially enhancing the sustainability of health financing in the light of ageing (Szabolcs et al., 2019).

Policy relevance and conclusions

This chapter has landscaped revenue raising for health via public financing – both general taxation and SHI – with an understanding that the compulsory and redistributive elements of this source of financing have been key for making sustained progress towards UHC. Public financing for health is predominant among HICs where key challenges faced include those of sustainability, diversification of revenue sources (especially where SHI is prevalent) and cost containment in light of demographic, epidemiological and technological trends. Among lower-income countries, on the other hand, the key challenge is navigating and accelerating the transition from predominantly private OOP financing of health systems towards greater levels and effective use of public resources for health. Lower-income countries that have successfully

made the transition to expanding public financing for health have done so by means of expanding general taxation through a combination of economic growth, improving government revenue generation and increasing the share for health in government budgets, and by targeting spending towards the poor (Cotlear et al., 2015).

We underscore the view that SHI financing for health is, in essence, earmarked taxation of wages and, over time and across countries, we are seeing a blurring of institutional and other differences between systems that were previously separately classified as general tax-financed models of health financing versus SHI-financed. Several general tax-financed health financing systems now include elements – for example, strategic purchasing of health services and a purchaser-provider split – that were previously considered to be hallmarks of SHI-financed systems. And SHI-financed systems are increasingly becoming dependent on complementary general tax-financed sources, especially for subsidizing financing of health care coverage for the poor, unemployed and retired populations. In some HICs, stakeholders oppose raising SHI contributions because of concerns about rising labour costs and implications for competitiveness. Such constraints have led many countries to subsidize and co-finance SHI programmes with revenues from general taxation. In such environments – with high levels of informal economic activity, competitiveness concerns and an ageing population – countries should consider delinking income-related contributions from entitlements and diversifying sources of earmarked taxation away from income (Kutzin, Yip & Cashin, 2016). The challenge of pervasive informality makes SHI an impractical and ineffective large-scale revenue-raising modality in LMICs (Yazbeck et al., 2020).

Globally, it is increasingly evident that expansion in general taxation, more so than SHI, has been central for precipitating health financing transitions as well as for making and sustaining progress towards UHC. Although SHI financing remains part of the revenue-generating arsenal to varying degrees depending on country context, the global policy dialogue is increasingly centred around constraints and opportunities related to diversifying revenue sources, delinking employment from entitlement and moving towards a more central role for general taxation as the core source of public financing for health.⁷

⁷ Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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1.2

Community-based health insurance

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Key messages

Chapter 1.2 assesses community-based health insurance (CBHI). CBHI is a voluntary, self-organized approach to financing health care for groups of individuals in the absence of other forms of health care coverage. CBHI scheme members organize themselves, collect and pool their insurance premiums, and use them to purchase health services for members. Key learning includes that:

- CBHI is not a miracle solution to affordable access to health care:
 - the very poor often do not enrol, and when they do, they tend to use fewer health services;
 - out-of-pocket (OOP) payments are not necessarily reduced.
- Low uptake, poor delivery of promised benefits and challenges around governance undermine the impact of CBHI.
- CBHI does not overcome broader issues, such as a lack of financial resources.
- CBHI might serve as a transitional mechanism towards universal health coverage (UHC) and offer some financial protection for the most vulnerable provided that:
 - policy-makers create a supportive political and economic environment;
 - social capital can be mobilized;
 - schemes are institutionalized within the health sector.

Introduction

CBHI is one of many terms used to describe small-scale schemes which aim to provide financial protection for individuals when they seek

medical care.¹ Community members organize themselves, collect and pool their insurance premiums, and use these to purchase health services for their members. Traditionally associated with settings where health care is not publicly funded or provided universally, CBHI schemes apply the same principles used in formal health insurance – in particular, resource pooling, prepayment and risk sharing – and adapt these to local social contexts.

CBHI's proponents advocate for its use on two main grounds. Firstly, it can provide an additional or alternative form of revenue-raising in low- and middle-income countries (LMICs) without a robust tax base and the institutional capacity to collect either taxes or insurance premiums effectively. Secondly, in the absence of universal public provision of health care, CBHI has the potential to overcome the financial barriers to accessing health care put up by formal private and social health insurance (SHI) schemes (see chapters 1.1 and 1.3). In particular, these formal schemes tend to exclude rural and informal sector workers and those with an irregular income or none. In many LMICs, those excluded constitute over three quarters of the population and the members of this already vulnerable group – often the most affected by ill health – are left without any form of financial protection from its effects (Donfouet & Mahieu, 2012).

CBHI schemes are intended to provide financial protection, cushioning households from potential poverty occasioned by catastrophic health care costs (Haddad et al., 2012; Rosner et al., 2012). They reduce members' vulnerability to health-related financial shocks by eliminating dependence on OOP payments at the point of health service utilization. Pooling risks across members enrolled in the CBHI scheme reduces the financial burden among the members, as they do not have to incur financial costs to receive health services (see Chapter 2.1). The removal or reduction of financial barriers is intended to increase access to health care and prevent absolute poverty among beneficiaries (Donfouet & Mahieu, 2012).

Some advocates of CBHI go further, suggesting that its implementation is a plausible option for countries seeking to achieve United Nations Sustainable Development Goal 3.8 of UHC, including financial protection (Seventieth United Nations General Assembly, 2015; Qin

¹ Community-based health insurance is variously referred to in the literature as community health insurance, medical aid societies/schemes, mutual health insurance/organizations or, in francophone countries, *mutuelles de santé* (Carrin, Waelkens & Criel, 2005; Adebayo et al., 2015).

et al., 2019; van Hees et al., 2019). International development agencies are leading the narrative that CBHI holds potential as a transitional mechanism for UHC and many LMICs now include CBHI in their strategies towards UHC (Mladovsky & Mossialos, 2008).

Countries vary in their definition of CBHI, however. In its purest form, CBHI is defined as a form of micro health insurance (Donfouet & Mahieu, 2012), which is distinguished from other health financing structures by five key characteristics: (i) voluntary enrolment; (ii) pre-payment of premiums; (iii) community ownership and participatory management of the schemes; (iv) solidarity, with membership not tied to risks and an emphasis on inclusivity; and (v) non-profit, with the primary goal being supporting members to assure the community's health status (Atim et al., 1998; Criel et al., 2008; Michielsen et al., 2010; Soors et al., 2010). However, in the case of some of the schemes held up as the success stories of CBHI, for example, in Ghana and Rwanda, enrolment is mandatory (among other differences), so their status as exemplars of CBHI is questionable (McIntyre et al., 2008; Witter & Garshong, 2009).

In this chapter, we look in more detail at how CBHI works and its impact, the challenges in implementing it, the preconditions required for its success (including a brief case study of CBHI as implemented in Senegal), and assess CBHI's potential as a transitional mechanism to UHC. First, however, we examine the nature and origins of the financial barriers that CBHI is intended to overcome.

Financial barriers to accessing health care

Since the 1980s, in response to structural adjustment programmes (SAPs) imposed by the World Bank and the International Monetary Fund, LMICs have introduced a series of health financing reforms to generate revenues for the health sector (Helleiner, 1983).

Initially, these reforms created a health care market, allowing for the introduction of user charges and the establishment of an insurance market, for both public (i.e. social) and private health insurance. Anyone wishing to access health care was therefore required to pay the user charges either by means of their health insurance or "OOP", i.e. with their own money. Unfortunately, the quantification of health as an economic good as envisioned by the proponents of such reforms was, and remains, far removed from the realities of many of the

countries where SAPs were imposed. Their realities include an economic and financial base which is too low to support individual OOP payments, a fiscal capacity too limited for governments to subsidize much of the population and similarly limited capacity to pool resources from the large informal economy (Helleiner, 1983).

In practice, targeting mechanisms for both social and private health insurance exclude rural and informal sector workers and those with an irregular or no income at all from coverage (Donfouet & Mahieu, 2012). Excluded households must instead pay user charges for their health care via OOP payments, which have been described by some as “the worst form of health care financing conceivable” (Rosner et al., 2012; Qin et al., 2019) (see Chapter 2.4). Many are unable to pay and, unprotected by health insurance, therefore are faced with an insurmountable financial barrier to accessing health care.

An overwhelming body of evidence confirms the negative effects of this form of financing on the utilization of health services and population health outcomes (Ridde, 2015; Leone et al., 2016; Ponsar et al., 2011; Qin et al., 2019; Tahsina et al., 2018; Watson et al., 2016). Further, it is now widely acknowledged that health service user fees are incompatible with UHC. Faced with health care costs, uninsured households either opt to forgo or postpone access to medical care, or resort to borrowing funds or selling household assets to meet the costs (Leive & Xu, 2008; McIntyre et al., 2006; Nguyen et al., 2012; Rosner et al., 2012; Sangar, Dutt & Thakur, 2019; Tahsina et al., 2018).

It is unsurprising that attempts to institutionalize reforms such as user fees at a national level have not yielded the desired impact – i.e. increased health revenues, greater access to health care and improved health outcomes (Ridde, 2015). Since the 1990s, then, many LMICs have looked to CBHI schemes as a way of overcoming the financial barrier faced by so many when in need of health care.

Diop and Ba (2010) highlight four forms/levels of financial exclusion which characterize population groups likely to be without both public insurance and SHI (Diop & Ba, 2010; Soors et al., 2010): (i) total exclusion – those who are unable to pay for health care services due to economic inability to do so; (ii) temporary exclusion – those who are unable to pay for health care services at the time of need and therefore opt to postpone care; (iii) seasonal exclusion – those who may be seasonally excluded owing to cash flow constraints resulting from the nature of their work, such as farmers dependent on harvests; and (iv)

partial exclusion – individuals who may not be able to cover part of their treatments. Therefore, theoretically CBHI mechanisms can fill a gap and offer health services and financial protection to individuals and households thus excluded, in particular those totally excluded (group i) and those seasonally excluded (group iv).

How CBHI works

The simplicity of CBHI designs, affordability by group members with flexible premiums and payment options and the community-based nature make CBHI schemes attractive. Their flexibility in design allows for different types of health insurance dependent on a community's specific set-up and needs. The schemes are often linked to a social, family, ethnic or community group or health care provider (Alkenbrack, Jacobs & Lindelow, 2013; Fadlallah et al., 2018; Musau, 1999; Nshakira-Rukundo, Mussa & Cho, 2021). Members often share residence; for example, a village or groups of villages in the same locality or neighbourhoods or other geographical and administrative boundaries. Some are user-initiated or local health care provider-initiated schemes, as is the case in Uganda (Basaza, Criel & van der Stuyft, 2010) and India (Devadasan et al., 2006), or schemes initiated by microfinance institutions, as in Kenya and India (Devadasan et al., 2006; Musau, 1999), cooperative movements and nongovernmental organization (NGO)-led schemes (Aggarwal, 2010; Devadasan et al., 2010; ILO, 2008; Kamau & Njiru, 2014; Yap, 2003).

The groups organize themselves in a voluntary capacity to pool resources, allocate these and purchase needed health services for their members. The community agrees the premiums and the range of benefits covered, which may be linked to the level of contribution. Premiums are paid in cash or kind, with some schemes designing payment to coincide with the availability of the means to do so; for example, following a harvest (Preker et al., 2001). By pooling both risks and resources from involved communities, members are responsible for ensuring the viability of the scheme (Criel et al., 2008; Soors et al., 2010).

Externally sponsored CBHI schemes

Since the 1990s, CBHI has been seen as the way to extend social health protection, with multiple experiences in LMICs. Interest in CBHI (re)intensified after 2015 when United Nations' Member States adopted

UHC, including financial risk protection, as part of Sustainable Development Goal 3.8.

Most CBHI schemes in Africa and Asia were introduced and supported by external actors; for example, Belgians and the French for CBHIs in west and central Africa. Many started as research projects or pilots, such as in Guinea (Sylla et al., 2002), Lao People's Democratic Republic (Bodhisane & Pongpanich, 2017), government trials, such as in China (Hsiao, 2001; Wang et al., 2005; Yip & Hsiao, 2008), the Philippines (ILO, 2004) and Ghana (McIntyre et al., 2008).

Some were initiated by NGOs, both locally and internationally; for example, the ORT Health Plus scheme in the Philippines (Aviva & Kupferman, 1996) and faith-based institutions, such as the Presbyterian Church of East Africa's CBHI scheme at Chogoria mission hospital in Kenya (Musau, 1999). In Mali, early CBHI schemes targeted specific members of the population; for example, pregnant women (Ndiaye et al., 2008) while the Bwamanda district hospital scheme in the Democratic Republic of the Congo started in 1986 with funding from the Belgian government which was targeted to health providers (Moens, 1990).

In Africa, CBHIs started in, and were more common in, West Africa than the rest of the continent. In Senegal, the first CBHI schemes were trialled during the colonial period from 1910 onwards, but they did not remain in place for long and covered very few people (mostly colonists) (Ridde, Diaw & Béland (2025). The Mutuelle Pharmaceutique de la Sainte Famille Tounouma in Burkina Faso was one of the first, initiated in 1986 (Soors et al., 2010). Senegal and Benin followed closely, with other countries in the continent establishing similar schemes albeit with variations in the designs (Atim et al., 1998; Criel et al., 2008; Musau, 1999).

In Asia, CBHIs were piloted primarily in Afghanistan, Bangladesh, India and Nepal (Bhageerathy, Nair & Bhaskaran, 2017; Criel et al., 2008; Devadasan et al., 2010; Soors et al., 2010). While CBHIs were mainly designed for and available in rural populations, schemes were also established in Tanzania and Ivory Coast targeting urban populations (Soors et al., 2010).

Subsequently, such schemes have been considerably expanded, in particular by government initiatives to subsidize contributions for people who wish to join CBHIs voluntarily, and thus to increase coverage. For example, in Mali and Senegal, the state subsidizes 50% of the annual premiums for the general population. In Senegal, the

state subsidizes 100% of premiums for indigent people with varied provisions for other population groups while in Burkina Faso the poorest pay 50% of the premiums (Ridde et al., 2018; Parmar et al., 2014). In 2019, the Senegalese government provided CFA franc 19 billion to cover 50% of the premium costs for 2.84 million general population CBHI members and 100% of coverage for 1.27 million indigent people (Ridde et al., 2018; Daff et al., 2020).

CBHI's impact: mixed evidence

Evidence on the impact of CBHI is mixed. Some is positive: for example, evidence from the first CBHI scheme in Mali suggested increased coverage across all dimensions, higher hospital utilization rates and a reduction in OOP payments for members compared to non-members (Soors et al., 2010). We present here some of the evidence of CBHI's impact on the level of utilization of health services, equity in using them (i.e. do the poor use them as much as the non-poor?), financial protection and population coverage.

Utilization

On the positive side, affiliation to a CBHI scheme has been associated with increased use of hospital-based health services in countries such as Ethiopia and Senegal (Mebratie et al., 2019; Joshi et al., 2020; Artignan & Bellanger, 2021), and greater use of preventive services, including insecticide-treated mosquito nets and deworming services in Uganda (Nshakira-Rukundo, Mussa & Cho, 2021).

Equity

There is positive evidence on equity in Rwanda (Collins, Saya & Kunda, 2016) – but questions surround whether Rwanda's health insurance scheme is CBHI in anything but name; and some evidence of success in Armenia (Polonsky et al., 2009) and Burkina Faso (Parmar et al., 2014). In most settings, the very poor are still less likely to enrol or to use health services even when enrolled in a CBHI scheme (Parmar et al., 2014). An evaluation of CBHI schemes in Senegal established that while membership increased utilization of services by the non-poor, the schemes had no impact on poor people's health care utilization and did not protect them against impoverishing catastrophic expenditures (Ly, Faye & Ba, 2022).

Financial protection

Overall, the evidence on the impact of CBHI schemes on financial protection has been either limited or very modest. A 2015 review of the role of CBHI in 14 Asian and nine African countries established that by reducing OOP payments, current health expenditure, total health expenditure, household borrowings and poverty in the majority of cases, targeted schemes contributed to the financial protection of members (Habib, Perveen & Khuwaja, 2016).

Evidence also suggests a reduction in OOP payments for enrolled households in some of the CBHI schemes in Senegal (Jutting, 2003), Burkina Faso (Parmar et al., 2014), Benin (Haddad et al., 2012), Tanzania (Msuya, Jutting & Asfaw, 2007), Rwanda (Lu et al., 2012; Saksena et al., 2011) and India (Aggarwal, 2010; Devadasan et al., 2007).

However, CBHI affiliation in China was associated with increased OOP payments and the risk of catastrophic health spending during the period 1991–2003 (Wagstaff et al., 2009).

With less than 1.5% of the Guinea population enrolled in a CBHI scheme as of 2006, there was no impact on financial protection and population coverage (Ndiaye, Soors & Criel, 2007).

Population coverage

In 2011, Ethiopia set a target of 80% CBHI coverage by 2020. However, more than a decade later, the national coverage is estimated as 50% with significant variations across the regions (Tahir, Abdilahi & Farah, 2022).

Higher rates are reported in Ghana and Rwanda, where management by government officials and mandatory enrolment have transformed community-based schemes into SHI. A strict enforcement of enrolment in Rwanda has led to near-universal population coverage (Chemouni, 2018). However, with minimal enforcement in Ghana, the expected coverage has not been attained (Kwarteng et al., 2019) and remains at under 40% (Salari et al., 2019).

Next we turn to the challenges in implementing CBHI schemes that help to explain why their overall impact so far is disappointing.

Challenges to implementing CBHI

Many CBHI schemes have collapsed after initial pilot phases or are struggling due to an array of factors, ranging from discontinuity of funds, heavy dependence on external funding for survival, limited

government involvement, lack of trust and non-affordability of premiums, to broader health system issues such as the inaccessibility of health facilities (Bennett, 2004; Criel & van Dornael, 1999; Kigume & Maluka, 2021; Muchabaiwa et al., 2017; Fadlallah et al., 2018; Waelkens et al., 2017; Umeh, 2018; Atinga, Abihiro & Kuganab-Lem, 2015). As already mentioned, Francophone west African countries have witnessed decades of trials and large-scale deployments of CBHI – yet they still fail to cover and protect many people in the informal sector, especially in rural areas (Ridde et al., 2018). Indeed, while seeking to provide a solution to the problems of exclusion from health care and financial protection, CBHI brings with it its own set of challenges – in particular, low uptake, inadequate benefits packages and issues of governance – as well as having to contend with broader health system issues. We explore each of these challenges briefly below.

Challenge 1: Low uptake

The uptake of CBHI schemes remains limited in many settings. A core barrier to increasing uptake of CBHI is the limited ability of people in the informal sector to pay for premiums (Adebayo et al., 2015). High poverty levels, lower education and the resultant limited purchasing power among households preclude the sustainability of CBHIs (Fadlallah et al., 2018; Shewamene et al., 2021; Umeh & Feeley, 2017; Adebayo et al., 2015). Evidence also points to a lack of awareness or limited understanding about health insurance generally, and CBHI specifically, which leads to poor uptake among communities (Alkenbrack, Jacobs & Lindlelow, 2013; Cofie et al., 2013; Kigume & Maluka, 2021; Noubiap et al., 2013; Shewamene et al., 2021). The limited uptake of CBHI schemes is also considered to be a function of the lack of supportive regulatory frameworks, and interpersonal, community- and system-level conflicts in horizontal and vertical relationships (Atim et al., 1998; Alkenbrack, Jacobs & Lindlelow, 2013; Bennett, 2004; Carrin, Waelkens & Criel, 2005; Purohit, 2014) (see the *Challenge 3: Issues with governance* section).

Challenge 2: Inadequate benefits poor delivery

The benefits expected with CBHI membership are not always delivered. For example, in one scheme in the Democratic Republic of the Congo,

while all costs were covered in theory, hospitals did not recognize CBHI cards (Soors et al., 2010). As a result, patients incurred significant OOP costs while accessing care, defeating the purpose of their CBHI membership. Similarly, in Bangladesh, the level of financial protection offered by the CBHI schemes often did not sufficiently protect households from incurring catastrophic health expenditures (Werner, 2009). Perceived poor quality of health services and frequent medication stockouts have also been documented (Criel et al., 2020; Kigume & Maluka, 2021). In part, CBHI's failure to deliver is a function of its low uptake: small-scale CBHI pools with very limited risk sharing present a serious organizational challenge (see Chapter 2.1), and the poor delivery of services then further discourages uptake.

Challenge 3: Issues with governance

CBHI issues with governance are both internal, related to the schemes' community base, and external, related to the quality and level of support they receive from outside agencies, including other parts of the health system, local and national government and NGOs (i.e. both horizontal and vertical linkages).

Internally, the weak managerial capacity in many CBHI schemes is attributed to the community ownership and management of the structures (Atim et al., 2001; Basaza, Criel & van der Stuyft, 2007; Kigume & Maluka, 2021; Mladovsky, 2014). By excluding non-members from their management and decision-making, CBHI schemes can lack necessary input from management experts, as well as health professionals (Soors et al., 2010). Lack of trust in CBHI leadership and among fellow members has also been associated with low enrolments and dropouts of previously enrolled members (Alkenbrack, Jacobs & Lindelow, 2013; Fadlallah et al., 2018; Muchabaiwa et al., 2017; Ozawa & Walker, 2009; Rao et al., 2009; Shewamene et al., 2021). The communal membership, which would otherwise be a strength, instead becomes a risk.

Externally, researchers have pointed out that some CBHI schemes are disconnected from the local health systems (Alkenbrack, Jacobs & Lindelow, 2013; Bousmah et al., 2021; Mladovsky, 2020). The non-recognition by hospitals of CBHI cards in the Democratic Republic of the Congo, as described above, constitutes a prime example (Soors et al., 2010).

Government support for CBHI schemes includes establishing a regulatory framework within which CBHIs can operate, monitor, coordinate and manage the schemes (but stopping short of mandating enrolment and transforming CBHI schemes into SHI). However, overall, the lack of, or often-limited, political buy-in has been highlighted as a major challenge facing CBHIs (Basaza, Criel & van der Stuyft, 2010; Purohit, 2014; Uzochukwu et al., 2009). There have been attempts to create and adopt legislative frameworks within which CBHIs can operate in countries such as Mali, Senegal and Togo (Barry, 2007; Diop & Ba, 2010; Letourmy & Ouattara, 2006). In India, a policy supporting the development of health insurance programmes encourages the involvement of community-based organizations in pro-poor risk pooling arrangements (National Rural Health Mission, 2005; 2007). Similarly, the SHI master plan in Cambodia, while offering a fragmented approach towards achieving UHC, recognizes the use of CBHI as one of the strategies and has established relevant implementation guidelines (Annear, 2009; ILO, 2008). The community health funds and TIKA schemes in Tanzania, and CBHI in Lao People's Democratic Republic, are backed by legislation (Alkenbrack, Lindelow & Jacobs, 2010; Jutting, Msuya & Afsaw, 2004) while in the Democratic Republic of the Congo, development of CBHIs was included in the country's 2009–2011 specific action plan (*Programme National de Promotion des Mutuelles de Santé*, 2009). However, the evidence on the impact of such policies aimed at enabling CBHI is limited.

It remains the case that most countries do not have regulatory frameworks supporting the operationalization of CBHI schemes and, where they do exist, for example offering financial support to cushion vulnerable population groups, or re-insurance of schemes and guarantees, they are perceived as weak (Atim et al., 1998; Diop & Ba, 2010). Nonetheless, there have been several initiatives to subsidize contributions for people who wish to join CBHIs voluntarily – again including in Mali and Senegal. In both countries, the state subsidizes 50% of the annual premiums for the general population (Ridde et al., 2018). In Senegal and Burkina Faso, the state subsidizes 100% of premiums for indigent people, with varied provisions for other population groups, while in Burkina Faso the poorest pay 50% of the premiums (Ridde et al., 2018; Parmar et al., 2014). However, there is limited evidence on the effectiveness of such subsidies on the utilization of services and financial protection for indigent people.

Challenge 4: Broader health and insurance system issues

Broader health and insurance system issues have also been highlighted as key barriers to enrolment in, and the sustainability of, CBHI schemes.

Moral hazard, adverse selection and supplier-induced demand

By being based in the community, theoretically, the occurrence of some of the challenges faced by private and SHI systems can be minimized, such as moral hazard, adverse selection and supplier-induced demand. This is because, theoretically, these can be accounted for at the design stage. However, CBHI faces these problems too, as well as underinsurance and information asymmetry.

Moral hazard refers to the situation where individuals alter their health-seeking behaviours, accessing or utilizing care simply because they are covered (Powell & Goldman, 2021). The voluntary nature of the membership of CBHI schemes makes them more prone to adverse selection, a situation where high-risk or sicker individuals are more likely to self-enrol than those who are deemed low risk or healthier (Parmar et al., 2012). Adverse selection has been identified among CBHI enrollees in Zimbabwe (Muchabaiwa et al., 2017) and elsewhere in sub-Saharan Africa (Wiesmann & Jutting, 2000); and especially following the introduction of subsidies in Burkina Faso (Parmar et al., 2012). Evidence of moral hazard and supplier-induced demand for services among members of CBHI schemes has also been documented in Ethiopia (Ayana, 2020) and Zimbabwe (Muchabaiwa et al., 2017). Supplier-induced demand occurs when health providers use their discretionary powers to influence change in demand; for example, by overprescribing services and commodities (Crane, 1992). Such malpractices threaten the sustainability of CBHIs.

Overall lack of resources for health care

Sparse distribution of health facilities and limited health benefits have been identified as contributing to low CBHI enrolment and dropout rates (Basaza, Criel & van der Stuyft, 2008; Hao et al., 2010; Shewamene et al., 2021). We have already noted the problems of perceived poor health services and frequent stockouts of medications (Criel et al., 2020; Kigume & Maluka, 2021).

Preconditions for CBHI's success

Are there, then, any conditions under which CBHI can succeed on its own terms, without giving up its voluntary nature and transmuting into SHI? To answer this, we first present a case study of CBHI as implemented in Senegal, before listing the preconditions identified as enabling CBHI schemes to work.

Evidence in practice: Senegal

In 2014, in Senegal, the communal mutuals of two departments were merged to create a single health insurance department (UDAM – *Les Unités Départementales d'Assurance Maladie*) managed by professionals (Ridde et al., 2022). Membership remains voluntary, so risk sharing on a large scale is still limited. However, through professional management and the recruitment of specialists, innovative strategies for recruiting members have been implemented. These include a state contribution for entire villages or schools which enables CBHI membership fee reductions for all those living, studying or working in these places and creates collective conduits to channel the state subsidy to the recipients. These UDAMs have a headquarters, general management and qualified support staff for all administrative tasks (Mbow et al., 2020). The scheme's management by professionals is the main way in which it deviates from the Donfouet & Mahieu (2012) definition of CBHI we introduced at the beginning of this chapter. The two UDAMs have been effective and able to cope with overdue subsidies from the state. In addition, all the health facilities in the region have transitioned from unit pricing for each service to a global flat rate, making the price predictable for patients (Mbow et al., 2020). UDAMs also influence the supply of care during the regional health team coordination meetings. In 2021, more than 50% of the population in the two districts were members of the UDAMs, which is an impressive achievement. In addition, between 30% and 60% of the region's hospital revenue comes from the UDAMs, which gives them undeniable power. The Senegal national UHC agency (ANCMU – *Agence Nationale de Couverture Maladie Universelle*) is scaling up this reform to other districts. This has been noted by neighbouring countries which have visited for benchmarking. However, the scalability of these reforms has been opposed by the

community mutualist movement, which is challenging the management of mutuals by professionals rather than volunteers (Ridde, Kane & Faye, 2025). With the support of the Belgian and French mutualist movements, the Senegal body has engaged in advocacy through the Lomé Platform so as to scale up these reforms.

What preconditions are needed for CBHI to work?

Available evidence suggests that success of a CBHI scheme is heavily dependent on its design and structure, including the affordability of the scheme, managerial capacity, benefits package, level of trust, distance to facilities and the perceived quality of health care covered by these schemes; as well as personal factors, such as individual knowledge and understanding of the scheme, among others (Dror et al., 2016). It is argued that barriers to the successful implementation of CBHI schemes are largely operational in nature (De Allegri et al., 2009) and these have been documented widely (Ekman, 2004; De Allegri et al., 2009; Ridde et al., 2010; Fadlallah et al., 2018).

Here we outline the underlying preconditions for the successful implementation of CBHIs, as follows: a supportive political and economic environment (from which several of the other preconditions flow); the availability of and ability to mobilize social capital; awareness of CBHI and issues of equity; the formalization/institutionalization of CBHI schemes within the overall health sector; and enhanced vertical and horizontal linkages.

Supportive political and economic environment

Country evidence shows that successful UHC schemes are politically driven or have government support (de Ceukelaire, de Vos & Criel, 2011). This ensures that the required economic and regulatory frameworks supporting CBHI are established. Such frameworks enable the creation of incentives for expanding access to health care to rural and informal sectors, and for insurers willing to establish a presence in these settings. The government can use its infrastructure to facilitate the pooling of multiple schemes, purchase health care, provide subsidies for the indigent, ensure civic education and harness support from civil society actors (Bennett, 2004; Fadlallah et al., 2018; Mladovsky & Mossialos, 2008). However, without the correct balance, such government intervention easily changes the scheme from CBHI to

a pooling and collection agency for SHI taxes. Therefore, an appropriate balance must be determined.

Availability of and ability to mobilize social capital

The central role of social capital in the success of CBHI schemes has been highlighted in the literature (Donfouet & Mahieu, 2012; Derosé & Varda, 2009). Social capital, in the context of health financing, is generally understood as the “norms and broader social networks that enable individuals to act collectively” (Woolcock & Narayan, 2000). These norms promote trust, build cooperation and move communities to work together towards an agreed objective. The networks thus enhance solidarity which is essential for pooling risks and resources within a community. Addressing individual and community level social capital is associated with willingness to enrol, contribute and stay in a CBHI scheme (Chemouni, 2018). The evidence from Senegal, for example, suggests that CBHI is more likely to thrive where individuals already possess social capital (Mladovsky, 2014).

Awareness of CBHI

An awareness of the possibilities of health insurance and issues of equity among the general population empowers target communities to actively engage in purchasing health care and demand accountability from health providers (de Vos et al., 2009). In addition, an overall awareness is necessary to address inequity, including strategies for dealing with inability to pay, identification of indigent people and targeting mechanisms in rural populations and the informal sector (Mladovsky et al., 2014). The government is often best placed to ensure civic education and create such awareness (Fadlallah et al., 2018).

Formalization/institutionalization of CBHI schemes within the health sector

Giving a CBHI scheme formal status facilitates linkages with other arms of the health sector and enhances the trust, sustainability and scalability of the schemes, as has been evidenced in Ethiopia (Tahir, Adilahi & Farah, 2022). Institutionalization would also facilitate required managerial support. As demonstrated by the UDAMs in Senegal, managerial capacity is critical for the effective functioning of CBHIs (Ridde et al., 2022).

Enhanced vertical and horizontal linkages

Enhancing vertical and horizontal linkages involves creating synergy between the central government, community, local government and other players in the health sector. It requires engaging with other actors such as civil society, the private sector and other relevant bodies who can support civic education or create awareness of health insurance and strengthen the managerial capacity of CBHIs. These linkages would also support the regulation and accountability of CBHI schemes. Relationships should also be developed with other CBHI schemes to facilitate pooling of risks and resources and enable the strategic purchasing of services.

CBHI and UHC

Available evidence to support the narrative that current CBHI schemes can be used as a vehicle to achieve UHC in their different settings is limited and patchy (Carrin, Waelkens & Criel, 2005; Ekman, 2004; Mladovsky & Mossialos, 2008; Soors et al., 2010), and thus researchers express cautious optimism about CBHI's potential.

Arguments against the use of CBHI to advance UHC relate primarily to design issues. The significant heterogeneity in current CBHI scheme designs poses challenges to building large-scale and sustainable financing mechanisms. The huge variation in coverage and the range of benefits offered also hinders measurement of CBHI's progress in achieving universal coverage. By design, the population group targeted by CBHI schemes (rural populations, informal sector and the indigent) all have irregular and often seasonal incomes. This creates barriers to effective and sustainable collection of CBHI contributions. Challenges related to unaffordability, small pools and limited contributions to the CBHI scheme lead to issues of equity. In the absence of significant support from other sources, the precarious financial state of CBHI schemes threatens their long-term sustainability (Atim et al., 1998; Creese & Bennet, 1997; Criel, 1998; Ekman, 2004).

Countries such as India, Ethiopia, Ghana and Rwanda have nominally embraced CBHI as one of the potential instruments to achieve UHC (Lavers, 2019; McIntyre et al., 2008; WHO, 2010; Urban Health Division, 2008). These countries have made pragmatic decisions to institute their own versions of CBHI, developing relevant regulatory frameworks to enable their schemes' establishment and

expansion. However, countries such as Ghana and Rwanda have deviated significantly from the CBHI concept by enforcing mandatory membership.

The enforcement of mandatory CBHI membership is the subject of ongoing debates across west African states. Some countries have suggested enforcing this by requiring proof of membership in a health insurance scheme for the issuance of administrative documents such as a passport, birth certificate or national identity card. However, this proposal has faced objections already. For example, unions in Mali won a legal battle rejecting mandatory contributions, but they finally reached an agreement several years later (Ridde et al., 2018). Time will tell whether these solutions are feasible in sociopolitical contexts very different from Rwanda, which has been able to make membership mandatory (Chemouni, 2018).

Policy relevance and conclusions

Theoretically, in the absence of state-provided, tax-funded health care or formal health insurance, CBHI has the potential to reach rural and informal sectors, helping to create awareness of the concept of health insurance and providing some access to health care. Ideally, CBHI schemes would help to build trust in the use of health insurance. This would facilitate the entry of insurers into this market (Rosner et al., 2012), including private and SHI schemes, and non-salary-based options. In addition, CBHI schemes could support functions such as the recruitment of community members and identification of indigent people requiring subsidies, as is the case with the Rwanda scheme (Diop & Ba, 2010; Chemouni, 2018). However, CBHI design attributes – in particular the voluntary nature of enrolment and contribution – often prevent it from being a successful mechanism to raise sufficient revenue in practice. CBHI may therefore be better suited as solely a collection mechanism, given its potential to reach rural and informal sectors. If successful, this would support at least two of the UHC coverage goals: expanding population coverage and enhancing financial protection. With relevant awareness, community members can also demand accountability from the health system which would hopefully enhance responsiveness to their health needs, improved efficiency and quality of care.

Based on the evidence presented in this chapter, current CBHI schemes are still a long way from making a significant contribution to

achieving UHC. Those held up as current examples of success can no longer be defined as CBHI schemes. Beyond the small pilots of CBHI schemes, there is very limited and often mixed evidence on the impact of pure CBHI across the different health financing functions and population health coverage. The role of the government is critical for the establishment and sustainability of effective CBHI schemes. Only then can CBHI be included in the suite of financing mechanisms that countries can use to advance the UHC agenda. Wide-scale adoption of CBHI rests on policy-makers' decisions to create a regulatory space where these systems can operate. This would also facilitate the generation of sufficient evidence to support definitive decision-making on the implementation of CBHI, including appropriate design and scale-up.²

Additional resources

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² Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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1.3

Voluntary health insurance

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Key messages

Chapter 1.3 considers voluntary health insurance (VHI). VHI is paid for privately by or on behalf of individuals and most often provides people with faster access to treatment and greater choice of health care provider. Premiums are not typically based on the policyholder's income but are likely to vary depending on their risk of ill health. Key learning includes that:

- Despite prepayment and risk pooling, VHI has limitations and does not align well with progress towards universal health coverage (UHC) because:
 - risk pools in VHI schemes are typically much smaller than pools established through statutory schemes, which means there are fewer people to share risk;
 - inequities are created because of the cost of premiums, which may not be affordable or accessible to everyone, including those most in need of financial protection.
- VHI has wider equity implications because it offers those who can afford to pay faster access to, or greater choice of, services (supplementary insurance) or coverage of excluded services or user charges for statutory care (complementary insurance).
- Governments seeking to use VHI to expand coverage typically have to make significant interventions, including through tax subsidies to make premiums more affordable, but this creates market distortions and is inefficient.
- Policy-makers can secure better health system performance by improving access to publicly financed health care than by promoting VHI.

Introduction

Economic theory and empirical evidence indicate that it is difficult to get VHI to cover all needed health services for all those who require health care. As a result, countries struggle to make progress towards UHC – ensuring everyone can use quality health care without financial hardship (WHO, 2010) – through VHI alone. Although VHI generally improves financial protection (affordable access to health care) for those who have it, it can undermine the performance of the health system as a whole, particularly where it plays a large role.

It is not always easy to address the challenges posed by VHI; doing so requires political willingness and ability to shape the role VHI plays through careful policy design and implementation, strong regulatory capacity to ensure VHI functions in line with health system goals, and effort to ensure that publicly financed coverage meets the needs of those who are less likely to be covered by VHI, i.e. people with lower incomes or chronic conditions.

This chapter has three sections: understanding the role VHI plays in health system financing; understanding the challenges it brings with it as a policy; and providing advice for any policy-maker contemplating its introduction or, with an existing system of VHI, seeking to make it work better.

In the first section, we explain how VHI works, set out its distinguishing features and compare it with out-of-pocket (OOP) payments and medical savings accounts (MSAs) (see Box 1.3.1), outlining the even-worse-than-VHI failings of the latter. We examine VHI's relationship with publicly financed health care coverage (supplementary, complementary or substitutive) and look at how much VHI is currently used and where, as well as reasons for changes in its level of use.

Understanding VHI's role in health system financing

VHI can cover all or some of the risk of a person incurring health care costs. It can be bought by individuals or groups (for example, employers on behalf of their employees) and it can be sold by a wide range of entities – not only by for-profit (commercial) and non-profit-making private organizations, but also by public and quasi-public bodies.

What differentiates VHI from other types of health insurance is that it is taken up *voluntarily*, i.e. there is no compulsion to buy it, and paid

Box 1.3.1 Medical savings accounts are inefficient, inequitable and do not provide sufficient financial protection

MSAs are another form of prepayment, but, unlike VHI, they do not allow the spread of financial risk across insured people and thus typically do not provide sufficient financial protection.

MSAs allow enrollees to withdraw funds set aside to cover eligible health care costs. They are usually coupled with a high-deductible insurance plan to cover very high costs, allowing those who hold such accounts to manage risks over time but not across the broader population. In terms of overall health system policy, MSAs have very limited ability to achieve goals such as efficiency, equity and financial protection.

Although the accounts are expected to enhance efficiency by reducing the use of low-value treatments and controlling health care costs, evidence shows that they can discourage the use of both low- and high-value treatments, leading to reduced adherence to medication and preventive care. People who switch to MSAs tend to spend less on health care initially, but the long-term impact on costs is unclear.

MSAs allow individuals to spread financial risk over time, but they may not be sufficient to cover some health care costs and are likely to discriminate against people who are less able to save, including unemployed, disabled or chronically ill people. Evidence also shows that enrolment in the accounts can lead to a reduction in beneficial care, potentially undermining the health of people with low incomes or chronic conditions.

Despite the policy challenges related to MSAs, policy-makers in some countries continue to regard them as a desirable health financing mechanism. This may be due to the common use of savings for pensions, leading to the mistaken belief that savings alone can cover health care costs, and due to lobbying by financial service providers who offer the accounts. MSAs play a role in health system financing in China, Singapore, South Africa and the USA.

Source: Wouters et al. (2016).

for *privately* rather than publicly: VHI premiums are typically delinked from a policyholder's income and often linked to a person's risk of ill health (Mossialos & Thomson, 2002; Sagan & Thomson, 2016a; Thomson, Sagan & Mossialos, 2020). VHI therefore tends to be more regressive and less efficient in terms of raising revenue than public spending on health, and those who need it the most may not be able to

access it or afford the premiums. The benefits offered by VHI can also be subject to user charges (co-payments) or limited in other ways to protect insurers from incurring losses, which means that some people may not be adequately protected from financial hardship caused by out-of-pocket (OOP) payments, even though they have VHI.

VHI is a form of prepayment, alongside other forms of prepayment such as taxes, mandatory health insurance contributions and MSAs (Box 1.3.1). In contrast to OOP payments, VHI premiums are collected in advance to pay for health care when it is needed, spreading the financial risk of ill health over time. In contrast to OOP payments and MSAs, VHI enables funds to be pooled, spreading financial risk across insured people. Financing health care through prepayment with risk pooling supports progress towards UHC by reducing financial barriers to access and financial hardship caused by OOP payments. However, VHI risk pools are generally much smaller than pools established through publicly financed coverage, which means there is less redistribution of financial risk.

The role of VHI in health system financing is usually defined in relation to gaps in publicly financed coverage (Table 1.3.1). It typically supplements or complements publicly financed coverage; in a few cases it substitutes publicly financed coverage.

Supplementary coverage

Perceived problems with the quality and timeliness of publicly financed health care can motivate people to buy supplementary VHI. Supplementary VHI plays a role in the majority of countries, but its role is usually small both in terms of contribution to spending on health and share of the population covered. Ireland, Israel and South Africa are key exceptions: in these countries supplementary VHI either covers a large share of the population (Ireland, Israel) or only covers a small share of the population but accounts for an unduly large share of current spending on health (South Africa) (Thomson, Sagan & Mossialos, 2020).

Complementary coverage

Gaps in the scope of the publicly financed benefits package or the existence of user charges for publicly financed health care can drive demand for complementary VHI coverage. Complementary VHI covering services excluded or not well covered by publicly financed

Table 1.3.1 *VHI plays a supplementary role in most countries*

Role	Nature of coverage	Country examples
Supplementary	Offers faster access to services, greater choice of health care provider or enhanced amenities	Most countries, with a particularly large role in Ireland, Israel and South Africa
Complementary (user charges)	Covers user charges (co-payments) for goods and services in the publicly financed benefits package	Very few countries, but a significant role in Croatia and France
Complementary (services)	Covers services excluded from the publicly financed benefits package – typically dental care	Many countries, often sold alongside supplementary VHI but with a significant role in a few countries only, including Canada and the Netherlands
Substitutive	Covers people excluded from or allowed to opt out of publicly financed coverage	Very few countries have a significant role for substitutive VHI: Bahamas, Botswana, Brazil, Chile and Germany

VHI: voluntary health insurance.

Source: Authors, adapted from Foubister et al. (2006).

health care usually plays a small role. It often focuses on dental care and is sold alongside supplementary VHI. The two main outliers are Canada, where outpatient medicines are not routinely publicly financed and many employers offer VHI to their employees, and the Netherlands, where over 80% of the population has VHI covering dental care and physiotherapy (Thomson, Sagan & Mossialos, 2020). Complementary VHI covering user charges also usually plays a small role. Globally, Croatia and France are the main countries in which this type of VHI plays a significant role (Thomson, Sagan & Mossialos, 2020). Slovenia was another notable case until 2024, when complementary VHI covering co-payments was abolished and replaced with a fixed compulsory contribution within the public health insurance scheme, and co-payments were removed.

Substitutive

People can buy substitutive VHI if they are excluded from publicly financed coverage or allowed to choose between publicly and privately financed coverage. Usually, only a small share of the population – often those with higher incomes – benefits from this type of coverage, but it can represent a more significant share of current spending on health. Substitutive VHI plays a significant role in a few countries only: Bahamas, Botswana, Brazil, Chile and Germany (Mathauer, Saksena & Kutzin, 2019; Thomson, Sagan & Mossialos, 2020). It was abolished in the Netherlands in 2006 (Sagan & Thomson, 2016b). Over time policy-makers in Chile and Germany have tried to limit the role of substitutive VHI because of its disruptive effect on the wider health system (Thomson, Sagan & Mossialos, 2020).

How much is VHI currently used and in which countries?

VHI makes a negligible contribution to spending on health in most countries.

In 2021, the VHI share of current spending on health exceeded 10% in only 22 countries globally (Fig. 1.3.1). VHI accounted for between 5% and 10% of current spending on health in a further 39 countries and was negligible everywhere else (WHO, 2023).

Across all countries for which data are available, on average VHI accounts for only 5.3% of current spending on health, ranging from 3.6% in lower-middle-income countries to 7.4% in upper-middle-income countries (UMICs) (Fig. 1.3.2).

In terms of World Health Organization regions, on average the VHI share of current spending on health was highest in the Americas (8.1%) and the lowest in Europe (3.2%) (Fig. 1.3.3).

Changes in levels of use of VHI

Only a handful of countries have seen large changes in VHI's contribution to current spending on health over time, with decreases usually recorded in high-income countries (HICs) and increases in middle-income countries.

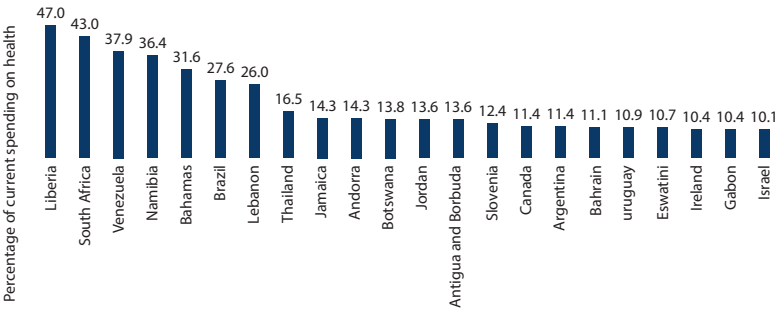


Fig. 1.3.1 In 2021, the number of countries in which VHI accounted for at least 10% of current spending on health was very small

Note: SHA: System of Health Accounts; VHI: voluntary health insurance, USA: United States of America. VHI here is defined as health insurance schemes that are based upon the purchase of a health insurance policy, which is not made compulsory by government using the SHA code HF2.1. The figure excludes previously voluntary forms of private health insurance in France and the USA, which have been reclassified as compulsory health insurance in health accounts.

Source: WHO (2023).

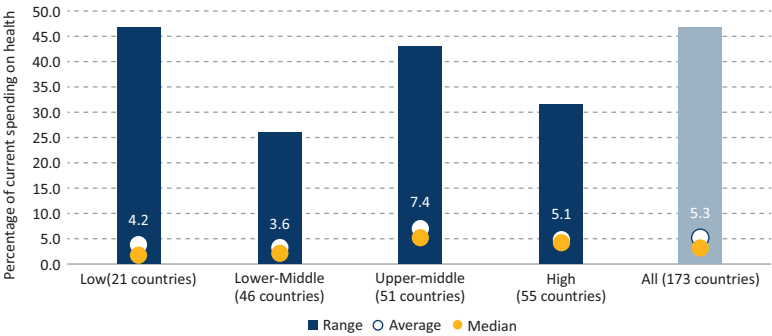


Fig. 1.3.2 In 2021, the VHI share of current spending on health was highest in UMICs

Note: SHA: System of Health Accounts; VHI: voluntary health insurance. Only includes countries for which VHI data were available. VHI here is defined as SHA code HF2.1.

Source: Adapted from Thomson, Sagan & Mossialos (2020) using the WHO Global Health Expenditure Database (WHO, 2023).

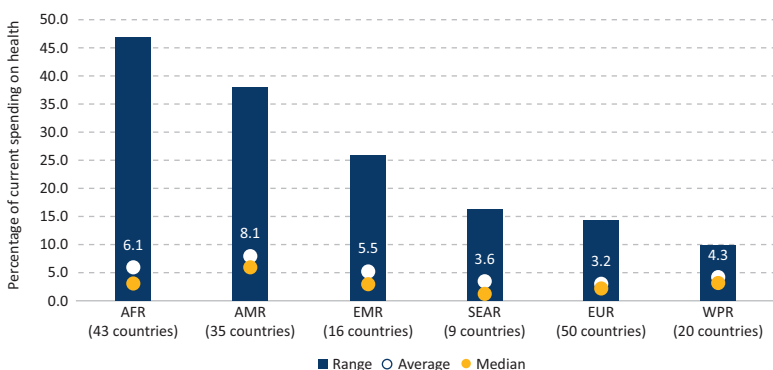


Fig. 1.3.3 In 2021 the VHI share of current spending on health was higher in the Americas than in other parts of the world

AFR: WHO African Region; AMR: WHO Region of the Americas; EMR: WHO Eastern Mediterranean Region; EUR: WHO European Region; SEAR: WHO South-East Asian Region; SHA: System of Health Accounts; VHI: voluntary health insurance; WHO: World Health Organization; WPR: WHO Western Pacific Region.

Notes: Only includes countries for which VHI data were available. VHI here is defined as SHA code HF2.1.

Source: WHO (2023).

VHI's share of current spending on health did not change much between 2000 and 2021 in most countries. Looking at changes between two points in time can conceal fluctuations, but during this period the VHI share fell by five or more percentage points in only eight countries globally (mostly HICs) and grew by five or more percentage points in 21 mostly lower-middle or UMICs (Fig. 1.3.4).

The large drop in the VHI share of current spending on health in France, Germany and the USA was due to changes in health accounting. VHI was reclassified as compulsory health insurance in National Health Accounts in response to reforms making private health insurance compulsory for some groups of people (OECD, Eurostat & WHO, 2017). In France, the VHI share fell from 13% in 2012 to 7% in 2016 following the government's introduction in January 2013 (with effect from 2016) of a mandate on all employers to offer complementary private health insurance covering user charges to their employees (Couffinhal & Franc, 2020; Bricard, 2024). The introduction of a universal mandate in Germany in 2009, making it compulsory for people who choose to opt out of publicly financed coverage to take up substitutive private health

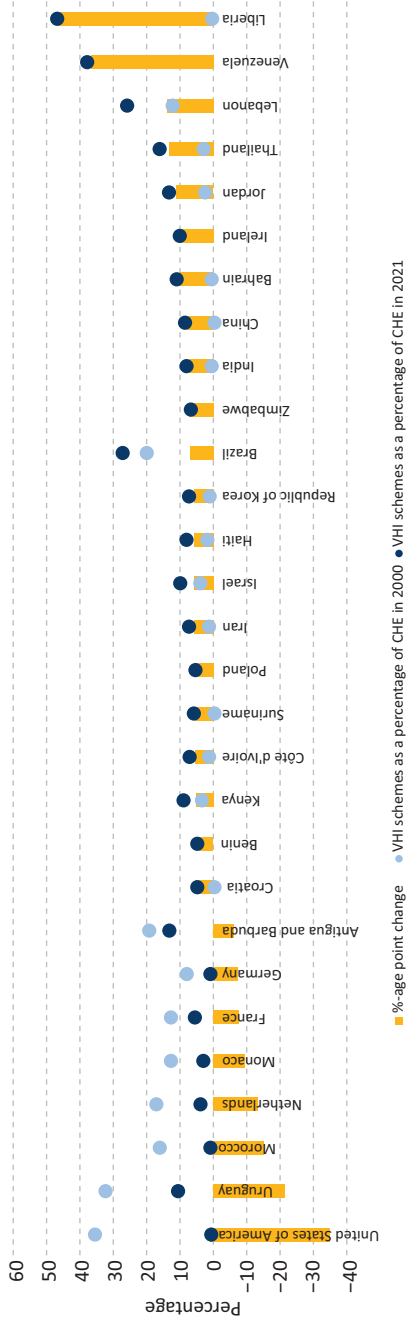


Fig. 1.3.4 Not many countries saw substantial changes in the VHI share of current spending on health between 2000 and 2021

Note: CHE: current health expenditure; SHA: System of Health Accounts; VHI: voluntary health insurance, USA: United States of America. VHI here is defined as SHA code HF2.1. In France, Germany and the USA the changes are due to changes in health accounting that resulted in VHI being reclassified as compulsory health insurance.

Source: WHO (2023).

insurance (as opposed to remaining without any coverage), resulted in the VHI share falling from 9% in 2008 to 1% in 2009 (Ettelt & Roman-Urrestarazu, 2020). In the USA, the implementation of the Affordable Care Act in 2014 made health insurance mandatory for people under the age of 65 years for the first time, leading the VHI share to fall from 33% in 2013 to 1% 2014 (Brown & Glied, 2020).

In Morocco, the Netherlands and Uruguay, the decline in the VHI share of current spending on health followed reforms to expand access to publicly financed coverage. A sudden fall in the VHI share in Morocco (from 12% in 2005 to 1% in 2006) followed the creation of a mandatory social health insurance (SHI) scheme, which extended publicly financed coverage from 16% to 30% of the population (Mulvihill, 2022). In the Netherlands, a national health insurance scheme introduced in 2006 abolished substitutive VHI for richer people, who had previously been excluded from publicly financed coverage, leading to a fall in the VHI share from 20% in 2005 to 6% in 2006 (Maarse, Jeurissen & North, 2020). In Uruguay the VHI share fell progressively from 32% in 2000 to 12% in 2020, following the establishment and gradual expansion of publicly financed coverage (Arbulo et al., 2015). The speed of decline in the VHI share was slower than expected, however, partly due to employers continuing to be allowed to provide VHI to their employees (Pettigrew & Mathauer, 2016).

The decline in VHI's share of current spending on health in South Africa is linked to a decline in VHI population coverage due to rising premiums (Pettigrew & Mathauer, 2016). Despite this, the VHI share in South Africa remains the highest in the world (43% in 2021), despite the fact that VHI only covers around 16% of the population (see Fig. 1.3.1) (McIntyre & McLeod, 2020).

In countries such as Jordan, Thailand and Venezuela, large increases in the VHI share of current spending on health reflect a combination of factors, including the poor performance of publicly financed coverage, growing purchasing power in the middle class and wider economic trends, including trade liberalization and privatization (Pettigrew & Mathauer, 2016).

Growth in public spending on health slowed significantly following the global financial crisis of 2007–2008, leading to an increase in the private share of current spending on health in many countries, but this often occurred due to increased reliance on OOP payments rather than growth in VHI (Thomson et al., 2015). In response to COVID-19, many

countries sought to increase public spending on health and some expanded publicly financed coverage, at least for services related to COVID-19 (Thomson et al., 2022; WHO Regional Office for Europe, 2021). Access problems, including large backlogs in health services and higher waiting times, have fuelled interest in purchasing VHI in countries like the United Kingdom (Campbell, 2022). Indeed, per capita spending on VHI in the United Kingdom rose from US\$ 123 to 140 between 2019 and 2021 (WHO, 2023). Over this period, 26 countries experienced an increase in per capita VHI spending by more than US\$ 10, with the most substantial increases observed in Canada, Australia, Ireland and Liberia (exceeding US\$ 50 per capita). Conversely, eight countries noted declines in VHI per capita spending of US\$ 10 or more, with the largest falls observed in Cyprus, Lebanon, Monaco and United Arab Emirates (WHO, 2023). However, on the whole, per capita VHI spending changed little in most (80%) countries (WHO, 2023).

Key policy challenges for the use of VHI

VHI on its own cannot help countries to progress towards UHC. It can help to fill some gaps in publicly financed coverage, but it is generally difficult to align VHI with the goal of ensuring that everyone can access health care without experiencing financial hardship. We identify four key policy challenges that explain this difficulty: VHI does not stop reliance on OOP payments; it is difficult to ensure affordable access to VHI for those who need it most; VHI undermines equity and efficiency in the use of resources; and history and politics get in the way of an effective VHI policy. We deal with each of these in turn below.

Policy challenge 1: VHI is unlikely to be helpful in making progress towards UHC in countries that rely heavily on OOP payments

Both economic theory and empirical evidence indicate that VHI is unlikely to provide comprehensive coverage for the whole population.

Economic theory

It is extremely difficult for VHI to provide comprehensive coverage for the whole population, even when it is heavily regulated, due to market failures. Market failures in health insurance are well recognized

(Barr, 1992). Problems such as moral hazard and monopoly issues afflict both compulsory and voluntary health insurance (Nyman, 2004; Barr, 2004; Einav & Finkelstein, 2018). In addition, VHI is prone to adverse selection and risk selection.

Adverse selection refers to a situation in which people with higher risks of ill health are more likely to take up VHI, which limits risk pooling and pushes up health care costs, leading insurers to increase premiums or reduce benefits. This in turn may make VHI less accessible for people with high risks and less attractive for people with low risks. If low-risk people stop buying VHI, the ensuing “death spiral” can lead to the collapse of an insurance company. Similarly, it is difficult to sustain VHI among people who are already ill or at high risk of becoming ill and when the risks of becoming ill are linked, such as during epidemics (Barr, 2004). Financial regulation of VHI can provide the necessary stability, but adverse selection is best prevented by making health insurance compulsory. In practice, adverse selection may be less of an issue because richer (and healthier) people are often more likely to buy VHI, especially when it is offered alongside publicly financed coverage.

Insurers typically try to prevent adverse selection by *selecting people with lower health risks*; for example, by excluding from coverage or charging higher premiums for pre-existing conditions. Again, this means that some people may not be able to obtain any or sufficient coverage through VHI, limiting risk pooling. Material regulation involving rules around premiums, benefits and other contractual conditions can help avoid some of these problems (Thomson, Sagan & Mossialos, 2020).

Empirical evidence

The empirical evidence supports economic theory. Historically, as the precursor to publicly financed coverage, VHI never succeeded in covering the whole or even most of the population. The goal of universality was only achieved through the introduction of mandates for publicly financed health care.

We can briefly recap VHI’s history, based on the account of Thomson, Sagan & Mossialos (2020). VHI is the earliest form of prepaid health financing. It first emerged in Europe in the Middle Ages, before the rise of modern medicine, and aimed to compensate people for loss of earnings due to illness, which is why it was linked to employment.

VHI offered by mutual-aid associations serving industrial workers had become the norm in Europe by the mid-19th century and spread via colonialism to countries outside Europe (e.g. South Africa, where it initially covered white mine workers).

Medical advances led to an increase in the cost of health care, motivating health care providers in the early 20th century to develop VHI, often in league with hospitals run by the charitable sector, so that people could continue to pay for their services. Provider-driven VHI proliferated in Europe and beyond, including Australia, Canada and the USA. Over time, these largely non-profit schemes were joined by commercial schemes.

Few of these early forms of VHI grew to cover more than a small share of the population, not only because health insurance was voluntary and also usually linked to employment, but also because it was unaffordable for many people. Starting with Germany in 1883, national governments began to introduce compulsory publicly financed schemes to extend coverage to more people, filling gaps that VHI could not cover.

Further empirical evidence is provided by data on health spending, which suggest that public spending on health is more likely to reduce OOP payments than VHI. Across countries there is very little association between spending through VHI and spending through OOP payments (Fig. 1.3.5a). Liberia, Namibia and South Africa are the only countries where the VHI share of current spending on health substantially exceeds the OOP payment share. In South Africa, for example, the decline in the OOP payment share (from 14% in 2000 to 5% in 2020) was accompanied by a small decline in the VHI share (from 47% to 42%) and a large increase in the public share (from 37% to 51%) (WHO, 2023). This means that it is unlikely that it was VHI that drove down OOP payments in South Africa. Across countries there is a much stronger correlation between public spending on health and OOP payments (Fig. 1.3.5b).

Policy challenge 2: It is difficult to ensure affordable access to VHI for those who need it most

Empirical evidence shows that VHI is more likely to be taken up by richer people, which exacerbates inequality in financial protection (affordable access to health care) (Sagan & Thomson, 2016a; Thomson, Sagan & Mossialos, 2020). This is sometimes the result of policy design – for example, in countries such as Germany where only

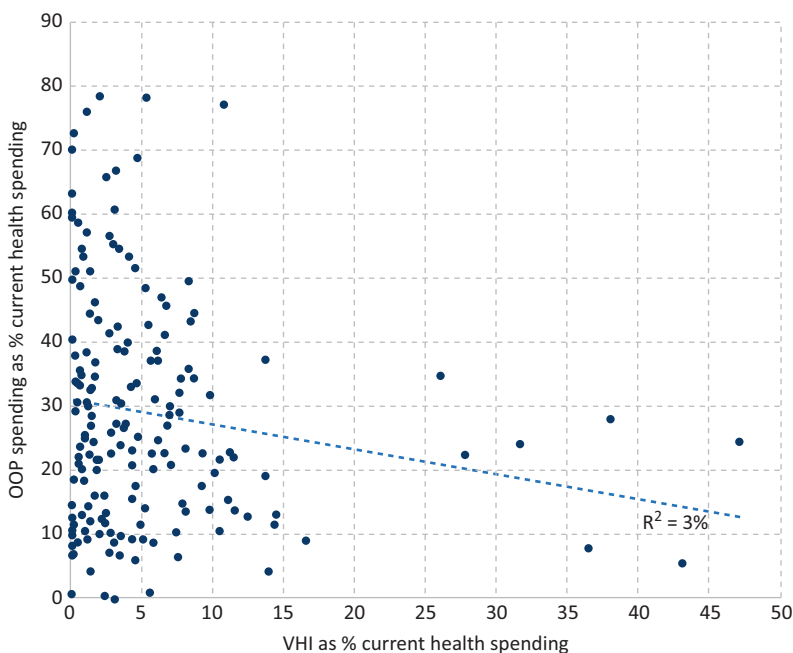


Fig. 1.3.5a Public spending on health is more likely to reduce OOPs than VHI

richer people are allowed to opt out of publicly financed coverage. More often, it is due to insurer behaviour, perhaps in response to concerns about adverse selection (as described above), which makes VHI less accessible to people with a higher risk of ill health and less affordable for people with lower incomes. As a result, it is generally difficult for VHI to improve financial protection in the health system as a whole – but the degree to which affordability is a problem varies according to whether VHI is playing a supplementary, complementary or substitutive role in the overall health coverage mix.

Where VHI plays a supplementary role

Problems with affordable access to VHI need not be a concern where VHI plays a supplementary role and the policy goal is merely for VHI to offer more choice to a small share of the population – as in the United Kingdom.

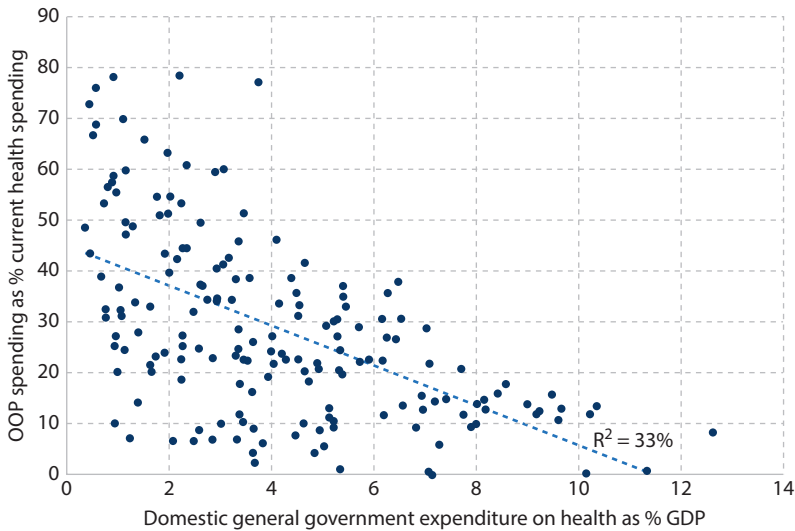


Fig. 1.3.5b Domestic general government spending on health as a percentage of GDP versus OOP payments as percentage of current spending on health, 2021

Note: GDP: gross domestic product; OOP: out-of-pocket; SHA: System of Health Accounts; VHI: voluntary health insurance. VHI here is defined as SHA code HF2.1. Domestic general government spending on health here is defined as health expenditure funded from general government domestic sources (government domestic revenues and SHI contributions). In SHA it is calculated as FS.1 (transfers from government domestic revenue allocated to health purposes) plus FS.3 (social insurance contributions).

Source: WHO (2023).

Where VHI plays a substitutive or complementary role

Affordability is more of a concern where VHI plays a substitutive role and is the only form of coverage for some groups of people or where VHI plays a complementary role and covers significant gaps in the publicly financed benefits package or user charges. In such cases VHI can be critical to ensuring financial protection and should therefore cover all those who need it, but many countries have struggled to achieve this.

Globally, only three main countries – Croatia, France and Slovenia – have managed to provide complementary VHI covering user charges to almost all those who need it, but this has involved heavy government intervention through regulation and tax subsidies for people with low incomes and, in France, making private health insurance compulsory for employees (WHO Regional Office for Europe, 2019; 2023).

VHI covering co-payments in Croatia, France and – until recently – Slovenia achieves very high rates of population coverage, reaching over 80% of those who have to pay co-payments in Croatia, around 90% of the population in France and around 95% of those with compulsory health insurance in Slovenia. Partly due to high take-up of VHI covering co-payments, the incidence of catastrophic health spending is very low in Slovenia and France and relatively low in Croatia (WHO Regional Office for Europe, 2019; 2023; Voncina & Rubica, 2019; Bricard, 2024; Šarec & Jošar, 2025).

High levels of VHI take-up in these three countries can be attributed to the following factors:

- People need VHI covering co-payments because user charges are widely applied in all three countries and are in the form of percentage co-payments for secondary care, meaning that people have to pay 20% of the cost of inpatient care. Although there are caps in place for inpatient care (France) and secondary care (Croatia), these caps are set at a high level; many households would face financial hardship before reaching them.
- VHI covering co-payments is accessible to all those who want to buy it due to regulation (open enrolment plus community-rated premiums) in Croatia and until recently in Slovenia and tax subsidies targeting people with low incomes in France (see Box 1.3.2).
- VHI covering co-payments is affordable for most people because it is free for people with very low incomes in Croatia and France. In Slovenia, people with very low incomes were exempt from co-payments and did not need VHI. However, for the rest of the population, complementary VHI was financed through flat-rate premiums rather than income-related contributions, raising longstanding equity concerns and making it politically contentious. Premium hikes in early 2023 risked pushing coverage out of reach for some households, prompting the government first to introduce a price cap and ultimately to abolish most co-payments (Šarec & Jošar, 2025).

Using complementary VHI to cover user charges is not a panacea, however. VHI premiums are regressive in comparison to public spending on health, undermining equity in financing health care; VHI does not eliminate inequalities in access to health care; and in spite of regulation and tax subsidies, people with low incomes are still more likely to lack VHI coverage and less likely to have good quality VHI coverage than richer people (e.g. in France) (WHO Regional Office for Europe, 2023; Bricard, 2024).

Box 1.3.2 France demonstrates how difficult it is to achieve high levels of population coverage for complementary VHI covering user charges

VHI in France is dominated by non-profit mutual associations and predates the establishment of national health insurance in 1945. VHI coverage grew from around 30% of the population in 1950 to 86% in 2000. In 2000, to address concerns about low VHI uptake among poorer households, the government introduced tax subsidies, making VHI free for people with very low incomes and cheaper for people with low incomes. VHI coverage subsequently reached 95% in 2013.

In 2016, the government required all employers to offer VHI to their employees – a measure intended to improve access to group VHI contracts, which are known to be more advantageous than individual contracts. Although this is expected to reduce inequities in VHI access among employees, it may widen disparities between salaried employees and students, pensioners and unemployed or self-employed people. Recent studies suggest that this policy could potentially diminish overall welfare, as employers are likely to pass on the cost of insurance contracts to employees through salary adjustments. The key net beneficiaries of this policy would likely be short-term unemployed individuals (around 7% of the population), who could retain their former complementary health coverage (Benoît & Coron, 2019). Recent data on population coverage indicates a slight decline from 93% in 2017 to 90% in 2018 (FNIM, 2019).

Sources: Couffinhal & Franc (2020); Bricard (2024).

Government intervention in VHI has generally intensified over time, regardless of VHI's role, for two reasons: changes in the nature of VHI with the entry of commercial insurers and, in some countries, growth in VHI, which has made its negative effects on health system performance more visible (Thomson, Sagan & Mossialos, 2020).

Policy challenge 3: VHI undermines equity and efficiency in the use of resources

Erosion of equity and efficiency in the use of health system resources is a particular challenge when VHI plays a supplementary or substitutive role.

VHI can undermine equity and efficiency in the use of health system resources in various ways (Box 1.3.3). This is most likely to occur in

Box 1.3.3 VHI distorts the use of health system resources

Tax subsidies benefit richer households: Tax subsidies introduced to promote VHI take-up usually benefit richer households. For example, in Brazil and South Africa tax subsidies amount to about 30% of federal government spending on health (Brazil) and all public spending on health (South Africa), despite VHI covering only 24% and 16% of the population respectively (McIntyre & McLeod, 2020; Montoya Diaz et al., 2020). There is no evidence to support the idea that general tax subsidies for VHI are an efficient use of public resources.

Inadequate compensation for VHI's use of public resources: In some countries, such as Brazil, Chile and Ireland, many people with VHI continue to use public facilities, including as backup cover. While this is permitted by law and private insurers are required to compensate public providers for the use of their facilities, this has been difficult to enforce (Brazil, Chile) or has never reflected the full economic cost (Ireland). Implicit subsidies also arise from public funding of medical education.

Migration of health professionals from public to private facilities: Since services covered by VHI are usually provided in the private sector, where earnings tend to be higher than in the public sector, this may lead to a migration of health professionals from public to private facilities, as in Kenya and South Africa. This can leave public facilities understaffed, with implications for quality of care.

Increase in waiting times for publicly financed treatment: Failure to align provider incentives leads to increased waiting times for publicly financed treatment because doctors permitted to work in both private and public sectors may face strong financial incentives to prioritize patients with VHI; for example, if they are paid more to treat people with VHI or when waiting times are the main reason for purchasing VHI, as in Ireland.

Loss of financial contributions to publicly financed coverage: In countries where people can choose between publicly financed coverage or substitutive VHI (Chile and Germany), the publicly financed scheme loses contributions from those with higher incomes and better health when they opt for private health insurance. If those who opt for private health insurance are allowed to return to the publicly financed scheme; for example, when they are sicker and their premiums increase, this may put pressure on the publicly financed scheme. On the other hand, if opting out of the publicly financed scheme is irreversible, heavy regulation is required to ensure that private health insurance is accessible and affordable for those who can no longer return to publicly financed coverage.

Source: Thomson, Sagan & Mossialos (2020).

contexts where, rather than complementing publicly financed coverage, VHI plays a significant supplementary or substitutive role, covering the same services as publicly financed coverage and drawing on the same pool of health care providers. Negative spillover effects are common when the services offered by VHI are more expensive than those offered by publicly financed coverage, creating incentives for providers to prioritize the treatment of people with VHI or to work in the private sector. Spillover effects may be present even where VHI plays a minor role, but they become more visible and more detrimental where VHI plays a more significant role.

Other concerns related to VHI include the inefficiencies that arise from duplication of administrative and other responsibilities for managing different risk pools (Smith & Witter, 2004). Risk-rating requires information and auditing capacity to assess individual health risks, write appropriate contracts and monitor health care use (Smith & Witter, 2004). Available data suggest that administrative costs are almost always higher in VHI than publicly financed coverage (Sagan & Thomson, 2016a).

Policy challenge 4: History and politics are a challenge to effective public policy towards VHI

Once established, VHI markets can be difficult to shape, especially where VHI plays a larger role.

Aligning VHI with the goals of UHC requires effective public policy. A government's ability to ensure this may be more difficult where VHI plays a large or significant role, which in turn may be the outcome of historical developments (path dependency), political ideology and the relative power and interests of different stakeholders (Thomson, Sagan & Mossialos, 2020).

Health care providers and insurers have frequently opposed efforts to expand access to publicly financed coverage or tighten regulation of VHI, sometimes with the support of employers, civil servants and richer people – those most likely to benefit from preserving the status quo. Private interests have blocked or delayed the implementation of universal schemes in a wide range of countries, including Canada, Chile, Germany, Ireland, Kenya, the Netherlands, South Africa, Switzerland and the USA (Thomson, Sagan & Mossialos, 2020). In some LMICs, the promotion of VHI by donors and other actors has given it disproportionate political power (Pettigrew & Mathauer, 2016).

In many countries, VHI does not fall under the purview of the health ministry but is regulated as a financial service by the finance ministry or other ministries concerned more with economic or industrial policy than social policy (Sagan & Thomson, 2016a). This is another obstacle to effective public policy and may explain why oversight of VHI is often weak in countries at all income levels (Thomson, Sagan & Mossialos, 2020).

Understanding how policy challenges can be addressed

Policy responses using VHI to fill gaps in publicly financed coverage can vary depending on the nature and size of the role VHI plays. We suggest strategies that policy-makers can implement to address the challenges that come with VHI according to two scenarios: where VHI is newly introduced, or plays only a small role, and another, where VHI is already well established.

If VHI does not yet play a role or only plays a small role in the health system

- Decision-makers should anticipate the policy challenges that VHI brings and consider whether there is enough capacity to monitor and regulate VHI and manage interests. Alongside this, they must remember that, once established, VHI may be more difficult to shape.
- If thinking about introducing VHI, careful consideration should be given to policy design so that it does not undermine publicly financed coverage. Further, clear boundaries between publicly and privately financed health care should be drawn.
- Supplementary VHI (offering people faster access to treatment) is best when it is limited to a small share of the population. Keep it that way. Do encourage growth through tax subsidies or material regulation to make VHI more accessible and affordable.
- Complementary VHI can protect against OOP payments where there are significant gaps in the publicly financed benefits package or heavy user charges. Globally, only a handful of countries have managed to achieve the high rates of population coverage needed if this type of VHI is to help meet UHC goals. Achieving high rates of population coverage comes at a cost: to ensure VHI is accessible and affordable for those

who need it most requires heavy government intervention, including tax subsidies exclusively for people with low incomes.

- Do not allow people to opt out of publicly financed coverage. Substitutive VHI does not enhance health system performance. Some countries have abolished substitutive VHI (Netherlands) and others are trying to limit its role (Chile and Germany).
- VHI is not a panacea for high OOP payments. Increases in public spending on health are more likely to reduce OOP payments than VHI, so rather than trying to encourage VHI through tax subsidies or other means, policy should focus on improving affordable access to publicly financed health care. Tax subsidies for VHI are generally inequitable and inefficient and waste public resources.

If VHI already plays a significant role in the health system

- Ensure there is sufficient capacity and political will to monitor and regulate VHI, enforce boundaries between publicly and privately financed health care and manage stakeholder interests.
- Enforce boundaries between publicly and privately financed health care so that VHI does not undermine equity and efficiency in the use of public resources. In practice this can be difficult to achieve due to entrenched stakeholder interests.
- Where VHI plays a significant complementary or substitutive role, careful intervention is needed to ensure affordable access to VHI for those who need it. This can be achieved through material regulation involving a wide range of rules, including open enrolment (guaranteed issue); lifetime cover (guaranteed renewal); community rating (delinking premiums from individual risk of ill health); premium review, approval or caps; mandated (usually minimum) benefits; prohibition of exclusion of pre-existing conditions; caps on user charges for VHI-covered services; and prohibition of benefit ceilings (Sagan & Thomson, 2016a).
- Country experience shows that it is not easy to ensure affordable access to complementary or substitutive VHI for people with low incomes or chronic conditions. Some countries have resorted to making VHI compulsory, but this has not been unproblematic, in part because it is a regressive way of financing health care, placing a disproportionate financial burden on those with lower incomes.

A better solution would be to make sure that people with low incomes or chronic conditions do not need VHI.

Conclusions

VHI plays a very minor role in financing health care in most countries, especially in countries that rely heavily on OOP payments. However, due to a combination of market failures and weaknesses in public policy towards VHI, it can have a disproportionately negative effect on health system performance. Although VHI does fill gaps in publicly financed coverage, it often favours richer people, exacerbating inequity in financial protection. It can also draw financial and human resources away from publicly financed coverage, particularly where it plays a substitutive role or a large supplementary role.

Ensuring that those who most need VHI can buy it – and that VHI does not undermine equity and efficiency in the use of public resources – requires significant capacity to monitor and regulate VHI and enforce boundaries between publicly and privately financed health care. Governments often struggle to shape VHI in the face of opposition from entrenched stakeholder interests. Even when VHI improves access and financial protection for people with low incomes, which is generally rare, it remains a regressive form of financing health care.

Given what we know about VHI from economic theory and empirical evidence, countries should lower their expectations about its ability to meet the goals of UHC and focus instead on improving affordable access to publicly financed health care.¹

Additional resources

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Sagan A, Thomson S (2016b). Voluntary health insurance in Europe: country experience. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies (<https://iris.who.int/handle/10665/326314>).

¹ Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

Thomson S, Sagan A, Mossialos E (2020). Private health insurance: history, politics and performance. Cambridge: Cambridge University Press (<https://doi.org/10.1017/9781139026468>).

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1.4 *Official development assistance for health*

AZUSA SATO¹

Key messages

Chapter 1.4 looks into official development assistance (ODA). ODA is provided by governments or multilateral development banks (MDBs) to support economic development in other countries. Key learning includes that:

- ODA is critical to achieving the Sustainable Development Goals (SDGs) in the world's poorest countries.
- Lower-middle and middle-income countries (MICs) tend to receive more ODA than lower-income countries (LICs) due to a number of factors, including precedence and project continuity, differences in the ability to borrow and attract higher volumes, and extenuating circumstances and differences in capacity to absorb additional funds.
- MDB funds are best utilized when they are invested in under resourced areas, such as global or regional public goods, and when they are well-aligned with domestic policies and national goals.
- ODA success (i.e. resources having a meaningful impact on development outcomes) depends on:
 - prioritizing the right long-term development challenges;
 - effective domestic governance and an active role for national-level stakeholders;
 - transparency around ODA activities;
 - continuous assessment, evaluation, learning and improvement.
- ODA and financing institutions must adjust to new challenges such as climate change – moving away from a sector-by-sector approach, addressing trends and emerging themes and delivering innovative and agile financing mechanisms.

¹ At the time of writing, the author was seconded to the Center of Global Development, from the Asian Development Bank.

Introduction

In years to come, the early 2020s may prove to be an anomalous period in terms of ODA² in health. In 2020, COVID-19 wreaked havoc and required development partners to rapidly scale up support for fragile health systems. In the years since, we have had the opportunity to carefully reflect on the performance of the initial COVID-19 responses and consider paths towards more resilient and inclusive recovery. However, recognizing that many countries – and particularly low- and lower-middle-income countries with financing constraints – fall in and out of emergency situations frequently, the lessons we can take from COVID-19 will be relevant for many years to come. One trend has been clear from the outset: COVID-19 derailed the SDGs and forced governments to reprioritize their budgets both at home and abroad. Many developing countries – already facing resource-challenges – experienced significant gaps in resources. As such, COVID-19 has provided a strong case for ODA to fill some of these gaps by way of fiscal and technical assistance – not least, to support struggling health systems.

This chapter argues that ODA finance, particularly that provided by MDBs, is – and will remain – central in supporting developing countries to reach their SDGs and achieve poverty reduction in the aftermath of the COVID-19 pandemic. The chapter looks first at what ODA is and how much there is of it. It contrasts the support given by different types of donor – individual governments (bilateral support), international financial institutions and multilateral organizations – and issues raised by the provision of support as loans rather than grants. Next it looks at the recipients of ODA – by sectors and level of development as measured by income level. It outlines the support given during and since the COVID-19 pandemic and why external development financing for health remains crucial. The focus then shifts to the particular role played by the MDBs and a case study of the response by the Asian Development Bank to COVID-19 is presented. Finally, the chapter sets out the implications for policy that flow from the use of ODA as a financing mechanism – how to assess its quality and impact; its

² Defined here as resources largely provided by Development Assistance Committee (DAC) donor countries, international financial institutions and multilateral bodies, primarily aimed at supporting economic development and welfare of developing countries.

continuing role in supporting countries post pandemic and in the context of climate change – and the concluding section summarizes key points and suggests ways forward.

ODA: definition and quantity

What is ODA?

ODA is defined as government aid that promotes and targets the economic development of developing countries. ODA constitutes over 70% of total external finance of the poorest countries in the world, and the Organisation for Economic Co-operation and Development (OECD) Development Assistance Committee (DAC) provides a unique platform for coordination among aid givers. Formed in 1961, the Committee's mandate is to promote development cooperation in order to help implement ODA and sustainable development. The Committee comprises an international group of some of the largest providers of aid, including 30 bilateral members (who give aid government to government), six observers (those who channel and pool aid, commonly known as international financial institutions) formed of four MDBs, the International Monetary Fund (IMF) and the United Nations Development Programme (UNDP), and other participants, which are countries who are not members of OECD but want to contribute to discussions of the DAC. The current seven participating countries include Bulgaria and United Arab Emirates.³ The DAC list of countries eligible to receive ODA, based on per capita income, is updated every three years. The Committee recognizes ODA as the gold standard of foreign aid, having provided billions of dollars in aid and technical support over the years (OECD, 2023).

How much ODA is there?

2009–2019

Total ODA remained robust in the decade prior to COVID-19. Between 2009 and 2019, there was a steady rise in ODA volume across

³ See www.oecd.org/dac/development-assistance-committee/ and www.oecd.org/dac/dac-global-relations/u.pdf for a full list of members and partners and information on how DAC functions.

all sectors from US\$ 119 billion to over US\$ 150 billion (2018 saw a high of US\$ 153 billion),⁴ albeit representing only a minor fraction of gross national income (GNI) per capita (OECD, 2023; OECD, 2021). Of this total ODA, support to the health sector consistently comprised about 13% each year (Knox, 2020). Multilateral organizations including the IMF, Asian Development Bank and the World Bank accounted for around 35% of health ODA, with DAC members (particularly USA and United Kingdom) disbursing the remainder.

Since COVID-19

During times of crisis, such as COVID-19, ODA is critical in maintaining development progress – or, at the very least, limiting regression. Preliminary analyses of figures give some insights into the scale of overall ODA growth. In 2020, ODA amounted to US\$ 161 billion, representing 0.32% of combined GNI of DAC (OECD, 2021). At the time, this amount was the highest level ever recorded and reflects the urgent response to COVID-19, made available by maintaining previously planned ODA commitments, reorienting funds, as well as mobilizing additional funds (Ahmad et al., 2020). Such records were broken again in 2021, when ODA reached \$178.9 billion (of which support for COVID-19 vaccines accounted for \$18.7 billion) (OECD, 2022).

ODA donors: bilateral support versus international financial institutions and multilateral organizations

While ODA levels increased overall, COVID-19 had differing impacts on the source of support. For example, as domestic economies were hit in 2020, ODA commitments from bilateral members fell by 26% compared to the same period in 2019. This decrease was somewhat offset by the increase in commitments by the international financial institutions, but trends depend heavily on contributing governments' priorities as much as – or perhaps more than owing to – the needs of developing countries.

⁴ New methodology of counting using “grant equivalent” methodology since 2018 (under “cash flow basis” methodology, US\$ 149.3 billion in 2018) (OECD, 2019).

Loans versus grants

Notably, most of the support is increasingly provided through loans as grant resources dwindle, which may have long-term consequences: 22% of gross bilateral ODA in 2020 comprised loans and equity investments, up from 17% in previous years. International financial institutions also increased the volume of commitments significantly between 2019 and 2020 from US\$ 21.6 billion to US\$ 62.5 billion (Dodd, Knox & Breed, 2021). Even though, compared to 2019, US\$ 40 billion more in concessional loans have been provided in 2020, overall, grants represent just 1.4% of ODA commitments from the international financial institutions. Even if concessional (i.e. on favourable lending terms), these loans carry significant implications because clients (particularly governments) must eventually pay them back. So while this aid may benefit countries in the short term, it can also result in a heavy debt burden which countries may not be able to manage, especially where unforeseen events occur. There have been many calls for eradicating all debt held by the poorest countries. Even prior to the fallout from COVID-19, the IMF found that 36 of 70 low-income countries (LICs) were at high risk of debt distress, or already in debt distress. Many countries have since turned towards debt restructuring, and the pandemic has forced countries to make the difficult trade-off between investments in health and social welfare, versus addressing debt (IMF, 2021).

ODA recipients: by sector and by country income level

Which sectors benefit?

Support continues to vary significantly by sector. With the onset of COVID-19, the social sector (including health, education, social infrastructure and services) took centre stage. Social infrastructure commitments by the international financial institutions comprised only a small portion of resources compared to physical infrastructure investments prior to COVID-19. This picture changed dramatically in 2020, when the largest increase in commitments was for the social sector, as measured by percentage change in share of total ODA, especially from international financial institutions. These increases have largely come at the expense of investments in transport, storage, energy and

industry. Moreover, worryingly, investments in water and sanitation – critical for the COVID-19 response – fell (Dodd, Breed & Coppard, 2020).

Which countries benefit, by income level?

Historically, ODA commitments from international financial institutions tend to be delivered to lower-middle and middle-income countries rather than lower-income countries; and this trend is likely to continue. The reasons behind this are linked to a number of factors: precedence; project continuity (hence once a client, always a client); the ability of larger and typically more developed countries to borrow and attract higher volumes; and extenuating circumstances (for example, natural hazards or political strife) which can delay or defer support to smaller and/or poorer, less developed countries. In 2019, as a proportion of the international financial institutions' commitment, middle-income countries received 83% while lower-income countries received 11% (Dodd, Breed & Coppard, 2020). Commitments to high-income countries (HICs) and upper-middle-income countries (UMICs) rose between March 2018 and February 2019 before stabilizing or falling only marginally between March 2020 and February 2021, while commitments consistently fell across 2018 to 2021 for LICs (Knox & Jalles d'Orey, 2021). While it is important to carefully consider the product type (for example whether ODA comes through grants or loans), it is clear there are significant differences in commitment volume across-country income groups.

ODA's role in the first years of the pandemic

Financing for sustainable development, marked by the inability to fulfil the SDGs, was in short supply even prior to COVID-19 (OECD, 2018). COVID-19 has added new development challenges while simultaneously undoing years of progress and forcing the re-evaluation of goals still unmet. In 2020, developing countries were estimated to require US\$ 2.5 trillion to respond to the pandemic and associated economic shocks (Georgieva, 2020; UNCTAD, 2020), yet existing mechanisms will only provide a fraction of this. Governments worldwide have diverted their budgets to address COVID-19, often taking a domestic policy first stance, and external private investments have

dropped significantly (OECD, 2020a). Research shows that domestic resource and external private finance including remittances, foreign direct investment and trade, were expected to have fallen by US\$ 700 billion in 2020 compared to 2019 (OECD, 2020a). The need for concessional development finance, including from ODA, has never been more acute.

Why ODA remains critical to health financing

In the medium- to longer-term, ODA for sustainable development financing, particularly for health, will remain critical for a few reasons: the magnitude and nature of support required; the need for consistent, reliable funding; and the weakness/failure of other funding mechanisms.

Magnitude and nature of support

Health has typically been underfunded and underinvested in domestically, and thus the foundations upon which COVID-19 responses were built were weak at the outset. In 2019, lower-middle-income country governments spent about US\$ 60 per capita on health while upper-middle-income governments spent over US\$ 270 (WHO, 2019). This underspend means that additional resources, such as ODA, are required to support the basic functions of health systems and put countries back on track to achieve universal health coverage goals, while also tackling more complex and newer challenges such as COVID-19. The pandemic has also renewed pressure for better preparedness, for which ODA is the most likely funding candidate given its public goods nature and investment returns that will only be seen in the medium- to longer-term.

Consistency and reliability

Governments are scrambling to allocate scarce resources to finance multiple crises, endangering prioritization for health. While economic growth was restored for many parts of the world by the end of 2022, governments will struggle to keep up high spending levels. This trend is even more likely to be mirrored in the health sector with an expected decrease in government health expenditures per capita of 3% in developing countries (Kurowski et al., 2021). In this sense, ODA, despite forming only a small fraction of all sources of finance, may prove to be the steadiest and most resilient, providing predictability for planning and strategic investments (OECD, 2020b).

Weakness/failure of other funding mechanisms

With increasing levels of poverty and job insecurity, private sources of financing, particularly those made out-of-pocket (OOP) by households, are falling. In almost every country, disruptions in essential health services have been experienced due to both demand- and supply-side factors, with knock-on effects on utilization (WHO, 2020). Worse still, poor households may defer utilizing health care until the sick household-er's health deteriorates irreversibly and to the point of catastrophic expenditure. Other private sources of finance such as remittances can be erratic and sensitive to changes in external circumstances, and subject to statistical inconsistencies between formal and informal channels (Dinarte-Diaz, Jaume & Medina-Cortina, 2022). Foreign direct investment shows a similar boom and bust pattern – and investments in least developed countries typically see more modest recovery following crises (UNCTAD, 2022). Thus, the public sector will remain a key source of financing, and ODA will become more important in safeguarding the poorest and vulnerable populations in developing countries. This is where MDBs can play an important role.

MDBs: their role in ODA

As introduced above, MDBs are international financial institutions which can play significant roles in channelling and pooling resources, most commonly from developed nations. After the Second World War, they were established in an avowed spirit of collaboration to help finance the development of poorer nations, and to help stabilize and rebuild the global financial system (The Rockefeller Foundation, 2021). The MDB Observers of the DAC are the Asian Development Bank, the African Development Bank, the Inter-American Development Bank, the IMF, the UNDP and the World Bank. Most MDBs declare their vision to end or reduce poverty and inequality, and target investments to strengthen the economy – for example, through public financial management, to support infrastructural development in the transport and energy sectors or funding for the social sectors of education and health, and so on. They have been evaluated as offering a low risk of default for investors because of strong shareholder support from their members, backed by powerful capital structures, high asset quality and strong risk-bearing capacity. MDBs can mobilize capital quickly, making them ideal providers of liquidity and countercyclical support in times of crisis

(for example, during the global financial crisis and during COVID-19). In theory, effective MDBs provide loans, which are often concessional (i.e. they have favourable terms, particularly related to interest rates and grace periods); grants, provided free; and technical assistance – all of which can complement core activities and assist governments and other clients in capacity-building activities or implementing policy reforms.

MDB resources have the potential to fill gaps left by governments, and invest in typically underinvested goods, such as global or regional public goods, thus helping to avoid negative externalities and amplify positive externalities. MDBs also act as catalysts for investment because they can use tools such as guarantees to hedge risk in areas that are often underfunded, but which offer significant medium- to longer-term returns and impacts (such as those in health, social protection and education). Further, MDBs can mobilize counterpart funding by governments and cofinancing with other development partners. In countries that are moving from lower to middle-income status, MDBs are thought to be important in filling a transition gap. Research finds that as per capita income rises, ODA in health and social protection declines, but domestic and private spending are not able to fill this gap fast enough and leave a void which can be filled by MDBs (Piemonte et al., 2019). Further, where domestic governments have started to increase spending, priority is often given to infrastructure, rather than human capital development, leaving this area for MDB assistance. Such countries also exhibit high inequalities that are yet to be addressed, and MDBs are well placed to step in during the transition period.

In the best-case scenario, MDBs adhere to several principles and characteristics to ensure their assistance can be used most effectively and efficiently. For example, they will maintain commitment to the idea of “sovereignty above all else” and ensure that their initiatives align with domestic policies and national goals (see the *Assessing ODA quality* section for the Quality of Official Development Assistance (QuODA) priority area “ownership”). Such a commitment can help ensure that all projects support – and build on – government strategies. Otherwise, if these are misaligned, ODA can run the risk of shifting financial decision priorities and, in terms of health care for instance, crowd out funding for certain disease areas. Relationships and dialogues between MDBs and governments are, in theory, strengthened through country-based offices that are staffed with both international and national experts whose backgrounds and specialisms are usefully varied.

Second, by having expertise in multiple fields and in multiple countries, MDBs not only have convening and coordination power among sectors, but also across countries, sectors and subregions. This has the potential for several positive knock-on effects. Importantly, it allows for development partners to avoid duplication and attain maximum synergies when thinking through work programmes, which can lead to more efficient use of limited resources. It also allows MDBs to play intermediary roles as poolers of resources, particularly finance, through the provision and management of trust funds. Hence, again, MDBs are seen as providing catalytic financing, including that which leverages private and philanthropic financing. MDBs can actively promote and facilitate the use of instruments such as guarantees, equity investment and blending (private and public funds) to maximize synergies and resources.

Third, MDBs are able to provide the checks and balances in areas that may benefit from additional external support. This includes anti-corruption measures, as well as safeguards – for minority ethnic groups, women, children and youth, remote and rural populations, people with disabilities and environmental and resettlement issues. Such checks and balances are reflected in legal agreements and project documents to ensure maximum accountability and transparency in operations.

In summary, MDBs can provide a speedy and powerful mechanism for filling gaps in underinvested areas, providing checks and balances and mobilizing finance and other resources from development institutions and governments.

Evidence in practice: the response of the Asian Development Bank to COVID-19

The Asian Development Bank, one of the largest MDBs, was established in 1966 with goals focused on poverty reduction and improvements in quality of life for all. In more recent years, the bank's objectives have been closely aligned with the SDGs (ADB, 2018).

When COVID-19 hit, the Asian Development Bank and many other MDBs swiftly committed resources to try to fill gaps in response and recovery efforts.

In mid-March 2020, the bank announced a US\$ 6.5 billion COVID-19 response package which was increased to US\$ 20 billion by

mid-April 2020. As part of the package, the bank expanded resources available for nonsovereign operations and established the COVID-19 Pandemic Response Option (CPRO) under the Countercyclical Support Facility. CPRO resources were used to help governments implement countercyclical expenditure programmes to mitigate the impacts of the pandemic, with a focus on the poor and vulnerable. In December 2020, the bank announced that it would provide an additional US\$ 9 billion for the Asia Pacific Vaccine Access Facility (APVAX) to help with COVID-19 vaccine procurement and vaccination programme implementation. In sum, the Asian Development Bank's commitments in 2020 increased by 33% compared to 2019, with a record US\$ 31.6 billion in 2020 (up from US\$ 24 billion in 2019), both to governments and to the private sector. Approximately half (US\$ 16.1 billion) of this was tagged for COVID-19 response.

Type of support offered

The Asian Development Bank's range of products is separated into regular ordinary capital resources (comprising loans, equity investment and other debt securities), concessional resources (loans and grants) and other special funds (grants only). Contrary to the general landscape of ODA which saw declines in grant resources, the volume of grants disbursed by the bank increased significantly from US\$ 514 million in 2019 to US\$ 877 million in 2020. Partly due to this, the net resources transfer (the net amount of disbursements in excess of payments of principal, interest and other charges) to Developing Member Countries more than doubled between 2019 and 2020. The bank also provided a record US\$ 41.6 million in technical assistance resources in 2020 for medical equipment, personal protective equipment and advisory services.

Which sectors benefited?

The portfolio of approved projects changed significantly owing to COVID-19. Pre-COVID-19, heavily committed sectors were classed as transport, finance and public sector management, with health ranked as the second smallest standalone sector (with commitments totalling just US\$ 644 million in 2019). With COVID-19, health operations increased more than fivefold, becoming the fourth largest by

volume of 11 sectors behind public sector management, finance and energy. As a share of the total Asian Development Bank portfolio, the health sector accounted for over 11% of the bank's commitments in 2020, significantly exceeding its target of 3–5% set in the Midterm Review of Strategy 2020. Such trends follow those found in the general ODA landscape introduced earlier.

Which countries benefited, by income level?

The increase in commitments resulting from the COVID-19 response, especially between 2019 and 2020, is reflected in increases in support to all countries, but lower-middle-income countries have benefited the most. In 2020, 67% of the Asian Development Bank's portfolio was found to have supported lower-middle-income countries (versus 0.2% to HICs, 28% to UMICs, 4% to LICs and 1.2% to the regional portfolio), reflecting their larger economies and higher absorptive capacities. Such trends are consistent with general ODA trends which showed commitments consistently fell across 2018 to 2021 for LICs, with larger volumes supporting middle and HICs.

Policy relevance and conclusions

Factors to consider when assessing ODA as a financing instrument

The concept of ODA – providing government aid to promote and target economic development in countries which need it – is fairly straightforward; however, measuring how successful ODA is executed in practice, and to the extent to which they contribute to sustainable development, is not simple. Some tools are offered here by way of example only.

Assessing ODA quality

The QuODA index summarizes four dimensions comprising: prioritization; ownership; transparency; and evaluation to consider when analysing aid effectiveness (Mitchell, Calleja & Hughes, 2021). Prioritization measures how well allocations are targeted to respond to long-term development challenges. Ownership demonstrates how

well providers work with countries to ensure ownership and use of national systems. Transparency considers how timely and comprehensive reporting on ODA activities are; and evaluation assesses quality of learning and evaluation systems.

In its most recent assessment referring to aid distributed in 2019, QuODA placed multilateral organizations at the top of overall rankings, scoring highly on all four dimensions. Nearly all resources provided by multilateral organizations reach their intended recipients, with a focus on the poorest and “under-aided” countries (Mitchell, Calleja & Hughes, 2021). Recipient countries promote domestic ownership and use of national systems, while untying their procurement practices from domestic contractors. Authors also find that donors that provide the most, also produce the highest quality of aid (Mitchell, Calleja & Hughes, 2021). Such trends are largely driven by Scandinavian and northern European providers, who are known for their strong commitment to development finance and impact (Mitchell, Calleja & Hughes, 2021).

Such indices provide a partial response to critics of ODA systems, who argue that to improve efficiency, accountability, performance and equity impacts of ODA, more detailed descriptions of financing are needed (McCoy et al., 2009). Critics argue that the landscape is so complex and involves so many stakeholders who are currently not accounted for (for example, non-OECD donors and funds, private sector, philanthropists, etc.) that the current system does not do a good job of tracking and monitoring aid activities. Indeed, the COVID-19 pandemic has shown that multiple stakeholders, not just public sector actors, are critical to overcome global challenges and their financial contributions should be reflected accordingly.

Impact at the organizational level

For donors, the professed priority is to ensure that their resources positively change the lives of those who need aid the most. Organizations, including MDBs, carry out regular evaluations by both internal project officers and independent, external others. Commonly, a systematic tool is deployed to monitor impact, for example, logframes. The extent to which projects are successful can generally be summed up across four aspects: relevance, sustainability,

efficiency and effectiveness.⁵ Relevance measures whether projects align with country and organizational strategic priorities. Sustainability evaluates if outcomes and outputs may last beyond project completion. Efficiency looks at the use of resources to achieve intended outcomes. Effectiveness refers to the extent to which outcomes and outputs were achieved. Achieving balance between these aspects and applying lessons in the pursuit of the SDGs is an ongoing challenge, in the light of financial considerations such as ensuring high disbursement rates.

Effect of COVID-19 on MDB operations and their health sectors

COVID-19 and its after-effects has given rise to new challenges – especially for MDBs working in the health sector – and will have long-lasting effects on how MDBs operate, and their place in the ODA sphere. Since 2020, not only has ODA been required to support developing countries in their urgent COVID-19 response, but it has also been needed to support medium- to longer-term health goals. For some MDBs, this required a recasting of corporate strategies to give a higher priority to health and social sectors since COVID-19 has taken centre stage in many developing countries in the last few years, even as investments have moved from emergency response towards more longer-term, sustainable outcomes.

In the health sector, increased investment to boost capacity to prevent, detect, and treat COVID-19 (including contact tracing, testing, vaccines and vaccinations, and therapeutics) has been critical. Now the focus has turned to mainstreaming COVID-19 as part of communicable disease control with an emphasis on primary care, basic infection prevention control and strengthening laboratory networks. Restoration of health services which were severely curtailed during the height of the pandemic, and clearing the backlog of missed appointments and surgeries is the first priority. At the same time, as the science evolves and longer-term effects of COVID-19 become better known, the health system will need to cope with the virus's detrimental consequences on physical and mental health.

⁵ For an example of how Asian Development Bank measures development impact and whether a project is deemed successful, see *2021 Annual Evaluation Review: supporting the Sustainable Development Goals*, www.adb.org/documents/2021-annual-evaluation-review-supporting-sustainable-development-goals.

In addition to disease control, addressing COVID-19 fully requires countries to focus on various newer areas, including medium- to longer-term vaccine supply for boosters and further R&D to provide these; genome sequencing; vaccination logistics; health data management; and digital or e-health including telehealth, among others. Investments in pandemic preparedness (still an underinvested area) are also required to help avert and mitigate future catastrophes. This, in turn, will require reforms to public financial management including the allocation of funding to health, but which go beyond the health sector alone.

COVID-19 has both highlighted and intensified health-related inequities across ethnicities, sexes, ages and within and across countries; addressing these divides will pose one of the most difficult challenges for the health sector, which must work harder to address the causes of health inequities that lie within its control, and the impacts of those root causes which lie beyond its control. Resources are required to increase access to health care for all – which calls for more outreach, better financial protection and increase in quantity and quality of health care in typically underserved areas. Critically, countries will need to increase cooperation to redistribute resources, recognizing that global public bads can only be controlled when everyone gains access to vaccines and treatments.

The development community will need to take a multisectoral and whole-of-government approach to cross-sectoral concerns. Provision of the following, and more, is needed: basic water supply and sanitation; safe and nutritious food; and clean air and safe environments. Investments to improve the quality of health infrastructure, especially green facilities, will require close coordination with environmental experts; a pivot towards patient-centred care and improved quality of health human resources will require more emphasis on health education and training; and addressing zoonoses will require increased research and cooperation with the agricultural sector. Accordingly, ODA must shift from a sector-by-sector approach towards addressing challenges along salient trends and themes.

Conclusions

This chapter has analysed what ODA is, why it is important and its major trends, highlighting health ODA trends. It has focused on MDBs as critical ODA players, using a case study of the Asian Development

Bank and its experience in financing COVID-19 response and recovery. ODA remains the main source of international development financing for many developing countries, and has proved its worth by stepping up during the COVID-19 pandemic. The DAC mechanism enables a consensus-led, concerted effort to deliver aid to those who need it the most, while supporting the monitoring of the quality of public spending and investments. However, the true test of ODA is whether resources have had a meaningful impact on development outcomes: while this chapter has touched on ODA volumes, effectiveness and its measurement with regards the health sector, focused research is required to fully comprehend medium- to long-term results and support evidence-based policy-making across multiple sectors and themes. This will become more salient as the world tackles other challenges such as the climate crisis and food insecurity. The Asian Development Bank and other such agencies must continue to build on the successes from the COVID-19 response, and stand ready with increasingly plentiful, innovative and agile financing mechanisms.⁶

Additional resources

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SECTION 2

Pooling resources and defining benefits

2.1 *Approaches to risk pooling*

SOPHIE WITTER, JOSEPH KUTZIN, SUSAN SPARKES

Key messages

Chapter 2.1 tackles risk pooling. Risk pooling refers to the way prepaid funds are combined and then used to provide care for a covered population. Pooling is an often underappreciated aspect of health financing which shapes the overall health system. Key learning includes that:

- Pooling prepaid funds is central to progressing towards universal health coverage (UHC). It bolsters health system efficiency and equitable access to services.
- Pooling maximizes redistributive capacity and allows the health system to align funding with needs and social priorities.
- Having multiple risk pools can be problematic, particularly if:
 - pools have too few people;
 - if everyone in the pool has similar risks; and
 - if there is no redistribution of resources across pools.
- Structuring and managing risk pools well can offset problems associated with fragmentation by:
 - reducing duplication or overlap, making purchasing and service delivery more effective;
 - avoiding disproportionately large financial burdens falling on particular pools; and
 - minimizing risk selection and “cream-skimming”, whereby pools try to exclude high-risk (and therefore high-cost) individuals.
- Policy-makers can use a range of pooling strategies to enhance efficiency, equity and access but path dependencies, politics and context matter. Options include:
 - encouraging the integration (i.e. consolidation or merger) or coordination of pooling schemes;
 - boosting funding for less endowed pools;

- equalization through risk adjustment across pools via direct transfers between schemes;
- making membership compulsory; or
- aligning data systems, benefit packages and payment infrastructure across pools.

Introduction

We first outline what pooling is and its purpose. We explain how risk pooling works and introduce the problems of incomplete risk pools and pool fragmentation that are particularly apparent in low- and middle-income countries (LMICs) and are key to much of what follows in the rest of chapter.

Pooling as a health financing function is concerned with the assignment of prepaid funds to the institutions that purchase health services on behalf of some or all of the population. As such, pooling is a policy instrument: pooling structures and related mechanisms can be changed as part of policy reforms to achieve wider objectives.

Pooling interacts significantly with other health financing functions. For example, revenue raising affects the overall magnitude of prepaid funds, i.e. the total amount that can be pooled. While pooling determines the redistributive potential of any given level of prepaid funds, redistribution only happens when the funds are spent, i.e. during purchasing. The method of pooling chosen can affect the overall efficiency of the health system: pooling structures can influence the extent of duplication or overlap in purchasing and service delivery, and help make purchasing incentives more or less coherent. However, even with a good pooling structure, poor purchasing or budgetary discipline can limit the amount of redistribution that actually takes place. So to properly understand pooling, it is important to understand how it aligns with other health financing functions.

The primary purpose of pooling is to maximize the redistributive capacity of prepaid funds and is referred to as risk pooling, which allows the decoupling of payments from service use. This means that the cost risks that ill health poses to individuals and households are also in effect pooled. Though risk pooling aims to redistribute resources according to need, it is difficult to predict an individual's or

a household's future need for health services. Without mitigating measures in place, potential illness and disease expose individuals and families to huge health and financial risks. For this reason, societies have developed various approaches towards pooling risk, so that the randomness is shared across a broader population, reducing the aggregate risk confronting that population. Such pooling is in effect an insurance function that usually entails redistribution from healthy to sick and, to the extent that poorer persons are in worse health, from wealthy to poor (Smith & Witter, 2004).

Risk pools can be formed at different levels of a health system and vary in size, from the whole nation to a local hospital which pools risks by offering free or subsidized access to a group within the local population. The nature of risk pools in a particular health system may result from historical path dependency and wider political decisions as much as explicit design choices. No society lacks pooling, nor is pooling ever complete – so all are on a spectrum of degrees of pooling which places individuals at a greater or lesser level of exposure to risk, often in the form of out-of-pocket (OOP) payments or barriers to access for health services.

Decisions about risk pooling are crucial to the operation of the health system and health care markets. However, recent papers argue that risk pooling issues have received much less attention than other health financing functions in the global literature (Mathauer, Saksena & Kutzin, 2019). Pooling also raises inherently political issues, as it is central to the distribution of costs and benefits across different social groups. In many LMICs, risk pools are incomplete – individuals remain exposed to coverage and payment risk – and fragmented, which means that an individual may get very different protection depending on which pool they belong to. Pool fragmentation means that, for any given level of prepaid funds in a health system, there are barriers to redistribution (e.g. across insurance funds, or across levels of government). Therefore, pool fragmentation undermines risk pooling because the more fragmentation that exists in a system, the lower the redistributive capacity of the aggregated prepaid funds. Fragmentation thus contributes to inequities in access and use, poor financial protection and inefficient purchasing (WHO, 2010).

High reliance on OOP payments, which is a feature of many low-income settings, is an indicator of limited fiscal capacity that leads to low levels of public funding for health, and hence constrains the

aggregate level of funds that are pooled in a health system. Poor pooling arrangements limiting the redistributive capacity of these funds (either across individuals or time) compound the problem.

In this chapter, we first examine what makes a good pooling system and then go on to describe how risk pools are organized in practice and the strategies adopted to overcome their problems of incompleteness and fragmentation. We present a case study of Thailand's reform of its pooling system and draw on this and other work on the political economy of health reforms to understand how best to manage the politics of pooling reforms.

What makes a good pooling system?

Pooling creates opportunities for the efficient redistribution of resources to support equitable access to needed services, with financial protection arising from any given level of prepaid funding (Mathauer et al., 2020). Ensuring redistribution at the system level and across different pools is key to making progress towards UHC. Closely related health financing actions are to decouple contributions, such as taxes or premiums, from health needs or risks, and move towards uniform benefits packages (WHO, 2010).

However, fragmented pooling creates its own set of problems. It often contributes to inequities, where people in different pools have different benefit entitlements; for example, de facto through varying levels of per capita funding across pools. It can contribute to health system inefficiencies, too, due to a duplication of tasks that results in higher overall health system administration costs, as well as, potentially, less effective purchasing, if providers are able to shift costs between multiple, uncoordinated purchasers (Mathauer, Saksena & Kutzin, 2019).

Desirable attributes of pooling

In response to the problems of fragmentation, the World Health Organization's (WHO's) health financing progress matrices highlight two main desirable attributes for pooling: integrating, or at least coordinating, pooling schemes and increasing the ability to redistribute available prepaid funds according to needs and social priorities (Jowett et al., 2020). Where there are multiple pools, risk adjustment between them can ensure that average per capita expenditure on health,

adjusted for the pool members' health risks, is equal or similar across pools, but this option is relatively complex to administer. Other corrective mechanisms include establishing common benefits packages and merging data systems across schemes.

Further desirable attributes of pooling include:

- compulsory membership (to avoid adverse selection, whereby only those with high needs join the pool, and cream-skimming, whereby insurers encourage membership only by healthier members, for example);
- payments by members being unrelated to utilization (otherwise it negates the sharing of risks); a large population size (to ensure diversity of risks and ability to cross-subsidize during health shocks) (Mathauer et al., 2020); and
- administrative feasibility (for example, for health insurance, the pool has to have the capacity to check on membership, ensure that entitlements are fulfilled, avoid illegitimate calls on funds and check on provider performance).

There are a number of rudimentary universal indicators of the success of risk pool harmonization arrangements (Smith & Witter, 2004), which include:

- the number of different pools in a health system and the population affiliated to or benefiting from each;
- variations in expenditure on the package of care: the extent to which there exist differences between risk pools in the expenditure per member, which may influence the real level of benefits available for covered individuals in each pool;
- variations in quality: the extent to which there exist qualitative differences in health care received by members of different risk pools; for example, in the form of waiting time variations, which may be a consequence of the level of per capita subsidy;
- variations in OOP spending: the extent to which there exist differences between risk pools in the OOP charges experienced by individuals in receipt of health care.

Some observed variations between pools may be due to factors other than risk pool fragmentation, such as variations in purchaser efficiency. However, large variations in such indicators offer strong *prima facie* evidence of the harmful consequences of fragmentation.

Evidence of poor risk pooling

Challenges can be seen in LMICs, in particular, regarding a lack of effective coverage and pooling demonstrated in variations of utilization, quality of care and financial protection (which also relate to health care supply features). WHO's 2019 UHC monitoring report, for example, found that in many systems poor people have lower coverage even for basic services such as immunization, sanitation and antenatal care (WHO, 2019). For these basic services, rural areas generally have lower coverage than urban areas. In addition, the global incidence of catastrophic health expenditure (Sustainable Development Goal indicator 3.8.2), defined as large OOP spending in relation to household consumption or income, increased continuously between 2000 and 2015. As risk-rated private insurance affiliation is low in most LMICs, it may pool risks over time but not across individuals, while community-rated health insurance schemes have typically suffered from adverse selection, whereby only the poor and sick join and risk pooling collapses (Ekman, 2004).

Fragile and conflict-affected settings have higher need and unmet need for health services as well as significantly higher OOP expenditure, external dependency and health-related impoverishment (Witter et al., 2020). Overall financing for health tends to be low and also inequitably distributed, and low trust and conflict undermine pooling and prepayment, as well as the stable institutions to oversee risk pooling. Risk pools therefore tend to be highly fragmented and with poor coverage, with populations further segmented where there are substantial refugee and displaced populations, having varying protection provided by different humanitarian agencies, each with their own mandate, resources and focus. These complex emergencies have been particularly challenging in the WHO African and Eastern Mediterranean regions.

The indicators of pool harmonization outlined above mask those who cannot afford to use care, which can be a *prima facie* indicator of inadequate risk pooling arising primarily from shortcomings on the revenue raising and supply side. Analysis shows that the incidence of catastrophic health expenditures or impoverishment due to OOP health expenditures (using global poverty lines) is negatively correlated with the share of compulsory prepaid and pooled expenditure (government spending) in total current health spending, and hence positively

correlated with the share of OOP health spending in total health expenditure. The 2019 report also found that the majority of household OOP health spending is related to medicines and outpatient care, and not necessarily to larger but more infrequent hospital bills (WHO, 2019). Further recent research has highlighted challenges for specific populations, such as women, female-led households and the large informal employment sector, when health coverage is linked to employment (Vijayasingham et al., 2020). It is important to focus on the indicators of failures in practice, rather than de jure pronouncements. The experiences of pool members can often vary considerably from their theoretical entitlements.

The objectives embedded in the concept of UHC offer good guiding principles for the design of risk pools, and the financial transfers between them. UHC is a set of health policy objectives that applies to an entire system and population, so calls for harmonization of benefits across that population (see Chapter 2.2).

How can countries organize risk pools?

Risk pooling typologies and features

A paper examined key features of risk pools for health care globally, highlighting the importance of the basis for enrolment (whether it is voluntary, compulsory or automatic), the number of risk pools, whether they are in competition, whether they cover specific population segments, and the extent of territorial overlaps. This led to eight different scenarios which can operate singly or multiply within a country (Fig. 2.1.1).

Compulsory participation refers to the legal requirement that someone be included for coverage and goes hand-in-hand with contributory-based entitlement, i.e. there must be a specific contribution made by or on behalf of the covered person. The “on behalf” may come from public budgets for specific groups of individuals whose participation is fully or partially subsidized, or it may come from traditional insurance contributions that cover individuals beyond the contributor (e.g. family members).

Automatic participation is typically based on legal or constitutional obligations, and the basis for entitlement is noncontributory, deriving from citizenship, residence or other factors, such as poverty status, etc.

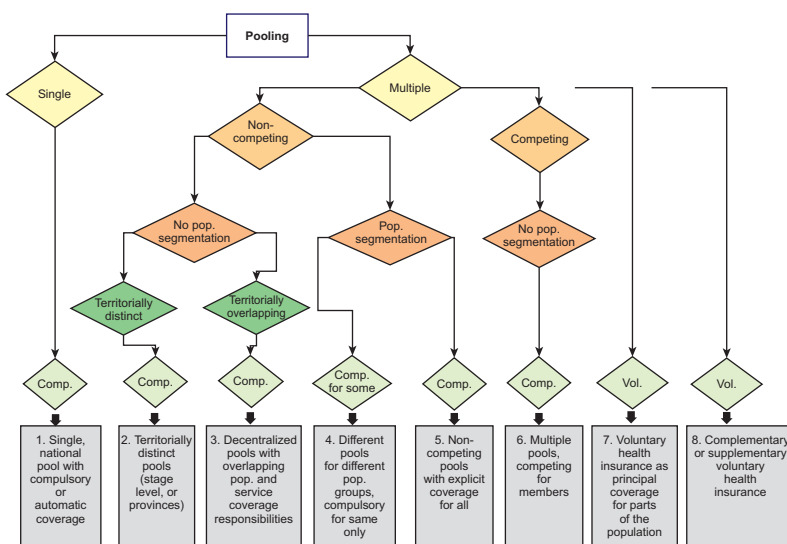


Fig. 2.1.1 Pooling arrangement classifications

Comp: compulsory; Pop.: population; Vol: voluntary.

Source: Mathauer, Saksena & Kutzin (2019).

As such, automatic entitlement is typically solely funded from general budget revenues. However, mandatory coverage is often not implemented effectively because it is difficult to enforce, while the de facto experience of automatic entitlement often differs from the de jure promise due to underfunding relative to promised entitlements, leading to supply shortages, informal payments or both.

Enforcement is a particular problem in countries where a large proportion of the population works in the informal economy. The result is that even where it is legally mandatory for the entire population, it is de facto voluntary coverage. For example, Ghana instituted “compulsory” social health insurance (SHI) in 2003 with numerous population groups covered by national subsidies, but by 2021 only 35% of the population was covered (Smith & Witter, 2004) (for multiple reasons, including residual access costs for these groups and reimbursement delays). This means that de jure pooling is not translated into de facto pooling of risks, leaving these population groups still exposed to access and financial barriers for health care.

What are the different ways countries can administer risk pooling? Are there key contrasts in decentralized versus centralized administration, or those formed by sociodemographic characteristics?

Most countries have limited and multiple funding sources and use different pools to fund specific programmes, with voluntary health insurance (VHI) sometimes existing in parallel. Where pools are multiple, they may compete for members (for example, through offering greater convenience or quality), or may cover different populations, such that there is no competition between them. Although there is an argument for competition driving choice and innovation, the evidence for this in practice is weak, and cream-skimming can occur, which adversely affects progress towards universal health coverage (Mathauer, Saksena & Kutzin, 2019). For those countries with insurance competition, such as Germany, the Netherlands or Switzerland, considerations need to be made about what combination of ex ante risk adjustment and ex post reconciliation will adequately reduce insurer interest in cream-skimming.

A one-pool system

However, some countries do have a single main national pool funded from general government revenues, covering the whole population. This may be administered by a ministry of health, through budgets to providers or via an independent purchasing agency. The agency, often a health insurance fund, may pool general tax revenues and insurance contributions from employers and employees. Both of these options offer maximum redistributive capacity from prepaid funds because of the integration of the main public revenue sources (social insurance contributions and general revenues, or just general revenues), into a single fund. A growing number of countries, for example, Kyrgyzstan and Moldova, have reformed their pooling arrangements to unify multiple funding sources into a common pool. In such cases, it is important to build on existing capacities and ensure that there are clear roles for any new fund and lack of duplication with the ministries of health, alongside a strengthening of the purchasing functions (Kutzin, Cashin & Jakab, 2010).

Employment-based pools

Pools may be segmented based on employment status (e.g. formal employment), demographic status (e.g. older people or young), health

status (e.g. pregnant women), location (targeting specific regions) or wealth (certain schemes being only affordable to higher income groups, or government-funded programmes for low-income persons, for example). Segmentation raises risks of inequity reflected in differences in benefits across pools.

Pools based on geographical area or administrative level

Decentralization can create separate risk pools by area or by administrative level of the system (with funds covering specific services and populations at each level, although there is sometimes duplication of coverage across levels, as in the former USSR (Union of Soviet Socialist Republics), where rayons and cities within oblasts often managed overlapping health networks and budgets). This can raise efficiency, capacity and stability concerns, if risk pools are small, as well as concerns about redistribution across pools (Mathauer, Saksena & Kutzin, 2019). A paper on health financing in devolved settings, which included seven case studies (Burkina Faso, Indonesia, Kenya, Mozambique, Nigeria, Philippines, Uganda), concluded that devolution contributed to fragmentation of the pooling function, making equitable distribution of resources across subnational units more difficult (ThinkWell & WHO, 2022). The study authors found that subnational territories differed in terms of their fiscal capacity relative to their needs, thereby requiring fiscal equalization arrangements (this was also at the core of the pooling reforms in Kyrgyzstan and Moldova (Kutzin, Cashin & Jakab, 2010)). Yet the existing intergovernmental grant transfers were not adequate to equalize these differences across territorial units, which is a common challenge. The authors also remarked that it is challenging to strike a balance in horizontal transfers between multiple considerations, such as the needs of health versus other sectors and allocating resources according to fiscal need, while also incentivizing fiscal effort.

Category-specific risk pools

Risk pools may be territorially overlapping but addressing different disease or condition categories. For example, in the USA it is common to find that health care costs associated with particular conditions (such as mental illness or end-stage renal failure) are “carved out” of regular risk pools, and placed in a condition-specific risk pool (Smith & Witter, 2004). A similar approach was taken by the Seguro Popular (People’s

Health Insurance) in Mexico. The intention is to remove very unpredictable but high-cost needs from the regular health care pool, and to transfer the associated risk to a higher level of aggregation (for example, from state to federal level, which has a larger population across which to share risks). However, in countries with limited health budgets, this can be regressive, with relatively small numbers of well-connected patients benefiting from support from the dedicated fund (e.g. to fund renal dialysis) while basic services used by the majority remain underfunded (Witter, 2010).

Overcoming the inequities of fragmentation: reforms to risk pooling

Where pools cover different socioeconomic groups, this often creates fragmentation and inequities, with better protection for more privileged groups such as civil servants or the formal employment sector through social or private health insurance, while mandates for the less powerful population segments, such as user fee exemptions for the poor, are typically underfunded and face challenges of quality and coverage (Witter, 2009). Such arrangements typically fail to redistribute effectively, especially when relying on de facto voluntary enrolment and contributions; for example, for the informal sector (Mathauer, Saksena & Kutzin, 2019).

Provide automatic coverage, retain separate pools

Some countries have successfully provided automatic coverage for their populations despite retaining risk pools which are segmented by population groups. For example, Thailand managed to increase equalization of funding for its Universal Coverage Scheme (UCS) and avoided eroding the existing benefits received by civil servants (Prakongsai, Limwattananon & Tangcharoensathien, 2009). This option can be politically easier, though while the Thai reforms introduced since 2002 have reduced fragmentation, they have not eliminated it (see the *Evidence in practice* section) (Mathauer, Saksena & Kutzin, 2019).

Risk adjustment of revenues

A few countries, such as the Netherlands, combine competition among insurers with individual choice of insurer and compulsory participation.

This is commonly referred to as a competitive SHI arrangement. Each of the insurance schemes thus constitutes a separate pooling agency. A critical requirement of this pooling arrangement is risk adjustment of the revenues that go to each insurer, either from a national fund or between pools, to reduce risk-based selection and inequalities of revenues and therefore benefits across pools (Mathauer, Saksena & Kutzin, 2019). If effective, this risk adjustment, which is more typically found in HICs, can reduce or eliminate the consequences of fragmentation while retaining devolved administration.

VHI generally covers small population segments. Premiums are often risk rated, and voluntary insurance may offer supplementary or duplicating services to the main risk pool. Typically, members have higher incomes and entitlements. South Africa provides the most extreme example, with 42% of its health expenditure coming from voluntary insurance in 2020, but only covering 15% of the population (Mathauer & Kutzin, 2017). Such schemes can be highly distorting, allowing enrolled members to disproportionately benefit from underlying public subsidies in terms of trained health staff and infrastructure. Supplementary insurance can fill gaps in publicly funded coverage but still risks increasing inequities unless it is covering a large part of the population (Thomson, Sagan & Mossialos, 2020).

Mathauer and colleagues set out four options for addressing fragmented risk pools, which can be used individually or in combination (Mathauer et al., 2020).

The first is consolidation or merger of pools, with the aim of increasing their size and the diversity of members' health needs and risks, so reducing administrative costs while at the same time increasing purchasing power and internal redistributive capacity. Consolidation may occur as part of wider changes, for example, recentralization, where regional pools are merged into a national one, or as vertical merging, where funds covering different levels of care for overlapping populations are merged. It could also take the form of merging coverage of population segments, i.e. bringing together health insurance programmes covering, for example, the informal sector and mandatory schemes for public servants. This type of merger typically generates more resistance as members of some pools may view the reforms as risking a dilution of their benefits. There may also be concerns about the institutional and administrative limits to the optimal size of purchasing agencies linked to risk pools; however, effective data systems can mitigate such concerns.

Despite these challenges, some countries have managed to merge risk pools in the past two decades, including Indonesia, the Republic of Korea and Türkiye (Mathauer et al., 2020). In each of these countries, the merging of pools significantly increased the risk diversity in the merged pool and was the starting point for reducing inequities in access to health services. However, in a review of these changes, authors noted that some undesirable effects also ensued; for example, when state budget transfers to finance the coverage of poor and vulnerable population groups were “captured” by better-off groups with better access to services (e.g. in urban areas) and therefore higher utilization. This reinforces the point that pooling alone only creates the potential for redistribution; other health system features have to be aligned to produce redistributive benefits. Indonesia provides a clear example of this: the Indonesian National Health Insurance Scheme, *Jaminan Kesehatan Nasional*, has national pooling, but there are major supply-side imbalances across the country, and at least for inpatient care, the payment methods relate to service use. Thus, the national pool is distributing to where the providers are, not to where the needs are (for example, in more remote rural areas) (Nugraheni, Mubasyiroh & Hartono, 2020).

A second option which may reduce the risk of those stakeholders who benefit from the status quo resisting reforms to pooling is to retain separate risk pools, but compensate for differences between them by, for example, increasing the funding to less endowed pools. Redistribution is achieved by providing budget transfers and gradually increasing these, with the ultimate aim of achieving equitable access to health services and harmonized benefit packages. Countries that have pursued this pooling reform option include, for example, Colombia, Gabon, Mexico, Peru and Thailand (Mathauer et al., 2020). In these countries, reforms have substantially reduced the differences in per capita expenditure between different population groups, and thus helped to improve financial protection and equitable access to health services.

Equalization through risk adjustment across pools is a more systematic approach to ensure equal spend per capita across pools. That can occur through direct transfers between insurance agencies or via a national risk adjustment fund, but also through adjustments of fiscal equalization arrangements between areas in a devolved context (see Box 2.1.1). ThinkWell and WHO’s (2022) multi-country study of devolved health financing, for example, found that more focus on

Box 2.1.1 Retrospective risk adjustment

Prospective risk adjustment between risk pools is almost invariably accompanied by a retrospective stage in which prospective allocations are altered in the light of actual expenditure experience (Smith & Witter, 2004). A number of arrangements exist for handling retrospectively variations in actual expenditure from the prospective budget. These include renegotiating the budget retrospectively with the central payer, running down (or contributing to) the pool's reserves, varying the future premiums or local taxes paid by the pool members, varying the user charges paid by the patients, varying the package of benefits available to patients, and delaying or rationing health care to the population at risk. However, some of these may perpetuate inequities between pools.

From a public policy perspective, in a competitive SHI context risk adjustment needs to be sufficient to reduce or eliminate the incentive for insurers to invest in risk selection. The combination of ex ante and ex post risk adjustment is adequate to the extent that it eliminates such socially unproductive investment.

health needs (rather than health infrastructure) was required in resource allocation and revenue sharing formulae in order to protect more disadvantaged areas. Conditional grants to local administrations, as used in countries like South Africa, and central government subsidies for health insurance coverage for the poor can indirectly contribute to resource equalization across subnational territories (ThinkWell & WHO, 2022).

In addition, where the above are challenging to achieve, is what the authors called “as-if pooling” (Mathauer et al., 2020), meaning taking measures such as harmonizing data systems, benefits packages, contracting and provider payments across pools. These actions fall outside of pooling but can mitigate the consequences of fragmentation and pave the way for future reforms to risk pools.

The role of external actors in fragile and conflict-affected settings is typically larger, and the ideal of integrating their funds into pooling arrangements to support broad packages of services may be limited by organizational policies as well as low trust in public financing systems (Witter et al., 2020). Strategies to address this may be similar to “as-if pooling”, including stronger aid coordination mechanisms and shadow

alignment. In these settings, policies to increase financial access and decrease OOP payments (for example, through user fee exemptions, health equity funds, health insurance, vouchers and cash transfers, conditional or unconditional) play an increased role, given the combination of low, unstable and inequitable incomes; social and cultural barriers to access, and high health needs.

Finally, making membership of risk pools compulsory is an important reform, although for lower income populations it will likely require public funding to support its realization. Reviewing experiences in reforming risk pools in transitional economies, Kutzin and colleagues observed that early health reformers had identified a number of expected gains from the introduction of compulsory health insurance (Kutzin, Cashin & Jakab, 2010). These included higher funding levels, improved accountability, greater efficiency and higher quality, through new payment incentives and the separation of purchaser from provider. Experience with the introduction of compulsory health insurance in LMICs elsewhere in the world suggested, however, that such reforms tend to worsen inequities and duplication by setting into motion the establishment of separate, segmented health financing (and often delivery) systems for the insured (often formal sector) and uninsured (often informal) populations. The core lesson for implementing compulsory risk pool membership reforms is thus to pool contributions from SHI schemes with general revenues from the outset, to ensure that contributors and non-contributors are in the same pool with the same benefits, rather than starting with the formal sector and then attempting to expand into the informal sector from there.

A sequencing of reforms will be contextual but might start with consideration of merger possibilities, depending on the political economy, which we discuss below. If those are not possible, compensation or equalization should be considered, which may meet less resistance as they do not directly threaten existing favoured group interests. This was the course taken by pooling reforms in Thailand, for example and Mexico (Mathauer et al., 2020). If neither of these approaches is possible, then mitigation strategies such as harmonized data systems to prepare for future pooling reforms could be pursued.

Evidence in practice: the UCS in Thailand

The following example is based on the analysis carried out by Bertone, Pholpark and Witter (2022).

Political background

During its modern history, Thailand has alternated periods of democracy with others of military rule. A major turning point was the 1997 Constitution (the “People’s Constitution”), which was the first to be drafted by a popularly elected Constitutional Drafting Assembly and entailed a reformist approach and renewed attention to civil liberties and public participation. This had important effects on the political and cultural context and influenced the results of the 2001 elections, paving the way for social reforms, including in the health sector.

However, the struggle to get the Constitution passed became intertwined with the Asian Financial Crisis of 1997. Thailand was one of the fastest growing economies in Asia between the 1960s and 1990s, but experienced cyclical economic crises, including the 1997 crisis, which led to the country relying on an International Monetary Fund support package to ensure recovery. The country completed the repayment of loans in 2003, but it took almost 10 years for gross national income per capita to reach 1997 levels. However, despite political and economic crises, social and health development has always been prioritized in Thailand, with a focus on pro-rural health development to help fight poverty.

In the 2001 elections, the newly formed, populist Thai Rak Thai Party led by Thaksin Shinawatra agreed with a proposal by health reformists to introduce a universal coverage programme that appealed to the mass electorate and won with a large popular mandate. Since 2001, the political history of Thailand has been dominated by the rise and fall from power of former Prime Minister Thaksin Shinawatra, and conflict over the rising military influence in politics.

Risk pooling context and reforms

Prior to the 2000s, there were multiple health risk pools in Thailand, including (i) the Civil Servant Medical Benefit Scheme (CSMBS) for government employees; (ii) SHI for private sector employees; (iii) a Health Welfare scheme for low-income households; (iv) a health coverage programme for older people; and (v) a public subsidized voluntary scheme for other population groups. Some 30% of the population was not affiliated to one of these explicit coverage programmes.

In 2002, the National Health Security Act was passed to set up the UCS, to provide essential health services for the population not covered

by the civil servant and private sector employees' schemes. This resulted in consolidation, with the low-income scheme, older people scheme and voluntary scheme all eliminated and explicit affiliation extended to all. This was later followed by the extension of health coverage to the stateless population in 2010, to ensure health coverage through annual budget subsidies for 0.45 million people, mostly marginalized minorities living in the mountainous northern provinces. Subsequently, there were several attempts to harmonize the three public health insurance schemes (CSMBS, SHI and UCS), without success. A new (successful) attempt started in 2012, with a focus on emergency medical services. Migrant VHI to provide health coverage to informal/undocumented migrant health workers was implemented in 2014, but with limited success because the scheme remains voluntary and needs to be purchased at designated one-stop service centres only in provinces where migrants reside.

Key features of the UCS

The aim of the creation of the UCS was to extend health coverage to the entire population. The scheme was tax-funded, initially with a co-payment of Baht 30 per visit or admission (which was then terminated in November 2006), to cover automatically those who were not covered by the civil servants' or private employees' schemes. It established a comprehensive benefits package, including a negative list, with a primary care focus and gatekeeping function. Strategic purchasing was introduced with a fixed annual budget per member (capitation based) and a cap on provider payments (age-adjusted capitation for outpatient services, and diagnosis-related groups within an annual global budget for inpatient services), which aimed to put a "hard" limit to the budget and contain costs. The reform also introduced a provider-purchaser split through the establishment of the National Health Security Office, responsible for purchasing health services, and its multistakeholder governing body, the National Health Security Board. The Board is chaired by the Minister of Health, and includes government officials, including the Ministry of Finance; representatives of local governments, nongovernmental organizations, health professionals and private hospitals; and experts in insurance, medical and public health, traditional medicines, alternative medicines, financing, law and social science. Overall, the reform has been considered a major

success and has improved access to essential health services, especially for the poor and all the informal sector. It has decreased catastrophic expenditure and increased the satisfaction of the UCS's beneficiaries and health care providers.

Analysis of the political economy of UCS reform

Analysis of the political economy of the UCS reforms using the WHO framework highlights the role of the change team in the design, adoption and implementation of the reforms. Technically strong, politically savvy and well-connected, the change team was ideologically committed to UHC, but seen as politically impartial and free from conflicts of interest. The change team was a close-knit group with key contacts inside and outside of the Ministry of Public Health. The change team demonstrated not only their technical skills and knowledge, but also their experience in navigating bureaucracy and governmental politics and their capacity to mobilize different sources of power at political, societal and international levels and use effective strategies to move the reform agenda forward. They saw themselves (and were in practice) policy entrepreneurs or “match makers” between evidence and politics.

Political leadership played a key role – UHC was promised in the Thai Rak Thai political manifesto and generated great popularity for the party, enabling it to win the election. Civil society was also a key player, strongly aligned to the UCS and working in alliance with the change team. The Ministry of Public Health was not a strong advocate as its financing authority was transferred during the reforms to the National Health Security Office as new purchaser. However, health workers were supportive of the scheme, having witnessed directly the access difficulties of the poor and informal sector workers, especially for high-cost interventions. The private hospital association and clinics were worried about losing business to public providers and wanted to maintain fee-for-service charging. The Ministry of Finance was neutral on the scheme, being mainly concerned with budget neutrality. International partners held less leverage, in that Thailand is not an aid-dependent country, but played a role in relation to normative power, with some players (such as the World Bank) being opposed initially, while others (such as WHO) were supportive and were mobilized by the change team.

In relation to strategies to manage the process of adoption, use of evidence and information was very important, along with coalition building, and enhancing the legitimacy of the policy (for example, by connecting to traditional social values in Thailand). Mobilizing support (for example, by creating alliances with civil society) and addressing opposition (for example, from beneficiaries of existing schemes who feared dilution of their benefits, from the Ministry of Public Health because of changes to its role, and from private providers) by meeting some of their demands were also key. In Thailand, the change team made strategic use of the evidence available and its capacity to generate locally relevant knowledge, based on experience and international literature. In relation to external actors, the change team drew on international learning early in the process, but also used international approbation to cement the reforms as the Thai experience was shared internationally and received a strong positive reaction. The successful reform of the scheme also highlights more overt political adoption strategies, including changing the decision-making processes (for example, shifting budget decisions to the Prime Minister to bypass challenges from the Ministry of Finance). Some of these, such as the establishment of the National Health Security Board and later the National Health Assembly, not only increased supporters for these reforms but also likely changed the margins of manoeuvre for future reforms.

Thailand's reforms: summary

Thailand has managed to provide near-universal access to essential health care by establishing a risk pool on the basis of automatic entitlement which covers all who were not already members of the civil servants' and private sector employees' schemes, including the previously unaffiliated 30% of the population. The UCS replaced three previously existing schemes but did not change the status of those for civil servants and private sector employees. Instead, it compensated for the existence of those two by extending coverage to the population groups that did not have access to them and gradually increasing the level of per capita subsidy to the new UCS as a means to reduce inequities in benefits, which was a more politically expedient route. Tangcharoensathien and colleagues (2019) highlighted this as an example of path dependency: although a merger of pools would have

been ideal, compromises had to be made to reduce threats to existing beneficiaries of other schemes, enabling overall gains despite reduced efficiency and equity relative to an optimal design.

The political economy of risk pool reforms

Risk pooling reforms are inherently controversial and political as they rely on a shared objective to move towards UHC, which itself depends on the existence of social solidarity – a willingness by the better-off and healthier to redistribute resources to the less well-off and sicker – and a feeling of connectedness with social groups despite their diversity (of ethnicity, religion, gender, region, caste, etc.). An investigation into solidarity for health risks across 24 countries in 2010 found wide support for assisting the poor and sick with health care costs, but only to some extent (most supported subsidies of half of the cost or less) (James & Savedoff, 2010). Although results varied by country, there was also evidence of self-interest in that healthier respondents were less likely to express solidarity. This suggests mixed support for pooling reforms that focus on redistributing benefits. These reforms are also quite public in that the changes in entitlement commonly require legislative change too, which is more complex to manage than reforms in other areas of health financing which can be achieved through technical reforms (e.g. adjusting provider payments).

WHO has developed a framework for analysing the political economy of health financing, which is structured by six main domains (Sparkes et al., 2019). It is interesting to consider each of these in relation to risk pooling and the kind of strategies which might enable more successful risk pooling reforms. The section below draws on work by Özçelik and colleagues (2003) to describe the potential political dynamics that play out during pooling reform, as well as strategies that were undertaken in a set of countries that successfully moved forward reform to manage these dynamics.

Interest group politics

Reforms are hard to achieve when perceived losses are focused on organized or higher profile groups, while potential winners are diffused. Where there is an entrenched private sector, or high-income group within society, that has claimed certain benefits and sees itself

as standing to lose from reforms to pooling (as is the case with the challenges made to the adoption of the National Health Insurance in South Africa) the resistance can be protracted and well resourced (McIntyre, Doherty & Gilson, 2003). The communication strategies around these reforms (and reform resisters) are often quite sophisticated, as the perceived losses may not accrue to the beneficiaries themselves, but rather to enterprises that enable coverage. This can be connected with inherent insurance market failures where relevant, whereby cream-skimming or risk profiling occurs by private sector actors in a way to maximize their profits rather than providing benefits for the whole. Strategies to manage interest group politics include building coalitions with groups that might favour reforms, engaging civic and professional groups before reforms and during the consolidation phase after they are implemented, mobilizing public support and ensuring a participatory approach to policy development. In recognizing the potential opposition to pooling expansion or consolidation, health reform leaders employed these strategies in Mexico and the Republic of Korea (Kwon & Reich, 2005).

Bureaucratic politics

Pooling reforms may threaten the role, resources and interests of influential organizations such as ministries and social insurance agencies, leading to blocking and other forms of resistance. This is particularly relevant in many LMICs where the government civil service often comprises a large share of the formal sector. This can create both a potential conflict of interest where a scheme already exists that extends preferential benefits to civil servants, and can also lead to capture, whereby SHI for the formal sector is put forward as a first step towards universal coverage reform. For example, these dynamics were present in Türkiye, but it was possible to put strategies in place to mitigate these bureaucratic interests. Beginning in 2001, plans were put in place to consolidate five pools under a new umbrella organization (Sparkes, Bump & Reich, 2015). Strategies to manage resistance from the Ministry of Labour and Social Security, which operated the largest social security system in the country, aimed to persuade, placate and reassure those whose interests it represented. These strategies included: developing a clear vision in the Ministry of Health and its reform team;

establishing an interministerial committee to voice and incorporate concerns from key ministries; using close personal relationships with the Prime Minister to address resistance; bundling the health care legislation with measures to address Ministry of Labour and Social Security concerns about retirement ages; and guaranteeing that no one would lose benefits through the reforms.

Budget politics

Reforms to pooling are often seen as presenting public finance risks to the Ministry of Finance in cases where the focus is on expansion of coverage expansion, while the Ministry of Health is seen as an advocate for more resources (though not always an effective advocate). To proactively manage these two sets of concerns, in Mexico, during the design of the Seguro Popular (People's Health Insurance), the Ministry of Health set up an Economic Analysis Unit to produce technical evidence to support its plans and built a reform team within the ministry with technical, political and communication skills (Gomez-Dantes, Reich & Garrido-Latorre, 2015). By institutionalizing the relationship between the Ministry of Health and the Ministry of Finance, concerns around fiscal sustainability could be incorporated into the reform plans as a way to build a coalition and assuage resistance. However, despite these efforts, the actual efforts to establish a single, unified risk pool at each state level did not succeed in Mexico.

Leadership politics

In the face of competing political and ideological interests, getting support from the head of government and making the risk pooling reforms a central part of a wider political manifesto can be effective, as illustrated in the Thai UHC reforms and, less successfully, in Mexico ((Tangcharoensathien et al., 2019; Gomez-Dantes, Reich & Garrido-Latorre, 2015). Framing policies in line with local historical and social values is key here. For example, in Ethiopia, it has been argued that the policy idea of health insurance secured elite commitment due to its fit with deeply held ideas within the ruling coalition concerning the importance of self-reliance and resource mobilization for development (Lavers, 2019).

Beneficiary politics

The implications of reforms in relation to changes in contributions and in benefits are not simple to communicate to the public and can also be subject to political capture. Where coverage has been extended to new population groups through expanded risk pools, this has often been communicated through political campaigning, making electoral promises through the media. This was the case in Ghana with the introduction of its National Health Insurance Scheme, which has gained traction with the public (previously widely opposed to the “cash and carry” user fee) to the extent that it is hard to envisage new governments or parties being able to withdraw the offer (Novignon, Lanko & Arthur, 2021). Democratic politics tend to encourage policies which increase coverage, though there are risks where this is done without adequate funding or implementation support (Witter & Adjei, 2007; Yates, 2009).

External actor politics

External actors can play a crucial role in the design and implementation of health financing policies in LMICs (Chi & Bump, 2018) and often have distinct agendas, which are sometimes in competition with one another as well as domestic policies. In particular, historically, global health institutions have funded priority programmes, creating fragmentation of risk pools by disease area (Biesma et al., 2009). Domestic fiscal capacity is a key factor, but even in aid-dependent settings, domestic reform teams can influence external actor policies through the development of clear national strategies, evidence and capacity to deliver, as well as drawing on their local legitimacy. A number of key pooling reforms, such as the National Health Insurance Scheme in Ghana and user fee removal in Uganda, took place despite, not because of, external actors, although they were engaged in technical support after the decision had been taken. However, despite these reforms, in both countries vertical, disease-oriented risk pools persist to this day, showing how powerful these interests can be in a system.

Policy relevance and conclusions

Risk pooling is critical for reducing the exposure of individuals and their families to health-related financial risks and securing equitable access to health services, alongside other relevant health financing reforms as

described. Historical performance in relation to UHC has been significantly associated with the level of pooled financial resources for health per capita (Global Burden of Disease Health Financing Collaborator Network, 2018). As risk pooling becomes more integrated, the uncertainty associated with health care expenditure can be reduced. Its importance is well recognized, as reflected in the WHO Health Financing Progress Matrices, which set a norm that pooling structures and mechanisms across the health system enhance the potential to redistribute available prepaid funds, and that health system and financing functions are integrated or coordinated across schemes and programmes (Jowett et al., 2020).

Risk pooling also affects and is affected by other health financing functions, including the health financing institutions, their governance, information flows and trust placed in them (Smith & Witter, 2004). Revenue-raising policies determine the prepaid share of health expenditure and whether funds are raised equitably (Mathauer et al., 2020). Pooling reforms are necessary but not sufficient to achieve redistribution if appropriate arrangements for purchasing health services are lacking (Kutzin, Cashin & Jakab, 2010). These arrangements include setting suitable and coherent incentives for providers to deliver quality and equitable health care services. Provider payment methods and amounts of payments to health care providers should in general (unless there is a need for enhanced benefits) be the same for all members of the pool, independent of whether people pay direct contributions or not.

Misalignment of pooling and purchasing arrangements is common, including in systems funded from tax revenues with universal entitlement on a noncontributory basis, in which the health budget is the dominant pooling arrangement; for example, if budgets and funds are poorly allocated across programmes and areas (and hence those programmes and areas become distinct pools) or if payment methods reflect and reinforce the distribution of service providers and infrastructure rather than population health needs. The nature of the benefits package is also key to the type of risks pooled (and the degree to which they are predictable or not) and the extent to which any cost-sharing obligations effectively limit the OOP liability of individuals relative to their capacity to pay. Effective public financial management procedures are also key, including those that determine how budgets are formulated and implemented.

Wider epidemiological factors are also crucial for risk pooling – as chronic illnesses rise, for example, risks become more predictable for some population groups (for example, those who are HIV-positive or

diabetic), which present predictable health care needs. These reduce the redistributive capacity of the pools; a substantial emphasis on prevention and health promotion will therefore be appropriate to reverse that trend and maintain risk pooling.

The evidence is clear on different pooling arrangements, their effects and how they can be mitigated in theory (through the various strategies for defragmentation, linked to appropriate changes to other connected health financing function), but understanding how to manage the politics of reform is more challenging, and this is an important focus for evidence gathering at present (Witter et al., 2024). Work is underway to document comparative lessons in how to overcome political economy blockages to reforms in different settings (and how these link to context features, such as the history and political settlement), as well as how shocks, such as the COVID-19 pandemic, may (or may not) be used to enable reforms (Witter et al., 2025). Lessons on sequencing, engagement strategies for the wide range of actors (internal and external) with power to advance or block agendas, and the capacities needed will be important to the next wave of pooling reforms globally.¹

Additional resources

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2.2 *Setting a health benefits package*

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Key messages

Chapter 2.2 investigates the design and implementation of health benefits packages (HBPs) in different contexts. A benefits package is the range of health care goods and services that people covered by a system or scheme are entitled to or should be able to access. Key learning includes that:

- All health systems have budgetary constraints and set some limits to entitlement, and therefore have some kind of benefits package.
- Benefits packages may be explicitly defined or implicit only, with the latter more common in high-income countries (HICs) and the former more common in low- and middle-income countries (LMICs).
- What is included or excluded, and the ways these decisions are made, vary widely but well-designed benefits packages should address population health needs and ensure the efficient use of health system resources.
- Defining a package of care is complex and often highly sensitive – using evidence and economic evaluation to determine what to include (or exclude) supports efficiency and equity and allows policy-makers to explain and defend their choices.
- There are a range of evidence-led instruments that can support policy choices such as health technology assessment (HTA), which incorporates economic evaluation.
- Any decision-making process should:
 - gain agreement and buy-in from key stakeholders on the ultimate goals of the benefits package and the level of explicitness;
 - take into account the specific characteristics of the setting where the benefits package will be implemented, including its cultural values, market configuration, political system and wealth.

Introduction

Every country's health care system embodies some form of benefits package – the range of health care treatments or services that should be accessible to those individuals entitled to health services in the country concerned. In countries with a national health service or national health insurance, this would normally be the whole population. In countries with social security or private insurance health care, the entitled individuals would be the members of the insurance plan. Explicit HBP's can serve several purposes, including setting standards for health care, or specifying the basic services that should be made available to all eligible individuals. They also offer the possibility for using analysis, such as HTA, incorporating economic evaluation, to determine which services should be included or excluded. However, in many HICs the HBP may be implicit, or defined only in general terms (e.g. free access to primary and secondary care services). Therefore, the role of analysis in setting the benefits package tends to be limited to decisions on whether new health technologies should be reimbursed. Explicit benefits packages, with more definition of the services included, are more common in LMICs, often in the context of initiatives to implement universal health coverage (UHC) (Jehu-Appiah et al., 2008; Youngkong et al., 2012). However, in HICs, in the absence of explicit benefit catalogues, inpatient and outpatient remuneration schemes often have the character of implicit or less explicit benefit catalogues (Schreyögg et al., 2005).

When elaborating on population coverage and benefits packages it is important to define the terms used as well as the scope of this chapter. We follow the definition of the EU HealthBasket project (Schreyögg et al., 2005) and use the term “benefit basket” to be synonymous with “benefits package”; we differentiate these from “benefit catalogues”. Benefits package refers to the totality of services, activities and goods covered by publicly funded statutory/mandatory insurance schemes (i.e. social health insurance (SHI)) or by national health services. Benefit catalogues are defined as the documents (e.g. for inpatient and outpatient care or for pharmaceuticals) in which the different components of the benefits package are stated in detail. These benefit catalogues can either be defined rather generally (e.g. inpatient care after acute myocardial infarction (AMI)) or by enumerating services or procedures in a more detailed way (e.g. insertion of stents after AMI)

(Schreyögg et al., 2005). Especially in LMICs, but also in HICs, there may be a disconnect between the aspirational health plans and the actual availability of funds and resources. It thus seems important to distinguish the benefits package offered in theory and the care actually received by patients (Glassman et al., 2016).

Further, a given benefits package can be characterized by different dimensions of coverage. “Breadth” can be defined as the extent of the covered population (e.g. certain parts of the population or full coverage). “Depth” is defined as the number and character of covered services (e.g. hip replacement for all persons up to the age of 80 years). The third dimension, “height”, specifies the extent to which costs of the defined services are covered by financial resources (e.g. full reimbursement of services versus cost-sharing requirements for certain services) (Busse, Schreyögg & Gericke, 2007). Fig. 2.2.1 displays the three dimensions of a benefits package. An ideal HBP would fill this box as much as possible. In this chapter we mainly focus on the “depth” dimension (service coverage).

In terms of service coverage, there are different ways of defining which services are included in the benefit catalogues forming a benefits package. Definition may be based on need, if enough financial

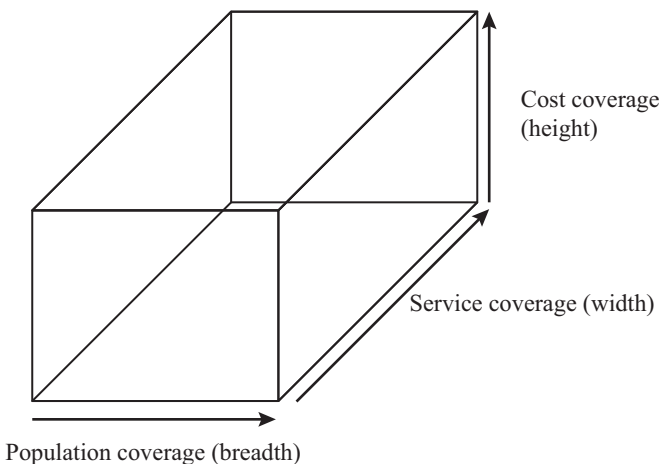


Fig. 2.2.1 A benefits package involves consideration of coverage in terms of cost, service and population

Source: Busse, Schreyögg & Gericke (2007).

resources are available to cover all the services required to address population needs. However, since most countries recognize the scarcity of resources, criteria such as effectiveness, cost-effectiveness or budgetary impact are often taken into consideration. An explicitly defined benefit catalogue, and more general benefits package, usually requires the formulation of evidence-based allocation criteria.

This chapter discusses the role of explicit benefits packages in achieving efficiency and equity in health care provision. It reviews the arguments for and against explicit benefits packages, provides examples from different health care contexts, and discusses the challenges in setting a benefits package. Although the chapter discusses a broad range of issues, one specific focus is on the use of evidence in determining the benefits package, in particular the use of HTA, incorporating economic evaluation.

The case for and against explicit benefits packages

The advantages of setting an explicit benefits package have been documented by Glassman et al. (2016) (Box 2.2.1). The advantages, along with the potential limitations, have been further discussed by Smith and Chalkidou (2017), using the English National Health Service as an example. They argue that an explicit package would: (i) encourage equitable access to health services, by reinforcing the principle of horizontal equity (i.e. equal access for equal need); (ii) ensure maximum benefit from the funds available, if appropriate cost-effectiveness criteria were used for coverage; (iii) improve transparency and clarity for the public, thereby empowering individuals in dealing with providers; (iv) provide clear signals to the market, by identifying which services will and will not be reimbursed; (v) protect politicians and clinicians from special pleading, reducing the risk of undue influence and corruption; and (vi) promote clarity for those involved in planning, funding and operating the health care system, by helping to identify where the highest priorities exist.

Furthermore, Smith and Chalkidou (2017) identify some of the potential challenges in setting an explicit benefits package: (i) the practical difficulties in specifying a package; (ii) the possible inhibition of innovation, if the package is not regularly updated; (iii) restrictions on legitimate variations in services, if local needs vary from place to place or among individuals; (iv) the creation of serious political and

Box 2.2.1 Benefits of setting an explicit benefits package

1. It creates explicit entitlements for patients, whose access to services might otherwise be largely determined by clinical professionals, with the consequent potential for arbitrary variations in access.
2. It helps to identify whether funds are being spent wisely on services that create the maximum benefit for the society.
3. By specifying the services to be delivered, it facilitates important resource allocation decisions, such as regional funding allocations, and other planning functions, creating a precondition for reducing variations in care and outcomes.
4. It facilitates orderly adherence to budget limits, which might otherwise be attained only through arbitrary restrictions on access and services.
5. It reduces the risk that providers will require informal payments from patients to secure access to high-value services.
6. The entitlements created empower poor and marginalized groups, who cannot be made aware of any specific entitlement without an explicit health benefits package.
7. It create the preconditions for a market in complementary health insurance for services not covered, with a number of potential benefits for the health system as a whole.

Source: Glassman et al. (2016).

legal difficulties, if the package is perceived as giving priorities for some groups over others, or inappropriately rationing care; (v) the difficulties caused by existing rigidities in the health care system, making changes in care difficult or costly; and (vi) the creation of uncertain financial liabilities, by making it difficult to limit access to services even if there is no budget.

In addition, politicians may be reluctant to engage in discussions on allocation decisions being inevitably linked to setting explicit benefits packages. The openness of societies to discuss allocation decisions in health care is certainly also determined by the culture and history of a given country (Torbica, Tarricone & Drummond, 2018). While, for instance, in the United Kingdom allocation decisions based on cost-effectiveness thresholds are commonly acceptable, historically, decision-makers in Germany have tended to avoid public allocation discussions as they may be too politically contentious. Moreover, since HICs use reimbursement schemes as benefit catalogues, they have to consider the

incentives for providers and patients. Fee-for-service (FFS) schemes explicitly listing single items to be reimbursed may lead to an overprovision of services.

The fact that relatively few HICs have a detailed explicit benefits package, listing items to be reimbursed, suggests that these limitations are perceived to be more important than the potential advantages, at least by the decision-makers who would be responsible for setting an explicit package. Many of the practical difficulties, such as the information required to set and update a package, could be overcome, albeit with some effort. This will be discussed later. However, it may be more difficult to overcome decision-makers' views about the political problems arising from setting a detailed explicit package, if it is perceived to make rationing more explicit or to reduce budgetary control. Nevertheless, it is important to recognize that *failure to specify* an explicit benefits package can cause similar political problems. The most obvious manifestation of this is the problem observed in many Latin American countries, where health is considered a basic right under the constitution. This has led to a situation where individuals often take legal action (known as "right-to-health litigation") to secure access to expensive health technologies that are not routinely available in the country's health care system (Reveiz et al., 2013). This can pose a threat to the health care budget, and/or distort health care priorities.

Evidence in practice: examples of setting explicit HBPs

Despite the practical challenges of setting an explicit HBP, several examples of doing this exist. Five case studies are discussed in this section, reflecting different health care settings and challenges for the process of developing and implementing a benefits package. The first case study on Italy exemplifies the approach of a HIC, with a decentralized national health service, to update its existing benefit catalogues. The second case of German inpatient care illustrates the trend in several HICs to move from rather implicitly defined to more explicitly defined benefit catalogues, including the challenges involved with this. The third case discusses a value-based approach for determining access to medicines, in a private health insurance setting of the USA. The fourth case study describes how Chile, an upper-middle-income country (UMIC), used an HBP to improve the quality of, and access to, health care for all of its citizens.

The final case study considers the establishment of HBPs in a LIC, and shows how an analytic framework based on economic evaluation can be used to support the development of an explicit benefits package. It might be argued that this poses additional challenges, since the relevant data and skills, although not absent, may not be as available as in HICs. In addition, the criteria considered in setting the package may place a greater weight on improving the equality of access to services, particularly for vulnerable groups and family welfare more generally. For example, in their work considering the inclusion of health interventions in the benefits package in Thailand (a UMIC), Youngkong et al. (2012) applied the criteria of “economic impact on household expenditure” and “equity, ethical and social implication”, alongside criteria such as effectiveness, disease severity and size of the population affected.

Example 1: Evolving a benefits package over time in the Italian National Health Service

The Italian National Health Service (INHS), known as *Servizio Sanitario Nazionale*, is characterized by universal coverage, providing comprehensive health care services to all citizens and residents across national territory. The issue of an HBP in Italy is deeply embedded in the history of the INHS and its reforms over the past four and a half decades. One of the main features of these reforms has been a progressive decentralization of the health care system, with regional governments gaining greater decision autonomy in planning, organizing and delivering health care services to their residents. While decentralization aimed to allow regions to tailor health care services to meet the unique requirements of their populations, it inevitably led to shaping a complex relationship between the central state and the various regions over a series of issues. The definition of what should be included in the HBP has been much debated within Italy’s health care system. The benefits package, intended as the overall set of services guaranteed to citizens under public coverage across the whole country, has changed over the years in its form, contents and objectives to become increasingly explicit.

From 1978 to 2017

The principle of a benefits package available to all citizens irrespective of age, social condition or income was introduced when the INHS was

established in 1978. Although the law introducing it listed the areas in which treatments were to be delivered directly by the INHS and used the expression “levels of care”, it was only in its health sector reforms of 1992/1993 that the national government explicitly defined the set of services to be provided under INHS coverage (“uniform levels of care”, *livelli uniformi di assistenza*, LUA). Since then, regions have been held accountable for providing the services included in the benefits package with the budgets allocated from the central government. In cases of overspending, the regions are financially responsible to cover the extra expenditure in order to guarantee the provision of the benefits package. They can also expand the services beyond what is set at the national level provided that they use their own resources. But there were demands for the benefits package to be made more explicit still. In the late 1990s, the National Health Plan produced guidelines as to what else was needed: a definition of principles (decision criteria), the amount of per capita funding required to provide guaranteed services, and a set of tools to monitor the implementation across regions. Subsequent reform, in 1999, specified guiding principles to determine the health care services to be included the benefits package – human dignity, effectiveness, appropriateness and efficiency. Underlining the importance of the equity principle in the access of care, the reform introduced a new expression – “essential level of care” (*livelli essenziali di assistenza*, LEA). Much debated during the years since, LEAs are considered key policy tools to regulate the relations (mainly financial) between the state and the regions and to ensure territorial equity within national borders. The services included at different levels of care, from community to hospital services, were defined at that time in a national law of 2001, and remained a pivotal element of the Italian HBP until its most recent redefinition in 2017.

Italy's health benefits package today

The services included in the benefits package are now defined at three major levels: (i) collective prevention and public health; (ii) community health care services; and (iii) hospital/inpatient care. A Permanent Committee within the Ministry of Health has responsibility for verifying and monitoring the provision by the regions of all services in the benefits package in line with the principles of appropriateness and efficiency in the use of resources, as well as ensuring congruity between the services to be provided and the resources made available by the

central government. In 2020, a National Commission responsible for updating the LEA was established with a three-year remit to ensure systematic and regular updating of the benefits package.¹

HTA, and more specifically economic evaluation, is also playing a role in shaping the benefits package in Italy, though so far it is largely limited to the evaluation of health care technologies for reimbursement decisions, namely pharmaceuticals and medical devices.

For pharmaceuticals, the Italian Medicines Agency (*Agenzia Italiana del Farmaco*, AIFA) undertakes the assessments. The decision-making power is concentrated in the Price and Reimbursement Commission (*Comitato prezzi e rimborso*, CPR), a technical body with 12 expert members that oversees the appraisal process. The criteria for appraisal include the degree of innovation, availability of existing products and extent of therapeutic benefit using clinical effectiveness, cost-effectiveness, risk-benefit ratio and budget impact studies, which constitute a support tool in the decision-making process. This type of assessment is used to support pricing and eligibility for reimbursement decisions and de facto determines which pharmaceuticals are included in the Italian benefits package and which are not.

The evaluation of medical devices is undertaken as part of the National Health Assessment Technology Programme for Medical Devices. The Programme was introduced by the Italian Stability Law of 2015, after a highly participatory, stakeholder-engaged, structured process of harmonization and centralization to address the hitherto fragmented system of appraisal and approval (Tarricone et al., 2021). The main objective is to ensure effective stewardship and guarantee equal access to innovative technologies in all parts of the nation, notwithstanding the decentralized nature of the INHS. The Programme includes the most updated methods in assessing medical devices, coherent with those developed by EUnetHTA (www.eunetha.eu) and other international scientific

¹ Health care stakeholders (the Ministry of Health, health institutes, hospitals, patient associations, etc.) can make requests for updating the benefits package. The Commission prioritizes the requests using the following criteria. The service: (i) could have a high impact on the health of the population and/or will satisfy an unmet health need; (ii) is in line with the health priorities defined at national and/or regional level; (iii) is supported by robust evidence of effectiveness. In the case of a positive decision, the inclusion of the specific service/technology in the benefits package depends on its impact on public health expenditure. If an increase in the health care budget is required, the final decision must be approved by the Prime Minister as well as the Ministry of Health.

consortia, such as, MedtecHTA (www.medtechta.eu), and links the recommendations of HTA with the most relevant policies in the health domain: coverage, reimbursement and procurement of medical devices. This initiative has the potential to break the traditionally “siloed” mentality and to foster a value-based approach in prioritizing, assessing, introducing and diffusing new technologies in the INHS.

Example 2: Germany: from an implicitly defined to an explicitly defined benefits package

A core principle of the German health care system is the sharing of decision-making powers between the governments of the federal states, the federal government and designated self-governmental institutions. Responsibilities are traditionally delegated to self-governing institutions of payers and providers that are involved in financing and delivering health care. Payers (sickness funds) and providers (physicians, dentists and hospitals) are represented by their associations, which are recognized as corporate bodies. These bodies constitute the structures of self-government that operate the financing and delivery of benefits covered by the Statutory Health Insurance scheme within the legal framework of the Social Code Book V. The most important body for the benefit negotiations between sickness funds and providers, concerning the scope of benefits, is the Federal Joint Committee (G-BA). Based on the legislative framework, the Committee issues directives relating to all sectors of care. The main body of the Committee consists of five representatives of the sickness funds, five representatives from provider groups, two neutral members and a neutral chairperson. The directives of the Committee are legally binding for all actors in the Statutory Health Insurance scheme. These directives primarily concern the coverage of benefits and ensure that Statutory Health Insurance services are adequate, appropriate and efficient. Beyond these general goals, the actual criteria for benefit definitions vary largely between sectors and types of catalogues (Blümel et al., 2020; Busse, Stargardt & Schreyögg, 2005).

In the outpatient sector, a service provided must be proven to fulfil the criteria “expedience, necessity and cost-effectiveness” to be included in the catalogue of services and benefits. In contrast, health care services in the inpatient sector will only be excluded from the

benefit catalogue of the sickness funds if the criteria are proven to be unfulfilled (Busse, Stargardt & Schreyögg, 2005). For this reason, several health care services provided in the inpatient sector are not included in the benefit catalogue of the outpatient sector. In other words, any authorized new procedure or service in inpatient care can be provided by hospitals on behalf of the Statutory Health Insurance scheme. The ability of hospitals to provide a certain service is primarily regulated by prices via the diagnosis-related group (DRG) catalogue and its appendices for cost-intensive drugs and procedures (see Chapter 3.2). The rationale behind this practice of setting the benefits package is that new (experimental) services should first be incorporated and tested in inpatient care before they are allowed to diffuse into outpatient care. For pharmaceuticals, like the benefit regulation in inpatient care, the benefits package includes all authorized products launched on the German market. There is no positive list for pharmaceuticals. The availability of a given pharmaceutical on the German market, and therefore being part of the benefits package, is mainly determined by price regulation.

The decisions on benefits taken by the G-BA finally shape the benefit catalogues of the different health care sectors, which were originally introduced for reimbursement purposes. Thus, the level of explicitness varies between sectors. FFS-based catalogues in outpatient care, such as the *Einheitlicher Bewertungsmaßstab* for physician services or the *Einheitlicher Bewertungsmaßstab für zahnärztliche Leistungen* for dental care services, list most reimbursable services and procedures in detail. In contrast, the DRG catalogue for inpatient care started in 2003 with 664 DRGs, which were meant to reimburse all services unless excluded by the G-BA. Therefore, in 2003 the approach of defining the benefit catalogue in inpatient care could be characterized as quite implicit. However, Gibis, Koch and Bultman (2004) anticipated that the DRG catalogue would be extended over time to a more detailed benefit catalogue, where most approved interventions are listed and grouped around the relevant diagnoses.

Indeed, in the last 10 to 20 years, the German health care system has moved towards a more explicitly defined benefits basket. Since the inception of the G-BA in 2004, the number of issued directives on reimbursement of benefits has increased substantially compared with its predecessor committees. This has led to more inclusions and exclusions of benefits in inpatient and outpatient care, and has certainly

contributed to a more explicit definition of benefits and in reimbursement catalogues. However, the most noteworthy change towards a more explicit definition of benefits took place in inpatient care.

In 2003, the DRG catalogue was introduced for inpatient care with the ambitious aim of reimbursing all inpatient services across all care structures, including academic medical centres with highly complex services. With 664 DRGs, the diagnoses-led catalogue acted as a rather implicitly defined benefit catalogue. It soon became clear that a given DRG did not sufficiently cover certain cost-extensive services and led to the threat of implicit rationing of certain services. This exerted a lot of pressure on the self-governing institutions to split DRGs and add reimbursement components. Thus, the DRG catalogue has been slowly transformed into a procedures-based catalogue with 1275 DRGs (50% of those is triggered by at least one procedure) and 275 fixed supplementary payments for explicitly mentioned high-cost drugs and procedures. On top of this, several other reimbursement components, such as separate payments for new technologies and negotiated supplementary payments for more established new technologies, were introduced (Ex & Henschke, 2019).

The case of the German DRG-catalogues reveals how what started out as an implicitly defined diagnoses-led catalogue can be transformed to an explicitly defined benefit catalogue without changing the rules for inclusion or exclusion of benefits. However, this development had certain side-effects. The more procedure-based catalogue led to incentives to increase treatment volume and treatment intensity (Bäuml & Kümpel, 2021; Schreyögg et al., 2014). It also created incentives to favour operative procedures over conservative procedures, since operative procedures receive a higher reimbursement price (see Chapter 3.2 for more on methods for paying hospitals).

Example 3: HBPs under private health insurance – the Premiera Blue Cross value-based formulary in the USA

The private health insurance sector of the USA's health care system comprises more than 900 health plans. These plans offer individuals and their employers health care coverage for an annual premium, and also stipulate co-payments for some services. An important component of the HBP is the drug formulary, which determines the access to medicines for plan enrollees. Typically, health plan formularies contain

most available drugs, organized in tiers, with the level of patient co-payment varying by tier, with inexpensive generic drugs being placed on a tier associated with a low co-payment. Branded drugs and expensive specialty drugs would be placed on tiers associated with higher levels of co-payment. In most health plans, formulary placement decisions are made by a Drug and Therapeutics Committee. Clinical evidence of drug effectiveness and safety is considered, but the use of economic evidence is sparse.

Premiera Blue Cross is a large not-for-profit health plan in the Pacific Northwest which has used economic evaluation as part of its decision-making in the adoption of new health technologies. In 2010 it decided to implement a value-based drug formulary, in which drugs would be placed on tiers based on their value for money, rather than based on their acquisition cost. It was considered that aligning the individual drug's co-payment to its specific value might yield greater clinical and economic benefits. However, in making this change, the health plan was also conscious of any impact it might have on enrollees' costs or utilization of medicines, since health plans in the USA operate in a competitive environment. This is different from setting a benefits package in a publicly funded or social security system, where individuals cannot change their basic health insurance because of changes in the benefits package, although they do have the option of paying for supplementary private insurance.

The design, implementation and first-year outcomes of the value-based formulary were analysed and discussed in academic literature (Sullivan et al., 2015). Value was assessed primarily by cost-effectiveness analysis, with the value for money of each drug assessed by the level of the incremental cost-effectiveness ratio (ICER) compared with the most relevant alternative (e.g. basic supportive care or an alternative drug). The value-based formulary was designed as a four-tier system, plus a "preventive" tier, for which the co-payment was set at zero. Higher rates of co-payment were set for the other four tiers based on commonly used cost-effectiveness thresholds identified from a literature review (Sullivan et al., 2015). To allow for the fact that the ICER does not consider all the factors that might be relevant for formulary listing decisions, a "special case" category was created to allow for other aspects of social value, such as treatment for serious rare conditions for which there was no other acceptable treatment. The main difference between the value-based formulary and a standard

Table 2.2.1 *Value-based formulary tiers, incremental cost–effectiveness ratio thresholds and co-payment levels*

Tier	Typical case ICER threshold	Special case ICER threshold	Co-payment (US\$) ^a
Preventive	Not applicable	Not applicable	0
Tier 1	Cost saving or <US \$ 10 000/QALY	Cost saving or <US \$ 50 000/QALY	20
Tier 2	US\$ 10 000–<US \$ 50 000/QALY	US\$ 50 000–US \$ 150 000/QALY	40
Tier 3	US\$ 50 000–US \$ 150 000/QALY	>US\$ 150 000/QALY	65
Tier 4	>US\$ 150 000/QALY or insufficient evidence to determine ICER	Insufficient evidence to determine ICER	100

ICER: incremental cost–effectiveness ratio; QALY: quality-adjusted life-year.

^a Amount of the retail co-payment for 30-day supply of medicine.

Source: Adapted from Sullivan et al. (2015).

formulary was that drugs with higher acquisition cost were not automatically assigned to a higher tier. They might be assigned to a lower tier if the benefits outweighed the costs. The tiers, ICER thresholds and co-payment levels are shown in Table 2.2.1.

In constructing the formulary, the clinical safety and effectiveness assessment followed Premera's normal practice. The value assessments were made by reviewing available ICER estimates from a variety of sources including: (i) economic models provided by manufacturers in their formulary submission; (ii) published economic studies; (iii) the Tufts Cost–Effectiveness Analysis registry (Tufts Medical Center, 2021); (iv) Cochrane Collaboration reviews; and (v) reviews by health technology agencies. In cases where no suitable evidence existed, Premera conducted its own economic analyses. Within the first year, value assessments were produced for drugs in each of the 25 highest volume drug classes used by Premera members in the previous year, accounting for approximately 75% of total drug utilization within the plan.

Since Premera was the first health plan to develop a value-based formulary, the level of acceptability to enrollees was unknown. Therefore, the new value-based formulary was initially only offered to Premera's employees and dependents enrolled in the standard preferred provider organization (Premera Associates Plan). Sullivan and colleagues (2015) report the results of the first-year evaluation. The distribution of drugs across the tiers were markedly changed, with 39.9% being on the new "preventive" tier, 14% on Tier 1, 36% on Tier 2, 7.4% on Tier 3 and 2.7% on Tier 4. Pharmacy costs decreased by 3% compared with the previous 12 months and 11% compared with expected costs. There was no significant decline in medication use or adherence to treatments for patients with diabetes, hypertension or dyslipidaemia. Sullivan and colleagues (2015) argue that these results suggest that it is possible to implement a value-based formulary in a USA employer-based health plan and achieve efficiency and value gains.

A longer-term evaluation of the value-based formulary, using an interrupted time series of employer-sponsored plans from 2006 to 2013, was reported in another paper by Yeung and colleagues (2017). They compared 5235 beneficiaries exposed to the value-based formulary with 11 171 beneficiaries in plans without any changes in pharmacy benefits. The primary outcome compared was medication expenditures from member, health plan and overall (member plus plan) perspectives. Secondary outcomes were medication utilization, emergency department visits, hospitalizations, office visits and nonmedication expenditures. It was found that member medication expenditures increased by US\$ 2 per member per month (95% CI US\$ 1–US\$ 3), whereas plan medication expenditures decreased by US\$ 0 (95% CI US\$ 18–US\$ 2), resulting in a net decrease of US\$ 8 (95% CI US\$ 15–US\$ 2). This translated into net savings of US\$ 1.1 million. Utilization of medicines moved into lower tiers increased by 17%, but total medication utilization, health services utilization and nonmedication expenditures did not change.

Example 4: Using the development of a health benefits package to improve the access and quality of services in a middle-income country – the Acceso Universal con Garantías Explicitas (AUGE) in Chile

Like several countries in Latin America, Chile relies on SHI to provide health care to a substantial proportion of its population. However, its

insurance scheme has been criticized over the years for having two separate components. The first is a large public insurer (Fonasa), using mostly public providers, covering about 75% of the population including those on low and middle incomes and indigent citizens. The other component consisted of several private insurers (Isapres), using mostly private providers, covering a further 16% of higher income citizens.

This fragmentation led to differences in the content and quality of services, and the level of access to them. Prior to 2005, Fonasa did not have an explicit benefits package and there was rationing of care through queues, denial of services and provision of low-quality services. Also, different Isapres could offer different health plans, with a different range of services of different levels of quality. The lack of a benefits package was seen as a major weakness of the scheme overall, which allowed for divergences in coverage between Fonasa and Isapres and for risk selection and limited risk pooling in the Isapres (Bitran, 2013).

Therefore, in 2005, Chile's government introduced the Universal Access with Explicit Guarantees (*Acceso Universal con Garantías Explícitas* – AUGE), which defined a basic HBP consisting of guaranteed and explicit treatments for 56 priority health problems. This was expanded to 69 priority problems in 2010 (see Table 2.2.2).

The AUGE not only guaranteed access to treatments for these priority programmes, but it also guaranteed quality of care by explicit definition of the interventions to be provided and the treatment protocols to be used, the adoption of maximum waiting times for treatment and limits on out-of-pocket (OOP) spending for health care. The Ministry of Health and Ministry of Finance determine the content of the benefits package, taking into account the burden of disease, the share of the population suffering from the disease, the expected cost per beneficiary, the supply capacity of the health network and the effectiveness of the interventions. Since the AUGE reform, there has been a sizeable increase in total health spending from both public and private resources, but by 2013 it had stabilized at around 7.5% of gross domestic product (GDP) (Bitran, 2013). The financial management of the AUGE has mainly been at an aggregate level, by monitoring the average cost per beneficiary, rather than by cost-effectiveness assessments of the services provided.

As reported by Bitran (2013), there have been several evaluations of the AUGE. Bitran, Escobar and Gassibe (2010) assessed the impact of AUGE on access to care, treatment outcomes, hospitalization rates and medical (sick) leave rates for six chronic conditions, including

Table 2.2.2 Current 69 priority health problems in the AUGE benefits package

Priority health problems in tde AUGE benefits package	
1. End-stage chronic renal failure	36. Acute stroke
2. Operable congenital heart disease (under 15 years of age)	37. Chronic obstructive pulmonary disease
3. Cancer of the uterus or cervix	38. Bronchial asthma
4. Cancer pain relief and palliative care	39. Newborn respiratory distress syndrome
5. Acute myocardial infarction	40. Orthesis and aids (65 years of age or more)
6. Diabetes mellitus type I	41. Deafness (65 years of age or more)
7. Diabetes mellitus type II	42. Ametropia (65 years of age or more)
8. Breast cancer (15 years of age or more)	43. Eye trauma
9. Spinal dysraphia	44. Cystic fibrosis
10. Scoliosis surgery (under 25 years of age)	45. Severe burns
11. Cataract surgery	46. Alcohol and drug dependency (10 to 19 years of age)
12. Total hip replacement in people with severe osteoarthritis of the hip (65 years of age or more)	47. Pregnancy and delivery integral care
13. Cleft palate	48. Rheumatoid arthritis
14. Cancer (under 15 years of age)	49. Knee arthrosis (55 years of age or more) and hip arthrosis (60 years of age or more)
15. Schizophrenia	50. Intracranial aneurysm and venous malformation rupture
16. Testicular cancer (15 years of age or more)	51. Central nervous system tumours
17. Lymphoma (15 years of age or more)	52. Herniated nucleus pulposus
18. HIV/AIDS	53. Dental emergencies
19. Ambulatory care lower acute respiratory illness (under 5 years of age)	54. Dental care (65 years of age or more)
	55. Politrauma
	56. Traumatic brain injury

Table 2.2.2 (*cont.*)

20. Ambulatory pneumonia (65 years of age or more)	57. Retinopathy of prematurity
21. Primary or essential arterial hypertension	58. Bronchopulmonary dysplasia of prematurity
22. Epilepsy (non-refractory) (1 to 15 years of age)	59. Bilateral sensorineural hearing loss of prematurity
23. Prevention and education for oral health (6 years old)	60. Epilepsy in patients over 15 years of age
24. Prematurity – retinopathy of prematurity –deafness of prematurity	61. Bronchial asthma in patients over 15 years of age
25. Conduction disturbance for those with pacemakers (15 years of age or more)	62. Parkinson disease
26. Bladder cancer preventive cholecystectomy	63. Juvenile idiopathic arthritis
27. Gastric cancer	64. Secondary prevention of chronic renal failure
28. Prostate cancer	65. Hip dysplasia
29. Adult leukaemia	66. Integral oral health in pregnant women
30. Strabismus (under 9 years of age)	67. Multiple sclerosis
31. Diabetic retinopathy	68. Hepatitis B
32. Retinal detachment	69. Hepatitis C
33. Haemophilia	
34. Depression (15 years of age or more)	
35. Benign prostatic hyperplasia	

Source: Bitran (2013).

hypertension, diabetes and depression. For most of these conditions the reform increased access to services, increased coverage and in some cases reduced hospital fatality rates. A study by Valdivieso and Montero (2010) found that AUGE's access guarantee has been a powerful instrument to improve equity in health care.

However, the consequences of AUGE for health system efficiency had not been measured by 2013, and there have been few assessments of the cost-effectiveness of individual health care interventions in Chile. Nonetheless, Bitran (2013) suggested that allocative efficiency may have been improved by the selection of cost-effective treatments in AUGE's benefits package, and that productive efficiency may have also improved through the adoption of explicit treatment protocols. However, an increased use of HTA including economic evaluation, particularly in the adoption of new treatments within AUGE, may generate further benefits. The opportunities and challenges of using economic evaluation in a LMIC are discussed in the next case study.

Example 5: Economic analysis in supporting the development of a health benefits package in Malawi

The constraints on the availability of public resources for health care in LMICs limits access to necessary services and shifts costs to patients and their households, inevitably resulting in financial hardship. Consequently, the development of HBPs is becoming increasingly frequent in these countries in relation to SDG 3.8 – UHC. Benefits packages have the potential to guide investment and strengthen weak health systems, while being mindful of budget constraints. However, the process of benefits package design in these contexts is often opaque and not informed by explicit analysis. In particular, one of the greatest limitations in the low-resource setting is that the health opportunity cost of decisions is rarely accounted for.

Ochalek and colleagues (2018) reported on the development of an analytic framework to guide resource allocation within the Malawi Health Sector Strategic Plan (HSSP) 2017–2022. The framework needed to inform the following key questions posed by the Ministry of Health.

- What is the appropriate scale of the HBP?
- Which interventions represent “best buys” for the health care system and should be prioritized?

- Where should investments in scaling up interventions and health system strengthening be made?
- Should the package be expanded to include additional interventions?
- What are the costs of the conditionalities of donor funding?
- How can objectives beyond improving population health be considered?

Since including an intervention in the HBP commits resources that could otherwise be used to fund alternative interventions that also improve health, it is important that the opportunity costs in foregone health care are considered. Therefore, an empirical estimate of the costs and effects of a range of health interventions was made using data from the Tufts Global Health Cost–Effectiveness Registry (Tufts Medical Center, 2021) and WHO-CHOICE analyses (Bertram et al., 2021). Budgetary analysis to determine the total cost of the package used drug and supply costs from a 2014 midterm review of the previous strategic plan. The size of the eligible patient populations for each intervention and an assessment of the extent to which interventions were implemented in Malawi in 2014 were obtained from data available locally.

The estimates of the cost per disability-adjusted life-year (DALY) averted for interventions for which all required data were available are shown in Fig. 2.2.2, ordered from lowest to highest. The height of each bar represents the intervention’s effectiveness–cost ratio, and the width of each bar represents the intervention’s total cost. Previous research has indicated that US\$ 61 spent on health care at the margin would be expected to avert one DALY (or 61 DALYs per US\$ 1000). Bearing in mind a possible budgetary limit of US\$ 265 million, this would imply that interventions 1–48 would be included in the benefits package (see vertical line A). Vertical lines B and C show the implication of higher budgets, representing higher willingness-to-pay thresholds per DALY-averted.

Ochalek et al. (2018) highlighted that while Fig. 2.2.2 provides a useful way to visualize the budgetary implications of using a higher or lower “threshold” value, cost per DALY-averted ratios are not useful for prioritizing interventions because they do not indicate the scale of the potential health impact. Therefore, Ochalek et al. (2018) also present data in their paper ranking interventions according to the net DALYs averted that they would achieve, assuming that they were fully implemented, or implemented to the extent they were in 2014.

These analyses were intended to provide an analytic framework for supporting the development of the benefits package, rather than

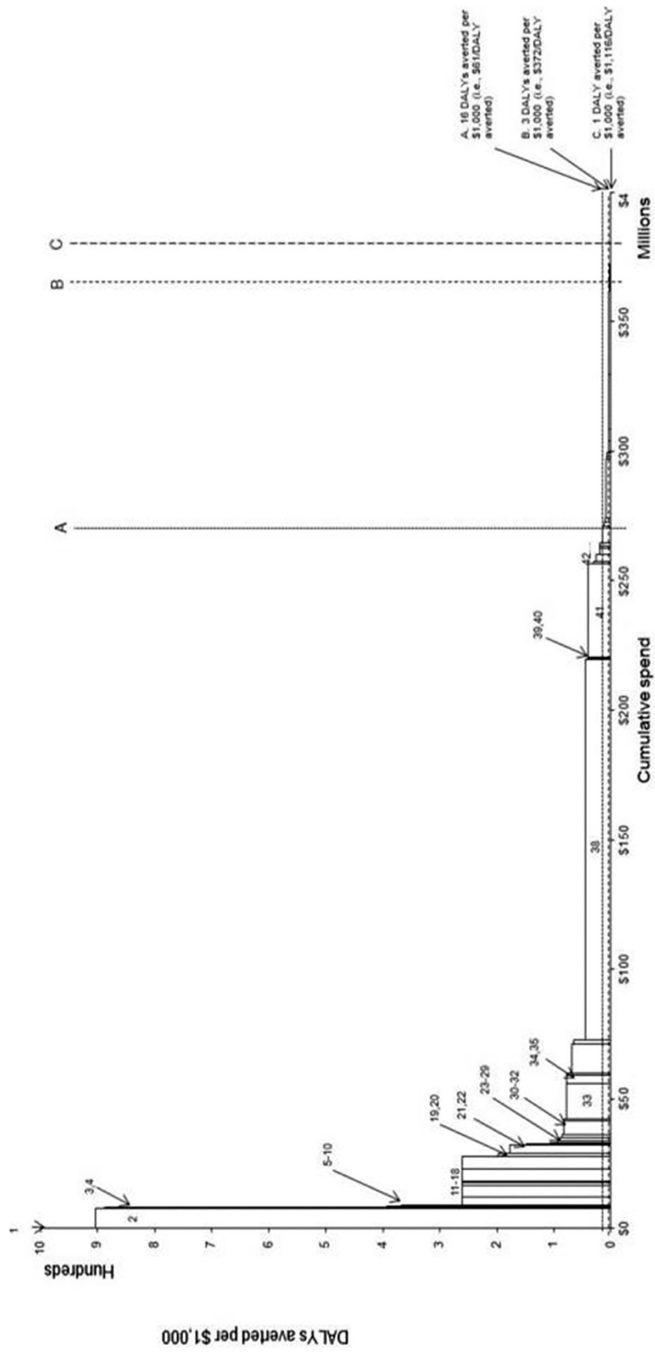


Fig. 2.2.2.2 A framework can be used to help identify “best buys” and priorities for the health system given different budget thresholds

Caption for Fig. 2.2.2 (cont.)

Key:

- 1 Co-trimoxazole for children
- 2 Mass media
- 3 Isoniazid preventive therapy for children in contact with patients with TB
- 4 Isoniazid preventive therapy for HIV-positive patients with no TB
- 5 First-line treatment for new TB cases for adults
- 6 First-line treatment for retreatment TB cases for adults
- 7 First-line treatment for new TB cases for children
- 8 First-line treatment for retreatment TB cases for children
- 9 Clean practices and immediate essential newborn care (home)
- 10 Case management of MDR-TB cases
- 11 Malaria treatment: uncomplicated (adult, <38 kg)
- 12 Malaria treatment: uncomplicated (adult, >36 kg)
- 13 Malaria treatment: uncomplicated – 2nd line (adult, >36 kg)
- 14 Malaria treatment: uncomplicated – 2nd line (adult, <36 kg)

- 15 Malaria treatment: uncomplicated (children, <15 kg)
- 16 Malaria treatment: uncomplicated (children, >15 kg)
- 17 Malaria treatment: uncomplicated – 2nd line (children, <15 kg)
- 18 Malaria treatment: uncomplicated – 2nd line (children, >15 kg)
- 19 Malaria treatment: first trimester – uncomplicated
- 20 Malaria treatment: second trimester – uncomplicated
- 21 Malaria treatment: pregnant women – complicated
- 22 Rotavirus vaccine
- 23 Management of pre-eclampsia (magnesium sulfate)
- 24 Tetanus toxoid (pregnant women)
- 25 Vitamin A supplementation in pregnant women
- 26 Measles vaccine
- 27 PMTCT
- 28 Labour and delivery management
- 29 Caesarean section (with complication)
- 30 Management of obstructed labour
- 31 Vaginal delivery, skilled attendance
- 32 Vaginal delivery, with complication
- 33 Households owning at least one ITN/LLIN
- 34 Pregnant women sleeping under an ITN
- 35 Children aged <5 years who slept under ITN/LLIN
- 36 Antenatal care (4 visits)

37	Blood safety	52	IPT (pregnant women)
38	Male circumcision	53	Condoms
39	Newborn sepsis – full supportive care	54	ORS
40	Antenatal corticosteroids for preterm labour	55	Hypertension
41	Voluntary counselling and testing	58	Treatment of depression
42	Schistosomiasis mass drug administration	57	Diabetes, type I
43	Caesarean section	58	Diabetes, type II
44	Maternal sepsis case management	59	ART for men
45	Antibiotics for pPRoM	60	ART for women
46	Management of severe malnutrition (children)	61	Ischaemic heart disease
47	Interventions focused on female sex workers	62	Treatment of bipolar disorder
48	Interventions focused on men who have sex with men	63	GIT, intestine cancer
49	High cholesterol	64	Paediatric ART
50	Basic psychosocial support, advice and follow-up, plus antiepileptic medication	65	Cervical cancer (first-line)
51	Zinc (diarrhoea treatment)	66	Treatment of acute psychotic disorders
		67	Treatment of schizophrenia

ART: antiviral therapy; DALY: disability-adjusted life-year; GIT: gastrointestinal; ITN: insecticide-treated bednet; IPT: intermittent preventive therapy; LLIN: long-lasting insecticidal net; MDR: multidrug-resistant; ORS: oral rehydration salts; PMTCT: prevention of mother to child transmission; pPRoM: preterm premature rupture of membranes; TB: tuberculosis.

Source: Ochalek et al. (2018).

prescribing decisions. Decision-makers in Malawi added other decision-making criteria (in addition to health maximization) such as equity (whether an intervention was for at risk or marginalized groups), continuum of care (where interventions are linked), complementarities (where interventions are a linked part of a given package of services), and exceptional donor-funded interventions that were expected to remain stable in the medium term.

Other issues emerged in the deliberative process. For example, some interventions that were good value for money were likely to be difficult to implement because of reluctance on the part of the population (e.g. male circumcision), or because some donors were rigid about the types of intervention they would and would not fund. There were other rigidities in the funding arrangements that made investment and disinvestment in various services difficult. Also, data limitations meant that complete evidence of cost-effectiveness and budgetary impact was not available for some services. However, the analyses performed showed that there were potentially substantial gains from investing in policies to reduce these constraints to implementation. The analytic framework developed provided a basis for conducting these debates and considering ways to improve the allocation of resources.

Policy relevance and conclusions

Key issues in setting a benefits package

The case studies presented above show that countries take very different approaches to drawing up a benefits package. Although it is acknowledged that benefits packages have the potential to strengthen health care systems and respond to population health need while controlling expenditure, the approach followed for each health care system strongly depends on cultural values, market configuration, political system, level of wealth and other determinants. Therefore, whatever system is used, it is important to gain agreement from key stakeholders (e.g. politicians and health professional groups) on the need for an explicit benefits package and on what the benefits package should seek to achieve (i.e. ensure equity, control costs).

Given the various contexts, it is ambitious to draft a generic framework for setting a benefits package. Fig. 2.2.3 visualizes the core steps involved in doing so, inspired by the approach taken by Glassman et al.

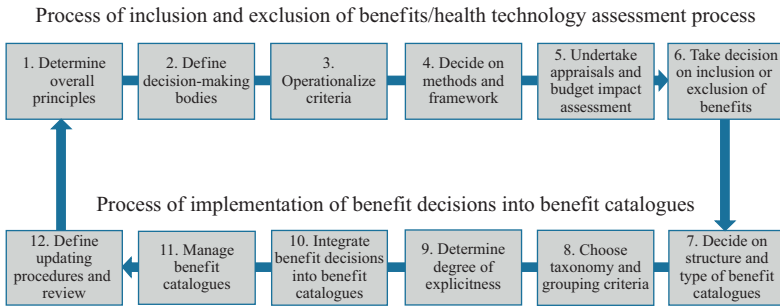


Fig. 2.2.3 A generic framework for setting a benefits package will require context-specific interpretation

Source: Adapted and modified from Glassman et al. (2016) and Busse, Schreyögg & Gericke (2007).

(2016). We have extended their framework by the process of implementing benefit decisions into benefit catalogues. Thus, our framework essentially contains two processes that are linked to each other. In the first process, inclusion and exclusion of benefits are defined, while in the second process benefit decisions that result from the first process are implemented into benefit catalogues.

The different steps of the two processes require more in-depth explanation.

1. *Determine the overall principles*: in the first step the guiding principles for setting a benefits package should be clearly stated by policy-makers and closely aligned with the general goals of the health care system. Typically, these principles are set by the parliament of a given country, in the context of national health service systems or SHI systems. The parliament of a given country will be held accountable to the general public for setting the package and monitoring its implementation. This may differ according to jurisdictions, but the overall principles should be rooted in broad support from the population.
2. *Define decision-making bodies*: responsibilities must be defined for the subsequent steps. In particular, the final decision-maker who determines the inclusion or exclusion of benefits, the structure and type of benefit catalogues, and the degree of explicitness of benefit catalogues must be defined. Decision-making bodies could either be ministries and parliaments or self-governmental institutions and

committees. SHI countries have a long tradition of delegating responsibilities to self-governing institutions (e.g. in France, Germany and the Netherlands), while in national health service countries ministries and committees play an important role in this process (e.g. in Italy and United Kingdom). For example, in the case study on Italy, the Ministry designed the process and criteria for updating benefits which were then implemented by a commission.

3. *Operationalize criteria*: coherent with the overall principles, criteria for benefit decisions must be defined. Results of the EUHealthBasket project demonstrated that the criteria used for inclusion and exclusion of benefits varied considerably between European countries. While most countries used variations of effectiveness, cost and cost-effectiveness, Denmark used need as the central criterion and Spain used efficacy, efficiency and safety as the main criteria (Schreyögg et al., 2005). Criteria often also differ according to benefit catalogues of different sectors or different types of health technologies; for example, different criteria for pharmaceuticals than for medical devices.
4. *Decide on methods and frameworks*: most countries, especially HICs, use some kind of health technology framework including economic evaluation to determine the inclusion and exclusion of benefits. Although most countries in fact apply a framework with different criteria, as shown in the case studies above, not every country publishes the applied criteria in a transparent way, for example, the Netherlands (Stolk et al., 2009). Schreyögg et al. (2005) found that in European countries, criteria for the inclusion in or exclusion from benefit catalogues are often fairly opaque.
5. *Undertake appraisals and budget impact assessment*: the formulated frameworks and criteria must be applied by a designated institution. Often, this institution is not the decision-making body, but it has the role to systematically collect evidence on (new) technologies and services as input to appraisals. This institution, often a HTA agency, may also perform a budget impact assessment to inform the decision-making body. One of the lessons from the Malawi case study above, and from attempts to use economic evaluation in the development of an HBP in the Netherlands (Stolk et al., 2009), is that assessments of clinical and cost-effectiveness may not be readily available for all the services or treatments in the benefit catalogue. Therefore, either substantial resources may be required, or priorities need to be set for which services to assess.

Tackling this issue is likely to be the main practical challenge in setting a detailed explicit benefits package.

6. *Take decisions on inclusion or exclusion of benefits*: after evidence is available and synthesized for decision-makers, the defined decision-making body has to make the final decision on inclusion and exclusion of benefits. At this point, services or technologies may be included/excluded completely or partially (e.g. tied to specific conditions). For instance, in several European countries, positron emission tomography-computed tomography scans are not regularly reimbursed, but are reimbursed for specific conditions such as suspected bronchial carcinoma. Decisions in certain countries may also allow regional differentiation. For example, Spain and Italy allow regions to include additional services in their benefits packages, which are not included at national level (Torbica & Fattore, 2005; Planas-Miret, Tur-Prats & Puig-Junoy, 2005).

A benefit catalogue may also be complemented by a negative list, explicitly listing services that are excluded from reimbursement (see Chapter 2.3). For instance, Germany uses a negative list for pharmaceuticals, clarifying that, among others, expectorants and laxatives are not reimbursable. Beyond this it may be a general principle to decide that all services can be reimbursed unless explicitly excluded; for example, in the German inpatient setting (see case study above). Finally, it is worth noting that inclusion/exclusion decisions can and should take account of considerations beyond the synthesized evidence (e.g. equity, continuity of care), consistent with the general criteria specified earlier (3. Operationalize criteria).

7. *Decide on structure and type of benefit catalogues*: benefit catalogues can be of very different structures and types. They may take the structure of aggregate and implicit definitions of certain service areas through reimbursement schemes (as one type of benefit catalogue); for example, the DRG system for inpatient care, often used by HICs. In contrast, LMICs often maintain detailed lists of services not indicated for reimbursement but give a guarantee that at least the listed benefits will be reimbursed if needed. For instance, in Chile, benefits are listed in the Plan AUGE as a minimum guaranteed health benefit catalogue, whereby prioritized services are made available to the entire population (Glassman et al., 2016; Bitran, 2013).
8. *Choose taxonomy and grouping criteria*: The decision on taxonomy and grouping criteria is relevant for further steps in the process, as it has a direct impact on the degree of explicitness and the ability to

integrate new technologies at a later stage of updating. European countries use some kind of taxonomy structured along medical specialities such as DRG classifications for inpatient care, or some kind of procedure-based classification for outpatient care; for example, the Common Classification of Medical Procedures in France. Regarding grouping criteria within taxonomies, the situation is quite heterogeneous including criteria such as age, comorbidity, area of care product group and procedures (Schreyögg et al., 2005).

9. *Determine degree of explicitness*: the fact that HICs tend to rely on reimbursement catalogues as a substitute for benefit catalogues does not necessarily imply that benefits are defined implicitly only. The EU HealthBasket project revealed that the degree of explicitness varies substantially both between European countries and sectors of care (Schreyögg et al., 2005). While inpatient services tend to be defined rather implicitly, outpatient services are often defined with a high degree of explicitness through procedure-based reimbursement schemes. But even implicitly defined reimbursement schemes may undergo a certain evolution, as presented above in the case of inpatient care in Germany. When deciding on the degree of explicitness, decision-makers, especially in HICs, are faced with a trade-off between the advantages of an explicit definition of benefits; for example, through encouraging equitable access and the threats of explicitness; for example, through over-provision of services in FFS reimbursement schemes.
10. *Integrate benefit decisions into benefit catalogues*: benefit catalogues/reimbursement schemes often have a long tradition and the ways in which taxonomies and groupings are defined influence whether innovations may be more or less easily integrated into existing schemes. Therefore, countries frequently decide to add lists of explicit inclusions/exclusions of new technologies.
11. *Manage benefit catalogues*: once a benefit catalogue is established, the government or other decision-making units have to continuously maintain it and monitor provision or reimbursement of benefits. Among other issues, this includes communication with stakeholder groups on included and excluded services, resolving disputes, and informing price negotiations with manufacturers (Glassman et al., 2016).
12. *Define updating procedures and review mechanisms*: an often-neglected issue is the process of updating procedures. Even HICs struggle with defining terms and conditions or technologies to enter

benefit catalogues. Manufacturers and providers typically demand innovation-friendly processes with low entry barriers, while governments and payers have to keep the balance between rapid access to new technologies and costs. Another important point to consider is the frequency of updates. While some countries continuously update their catalogues, others define fixed periods; for example, every year. Finally, whether the development of benefit catalogues is aligned with the overall principles and available resources of a given health care system should be regularly reviewed. This relates back to the first step of determining the overall principles. Changing those principles may require changes in both processes.

Conclusions

HBP differ in their level of detail and explicitness. There are both advantages and disadvantages of setting an explicit package, and this is an important policy choice. For those considering setting an explicit HBP, we have outlined the key steps, illustrated by examples from high-, middle- and low-income countries with different types of health care systems. Our particular focus has been on the use of HTA and economic evaluation, as this is one of the main practical issues that must be resolved in setting an explicit HBP.²

Additional resources

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² Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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2.3 *Decommissioning/disinvestment: reducing the provision of low-value care*

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ELIAS MOSSIALOS

Key messages

Chapter 2.3 reports on low-value care and how to reduce waste. Decommissioning or disinvesting from low-value care means taking money away from health care services that give poor value for money. Key learning includes that:

- Ending investment in health technologies or treatments that are ineffective releases resources for more effective high-value care, increases efficiency and quality and contributes to sustainability.
- Disinvesting from or decommissioning low-value care often faces institutional barriers.
- Health technology assessment (HTA) and the continuous monitoring of peer-reviewed evidence and administrative health care data are key in identifying low-value care and prioritizing what should be decommissioned.
- Combining financial and nonfinancial mechanisms can help influence both the supply of and demand for low-value care and stop its provision.
- Broad stakeholder consultation and engagement is a key part of ending the use of low-value care because patients, clinicians, health-related organizations and health system norms and structures can all create barriers to change.
- Decision-makers need to address how resources released by disinvestment can best be reinvested to strengthen efficiency, quality and access.

Introduction

There has been significant attention afforded to the challenges associated with assessing the value and introduction of novel health technologies, but much less attention afforded to how to disinvest from or decommission pre-existing health technologies or treatments which may be considered as low value. This is an important consideration for the sustainability of health care financing, particularly as this disinvestment or decommissioning has the potential to release resources which can be invested elsewhere, thereby improving the overall efficiency of the health care system.

The potential rewards are significant. For example, it has been estimated that approximately 30% of the USA's health expenditure is on treatments and services considered as low value (Shrank, Rogstad & Parekh, 2019). However, defining what is meant by "low value" is challenging and context dependent. A common definition used in the literature is the "use of an intervention where evidence suggests it confers no or very little benefit on patients, or risk of harm exceeds likely benefit, or, more broadly, the added costs of the intervention do not provide proportional added benefits" (Scott & Duckett, 2015). While this may seem relatively straightforward, it is important to understand that whether a health technology or treatment is considered low value or not is usually determined by the specific indication, patient characteristics and preferences (Verkerk et al., 2018). With some understanding of the challenges in defining instances of low-value care, one will begin to understand the difficulties in developing strategies to disinvest from low-value care and monitoring implementation. In the simplest scenario, there may be broad consensus among the clinical and patient community that a health technology is not effective or has been superseded by a novel health technology that is more effective or cheaper. In this case, commissioners and policy-makers often chose to reduce coverage of the low-value health technology and remove it completely from relevant benefits packages. However, this scenario rarely exists and instead in most cases the classification of health technologies as low value is more nuanced and dependent upon specific circumstances. In these cases, a broader set of financial and nonfinancial approaches is needed to encourage disinvestment.

This chapter discusses these challenges in detail, and presents a conceptual framework for disinvestment from low-value care.

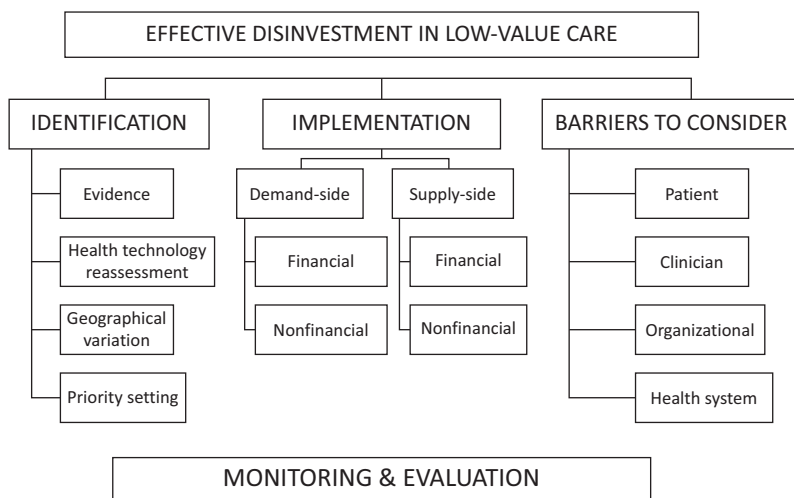


Fig. 2.3.1 Conceptual framework for disinvestment from low-value care

Source: Authors.

Fig. 2.3.1 details the conceptual framework. We begin by outlining approaches to identify potential instances of low-value care which may be candidates for disinvestment. We then discuss strategies to disinvest from low-value care and classify them as demand-side, supply-side, financial or nonfinancial interventions. We also consider what barriers to implementation exist from the patient, clinician, organizational and health system perspectives. Finally, we present a case study of a programme which has attempted to overcome these barriers and draw upon learnings from different approaches to disinvestment from low-value care over the last two decades: the NHS England Evidence-Based Interventions (EBI) programme.

Identifying candidates for disinvestment

The first stage of disinvestment from low-value care is the identification and classification of certain health technologies as low-value. Various approaches have been tried. The most prominent methods discussed in the literature include appraising published evidence, health technology (re)assessment and exploring variation (Elshaug, McWilliams &

Landon, 2013; Malik et al., 2018; Public Health England, 2016). While these are sometimes discussed as distinct approaches, in reality the principles which underlie these three approaches overlap and they are conducted in parallel. Once instances of low-value care have been identified, a process of prioritization to identify targets for disinvestment is then undertaken at either the national or local level.

Appraising published evidence

The initial step to identifying potential candidates for disinvestment is typically systematic searches of the published evidence to find instances of low-value care (Brook, 2010; NHS England, 2018; NICE, 2014). Ideally, the development of the search criteria should be transparent and involve multiple stakeholders including patients, commissioners and health care professionals. Searches must also include strict inclusion and exclusion criteria, and to narrow the scope searches are often conducted on a specialty or indication basis with the involvement of professional societies. The Cochrane Library is a particularly useful resource for such searches, as it incorporates a repository of systematic reviews of the comparative clinical and cost-effectiveness of health technologies. It has been shown to include many recommendations for disinvestment suitable for translation into practice (Garner et al., 2013).

One practical demonstration of this approach took place in Australia, where a team of academics was commissioned by the Australian Government to draw up recommendations for disinvestment, and subsequently identified over 150 low-value care interventions in the Australian Medicare Benefits Schedule based on a review of the literature, the Cochrane Library, and nominations from both clinical and non-clinical stakeholders (Elshaug et al., 2012). The *BMJ Rapid Recommendations* series is another useful resource, combining systematic literature reviews with economic evaluations to develop recommendations on disinvestment from low-value care (Siemieniuk et al., 2017).

Health technology (re)assessments

While appraising already published evidence is an essential component of identifying potential candidates for disinvestment, comparative HTA processes are sometimes required to establish whether a pre-existing or

established health technology is no longer cost-effective compared to other health technologies or against a relative cost-effectiveness threshold. This requires the calculation of costs per quality-adjusted life-year. However, there is considerable variation in the role of HTA agencies internationally with regards to disinvestment. These agencies are typically focused on evaluating novel health technologies rather than providing disinvestment recommendations for pre-existing health technologies. A review of 62 HTA agencies conducted in 2015 found evidence of methodological frameworks for disinvestment from only four countries, specifically Austria, Italy, Spain and the United Kingdom (Calabrò et al., 2018). The same review also commented how most HTA activities in disinvestment were in the field of research and not widely applied in practical clinical settings.

England's National Institute for Health and Care Excellence (NICE) has the most experience of encouraging disinvestment from low-value care. In 2005, the government requested that NICE pilot an "ineffective treatment programme", and following consultation, this led to the belief that the best approach to disinvestment was through the publication of clinical guidance and associated "do not do" lists. NICE subsequently reviewed all pre-existing HTA recommendations and guidance, and identified over 2000 clinical interventions as candidates for disinvestment (Garner & Littlejohns, 2011). However, this programme has subsequently been replaced by national initiatives, such as the EBI programme (see the *Evidence in practice: the NHS England Evidence-Based Interventions (EBI) programme* section), that are more focused on co-development and ownership with clinicians with hopes of increased engagement. Other HTA agencies have come to similar conclusions: that their efforts may be enhanced with improved collaboration with specialty organizations. For example, the Canadian Agency for Drugs and Technologies in Health has recently published recommendations of low-value care in conjunction with Choosing Wisely Canada, a grass roots movement encouraging clinicians to abstain from unnecessary interventions (Basharat & Born, 2021).

Variations in level of use

A key component of identifying potential candidates for disinvestment is to analyse administrative health care data to explore to what extent there is current variation in utilization. Low volumes of an ineffective

health technology suggest that disinvestment is feasible, best practice is being achieved and learning can be shared with areas that are not achieving low volumes. In contrast, high volumes suggest an area of high resource use and potentially unwarranted clinical variation. However, it must be remembered that substantial variation may either demonstrate inequity of care (underuse of high-value health technology) or inappropriate use of resources (overuse of low-value health technology). Therefore, while broad geographical variation implies inappropriate care, whether it constitutes overuse or underuse requires further assessment (Appleby et al., 2011; Public Health England, 2016; Wennberg & Gittelsohn, 1973).

Making that assessment requires some level of understanding of what an appropriate or expected level of utilization should be for relevant health technologies for specific populations based upon characteristics such as age, gender and comorbidities. However, challenges with data availability and suitability are common and identifying a suitable threshold for when variation may warrant further investigation is not straightforward. Many countries, including Australia, Canada, Germany, the Netherlands, New Zealand, Spain, the United Kingdom and the USA, have focused on establishing Atlases of Variation, which use data on geographical variation to benchmark health care providers and guide efforts to reduce unwarranted clinical variation (DaSilva & Gray, 2016; Harrison et al., 2020; Health Quality & Safety Commission New Zealand, 2021; World Bank, 2015). A review of the effectiveness of these programmes found that providing feedback on variation was associated with reductions in overuse of tests and treatments, and improvements in adherence to guidelines and protocols (Harrison et al., 2020). However, more evidence is needed on the relative effectiveness of particular feedback approaches.

Prioritizing candidates for disinvestment

Once candidates for investment are identified, a major challenge is prioritizing which low-value health technologies should be targeted for disinvestment. This is a complex process which needs to consider the relative trade-offs between alternative candidates for disinvestment, including potential savings, certainty of evidence on lack of clinical and cost-effectiveness and the potential unintended

consequences, such as substitution by other types of care or inequity in access. If there is significant heterogeneity in clinical practice and patient needs between regions, these trade-offs may be very different at national and local levels.

In England, local efforts to prioritize candidates for disinvestment are common, for example through listing Procedures of Limited Clinical Effectiveness or Procedures of Limited Clinical Value (Coronini-Cronberg et al., 2015). These typically involve an evidence review and a local resource impact assessment, but have been criticized for a lack of transparency and accountability, and for resulting in a so-called “postcode lottery” whereby patients are confronted with sometimes unexplained variations in eligibility criteria to access different treatments based upon where they live (Russell et al., 2013). Other countries such as Wales (Charles et al., 2016) and Canada (Smith et al., 2016) have focused on utilizing resource management frameworks such as programme budgeting and marginal analysis to establish systematic approaches to disinvestment at the local level that improve transparency, accountability and public participation in decision-making. This typically involves mapping candidates for investment or disinvestment, and evaluation of the relative benefits and drawbacks of alternative candidates based upon stakeholder perspectives, and the economic concepts of opportunity cost and marginal gain (Donaldson et al., 2010). However, there is significant variation in engagement and approach to public involvement, and these frameworks are often only utilized sporadically or for research purposes rather than routinely in practice (Tsourapas & Frew, 2011).

Evidence on approaches to disinvestment from low-value care

Financial and nonfinancial mechanisms exist, both on the demand and supply side. Once low-value interventions are identified, several approaches to disinvestment can be utilized; there is now growing evidence on the effectiveness of these alternative approaches. Colla et al. (2017) classified these according to demand-side (i.e. patients and consumers) and supply-side (i.e. health care providers) interventions. We offer a similar approach encompassing more recent studies, and further categorize these interventions according to which are financial or nonfinancial mechanisms (Table 2.3.1).

Table 2.3.1 *Evidence on demand- and supply-side disinvesting interventions*

Demand-side interventions	
Nonfinancial	Financial
• Educational interventions (public awareness campaigns and patient information leaflets) – strong evidence • Shared decision-making between patients and clinicians – mixed evidence • Public reporting of variation in provision of low-value care between health care providers – weak evidence	• Cost-sharing for low-value health technologies and treatments (co-payments, deductibles, and co-insurance) – strong evidence • Removal of low-value health technologies and treatments from a benefits package (i.e. delisting or negative lists) – strong evidence • Reference pricing to improve generic prescribing – strong evidence
Supply-side interventions	
Nonfinancial	Financial
• Clinical decision support tools (embedded in health information technology systems, patient pathways and policies) – strong evidence • Educational interventions (awareness campaigns, continuing professional development) – mixed evidence • Feedback to providers (cycles of audit and feedback, individual feedback to prescribers) – mixed evidence	• Pay for performance (financial incentives to reduce provision of low-value health technologies and treatments) – strong evidence • Penalties or fines for overprescribing or providing unnecessary care – weak evidence • Payer restrictions (through gate-keeping, or prior approval mechanisms) – strong evidence • Risk sharing (through capitation or global budgets) – mixed evidence

Evidence on demand-side financial disinvestment interventions

Evidence of financial disinvestment mechanisms on the demand side shows promising impacts; however, it also exposes potential unintended consequences.

Demand-side interventions aim to curb the provision of low-value care through influencing patient or consumer behaviour. The predominant financial mechanism utilized for this purpose is cost-sharing, whereby costs of unnecessary procedures are shared between patients and payers through different co-payments, deductibles and co-insurance in an attempt to communicate value to patients. The introduction of targeted co-payments (ranging from US\$ 100–500 in the fiscal year 2011/2012) for several low-value diagnostics (sleep studies, computed tomography scans, magnetic resonance imaging scans, positron emission tomography scans and upper gastrointestinal endoscopies) and surgical procedures (spine surgeries for pain, shoulder and knee arthroscopies, and hip and knee replacements) by a large insurer in the USA found significantly reduced use of targeted services, with a price elasticity of -0.22 (Gruber et al., 2020). Crucially, the same study found no impact of substitution between targeted and non-targeted services. However, when non-targeted, there is a risk that patients will forgo both high-value and low-value care, with several studies concluding that patients may not necessarily be able to distinguish between the two (Lohr et al., 1986; Wharam et al., 2011). Moreover, there is a risk that cost-sharing will have differential impacts between socioeconomic groups, with cost-sharing disproportionately impacting people of lower socioeconomic groups (Wharam et al., 2011). Reference pricing is an example of cost-sharing commonly utilized in Europe to discourage the use of brand-name medicines – which can be understood to be an example of low-value care when equivalent generic versions exist – in favour of generic medicines. Evidence suggests that reference pricing can generate higher generic medicine use, but also unintended consequences such as the complete discontinuation of cost-effective treatments for chronic diseases (Gibson, McLaughlin & Smith, 2010).

Cost-sharing is different to the complete removal of low-value health technologies or treatments from a defined benefits package, as when this strategy is adopted costs are not shared between the patient and payer and the patient is exposed to 100% of the costs. This type of financial intervention, sometimes called “delisting” or creating “negative lists”, is most easily applied to pharmaceuticals which have clear indications. This strategy has been applied to hundreds of pharmaceuticals in France and has reduced relevant prescriptions by up to 50% (Pichetti & Sermet, 2011), but has been controversial for some

pharmaceuticals such as the use of acetylcholinesterase inhibitors for patients with dementia (Walsh, King & Brayne, 2019). Delisting or removal from the benefits package has also been used effectively in many other European countries including Czechia (Chytilová & Šebesta, 2015), Denmark (Hesse et al., 2013), Italy (Rocchi et al., 2004) and the Netherlands (Kroneman & de Jong, 2015).

Evidence on demand-side nonfinancial disinvestment interventions

There are several nonfinancial demand-side mechanisms that have been used to influence patient or consumer demand for low-value care including improved education, shared decision-making and public reporting. Excess antibiotic use is a key example of low-value care, and there are many pre-post studies which demonstrate that large-scale multimodal public awareness campaigns can change knowledge, behaviours and usage of antibiotics (Price et al., 2018). There is also evidence for other pharmaceuticals: for example, a patient information leaflet on the indication, harms and drug interactions of benzodiazepines, as well as visual tapering recommendations, has been shown to increase discussions around cessation, and numbers of patients achieving full cessation (Tannenbaum et al., 2014). Shared decision-making involves patients and clinicians having a focused and detailed discussion regarding the low-value treatment in question, thereby enabling the patient to make a fully informed choice regarding their care (Elwyn et al., 2012). A review of the public's role in reducing low-value care found that decision-making tools that supported shared decision-making between clinicians and patients, such as the educational materials produced by the international Choosing Wisely initiative, were effective (Reyes et al., 2020), although rarely utilized in practice (Sykes et al., 2020). Increasingly, public reporting is used to show variation in provision of low-value care between health care providers (Maratt et al., 2019; Reyes et al., 2017). In theory, this has the potential to alter the behaviour of health care providers if patients make choices based upon this information. However, this is dependent upon patients being able to easily view and understand this information, as well as being able to change which health care providers they access. In reality, largely because these conditions are often not met, evidence suggests that public reporting generally may have negligible or limited impact

on health care quality (Joynt et al., 2012; Ryan, Nallamothu & Dimick, 2012). However, more research is needed to understand the impact on the provision of low-value care specifically (Maratt et al., 2019).

Evidence on supply-side financial disinvestment mechanisms

Supply-side interventions aim to change the behaviour of health care providers at either the organizational or individual level. The four financial mechanisms commonly utilized to incentivize health care providers to reduce provision of low-value care are: pay for performance (P4P); penalties; payer restrictions; and risk sharing. P4P programmes provide financial incentives to health care providers to reduce the provision of inappropriate care – for example, excess antibiotic prescriptions or unnecessary laboratory tests. Evidence from the United Kingdom has indicated that a nationwide P4P programme, the Quality Premium, has been effective at reducing inappropriate antibiotic prescribing (Bou-Antoun et al., 2018). Evidence from the USA has also shown that a financial incentive scheme for residents reduced unnecessary blood tests and adherence to clinical guidance (Han et al., 2014). In contrast to P4P programmes which reward health care providers, penalties have been used to fine clinicians who overprescribe unnecessary or potentially harmful treatments. These were used in France between 1994 and 1996, when approximately 13 000 doctors were surveyed over two years and ultimately 75 were fined for inappropriate prescribing (Busse et al., 2015). However, in 1999 the sanctions were declared illegal and the policy was abandoned. A systematic review of measures in six high-income countries for curbing overprescribing also found that penalties are rarely used (Rashidian et al., 2015).

Payer restriction involves only providing reimbursement for certain indications and contexts, and is often implemented and monitored through some form of prior approval or gatekeeping mechanism to access the relevant low-value health technology or treatment. One study demonstrated that introducing a gatekeeping policy based upon patient symptoms for an autoimmune blood test reduced inappropriate testing (Sinclair, Saas & Stevens, 2004). Similarly, another study demonstrated that introducing an infectious disease consultation requirement for parenteral antibiotic therapy in the outpatient setting reduced inappropriate prescribing (Conant, Erdman & Osterholzer, 2014).

Risk sharing involves utilizing reimbursement mechanisms that expose health care providers to the financial cost of services provided. These typically involve some form of global budget or capitation payment, and in theory, could encourage the provider to disinvest from low-value care, thereby maximizing the value for patients from restricted funds. In the USA, Blue Cross Blue Shield introduced an Alternative Quality Contract in 2009 for health care providers, which incorporated global payments and found that cardiovascular services reduced by 7.4% and imaging services reduced by 6.1%, but colonoscopies increased by 5.2% (Song et al., 2013). However, another study from the USA found no association between capitation payments and low-value imaging for low back pain and headache in the primary care setting (Liao et al., 2020). Moreover, other studies have commented that reimbursement mechanisms such as capitation or global budgets are unlikely to incentivize disinvestment from low-value care in isolation, and they must be utilized as part of multicomponent strategies (Lee et al., 2016; Mafi et al., 2019).

Evidence on supply-side nonfinancial disinvestment mechanisms

There are three nonfinancial supply-side mechanisms utilized to encourage health care providers to reduce provision of low-value care; clinical decision support tools; education; and feedback to providers. Clinical decision support tools aim to reduce unnecessary tests and unsafe prescribing while promoting compliance with guidelines on evidence-based care, and can be embedded into health information technology systems, patient pathways or policies. Prompts integrated into health information technology systems that alert clinicians they are potentially non-compliant with guidance or ordering unnecessary tests have been shown to be effective in reducing the provision of unnecessary blood transfusions (Baer et al., 2011), inappropriate use of imaging (Aston, 2010; Solberg et al., 2010) and duplicate blood tests (Levick et al., 2013; Niës et al., 2010). Moreover, other studies have demonstrated that adapting prescription order displays to show only generic medicines (Patel et al., 2014), or incorporating infection disease specialist reviews into a computerized antibiotic authorization system can reduce low-value prescribing (Potasman, Naftal & Grupper, 2012). However, it is important to consider the risk of alert fatigue in clinicians who can

then choose to ignore or override notifications. The evidence regarding education for clinicians, who may be reluctant to engage with such efforts, is mixed. Evidence on trends in the provision of 32 low-value services for Medicare recipients between 2014 and 2018 (Mafi et al., 2021) concluded there were only marginal reductions in provision of low-value care despite a national education campaign to limit the provision of these services in collaboration with specialty societies. It appears that educational programmes may be more effective if more targeted and multimodal. For example, a continuing medical education programme involving tutorials and an interactive seminar on shared decision-making has been shown to result in lower levels of inappropriate antibiotic use, with 52% of patients in the control group and 27% of those in the intervention group deciding to use antibiotics' after consultation (Légaré et al., 2012). Similarly, lectures and the introduction of a medicines reconciliation form have been shown to reduce inappropriate acid suppression therapy during hospital admission from 51% to 22% (Gupta et al., 2013). Feedback to providers on the extent of the provision of low-value care can also reduce its provision. Cycles of audit and feedback at the local level have been associated with significant reductions in low-value care, with a systematic review on this topic highlighting reductions achieved in inappropriate polypharmacy, antibiotic use and imaging (Ivers et al., 2012). Results at the national level are more mixed. A study from the United Kingdom which evaluated the use of feedback to individual practices that were in the top 20% of antibiotic prescribers was shown to reduce antibiotic prescriptions by 3.7% (Ratajczak et al., 2019). However, two other studies from Switzerland and Denmark respectively, which evaluated the use of individual provider feedback alongside a nationwide antibiotic stewardship programme, found no associated change in antibiotic use (Hemkens et al., 2017; Søndergaard et al., 2003).

Evidence on multicomponent disinvestment interventions

Evidence on multicomponent interventions shows that by combining different approaches, sustainable reductions in the provision of low-value care are possible.

Colla and colleagues concluded that multicomponent interventions are more likely to achieve sustainable reductions in the provision of low-value care (Colla et al., 2017). These multicomponent

interventions typically involve a combination of nonfinancial supply-side mechanisms, incorporating clinical decision support tools, education and feedback to providers. For example, a study found that an educational programme involving a lecture, information card and twice weekly feedback on individual ordering behaviour reduced inappropriate echocardiography use (Bhatia et al., 2013). Similarly, another study focusing on the impact of audit and feedback, lectures and participation of pharmacists in ward rounds, found significant reductions in inappropriate acid suppression therapy (Khudair et al., 2011). Other examples involving the combining of educational campaigns, clinical decision support systems and cycles of audit and feedback have been shown to reduce prevalence of inappropriate use of blood transfusions (Arnold et al., 2011; Rothschild et al., 2007).

Barriers to the implementation of disinvestment strategies

There is a growing literature base on the barriers to implementation to consider when developing strategies to disinvest from low-value care.

Despite growing efforts to reduce the provision of low-value care, the evidence on many supply- and demand-side mechanisms is mixed. Below we discuss these barriers from a patient, clinician, organization and health system perspective.

Barriers to disinvestment at patient level

At the patient level, information asymmetry, lack of trust and limited patient involvement can get in the way of disinvestment efforts.

From a patient perspective, patients often lack the capability to differentiate between high- and low-value care (Lohr et al., 1986). Patients may therefore be reluctant to forgo unnecessary screening or testing due to fear of delayed diagnosis. Moreover, it has been emphasized that patients may mistrust the medical establishment, and feel that care is being withdrawn or restricted unfairly (Norton & Chambers, 2020). This can be particularly damaging to the patient-clinician relationship, and clinicians may therefore be unwilling to restrict access to low-value care. These tensions are intensified when disinvestment initiatives are developed with limited public involvement (Sypes et al., 2020), or lack of engagement from either patients or clinicians in shared decision-making (Allen et al., 2019). While

disinvestment initiatives such as Choosing Wisely have focused on developing patient decision aids to promote awareness and shared decision-making, a review of these materials found few provided balanced information on the benefits and harms of alternative interventions and therefore may be misleading or confusing for patients (Légaré et al., 2016).

Barriers to disinvestment at clinician level

From the clinician perspective, disinvestment from low-value care is often perceived as a cost-cutting exercise rather than for quality improvement (Embrett & Randall, 2018), and many clinicians fear lost revenue (Zadro et al., 2019). Other barriers discussed in qualitative interviews are time constraints, which prevent clinicians from engaging in shared decision-making with patients (Kool et al., 2020; Zikmund-Fisher et al., 2017), and fear of patient dissatisfaction or litigation that may result from withdrawing or restricting access to care (Lin et al., 2017; Osorio et al., 2020; Pausch et al., 2020; Zikmund-Fisher et al., 2017). Clinicians also discussed difficulties in overcoming patients' preferences (Smith et al., 2020), and emphasized there is a lack of tools available to support shared decision-making. Most surveys indicated there was a high awareness among clinicians of low-value care initiatives and the need to manage limited resources efficiently (Buist et al., 2016; Kool et al., 2020), but most clinicians nonetheless reported they would still order unnecessary tests or procedures if a patient insisted.

Barriers to disinvestment at the organization level

From the organizational perspective, lack of resources to implement disinvestment initiatives, for example to create additional clinic time to facilitate shared decision-making, is discussed frequently in the literature (Dulmen et al., 2020; Ellen et al., 2018; Norton & Chambers, 2020). Concern about resources is exacerbated by the perception that engagement with disinvestment initiatives could further reduce available resources if they lead to lost revenues and increased litigation. Organizations may also resist collaborating with other organizations if they are perceived as having competing interests or priorities (Ellen et al., 2018). Other barriers discussed within the literature include the

risk of change fatigue if organizations are exposed to repeated quality improvement efforts (McMillan & Perron, 2020), and inadequate infrastructure – in particular, health information technology systems – to implement, monitor and evaluate disinvestment initiatives (Dulmen et al., 2020).

Barriers to disinvestment at the health system level

From a health system perspective, reimbursement mechanisms that reward volume of care, such as fee-for-service payments, rather than those which incentivize the reduction of unnecessary care, such as capitation or global payments, were repeatedly emphasized as a barrier to disinvesting from low-value care (Dulmen et al., 2020). Other barriers discussed in the literature include poor awareness or commitment on the part of policy-makers and leadership regarding the need to address low-value care (Ellen et al., 2018); difficulties in coordination and building consensus between stakeholders at different levels of the health care system (Ellen et al., 2018); and a lack of resources to undertake the academic work required to identify low-value care (Garner et al., 2013). A review of involvement by HTA agencies in disinvestment initiatives in Europe also identified a lack of guidelines for the identification of obsolete technologies (Calabrò et al., 2018), and discussed how disinvestment remains a relatively new concept within these agencies. Moreover, a lack of data or suitable measures for monitoring and evaluation has been highlighted (Chalmers et al., 2018).

Evidence in practice: the NHS England Evidence-Based Interventions (EBI) programme

Most recently, the National Health Service (NHS) in England has accelerated efforts to disinvest from low-value care by developing the EBI programme, which aims to reduce avoidable harm to patients, maximize value and avoid waste by reducing unnecessary interventions. Statutory guidance for the EBI programme was published in November 2018 (NHS England, 2018), and the programme was officially launched in April 2019.

Table 2.3.2 *Surgical procedures under the remit of phase one of the NHS England EBI programme*

Category 1: not clinically or cost-effective

Surgical intervention for snoring (not obstructive sleep apnoea)

Dilatation & curettage for heavy menstrual bleeding

Knee arthroscopy with osteoarthritis

Injection for nonspecific low back pain without sciatica

Category 2: clinically and cost-effective only in certain circumstances

Breast reduction

Removal of benign skin lesions

Grommets

Tonsillectomy

Haemorrhoid surgery

Hysterectomy for heavy bleeding

Chalazia removal

Shoulder decompression

Carpal tunnel syndrome release

Dupuytren's contracture release

Ganglion excision

Trigger finger release

Varicose vein surgery

Source: Authors, based on NHS England (2018).

Identification of candidates for disinvestment

To identify potential candidates for disinvestment, the programme first undertook a thorough review of published evidence and HTA recommendations and explored variation between local commissioning bodies. The team developing the programme was conscious of how previous initiatives to disinvest from low-value care – in particular, the NICE “do not do” lists and locally developed procedures – had failed to engage with relevant stakeholders. Therefore, the EBI team launched a consultation aimed at the public, commissioners and health care professionals (the latter through their specialty organizations). As a result, the first phase of the EBI programme identified 17 low-value procedures within two categories (Table 2.3.2).

Category 1 interventions have been shown not to be clinically or cost-effective and there is consensus among health care professionals

that the procedures should no longer routinely be offered to patients. Category 2 interventions are only clinically or cost-effective for certain types of indication and/or patients.

Implementing the disinvestment

The EBI programme draws upon learning from many previous initiatives undertaken to disinvest from low-value care, and uses a multicomponent approach to encourage disinvestment from these low-value procedures. The programme has set targets for each local commissioning body to reduce the number of category 1 interventions to “near zero” and category 2 interventions to 25% of current levels nationally. The latter target involved calculating an expected rate for each local commissioning body based on population characteristics. They delisted category 1 interventions, introducing a zero tariff, with health care providers no longer reimbursed by the NHS for these interventions. Local commissioning bodies were asked to implement a prior approval process for category 2 interventions, with clinicians now expected to seek approval from local commissioning bodies for appropriate indications and/or patients. Progress in meeting agreed targets continues to be monitored and shared with hospitals and clinical commissioning groups by means of a publicly available dashboard to allow benchmarking (NHS Business Services Authority, n.d.). The identification of low-value procedures is based upon combinations of operation and diagnostic codes that are continually refined based upon feedback from commissioners, hospitals and health care providers. Crucially, this allows the identification of low-value procedures according to specific indications, and relevant exclusion criteria for other indications when the procedure is considered as high-value. To support improved awareness, education and shared decision-making between patients and clinicians, a series of patient information leaflets and videos was also developed (AMRC, 2022). The EBI programme has since expanded to a second phase, with a further 31 low-value procedures, diagnostics and treatments, and the statutory guidance was published in November 2020 (AMRC, 2020).

Evaluation of the EBI programme

Conclusive evaluation of the EBI programme is not yet complete, as this has been hampered by the emergence of the COVID-19 pandemic.

A preliminary analysis of the first 11 months following implementation, against a control group of other yet to be identified low-value procedures, concluded that the EBI programme encouraged a general culture of disinvestment from low-value care but did not accelerate disinvestment for the low-value procedures under its remit (Anderson et al., 2022). Nevertheless, the EBI programme remains the most robust and comprehensive approach to disinvestment from low-value care in England to date. The EBI programme draws upon learning from many previous initiatives to disinvest from low-value care, and uses several financial and nonfinancial supply and demand-side approaches to encourage disinvestment. The EBI programme also attempts to overcome many barriers to implementation through a broad consultation process, transparent monitoring and evaluation mechanisms, feedback to individual hospitals and commissioners, and public reporting. Despite this, Anderson and colleagues (2022) conclude that the EBI programme may have taken an approach to implementation that it is too top-down, and that the success of the programme is also heavily dependent upon successful collaborations between local commissioning bodies, hospitals and clinicians at the local level.

Policy relevance and conclusions

While there is broad consensus that disinvestment from low-value care is crucial to the financial sustainability of health care systems, there continues to be disagreement among relevant stakeholders about how best to identify potential candidates for disinvestment and what approaches should be taken to encourage disinvestment. The complexity of these challenges is further compounded by uncertainties in defining in what circumstances specific health technologies or interventions may be considered low-value, and technical difficulties in the monitoring and evaluation of initiatives. The resulting lack of clarity has often led to differing levels of success and fractured relationships between policy-makers, clinicians and patients. One thing is clear: no perfect mechanism for disinvestment has been identified to date – highlighting how great the challenge of disinvestment from low-value care is.

As we look to the future, lessons can be drawn from the experience acquired over the past two decades. Disinvestment must be sensitive to the opinions of all stakeholders, in particular those who drive the persistent use of low-value care; it must be rigorous and transparent in

the identification and prioritization of potential candidates for disinvestment; and its implementation must draw upon multiple approaches that consider both demand- and supply-side perspectives. The implementation of disinvestment needs to be understood as a dynamic process that involves continual monitoring and evaluation, with concomitant feedback to individual clinicians and health care providers. Finally, released resources need to be reinvested into other areas of high-value care so patients, clinicians and policy-makers can see the benefits of engaging with these initiatives, and to ensure that disinvestment from low-value care is not perceived as a cost-cutting exercise.¹

Additional resources

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¹ Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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2.4 *User charges*

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Key messages

Chapter 2.4 gives an overview of user charges. User charges are out-of-pocket (OOP) payments made at the point of use for health services. Nearly all countries have some user charges, most commonly for medicines. They are intended to raise revenue and also to reduce the use of unnecessary health services and products. Key learning includes that:

- User charges can generate revenues but have many unintended negative consequences – creating barriers to access, contributing to inequities and increasing the risk of financial hardship for households.
- Health systems can reduce unnecessary or wasteful use of care without user charges by:
 - strengthening prescribing and referral systems to make sure care is appropriate;
 - offering information to steer patients and providers towards more cost-effective care.
- Supply-side mechanisms that guide providers' behaviour are more equitable and effective than demand-side mechanisms, such as user charges, and have fewer negative impacts on patients – especially those with chronic or severe conditions or the economically disadvantaged.
- User charges are a suboptimal policy but – if they are to be used – health systems can mitigate the harm they cause and protect health care users through mechanisms such as exemptions, reduced co-payments, income-related co-payment caps and, to a lesser extent, price control and regulation.

Introduction

All health systems face the combined challenge of constrained financial resources and steady growth in health expenditures due to increasing demands for health care and expensive technological advances. In response, most health policy-makers have chosen – among a range of options, many of which are discussed in this volume – to put the onus for rationalizing health care use on patients themselves, by introducing user charges. In this chapter, we consider user charges (also referred to as user fees, cost-sharing or co-payments) as OOP payments at the point of use for covered services. They are intended to cover some portion of the cost of services, but not the full cost; for our purposes, this means that user charges do not include direct payments for non-covered services, nor informal payments. Likewise, some people may choose to obtain care privately, paying the full cost OOP due to perceptions about public sector quality or waiting times. Our focus in the chapter, however, remains firmly on OOP payments formally required for health services provided within the public system.

Ensuring that patients have “skin in the game” is thought by some to cause patients to carefully consider their care needs and only pursue expensive care which is necessary and high-value in terms of their health, thus reducing unnecessary utilization, enhancing efficiency and slowing expenditure growth. At the same time, user charges may be seen as required to generate additional revenue for the health system, further reducing budgetary pressures.

While these arguments capture the broad rationale for implementing user charges, the key question for policy-makers is whether the available evidence demonstrates that user charges work this way in practice. And, if that is the case, is there an “optimal” way to set the charges which improves a health system’s financial position without jeopardizing health outcomes and other health system objectives? What are the consequences if user charges are imposed on the wrong people, wrong services, at the wrong level or just generally in the wrong way?

The chapter falls into three main sections. The first looks at what user charges are and the forms that they take in different systems. The second section examines the policy’s effects both on households and health systems; we outline the rationale for introducing user charges in order to examine whether they achieve the objectives desired, as well as reviewing the evidence on the charges’ unintended

consequences. The third section suggests ways forward for health systems implementing user charges: mechanisms to protect people from the adverse consequences, examples of successes and failures in practice, and policy lessons that can be drawn.

How are user charges used?

Fixed co-payments and percentage-based co-payments

There are two main ways that user charges are implemented: fixed co-payments and percentage-based co-payments. In a fixed co-payment system, some fixed amount of payment is required for a health care good or service, irrespective of the underlying cost of that item. This has an advantage in that it gives financial certainty to patients since they know how much they will pay in advance; it also may be more equitable since people will not face different prices just because they require different treatments (Thomson, Cylus & Evetovits, 2019). For example, in England, anyone required to pay for prescriptions paid a fixed fee of £9.35 per item in 2020/21 regardless of what the item was, although the price paid by the National Health Service for the 10 most commonly dispensed items actually ranged in cost from £1.12 for bisoprolol fumarate to £5.20 for metformin hydrochloride, with a mean cost per item of £2.09¹ (Wilson, 2021). Nevertheless, many less commonly prescribed items greatly exceed the fixed co-payment.

Alternatively, percentage-based co-payments mean that the amount paid OOP varies depending on the underlying price of an item. For example, a payer may require a 10% co-payment for a service, meaning that 10% of the cost is to be paid at the point of use by the patient; this may create some financial uncertainty for patients. While for very low-cost goods and services a health care user will end up paying a fairly small amount OOP using percentage-based co-payments, for big ticket items, the patient will have much greater financial exposure to cost. Ultimately, people with different conditions or those requiring different treatments may pay very different prices, exacerbating inequities. Sometimes, third-party payers decide to remove co-payments or apply lower percentage rates to items where they want to encourage uptake, and higher

¹ The mean cost per item is the average calculated by dividing the total cost of the substance by the total number of items dispensed for that substance.

percentage rates to items that they perceive to have lower value, in an effort to dissuade use; this is referred to as value-based co-payments, value-based cost-sharing or value-based insurance (Chernew et al., 2008).

Reference pricing

Percentage-based co-payments can also be implied, rather than explicit. For example, the cheapest active substance may be covered in full by a third-party payer, or a third-party payer may set some maximum price that they are willing to reimburse through an alternative mechanism, with the patient paying the remainder if they choose a more expensive medicine or if a more expensive medicine is all that is available (Thomson, Schang & Chernew, 2013). In practice, this functions similarly to an explicit percentage-based co-payment. This is the case in Lithuania where, often in addition to percentage-based co-payments, people pay the difference between the actual retail price and the reference price OOP; this system is known as internal reference pricing (Murauskienė & Thomson, 2018). Internal reference pricing is often used to control costs but can have adverse effects on financial protection (WHO Regional Office for Europe, 2025a).

Mixing co-payments

Sometimes both fixed and percentage-based co-payments are used in tandem. One example is where percentage-based co-payments are used, but there is a fixed dispensing fee in addition. Such was the case in Greece, where a fixed co-payment was charged for outpatient services (€5) or admission to a state hospital (€25). In addition, percentage-based co-payments were in place for inpatient stays, medical devices and diagnostic or laboratory tests (Economou et al., 2017). These percentage-based charges currently remain in place without the fixed co-payments, which were removed in 2015, but Greece has maintained this combination of fixed and percentage-based co-payments for prescription drugs. Users pay €1 per prescription along with a percentage-based co-payment, which is reduced for specific populations (Vogler et al., 2018).

User charges for prescriptions

Any health service can have user charges, although they are most widely used for medicines and least commonly used for inpatient

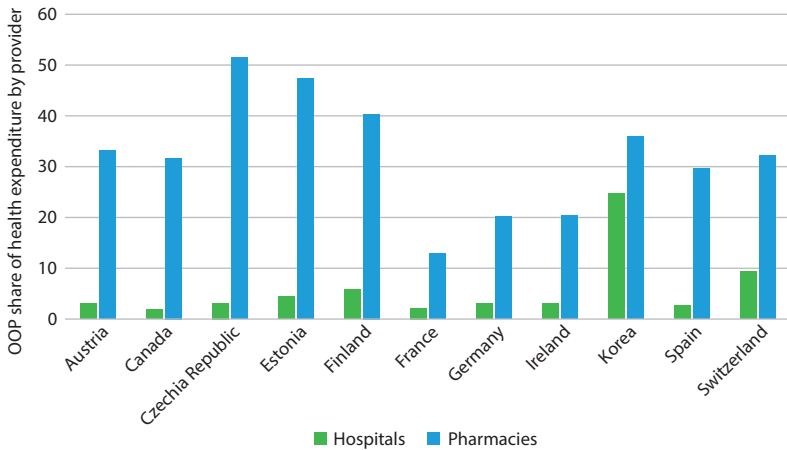


Fig. 2.4.1 OOP spending disproportionately finances pharmacies as compared to hospitals

Source: OECD (2023).

care. The outcome of this tendency can be seen in Fig. 2.4.1, where OOP spending disproportionately finances pharmacies as compared to hospitals. One possible explanation is that prescription drugs do not have the same natural supply constraints as other health services, which are typically labour-intensive and limited by the number of providers, facilities or technology available. Medicines, on the other hand, may be thought to require some other constraint to prevent inexorable increases in use and ultimately in expenditures.

However, evidence suggests that user charges do not temper demand for prescription drugs very much. For example, some research indicates that the demand for prescription drugs is largely price inelastic (less than proportionate); a 10% increase in price results in between a 0.2–5.6% decrease in use. Thus, implementing user fees shifts the burden of paying for medicines to patients rather than substantially decreasing total demand for prescriptions (Gemmell, Thomson & Mossialos, 2008). Other studies find that patients decrease adherence to treatment when faced with even a small co-payment, skipping doses or cutting pills in half (Gemmell, Thomson & Mossialos, 2008; Poirier et al., 1997; Hernández-Izquierdo et al., 2019). These behaviours occur even among patients who are at a high risk of an adverse health

event, such as a heart attack or stroke (Chandra, Flack & Obermeyer, 2021). As a result, user charges may contribute to poorer health outcomes.

The unintended consequences outlined here are specific to prescription charges. In the section that follows we look at the consequences relating to user charges overall.

Intended and unintended effects

As mentioned at the outset of this chapter, there are two primary reasons why health systems apply user charges: to reduce unnecessary health care use and to raise revenues for the health system. Here, we first discuss the evidence on the extent to which these intended effects occur in practice. We then turn to two key unintended consequences of user charges: financial hardship and unmet need for health care.

Intended effect 1: to reduce the use of unnecessary health care

One of the main arguments used to justify user charges is that they are required to reduce unnecessary demand for health care, which they do by steering patient behaviour; this argument is underpinned by a concept called moral hazard. In technical terms, moral hazard refers to the idea that an individual will increase their exposure to risk if they do not bear the full cost of risk. In the context of health care, the concept implies that an individual will use more health care than needed if they do not have to pay for it themselves. There is a huge amount of literature on moral hazard in health care dating all the way back to Kenneth Arrow in 1963 (Einav & Finkelstein, 2018; Gagnon, 2017; Arrow, 1963). Some also consider that moral hazard means people will not invest fully in their health (i.e. they will engage in poor health behaviours) if they do not face the costs of health care, which may in turn contribute to additional health spending, although this form of moral hazard has received less academic attention.

The seminal work from the RAND health insurance experiment of the 1970s in the USA is often touted as presenting some of the strongest evidence of the effects of user charges. Households were randomly assigned to different health plans that varied according to their degree of cost-sharing; one plan had zero cost-sharing, and all had an OOP cap above which full insurance kicked in (Aron-Dine, Einav &

Finkelstein, 2013). The results from the RAND experiment were initially interpreted as showing that health spending does change with user charges, since patients with higher cost-sharing had significantly less overall health spending. Researchers have revisited the data, however, and argue that this difference is small, especially for inpatient care, but also for demand for prescription medicines (Aron-Dine, Einav & Finkelstein, 2013). Moreover, the experiment did not include people aged over 62 years old or people too disabled to work, limiting its relevance among groups most likely to use health services. Indeed, the RAND experiment's results may not provide as strong a basis to claim that implementing user charges will create lower health care expenditure as some have previously argued.

Another criticism of the argument that user charges reduce unnecessary care is that patients are not consistently able to distinguish between efficient and inefficient uses of health care (Gemmell, Thomson & Mossialos, 2008). In the RAND experiment, participants reduced their use of both effective and ineffective care to nearly the same degree (Lohr et al., 1986). User charges can discourage patients from seeking preventive care or cause them to dismiss health concerns because of the cost associated with a medical consultation (Greenfield et al., 2019; Swartz, 2010). While this may decrease health expenditures for a short period, it can cause a “squeezed balloon effect” and result in the increased use of other services which are free to use but costly to provide, such as inpatient hospital care or emergency care (Chandra, Gruber & McKnight, 2010; Thomson, Foubister & Mossialos, 2010). Studies focused on patients with chronic conditions find a correlation between higher user charges for prescription drugs and a greater use of inpatient and emergency services due to reduced adherence (Tamblyn et al., 2001; Goldman, Joyce & Zheng, 2007; Swartz, 2010). Thus, broad user charges may not actually encourage patients to be selective about care but, rather, discourage them from seeking care altogether.

Intended effect 2: to raise revenues

The second key reason cited for policy-makers opting to use user charges is to raise revenues. However, compared to prepayment mechanisms, user charges are an inefficient and inequitable means to raise revenues since they are based on people's health care needs as opposed to their ability to pay. Administrative costs associated with collecting

user charges can also outweigh the revenue gains, especially when exemptions are introduced, which require additional oversight (Dupas, 2014).

Despite their limited potential, user charges are perceived as an important source of funding in some countries, particularly at the facility level. For example, public hospitals in Kenya rely heavily on user charges due to low public funding (Kairu et al., 2021). Although user charges may only comprise a small amount of total revenues for a facility, they may be a more flexible source of revenues than other sources of funding if public financial management systems are quite rigid. User charges may be the only funds that facilities have complete control over, causing facilities to depend heavily on user charges to cover variable costs. In these settings it is possible to reduce or remove user charges, but this should be done in tandem with more flexible financial management and with additional funding to offset any losses.

One example of a country which has tried to remove user charges as a revenue-raising method is China. Prior to 2009, China allowed public hospitals to raise revenues from prescription medicines by imposing a 15% profit margin, but has since spent considerable effort attempting to do away with this (Li & Yu, 2021). The government created several policies to remove prescription drug mark-ups, including a pilot programme in 2015 and a full elimination of mark-ups from urban hospitals by September 2017. To compensate hospitals for this change, revenue structures were altered to receive larger government subsidies and increase the prices of medical services, although data are inconclusive on whether these measures have been sufficient to compensate facilities for the lost revenue (Cheng et al., 2021).

While the above highlighted the intended effects of a user charging policy, below we turn to two key unintended effects.

Unintended effect 1: financial hardship

Unfortunately, there are a number of unintended adverse consequences commonly associated with user charges. One of the most commonly discussed consequences is financial hardship for those who utilize health services. For some households, OOP spending can either be so large in relation to a household's ability to pay that it is considered to be catastrophic and, for others, OOP spending can push a household into poverty (Cylus, Thomson & Evetovits, 2018). As shown in Fig. 2.4.2,

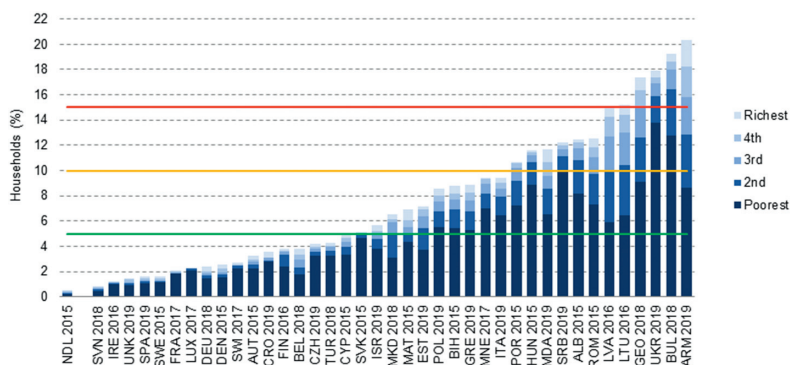


Fig. 2.4.2 Households in the poorest quintile have the highest level of catastrophic spending due to OOP payments

ALB: Albania; ARM: Armenia; AST: Austria; AUT: Austria; BEL: Belgium; BIH: Bosnia and Herzegovina; BUL: Bulgaria; CRO: Croatia; CYP: Cyprus; CZH: Czechia; DEU: Germany; DEN: Denmark; FIN: Finland; FRA: France; GEO: Georgia; GRE: Greece; HUN: Hungary; IRE: Ireland; ISR: Israel; ITA: Italy; LTU: Lithuania; LUX: Luxembourg; LVA: Latvia; MAT: Malta; MDA: Moldova; MKD: North Macedonia; MNE: Montenegro; NDL: Netherlands; OECD: Organisation for Economic Co-operation and Development; OOP: out-of-pocket; POL: Poland; POR: Portugal; ROM: Romania; SRB: Serbia; SPA: Spain; SVK: Slovakia; SVN: Slovenia; SWE: Sweden; SWI: Switzerland; TUR: Türkiye; UKR: Ukraine; UNK: United Kingdom.

Note: Consumption quintiles are based on per person consumption using OECD equivalence scales. The Netherlands cannot be compared to other countries because the data used do not include the annual deductible amount households pay OOP for covered health care; our simulations suggest that catastrophic health spending is underestimated by up to 1.8 percentage points in the Netherlands in 2015. The lines represent a spectrum from lower to higher levels of financial hardship set at 5% (green line), 10% (yellow line) and 15% (red line).

Source: WHO Regional Office for Europe (2023b).

in European countries, households in the poorest quintile have the highest level of catastrophic spending due to OOP payments, which includes user charges (WHO Regional Office for Europe (2023a); WHO Regional Office for Europe (2023b)).

Impoverishing spending is another measure used to track financial protection. It captures the percentage of households (or the population) who, after making OOP payments, are pushed below a poverty line.

Different methods use different poverty lines; the World Health Organization Regional Office for Europe defines the poverty line as the cost of meeting basic food and housing needs. Some analysts also consider households already below the poverty line who still spend OOP on health care as a part of this metric (sometimes referred to as the further impoverished). Fig. 2.4.3 shows recent data on the percentage of households in European countries with impoverishing spending (WHO Regional Office for Europe 2023a; WHO Regional Office for Europe 2023b).

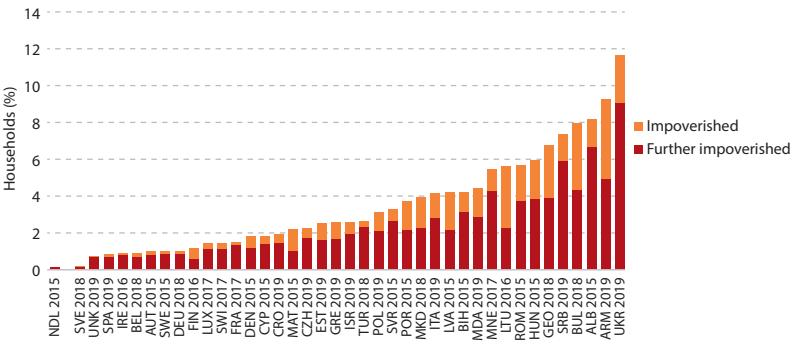


Fig. 2.4.3 OOP spending can push households below or further below the poverty line

ALB: Albania; ARM: Armenia; AUT: Austria; BEL: Belgium; BIH: Bosnia and Herzegovina; BUL: Bulgaria; CRO: Croatia; CYP: Cyprus; CZH: Czechia; DEU: Germany; DEN: Denmark; EST: Estonia; FIN: Finland; FRA: France; GEO: Georgia; GRE: Greece; HUN: Hungary; IRE: Ireland; ISR: Israel; ITA: Italy; LTU: Lithuania; LUB: Luxembourg; LUX: Luxembourg; LVA: Latvia; MAT: Malta; MDA: Moldova; MKD: North Macedonia; MNE: Montenegro; NDL: Netherlands; OOP: out-of-pocket; POL: Poland; POR: Portugal; ROM: Romania; SRB: Serbia; SPA: Spain; SVK: Slovakia; SVN: Slovenia; SWE: Sweden; SWI: Switzerland; TUR: Türkiye; UKR: Ukraine; UNK: United Kingdom.

Note: A household is impoverished if its total spending (consumption) is below the basic needs line after OOP payments (i.e. it can no longer afford to meet its basic needs) and further impoverished if its total spending is below the basic needs line (i.e. it is already unable to meet its basic needs) and it incurs OOP payments. The Netherlands cannot be compared to other countries because the data used do not include the annual deductible amount households pay OOP for covered health care; our simulations suggest that catastrophic health spending is underestimated by up to 1.8 percentage points in the Netherlands in 2015.

Source: WHO Regional Office for Europe (2023b).

It should be noted that in most countries, financial protection metrics cannot distinguish between user charges for statutory benefits versus other OOP expenditures (i.e. direct payments), though there are some exceptions, for example, Japan (Hashimoto & Tokunaga, 2021).

Unintended effect 2: unmet need for health care

While some households experience financial hardship due to user charges, some simply are unable to use services altogether or use fewer services than needed because they cannot afford to pay user charges. These households are considered to have experienced unmet health care needs due to the cost of care. It should be noted there are other nonfinancial causes of unmet need, including a lack of available services and waiting times, among others (Fiorillo, 2020). However, financial reasons are often cited when people do not use health services. Fig. 2.4.4 shows unmet need due to cost, distance or waiting time for a selection of European countries. Low-income individuals are particularly vulnerable to experiencing unmet needs, especially when compared to the wealthiest residents of the same country.

Unmet needs naturally have consequences for health outcomes, though it can be challenging to draw direct links between the use of health services and health outcomes (Lagarde & Palmer, 2008). Self-assessed unmet need is correlated with worse future health outcomes (Gibson et al., 2019). Low-income populations are at a greater risk of poor health outcomes due to cost, showing the greatest reductions in health service utilization from implemented user charges (Swartz, 2010). A study of patients with chronic conditions found that, among those whose medication co-payments were raised, patients living in high-income areas were more likely to continue taking their medications than those living in low-income areas, exposing nonadherent patients to the risk and associated expenses of future medical complications (Swartz, 2010).

Policy relevance and conclusions

Protective mechanisms

There are a variety of approaches that can be used to protect people from the adverse consequences of user charges outlined above. Many of these can be considered under the broad umbrella of coverage policies.

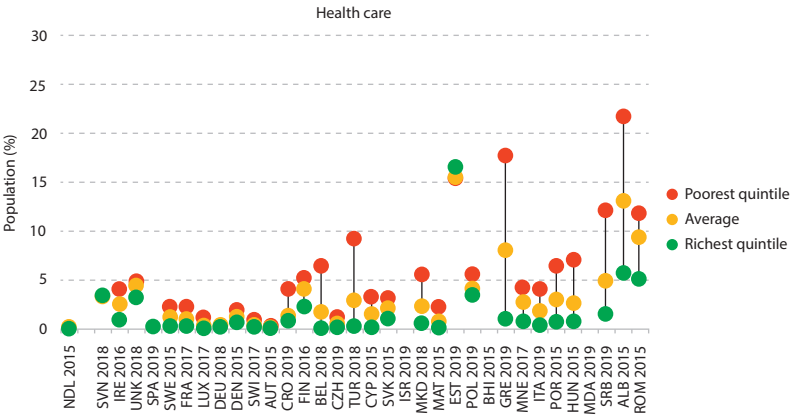


Fig. 2.4.4 Low-income individuals are particularly vulnerable to experiencing unmet needs for health care due to cost

ALB: Albania; AUT: Austria; BEL: Belgium; BIH: Bosnia and Herzegovina; CRO: Croatia; CYP: Cyprus; CZH: Czechia; DEU: Germany; DEN: Denmark; FIN: Finland; EST: Estonia; FRA: France; GRE: Greece; HUN: Hungary; IRE: Ireland; ISR: Israel; ITA: Italy; LUX: Luxembourg; MAT: Malta; MDA: Moldova; MKD: North Macedonia; MNE: Montenegro; NDL: Netherlands; OOP: out-of-pocket; POL: Poland; POR: Portugal; ROM: Romania; SRB: Serbia; SPA: Spain; SVK: Slovakia; SVN: Slovenia; SWE: Sweden; SWI: Switzerland; TUR: Türkiye; UNK: United Kingdom.

Notes: Countries are ranked from low to high by the incidence of catastrophic health spending. For catastrophic health spending, the Netherlands cannot be compared to other countries because the data used do not include the annual deductible amount households pay OOP for covered health care; our simulations suggest that catastrophic health spending is underestimated by up to 1.8 percentage points in the Netherlands in 2015. Health care refers to “medical examination or treatment”. Data on unmet need are for the same year as data on catastrophic health spending, except for Albania (2017) and the United Kingdom (2018). Unmet need quintiles are based on income.

Source: Eurostat (2023) (European Union statistics on income and living conditions).

We identify and discuss four of these briefly below: exemptions and reduced co-payments; co-payment caps; price control and regulation; and voluntary health insurance (VHI).

Exemptions and reduced co-payments

The most straightforward approach to limit the risk of financial hardship caused by user charges is to create exemptions. Exemptions can be applied in a variety of ways. In some countries, people at a particularly high risk of financial hardship or frequent users of health care services are exempt from all user charges. In others, people are eligible for exemptions based on their age or occupation. Still, people may be exempt only for particular goods or services. For example, it is very common that someone with a particular disease may be exempt solely from user charges for all services related to treating that condition.

There are also instances where people are eligible to pay reduced co-payments, though they still must pay some nominal amount. In Ireland, low-income people and other groups based on age and health status are eligible to pay a low fixed co-payment for prescription medicines, rather than a percentage-based co-payment which may be more expensive (Thomson, Cylus & Evetovits, 2019).

One challenge is that it can be difficult to identify people who are most at risk of experiencing financial hardship due to data issues. To identify who experiences financial hardship and who would benefit from exemptions, one needs up-to-date information on things like a household's income or employment status, which, if available at all, may only be so with a delay. For example, someone's employment status may not be available at a health facility level. Making such data available for these purposes can be costly. Additionally, in many cases, there are administrative hurdles to becoming recognized as exempt. This may result in people who are eligible for exemptions not receiving them, leaving them vulnerable to the burden of OOP payments.

Co-payment caps

Another commonly used mechanism is a co-payment cap or, alternatively, a co-payment maximum. In this case, individuals must pay user charges up until reaching a certain amount of spending, after which user charges are no longer required. This maximum can be an absolute amount (e.g. no more than € χ per individual spent) or a relative amount (e.g. no more than a certain percentage of gross annual income spent

OOP). For example, in Austria, there is an income-related cap set at no more than 2% of the net annual income of the person in the household who pays for contributions to the social insurance system (WHO Regional Office for Europe 2023a, 2025b).

In Belgium, there is an OOP maximum, referred to as maximum billing, but the level varies across households. The maximum billing system places a ceiling on the amount spent in co-payments by a household per year. All households are eligible for the maximum billing system, with the ceiling dependent upon household income. Low-income households, children and those with a chronic illness are eligible for lower maximum billing ceilings as a form of financial protection (Bouckaert, Maertens de Noordhout & Van de Voorde, 2023).

A cap might be applied to all spending on public health services, but there are often examples where the cap is applied to some services and not others. For instance, Cyprus has previously had an income-related cap which is determined by household income and number of children. However, this cap only applies to services provided in public facilities and excludes outpatient prescription medicines (Thomson, Cylus & Evetovits, 2019; Kontemeniotis & Theodorou, 2021).

Some might consider deductibles to be a form of OOP caps. Deductibles are user fees where patients are responsible for paying for covered care up to a certain fixed amount, after which their insurance will kick in. Insurance may provide full coverage (covering 100% of costs, in which case it is the same as an OOP cap) or partial coverage after reaching the deductible. In Switzerland, there is a compulsory annual deductible, after which users still pay a 10% co-payment on any future health care charges (de Pietro et al., 2015). With some health insurance providers, users can also opt to have a higher deductible and pay lower premiums. Total user charges (deductibles and subsequent co-payments) are eventually capped at a certain level depending on the size of the deductible. Given that most of the time deductibles do not offer a hard cap, they may be better thought of as simply a type of user charge (i.e. paying the full price up to some amount) rather than a protective mechanism.

Price control and regulation

In settings where health care users pay percentage-based co-payments, the price of a service has an effect on the risk of financial hardship. For example, 10% co-payments for a €5 medicine versus a €500 medicine

will invariably mean very different levels of spending for an individual. There are mechanisms to control price growth, such as the use of health technology assessment (HTA) which are one tool that can enable purchasers to put some downwards pressure on medicines and medical technology prices, which go beyond the scope of this chapter (but see Chapter 2.2). Nevertheless, consumer prices need not reflect purchaser prices. It is important to highlight that variations in consumer list prices mean that individuals can face different risks of financial hardship depending on whether their condition is priced high or not.

VHI

Though it is not widely used, complementary VHI can be used to reimburse households for the cost of user charges (see Chapter 1.3). The risk of relying on VHI to protect households from the consequences of user charges is that, in many settings, only people who can afford to take up complementary VHI do so unless governments subsidize (or otherwise cover) VHI premiums. Slovenia has historically been an exception. In Slovenia up until 2024, the vast majority of residents voluntarily enrolled in a complementary VHI scheme to pay their co-payments. This meant that in practice, there was virtually no exposure to otherwise high co-payments (Albreht et al., 2021). While this system was advantageous from the perspective of ensuring financial protection, it raised questions about the purpose of having user charges in the first place. As of January 2024, Slovenia abolished co-payments and replaced them with a pre-paid levy to raise additional public funds. By doing this, Slovenia managed to eliminate VHI without substantial increases in out-of-pocket spending or catastrophic spending levels (Šarec E, Jošar D, 2025).

Evidence in practice: successes and failures in user charges implementation

Countries have implemented a number of user charge policies in recent years with varying success.

For example, Latvia introduced user charge exemptions in 2009 for its poorest households and further extended them in 2010 to include poor households. During this period, the country experienced a drop in catastrophic health care spending among the poorest quintile (Taube, Vaskis & Nesterenko, 2018). This change was successful in protecting poor users from experiencing additional financial hardship due to

health care costs. However, in 2012, Latvia rolled back on these exemptions due to budgetary constraints, leading to a rise in catastrophic health care spending among the same quintile in 2013.

Several countries have tried to add small, fixed user charges to discourage unnecessary care and slow the rate of expenditure growth, but this strategy can also have unintended consequences. In 2004, Germany implemented a €10 user charge for a patient's first outpatient visit of every fiscal quarter. At the same time, Germany replaced exemptions for low-income users with annual spending caps based on income. The total rise in OOP spending coming from these changes led to an increase in catastrophic spending on health care in the nation (Siegel & Busse, 2018). Additionally, there was an increase in the number of patients who avoided or delayed seeing a doctor because of the charge, especially among young adults and low-income patients (Rückert, Böcken & Mielck, 2008). The user charge was abolished in 2012, and catastrophic spending subsequently fell, but still remained elevated due to the concomitant abolition of exemptions.

User charges are used in nearly all countries but they are particularly common in LMICs that struggle to generate sufficient funding for health from domestic government resources. However, evidence has shown in these contexts that reducing user charges in LMICs is associated with better health outcomes, lower mortality, and improved chronic disease management (Qin et al., 2019). Several studies attribute these improved outcomes to increased access to care due to lower user charges (McKinnon et al., 2015; Sood et al., 2014; Lamichhane, Sharma & Mahal, 2017). Although making progress towards universal health coverage may be more difficult in LMICs due to a lack of fiscal space, prioritizing it can prove beneficial for population health.

Policy lessons

User charges are a common, though as we have discussed in this chapter, also undesirable feature of health financing systems. While user charges are intended to steer health care consumption and raise revenue, alternative mechanisms may prove more effective at achieving these goals with fewer drawbacks. Implementing user charges can contribute to inequities in health care access, creating a financial barrier to care and contributing to unmet health care needs and financial hardship. Individuals with chronic health conditions or other severe

conditions can be disproportionately impacted by user charges, both in terms of their health and finances (Swartz, 2010). It is important to consider the objectives of user charges, and whether user charges actually achieve these goals, in conjunction with their possible unintended effects, especially among vulnerable populations.

Alternative mechanisms can prove better at accomplishing the same goals as user charges without the detrimental effects. For example, referral systems (also referred to as gatekeeping) can be an effective way to steer patients to high-value care and minimize waste while also ensuring that patients are seeking appropriate care for their health concerns (McIntyre & Meheus, 2013). Another strategy is to target providers, rather than patients, with information and incentives to steer patients towards more cost-effective care (Chernew et al., 2021).

If user charges are deemed necessary for a health system, perhaps for political reasons, there are ways to implement them while still being mindful of equity and financial protection. Indeed, even looking across Europe, one can see countries with comparable reliance overall on OOP spending to finance the health system but vastly different rates of catastrophic spending. For example, in both Spain and Romania just over 20% of health spending is paid for OOP, but catastrophic spending in Spain is under 2% and in Romania it is over 12%. These differences can largely be explained by these countries' different approaches to co-payment policy (WHO Regional Office for Europe, 2023a).

Exempting users who are most likely to experience financial hardship can prevent those who are on low income or have chronic conditions from facing high amounts of user charges. Additionally, when applied to all services, caps can be an effective method of limiting OOP costs. To prevent high spending on costlier services or medicines, fixed co-payments are a better alternative to percentage-based co-payments.

User charges can act as barriers to care, preventing vulnerable groups from seeking health care due to costs. While it is one of the most common strategies to attempt to steer health care and keep expenditures low, the wide use of user charges does not necessarily mean that it is the best or most effective policy to achieve these goals. Equitable reform or alternative policies may prove better at decreasing unmet health care needs and improving health outcomes.²

² Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

Additional resources

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2.5 *Long-term care: its financing and provision*

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Key messages

Chapter 2.5 sets out how long-term care (LTC) is provided and how it is paid for. LTC refers to a broad package of personal, social and medical services provided over extended periods of time which may be delivered by care professionals or by informal care givers. Key learning includes that:

- Population ageing, particularly in advanced economies, creates growing demands for LTC.
- There are inequities in the need for and access to LTC. Older people, women, those with lower incomes and lower levels of education are all more likely to need care, but less likely to have access to it.
- Funding arrangements for LTC are problematic in many countries:
 - voluntary insurance and out-of-pocket (OOP) payments commonly fill public coverage gaps but create inequities;
 - asset-tests for eligibility for publicly funded care are essentially regressive wealth taxes due to the unequal distribution of LTC needs;
 - encouraging for-profit provision theoretically fosters competition, availability and responsiveness but the pressures to generate profits can jeopardize quality and safety.
- Countries face urgent pressures on LTC and could usefully consider:
 - increasing public expenditure and broadening the funding mix for LTC;
 - better, fairer pooling of resources across generations;
 - revenue sources independent of payroll contributions since labour markets as a revenue base will shrink at the same time that demand for ageing-related LTC increases;

- better data and indicators to assess access, quality and value for money;
- patient-centred and coordinated approaches to LTC.

Introduction

In virtually all countries around the globe, and especially in advanced economies, populations are ageing rapidly due to declining fertility and increasing longevity. In 2018, for the first time ever, the worldwide population aged 65 years and older surpassed children under 5 years old (United Nations, 2019). Longer overall life expectancies are a remarkable achievement. Yet, globally, between 2000 and 2019, life expectancy increased faster than healthy life expectancy (a measure of whether years of life are spent in good health) for both men and women (WHO, 2020). According to Eurostat, on average across the 27 Member States of the EU, people aged 65 years old can expect to live another 20 years, but only 10 of those years will be spent in good health. Older people living with disability and in ill health may eventually struggle with everyday activities, from getting dressed, to shopping or going for a walk, and may at some point require a range of personal care and assistance services that is commonly referred to as LTC.

At the same time that population ageing is likely to lead to greater demands for health and LTC, ageing will also introduce stress on the financing and availability of care. The old-age dependency ratio – the number of people aged 65 years old or older as a percentage of the number of people aged 20 to 64 years old – is projected to jump from 30% in 2015 to more than 50% in 2050 on average across Organisation for Economic Co-operation and Development (OECD) countries (OECD and KIPF, 2020). This will create unprecedented pressures on economies, societies and governments. In order to maintain current public debt-to-gross domestic product (GDP) ratios, tax revenue would need to increase by between 4.5 and 11.5 percentage points of GDP by 2060 in G20 countries just to counteract the impact of ageing (Rouzet et al., 2019).

Economies and societies are also changing in other ways, potentially further hindering the financing and provision of LTC. Social structures are changing, with childless couples, single-parent families, divorce and single-adult households all on the rise. These trends could lead to fewer

people being able, or willing, to care for their older relatives. On the other hand, networks of loosely connected family members from different marriages, partnerships and generations may emerge, with fresh approaches to cohesion and solidarity. The nature of work is also evolving, with non-standard forms of employment on the increase, from self-employment to temporary contracts (OECD, 2020a). Along with small but rising numbers of people in new forms of employment such as platform and casual work, these workers have less access to social protection and make fewer contributions over their careers. It is possible that medical progress and technological innovation, such as in remote monitoring and assisted living, will help alleviate the strains on families caring for older relatives and friends (OECD, 2020c), but that remains to be seen.

Against this challenging backdrop, we provide an overview of how LTC is defined, how it is provided, who pays for it and how, and, finally, how we might assess its performance, in terms of quality, access and value for money. Throughout the chapter, we provide examples of international approaches to designing and delivering LTC in old age, illustrating broad heterogeneity across countries and even regions. We conclude with priorities for research and policy. Although people of any age can become dependent on others through illness or disability, this chapter focuses on people who are aged 65 years or older.

In this chapter, we focus on what is commonly referred to as social LTC, as other parts of this book deal in greater detail with health care. It is the fact that LTC has a social component that makes it quite distinct from other types of health care. For example, as discussed in more detail below and in Chapter 3.6, in many countries LTC is not solely the responsibility of the Ministry of Health (often responsibilities are shared with the Ministry of Social Affairs), and many LTC services are not provided by licensed medical staff but by personal carers and families. Moreover, unlike with medical care, where most OECD countries have near-universal coverage, eligibility for LTC is contingent on onerous needs assessments (including multiple administrative procedures), and OOP costs are often tied to care recipients', and sometimes their relatives', income and wealth.

What is LTC?

LTC includes personal care, assistance service and social activities as an individual ages and becomes more dependent on others. As individuals

grow older, their health deteriorates and they are more likely to need help from other people to carry out the activities that make up their daily lives, and which most of us take for granted. These activities include bathing and getting dressed as well as housekeeping tasks, like cleaning and shopping. As older people become more dependent, they may also find it difficult to maintain social relationships and participate in their community; for example, attending a community club or going out to meet friends. Finally, people who are dependent on others often need ongoing medical care to manage, commonly multiple, chronic conditions and ensure that they remain as healthy as they can be.

In this chapter, our definition of LTC encompasses personal care, assistance services and social activities, for periods of over six months or until end of life. Personal care services seek to provide support for activities of daily living (ADLs) including eating, bathing, washing, dressing, getting in and out of bed, and getting to and from the toilet and managing incontinence. Assistance services look to help individuals with instrumental activities of daily living (IADLs), such as shopping, laundry, vacuuming, cooking and performing housework, managing finances and using the telephone, among others. To prevent social isolation and further deterioration of physical and mental health, social care services may promote community activities whose primary purpose is social and leisure. This definition is slightly different from the definition of LTC in the System of Health Accounts (SHA) (and the definition used in Chapter 3.6), as it excludes nursing/medical care and furthermore restricts the target population to those aged 65 years old or older (OECD, Eurostat & WHO, 2017). Rehabilitation services are typically considered medical/nursing care and are thus not discussed here.

How is LTC provided?

LTC is provided in a variety of ways across countries and subnational areas. Differences in how LTC is organized and delivered stem in large part from social norms regarding whose responsibility it is to care for older populations who become dependent on others. In some countries and regions, the responsibility falls first on spouses and children, with states acting as a safety net only for the most vulnerable groups, while in others LTC is considered a collective responsibility, with

governments typically taking a leading role (Colombo, et al., 2011). Very generally, LTC can be provided: by formal and informal carers; in different settings, including the care recipient’s home and outside it; by public and private providers; and in kind (i.e. services) and in cash.

Who provides LTC?

Formal carers

Formal LTC workers are paid staff – typically nurses and personal carers – who provide care and/or assistance to people limited in their daily activities at home or in institutions, excluding hospitals (OECD, 2020c). In 2016, on average there were five LTC workers per 100 people aged 65 years and over in 28 OECD countries, ranging from 13 workers in Norway to less than one per 100 older people in Greece, Poland, and Portugal (see Fig. 2.5.1). On average, across OECD countries, over 70% of formal LTC workers are personal care workers. Personal care workers include formal workers providing LTC services at home or in institutions (other than hospitals) who are not qualified or certified as nurses. Personal care workers provide routine personal care, such as bathing, to older, convalescent or disabled persons. Most workers have obtained a high school diploma or attended vocational schools, but 16% have lower education. LTC workers generally have lower qualifications than health workers do.

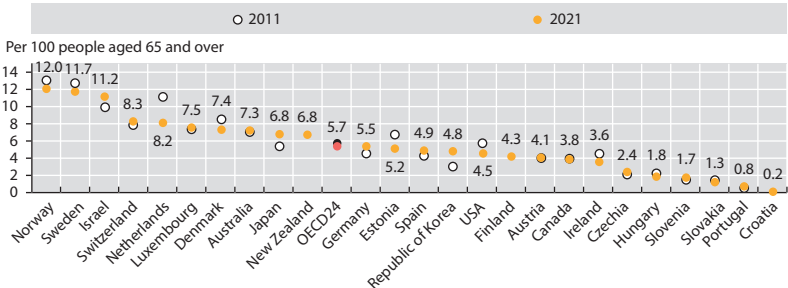


Fig. 2.5.1 On average, OECD countries have five formal LTC workers per 100 people aged 65 years and over

OECD: Organisation for Economic Co-operation and Development.

Note: For New Zealand, latest data refer to 2018.

Source: OECD Health Statistics (2023).

Working conditions in this sector tend to be poor, which disproportionately affects women since, on average across the OECD, women hold about 90% of the jobs in the LTC sector. Almost half of LTC workers in the OECD (over half in northern and central European countries) work part time and over a fifth of declared formal carers, on average across the OECD, are foreign-born (OECD, 2020c). In addition, half of LTC workers experience shiftwork and almost one quarter are on temporary contracts. While the work tends to be demanding, both physically and mentally, pay is often low (Rapp, Ronchetti & Sicsic, 2021).

Informal carers

The definition of an informal carer is not straightforward. The two cornerstones of the definition are usually that: (i) an informal carer is a family member, close relative, friend or neighbour; and (ii) carers are non-professionals who did not receive qualifying training to provide care (even though they may undertake special training). Definitions tend to exclude paid non-professional carers providing care in private households, such as undeclared carers working in the “grey economy”. The extensive use of live-in, and to some extent live-out, migrant care workers, whose status lies between the two distinct categories of formal and informal carers, can make the line blurry between formal and informal caregiving.

Many older people who struggle with everyday activities may either prefer, or have no choice but, to find informal support in their partners, children, friends and neighbours. Informal carers are people providing any help to older family members, friends and people in their social network, living inside or outside their household, who require help with everyday tasks. These informal carers are generally the first line of support for older people, and in some countries, informal care is the most prevalent form of support (Colombo, et al., 2011). An average of 14% of individuals aged 50 years old and older in 18 OECD countries report providing informal care at least weekly (OECD, 2020c) (Fig. 2.5.2). As with informal LTC, women make up the majority of informal caregivers (Fig. 2.5.3).

Formal versus informal care

Formal and informal care can either substitute for or complement each other, depending on the country and availability of various forms of formal care. Findings from the USA suggest that increased paid home

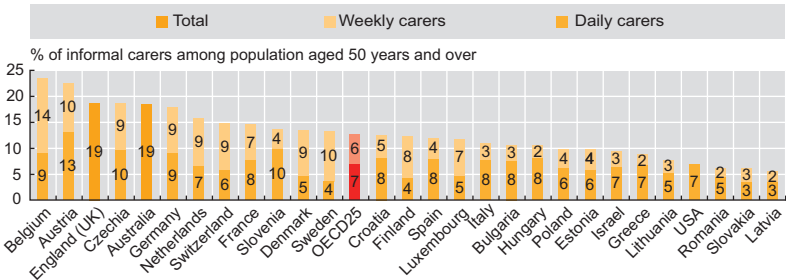


Fig. 2.5.2 Across 18 OECD countries, more than 1 in 10 people aged 50 years and older report providing informal care at least weekly

ELSA: English Longitudinal Study of Ageing; HRS Health and Retirement Study; OECD: Organisation for Economic Co-operation and Development; SDAC: Survey of Disability, Ageing and Carers; SHARE: Survey of Health, Ageing and Retirement in Europe.

Note: The definition of informal carers differs between surveys. Data are for 2019 (or nearest year).

Sources: SHARE, wave 8 (2019–20); SDAC (2018) for Australia; ELSA, wave 9 (2018–19) for the United Kingdom; HRS, wave 14 (2018–19) for the USA.

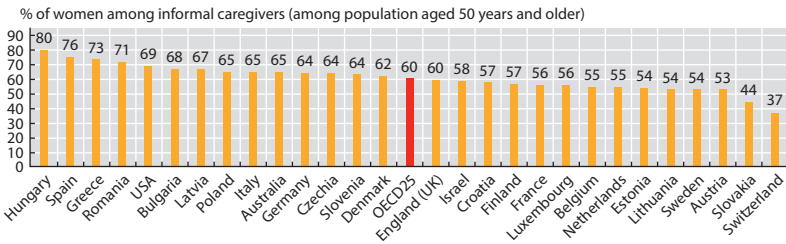


Fig. 2.5.3 Women are most likely to take on the role of informal carer

ELSA: English Longitudinal Study of Ageing; HRS Health and Retirement Study; OECD: Organisation for Economic Co-operation and Development; SDAC: Survey of Disability, Ageing and Carers; SHARE: Survey of Health, Ageing and Retirement in Europe.

Note: The definition of informal carers differs between surveys. Data are for 2019 (or nearest year).

Sources: SHARE, wave 8 (2019–20); SDAC (2018) for Australia; ELSA, wave 9 (2018–19) for the United Kingdom; HRS, wave 14 (2018–19) for the USA.

care primarily went to people who were already receiving a greater amount of informal care from their adult children (Liu, Manton & Aragon, 2000; Langa et al., 2001). In Europe, informal care tends to be a substitute for formal home care and paid domestic help, and informal care is more prevalent in countries where formal care is not as well developed or comprehensive (Van Houtven & Norton, 2004; Bonsang, 2009; Bolin, Lindgren & Lundborg, 2008). While typically unrecognized and uncompensated, informal care is not without costs. Families and friends that provide support to dependent older individuals may suffer physical and mental stress, and are more likely to drop out of the labour market or reduce working hours. Income levels of working-age family carers are also likely to decline as a result of providing care.

Where is LTC provided?

The provision of LTC occurs in diverse settings and at different levels of intensity. Broadly, LTC can be home-based, facility-based or community-based. Settings include the older person's own home, the home of relatives, friends or other individuals (e.g. a foster home), assisted living facilities, institutions and nursing homes, as well as community and day care centres. Services vary from alarm systems to constant personal care 24 hours per day seven days per week, depending on the older person's specific needs and limitations. Different locations are considered better suited for different needs, limitations and preferences, with intensity and composition of care playing a key role in determining which location is better suited (OECD, Eurostat & WHO, 2017).

In most countries, LTC for older people with less severe limitations will first be provided in their own home. If and when independent living in the home environment is no longer possible, older people may move into assisted living facilities where LTC workers are available onsite or on-call. If the older person becomes more dependent, they may be moved to an institution with permanent LTC staff providing predominantly nursing care or help with ADLs. Institutions that provide round-the-clock care may also have day care wards, where older people who are not staying in the institution can spend the day, thus providing respite for informal carers or formal home care workers.

In recent years, in response to both limited budgets and population preferences, many countries have started supporting the idea of a

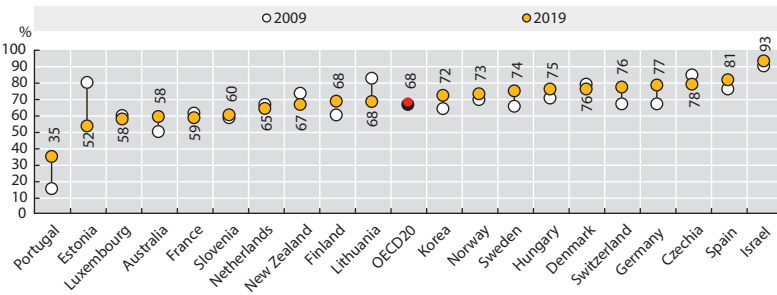


Fig. 2.5.4 A majority of OECD countries are moving LTC from residential facilities into the community

OECD: Organisation for Economic Co-operation and Development.

Source: OECD Health Statistics (2021).

“deinstitutionalization” of LTC: promoting home- and community-based care rather than institutional care. Besides enhancing home-based services, these countries have promoted the use of community-based facilities such as hospices for terminally ill people, day-care centres and homes for the disabled. More than half of OECD countries have started to move LTC out of residential facilities, and towards the community (OECD, 2020c). Between 2007 and 2017, the percentage of LTC recipients who received care at home increased 4 percentage points, from 64% to 68% (OECD, 2019) (Fig. 2.5.4).

Public versus private provision

LTC can be provided by public (be it national or subnational governments), not-for-profit (volunteers and organizations managed or owned by religious or civil society groups) or for-profit (privately owned) providers (Colombo, et al., 2011). Virtually all European countries allow voluntary and private provision of LTC (see the comparative tables from the Mutual Information System on Social Protection, www.missoc.org/missoc-database/comparative-tables/), but they differ widely in how they do so. Most commonly, a form of purchaser-provider split is used, so that governments continue to fund LTC services but provision is devolved to voluntary or private providers in some form of managed market or quasi-market (Fine & Davidson, 2018). The private sector

may also be involved in financing LTC, through insurance (see the *How is LTC financed* section).

The data on public, not-for-profit and for-profit provision of LTC are sparse and outdated, but estimates for Europe and North America suggest there is significant heterogeneity across countries and settings (Table 2.5.1). For-profit provision is highest in England and the USA, followed by Brussels and Germany. Non-profit provision is highest in the Netherlands and for home care in Austria.

The main rationale for private provision is competition, which in turn is thought to lead to more cost-efficient care that is also better aligned with the preferences of care recipients and their advocates (family and friends). On the other hand, there is concern that for-profit providers may put competitive advantage and profit margins ahead of quality and safety, and that regulating and auditing private actors is both costly and challenging (Fine & Davidson, 2018; Harrington et al., 2017; Chon, 2019; Maarse, Jeurissen & Ruwaard, 2015). Whether or not to promote not-for-profit and for-profit provision, i.e. to facilitate the marketization of LTC, is not a trivial decision and the way it is operationalized and governed, for example, through contracts, is also not straightforward (Rodrigues, Leichsenring & Winkelmann, 2014). There are many forms of non-public provision, including contracting out the provision of specific LTC services (e.g. personal care) to single providers, providing vouchers to care recipients to spend how they see fit, and establishing lists of certified providers from which older people and their advocates can choose from (Fine & Davidson, 2018).

Help to access LTC provision: in-kind support versus cash

LTC can be provided in kind (as goods, commodities or services) or in cash (as money transfers to the care recipient, the household or the informal carer). In-kind support includes care provided by formal carers (regardless of setting) as well as special aids and equipment. In cash support can be used to purchase or obtain care services from formal public, voluntary and private providers, as well as to compensate informal carers, depending on the specific regulations governing cash benefits. In some countries, as in France and Belgium (Flanders), cash transfers (often in the form of vouchers) can only be used to pay for LTC services from accredited and certified providers, while in

Table 2.5.1 *Higher-income countries tend to favour a mix of public, non-profit and for-profit provision of LTC*

Country	Public provision		Not-for-profit provision		For-profit provision	
	Institutional (%)	Home care (%)	Institutional (%)	Home care (%)	Institutional (%)	Home care (%)
Austria	55	8	24	91	21	1
Belgium (Flanders)	36		52		12	
Belgium (Wallonia)	26		21		52	
Belgium (Brussels)	24		13		62	
Canada	32	–	31	–	37	–
Czechia	59		38		3	
United Kingdom (England)	7	14	13	11	80	74

Table 2.5.1 (*cont.*)

Country	Public provision		Not-for-profit provision		For-profit provision	
	Institutional (%)	Home care (%)	Institutional (%)	Home care (%)	Institutional (%)	Home care (%)
Finland	56	93	–	–	44	7
France	23	15	55	65	22	20
Germany	5	2	55	37	40	62
Italy	30		50		20	
Netherlands	0		80		20	
Slovakia	75		23		2	
Spain	23		24		53	
Sweden	75	–	10	–	15	16
Switzerland	30		30		40	
USA	6	–	24	–	70	–

Note: For certain countries only aggregate data are available and it is not possible to separate institutional and home care; in Spain, no clear distinction can be made for not-for-profit and for-profit providers.

Sources: Estimates for Canada and USA from Harrington et al. (2017); all others from Rodrigues, Huber & Lamura (2012).

others, as in Austria and Czechia, transfers are provided directly in cash and there is little control over how the cash is used (i.e. can be used to pay for non-LTC goods and services). Most countries have multiple forms of LTC benefits and schemes, some of which are provided in kind and some in cash, although some countries rely exclusively on cash benefits or purely on in-kind services (Cravo Oliveira Hashiguchi & Llana-Nozal, 2020). In certain countries, such as Japan and Korea, LTC is typically provided in kind, but care can be provided in cash in remote areas where public LTC provision is more restricted (Colombo, et al., 2011; Cravo Oliveira Hashiguchi & Llana-Nozal, 2020). Both in-kind and cash schemes may require care recipients to share a part of the costs (Colombo, et al., 2011), as discussed further below.

Cash transfers are touted as a way to promote user choice and allow older people and their advocates to select the providers that best align with their preferences and needs. The Netherlands introduced a system of personal budgets in the late 1990s (Box 2.5.1) that in some circumstances also allow in-kind support. Cash transfers, depending on the exact rules and regulations, can be easier to set up and have lower operational costs than services provided in kind (Creti & Jaspers, 2006). Limiting cash transfers may also be an easy response to tightening of budgets, but this may lead to higher out-of-pocket (OOP) spending for care recipients and their families, with potentially negative consequences for access and affordability. Indeed, in-kind services may be a better way to target scarce public support and to make sure public resources are used in the consumption of LTC goods and

Box 2.5.1 Personal budgets in the Netherlands

Personal budgets (*persoonsgebonden budget*, in Dutch) were introduced in the Netherlands in 1996 as a way to encourage the marketization of LTC and competition among new for-profit providers, as well as to promote user choice in line with individual needs and preferences (Rodrigues, Leichsenring & Winkelmann, 2014). Depending on the type of care needs older people have, they can apply for a personal budget from their regional care administration office (under the Chronic Care Act), their health insurance company (under the Health Care Insurance Act) or their municipality (under the Social Support Act) (Government of the Netherlands, 2021).

services and not, as may be the case with cash transfers, for purposes other than care.

Older people with more severe LTC needs may use a personal budget to contract home care but only if the costs of home care do not exceed the costs of institutional care. If requesting their budget from their regional care administration office, applicants must create a budget plan describing which services they intend to purchase and from whom, and must sign contracts with each care provider; they can combine the budget with care in kind. Older people requesting their budget from their health insurance company or municipality must explain why they want a personal budget, and the company or municipality will then assess the quality of the services and equipment that is purchased. For budgets agreed by the regional office or municipality, payments are made directly by the Social Insurance Bank (or SVB, which is the organization that implements national insurance schemes) to providers from the care recipient's personal budget (Government of the Netherlands, 2021).

Under budgets agreed by the municipality, funds can be used to compensate informal carers such as relatives and friends – provided the particular municipality allows this within its own rules and as long as a contract is established between the parties stipulating what care will be provided and for what payment (Eurocarers, 2023). Furthermore, payments to informal carers from personal budgets are considered taxable income, but they do not cover social or pension contributions (Eurocarers, 2023).

Between 2005 and 2008 the number of personal budget holders in the Netherlands grew by an average of 28% every year (Maarse & Jeurissen, 2016). In 2014, around 120 000 people had personal budgets, but this number went down substantially to 38 500 in 2016 for a number of reasons (Kelders & de Vaan, 2018). The scheme is believed to be more susceptible to fraud, and the quality of care provided is difficult to control (Kelders & de Vaan, 2018). There have also been concerns that the budgets did not, despite expectations, entice new entrants into the LTC market, nor bring down total costs of care through competition. Rather, it would seem that personal budgets were used to compensate relatives and friends who were already providing care, that the budgets only partially substituted for in-kind care, and that people who would not otherwise have applied for care had applied for and been granted a personal budget (Rodrigues, Leichsenring &

Winkelmann, 2014). A recent analysis also found that recipients of the budgets did not have more independence, social participation nor a higher quality of life than those receiving help in kind (Marangos et al., 2020). Thus, despite its good intentions, the personal budget system has not been as successful in the long-term as hoped, in terms of marketizing LTC, increasing competition among new for-profit providers, and promoting user choice in line with individual needs and preferences.

How is LTC financed?

In many high-income settings, public sources cover at least some portion of LTC financing, but voluntary insurance and private payments often also play a significant role. In most OECD and EU countries (OECD, 2020b), the costs of LTC are covered to some extent either by a government scheme, at national or subnational level, or through compulsory insurance (mainly social insurance). Public schemes typically only partially cover the total costs of LTC, and so voluntary insurance and private payments (OOP) represent a nontrivial share of total LTC spending. Government schemes are used in Scandinavian countries, Australia, New Zealand and in Austria. Nordic countries typically have universal coverage under one single programme. Countries which have a dedicated social insurance scheme include Germany, Japan, Korea, the Netherlands and Luxembourg, whereas parts of Belgium arrange coverage mostly within the health system.

How much is spent on LTC, in total?

Spending on LTC varies, but tends to be higher in countries where government spending on health is higher in general. On average across the OECD, 1.5% of GDP was spent on all LTC services (health and social) in 2018, equating to around US\$ 760 per capita (adjusted for differences in price levels across countries; see Fig. 2.5.5) (OECD, 2020b). Spending data from the OECD generally cover both the health and social components of LTC. The health component includes help with ADLs (along with nursing care, like treating pressure ulcers), while the social component covers primarily help with IADLs (OECD, 2019). For some countries, the social part of LTC spending is not reported (but in some cases it is implicitly included under the

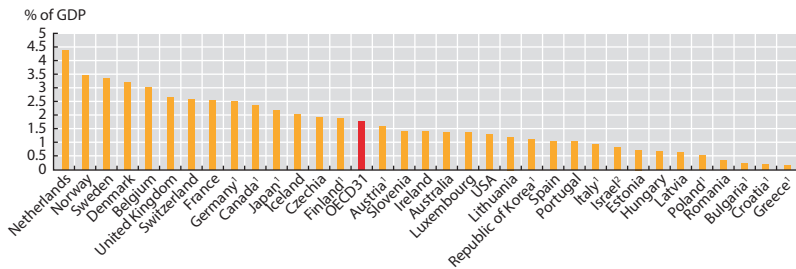


Fig. 2.5.5 Total spending on LTC as a share of GDP varies across OECD countries

Notes: 1. Country not reporting spending for LTC (social). In many countries this component is therefore missing from total LTC, but in some countries it is partly included under LTC (health). 2. Country not reporting spending for LTC (health). Data are for 2021 (or nearest year).

Source: OECD Health Statistics (2023).

health component). In some countries, various elements of private spending are also not reported.

Out of OECD countries, total spending on LTC as a share of GDP is highest in the Netherlands and Scandinavian countries, reflecting more developed formal LTC benefits, services and schemes. There is then a second group of countries (which include France, Germany, Japan and the United Kingdom) where total LTC spending accounts for 2% to 2.5% of GDP. A third group, composed mostly of south-eastern European and Latin American countries, spends significantly less on LTC, relying on unpaid or unaccounted informal caring. In countries that report on both health and social components of LTC spending, the health component accounts for around 70% of total spending, on average (OECD, 2020b). Total LTC spending has increased gradually in the last decades, both as a share of GDP and as a share of total health spending (OECD, 2020b).

As stated, governments and compulsory social insurance cover the bulk of the costs of LTC provision. Countries where total LTC spending is high also tend to have high shares of government spending (between 92% and 94%). Conversely, in Estonia and Portugal, public spending accounts for only 60% or less of total LTC spending (OECD, 2020b). The largest share of total LTC spending is devoted to nursing homes (mostly institutional care, although some nursing homes

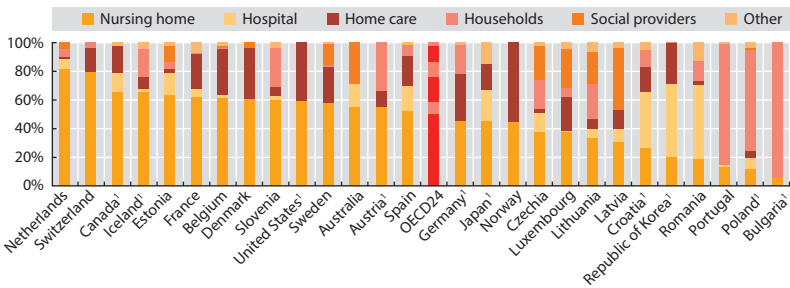


Fig. 2.5.6 The largest share of total LTC spending in OECD countries is on nursing homes

IADL: instrumental activities of daily living; LTC: long-term care.

Note: Countries not reporting social LTC. The category “Social providers” refers to providers where the primary focus is on help with IADL or other social care. Data are for 2021 (or nearest year).
Source: OECD Health Statistics (2023).

provide home care and help with IADLs), accounting for 80% of total spending in the Netherlands (see Fig. 2.5.6). By contrast, nursing homes account for only 20% of total spending in Korea and Portugal, two countries where total spending as a share of GDP is also lower. The heterogeneity in spending devoted to different types of providers is significant, with different providers playing more important roles in different countries (e.g. hospitals in Japan, social providers in Portugal, home care in Norway, etc.). Some countries provide cash benefits and allowances for family carers, a spending category (“households”) that can account for a significant share of total spending, as in Austria.

How much do individuals spend on LTC?

Costs and use of LTC varies, but the price for intensive and sustained support adds up quickly and can become catastrophic for individuals.

Data on aggregate spending on LTC provide limited insights into the OOP costs of LTC services for older individuals, and whether older people with LTC needs might be impoverished due to high OOP costs. LTC needs are difficult to predict, even at older ages and while many older people will never require formal LTC, some will need intensive and sustained support, the costs of which may add up over time (Muir,

2017). Moreover, and as previously discussed, LTC needs and use of services are not equally distributed among older populations. Importantly, in the context of OOP spending, survey data suggest the prevalence of LTC needs is higher among older people on lower incomes. It is thus appropriate to explore individual spending on LTC services, and to understand how aggregate spending is associated with individual affordability and protection from poverty, especially among those older people who most need care.

On average across 25 OECD and EU countries for which data are available, the total costs of LTC that older people could face if they did not have access to public social protection represent up to five times the median disposable income of individuals of retirement age or older (Fig. 2.5.7). Without public social protection, the majority of older individuals would not be able to afford LTC from their incomes alone, especially those on lower incomes. To protect older people with LTC needs from these potentially catastrophic expenses, most OECD and EU countries provide some level of public risk pooling, whether predominantly tax-funded (e.g. Finland), based on compulsory social insurance (e.g. Germany), or a mix of these two (e.g. France). The scope, breadth and depth of these public social protection systems for LTC vary widely across countries, with some providing universal comprehensive coverage (e.g. Luxembourg) and others providing targeted means-tested safety nets (e.g. USA) (Cravo Oliveira Hashiguchi & Llana-Nozal, 2020).

Older people with similar LTC needs often face significantly different OOP costs depending on their means, and where they live and seek formal care. Most countries will cover part of the total costs of LTC, but in most cases users will still need to contribute. Research based on a set of typical cases of LTC needs that has been used to achieve comparability across countries indicates that in most OECD countries, public social protection schemes would cover at least 60% of the total costs of care for moderate needs (Cravo Oliveira Hashiguchi & Llana-Nozal, 2020). The remaining share of costs – the OOP costs – are typically determined based on, often intricate, rules and calculations that can differ depending on the exact benefit and scheme that applies or the type of help provided (e.g. coverage for help with IADLs is often more limited). Many countries provide greater cost coverage

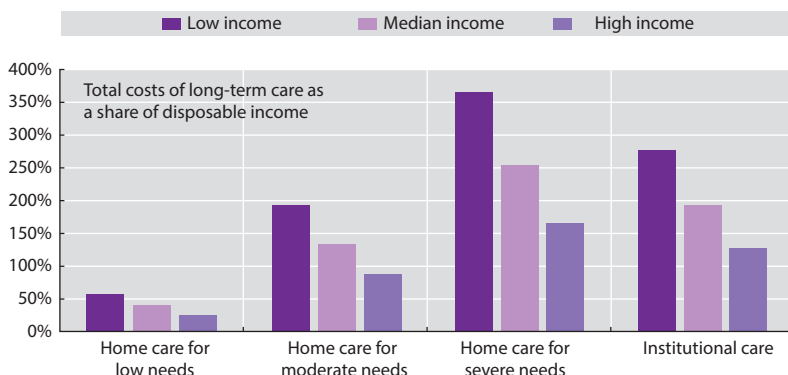


Fig. 2.5.7 Without public social protection, the majority of older individuals would not be able to afford LTC from their incomes alone

Note: Bars show averages for 25 countries in the OECD and EU. Low income refers to the upper boundary of the 20th percentile, and high income to the upper boundary of the 80th percentile. Low, moderate and severe needs correspond to 6.5, 22.5 and 41.25 hours of care per week, respectively. The costs of institutional care include the provision of food and accommodation, so are overestimated relative to home care.

Sources: OECD analyses based on the Long-Term Care Social Protection questionnaire and the OECD Income Distribution Database.

to older individuals with more severe LTC needs and lower means but in a few countries, due to ceilings on public support, the opposite is true. The large majority of LTC benefits and schemes, across countries, have means-tested coverage of costs (Table 2.5.2). The exact form of means-testing varies widely across countries, with some countries providing very comprehensive cost coverage and others providing no support whatsoever to older people with higher incomes and assets.

Due to differences in cost coverage across countries, needs and means, older people with similar LTC needs could face significantly different OOP costs depending on where they live and seek formal care. In a number of EU countries (e.g. Croatia and Latvia), older people with severe needs and median incomes would face OOP costs for home care that are higher than their income (Cravo Oliveira Hashiguchi &

Table 2.5.2 *Overview of the use of means-testing in public support for LTC*

	Assets-tested	Not assets-tested
Income-tested	Flanders (Belgium), Croatia, England, Tallinn (Estonia), France, Germany, Hungary, Ireland, South Tyrol (Italy), Japan, Lithuania, Netherlands, Slovenia, Spain, California (USA), Illinois (USA)	Vienna (Austria), Flanders (Belgium), Ontario (Canada), Tallinn (Estonia), Finland, France, Hungary, Reykjavik (Iceland), Korea, Latvia, Lithuania, Luxembourg, Slovakia, Sweden
Not income-tested	Croatia	Vienna (Austria), Flanders (Belgium), Ontario (Canada), Czechia, England, Finland, Germany, Reykjavik (Iceland), Ireland, South Tyrol (Italy), Latvia, Lithuania, Luxembourg, Slovakia, Slovenia, Spain

Note: Countries and subnational areas can belong to more than one category if they have multiple benefits and schemes.

Source: OECD compilation based on the Long-Term Care Social Protection questionnaire.

Llena-Nozal, 2020). In other places (e.g. Estonia, Slovenia and parts of the USA), OOP costs of home care for moderate needs would represent over half of median incomes among older individuals, leaving the other half to pay for basic costs of living, such as electricity and food. OOP costs of institutional care for severe needs are almost universally lower than OOP costs of home care for severe needs. While most countries have safety nets to protect the most economically vulnerable older people, many countries set eligibility thresholds far below international relative income poverty lines (e.g. 50% and 60% of median equivalized disposable income after social transfers in the OECD and EU respectively). High OOP costs are likely to lead older people to deplete their assets to pay for care, seek alternatives (like informal care) or forgo care altogether.

Some countries use asset-tests to determine eligibility and support levels granted to individuals who need LTC. Across OECD countries,

older people are more likely to have lower incomes (compared to their younger peers). However, they are also more likely to have accumulated assets over their lifetimes and thus have comparatively higher net wealth (Balestra & Tonkin, 2018). For this reason, and in response to budgetary constraints, some governments have adopted assets-tests to determine eligibility for and level of support from public social protection systems. Assets-tests are implemented in a myriad of ways across the OECD. Some systems protect assets below a certain threshold by excluding them from assets-tests and some exclude certain types of assets like an older person's primary residence (especially if the older person is receiving home care). More recently, some countries (e.g. France, USA) have sought to implement deferred payment agreements or reverse mortgages, whereby governments will pay for care but older individuals agree to use their assets (including their primary residence) to partly or fully repay the state at a later date (e.g. when they move to institutional care or when they pass away). Assets-tests need to be well-designed to avoid distorting saving behaviour. Furthermore, considering the unequal distribution of LTC needs, assets-tests can be considered a regressive wealth tax on those who need LTC.

Public coverage of the total costs of LTC is crucial. Without it, the majority of older people in the OECD and EU would not be able to afford the OOP costs of care without falling below relative income poverty lines. Social protection is especially vital in protecting older people from the very high costs of care for severe needs. However, public support does not completely eliminate the risks of income poverty associated with LTC in old age. Even with social protection, poverty risks are often still higher among older people with LTC needs than among the general older population (Cravo Oliveira Hashiguchi & Llena-Nozal, 2020).

LTC support: who needs it, and who receives it?

Due to data scarcity, it is difficult to determine who applies for, qualifies for and takes up public LTC support, who receives informal LTC and who has unmet LTC needs.

When an older person becomes dependent on others, they and perhaps their family and friends face the choice of seeking support from the state or finding other alternatives, such as informal care or support from carers in the grey economy (Fig. 2.5.8). Ultimately, if an older

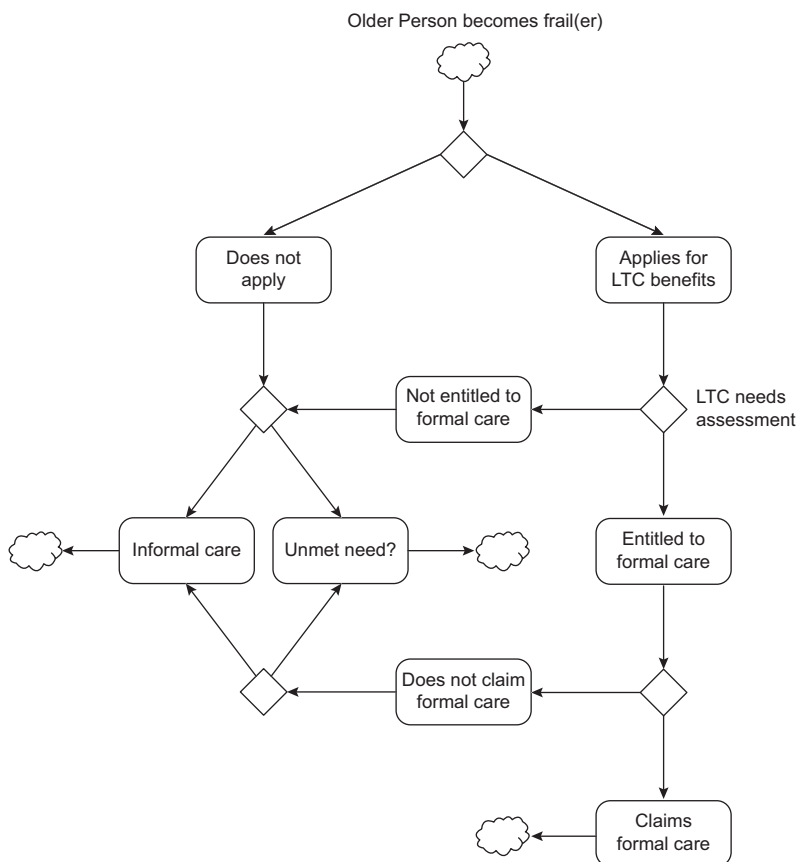


Fig. 2.5.8 Instruments and procedures used to assess LTC needs vary widely
LTC: long-term care.

Note: Clouds represent boundaries of the diagram (entries and exits into system); exit does not mean person cannot re-enter the system at a later point in time. Diamonds represent decision points.

Source: Authors.

person cannot find care, this may lead to unmet needs. Decisions to apply for public support may be driven by several factors, including awareness of public benefits and schemes, knowledge of where and how to apply, and availability of regional care administration offices, for example. If the older person does apply, a process of formal needs assessment begins. This may not be immediate and there may be

waiting times between requesting an assessment and receiving one. Once the older person's needs have been assessed, they may or may not qualify for public support. If they do qualify, the level of support they receive will likely depend on their needs but, potentially, also their means (income and net wealth). Once the level of support is determined, the older person and their advocates may choose to take it up or not. They may find it does not meet their expectations and seek alternatives.

Comprehensive and comparable data on the decision points in Fig. 2.5.8, and the reasons behind the decisions taken, are scarce, making it difficult to quantify, in any given year, the numbers of older people who: apply for public LTC support (which could be used as a proxy for self-assessed LTC needs); qualify for public support; take up public support; receive and/or prefer informal care; and have unmet LTC needs.

Assessments of LTC needs vary widely across countries

While a definition of LTC has been agreed to in the SHA, in practice there is a wide range of definitions implicit in needs assessments applied by countries, and in some cases, subnational areas. Assessments of LTC needs vary widely across countries, in terms of who undertakes the assessment, which types of needs are considered, the scoring systems used to rate the severity of needs, whether social structures and external factors are taken into account, how scores are aggregated and, finally, how scores relate to service and benefit levels (Cravo Oliveira Hashiguchi & Llena-Nozal, 2020). The determination of whether an older person is dependent on others and needs LTC is as much a result of their limitations with everyday activities as it is driven by needs assessments (Brugiavini et al., 2017).

Assessments of LTC needs are used by countries, and some subnational areas, to determine whether an older person has limitations that qualify them for public LTC benefits, services and schemes and may also be used to determine the level of support that older people qualify for. Several concepts have been used to describe the conditions that lead an older person to require LTC, including terms like vulnerability, frailty, comorbidity, disability and dependency (Brugiavini et al., 2017; Rodríguez-Mañas et al., 2013; Fried et al., 2004; De Vries et al., 2010; Pel-Littel et al., 2009). Definitions for these concepts

vary, and it is difficult to establish how they differ, how they relate to one another, and how they might be measured. One study found 20 instruments to measure frailty alone (De Vries et al., 2010). The most commonly used instruments are the Lawton Instrumental Activities of Daily Living Scale for measuring difficulties with IADLs, which gives a score between zero (totally dependent) and eight (totally independent), and the Barthel Index of Activities of Daily Living for measuring limitations with ADLs, which gives a score between zero (totally dependent) and 20 (totally independent).

There is no standardized, internationally recognized, instrument to determine whether an older person has LTC needs and how intense they are. Instruments and procedures used to assess LTC needs vary widely (Cravo Oliveira Hashiguchi & Llana-Nozal, 2020). Across OECD and EU countries, needs assessments use different combinations of ADLs, IADLs and even, in some cases, factors such as loneliness and self-assessed ability to cope with difficulties. For example, being aware of dangers and being able to have a social life are included in needs assessments in Belgium. In Croatia, Italy, Ireland and the Netherlands, social networks and external factors, such as the availability of an informal carer, are taken into account in needs assessments. In recent years, countries have revised their needs assessments to gauge not just physical limitations but also mental and cognitive impairments. For example, Austria included dementia explicitly in needs assessments in 2009 while Germany added cognitive and psychological impairments in 2017. These developments are significant, given that an estimated 19 million people in the OECD are living with dementia (OECD, 2018), and that instruments that measure only ability to perform ADLs and IADLs may miss important limitations that are driven by cognitive impairments (Bucks et al., 1996).

The way different limitations are combined to produce an overall level of LTC needs also varies across countries, and naturally implies distinct hierarchies of limitations. Different weights are used for different types of limitations and factors. For example, in Germany, the highest weights are placed on “self-sufficiency”, a category that comprises 13 indicators, and within which items such as eating, drinking and using the toilet have higher weights than others. Mobility (comprised of five indicators) has the lowest set of weights. In Lithuania, each factor contributes a specified amount to the overall composite score of needs, but factors are scored differently so that some implicitly

count more towards the final score. The final composite score of needs is used to categorize an older person in terms of the severity of their needs. The number of categories varies across countries. For many countries, the number of categories and levels is between three and five categories. Luxembourg is an exception, with 15 categories based on minutes of care needed per week (Cravo Oliveira Hashiguchi & Llana-Nozal, 2020). Some of the categories may not be eligible for any public support.

Countries also differ in terms of who is responsible for conducting the needs assessment. In Belgium and Finland, assessments are performed by multidisciplinary teams. In Latvia, assessments are conducted by general practitioners and social workers, while in Germany specialized doctors and nurses are involved. In Austria and England, assessments are based on a physician's evaluation. In Japan, a computer-aided initial assessment (based on an 85-item questionnaire) is used to assign each applicant to one of seven levels of LTC needs. The Japanese Care Needs Certification Board, a committee of medical and other professionals, then reviews the results and makes a final decision.

Assessments of LTC needs also vary within countries

Needs assessments are not always standardized within countries, which introduces variation at the subnational level. Austria, Germany and Luxembourg, for example, have nationwide instruments while in Italy, instruments are regional. France uses a standardized assessment tool nationwide but there seems to be variation across regions in the interpretation, generating differences in the number of beneficiaries. In Estonia, different agencies have different assessment scales and procedures. In Belgium, Canada and the USA there are both federal and regional benefits and schemes, with their own specific rules and regulations, including needs assessment instruments. In Portugal, there is one needs assessment scale for cash benefits and another for in-kind care. In Denmark, Finland, Iceland, Norway and Sweden, municipalities are responsible for conducting needs assessments and setting eligibility criteria, based on a set of guiding principles (e.g. universal care in Denmark).

Because there is no single internationally accepted and standardized approach to identify and measure LTC needs, cross-country comparisons of administrative data on the number of recipients reflect

differences in eligibility, scope and depth of public support. Administrative data on applications for, and results of, needs assessments would be very useful but these data are not available for the majority of countries. Existing cross-country estimates of the prevalence of LTC needs in older populations are thus based on survey data. The exact questions used vary across surveys, with some estimates relying on a single question to establish self-assessed needs, and other studies using some aggregation of self-reported limitations in ADLs, IADLs and physical functioning.

The World Health Organization estimates that, globally, at least 142 million people, equivalent to around 15% of those aged 60 years old or older in the world, lack the ability to meet basic needs (WHO, 2020). This estimate is based on three elements (ability to get dressed, to take medication and to manage money) in national surveys from 37 countries (together these countries account for 49% of the world's population aged 60 years old and older). The *2021 Ageing Report of the European Commission* estimates that 34% of individuals aged 65 years and older in the 27 EU Member States plus Norway are dependent and may require LTC (Directorate-General for Economic and Financial Affairs, 2021). The estimate is based on “self-perceived long-standing limitation in activities because of health problems [for at least the last 6 months]”, as reported in the EU Statistics on Income and Living Conditions (EU-SILC). A different estimate, also by the European Commission, indicates that 31% of people aged 65 years and older in 22 EU Member States were in need of LTC in 2019 (European Commission, 2021). This estimate uses data from the European Health Interview Survey or EHIS.

Responses to the Survey of Health, Ageing and Retirement in Europe (SHARE) indicate that, on average across 26 EU Member States, 16% of the population aged 65 years and older report at least one limitation in ADLs, 24% report one or more limitations in IADLs and closer to 30% report at least one limitation in either ADLs or IADLs (Fig. 2.5.9). There is wide variation across countries. For example, the percentage of older individuals reporting limitations in IADLs in the Netherlands and in Sweden are around 14%, while in Hungary and Romania, over 30% of older people report limitations in IADLs. Data from SHARE indicate that older people reporting limitations in ADLs and/or IADLs are more likely to be women, aged 80 years old or older, have lower levels of education, earn lower incomes and live in single households.

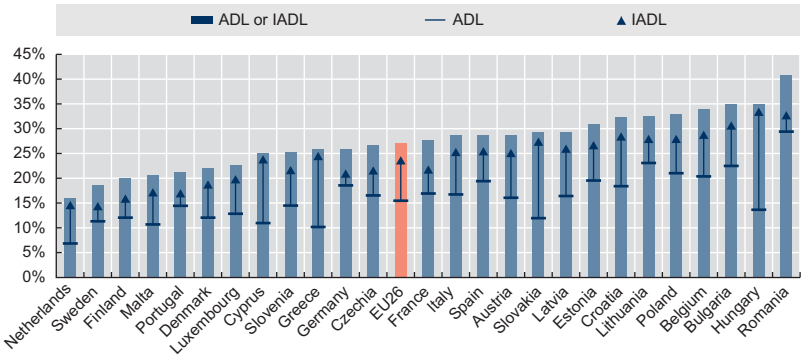


Fig. 2.5.9 Nearly a third of people 65 years and older in the EU report at least one ADL/IADL limitation

ADL: activities of daily living; IADL: instrumental activities of daily living; SHARE: Survey of Health, Ageing and Retirement in Europe.

Note: EU26 is the unweighted average of population-weighted national shares; data refer to 2015 for the Netherlands and 2017 for the rest of countries. Older people are those aged 65 years old and older.

Source: SHARE Wave 7.

Women, older people, those with less education and those who earn less are more likely to have greater LTC needs, but in some cases have less access to it.

On average across 26 EU Member States, 18% of older women report at least one limitation with ADLs compared to 14% of older men, and 28% of older women report at least one limitation with IADLs compared to 18% of older men. Individuals aged 80 years old or older are almost three times more likely to report limitations in ADLs and IADLs than individuals aged 65–79 years (31% and 48% of people aged 80 years old and older report limitations in ADLs and IADLs respectively, compared to 11% and 15% of people aged 65–79 years). The shares of older people reporting at least one limitation in ADLs and/or IADLs are higher among those with lower levels of education compared to those with medium and high educational attainment (International Standard Classification of Education (ISCED) 1997 codes used to define the levels of education; codes 0–2 for lower level, codes 3–4 of medium level and codes 5–6 for higher level). On average across 26 EU Member States, the prevalence of self-reported limitations in ADLs among older people with a low level of

education is more than double that among older people with a high level of education (22% compared to 10%). With respect to IADLs, 13% of older individuals with a high level of education report limitations, compared to 33% of older people with a low level of education.

On average across 26 EU Member States, the prevalence of self-reported limitations in ADLs among older people earning in the bottom income quintile is around 22% compared to a prevalence of 9% among older people with earning in the top income quintile (income refers to households equivalized income using the square root of household size as an equivalence scale). Moreover, older people with self-reported limitations in ADLs and IADLs are more likely to live in single households, limiting their ability to access informal care.

On average across OECD countries, just over one in 10 people aged 65 and older received formal LTC benefits and services in 2017, according to administrative data from national authorities (OECD, 2019). The range across countries is broad, from 22% in Switzerland to 1% in Poland. Data on recipients of LTC provided by voluntary and private providers are more difficult to collect, especially when the state is not paying the costs of care. For this reason, countries where privately funded care is more prevalent may report lower numbers of recipients. The majority of LTC recipients are aged 80 years old and older and women, in line with the distribution of LTC needs shown previously. On average across the OECD, 65% of older people receiving LTC are aged 80 years or older (OECD, 2019). In all OECD countries for which data are available, women make up the majority of LTC recipients aged 65 years or older, both in institutions and at home (Fig. 2.5.10). Further breakdowns of administrative data on recipients, for example for education and income, are not possible due to data gaps.

Regardless of which estimate of prevalence of LTC needs is considered, the number of recipients falls short of the number of older people who might need LTC. There are a number of reasons why older people who need LTC may not be counted as recipients of LTC benefits and services in administrative data. First, as discussed (see Fig. 2.5.8), not all older people who have LTC needs or limitations apply for benefits and services. They may seek support from their families first, a decision that is likely affected by cultural norms around the degree to which families look after older people. Second, older people who have LTC needs may not qualify to receive LTC. Third, older people may also pay for care in the voluntary or private market, or seek care from providers in the grey economy.

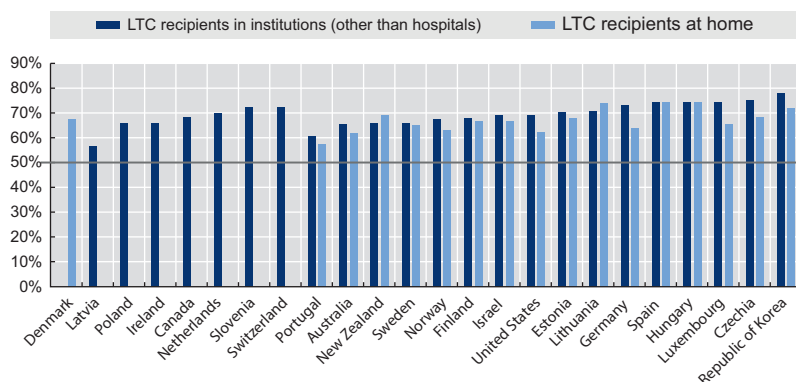


Fig. 2.5.10 The majority of LTC users are women and those aged 80 years and above

LTC: long-term care.

Note: Data for the USA are from 2016, and for Slovenia and the Netherlands for 2017. All other data are for 2018.

Source: OECD Health Statistics (2020).

Across 17 EU Member States, an average 54% of older people who report having limitations with ADLs or IADLs also report they receive help with activities they have problems with, including help from their spouses and other people in their household (Fig. 2.5.11). This compares to 9% of older people who report no limitations in ADLs or IADLs but do report receiving help (these older people may still have limitations in physical functioning). As with recipients of formal LTC, women and those aged 80 years old or older are more likely to report receiving help.

Policy relevance and conclusions

Our conclusions and policy suggestions fall into two areas: the financing of LTC, and how best to assess its quality.

How else to finance LTC?

As populations age and demand for LTC rises, countries face challenges finding the financing to expand LTC coverage for high-quality, accessible, affordable and equitable services.

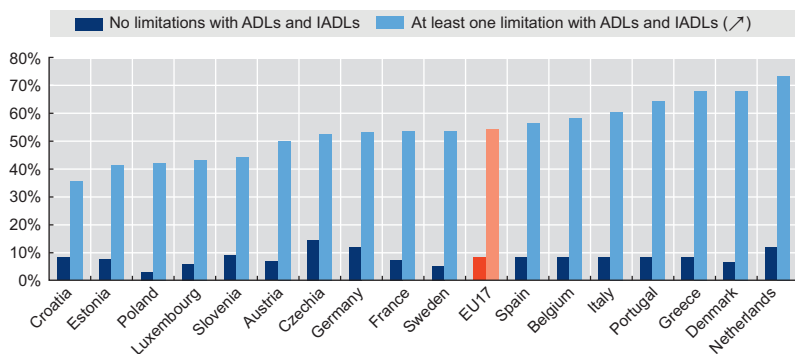


Fig. 2.5.11 Just over half of older people reporting a need for help also report receiving help for it

ADL: activities of daily living; EU: European Union; IADL: instrumental activities of daily living; SHARE: Survey of Health, Ageing and Retirement in Europe; TILDA: The Irish Longitudinal Study on Ageing.

Note: Help from partner or other people in household is included; the EU17 average is the unweighted average of the population-weighted national shares in each country.

Source: SHARE Wave 7 and TILDA Wave 3.

Many countries are trying to find sustainable solutions for financing LTC in the face of increasing demand due to population ageing. As previously discussed, countries use a variety of cost-sharing mechanisms or strict eligibility criteria to have a form of targeted universalism (OECD, 2011).

Options for governments to finance growing needs include better pooling of financing across generations, broadening of financing sources beyond payroll contributions, and introducing elements of pre-funding. Funding through a rise in social security and payroll taxes would be a major challenge as in some countries taxpayers already feel overburdened. Other forms of taxation outside of income taxes could be considered; for example, earmarking a fixed percentage of the value-added tax to finance reserve funds or a percentage of the tax revenue of other taxes, such as local property taxes (as is the case in France) would in practice increase the tax base of LTC financing. Certain countries have considered the (re)introduction of a wealth tax or increasing the

tax levied on the highest incomes as alternative options to finance LTC but these options are likely to be controversial.

Debates about raising taxes have enhanced the attractiveness of introducing a public LTC insurance. The advantages of a dedicated insurance scheme include more transparency in managing funds and a possibility to prefund care instead of creating debts for the future. Disadvantages of such a scheme include its reliance on employee contributions, which can have negative impacts on employment and growth, as well as raise issues with respect to equity and intergenerational fairness. Unless the scheme was extended to the unemployed and the self-employed, it would have a limited tax base, which raises issues regarding equity. For those who are not working, the LTC insurance contribution would still need to be paid from taxes.

In addition, countries could facilitate the development of financial instruments to pay for the board and lodging costs of LTC provided in institutions. Options include bonds or equity release schemes (as in Australia and Ireland), public measures to defer payments (as in the United Kingdom and the USA), and private sector products, such as reverse-mortgage schemes and combinations of life and LTC insurance policies. So far, the development of such products remains limited due to minimal interest from providers and citizens, as well as complex regulatory challenges.

How do we assess LTC performance and quality?

There is limited evidence and understanding around what works in LTC, and thus it is difficult to design and implement effective policy reforms. How to assess the performance of LTC systems remains a challenging yet crucial question. The quality of LTC is important for at least three reasons. First, users of care services increasingly demand more voice and control over their lives. Second, LTC services are under pressure to improve their accountability. Third, governments have a responsibility to protect vulnerable older people from potential abuse. Besides being high-quality, LTC systems that perform well are also accessible to older populations and provide good value for money. There is limited understanding of what works well in LTC, in what contexts and at what costs. This in turn makes it difficult to design and implement effective policy reforms.

Indicators of LTC quality are useful for government regulatory oversight, help providers identify problems and point to adverse events in the provision of care, and can help users make informed choices. Yet, few countries systematically measure whether LTC is safe, effective (or what constitutes effective LTC), and centred around the needs of care recipients. Most available indicators focus on inputs and processes, rather than outcomes and quality. Three groups of dimensions are generally accepted as critical to achieving high quality in care effectiveness and safety; patient-centredness and responsiveness; and care coordination (OECD, 2017).

The COVID-19 pandemic has laid bare deficiencies in LTC safety. Across OECD countries, around four in every 10 deaths due to COVID-19 were among LTC residents (Rocard, Sillitti & Llana-Nozal, 2021). A lack of resources is likely behind these dire statistics. LTC settings are often inappropriately staffed, they lack supplies and struggle to access clinical treatments, all of which can lead to poor safety. Both an absence of quality standards, and limited monitoring and enforcement of quality standards, make matters worse. A lack of data makes it difficult to quantify safety failures, and truly understand the magnitude of the challenge.

In general, countries with higher spending on LTC tend to report better access to, higher quality of and more satisfaction with public LTC services. Across 21 countries, close to a third of respondents to the 2018 OECD Risks That Matter survey identified accessing LTC as one of the three greatest risks to themselves or their immediate family, and 40% of respondents report that ensuring the LTC of family members is among the three greatest risks to themselves and their families. While simple correlations are necessarily imperfect, they indicate that satisfaction with access to high-quality and affordable LTC services is associated with the generosity of public systems. Countries that spend more on public LTC, like Denmark, Norway and the Netherlands, have smaller numbers reporting unhappiness with access to public LTC services for older people, and those countries that spend less have higher shares of respondents expressing dissatisfaction. This would suggest that LTC in some countries is not patient-centred nor responsive to population needs and wants.

The pandemic has also laid bare failings in care coordination across the health and LTC sectors (Rocard, Sillitti & Llana-Nozal, 2021). Poor coordination of care (as discussed in Chapter 3.5) further reduces

effectiveness and safety of care. Coordination with primary health care is especially important, as older people tend to have multiple chronic conditions and are at higher risk of hospitalization if not properly monitored. Collaboration across teams of professionals in the health and LTC sectors is key to ensure high quality of care and reduce unsafe and wasteful practices. In Japan, for example, community-based integrated care centres have been opened in every district, with care managers coordinating different services for older people.

Besides the quality of care, it remains unclear whether older people are able to access the LTC services that they need. As mentioned in previous sections, not all older people who are estimated to have LTC needs report using formal care. Moreover, when self-reported receipt of formal and/or informal care is considered, there remain large shares of older people with estimated needs that do not report receiving any help. Across 22 EU Member States, almost half of older people reporting severe difficulties in personal care or household activities stated they had unmet needs for help with those activities (Directorate-General for Economic and Financial Affairs, 2021). Older women and those on lower incomes were more likely to report unmet needs than older men and those on higher incomes (Directorate-General for Economic and Financial Affairs, 2021). Self-reported data are naturally influenced by cultural differences across countries and by factors other than LTC costs and quality, yet these high rates of unmet need suggest there are important perceived challenges in access to care. Among barriers to access are financial limitations (compounded by insufficient social protection), geographical disparities and shortages of care workers, complex administrative procedures that are difficult to navigate, and limited support for informal carers who often have to choose between employment and caring for relatives.

With respect to financing, it remains very difficult to establish whether current total and government spending on LTC constitutes good value for money. Indications are that the sector would benefit from both more funding but also better understanding of how to allocate current and future investments. Fiscal space is already limited today, and will only become more constrained as populations age and old-age dependency ratios increase. Thus, public and private funding for LTC must not be wasted, and should promote high-quality care that is accessible to all who need it, especially those who are most economically vulnerable and least likely to be able to afford it (see Chapter 3.6).

As with quality, indications are that not all countries have social protection that sufficiently cover the costs of LTC for older people with more severe needs and fewer means.

As with safety and effectiveness of provision, there is limited analysis of performance indicators in LTC financing. Comparability of data on LTC spending is limited, with elements being excluded or underreported even at the level of total public spending (OECD, 2020b). Performance indicators, such as share of households with catastrophic spending, national-subnational financing splits and percentage of expenditure on administrative processes are not available.

Governments, societies and economies face major challenges in planning, financing and providing high-quality care that is accessible and constitutes good value for money. While governments have some visibility of LTC needs via needs assessments and information on recipients, it is unlikely that all older people who have LTC needs apply for public benefits and schemes. It is sensible to assume that there are gaps in the measurement of LTC needs at population level, and that these gaps make it difficult to determine whether current provision is appropriate and how well systems will meet future demand for care. Moreover, without good data on needs and provision, it is also virtually impossible to determine the true societal and economic costs and consequences of informal care provision. With limited understanding and data on quality, specifically on effectiveness and safety, patient-centredness and responsiveness and care coordination, it is very challenging for policy-makers to make evidence-based decisions in this sector.

Going forward, it is thus crucial that governments invest more funds and efforts in data collection, international comparisons and analysis so that best practices can be identified and good solutions can be disseminated and shared widely. The clock is ticking, and unexpected and hugely consequential events like COVID-19 will only increase the urgency for action. The sector is far too complex for short-term thinking, and tackling these significant challenges requires long-term vision and policy action.¹

¹ Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

Additional resources

- Cravo Oliveira Hashiguchi T, Llana-Nozal A (2020). The effectiveness of social protection for long-term care in old age. Paris: OECD Publishing (OECD Health Working Papers, No. 117; <https://doi.org/10.1787/2592f06e-en>).
- Integrating services for older people in Lithuania. Paris: OECD Publishing; 2022 (<https://doi.org/10.1787/c74c44be-en>).
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SECTION 3

Commissioning and purchasing

3.1 *Paying for primary care*

ANNE SOPHIE OXHOLM, ANTHONY SCOTT

Key messages

Chapter 3.1 draws out insights into the way primary care is paid. Primary care delivers first-contact access to health services and seeks to coordinate care. It is paid for in different ways in different settings: through salary, capitation (a fixed payment per enlisted patient), fee-for-service (FFS), pay for performance (P4P) or through blended payments that combine two or more of these methods. Key learning includes that:

- The way health systems pay for primary care can incentivize treatment that supports wider health systems' goals, such as:
 - reducing avoidable referrals to secondary care, improving efficiency and reducing waste; and
 - encouraging adherence to evidence-based clinical guidelines, enhancing quality.
- P4P is often used to improve quality but the evidence on how effective it is, is mixed. If performance measures are not carefully designed to be context specific and adjusted for risk appropriately, they can create unintended barriers to and inequalities in access.
- The design of primary care payment models needs to be “holistic”, to consider the goals of the health system and to underpin quality, access and efficiency.

Introduction

Payment models are increasingly being used by governments and health insurers to support and help drive efficient and equitable health care systems. This chapter examines the evidence on how payment methods

in primary care can help solve global policy challenges faced by the primary health care sector.

The primary health care sector is usually the first point of contact for patients in need of health services. The sector is usually, though not exclusively, organized around primary care physicians (PCPs) (also referred to as general practitioners (GPs)), who can be supported by nurses, allied health professionals and other community health workers. However, there are also examples of other health professionals providing some primary care services, such as community pharmacists. Given the need for easily accessible health care by the population, primary care is usually geographically dispersed and organized into small community-based medical groups or health centres – primary care organizations (PCOs). In some countries, the population enrolls with a PCP, PCO or health insurer, where continuity of care reflects a key defining element of primary care.

The organization of primary care across countries is varied. PCOs can be owned and run by local or national governments, or by vertically integrated health insurers, or can be privately owned by PCPs or private companies. In most health care systems with some form of health insurance, providers or their patients will receive payments and/or subsidies from insurers (including governments) for the care provided. Payments can be made to an individual PCP and/or to the PCO, who then distributes the payments to health professionals within that group. For example, the PCO could be paid on the basis of capitation, while the PCP is paid a fixed salary.

The aim of this chapter is to describe how different primary care payment models can be used to help solve two common global policy challenges relevant to the primary health care sector: (i) how to reduce avoidable secondary care; and (ii) how to improve the quality of primary care. These two policy challenges were selected because they contribute to achieving the overall goals of payers (defined as third-party insurers, such as health insurers and governments, as well as patients), they are relevant to primary care, and they are common issues faced by many health care systems. Primary care payment models provide financial incentives that can be used to solve these policy challenges. Different payment models may help solve different challenges, which explains why payment models are often blended.

Using payment models to help solve policy challenges assumes that income plays a role in motivating the clinical and labour market behaviour

of PCPs. This assumption generally holds, but nonfinancial motives may also influence their behaviour, presumably to a greater extent if their target income is reached. To understand PCPs' behaviour, the literature often uses the principal–agent framework (Scott, 2000). This framework assumes that PCPs (agents) seek to maximize their own utility, which depends on their income but also their altruistic concerns towards the patient (principal) and own leisure time (Ellis & McGuire, 1986; Dionne & Contandriopoulos, 1985). Some studies also include altruistic concerns towards a third-party insurer or society at large to capture PCPs' double-agency role (e.g. Allen et al., 2022; Blomqvist, 1991; Oxholm et al., 2024). PCPs may also be motivated by other nonfinancial drivers such as their reputation among colleagues and patients and intrinsic motivation (enjoyment of tasks) (Pedersen et al., 2018; Sicsic, Le Vaillant & Franc, 2012; Pedersen et al., 2021; Godager, Hennig-Schmidt & Iverson, 2016; Bénabou & Tirole, 2006; Yordanov et al., 2023). As PCPs may be motivated to different degrees by these factors, responses to payment models are thus often heterogeneous across providers (Hennig-Schmidt, Selten & Wiesen, 2011; Godager & Wiesen, 2013).

PCPs may also respond differently to the same payment models depending on their context and setting. For example, any payment model can be accompanied by global budget mechanisms that provide overall caps to spending. PCPs could also receive income from many different payers (e.g. insurers) each with a different method of payment, such that the expected behavioural effects when one payer changes its payment model are muted. Availability of resources (Di Guida et al., 2019; Oxholm et al., 2019; Oxholm, Guida & Gyrd-Hansen, 2021) and the degree of competition among providers (Brosig-Koch, Hehenkamp & Kokot, 2017; Iversen, 2016; Scott & Sivey, 2022) could also affect providers' responses to changes in the level or type of payments. Payment methods could also influence the mix and characteristics of PCPs and PCOs through selection. This includes the entry and exit decisions of PCPs and PCOs, PCP hours of work, as well as the location decisions of PCPs and PCOs, such as practising in a rural or urban area or in an area with a high-need population (Li et al., 2014; Günther et al., 2010; Pedersen & Gyrd-Hansen, 2014; Anell, Dackehag & Dietrichson, 2018).

The next section outlines how the basic types of primary care payment models affect PCPs' behaviour and their ability to reach payers' different goals. Afterwards, for each of the two policy challenges introduced above, we examine its context and then the extent to which primary care payment models could help solve the challenge.

Overview of primary care payment models and their effects

First, we summarize, from the payers' perspective, the advantages and disadvantages of using the most common payment methods for PCPs. Any payment model involves an explicit or implicit contract between a payer and a provider. These contracts specify the unit of payment. The unit of payment has behavioural consequences as it defines the behaviour the payer is expecting in exchange for the payment. For example, salary payment is based on working a specified number of hours; capitation payment is paid per enrolled patient and so is related to the list size; FFS is related to the volume of services provided, usually defined in terms of consultations/visits, treatments or diagnostic tests; and P4P is based on a range of different quality measures that could be related to clinical guidelines or health outcomes (Quinn, 2015; Jia et al., 2021; Stokes et al., 2018). These different payment models can also be blended together.

Even though it may be the patient and/or insurer that pays for the care, the financial risk of treating patients may be shared between the payers and the providers. Who bears this risk depends on the unit of payment. For salary and capitation payments, payers can relatively easily predict total expenditures and so face little financial risk themselves. Instead, this risk is borne by the providers who are not compensated for changes in demand and workload, for example, increases in the numbers of patients with complex conditions. Capitation payment can partly account for financial risk through risk adjustment of payments that take into account the additional costs of treating more complex patients. For FFS and P4P, payers typically bear a higher financial risk as providers are compensated for additional workload. Providers' financial risk can significantly influence the strength of their incentive to provide care themselves rather than refer to other health professionals. More specifically, a lower financial risk, such as under FFS and P4P, increases providers' financial incentives to provide care themselves. These types of payments may also be used to incentivize providers to deliver different types of care through different price signals (Hsiao et al., 1992).

PCPs and PCOs may often receive remuneration from a blend of different payment methods to achieve the different goals of the payer. Table 3.1.1 shows whether these payment methods provide financial incentives to help achieve common high-priority payer goals. The following discussion of each payment method goes through the table in

Table 3.1.1 *The impact of different primary care payment models on health care system objectives*

Do payment models meet payers' objectives?	Payment models			
	Salary	Capitation	FFS	P4P
<i>Better access</i>				
Increase number of patients seen (list size)	✗	✓	✓	✓
Treat patients most in need (no “cream-skimming”)	✗	✗ ^a	✓ ^b	✗ ^a
<i>Higher quality of care</i>				
Maximize provision of effective care ^c	✗	✗	✗	✓
Increase preventive care	✓ ^d	✓ ^d	✗ ^e	✗ ^{e,f}
<i>Lower expenditures</i>				
Fewer referrals to specialists	✗	✗	✓	✓ ^g
Minimize physician effort and treatment costs	✓	✓	✗	✗
Higher budget security	✓	✓	✗ ^h	✗ ^h
Lower administrative costs	✓	✓	✗	✗

FFS: fee-for-service; P4P: pay for performance.

^a If payment is risk adjusted there will be a financial incentive to enlist high-need patients which also provides a signal from the payer to prioritize these patients' treatment.

^b Unless fees are paid to PCPs by patients (in whole or in part), which may reduce demand among those in most need, compared to fees being paid to PCPs directly by third-party insurers. It also assumes that fees are sufficiently differentiated to reflect the costs of treating different types of patients.

^c Depends on adherence to clinical guidelines.

^d Depends on the difference between PCPs' costs of prevention and otherwise expected increase in PCPs' future workload and costs of care.

^e Unless payments are made for preventive activities such as immunization.

^f Depends on whether prevention impacts reported performance.

^g Depends on whether performance links to PCPs providing the services themselves or rewards “appropriate” referrals.

^h Budget security may be higher if there is a cap on total payments and fees are set (regulated) by the payer.

Source: Authors.

more detail. Box 3.1.2 briefly describes payment methods that are increasingly being used for community pharmacists as their role in the provision of first-level care expands to some primary care services in certain settings.

Payment method 1: salary

Salaried providers receive a fixed revenue for working over a given time period. This payment method is typically used to pay providers who are employees of a PCO. Payers may find the fixed salary payment scheme attractive for several reasons. One is that a fixed salary ensures budget security for the payer because it shifts financial risk to providers. Another reason is that the payment method is easy to administer as it only requires information about the employed providers. A fixed salary, however, also has some unattractive features. As providers are not paid for their activities, they are (in the short run) not financially incentivized to exert more than the minimum required effort to avert being laid off. Generally, PCPs may provide less effort by, for example, avoiding costly patients, reducing the frequency of services, or referring patients to other providers. In the longer run, the prospect of receiving a promotion and pay rise as well as the fear of being laid off may financially incentivize them to increase effort beyond the minimum required level. The focus for the provider then becomes the criteria used by employers to enable progression up the career ladder. These criteria can create career incentives that are related to objectively or subjectively assessed performance (Prendergast, 1999).

Payment method 2: capitation

Providers paid by capitation receive a fixed payment per enlisted patient for a given time period. The payment is independent of the amount of provided care. However, it may be risk adjusted such that patients with characteristics that indicate they are more costly to treat are linked to a higher payment. As the size of the served patient population is typically stable due to patient enrolment with a PCO, this payment method gives payers budget security by shifting financial risk to providers. Capitation payments financially incentivize providers to attract and keep patients on their lists when facing competition, thereby potentially increasing access to care and also

improving those aspects of quality that patients can observe. However, if competition for patients is low, providers have less of a financial incentive to exert effort above the minimum requirement. An exception to this lack of financial incentive may be preventive care that reduces providers' required effort in the longer run.

As with any fixed payment, capitation payments incentivize the providers to minimize their costs of providing care, which may lead them to provide less care than is necessary when quality is difficult to observe (Hennig-Schmidt, Selten & Wiesen, 2011; Brosig-Koch et al., 2016; Oxholm et al., 2019). Capitation may also lead providers to only enlist patients whom they expect to be less costly to treat compared to the capitation payment itself ("cream-skimming" behaviour). This behaviour may increase inequality in patients' access to care. Such selection issues may be alleviated by regulating patients' access to providers' lists or by risk-adjusting the payments based on patients' expected treatment costs. Risk adjustment shifts some of the financial risk away from the provider to the payer and thereby weakens the providers' incentives to reduce costs by exerting cream-skimming behaviour. The risk adjustment may also send a signal to providers about patient prioritization (Oxholm et al., 2019), but there is no direct financial incentive to prioritize already enlisted high-need patients.

Payment method 3: *FFS*

PCPs can receive a fee for each service they provide. This payment method requires providers to report and bill for the number of activities (e.g. consultations, visits, procedures, episodes). The advantage of FFS over salary and capitation is that providers have a financial incentive to deliver care themselves rather than referring patients to other providers (Hennig-Schmidt, Selten & Wiesen, 2011; Krasnik et al., 1990; Brosig-Koch et al., 2016). A disadvantage of FFS is that providers may be reluctant to provide services that are not covered by the fee schedule, unless some services are bundled together. Another concern for the payer is that they bear most of the financial risks, especially when fees are unregulated. Consequently, FFS increases the risk of overtreatment and supplier-induced demand (Di Guida, Gyrd-Hansen & Oxholm, 2019; Longden, Hall & Van Gool, 2018), gaming of the system and budget deficits for payers. To minimize these risks some payers may choose to closely monitor service patterns through utilization reviews

or to set caps on the payments to providers through controls on fees that can be charged (Wickizer & Lessler, 2002). The fees may be set by either the payers or the PCPs themselves or through negotiations. In cases where PCPs set the fees, they may choose to price discriminate, i.e. charge payers different fees based on patient characteristics. In cases where the payers are the patients themselves, the fee is an out-of-pocket (OOP) cost, and higher fees may reduce demand and thereby have implications for equity in access to care.

Payment method 4: P4P

P4P has become a popular way of remunerating PCPs (Cashin et al., 2014). This payment method links payments directly to performance measures. The performance measures may be based either on completion of processes (e.g. recording blood sugar levels) or on achieving specific intermediate health outcomes for patients (e.g. whether blood sugar levels are in accordance with clinical guidelines). The schemes require an administrative system that measures providers' performance (which may rely on digital health infrastructure (see Box 3.1.1)).

Box 3.1.1 The role of information technology and digital health infrastructure for primary care payment models

The choice and sophistication of payment models depend on the availability of information technology and digital health infrastructure. Electronic medical records can often support new payment models that require either extensive risk adjustment of payments or the automation of the collection of data on quality and activity to support P4P and other quality improvement policies. Small private PCOs may find it difficult to transition to digital technology without outside investment. In high-income countries (HICs) there has therefore been a trend towards larger sizes of PCOs that benefit from economies of scale to spread out the fixed costs of new infrastructure. Often payers provide separate payments or block grants to support information technology and digital health infrastructure, but such funding may be unavailable in some low- and middle-income countries (LMICs) with more severe resource constraints. In settings where PCOs are in the private sector or in vertically integrated insurance systems, it can also be difficult to coordinate a single information technology health platform that can be used to support system-wide payment models and the sharing of electronic health records.

Depending on the performance measures in question, such administrative requirements may be costly. An advantage of P4P is, however, that providers receive feedback on their performance, which may improve the quality of care over and above the effect of the financial incentives (Kolstad, 2013; Godager, Hennig-Schmidt & Iverson, 2016).

P4P may be designed in different ways, which creates different incentives for the provider (as discussed later in the chapter). These design differences may explain why evidence on the impact of P4P on the provision of care is mixed. The mixed evidence, however, may also be a result of weak evaluation designs of existing studies (see, for example, reviews by Van Herck et al., 2010; Jia et al., 2021; Eijkenaar et al., 2013; Diaconu et al., 2021; Zaresani & Scott, 2021; Scott, Liu & Yong, 2018). Despite the different designs of P4P schemes, they also share several common features that make them attractive to payers. P4P schemes (as opposed to FFS schemes) incentivize providers to only deliver care defined as high quality. For example, by rewarding providers for only one blood sugar level measurement per diabetes patient per time period, as opposed to a FFS scheme rewarding providers for all such measurements independently of the number of previous measurements and the recipient. This focus on what constitutes high-quality care may also reduce heterogeneity in care across providers.

A disadvantage of P4P is that payers may find it difficult to predict providers' performance and thereby risk facing overrun budgets. Payers may also end up paying for performance that is only weakly related to the individual provider's efforts. Providers may also have financial incentives to treat patients who are close to meeting or have already met the performance requirements (cream-skimming behaviour), thus minimizing provider effort (Gravelle, Sutton & Ma, 2010). P4P may thereby increase inequality in patients' access to care in some cases (Oxholm, Di Guida & Gyrð-Hansen, 2021). By risk-adjusting the performance requirements, payers could potentially alleviate such issues. Similar to the case of FFS, multitasking issues may also arise under P4P if focus is diverted towards more profitable care (Doran et al., 2011). Under P4P, providers also have an incentive to game the system to secure higher payments (Gravelle, Sutton & Ma, 2010; Kalk, Paul & Grabosch, 2010; Wilding et al., 2022). There may also be spillovers of P4P to other non-incentivized areas of care. For example, resource-constrained providers may choose to focus on incentivized

treatments at the expense of non-incentivized treatments (Singh et al., 2020), whereas non-incentivized care which is complementary to incentivized care may be positively affected by P4P.

Payment method 5: blended payments

To balance the incentives of the pure payment methods, payments are often blended in primary care (Robinson, 2001). Blended payments are attractive because they enable payers to both incentivize providers to deliver care (e.g. using FFS and P4P) while limiting their spending (e.g. using salary and capitation). Theoretically, it has been shown that mixed payment methods are superior to pure payment methods (Ellis & McGuire, 1986). However, in practice, the complexity of these methods may impose high transaction costs and difficulties in predicting behaviour. Empirical evidence on providers' response to blended payment methods is limited. The results of a laboratory experiment with medical students show that the introduction of a mix of FFS and capitation leads to greater health benefits from care compared to the pure payment methods (Brosig-Koch et al., 2017). Other studies, using real-world data, show that a change in provider payments from pure capitation to a mix of capitation and FFS increases PCPs' activity levels and reduces their referral rates (e.g. Krasnik et al., 1990; Flierman & Groenewegen, 1992). P4P schemes are also often blended onto other payment models, which accounts for the majority of funding. The blend that best achieves payers' different goals is, however, difficult to determine in a real-world setting and is likely context dependent.

Policy challenge 1: Can primary care payment models reduce avoidable secondary care?

Background to policy challenge

Many policy-makers believe that a strong primary care system can help reduce the growth or level of health care expenditures of more specialized hospital care. There exists a large literature showing strong associations between the strength (e.g. number of PCPs) of primary care and patients' health outcomes (Starfield, Shi & Macinko, 2005). Some of this literature also finds associations between a strong primary care system and lower total health expenditures (Baicker & Chandra, 2004;

Starfield & Shi, 2002) and fewer inpatient and emergency hospitalizations (Chen et al., 2010; Jacobs et al., 2020; Fortney et al., 2005; Lippi Bruni, Mammi & Ugolini, 2016; Whittaker et al., 2016; Morciano et al., 2020; Dolton & Pathania, 2016). However, if primary care is expanding and the number of specialists and hospitals remain the same, then total health care expenditures will increase overall at the system level (Lau et al., 2021; Miller et al., 1999).

PCPs can potentially play an important role in improving efficiency by acting as gatekeepers to more expensive specialized care and by providing preventive care. Primary care can also be a substitute for or complement to more specialized care (Lau et al., 2021). Primary care can act as a direct substitute when the same tasks can be provided with equal effectiveness by PCPs and specialists (Van Hoof et al., 2019). This substitution can, for example, include general health checks, skin checks, minor surgical procedures, antenatal care, care for less severe mental health conditions, child health (in the USA paediatricians act as PCPs for children whereas GPs take on this role in other countries), and monitoring patients with chronic diseases. In cases of substitution, the policy challenge is to ensure that the same quality of care is provided by the least costly health professional, which often is the PCP.

PCPs are usually paid less (Cheng et al., 2012; Leigh et al., 2010) and face lower fixed costs of providing care than specialists. From the patient's perspective, it may also be less costly to access primary care in terms of travel time and time off work to visit a PCP (or a community pharmacist (see Box 3.1.2)) closer to home than to receive more specialized care in a more distant hospital. Lower costs of accessing care are especially relevant in rural areas where the distance to health care providers is a key issue. However, lower unit costs in primary care do not always translate into lower overall health care expenditure. As expenditure is a function of both unit costs as well as the volume of care, effects on expenditure also depend on the volume of care provided, which could increase in primary care if PCPs, for example, spend more time with patients or see more patients. A systematic review comparing consultations by PCPs to other specialists found that though outcomes were similar and waiting times were lower, costs were generally higher when treating patients in primary care compared to secondary care (Van Hoof et al., 2019). Despite the possibility of higher costs of treating patients in primary care, these may be partly offset by lower volume of referrals if the number of patients treated in

Box 3.1.2 Payment methods for community pharmacists as their role expands to a first-contact point with the health system

After nurses and physicians, pharmacists are the third largest group of professionals in the global health workforce. In many places, the role of pharmacists is expanding and patients are seeking their first point of contact with the health care system in community pharmacies rather than medical offices. For example, a study in the USA demonstrated that patients visit community pharmacists almost twice as often as their physicians and other qualified health care professionals (Cheema, Sutcliffe & Singer, 2014; Santschi et al., 2011; Newman et al., 2020). Having roles in prescription counselling, medication therapy management, health screening and immunizations (generally referred to as either extended pharmacy services or cognitive pharmaceutical services), pharmacists actively provide education, including smoking cessation services and distributing health education leaflets that cover the issues related to contraception and the prevention of cardiovascular diseases (Urick & Meggs, 2019; Anderson, 2007). As countries face physician shortages and ageing populations, the evolving model of pharmacy care may offer additional routes to enhance access to some primary care services, improve disease-related health outcomes and reduce health care costs.

In most places, pharmacy remuneration is concentrated on dispensing (a margin, maximum reimbursement price, or dispensing fee) (WHO Regional Office for Europe, 2020). However, some countries have started transitioning towards payment models (primarily FFS, capitation and blended payments of the two) to align funding with the expansion of cognitive pharmaceutical services; and some are opting for different modes of reimbursement for different pharmaceutical services. For example, Australia, Belgium, Canada, Germany, Japan, the Republic of Korea, Switzerland and some USA states are employing FFS schemes; Denmark, England, Ghana, Indonesia, the Netherlands, Portugal, Thailand, and some places in the USA (including Medicare and Medicaid) are using capitation; and Canada, China, and New Zealand are utilizing blended payments (mostly FFS integrated into capitation models).

These payment models for community pharmacists can have similar effects as they do in the primary care setting. FFS can encourage pharmacists to actively provide services (Jackson & Urick, 2019), but the fee does not account for the quality of the service provided and risks encouraging overprescription and overcounselling (Standridge, Fisher

Box 3.1.2 (cont.)

& Tsai, 1983). In capitation systems, pharmacists are reimbursed based on the number of patients on their lists, which can incentivize improved service quality and reductions in the costs of prescriptions (Yesalis et al., 1980). This type of payment system can also allow for better financial planning, as pharmacies can better predict their revenue flows. However, this system gives less financial incentive for pharmacists to provide extended pharmacy services or cognitive pharmaceutical services because it does not change the individual payment received for services. Blended payments are often used to address the shortcomings of the two models when they are used alone (Jackson & Urick, 2019; Freeman et al., 2016).

As the role of community pharmacists continues to evolve, information sharing across the health care system (e.g. primary care, hospitals, long-term care) is becoming increasingly important to not only ensure the provision of safe, efficient and coordinated care delivery, but also to develop appropriate remuneration models for different health care providers. After all, there is an opportunity for community pharmacists to fill growing gaps in other parts of the health workforce, and appropriate payment models will be important to fully scale up the services provided in the community pharmacist setting.

Source: Hussain & Babar (2023).

primary care increases. The most cost-effective setting will, however, differ depending on the health condition and context.

In cases where primary care acts as a complement to specialized care, the policy challenge is to ensure the optimal mix of and collaboration between PCPs and other specialists for each patient. This challenge is related to integrated care for patients with multimorbidities and complex conditions (see Chapter 3.5) and is also related to referrals between PCPs and specialists. More generally, complementarity is about how PCPs and other health professionals with different skill sets can work to achieve the most cost-effective care for each patient. There will be much variation in the most cost-effective mix of PCPs and other specialists across different health conditions, with patients with multimorbidities and chronic diseases more likely to require care from providers across a range of specialties. In these cases, the impact of

primary care on reducing the costs of specialized care is much less obvious, though it is believed that generalists, such as PCPs, will have a more holistic view of the patient's health and circumstances.

The role of primary care payment models in reducing avoidable secondary care

Primary care payment models influence avoidable secondary care through their effects on PCP referrals to secondary, more specialized care (Forrest, 2003). Gatekeeping is a system where a referral from a PCP is required before a patient can visit a specialist. If gatekeeping does not exist then patients can access specialists directly, thereby reducing the impact of primary care payment models. Patients' direct access could result in specialists seeing patients who do not "need" specialized care, such that specialists are not using their more costly time and training to its maximum benefit. In the longer term there would then be a higher demand for specialists and a misallocation of resources between primary and secondary care, which may also lead to higher health care expenditures overall. If gatekeeping does exist, then different primary care payment models can be used to influence the probability of a referral. More specifically, payment models can provide financial incentives to provide additional care (such as under FFS and P4P) and so reduce referrals, or share the financial risk of care with secondary care providers in vertically integrated systems which have pooled primary and secondary care budgets.

Capitation payment is one payment method which may influence referrals to more specialized care. However, its effect on referrals depends crucially on whether the capitated budget is pooled (also known as a "global" budget) across primary and secondary care, or only covers primary care ("single" budget). Single budget capitation may be paid to the PCO or directly to the PCP based on the number of enrolled patients and covers only the care provided by the PCPs themselves. In this situation, PCPs have an incentive to minimize their own treatment costs, which can be achieved by increasing referrals (Iversen & Lurås, 2000). They may also minimize their own costs by choosing to spend less time with each patient and be less focused on coordination of care compared to under FFS and P4P payments. These financial incentives are similar to those present under salaried payment (see Table 3.1.1).

Empirical studies comparing single budget capitation payment to other payment models such as FFS and P4P have confirmed these hypotheses. With FFS payments, PCPs are paid on the basis of volume. PCPs therefore have a financial incentive to do more themselves, such as more follow-up visits. Referrals to specialists may therefore be delayed and be less likely under FFS compared to under (single budget) capitation or salary. Krasnik and colleagues (1990) found in Denmark that introducing FFS on top of single budget capitation substantially reduced GPs' referrals to specialists and hospitals, while these GPs increased the number of face-to-face consultations and the number of diagnostic services undertaken themselves. The net effect on costs and health outcomes was not examined. Flierman and Groenewegen (1992) also reported increased activity under FFS mixed with capitation compared to capitation alone. The introduction of capitation in addition to FFS in Norway resulted in more referrals (Iversen & Lurås, 2000), but in Canada there was no impact on hospital utilization when physicians switched from FFS to capitation payments plus an incentive to reduce hospitalization (Hutchison et al., 1996).

Similar to FFS, P4P may encourage PCPs to provide more care themselves than under a fixed payment scheme such as capitation and salary. This increased activity may reduce referrals to hospital. Several studies have examined the spillover effects of P4P on secondary care in the context of the Quality and Outcomes Framework (QOF) (see Box 3.1.3), which is a large-scale P4P scheme added to an existing capitation payment model for PCPs in the United Kingdom (Doran et al., 2006). Grigoroglou and colleagues (2020) found a very small reduction in avoidable hospitalizations for incentivized health conditions, while Harrison and colleagues (2014) found a larger reduction in avoidable hospitalizations. Gunn et al. (2021) found a substantial reduction in all-cause, diabetes and cardiovascular disease hospital admissions and emergency admissions for patients with diabetes if QOF targets were attained.

For some treatments, however, the Framework led to an increase in referrals. Gutacker and colleagues (2015) found that it led to an increase in psychiatric hospital admissions for people with serious mental illness. This finding suggests that in some circumstances P4P may lead to the identification of unmet need or incentivize more appropriate care. P4P can also directly reward more referrals if this is thought to improve health outcomes (Mcmanus et al., 2021). A local P4P

Box 3.1.3 Case study: the Quality and Outcomes Framework (QOF)

The United Kingdom's QOF is one of the most comprehensive P4P schemes within a primary care setting. The scheme was introduced in 2004 with the aim of improving GPs' job satisfaction, pay and quality of care (Doran & Roland, 2010). Participation in the scheme was voluntary, but almost all general practices signed up (Campbell et al., 2009). General practices in the United Kingdom were also remunerated based on capitation, which gave them a financial incentive to keep costs down. The performance payment was added to this remuneration, thereby incentivizing general practices to improve quality of care. GPs' personal income increased around 30% the first year of the QOF (Allen, Mason & Whittaker, 2014).

Initially the scheme included 146 performance indicators, which were linked to clinical care, patient experience, organizational standards and additional services. A barrier for implementation of the QOF was the continuous measurement of practices' performances on these indicators, which required automatic extraction of data from electronic records. A large investment in health information technology systems was therefore made prior to the introduction of the scheme. The practices were fully reimbursed for these information technology-related costs (Doran & Roland, 2010).

For most performance indicators practices received payments determined by a threshold-based payment function, by which additional absolute performance below a lower (25%) and above an upper (50–90%) threshold was not financially rewarded. The payments were adjusted for disease prevalence and list size of practices. Practices could also exclude patients from the performance measurement if they were untreatable or not willing to be treated. Practices' performance on each quality indicator was made publicly available (Doran & Roland, 2010). Since the introduction of the scheme, many changes have been made both in terms of the basis for reward and the incentivized indicators.

scheme in the United Kingdom found that emergency hospital admissions fell when GPs were directly rewarded for reducing them, but health outcomes were not examined (Khedmati Morasae et al., 2021).

Even though there may be exceptions as described above, capitation under a single budget is generally found to increase the referral rate compared to FFS and P4P schemes. This financial incentive to refer

patients under a single budget capitation-based system may be strengthened further if there is competition for patients. Iversen and Ma (2011) show that incentives to refer under capitation payments are higher for PCPs facing more competition, because they may be more likely to respond to patients' requests to be referred to prevent the patient from moving to another PCP.

The second main form of capitation is global capitation payment, which is where there is a "global" or "pooled" budget that includes total spending on primary *and* secondary care (and potentially other services). This budget may be held by a practice or a medical group or within a vertically integrated insurance system. Global capitation payments thereby provide a total health care budget based on the number of patients in the population or enrolled with an insurer, which is typically risk adjusted to account for patient complexity. An example is GP Fundholding in the United Kingdom or the use of capitated budgets in Health Maintenance Organizations and Accountable Care Organizations (ACOs) in the USA. In these cases, as under the first type of capitation payment (single budget), there is a financial incentive to minimize costs as providers can keep the savings. But in cases of a global (pooled) budget, this cost minimization includes keeping the savings that would have otherwise been used to pay for hospital care, which is why this payment method is also known as a shared-savings model. Several studies have shown that referrals by PCPs are lower with this type of global capitation payment (Davidson et al., 1992; Lurie et al., 1992; Dusheiko et al., 2006).

In ACOs, the global budget has also been combined with P4P. In these models, medical groups can share in any savings made from the global budget as long as they meet a minimum quality threshold (Chernew et al., 2011). Systematic reviews find positive evidence including reductions in spending and no deterioration of outcomes (Cattel & Eijkenaar, 2020; Kaufman et al., 2017). Global budgets may also involve pooling of budgets across different sectors of care. For example, this approach has been tried for health and social care budgets in the United Kingdom, though it was found to have no impact on the utilization of hospitals, but there was some evidence of increased utilization for the most complex patients (Stokes et al., 2019). In this way global budgets that merge primary, secondary care, and social care budgets aim to help support integrated care across different settings (see Chapter 3.5).

A derivative of capitation payments are bundled payments. Bundled payments have been discussed as a way to incentivize integrated care across different sectors and settings for specific groups of patients defined by disease or diagnosis (Tsiachristas et al., 2013; Stokes et al., 2018). Instead of the fixed capitation payment covering all care for each enrolled patient, fixed bundled payments are disease specific. They are designed as a single payment for all care required by a patient in the same episode or multiple services provided across different providers or sectors. Often, multiple FFS payments across a hospital episode may be “bundled” into a single payment (e.g. a diagnosis-related group). Alternatively, a single payment may be used to cover the care of patients in hospital and after they are discharged if they have a chronic disease. Similar to capitation payment, bundled payments provide incentives to reduce costs through providers being able to retain savings.

In the USA’s Medicare, bundled payments have been aimed at hospitals which become responsible for the care of patients up to 90 days after discharge. Though the role of primary care in these schemes is unclear, these schemes have some effects on reducing Medicare spending (Joynt Maddox et al., 2018; Barnett et al., 2019). In the Netherlands, bundled payments in primary care increased total health care expenditures, especially for those with multimorbidities. Medication and spending on medical specialists increased, while spending on primary care did not. The Dutch PCPs may have increased referrals because they were unable to keep savings from the reduction in use of specialists or because unmet needs were identified. In this context the “bundle” may have been too narrow by only including primary care, such that PCPs were incentivized to reduce only their own costs (Karimi et al., 2021; Stokes et al., 2018).

Until now, our focus has been on whether capitation (single or pooled budgets) may reduce avoidable hospitalizations, also in comparison to other payment models such as P4P and FFS. Adding P4P to FFS may also impact patients’ use of the secondary care sector. The effect on referrals depends on the precise performance measure used in P4P. If for a specific condition referral is a part of improving health outcomes, then PCPs’ referrals to specialists may increase. Several studies have examined the impact of adding other types of P4P to FFS. For example, Chen and colleagues (2017) found no impact of P4P on hospitalizations for hepatitis in Taiwan, where this payment was added onto FFS payment. In Canada, Lavergne and colleagues (2018) examined the introduction of an annual payment for

guideline-based care plans on top of existing FFS for patients with diabetes, hypertension or chronic obstructive pulmonary disease (COPD). There were no changes in total hospitalizations, though for hypertension hospitalizations for stroke and acute myocardial infarction fell. The addition of P4P to existing FFS payment was also examined in the USA by Rosenthal et al. (2016). They found that inpatient admissions fell in two out of the three examined states. Chen and colleagues (2010) found that after three years of P4P added to FFS payment, patients with diabetes were less likely to be hospitalized. There also exists a specific form of P4P directly incentivizing better coordination of care, called pay for coordination (P4C) (Stokes et al., 2018; Tsiachristas et al., 2013). Under P4C additional payments are made to improve integration with other providers through information sharing. Less evidence exists on the effect of these types of payments on referrals and the use of secondary care.

In summary, there is evidence that primary care payment models can provide financial incentives that influence referrals to more specialized care depending on payment design. Single budget capitation models that only cover PCPs' care can increase referrals. Generally, FFS and P4P encourage PCPs to undertake more care themselves and so are likely to reduce the use of secondary care compared to other forms of payment, though for P4P this depends on whether referrals are appropriate and lead to improved health outcomes. Global budget capitation payments that pool primary and secondary care funding can also reduce hospitalizations and encourage integration of care across settings. Though we have not examined the quality of the above evidence, many studies across a range of settings and countries had consistent findings. We could find little evidence, however, on how increases or reductions in referrals influence health outcomes and so this question remains an important avenue for further research.

Policy challenge 2: Can primary care payment models improve the quality of primary care?

Background to the policy challenge

A recent focus on quality of care and avoiding low-value care has increased the interest in ensuring that primary care payment models support the provision of high-value health care. In most health care

systems, there is a difference between the actual care delivered by PCPs and the care recommended in evidence-based clinical guidelines. This difference is particularly present in LMICs (Das & Hammer, 2014). If patients do not receive high-quality primary care, it may reduce their quality of life and increase their need for more acute and specialized treatment, which is expensive for payers. As many PCPs face an ageing patient population with more complex care needs, following clinical guidelines is becoming even more important. A key policy challenge is therefore to improve the quality of primary care. This challenge is a part of a larger policy agenda on creating value-based health care systems (Smith et al., 2021; Porter, 2010). Policy-makers may use different interventions to try to improve the quality of primary care. One of these interventions is paying PCPs for their performance.

How can primary care payment models be used to improve quality?

The key payment method used to improve quality of care is P4P. Such schemes are characterized by linking PCPs' payments directly to their attainment of quality standards. Even though P4P schemes are based on a quite simple concept, they can be designed and implemented in many different ways and settings and can become complex. These design and implementation choices require careful consideration as they may affect PCPs' provision of care (Mehrotra, Sorbero & Damberg, 2010; Eijkenaar, 2013). In the following text, we highlight some of the key features to consider for P4P schemes that aim to improve the quality of primary care.

One key feature is the chosen performance indicators. The indicators should ideally reflect patients' outcomes from care. However, patients' outcomes may be difficult to measure and depend on factors unrelated to PCPs' care. Consequently, the schemes instead often include structure and process indicators (Donabedian, 1988). An example of a structure indicator could be "whether PCPs have a register of their patients' smoking status", whereas an example of a process indicator could be "whether patients with COPD were given a spirometry test". The schemes may also include indicators related to changes in clinical measures that are more closely related to health outcomes, such as the reduction of blood pressure or blood sugar for diabetes. The different types of indicators to a different degree affect PCPs' ability to control

their own performance, potentially affecting their response to the payment scheme (Oxholm, Kristensen & Sutton, 2018).

As all aspects of quality of care cannot be captured by a single performance indicator, payers therefore need to consider the number of indicators to incentivize. On one hand, incentivizing only a few indicators could introduce multitasking issues and myopia because providers may choose to focus only on certain aspects of care (Eggleston, 2005; Holmstrom & Milgrom, 1991). On the other hand, an increase in the number of incentivized indicators may increase the administrative burden and the complexity of the scheme (e.g. the United Kingdom QOF initially listed 146 performance indicators (see Box 3.1.3)). PCPs who operate in small PCOs may find the administrative burden of P4P schemes, including information technology infrastructure, particularly challenging (see Box 3.1.1). Therefore, P4P schemes should strike a balance between these two conflicting concerns.

Providers' responses to P4P may depend on the basis for their reward – more specifically, the performance measure and the payment function that trigger the payment (Eijkenaar, 2013). The performance measure may be based on their absolute performance (one time point), their improved performance (two time points), or their relative performance (comparison to other providers at one point in time or over two time points). An example of an absolute performance measure could be “the share of patients with COPD who received a spirometry test in a given year”, whereas an improvement in performance could be “the change in the share of patients with COPD who received a spirometry test in a given year compared to one year ago”. An example of a relative performance could be “the share of patients with COPD who received a spirometry test in a given year compared to the share provided across all PCPs”.

Each of the different types of performance measure comes with both advantages and disadvantages from the payer's perspective. While rewards based on absolute performance may be perceived as transparent, this approach rewards previously achieved performance. In contrast, payments based on improvements reward only performance that has not previously been achieved. The issue with the measure of improvement is that it gives PCPs a financial incentive to lower performance in one year to be able to improve performance in the subsequent year. Paying based on relative performance (such as tournament-based payments) ensures

that the reward adapts to general time trends in performance across PCPs. PCPs may, however, then be rewarded without having changed their behaviour, simply by performing better than others. The relative reward may therefore discourage collaborations between PCPs, unless it is paid at a “team” level such as a medical group.

The payment function determines the level of performance that triggers a reward. The function is often linear (flat rate) or non-linear based on thresholds. Flat-rate payments reward PCPs the same amount for each unit increase in their performance measure. For example, PCPs are rewarded for “each COPD patient that has received a spirometry test in a given year”. This payment function is simple and incentivizes continuous increases in the performance measure. However, it does not provide a clear overall performance target for the PCPs to reach. An alternative is to use threshold-based payment functions, which are characterized by lower or upper limits on the performance payments. One example is target-based payments, where a payment is made only if a certain performance target is met. For example, PCPs are only rewarded if “90% of patients with COPD receive a spirometry test in a given year”. Target-based payment schemes set a clear goal for the PCPs to reach, but only focus on the top end of the performance distribution and may thereby fail to incentivize PCPs who either cannot reach the target or have already reached it. Setting multiple targets may solve this issue by setting obtainable goals for those at the lower end of the performance distribution (Eijkenaar, 2013; Mehrotra, Sorbero & Damberg, 2010).

The basis of reward may also affect patients’ access to care. Providers may choose to prioritize patients where the costs of triggering a performance payment is low, to the detriment of patients where the cost of improving performance are higher, such as those with more complex conditions (Oxholm, Di Guida & Gyrd-Hansen, 2021). A solution to this unintended consequence of P4P could be to risk-adjust the performance requirements, similar to capitation payment. Another factor that may affect patients’ access to care is whether P4P affects patients’ OOP spending. In many LMICs patients pay OOP for their care. P4P may influence these payments if, for example, providers are incentivized to stimulate patients’ service use to improve their performance (Anselmi, Binyaruka & Borghi, 2017). In such cases, P4P may make care more accessible to lower socioeconomic patient groups.

The size of the payments may also affect PCPs' responses to the scheme (Eijkenaar, 2013; Mehrotra, Sorbero & Damberg, 2010; Zaresani & Scott, 2021). The payment should be sufficient to cover the costs of changing behaviour, but not of a magnitude that creates budget deficits or removes focus from non-incentivized tasks. The costs of achieving a certain level of performance differ across indicators, PCOs and populations, which must be taken into account when setting payment rates.

The salience of the payment also influences the effectiveness of the scheme. A separate bonus may have more of an impact than if the same payment were delivered as part of usual revenues. The time lag between PCPs' effort and payment may also affect their response to the scheme, with long lags being demotivating for PCPs (e.g. McMahon, Muula & De Allegri, 2018). Such delays may in some cases be due to auditing of the performance data. Auditing is an important task for reducing the risk of gaming under P4P, which has been found to be present in both HICs and LMICs (e.g. Gravelle, Sutton & Ma, 2010; Kalk, Paul & Grabosch, 2010; Wilding et al., 2022). The payers should therefore try to strike a balance between reducing payment delays and ensuring data accuracy.

Payments made to the medical group rather than the individual PCP may decrease the saliency of the scheme as the medical group may decide not to use the payment to increase the personal income of PCPs but for some other purpose. Earmarking the reward for specific quality-enhancing initiatives instead of to PCPs' personal income could, however, also put focus on continuous quality improvement. In cases where the reward is given as personal income to the PCPs, the payers may choose to allocate payments in a way that reduces the strength of the incentives, such as sharing the payments equally rather than according to relative performance. This approach incentivizes collaboration among PCPs, but may also create so-called free-riding problems (Prendergast, 1999), where some PCPs receiving the bonus do not contribute their fair share to the joint achievement.

The saliency of the scheme is also affected by feedback to PCPs on their performance. Some electronic health record systems allow for real-time feedback to PCPs or may automatically prompt PCPs to undertake certain actions based on clinical guidelines, which may improve the quality of their care beyond the financial incentives. The feedback on performance may also be made publicly available. As

reputation among colleagues and patients may be important to the PCPs, public access to this information could potentially incentivize PCPs to improve their performance further (Prang et al., 2021).

Evidence of the consequences of P4P for primary care

The majority of the many literature reviews on the effectiveness of P4P schemes in health care conclude that the effect of P4P on quality of care is mixed and limited (see, for example, the reviews by Van Herck et al., 2010; Eijkenaar et al., 2013; Scott et al., 2011). This conclusion also holds when only considering schemes implemented in LMICs (Diaconu et al., 2021; Singh et al., 2020). Whether care is provided in the primary or secondary health care sector may, however, affect the effectiveness of P4P. Some reviews state that the effect of P4P on the quality of care tend to be more positive when targeted at primary care rather than hospitals (Eijkenaar et al., 2013). A recent systematic review of studies based only on outpatient health care finds that P4P slightly improves the quality of incentivized care (Jia et al., 2021).

When assessing the consequences of P4P for primary care, most evidence has come from one of the most comprehensive schemes, the United Kingdom's QOF (see Box 3.1.3). Studies conclude that in the first years of the QOF the performance on several incentivized indicators; for example, related to diabetes and asthma, improved at a faster rate than before the scheme (Gillam, Siriwardena & Steel, 2012; Roland & Guthrie, 2016; Campbell et al., 2009). In fact, many practices received maximum performance payment in the first year of the scheme (Roland & Guthrie, 2016). In the longer run the GPs' performance on the incentivized indicators generally remained at a high level but without further improvements (Guthrie & Tang, 2016). Studies also find indications of the scheme leading to relative reductions in some emergency hospital admissions (Harrison et al., 2014), but no effects on mortality rates (Ryan et al., 2016; Kontopantelis et al., 2015).

P4P's moderate impact on quality of care could be explained by poor evaluation designs, but also by the schemes being designed and implemented in many different ways and settings. For example, small sizes of payments have been highlighted as an explanation for providers' lack of response. However, a recent meta-regression analysis finds only weak evidence of a positive association between payment size and the

effectiveness of P4P schemes (Zaresani & Scott, 2021). In fact, the analysis finds only a few design features to be associated with the effectiveness of P4P. This conclusion should, however, be interpreted with caution as P4P studies often lack a detailed description of the design features of the interventions. More evidence is therefore needed on the impact of different designs of P4P on the quality of primary care.

P4P may not only impact quality of care but also access to care. The evidence on how P4P affects access to care is limited. Access issues are especially present in LMICs (Diaconu et al., 2021). Some studies based on LMICs suggest that P4P may improve access to care (Singh et al., 2020). This finding may partly be explained by providers doing more outreach work under P4P. For example, a study evaluating a P4P scheme in Rwanda suggests that community outreach may play a role in improving quality of child and maternal care services under P4P (Basinga et al., 2011). Several studies based on LMICs also mention the importance of availability of skilled personnel, drugs and equipment to improve patients' access to care under P4P (Singh et al., 2020). P4P may, however, in itself also have a positive effect on the availability of these resources and thereby improve patients' access to care. Another factor that may affect patients' access to care is OOP payments. A recent review of P4P based on LMICs, however, finds no clear changes in user fees under P4P (Diaconu et al., 2021).

Conclusions

Payment models for primary care can influence broader health system objectives. This chapter, after summarizing the basic methods of payment, explored the extent to which two global policy challenges can be met through primary care payment methods. The evidence suggests primary care payment methods can be used to reduce avoidable secondary care and can influence the quality of primary health care. Though we have not provided a critical review of the quality of the evidence, previous studies suggest that these effects are context dependent and their measurement may vary with the quality of study designs. Furthermore, most studies focus on a subset of outcomes and rarely fully examine cost-effectiveness or effects on health outcomes of patients.

Strengthening primary care to keep patients out of hospital is an important solution to keep health care costs down, but it might not

keep costs down if primary care is expanded while secondary care is not reduced. This solution therefore ignores the much more relevant policy question of the optimal mix between primary and secondary care. Existing empirical evidence suggests that payment models can help achieve an appropriate balance between primary and secondary care. This is possible with FFS which encourages PCPs to provide more care themselves, or with pooled capitation budgets, which can exist in vertically integrated health systems. However, expenditures may increase for single budget capitation, where the capitated budget covers only primary care. There also exists some evidence that P4P can encourage more appropriate referrals if performance is measured in terms of health outcomes or following evidence-based guidelines.

Evidence on whether payment models, in the form of P4P, can improve quality of care has mixed results. However, studies based on the primary care setting generally suggest that P4P slightly improves quality of care. The moderate response to P4P could be due to poor evaluation designs, but also due to the schemes being implemented in different contexts and with different payment designs. These design- and context-specific elements therefore require careful consideration. For example, if performance measures are not appropriately risk adjusted, P4P could lead to inequalities in access to primary care. Context-specific factors, such as availability of health care resources and OOP payments, could also impact the effectiveness of P4P. This might especially be the case in LMICs where many patients pay OOP for their care and access to skilled staff, equipment and medicine may be limited. Meanwhile, P4P may in some cases also be used as an instrument to improve the availability of these resources in such settings.

Payment methods in primary care are often blended to create a balanced mix of incentives. For example, salary and capitation payments provide an incentive to minimize costs, whereas P4P and FFS incentivize the PCP to increase activity. The precise blend of these different payment schemes required for payers to reach their goals is difficult to determine as it may depend on the health care setting and context, such as availability of resources or competition among providers. More knowledge is therefore needed on how to blend payments to achieve payers' goals.

Primary care payment models are of course only one way to help meet health care payers' goals. These payment models need to be carefully considered within the context of each health care system and its level of

development and funding. For example, there are clear differences between HICs and LMICs, where in the latter primary care is usually publicly funded and the last part of the health care system to develop after more specialized hospital care in metropolitan areas. In addition, LMICs generally have fewer resources and so are less likely to have the digital infrastructure that is needed to underpin some payment models such as P4P and the extensive risk adjustment necessary in capitation models (see Box 3.1.1). Payers therefore often face a trade-off between complexity and effectiveness when designing a primary care payment model.

We have examined two important global policy challenges that primary care payment models may impact, i.e. reducing avoidable secondary care and increasing quality of care. There are also many other aspects of health care that primary care payment models can potentially influence, including access to health care such as PCPs' labour supply, geographical distribution and specialty choice. Reforms to primary care payment models therefore need to be considered holistically in terms of their effects on payers' goals.¹

Additional resources

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3.2 *Methods for paying hospitals*

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Key messages

Chapter 3.2 covers the way hospitals are paid. Methods for paying hospitals vary across countries and include fee-for-service (FFS), block contracts, line-item budgeting (where purchasers specify exactly what funds are used for) and activity-based funding (with a fixed rate for each episode of care independent of the hospital's costs of care). Increasingly, pay for performance (P4P) elements are also used. Key learning includes that:

- Third-party purchasers: government agencies, social health insurance (SHI) funds or insurance companies provide the bulk of hospital revenue giving them levers to shape provision.
- Purchasers and hospitals have distinct objectives that are not always aligned – purchasers will pursue the best quality of care at the lowest price for their covered population while hospitals seek stable revenue streams to cover their costs.
- Information asymmetries give hospitals advantages over purchasers.
- Purchasers use payment methods and financial rewards to incentivize the volume and quality of care, patient-mix and management effort they want. There are complex challenges around:
 - specifying the details;
 - negotiating effective contracts; and
 - managing payment systems.
- Monitoring outputs and safeguarding quality requires structures and systems which are costly.
- Reforming funding or transitioning from one payment model to another is often a long process that demands sophisticated design and careful implementation.

Introduction

In most countries the greater proportion of hospital income does not come from patients themselves paying for the care they received. Instead, as detailed in section 1 of this volume, it comes from third-party payers: in tax-based health systems, these payers are government agencies; in social and private insurance-based systems, the payers are sickness funds and insurance companies (see chapters 1.1 and 1.3). Whatever their form, payers share a common set of general funding objectives when it comes to how they pay hospitals, but they may prioritize these objectives differently, and their priorities may change over time.

In this chapter, we discuss the dynamics of the payer–hospital relationship: how payers can use the financial rewards or incentives built into contracts to try and reach their goals and how hospitals use informational advantages about the provision of care to pursue their objectives.

We begin by discussing the relationship between the payer and the hospital and key considerations in any funding policy. Next, we outline the respective funding objectives of payers and hospitals and set out four distinct payment models: line-item budgeting, FFS, block contracts and activity-based funding. We then go on to examine the factors influencing design choice, namely the number of payers and hospitals in the system, what weight payers attach to each objective, and the effort involved in designing and managing the payment mechanism. We consider the issues involved in transitioning from one payment mechanism to another and discuss how to incorporate quality in payment design. Finally, we review the practical issues involved in paying hospitals, by way of a case study of changes in England’s National Health Service (NHS) hospital payment methods between 2002 and 2021. We conclude that there is no “best” payment model, the choice being critically dependent on system characteristics and capacity and related to which objectives the payer wishes to prioritize.

The payer–hospital relationship

Health systems differ widely in their number of payers and hospitals. At one extreme, in a health system in which everybody pays the full cost of care themselves, there are as many payers as there are patients. At the

other extreme, patients pay nothing out of pocket (OOP) but instead a single payer, usually a government body, takes responsibility for paying for care. Between these extremes, other health systems feature multiple payers, such as insurance companies, sickness funds or regional health authorities. On the hospital side, some small countries have only a single hospital; in other countries there are many hospitals, sometimes located quite close to each other and, perhaps, in competition with one another. In due course, we shall argue that the number of payers, in particular, and, to a lesser extent, the number of hospitals, are key factors in the choice of payment method.

The choice of payment method is also determined by what payers and hospitals wish to achieve and the system context. To help shape the discussion that follows, we start with a stylized health system with a representative payer and a representative hospital, each with their own set of interests and objectives. We use a principal–agent set-up to describe their relationship, in which the principal (here, the payer) uses a contract (the payment method) to encourage the agent (the hospital) to work in the principal's interest.

This principal–agent relationship is likely to be imperfect, for two main reasons. First, even if the payer and hospital share some common objectives, they will not coincide exactly. The payer and hospital may attach different weights to those objectives that they have in common, and there might be some objectives that they do not share. The payer uses the contract to better align the interests of the hospital with its own objectives, offering the hospital some form of reward (usually financial) if the hospital does what the payer wants.

Second, the hospital will enjoy informational advantages over the payer: the skills of the payer (priority-setting, pricing, benchmarking) are normally quite different from those of the hospital (operational management and service delivery). As such, the hospital will normally be better placed than the payer to know which combination of inputs (skills, technology) is most likely to lead to the best outcome for an individual patient, and the average and marginal cost to the hospital of treating the patient in this way. But the hospital might exploit informational advantages to further its own interests, both during contract negotiation and in contract delivery (Mühlbacher, Amelung & Juhnke, 2018; Jiang, Pang & Savin, 2020). During negotiations, the hospital might be able to secure a more generous contract by quoting a higher price than if both parties were equally informed about

precisely what work was involved and the marginal cost of that work. If the hospital exploits this advantage, it would mean the payer ends up paying more than it needs to get the job done. Alternatively, or additionally, the hospital might fail to fulfil its contractual obligations in full, perhaps by not delivering contracted services to a professional standard, or perhaps, discharging patients before they have recovered sufficiently to be able to cope at home. To guard against such possibilities, the payer might include specific incentives in payment method design, notably to safeguard quality, as we shall discuss later, and may need to monitor delivery and threaten sanctions if delivery is not to the desired standard.

Key elements of hospital funding policy

In an ideal world hospital funding policy would ensure that the right member of the health care team enables the right care to be delivered, in the right setting, on time, every time, at the right cost (see e.g. Nowak et al., 2012). Hospital funding design should also anticipate and address potentially perverse incentives which militate against achieving the broad overall policy; for example, by encouraging hospital admissions rather than care in the community when the latter might be more cost-effective.

Funding policy has two key elements: the design of payment flows, and the conditions or rules associated with the payment flow. These need to reinforce each other, reduce the risk of gaming and perverse incentives (Steinbusch et al., 2007) and capture the nuances required in a comprehensive funding policy. Policy-makers in different jurisdictions undertaking funding reform will face different challenges – including availability of information, industrial relations constraints, providers' management skills – and, consequently, the choice of payment model will partly reflect these local issues.

Different funding designs can emphasize one objective over another, and the priorities for different objectives will change over time, but we can consider the main objectives typically seen in hospital funding policy (Geissler et al., 2011).

Payer objectives: how they affect payment model design

From the payer's perspective, there are four key issues to consider when designing how to pay hospitals: the number and type of patients to pay

for, the quality of care, how much to pay hospitals, and how much effort the payer has to put into managing the payment method(s).

Issue 1: number and type of patients

Payers want the payment model to provide incentives for hospitals to treat patients, but specifying this incentive is challenging, again for two main reasons. First, while it is straightforward to quantify patient numbers, it is more difficult to take account of differences between patients: some are admitted for fairly routine operations, many are admitted without warning in need of immediate emergency care, some require ongoing care for multiple long-term conditions. As we shall see, one of the key distinguishing features of alternative hospital payment models is in how different types of patients are described.

The second difficulty in designing a payment model to incentivize treatment is that it might be better for some people to receive their care in settings other than the hospital. Payers want to ensure that unnecessary admissions are minimized, these being potentially preventable hospitalizations and those offering no or low-value care. However, there is information asymmetry between the payer and hospital on the need for admission, as hospitals will have more information about the patient's health status at the point of admission than the payer. Measurement tools for no and low-value care and potentially preventable admissions are not sufficiently refined to make case-by-case determination of the potential benefit of admissions but may be able to be used for retrospective monitoring.

Issue 2: quality of care

Defining quality of care is also tricky. Its definition needs to capture concepts associated with how hospitals are organized (structure), how patients are managed (process), and how health problems are addressed (outcome). Typically, quality has been poorly defined in the design of hospital payment arrangements, though that is beginning to change.

The simplest funding design includes an implicit assumption about the quality of service provision, the hope being that payers and hospitals attach equal weight to quality, such that it will not be compromised. However, because it might be costly to provide higher-quality services and quality is difficult to measure, hospitals might reduce quality in order to treat more patients, especially if this generates higher

revenue. This might be manifested as poorer process quality, such as patients having to wait a long time before their hospital appointment. Delayed access may then exacerbate their health problem, thereby proving more costly than quicker access, and long waits for access could cause reputational damage to payers and their political overseers; and/or health outcomes might be compromised. Alternatively, hospitals might discharge patients from hospital too early, transferring responsibility for care and shifting costs onto the family and primary or community care providers, a phenomenon dubbed “quicker and sicker discharge”, which has been the subject of many studies (Kosecoff et al., 1990; Qian et al., 2011). Other adverse quality consequences are harder to assess, but recently funding policies have elaborated on the quality dimensions of funding design so as to explicitly incorporate factors related to clinical quality, patient experience, patient-reported outcomes, timeliness, appropriateness and other aspects of care valued by patients and payers. We discuss incentives for high-quality care below (sometimes called P4P).

Issue 3: size of payment

The payer’s utility is decreasing in the amount it pays to the hospital: given the choice, the payer would prefer to make lower payments to the hospital and this might motivate the payer to design a payment system that encourages efficient practice by the hospital. These payments will be related to the amount of money that the payer has available to meet its objectives. Ensuring that the payer pays the “right” amount to hospitals is an important overall policy goal. But there are two quite distinct ways in which the “right amount” can be expressed: the total amount to be paid for all patients to be treated, or the amount for each patient individually. If the payer is a government agency, the total amount may take the form of a budget constraint imposed by the government, and might reflect the size and composition of the population served. If the payer is a sickness fund or insurance company, the amount will depend on the insurance premiums made by its enrollees but also other contributions such as co-payments. If there is no third-party funding, with patients having to pay for everything themselves, the constraint reflects the financial resources each individual patient has available.

In any system – whether tax-based, insurance-based or privately funded – there are trade-offs in how money is spent. More

spending on hospital care means individuals or societies have less to spend on other types of health care or on other individual or social goals. The ideal is that the marginal benefit of any increment in spending on hospitals yields the same marginal benefit as an investment in public health, primary care, education, defence, transport or anything else. In a publicly funded system, governments make decisions about total spending on health, and within health portfolios, on hospitals, given the budget constraints of the payer. The calculus behind these decisions might involve sophisticated analysis of marginal benefits and marginal costs using techniques such as programme budgeting and marginal analysis (Tsourapas & Frew, 2011; Kipiriri & Razavi, 2017), but are more likely to be shaped by path dependency, history and politics in assessing what marginal changes can be implemented in the current budget.

Recognizing that resources are scarce and choices have to be made, an objective of hospital funding policy might be to control total hospital spending, to keep within the resources available to the payer. A related funding objective would be to give hospitals incentives via the payment system to pursue technical efficiency, namely to treat patients at lowest cost, subject to there being no adverse quality consequences. Objectives about promoting efficiency can only be pursued with reasonable amounts of effort by the payer if there are robust ways of measuring the quantity and quality of care that hospitals provide. These two funding ambitions – about controlling total expenditure or ensuring optimal efficiency – can be met simultaneously. However, it is much more common for one objective to be emphasized over another, or for efficiency objectives to be seen as part of the strategy to achieve expenditure control.

Issue 4: amount of management effort needed

In designing a payment model, the payer will also consider how much effort they – and hospitals – have to put into negotiating and managing the contract, making the payer averse to implementing a payment system with overly complex design features or contract monitoring requirements, especially in places where the capabilities to implement and manage a complex payment system are in short supply. We discuss this issue in more detail below.

Hospital objectives

We turn now to what hospitals wish to achieve. Like the payer, the hospital also cares about the number and type of patients treated and the quality of care they receive. If the payer and hospital attach exactly the same weight to these concerns and provision of care is costless, there would be no need for a contract: the hospital would do what the payer wants, without needing to be asked. This situation is referred to as perfect agency. But, in practice, the interests of the payer and hospital are likely to differ. They might disagree about how many and which type of patients should be admitted to hospital; they might also have different views about the appropriate quality of care. In addition, hospitals are concerned that their income covers their costs and enables them to function; and that the payment system can be managed to serve their interests.

Sufficient income to cover costs

The main reason that the interests of payer and hospital differ is that provision of health care is not costless. The hospital has to employ a variety of labour and capital resources in order to deliver care, incurring various costs in the process. Consequently, the hospital requires a stream of revenue to ensure that it can function. The hospital will be concerned that the money received from the payer is at least sufficient to cover these costs. The more that the hospital is driven to make its income from the payer exceed its costs – be that by increasing the former or by reducing the latter – the greater the weight it will place on this element in its objective function.

A manageable model

It also takes effort to manage the contract with the payer – directly (in terms of the hospital's administrative burden) and indirectly (in terms of how stretching the contract's terms are on the hospital's staff). Like the payer, the hospital might prefer a simpler payment model, with minimal reporting requirements. This preference will be driven partly by a desire to reduce its administrative burden, but a simpler model might also provide greater scope for the hospital to increase the surplus of its revenue over its costs, by exploiting its information advantages. For this reason, the payer might not choose to adopt the simplest payment model.

Hospitals as “multi-product” firms

Hospitals may be characterized as multi-product firms, and so payment policy must recognize and pay fairly for all appropriate services, with “appropriate” here being from the perspective of the payer. If paying for activity, payers will need to ensure that activity is appropriately described. Diagnosis-related groups (DRGs) are the most common classification for inpatient activity but cannot be used for outpatient activity, and have poor explanatory power for mental health activity and other activity, such as rehabilitation, so service-specific classifications have been proposed in these areas (Jackson & Sevil, 1997; Mason et al., 2011; Sutherland & Walker, 2007). As well as caring for patients, some teaching hospitals engage in the education and training of future generations of health professionals and undertake research, which also need to be paid for in some way.

Better payment models minimize the extent to which the characteristics of providers are used in funding design, emphasizing payment for what is provided rather than who provides it. The one exception to this rule is for smaller hospitals – typically located in rural areas – where a key role of the hospital is ensuring access in these areas. Here, alternatives to standard payment methods will be required to protect viability and ensure an appropriate service response to community need (Holmes, Pink & Friedman, 2013; Murphy, Hughes & Conway, 2018).

Payment methods for hospitals: four key types

Hospital payment methods can be categorized into four archetypal groups. In this section we set out the key features of each, summarized in Table 3.2.1, allowing us then to discuss the factors influencing which model payers are likely to adopt.

Line-item budgeting

Under line-item budgeting hospitals are funded according to the type and amount of resource inputs used in delivering care. Budget lines tend to be itemized in fairly crude terms as inputs, such as medical and nursing staff, medicines, meals, laundry, materials, equipment, energy, estate and management costs. The payer, usually a government agency, sets the budget in advance, often built up by categories of inputs (e.g.

Table 3.2.1 *Key types of hospital payment method*

Criterion	Line-item budgeting	Fee-for-service (FFS)	Block contracts	Activity-based funding (ABF)
Description of patients	Not applicable	Individual patients	By cohort, such as department, hospital, locality, region or demographic (e.g. frail and elderly patients with multiple chronic conditions)	DRG for inpatients and other classifications for outpatients, mental health care, community health care
Price setting	Expected cost of resource type	Price list for each service or payment per day	Price is out-turn of negotiated total contract value divided by cohort covered	Prospective price set by payer so as to incentivize hospitals (e.g. by yardstick or actual competition)
Volume of activity	Not specified	Hospitals face no restrictions on volume	Expectations on hospital – normally including activity levels per cohort – set out in contract	In the simplest form of unit pricing, no restrictions of volume. In more complex forms of bundled pricing, implicit constraints on volume

Table 3.2.1 (cont.)

Criterion	Line-item budgeting	Fee-for-service (FFS)	Block contracts	Activity-based funding (ABF)
Quality	Not specified	Not specified, but implied that more services indicate higher quality	May be set out in contract	May be included in payment function
Administrative complexity/effort	Low complexity: need method to link costs to be funded (staff, medicines, etc.) to hospital role	High complexity: need for itemized bills, may involve fee schedule to reflect costs of different items, and monitoring systems to avoid overservicing and ensure payment integrity	Moderate complexity: need to develop systems to ensure adequate services are provided to meet needs of patient cohorts and to ensure efficiency	Highest complexity: need to implement DRG classification, develop tariff or prices (unit and/or more complex) and monitor systems for payment integrity (e.g. code, count and cost units of activity)

DRG: diagnosis-related group.

Source: Authors.

approval to employ a specific number of nurses for a given amount of money) so that the hospital has clarity about the money it will receive to pay for these items.

This was the form of funding across the former Soviet Union in which central government determined the quantity of resources available to each hospital and fixed wages and prices (Mikesell & Mullins, 2001; Street & Haycock, 1999; Moreno-Serra & Wagstaff, 2010).

Advantages

The principal attraction of line-item budgeting is that it provides certainty to both the payer and hospital about the amount of revenue to be made available over the coming budgetary period, with tight expenditure control being the guiding principle. It also comes with a low administrative burden, the budget being based on readily measurable inputs and with monitoring usually limited to ensuring that the budget was spent on the inputs as specified.

Disadvantages

This funding arrangement has several drawbacks (Langenbrunner & Wiley, 2002). First, hospitals have no incentive to reduce the use of inputs – indeed the reverse, because any input reductions would probably be met with subsequent budget reductions. Second, just as the overall budget is tightly controlled, so is each line item, thereby ruling out substitution of one type of input for another. Third, the budget says nothing about how the money should be spent on those requiring care: the budget is unrelated to the number and type of people treated at the hospital. Overall, viewed in these terms, line-item budgeting provides little or no incentive for innovation, is unresponsive to the needs of patients and can be viewed as a simple, static payment system.

FFS

FFS is particularly common in health systems in which patients (or their insurers) pay for care themselves, with hospitals issuing bills for the care and treatment provided. Under FFS, hospitals receive a fee for each medical service provided to each patient, these being itemized on the bill. The services will include diagnostic tests, operative procedures, medications and a daily “hotel” charge to cover such costs as laundry, cleaning, meals, energy and general overheads. Hospitals in some

health systems use a simple billing arrangement, loading everything onto the daily charge, with hospitals receiving daily payments rather than a price for each itemized service.

Advantages/disadvantages

Under FFS, the more medical services provided and the longer the length of stay, the more a hospital earns in revenue. Hence, as long as it believes that patients are able to settle their bills, the hospital may be incentivized to treat every patient seeking care and to do as much as possible for them. For those able to pay, FFS might provide access to better amenities and more services (Ikegami, 2015). If so, and if “more is better”, FFS provides greater incentives to provide higher-quality care than the alternative payment models. But it could also lead to overtreatment and the provision of low-value services (Zhao et al., 2018; Chalmers et al., 2019).

The hospital issues its bills retrospectively, after services have been rendered, either to the patient or the patient’s insurer. Whoever the payer is, there is little choice but to settle the bill, putting the payer at high financial risk. In countries without universal health insurance, this can lead to catastrophic health expenditures for patients, whereby patients may receive bills amounting to anything between 10–40% of family income, or bankruptcies due to health care costs (Himmelstein et al., 2019; Dobkin et al., 2018; Xu et al., 2003a; 2003b; 2003c; Wagstaff, Eozenu & Smitz, 2020).

Sometimes insurers question whether particular services given were necessary. Utilization reviews are the most common way to do this, but these are expensive and have little effect on the volume of services provided (Rosenberg et al., 1995). In practice, then, the quantity of services is largely determined by the hospital. Most usually, insurers try to limit financial risk by imposing a fee or price schedule, detailing the price per service that they are prepared to pay. This would mean that the price for each service is determined by the payer. In the absence of insurance, patients have no ability to influence these prices.

Block contracts

The key idea of the block contract funding model is that the amount to be paid is determined in advance. As a minimum, block contracts

stipulate the delivery timescale, the total amount of money to be paid, and the cohort (that is, type and number) of patients to be treated. There might also be some specification of quality. Sometimes the block contract will take the form of a capitation payment model covering a particular patient population, with the amount reflecting expectations about utilization among that cohort. The capitation payment (or price per patient) is simply the total amount of money specified in the contract divided by the number of patients in the cohort. The payer and hospital are likely to enter into several contracts, differentiated according to how cohorts are described. The cohort might reflect the hospital department with primary responsibility for delivering the particular type of care, the hospital's catchment area, the wider geographical region the hospital serves, or some indication of the type of patient in the cohort (e.g. frail and elderly patients with multiple chronic conditions). Sometimes a hospital might enter into a single contract for an especially large patient cohort, this special case being referred to as a "global budget". Where capitation payments rely on the clinical characteristics of enrollees, the payer has to be wary of gaming risks where the funded entity artificially inflates diagnoses (Geruso & Layton, 2020; Porter & Kaplan, 2016; Chernew et al., 2021).

A block contract can be used in a variety of different circumstances, with different effects. For instance, block contracts might be the historical form of the payer-hospital relationship, with contracts determined by history or past negotiations. Here payers put a high value on their effort in determining and monitoring contracts, with less emphasis on quantity or quality. Negotiation-based block contracts might involve an expected quantity to set the value of the contract, but with little scope for variation from the total spend if volume exceeds expectations. If so, activity-related cost risk sits with the hospital, not the payer. So this form of block contract might be preferred by payers with tight budget constraints. Because of their relative simplicity, block contracts are often used for services which cannot be described particularly well, such as where an activity measure has not yet been developed (e.g. mental health services); it is a unique service (e.g. highly specialized care); or the service would be unviable under other methods of payment, but the payer wants to ensure the service continues (e.g. small rural hospitals necessary for access). With this form of block contract, the activity-related cost risk sits with the payer.

Advantages/disadvantages

Block contracts provide financial certainty for both the payer and the hospital, as the total contractual value is decided in advance, particularly if the payer imposes a “hard” cap where activity beyond the contracted amount is not reimbursed. The danger of a hard cap is that the hospital risks being unable to cover its costs if demand exceeds the contracted volume, because they will not receive extra funding. This might encourage hospitals to do just enough to fulfil their contractual obligations and refuse to treat more patients than the contracted volume. This would result in either denied or delayed care. Indeed, hospital waiting lists are often evident where block contracts are the dominant form of hospital funding (Iversen, 1993; Street & Duckett, 1996). This problem might be mitigated if the contract allows for a “soft” cap, permitting partial reimbursement of extra activity (Chen & Fan, 2016).

Although contracts provide certainty, payers may still make excessive payments. This is because the values for both the target volume of patients and the price are a matter of negotiation between payer and hospital. As the hospital enjoys an informational advantage on both counts, it may be able to secure a higher contract value than if both parties were equally informed.

Activity-based funding

The fourth payment type is activity-based funding, which is sometimes referred to as case mix funding, DRG funding or the prospective payment system.

In terms of how patients are described, activity-based funding can be considered a half-way house between FFS and block contracts. Under FFS, a personalized bill is drawn up for each individual patient. Under block contracts, the contract is usually specified at cohort – often departmental – level, implying that patients are described in fairly large and heterogeneous groups in the contract. Under activity-based funding, patients admitted to hospital are usually described using DRGs for patients, though other DRG-like classifications might be used for activity conducted in emergency departments, outpatient or other (e.g. mental health, community) settings. DRGs were first developed by Fetter et al. (1980) as a means to identify groups of admitted patients with similar diagnoses who were expected to have similar

resource requirements during their hospital stay. This design principle has guided the development of DRG systems around the world (e.g. Busse et al., 2011; Kimberly & de Pouvourville, 1993). The design of the DRG classification aims to maximize within-group homogeneity but, because there is a limited number of groups in the DRG classification, inevitably each group is still somewhat heterogeneous. Consequently, activity-based funding entails a less precise description of patient specificity than under FFS (where effectively each patient is their own group) but a more precise description than under block contracts.

Importance of clinical accounting skills: coding, counting and costing

Activity-based funding cannot be adopted without some form of system for classifying activity – known as coding, counting and costing – and countries have to decide whether to adopt or adapt systems developed elsewhere or create their own (Mathauer & Wittenbecher, 2013). Usually there is quite a protracted transitional period between introducing a coding-counting-costing classification system to describe hospital activity to its being used for payment purposes (Bredenkamp, Bales & Kahur, 2020). The choice of classification system is dependent on the underlying information infrastructure for coding, counting and costing activity, which influences how electronic data are collated from each patient's medical record, how data are shared between hospitals and payers, and how these data are verified. Developing and maintaining coding-counting-costing classifications across the range of hospital activities – including acute inpatients, outpatients, mental health patients, activity in emergency departments, ambulatory patients and others – requires good information systems and technical clinical recording, i.e. clinical documentation and coding skills.

All classification systems begin with good clinical recording. This is not a minor issue, even in high-income countries (HICs) with a long tradition of clinical coding and using patient records for research (e.g. the English NHS), but in low- and middle-income countries (LMICs) a patient's complexity may not be fully reflected in diagnoses recorded in routine data sets, which may especially miss out on comorbidities (Dyers et al., 2016). Preparing for activity-based funding in these countries should include strategies to improve clinical accounting skills (Moghaddasi, Rabiei & Sadeghi, 2014).

Mis-recording of comorbidities will weaken the discriminatory power of a classification system but will not necessarily preclude the use of activity-based funding. Kyrgyzstan, for example, started its transition from line-item budgeting to activity-based funding in 1997 with a home-grown classification system comprising just 28 DRGs (known there as clinical costing groups), expanding to 144 DRGs in 1998 and to 284 in 2019 as information systems better recorded diagnoses and procedures (Bredenkamp, Bales & Kahur, 2020).

Price setting

As with block contracts, activity-based funding prices are set in advance and are not related to the costs of any specific hospital but rather are set by the payer, usually following its review of the totality of costs for each DRG reported by all or a large selection of hospitals in the payer's jurisdiction. This form of price setting is known as "yardstick competition", a term coined by Shleifer (1985). Crucially this means that each hospital is a "price-taker", unable to influence the price it faces, mirroring what would be the case in a perfectly competitive market. By translating the cost information into prices, the payer effectively is making hospitals benchmark themselves against each other to reduce their costs, the price acting as a yardstick to which higher-cost hospitals should aspire. This should encourage hospitals to improve efficiency and minimize overprovision of services to the patient (Vladeck & Kramer, 1988). The payment system is also perceived as fair, offering "equal pay for equal work", with hospitals receiving the same price for each patient allocated to the same DRG. To function, this arrangement requires cost information from a sufficient number of hospitals for the benchmark to bite, the more the better. Of course, some health systems have very few hospitals, in which case the payer might need to seek benchmark information from elsewhere, perhaps from other health systems. For example, when activity-based funding was introduced to fund the main Landspítali University Hospital in Iceland, benchmarking information about hospitals in Sweden was used to inform prices (Hafsteinsdóttir & Siciliani, 2012).

Advantages/disadvantages

As hospitals receive a predetermined DRG price for each patient assigned to that DRG, regardless of the actual cost, some of the financial risk is shifted from the payer to the hospital. This happens because, although patient volume remains a risk for the payer, the hospital

assumes risk for its case mix. The more complex (and therefore costly) that the hospital's patients are in a given DRG, the less likely it is that the predetermined DRG price will cover its cost of treating them.

Activity-based funding could stimulate undesirable behaviour; for example, hospitals might engage in coding-creep, "cream-skimming" or skimping. Coding-creep arises when a hospital classifies "a patient in a DRG that produces a higher reimbursement" (Herwartz & Strumann, 2014; Simborg, 1981; Steinbusch et al., 2007; Carter, Newhouse & Relles, 1990; Steinwald & Dummit, 1989), evidence suggesting such practices do occur (Jürges & Köberlein, 2015). With cream-skimming, hospitals actively select patients that are cheaper to treat. Hospitals might be able to do this because they have better information about the patient's condition and prospects than those designing the DRG categories. Cream-skimming allows a hospital to identify more profitable patients, i.e. those with expected costs lower than the prospective price. Skimping involves underproviding services, perhaps by discharging a patient too early (Ellis, 1998). These undesirable responses can occur with other funding models too. However, because the link between clinical accounting and income is more pronounced under activity-based funding and FFS than block contracts or line-item budgeting, these responses are more of a risk under activity-based funding and FFS than for the other funding models.

In combination with other methods

Activity-based funding is often coupled with one of the other types of payment system, as not every type of hospital activity can be described using activity measures. For example, Kwon and Shon (2015) report that hospital income in Australia, Japan, Korea, New Zealand and Singapore is a mixture of activity-based funding and FFS, with hospital income in Thailand a mixture of activity-based funding, FFS and block contract. Especially in early phases of activity-based funding implementation, it may be coupled with FFS or block contract to pay for services to describe teaching and research activity, or services which may span inpatient and community care boundaries.

Influences on choice of payment model

There are four key factors influencing the choice of payment model: the number of payers, the number of hospitals, the relative importance the

payer attaches to their objectives, and payer (and to a lesser extent, hospital) effort in managing the system.

Key factor 1: number of payers

The first and most important factor is the number of payers in the health system. The fewer payers there are, the more power they are able to exercise in negotiations with hospitals. In health systems with no third-party payers, each patient is a payer, with minimal bargaining power. In such circumstances, patients are price-takers, having to pay what hospitals ask, with FFS being the typical payment model. If the health system features third-party payers in the form of insurance companies or sickness funds, FFS is also common, but these payers may be able to exert collective influence on hospitals in the form of a fee schedule in order to contain overall payments. But, even so, hospitals enjoy considerable power in deciding what volume of services to provide to each insured individual.

In other health systems, notably where health care is funded via taxation, third-party payers often take the form of government agencies with responsibility for specific populations, perhaps defined on the basis of geography, income or age. These payers receive a share of national tax funds to fulfil these responsibilities, this share usually calculated using a capitation formula reflecting the size and composition of the population. If there are only a few hospitals in their area, agencies may prefer to negotiate block contracts with hospitals (because of their lower administrative burden) which will likely reflect the volume (number) and type (composition) of hospital patients covered by the contract. As there are just two parties to each contract, the hospital may be able to exploit its information advantage to secure favourable terms.

Some health systems feature just a single payer. This shifts the balance of bargaining power from hospitals to the single payer, who is able to exploit its monopsony purchasing power and force hospitals into being “price-takers” rather than “price-makers” by imposing either line-item budgeting or activity-based funding payment models.

Key factor 2: number of hospitals

The second factor influencing the choice of payment model is the number of hospitals to which payments are to be made. If there were

a very large number of hospitals, all providing similar services and competing with one another to attract fully informed patients, FFS would be an efficient choice. This competitive environment would ensure that high-quality services were provided and fees were kept low. But this is not the customary environment that prevails in the hospital sector because of the asymmetry in information between hospitals and their patients. Rather, it is much more common for hospitals to face little competition, instead enjoying a degree of local monopoly power. A hospital might even have national monopoly power, in smaller countries or if they are the only providers of specialized care. The greater its monopoly power, the more ability a hospital has to set its own fees, thus making the FFS model less attractive to payers.

The other three payment models impose more financial control over hospitals than the FFS model, and line-item budgeting and block contract can be applied irrespective of the number of hospitals in the health system. However, under activity-based funding prices are set by comparing costs across hospitals, so there needs to be a sufficient number of hospitals from which the payer collects comparative data. As with FFS, the fewer the hospitals, the greater the scope for a hospital to influence prices advantageously, because its own data will have greater influence on the price it faces. To limit this influence, payers implementing activity-based funding may set prices using comparative cost or pricing information from hospitals in other jurisdictions.

Key factor 3: relative importance of payer objectives

The third determinant of the choice of payment model is the relative weight that payers attach to their different objectives, in particular: controlling hospital costs, volume of activity and quality of service.

Budget constraint

The greater the weight attached to controlling hospital costs (especially for payers subject to a hard budget constraint), the more likely that line-item budgeting and the less likely FFS and activity-based funding will be adopted. This is because FFS and activity-based funding both encourage additional activity, unless explicit activity capping mechanisms are introduced. Block contracts make management of the budget constraint easier for the payer than FFS and activity-based funding, but not as easy as line-item budgeting.

Volume of activity

FFS exercises no restriction on the volume of activity. Neither does activity-based funding, at least in its simplest form (i.e. with unit prices). Because line-item budgeting is concerned with resources more than quantity and quality, it neither specifies activity levels nor places restrictions on them. Again, block contracts lie somewhere in the middle from the payers' perspective, depending on how the contract is specified. At its crudest, the block contract could be whatever was agreed financially between payer and hospital for the last contracting period, increased for anticipated inflation (in activity and/or costs) over the current contracting period and decreased for expected efficiency (in activity and/or costs) over the current period. Here, the payer's target level of activity is included only in an aggregate sense, through the interaction of the last contracting period's activity and the uplift and reduction for the current period. In other cases, however, the block contract may be built bottom-up and not top-down. In this case, the payer's target level of activity is explicitly included at a disaggregated level (e.g. by hospital department or point of delivery).

Quality

From the payer's perspective neither line-item budgeting nor FFS inherently specify quality. That said, under FFS, hospitals earn more revenue by providing more care so, provided more care is better care, then FFS incentivizes quality. The same argument applies to activity-based funding, which incentivizes hospital activity, if more activity equates to better quality. In practice, however, more care may not equal better care. That said, if there is head-to-head competition between hospitals, by setting prices prospectively both activity-based funding and block contracts ensure that competition drives quality up rather than driving prices down. In addition to this inherent quality assurance mechanism, both block contracts and activity-based funding can incorporate specific payment for quality.

Key factor 4: administrative effort

The final relevant factor is the effort involved in managing the payment methods (Baxter et al., 2015). Payers and hospitals need to optimize the amount of effort involved. Payment arrangements are

not frictionless: both payers and hospitals need to exert effort in agreeing and managing the contractual relationship between the two parties. For hospitals, this will require ensuring that internal structures of the hospital make it easy to address the exogenous incentives – control of the mix of services used in treating a patient typically rests in the hands of the medical staff and so the job of hospital senior management includes ensuring that hospital doctors recognize the hospital's funding constraints (Young & Saltman, 1985).

Payers also need to exert effort to ensure that the funding design delivers on the objectives that they have prioritized. The more complex the funding model, the more effort is expended by both hospitals and payers in managing and monitoring it. Payers, especially, have to be wary of making the funding model overly complex. The more complex the model, the more difficult it will be for hospitals to understand the nature of the incentives at play and the more likely they are to ignore the incentives or respond to what they perceive the incentives to be (Abeler & Jäger, 2015). Moreover, if the incentives are unstable – for example if prices vary widely from year to year – hospitals may decide that the effort in responding to a given year's incentives is not worth the benefit, and so they might ignore the incentive.

Line-item budgeting involves minimal administrative complexity, both in terms of how the budget is specified and in how spending is monitored. As such, this payment method is likely to be preferred in places where information systems are poorly developed. Activity-based funding is the most complex of the payment methods, requiring implementation and maintenance of a classification system to describe patients, a pricing schedule and a monitoring system to verify the integrity of payments made by payers to hospitals. FFS and block contracts lie between these extremes.

The importance of management and policy skills can be seen in the results of the implementation of activity-based funding in central and eastern Europe, and central Asia. In their study of the system-wide impacts of hospital payment reform, Moreno-Serra and Wagstaff (2010) found that, contrary to theory, total health expenditure increased following implementation of activity-based funding. Moreno-Serra and Wagstaff hypothesized that this may have been due to DRG coding-creep. The potential for coding-creep should have been foreseen and its effect mitigated through a variety of strategies such as assuming a DRG effect of a particular size and factoring that into the price in advance, or

through rigorous auditing of coding. The impact of coding-creep could also be ameliorated by imposing lagged soft expenditure caps (Hahn, 2014; Holahan & Zukerman, 1993).

Transitioning from one payment method to another

The choice of payment method and its specific design features is context dependent and that context may change (D'Aunno, Kimberly & De Pourvoirville, 2008; Mathauer & Wittenbecher, 2013). Funding reform often adopts the twin system objectives of *transparency* of processes and outcomes, and *fairness* between hospitals, to facilitate support for implementation of the system change. In these circumstances, the key design elements of the payment method need to be clear and understood, and there needs to be a clear line of sight between the work performed by the hospital and the payment flow.

We have set out the key drivers of the choice of model in the previous sections, but other factors also play a part, perhaps relating to management, policy, information system readiness or path dependence. The payer's objectives, however, are the dominant driver, and these might change over time, triggering a move away from one type of payment method to another.

The process of transition: what is involved?

The transition process is often a long one, as the preconditions are developed (Annear et al., 2018), or the right policy window appears. Improved provision of comparative information to providers – to allow them to see where they stand on efficiency and other variables – is often part of a capacity-building phase.

A common next step is that this comparative information is used to inform budget setting – benchmarking here is an input into the budget negotiating process or used to inform the block contract. For example, in their review of the development of activity-based funding in 12 countries in Europe, Busse and Quentin (2011) showed that in half the countries the original use of the DRG classification system was simply descriptive or to inform budget allocation. Bredenkamp, Bales and Kahur (2020) drew a similar conclusion in their review of the transition to activity-based funding in nine countries. Indeed, the

possibility for such benchmarking was one of the drivers of the initial development of DRGs (Fetter, Brand & Gamache, 1991).

Transitioning: key questions and trends

Payers normally will have objectives about how the health system transitions from the old funding system to the new. These objectives might be about the pace of the transition. Over how many years is the phase-in? What proportion of funding is on the old versus new basis? And what should be the ordering of the transition – for example, starting with patients having elective procedures, or particular classes of patients or particular types of costs (Duckett, 2015)? Because there will be winners and losers from any transition between funding systems, the payer's objectives about the pace and phasing will often also factor in how to manage these gains and losses (Short & Goldfarb, 1987).

The introduction of new funding systems also often provides the opportunity to revisit the nature of the relationship between the payer and the hospital— what types of controls might be kept or changed? How much autonomy will hospitals have in the new environment? What constraints might there be on hospital innovation? Introducing new funding systems may even be driven by a desire to change that relationship.

Payers might try to pursue multiple objectives simultaneously, although this will require a more sophisticated design pursuant to the Tinbergen Rule, that multiple objectives require multiple instruments (Tinbergen, 1952). For example, one of the early implementations in 1993 of activity-based funding, in Victoria, Australia, had three objectives: to reduce total hospital expenditure; to improve the efficiency of hospitals; and to increase the number of patients treated and reduce elective procedure waiting lists (Duckett, 1995). Activity-based funding in Victoria replaced a system of negotiated block contracts. The stimulus for the introduction was a significant budget cut (15% over three years), effectively a tightening of the budget constraint, and a recognition that a reduction in the budget of that magnitude would, under a block contract system, probably result in a significant reduction in the quantity of services provided (and hence access). An activity-based funding model for acute inpatient activity was implemented – with hospital-specific activity caps but a potential to share in a capped allocation of extra funds for extra activity (Street & Duckett, 1996) – with all other hospital

services paid on a block contract in the absence of robust activity measures for those services.

Preconditions for transitioning from simpler to more complex methods

In view of the considerations set out in this section, it is common in practice to see a mix of funding methods used within any given health system, thereby moderating the extreme effects of any single method. “Transition” then means altering the mix of methods, rather than shifting wholesale from one to another. Yet regardless of whether transition is from one method to another or is a shift in the mix of methods from one to another, there are four preconditions for shifting from simpler funding methods (line-item budgeting, block contracts) to more complex ones (FFS, activity-based funding):

1. The development of robust risk-adjustment measures, generally based on an already established version of the DRG classification; but the larger the jurisdiction, the more likely an internationally imported version will be adapted to reflect local clinical practice.
2. The implementation of information systems – notably coding systems and grouping software. This is required to ensure that hospital managers have the appropriate information to identify where there is scope for performance improvements.
3. The development of administrative skills in the payer to design and manage the new system. This is a nontrivial task as poorly designed payment systems may not be seen as legitimate and are unlikely to gain acceptance; or may fail to anticipate the full range of perverse provider responses, including gaming. Poor ongoing management of a new funding system may not incorporate appropriate monitoring and interventions to sanction poor performance and again undermine confidence in the system, or may not incorporate adaptation for new technology.
4. The development of management skills in hospitals. A change of budget processes will also require a different set of skills – perhaps from managing negotiations with the payer to managing efficiencies within the organization more tightly.

The scarcer that administrative and management skills are, and the more challenging the development of risk-adjustment measures and

information systems is, the more likely it is that the funding model or mix of models will gravitate towards simpler forms (Baxter et al., 2015).

Ensuring quality: P4P

Increasingly, hospital payment models incorporate elements of P4P, either to address additional adjunct goals – most commonly quality or timeliness of care – or to mitigate design risks inherent in the payment system (Duckett, 2008). P4P comes in many different forms with different objectives, including paying for additional information provision, paying for adherence to standards, or paying for meeting a particular quality threshold or quality improvement (Milstein & Schreyoegg, 2016). A P4P approach has been proposed as a way of paying for better outcomes (Siciliani et al., 2021).

P4P: what it is

Health care funding contracts are often “incomplete” in the sense that they are not able to specify fully what is to be provided, especially in terms of quality, and this carries an inherent risk that providers might skimp on quality to reduce costs. In addition to evidence-based governance strategies to encourage quality improvement (Donabedian, 2002; Langley et al., 2009; Tello, Barbazza & Waddell, 2020), payers mitigate this risk by incorporating into payment design additional payments against additional metrics. Importantly, P4P is described here as a *supplement*: the basic stream of revenue needs to be adequate for all hospitals and the P4P supplement is an add-on, to reward superior performance on the relevant dimension (Cattel, Eijkenaar & Schut, 2020; Cattel & Eijkenaar, 2020). There is now an extensive literature about P4P, and an array of potential P4P designs (Cromwell et al., 2011; Conrad, 2015), with the net impact of a specific implementation the result of the interplay of several factors including gaming, target and reward setting, and health increasing and health decreasing substitutions (Friedman & Scheffler, 2016). Perverse responses – including gaming (Carter, Newhouse & Relles, 1990; Rosenberg, Fryback & Katz, 2000; Bevan & Hood, 2006; Steinbusch et al., 2007; Mannion & Braithwaite, 2012; Georgescu & Hartmann, 2013) – can be mitigated with regulatory strategies including monitoring, and penalties.

Difficulties with P4P

Although intuitively and theoretically sound, in practice P4P implementations – especially those which focus on changing a single provider type (hospital or primary care) or specialty – have generally not lived up to the expectations and rhetoric (Mendelson et al., 2017; Scott, Liu & Yong, 2018; Cattel, Eijkenaar & Schut, 2020; Cattel & Eijkenaar, 2020; Singh et al., 2021). Song's summary of the state of evidence about "accountable care" in the USA can equally apply to P4P:

Today, a verdict on payment reform resembles less the fork in the road between success or failure and more a work-in-progress that has improved the value of care in some situations but needs refinement (Song, 2021).

Unfortunately, P4P, especially when poorly designed, may crowd out intrinsic professional motivation and can create perverse incentives as evidenced in both the mid-Staffordshire scandal in England (Francis, 2013; Powell, 2019; Smith & Chambers, 2019; Entwistle & Doering, 2024) and the Bundaberg Hospital scandal in Queensland, Australia (van der Weyden, 2005; Thomas, 2007; Casali & Day, 2010; Edwards, Lawrence & Ashkanasy, 2016), where organizational targets and incentives for budget control or additional activity created environments where safety concerns were ignored. However, well-designed performance monitoring and P4P incentives can help to ensure that organizations pay appropriate attention to their processes and outcomes (Conrad & Perry, 2009; Conrad, 2015; Young & Conrad, 2007; Smith et al., 2009), particularly as they impact on the most vulnerable.

The evidence suggests, therefore, that careful consideration has to be given to how to incorporate P4P arrangements within the hospital payment model. The cost of including a P4P component may be modest, especially where the cost of the ostensible reward is transferred from other streams of the hospital revenue. In these circumstances, P4P simply leads to a slightly different distribution of a capped budget. P4P incentives serve a political and rhetorical purpose signalling that the payer values the metric rewarded and directing hospitals – who could be expected to respond to incentives at the margin – to pay attention to this metric too.

Evidence in practice: paying hospitals in the English NHS

In this section we consider how the discussion thus far has played out in practice, by considering how payments to hospitals in the English NHS have changed since 2002.

The NHS is taxpayer funded and universal. Fig. 3.2.1 below gives a simple schematic of how NHS care is paid for in England since 2021. The accountable government department (currently the Department of Health and Social Care) allocates funding agreed by Parliament to a government agency, NHS England. NHS England distributes funding to several hundred local buyers of health care, known as commissioners. In addition, NHS England distributes funding to primary care and buys specialized health care itself. Commissioners pay for health care from acute care providers (hospitals) as well as providers of NHS mental health services, community services and ambulance services. The NHS payment system in this schematic is represented by the shaded box. To give an idea of scale, in 2019/20 NHS England allocated nearly £79 billion to commissioners, £18 billion to specialized services and £8 billion to primary care (Bell, Charlesworth & Lewis, 2021).

There have been four major changes since 2002 in how hospitals are paid: the move from block contracts to activity-based funding for

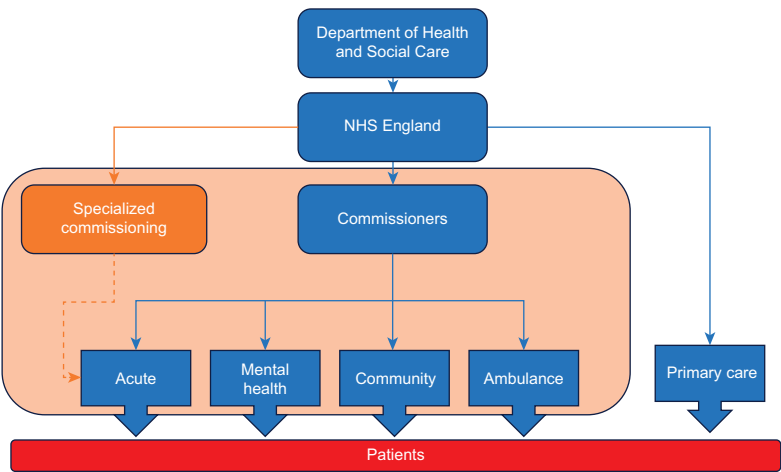


Fig. 3.2.1 Schema of payment flows in England

Source: Authors.

hospitals; changes in the number of payers; increasing complexity in activity-based funding for hospitals; and replacing competition between hospitals with collaboration as the main driver of improvement. Each is discussed below.

From block contracts to activity-based funding

Until 2002, acute-care services and mental health, community and ambulance services were paid for with block contracts. From 2003, activity-based funding began to be phased in to gradually replace block contracts for acute hospital care. It began on a small scale, with just 15 prices for elective surgery (and just 0.2% of commissioners' budgets) during a time of increases in NHS funding. It did so to address growing waiting lists and a so-called postcode lottery in access to care (Martin et al., 2003). Activity-based funding expanded steadily until by 2012 it had grown to 3000 prices for 1400 DRGs, covering 34% of payers' budgets. It grew further from 2013 following an expansion in the scope for payment to follow patients' choices; to 9000 prices for 2800 DRGs and 40% of commissioners' budgets. It included P4P elements linked to quality.

As it expanded, activity-based funding for acute care promoted productivity in hospitals (Farrar et al., 2009). Its P4P schemes improved quality (Meacock, Kristensen & Sutton, 2014). It also helped amass rigorous data on activity, costs and outcomes. Set against this, it rewarded unilateral interest and not collaboration (Cooper et al., 2011; Bevan & Skellern, 2011). It hampered management of expenditure and of unwarranted variation in activity (Mannion & Street, 2009) and it was burdensome to administer (Marini & Street, 2007). In addition, the mix of activity-based funding for hospitals with block contracts for community, mental health and ambulance services frustrated better integration of health care (Bevan & Janus, 2011).

Changes in the number of payers

Until 2005 each hospital entered into contracts with around two dozen payers, then termed district health authorities. Tax funding was allocated to authorities according to estimates of the health needs for the population of each district. From 2006 the landscape for payers changed from district health authorities to over 300 local, primary

care-led clinical commissioning groups. Hospitals then entered into thousands of contracts with these payers. As these contracts moved from block contract to activity-based funding, the system's demands on management skills and information systems increased.

At its peak in 2015, 88% by value of contracts between hospitals and payers used activity-based funding. By 2018 that had reduced to 58%. There were two drivers for this reduction: administrative burden and budget. In a typical year in this period, hospitals issued some 600 000 monthly invoices to payers. Almost 200 000 of these were for less than £1000 as hospitals and payers argued about month-end bills. A shared desire by some local hospitals and payers to reduce this administrative effort saw many move reimbursement away from activity-based funding.

A sustained period of austerity in United Kingdom government spending followed the 2008 global financial crisis (Ford, 2013). This reduced the rate of annual funding growth to the NHS to less than half its long-run average (Walshe & Smith, 2015; Charlesworth & Bloor, 2018). By 2015 this manifested itself in a lack of hospital capacity and in large and growing hospital deficits, as prices for DRGs were scaled down by more than 10% below average unit costs. As a consequence, the incentives for head-to-head competition between hospitals declined, as did the desire of payers and hospitals to contract using activity-based funding.

Increasing complexity in activity-based funding

Initially, as activity-based funding was expanded to support patient choice and head-to-head competition between hospitals, it became more complex (Marshall, Charlesworth & Hurst, 2014). As well as the number of DRGs attracting activity-based prices expanding greatly, four types of financial incentives for quality were added to the payment system. The first enabled hospitals to reclaim funding held back by payers (of a few percentage points of their budgets) when they achieved improvements in process quality (e.g. ensuring hospital staff had winter flu vaccinations) and patterns of care, especially preventive care (e.g. screening infants for malnutrition). The second rewarded outcome quality, with hospitals paid a higher price for “best practice” (meaning high-quality and cost-effective) care, with the goal of reducing unexplained variation in hospitals' clinical quality in areas such as adult

stroke care and children's diabetes care. The third enabled payers to claw back activity-based funding (of a few percentage points of their budgets) if hospitals did not meet standards for quality on metrics such as hospital-acquired infections, waiting times for elective care or emergency admissions for non-elective care. And the fourth gave hospitals top-up payments, either for extra cost incurred (e.g. on long staying or very complex patients) or for exceeding activity thresholds in certain areas (e.g. faster emergency care, more elective care). Later versions of these top-up payments included risk-sharing mechanisms, to help ensure spending did not exceed payers' funding allocations.

Even where head-to-head competition between hospitals was not possible (or became less desirable), activity-based funding was used to underpin comparative competition. This is because prices were based on reported costs. Each year hospitals submitted to NHS England data on the cost of each unit of activity for each DRG. Subject to adjustments, the average unit cost for each DRG was the activity-based price for that DRG (Street & Maynard, 2007). A hospital whose cost lay below the activity-based price it received earned a surplus on each unit of that activity; one whose cost lay above was incentivized to reduce its unit costs.

Replacing competition with collaboration as the main driver of improvement

To incentivize increased activity, activity-based funding introduced unit prices for individual DRGs. As activity-based funding expanded to support patient choice, prices continued to be unitary to ensure the right type of head-to-head competition between hospitals. Because in reality English hospitals faced little competition, they had influence over the prices they faced. Competition between hospitals then had two countervailing effects on quality. On the one hand, it encouraged hospitals to improve quality for a given price in order to attract patients and funding. On the other hand, higher quality may be costly to provide and is hard for patients and payers to judge. So by reducing profitability, competition discouraged hospitals from spending on (hard-to-judge) quality, in order to keep costs and (easy-to-judge) prices down. The overall impact of competition on quality is the net of these two effects. To ensure patient choice drove quality up rather than prices down, activity-based funding prevented price competition by fixing unit prices above average unit costs.

As the impact of government austerity on NHS funding was felt, hospitals lacked capacity and financial deficits grew. With little incentive for hospitals to compete, there was little head-to-head competition between them. Collaboration and not competition became the principal driver of improvement in hospital performance (Allen et al., 2017; Alderwick & Ham, 2016). The 2019 NHS Long Term Plan cemented this, foreshadowing multilateral, integrated local care systems to replace bilateral commissioner-provider relationships, the better to promote integrated care (NHS England, 2019). To support this multilateralism, the Long Term Plan ushered in population-based funding and a return to block contracts to replace activity-based funding.

Policy relevance and conclusions

In this chapter we have set out a stylized description of the relationship between those who pay and those who provide hospital care. This recognizes that both parties have an interest in the quantity and quality of care provided, and the costs incurred in providing it, but are likely to attach different weights to these interests. Payers use payment arrangements to align the hospitals' interests with their own, and we described four archetypal methods: line-item budgeting, FFS, block contracts and activity-based funding. We then set out the reasons why one of these methods may be adopted rather than another, and considered issues involved in transitioning from one to another and how each might evolve to capture more complex elements in the payment model, notably quality.

We draw three conclusions from this assessment. First, there is no "best" payment model. Rather, the choice is service and context specific, depending on the number of payers and providers in the health system, the objectives that they wish to achieve, and the relative weights attached to these objectives.

Second, the payment model is not a static set of immutable rules. Rather, the details of how the model operates are regularly updated, with payers and hospitals agreeing specific arrangements, usually for the year ahead. This evolution will be driven by various factors, particularly during the transition phase from one payment model to another. Payment adaptations will also be required to reflect new technologies and innovations in the ways that care is delivered, particularly if it becomes possible to provide care in alternative settings. But a key driver

of this evolution is changes in the relative weights that payers attach to their objectives. Even small changes in emphasis can have a large impact on payment design, to the extent that previous preference for one method might shift to another, as evidenced by the English case study. A change of government might also lead to tectonic shifts in weights.

The third conclusion is that, even though we have described these payment methods in stylized, simplified forms, in practice paying hospitals is a complex process and difficult to get right. This is not surprising because providing hospital care is complicated, tailored to the specific needs and characteristics of each patient. A simple payment method will be easy to implement and monitor but comes at the risk that patients will not receive the right care, at the right time, in the right setting. More complex payment models aim to protect against this risk, but at the cost of extra effort that needs to be exerted by payers and hospitals in understanding and abiding by the contractual arrangements.¹

Additional resources

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¹ Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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3.3 *Informal payments in health care*

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Key messages

Chapter 3.3 examines informal payments. Informal payments are unsanctioned, unregulated payments made out-of-pocket (OOP) by patients directly to their health care provider for services that are covered by third-party purchasers. They are not recorded in routine administrative databases but can be captured in surveys, although they are usually underreported. Key learning includes that:

- Informal payments reduce access to health care and financial protection. They can undermine population health and reduce trust in providers and governments in the long run.
- Informal payments often stem from unmet desire for safe, timely or high-quality care and imply a mismatch between supply, demand and pricing in the formal health care payment system. When formal system payments are felt to be inadequate, informal payments may also be used to express gratitude to providers.
- Settings with low physician density, and/or where the share of gross domestic product (GDP) spent on health care is low, tend to have higher levels of informal payments.
- Informal payments are also associated with settings with high reliance on formal OOP payments (user charges).
- Reducing or ending informal payments is difficult and requires a combination of specific, targeted measures and broad health systems reforms that address underlying causes.
- The policy measures that may reduce informal payments include:
 - formalizing OOP payments, with exemptions to protect vulnerable populations;
 - making clear and explicit what the health care benefits package covers;

- better monitoring and enforcement of rules and penalties;
- maintaining and expanding publicly financed statutory coverage.

Introduction

Payments made directly by patients or users of the health system to their health care provider are known as OOP payments and comprise three types. Two are formal: (i) direct payments for services or goods that fall outside the remit of the official third-party payer such as government-funded health coverage programmes, private health insurance, or social health insurance (SHI); and (ii) cost-sharing, which refers to the contractual requirement by these third-party payers for individuals to pay a portion of the cost of goods and services that the third parties cover (Rechel, Maresso & van Ginneken, 2019). The third type of OOP payment is informal and outside the system – and it is these payments that form the focus of this chapter.

There is a lack of clarity about both the overall incidence of informal payments worldwide and the reasons for them. Informal payments are often not recorded in any accounting systems and may be illegal, depending on the type of exchange. These features make it difficult to measure their prevalence and frequency within a country, let alone make comparisons between countries. Also, informal payments can vary widely across key dimensions, such as: who initiates the payment (patient, provider); who pays (patients, families); who are the recipients (often physicians, but also other health care providers or administrative staff, or even hospitals or other health care organizations); what form they take (cash, in-kind medical supplies or equipment, or in-kind, unrelated to health care); and when they are made (before, during and/or after accessing health care) (Gaal et al., 2006). Additionally, whereas cost-sharing may be introduced into a health system to either raise revenue or to reduce/redirect health system utilization, the motivations or purposes of informal payments vary within and between countries. On the one hand, informal payments may be a form of gift-giving or expression of gratitude that is unrelated to the receipt of care or its quality. On the other hand, informal payments are commonly used to facilitate access or to secure higher quality health care.

The chapter presents our exploration of the phenomenon of informal payments as follows. We look briefly at how they are defined in the

literature, the descriptions given of their motivation, and the detrimental effects they have on health system performance. We then discuss both the theoretical drivers of informal payments and empirical evidence that helps explain why they emerge. The next section then provides estimates of the global prevalence of informal payments before we zoom in on the Greek health system in a case study outlining their use there. The chapter concludes with suggestions of mechanisms to reduce/end informal payments and thus improve health system performance.

Informal payments in the literature: definitions and motivation

Three definitions of informal payments

A comprehensive review of the literature in 2013 identified 61 studies that defined informal payments in health care, and suggested that there were three distinct and original definitions (Cherecheş et al., 2013). The first was proposed by Lewis (1999) who defined informal payments as:

payments to individual and institutional providers in-kind or cash that are outside the official payment channels, or are purchases that are meant to be covered by the health care system.

The second definition was introduced by Belli, Gotsadze and Shahriari (2004) who explicitly positioned informal payments within the broader category of OOP payments. Specifically, they noted that informal payments are:

all payments that patients report to pay directly to their health care individual or institutional provider above the legally set co-payments for basic benefits package (BBP) services and above (or below) the regulated fee-for-service (FFS) fees for non-BBP services, plus all in-kind contributions and gifts. Thus, we consider informal payments as a subset of the OPPs (OOP payments). According to this definition, it is not really important whether or not transactions between patients and providers are registered for tax purposes, but whether such payments are or aren't different from the legally set co-payments or regulated fees. We assume that all transactions where the patient reports he/she was not given any information about official co-payment rates or fees are to be considered as informal.

Finally, a now widely used definition of informal payments was developed by Gaal and colleagues (2006) which captures the full spectrum of

informal payments globally and underscores the importance of entitlements as the defining feature of informal payments that distinguishes them from other payments in the health sector. Thus, according to this definition, an informal payment is:

a direct contribution, which is made in addition to any contribution determined by the terms of entitlement, in cash or in-kind, by patients or others acting on their behalf, to health care providers for services that the patients are entitled to.

Therefore, in order to define and measure informal payments in the health sector, we need to understand the services that individuals are entitled to within the publicly funded, statutory health programmes.

Motivation: donation, FFS, tax avoidance

The question of motivation for the payment is an important consideration because, at one end of the spectrum, gift-giving that is common cultural practice may be a nuisance for some but may not in fact represent a policy problem in a jurisdiction. However, at the other end of the spectrum, an informal payment that is motivated by pressure on patients may have adverse impacts on intermediate and final health system objectives including efficiency, quality, equity in access, equity in finance, financial protection and health outcomes (see Box 3.3.1). Gaal and colleagues (2006) delineate the two dominant motivations of informal payments as donation and FFS. The former is a “benign informal payment”, often called a “gratitude payment” because it is given voluntarily, is considered a form of appreciation, and is not given with the intention of directly impacting the services being provided. The latter is an “under-the-table” payment motivated by either an individual’s desire to receive safe, timely or good quality care, or to ensure or facilitate access to care, thereby potentially impacting health outcomes. Due to the lack of transparency, an under-the-table payment also limits the health system’s ability to protect individuals financially (e.g. by means of exemption mechanisms) and to ensure funds are reinvested into health systems in a way that is aligned with health system goals (Gaal et al., 2006).

Beyond these two major categories of motivation for informal payments – donation and FFS – there is a third which falls in between: a form of patient–doctor collusion with the primary

Box 3.3.1 Adverse effects of informal payments on health systems

1. Informal payments distort the allocation of resources for health care. In the presence of informal payments, resource allocation decisions do not incorporate elements related to clinical value and patient benefit, efficiency and cost-effectiveness. Instead, such decisions are largely based on market forces rather than evidence-based planning and public policy goals (Lewis, 2002). Resource allocation is thus driven by patients' willingness to pay and providers' coercion factors, with payments being independent of the value of care they provide or medical needs; the government has no role in setting these payments or prioritizing decisions and expenditure.
2. Informal payments impose substantial barriers to accessing health care and therefore undermine equity in access. Low-income patients might delay or forgo treatment or seek less specialized care due to limited affordability (Belli, Gotsadze & Shahriari, 2004; Habibov & Cheung, 2017). This also has significant implications for patient outcomes and population health.
3. Informal payments undermine equity in financial protection. Given that informal payments are regressive, individuals often need to cut down expenses for other goods or services to finance their health care or even face the risk of financial catastrophe and poverty.
4. Informal payments tend to worsen quality of care, with patients often following suboptimal models of care due to lack of affordability or doctors recommending clinical processes driven by income generation rather than maximization of therapeutic value (Mæstad & Mwisongo, 2011; Vian et al., 2006).
5. Informal payments lead to lower patient satisfaction with health services and undermine transparency, accountability, and trust in the health system and health workers (Kabia et al., 2021; Stepurko, Pavlova & Groot, 2016).

aim of tax avoidance. All three of these exchanges have negative impacts on the health system, notwithstanding the benign intentions of straightforward gift-giving. For example, all can lead to reduced levels of trust in the doctor-patient relationship which may in turn lead to underutilization of health services. If patients anticipate additional fees for care that they are entitled to, they

might be disincentivized to seek physician services. Also, there may be spillover effects on other parts of the health system (Currie, Lin & Meng, 2013), such as incentivizing physicians to provide more care, including potentially unnecessary care, to patients who pay informally.

There is limited, and often contradictory, evidence to support one motivation or the other (Gaal et al., 2006). A systematic review of 31 studies (globally) found the same number of studies that reported the purpose of an informal payment as an expression of gratitude (10 studies) as those that reported the purpose as consistent with the FFS or fee-for-commodity hypothesis (10 studies) (Stepurko et al., 2010). Others reported that the reasons for informal payments were to gain: better quality of care (10 studies); access to care (four studies); faster access (six studies); and psychological comfort (four studies). That same review found that nine studies reported the patients as initiating the payment (as an expression of thanks) and a further nine studies found the providers initiated it (as a required payment for service). Empirical literature on the motivation behind informal payments is sparse, and we look first at the theoretical drivers of informal payments.

Theoretical drivers of informal payments

The presence of rigidity in prices generates a mismatch between supply and demand for health care and can result in a lack of market equilibrium. Such an argument would suggest a need to increase the payments to providers (e.g. salaries, or formal OOP payments). Apart from the classical economic argument, health policy literature provides additional insights towards a better understanding of the drivers of informal payments, considering the motivation at individual level (cognitive behaviour theory), as well as from the broader institutional perspective (institutional theory).

Cognitive behaviour theory

Gaal and McKee (2004) developed a theoretical framework drawing on cognitive behaviour theory to explain the causes of informal payments. They posit that informal payments are a “reaction by dissatisfied patients and physicians to shortage – a manifestation of

deteriorating organization/system performance". They extend Hirschman's (1970) theory of "exit, voice and loyalty" as reactions to failures in organizations or states, by adding a new option/reaction which they call "inexit" (or a "informal/internal exit") whereby dissatisfied patients and providers do not leave the system (exit), nor express their disappointment by complaining to bring about change in the system (voice), but rather they "seek to change its activities, not through open complaints, but using informal methods, such as payment or connections".

The Gaal and McKee (2004) cognitive behavioural model helps to explain why informal payments may arise under economic conditions of shortage. Specifically, when there is no option to leave the system (exit), as in Semashko systems with no private options, and there are no mechanisms for complaints to be heard (voice), then "inexit" as manifested by informal payments is the only possible reaction by patients to deteriorating health system performance. Thus, the policy solutions to address informal payments must simultaneously address the problem of shortage (e.g. by increasing investment in the system and health worker salaries) and expanding the formal options available to patients and providers to express their concerns with poor quality care; for example, through performance measurement and (enhanced) complaints procedures, or possibly with additional options to exit the public system (though this may exacerbate inequities).

Institutional theory

Additional explanations of the drivers of informal payments draw on institutional theory, considering both formal institutional shortcomings as well as informal institutions such as unwritten conventions and practices. Some of these institutional shortcomings include corruption in political systems and public programmes, lack of trust in government, and lack of government oversight over public programmes (Allin, Davaki & Mossialos, 2006; Pourtaleb et al., 2020). Moreover, informal payments are expected to arise when "norms, practices and values of the informal institutions are not in symmetry with the formal rules of the game (i.e. laws and regulations)" (Williams & Horodnic, 2017).

Recently, Binyaruka and colleagues (2021) developed a supply-side theoretical framework which conceptualizes informal payments by

placing the notion of concentrated power (which is similar to the issues arising from information asymmetry that affords more power to physicians than to both payers and patients) as a means to extract rent from various institutions and relationships. In Binyaruka et al.'s (2021) model, individuals who have more power are more likely to obtain informal payments. Moreover, these individuals are more likely to bypass any transparency and anticorruption mechanisms because they have the power to game the system without consequences (Binyaruka et al., 2021). Thus, informal payments can arise in contexts where there is inadequate oversight in place to prevent abuse, suggesting a need for anticorruption measures and supervision along with awareness campaigns to address information asymmetry. The level of informal payments in a jurisdiction will relate to the health system and broader institutional context, including the extent of resource shortages and trust in government to address aspects of deteriorating health system performance, as well as the level of power held by medical professionals and health organizations.

Empirical evidence on the drivers of informal payments

A wide range of factors emerge in the empirical literature to help to explain the emergence and persistence of informal payments. Drawing in part on the theories above, these factors can be grouped into four broad categories: (i) economic; (ii) sociocultural; (iii) those related to governance and institutions; and (iv) those related to the health system. Existing evidence mainly reveals associations, and the findings should not be therefore interpreted as causal relationships.

Economic factors

Economic factors broadly concern shortages, or a scarcity of resources in the publicly financed health system. Shortages – or a mismatch between the health care needs and expectations of the population and the supply and accessibility of care – are seen to be a necessary but not sufficient condition for informal payments to arise (Gaal & McKee, 2004). Data from Transparency International's Global Corruption Barometer (Fig. 3.3.1) show that informal payments are present mostly in LMICs and that there is a correlation between health spending as

a share of national income and prevalence of informal payments. (This correlation is also depicted in Fig. 3.3.4.)

Several studies have demonstrated the link between economic conditions and informal payments. For example, Tambor and colleagues (2013) grouped 35 European countries into three categories drawing on a Health Consumer Powerhouse survey: no informal payments reported; some incidence of informal payments reported; and widespread informal payments reported. They found that countries with widespread informal payments had significantly lower public health expenditure as a share of total health spending.¹ Also, a cross-sectional analysis of Eurobarometer data from 28 European countries found a higher likelihood of patients reporting having made an informal payment in health care for countries with lower levels of health expenditure, either as a percentage of GDP or per capita (Williams & Horodnic, 2018).

Sociocultural factors

Sociocultural reasons generally refer to a nationally embedded culture of tipping or custom of expressing gratitude through payments or gifts. Though there is probably a role played by cultural norms in explaining the origin and persistence of informal payments in many countries, and this appears as a theme in recent systematic reviews (Pourtaieb et al., 2020), such explanations are insufficient to explain the majority of informal payments. For instance, the inability to identify a clear beginning and end to many clinical encounters, such as with chronic diseases management and primary care, make it difficult to separate gifts as an expression of gratitude from gifts/payments with a different motivation (e.g. to gain higher quality care/better access) (Gaal, Jakab & Shishkin, 2010). Also, the fact that informal payments often take the form of in-kind contributions to the health care intervention itself, such as medical supplies or medicines, suggests that informal payments may not be a simple expression of gratitude in these contexts.

¹ Specifically, a correlation was found between public health expenditure as a percentage of total health expenditure and informal payments: 12 countries had widespread informal payments – and had an average of 64.1% public health expenditure (compared to 73% among eight countries with some informal payments, and 75% among those with no informal payments) (Tambor et al., 2013).

*Factors related to governance and institutions***Institutional asymmetry**

Williams and Horodnic (2018) tested the theory of “institutional asymmetry” as a driver of informal payments with a multi-level regression analysis of Eurobarometer data from 35 countries. They developed an index of institutional asymmetry based on answers to survey questions about the acceptability of three behaviours: to give money, to give a gift or to do a favour in order to get something from a public administration or public service. The index aims to capture the extent to which individuals believe that they should follow the legal and regulatory rules in society, though arguably it also reflects the country’s social norms and cultures, and therefore overlaps with the sociocultural explanation. The regression models revealed a strong association between higher levels of institutional asymmetry and the likelihood of making an informal payment in health care, even after adjusting statistically for individual level characteristics (e.g. demographics, rurality, socioeconomic status) and country-level economic and health system factors. The authors suggest that this finding supports their institutional theory-based explanation of informal payments. They further tested this theory during the COVID-19 pandemic and found significant associations between the prevalence of informal payments and both public acceptance of corruption and perceptions of the transparency of governments in their responses to the pandemic (Horodnic et al., 2021). Also, a study in China found that informal payments were associated with lower levels of trust as well as poor communication with physicians (Li, Li & Yip, 2022).

Quality of governance

Some empirical support for the link between quality of governance and the incidence of informal payments can also be found in multi-country studies. For example, Tambor and colleagues (2013) found that countries where informal payments are widespread also had the lowest perceived level of government effectiveness (average of 0.3 on a scale of –2.5 weak to 2.5 strong compared to 1.2 in countries with some informal payments, and 1.6 in countries with no informal payments). Also, Williams and Horodnic (2018) used the European Quality of Government Index (which combines perceptions with experiences of public sector services) and found strong evidence that informal payments are higher among countries with a lower quality of government (in their study of 27 European countries).

Role and size of the private sector

A further strand of the literature discusses how the role and size of the private sector relates to the incidence and intensity of informal health payments. In some settings, physicians have the option to exit the public system and provide care in the private sector either on a full- or part-time basis, thus allowing them to potentially earn higher income. The private sector also allows patients who are able to pay to opt out of the publicly financed system. The empirical support for a link between informal payments and the size of the private sector is mixed. Most studies rely on crude measures of the size and role of the private sector such as OOP payments as a share of total health expenditures. For example, Incaltarau and colleagues (2021) used several years of pooled survey data across 117 countries and found higher shares of private finance (OOP and domestic private health expenditure) were correlated with a lower prevalence of informal payments. Also, Liu, Bau and He (2020) analysed panel data using the China Health and Retirement Longitudinal Survey and found that an increase in private health insurance coverage in China was associated with a reduction in informal payments. However, studies have also reported a positive association between the level of OOP payments and informal payments; for example, in some eastern European countries (Tambor et al., 2013) (Fig. 3.3.2). Further evidence is needed to uncover the actual impact of private sector development (in terms of financing and delivery of care) on the incidence and intensity of informal health payments.

Health system-specific factors

There are also numerous other health system reasons that help explain informal payments. Some of these relate to the broader economic context but are specific to health care; for example, low expenditures on health care, shortages of both human resources and medical supplies, low salaries for workers (Allin, Davaki & Mossialos, 2006; Gaal, Jakab & Shishkin, 2010). Other health system factors relate to system governance and stewardship; for example: the lack of transparency and accountability in the health system; and inadequate public information and awareness about the benefits packages and what individuals' entitlements and rights are in the publicly funded health systems (Pourtaieb et al., 2020). Inefficiency in resource allocation and care delivery also appear as common explanations in the

literature on informal payments, including the maldistribution of health workers and an overemphasis on curative over preventive care (Pourtaieb et al., 2020; Williams & Horodnic, 2017). Shortcomings in access to and quality of care are also frequently cited contributors to informal payments (Pourtaieb et al., 2020). In some contexts, informal payments are a reaction to the problem of shortages and insufficient supply of health care, seeking to augment providers' incomes, which may allow care to be provided, in particular in periods of economic difficulty.

How pervasive are informal payments?

The measurement of how pervasive informal health payments are is more challenging than with other mechanisms of health financing. Given the lack of data and records for pricing, utilization rates and transactions, estimates on the prevalence of informal payments are generally derived from surveys of patients or the public, which often use different sampling techniques and survey methods (Lewis, 2000).

View from the literature

A systematic review of 38 studies (globally) reported the variation in prevalence of informal payments (the percentage of patient encounters that had any type of informal payment) ranged from 2% to 80%, with higher prevalence in the inpatient sector than the outpatient (Khodamoradi et al., 2018). Another systematic review of 33 studies (globally) also found informal payments were more common in inpatient services, surgery/delivery services (Amiri et al., 2019). A scoping review of the Western Balkans included 24 studies and found the highest prevalence of informal payments in the region was in Albania (19–91%), compared to 7–70% in Kosovo², 7–23% in Serbia, and 5–22% in Bosnia and Herzegovina (Buch Mejsner & Eklund Karlsson, 2017). Another systematic review and meta-analysis of 15 studies in Iran estimated that the prevalence of informal payments was approximately 35%, with the main reasons provided as

² All references to Kosovo in this document should be understood to be in the context of the United Nations Security Council resolution 1244 (1999).

appreciating the staff, and in response to requests made by hospital staff (Mirabedini et al., 2017).

Measuring informal payments using cross-sectional survey data

As there is (most often) a lack of recording of informal payments in any state accounting or information system, national and international surveys are the main source of data on informal payments. Nevertheless, due to the often illicit nature of the practice and subsequent underreporting, these surveys might also underestimate the true prevalence. Another challenge of measurement relates to the methods followed, as different studies may adopt different definitions and approaches that make international comparisons challenging and not easily interpretable (Cohen, 2012).

In response to this, we compiled a list of cross-sectional surveys that measure informal payments. The list in Table 3.3.1 describes how the question of experience concerning the practice has been approached by various organizations in different regional settings. Further, we draw on the Global Corruption Barometer by Transparency International in this section because it utilizes a uniform survey design to compare the prevalence of informal payments across regions. The surveys measure patients' experience of paying physicians informally for care they are otherwise entitled to. This includes information on the public health sector in Latin America and the Caribbean, the Middle East and north Africa, Africa, Asia and the Pacific, and the EU. We used the most recent data available for each region, which meant that the time of collection varied across the global sample – EU (2021), Asia and the Pacific (2020), Latin America and the Caribbean (2019), Middle East and north Africa (2019), Africa (2019). Globally, 11% of patients made an informal payment in the 12 months prior to the survey. Fig. 3.3.1 illustrates the variation in prevalence of informal payments across regions.

There is significant variation between regions globally. In the EU 6.9% of patients paid informally, compared to 10.9% in Latin America and the Caribbean, 11.6% in the Asia-Pacific region, 14.2% in sub-Saharan Africa and 16.6% in the Middle East and north Africa.

Importantly, informal payments also vary within regions. Fig. 3.3.2 illustrates the share of patients in the EU who paid in 2019. While the EU scores the lowest on this indicator across the globe, in parts of

Table 3.3.1 *List of cross-sectional surveys on informal payments*

Survey and round	Question on incidence rate	Type of service or service provider specified	Possible responses	Regions included in the sample	Countries covered	Source
Special Eurobarometer (245, 291, 325, 374, 397)	Thinking about these contacts in the past 12 months, has anyone in (YOUR COUNTRY) asked you, or expected you, to pay a bribe for his or her services?	The health care sector	Binary response (Yes; No)	European Union	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden	European Commission (2005; 2007; 2009; 2011; 2014)
Special Eurobarometer	Apart from official fees did	Public health care practitioner such		European Union	Austria, Belgium, Bulgaria, Croatia,	European Commission

Table 3.3.1 (cont.)

Survey and round	Question on incidence rate	Type of service or service provider specified	Possible responses	Regions included in the sample	Countries covered	Source
(397, 470, 502, 523, 534)	you have to give an extra payment or a valuable gift to a nurse or a doctor, or make a donation to the hospital in the past 12 months	as a GP (general practitioner) or a public health care institution such as a public hospital in the past 12 months	Binary response (Yes; No)		Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden	(2014; 2017; 2020; 2022; 2023)
Special Eurobarometer (470, 502, 523, 534)	Thinking about these contacts in the past 12 months has anyone in (YOUR COUNTRY)	The health care sector	Binary response (Yes; No)	European Union	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece,	European Commission (2017; 2020; 2022; 2023)

Afrobarometer (Rounds 5, 6, 7, 8)	And how often, if ever, did you have hospital to pay a bribe, give a gift, or do a favour for a health worker or clinic or hospital staff in order to get the medical care you needed?	Public clinic or hospital	Categorical response (Never; Once or twice; A few times; Often)	Africa	Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden Algeria, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Côte d'Ivoire, Egypt, Ethiopia, Gabon, Ghana, Guinea, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritius, Morocco,

Table 3.3.1 (cont.)

Survey and round	Question on incidence rate	Type of service or service provider specified	Possible responses	Regions included in the sample	Countries covered	Source
LITS (Round 1)	In your opinion, how often is it necessary for people like you to have to make unofficial	Receive medical treatment in the public health system	5-item Likert scale (Never; Always)	Eastern Europe, central Asia	Mozambique, Namibia, Niger, Nigeria, Sao Tome and Principe, Senegal, Sierra Leone, South Africa, South Sudan, Sudan, Swaziland, Tanzania, Togo, Tunisia, Uganda, Zambia, Zimbabwe	EBRD (2006)
					Albania, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Bulgaria, Croatia, Czechia, Estonia, Georgia, Hungary,	

LiTS (Round 2 and 3)	Did you or any member of your household make an unofficial payment or gift	Medical treatment in the public health system	Binary response (Yes; No)	Eastern Europe, central Asia	EBRD (2011; 2016)
					Kazakhstan,
					Kyrgyzstan, Latvia,
					Lithuania,
					Moldova,
					Mongolia,
					Montenegro,
					North Macedonia,
					Poland, Romania,
					the Russian
					Federation, Serbia,
					Slovak Republic,
					Slovenia,
					Tajikistan,
					Türkiye,
					Turkmenistan,
					Ukraine,
					Uzbekistan
					Albania, Armenia,
					Azerbaijan,
					Belarus, Bosnia and
					Herzegovina,
					Bulgaria, Croatia,

Table 3.3.1 (cont.)

Survey and round	Question on incidence rate	Type of service or service provider specified	Possible responses	Regions included in the sample	Countries covered	Source
	when using these services over the past 12 months?				Cyprus, Czechia, Egypt, Estonia, Georgia, Greece, Hungary, Jordan, Kazakhstan, Kosovo ³ , Kyrgyzstan, Latvia, Lithuania, Moldova, Mongolia, Montenegro, Morocco, North Macedonia, Poland, Romania, the Russian Federation, Serbia, Slovakia, Slovenia, Tajikistan, Tunisia, Türkiye, Turkmenistan, Ukraine, Uzbekistan	

³ All references to Kosovo in this document should be understood to be in the context of the United Nations Security Council resolution 1244 (1999).

LiTS (Round 3)	Have you encountered any [payments required for services that should be free] with your local public health clinic or hospital during the past 12 months?	Public health clinic or hospital	Binary response (Yes; No)	Eastern Europe, central Asia, western Europe	Albania, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czechia, Egypt, Estonia, Georgia, Germany, Greece, Hungary, Italy, Jordan, Kazakhstan, Kosovo ⁴ , Kyrgyzstan, Latvia, Lithuania, Moldova, Mongolia, Montenegro, Morocco, North Macedonia, Poland, Romania, the Russian
					EBRD (2016)

⁴ All references to Kosovo in this document should be understood to be in the context of the United Nations Security Council resolution 1244 (1999).

Table 3.3.1 (cont.)

Survey and round	Question on incidence rate	Type of service or service provider specified	Possible responses	Regions included in the sample	Countries covered	Source
Global Corruption Barometer: Africa (2019)	In the past 12 months have you had contact with a public clinic or hospital? How often did you have to pay a bribe, give a gift, or do a favour for a health worker or clinic or hospital	Public clinic or hospital	Categorical response (Never; Once or twice; A few times; Often)	Africa	Federation, Serbia, Slovakia, Slovenia, Tajikistan, Tunisia, Türkiye, Turkmenistan, Ukraine, Uzbekistan Benin, Botswana, Burkina Faso, Cabo Verde, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Eswatini, Gabon, Gambia, Ghana, Guinea, Kenya, Lesotho,	Transparency International (2019a)

staff in order to
get the medical
care you needed?

Liberia,
Madagascar,
Malawi, Mali,
Mauritius,
Mozambique,
Namibia, Niger,
Nigeria, Sao Tome
and Principe,
Senegal, Sierra
Leone, South
Africa, Tanzania,
Togo, Uganda,
Zambia,
Zimbabwe

Global Corruption Barometer: Latin America (2019)	In the past 12 months have you had contact with a public clinic or hospital? How often did you have to pay a bribe, give a gift, or do	Public clinic or hospital	Categorical response (Never; Once or twice; A few times; Often)	Latin America, Caribbean	Argentina, Bahamas, Barbados, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador,	Transparency International (2019b)

Table 3.3.1 (cont.)

Survey and round	Question on incidence rate	Type of service or service provider specified	Possible responses	Regions included in the sample	Countries covered	Source
	a favour for a health worker or clinic or hospital staff in order to get the medical care you needed?				Guatemala, Guyana, Honduras, Jamaica, Mexico, Panama, Peru, Trinidad and Tobago, Venezuela	
Global Corruption Barometer: MENA (2019)	In the past 12 months have you had contact with a public clinic or hospital? How often did you have to pay a bribe, give a gift, or do a favour for a health worker or clinic or hospital	Public clinic or hospital	Categorical response (Never; Once or twice; A few times; Often)	Middle East, north Africa	Jordan, Lebanon, Morocco, Palestine, Sudan, Tunisia	Transparency International (2019c)

staff in order to get the medical care you needed?					
Global Corruption Barometer: MENA (2019)	In the past 12 months have you used wasta in order to get the medical care you needed?	Public clinic or hospital	Categorical response (Never; Once or twice; A few times; Often)	Middle East, north Africa	Jordan, Lebanon, Palestine Transparency International (2019c)
Global Corruption Barometer: Asia (2020)	And how often, if ever, did you have to pay a bribe, give a gift, or do a favour for a health worker or clinic or hospital staff in order to get the medical care you needed?	Public clinic or hospital	Categorical response (Never; Once or twice; A few times; Often)	Asia	Bangladesh, Cambodia, China, India, Indonesia, Japan, Malaysia, Maldives, Mongolia, Myanmar, Nepal, Philippines, Republic of Korea, Sri Lanka, Taiwan, Thailand, Viet Nam, Transparency International (2020)

Table 3.3.1 (cont.)

Survey and round	Question on incidence rate	Type of service or service provider specified	Possible responses	Regions included in the sample	Countries covered	Source
Global Corruption Barometer: European Union (2021)	And how often, if ever, did you have to pay a bribe, give a gift, or do a favour for a health worker or clinic or hospital staff in order to get the medical care you needed?			European Union	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, France, Finland, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Hungary, Sweden	Transparency International (2021)

Note: The datasets listed in the table above are all publicly available and were screened to identify the relevant questions.

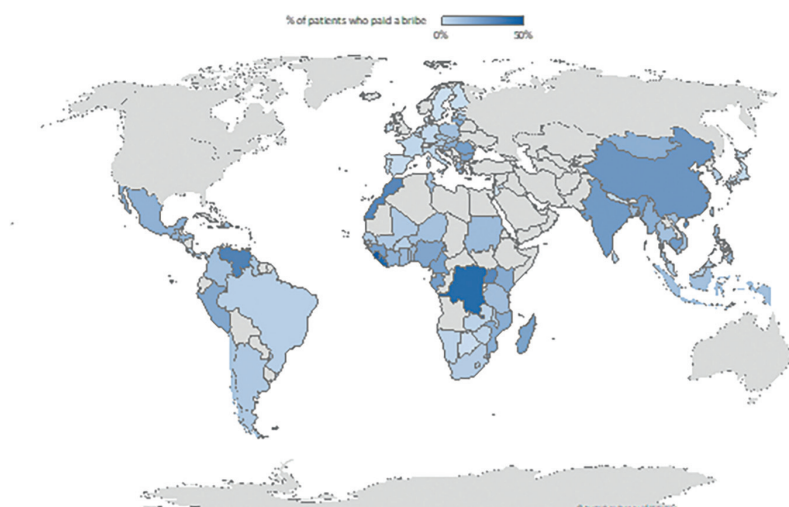


Fig. 3.3.1 Prevalence of informal payments in selected countries, 2019–2021

Source: Transparency International (2019a; 2019b; 2019c; 2020; 2021).

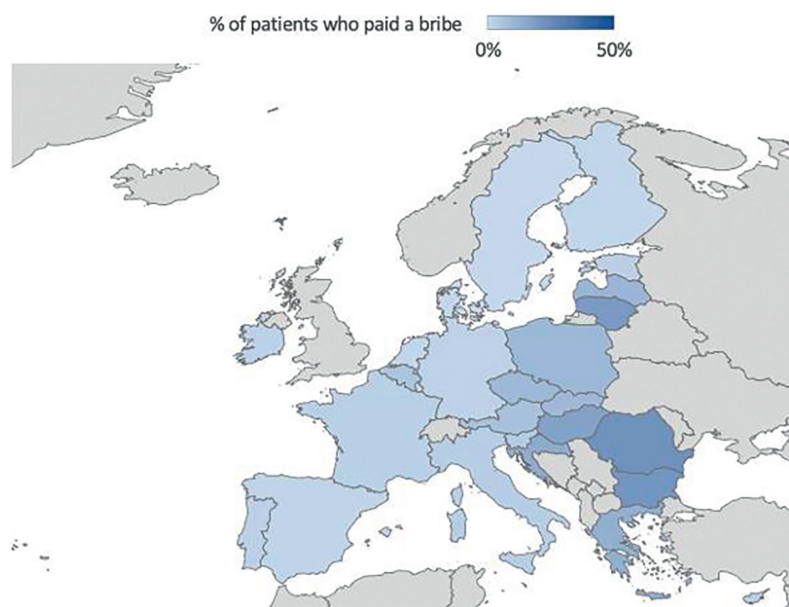


Fig. 3.3.2 Prevalence of informal payments in the EU, 2021

Source: Transparency International (2021).

Table 3.3.2 *Countries in the EU by highest/lowest prevalence of informal payments, 2021*

Country	Prevalence (%)
Romania	22
Bulgaria	21
Lithuania	19
Europe average	7
Luxembourg, Netherlands, Finland, Denmark	1
Sweden	0

Source: Transparency International (2021).

eastern Europe over 22% of patients have had to pay informally when using the publicly financed health care system (Table 3.3.2).

A similar trend is observed in other geographical contexts. For example, Fig. 3.3.3 shows that in the Asia–Pacific region, the prevalence varies between 1% of patients in the Maldives to 26% in China (Table 3.3.3).

Cross-sectional survey data: associations between informal payments and levels of health finance, OOP payments and physician density

Below, we explore the association between the share of patients who have made an informal health payment and health financing levels, OOP payments and physician density. These reflect the financial sustainability and resourcefulness of the health care institutions and allow us to compare settings which have different types of health system organization. Public spending on health care affects scarcity of resources in the system, potentially leading to increased competition between patients for access to treatments. On the supply side, low expenditures are associated with low physician pay which could increase the demand for informal payments as a subsidy.

Fig. 3.3.4 visualizes a modest negative association between GDP spending on health and informal payments across the world. As

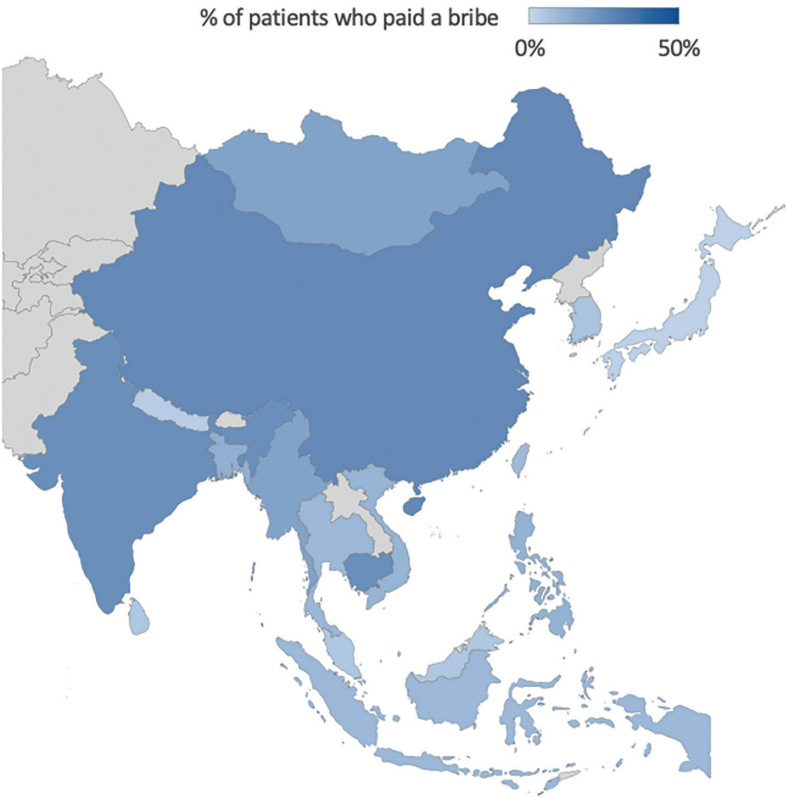


Fig. 3.3.3 Prevalence of informal payments in the Asia-Pacific region, 2020

Source: Transparency International (2020).

countries spend a larger share of their GDP on health care, the prevalence of informal payments goes down. The relationships differ by region, with countries in the Latin America and Caribbean region and Europe displaying more statistically and economically negative associations when compared with other regions.

Next, we consider the relationship between formal OOP payments and informal payments. Unfortunately, it is not possible to distinguish between the two types of formal OOP payments – direct payments for costs incurred outside of the publicly financed or other third-party insurance coverage programme, and cost-sharing, or user charges to cover part of the costs of care within the public or private insurance coverage programme. There may be theoretical arguments for

Table 3.3.3 Countries in Asia by highest/lowest prevalence of informal payments, 2020

Country	Prevalence (%)
China	26
India, Cambodia	24
Asia–Pacific average	11
Nepal	3
Japan	2
Maldives	1

Source: Transparency International (2020).

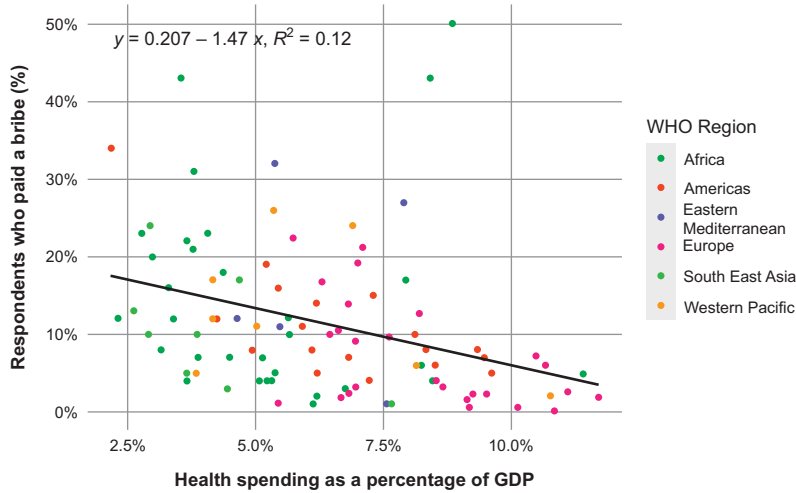


Fig. 3.3.4 Share of GDP spent on health care versus percentage of patients who paid informally in the past 12 months, 2019–2021

Note: A simple linear regression between the share of GDP spent on health care and percentage of patients offering informal payments shows a negative relationship ($y = -1.47x + 0.207$) with an R-squared value of 0.12, suggesting minimal association between these two variables.

Sources: Transparency International (2019a; 2019b; 2019c; 2020; 2021) and WHO (2023a).



Fig. 3.3.5 OOP payments as share of total health spending versus percentage of patients who have paid informally in the past 12 months, 2019–2021

Note: A simple linear regression between household OOP spending and percentage of patients offering informal payments shows a positive relationship ($y = 0.00263x + 0.0295$) with an R-squared value of 0.21, suggesting modest positive association between these two variables.

Sources: Transparency International (2019a; 2019b; 2019c; 2020; 2021) and WHO (2023b).

a negative association, for example if private options allow health care providers to supplement their income in formal, legitimate ways, and allow patients to express their dissatisfaction with the publicly financed health system by opting out and paying privately. However, Fig. 3.3.5, which illustrates this relationship between the two payment types on a global level, shows an overall positive association between the two: higher levels of OOP payments are associated with a higher prevalence of informal payments.

Absolute health system constraints or resource shortages may also contribute to informal payments. A commonly used measure of the extent of resource shortages in a health system is the density of physicians per 1000 people. Our measure here includes both primary and specialized physicians. The fitted regression line in Fig. 3.3.6 illustrates the negative association between physician density and prevalence of informal payments. In accordance with theories of market supply and

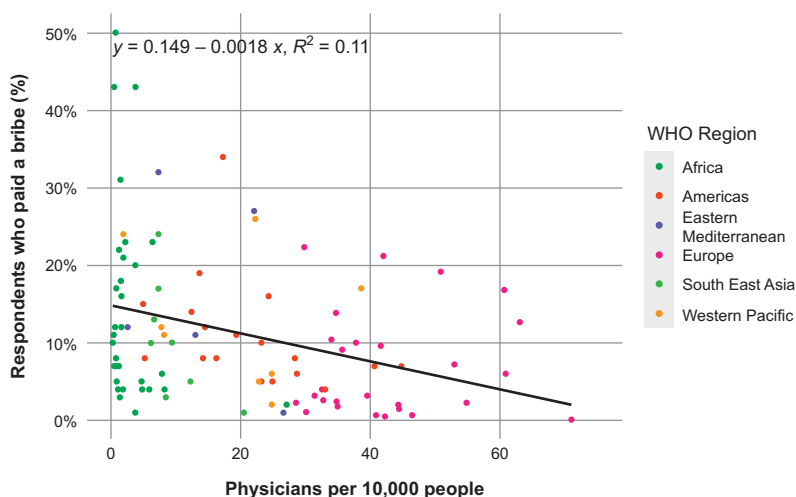


Fig. 3.3.6 Physician density versus percentage of patients who have paid informally in the past 12 months, 2014–2021

Note: A simple linear regression between physician density care and percentage of patients offering informal payments shows a negative relationship ($y = -0.00182x + 0.15$) with an R-squared value of 0.11, suggesting minimal association between these two variables.

Sources: Transparency International (2019a; 2019b; 2019c; 2020; 2021) and World Bank (2023).

demand, patients in systems with better availability of physicians would on average be less likely to experience informal payments. Where physician density is high, shortages of doctor appointments/visits are less likely, and so informal payments are not needed to bridge the gap between the current market price and equilibrium price. Greece, which we discuss in more detail in our case study, is one of the outliers. Although physician density in the country is relatively high at around 5.5 doctors per 1000 people, the corresponding prevalence of informal payments is around 13%.

Prevalence of informal payments: summary

The global prevalence of informal payments is characterized by wide variation, notably in terms of both within-region and across-region variation. In addition, we explored three health systems indicators that have

been shown to be significantly associated with informal payments: level of spend on health care, level of OOP payments and physician supply – and we provide some support for these associations on a global scale. Importantly, there are major data gaps in the comparable data on both the prevalence and frequency of informal payments but also the institutional and health system factors that may contribute to these payments. The continued use of comparable national surveys and reporting by organizations such as Transparency International is vital to support scholarly research and routine monitoring and tracking of the trends in informal payments over time.

A case study of informal payments in Greece

Financing arrangements in the Greek health system: a brief overview

Health financing in Greece is mixed, funded by both public and private expenditure. Public funding accounts for almost 60% of total health expenditure and consists of resources from taxation and social insurance, with each of them having almost equal contribution. Formal OOP payments make up more than a third of total health expenditure, a much higher share than the EU average of 22% (OECD & EU, 2020). In terms of funding, the Greek health system is historically considered as one of the most privatized among EU countries, with OOP payments being the main source of private funding and a major health financing mechanism (Abel-Smith et al., 1994; Kyriopoulos, Nikolosi & Mossialos, 2019; Mossialos, Allin & Davaki, 2005). At the same time, private health insurance is underdeveloped due to several economic, social, cultural and market-related aspects (Davaki & Mossialos, 2005; Economou, 2016). Greece's funding mix can be mainly attributed to the chronic weaknesses of the public sector, such as long waiting lists, low levels of satisfaction and responsiveness, weak primary care and undersupply of some types of services (Kanavos & Souliotis, 2017; Mossialos, Allin & Davaki, 2005).

The scale of informal payments in Greece

A significant proportion of household health expenditure arises from informal payments, which are traditionally regarded as one the main

idiosyncrasies and policy challenges in Greece's health financing system. Informal transactions are generally widespread in both hospital and outpatient care and across public and private services (Economou et al., 2017). Using data from 2012 and some extrapolation assumptions, Souliotis and colleagues (2016) estimated that informal health payments amount to €1.5 billion, accounting for 28% of household health expenditure in Greece. Findings for inpatient services demonstrate that informal payments accounted for 20% of household payments for inpatient care in 2005 (Siskou et al., 2008), while a more recent survey revealed that the respective figure was 13% (Grigorakis et al., 2016).

Evidence from survey data reveals that informal payments were incurred in almost one third of admissions to public hospitals and in 36% of visits to private practitioners (Souliotis et al., 2016). In addition, they were made in 13.5% of visits to private hospitals and 19% of appointments to private diagnostic centres. These findings are generally in line with those of an earlier study, which showed that 36% of patients admitted to public hospitals reported informal payments. In addition, patients who underwent a surgical procedure were more than twice as likely to incur informal payments (Liaropoulos et al., 2008). Another study, of a sample of women who received obstetric care in public hospitals, revealed that more than seven out of 10 women faced informal payments (Kaitelidou et al., 2013). Using data from a convenience sample, a more recent study showed that informal transactions were undertaken in 63% of health care incidents, the rate being greater for the utilization of oncology and surgical and emergency care (Giannouchos et al., 2020). Informal payments were reported in more than 43% of a sample of 217 admissions to private hospitals for surgical care (Grigorakis et al., 2016). Evidence from patients who visited contracted physicians also reveals that 47% of them made informal payments to get prescriptions (Kyriklidis et al., 2016).

Explaining informal payments in Greece

Informal payments have traditionally served as a complement to inadequate public funding and can be largely attributed to the fragmented and patchy design of health coverage (Mossialos & Allin, 2005) and the inefficient pricing and doctor reimbursement systems,

while also reflecting the lack of effective control mechanisms (Economou et al., 2017).

In a recent qualitative report, key informants identified both direct and indirect motives for the incidence of informal payments in Greece (WHO Regional Office for Europe, 2018). Doctors' demand for additional payment, better access to high-quality care, provider choice, fear of getting inadequate care and adherence to the common practice were considered as the key reasons for the extensive informal transactions within the Greek health system. However, earlier studies report mixed findings. A strand of the evidence shows that patients tend to incur informal payments in order to skip the long waiting lists in Greek health system and facilitate access to care (Economou & Giorno, 2009). This is also confirmed by quantitative evidence. According to survey data, more than 70% of patients who incurred informal payments did so to facilitate access and reduce waiting times. The corresponding figure was greater among respondents who visited public hospitals, private practitioners and private diagnostic centres, exceeding 80% (Souliotis et al., 2016). The findings on the importance of access to health care as the key explanation for the incidence of informal payments contradict earlier evidence, which reveal that fear of receiving suboptimal care was the most common reason for paying informally in Greek public hospitals (Liaropoulos et al., 2008). Almost nine out of 10 Greek patients who incurred under-the-table payments in public services did so following a doctor's request, rather than offering them as a gratuity (Souliotis et al., 2016). This is consistent with some earlier findings, showing that the primary reason for making such payments was doctor demands, with a smaller share of patients offering them as an expression of gratitude to health providers (Davaki & Mossialos, 2005; Kaitelidou et al., 2013; Liaropoulos et al., 2008).

Impact of informal payments on the Greek health system

Informal payments have detrimental effects on Greece's health system performance, with their prevalence partly explaining the high rates of dissatisfaction with the public health services (Kyriopoulos & Mossialos, 2021). Their high frequency does not merely reflect luxury preferences or cultural idiosyncrasies. Rather, informal transactions are an established practice and widespread behaviour, with a large share of doctors demanding such payments to facilitate access to care

(Souliotis et al., 2016). This practice directly compromises access to care, with those who cannot afford such payments facing additional barriers reflected in different quality of care or longer waiting lists (Mossialos, Allin & Davaki, 2005).

There is conflicting evidence on the link between financial status and the probability of informal payments in Greece. A strand of the literature has shown that socioeconomic characteristics are not associated with the incidence and intensity of informal payments (Horodnic et al., 2017; Liaropoulos et al., 2008), whereas a more recent study found that the better-off tend to make larger informal payments (Giannouchos et al., 2020). This discrepancy is potentially explained by the decreasing capacity to pay during the Greek economic crisis, especially among poorer households. But even if the worse-off pay less than their richer counterparts, their payments correspond to a higher share of their household income (Economou & Giorno, 2009). In this context, informal payments further exacerbate the regressivity of an already regressive funding mix, disproportionately burden poorer households and compromise equity in financing and financial protection (Economou et al., 2017; Kyriopoulos, Nikolosi & Mossialos, 2021). For example, recent qualitative findings shows that Greek households may even cover their informal expenses for health care through credit (WHO Regional Office for Europe, 2018). Evidence from self-reported data demonstrates that informal payments had a large impact on living standards for 56% of people with poor financial status and for almost a third of their better-off counterparts (Souliotis et al., 2016).

Patient pathways are currently guided by an informal referral process, given the lack of a well-functioning referral system and explicit official clinical guidelines. This system is largely driven and reinforced by informal payments, exacerbating inefficiency as a result of provider incentives for supplier-induced demand and suboptimal use of existing resources (WHO Regional Office for Europe, 2018).

Policy responses to informal payments

In Greece, there have been efforts to address the persistence of informal payments and minimize their adverse impacts. There have been multiple measures proposed for short-term implementation and impact: (i) focusing on the legal prohibition along with active

enforcement of preventive regulations; (ii) increasing doctors' salaries; (iii) providing information to raise awareness and increase transparency; (iv) introducing channels of voice and public opinion; and (v) formalizing informal payments. Apart from the short-term measures, there are several long-term policies for reducing fragmentation, inefficiencies and structural weaknesses in financing and delivery of care, which can help reduce the incidence and intensity of informal payments (Kyriopoulos & Mossialos, 2021). For example, a list of such measures includes changes in provider payment and pay for performance schemes, reduced fragmentation of pooling, reform of primary care and the referral system, better care coordination, and expansion of the benefits package. To date these have had limited effects, due in part to the external environment: the financial crisis of 2008 and subsequent austerity measures, and the global COVID-19 pandemic have further challenged efforts to reform and strengthen the health system in Greece and to make a dent in informal payments. In addition, there are endemic and deep-rooted vested interests that often block the required reforms (Mossialos, Allin & Davaki, 2005; Kyriopoulos & Mossialos, 2021). Some of the doctors' associations are powerful interest groups with strong incentives to maintain the status quo, which allows them to secure higher income and autonomy. In addition, although politicians rhetorically emphasize the importance of addressing informal payments, they have not yet devised a comprehensive strategy for doing so. The reason for this possibly relates to the additional fiscal space needed for increasing public spending for health care and the political commitment required for the introduction of comprehensive auditing mechanisms.

Policy relevance and conclusions

Globally, informal payments play a role in financing health care in a diverse set of jurisdictions; they arise in the context of resource constraints, institutional deficiencies such as government corruption, and have multiple impacts on health and health systems. Within the literature on informal payments, there is strong evidence concerning the impacts on access to care and financial protection, as well as potentially on trust in providers and governments. Poorer patients may be forced to make significant sacrifices (e.g. borrowing money,

selling produce, valuables or livestock), to pay for essential health services (Allin, Davaki & Mossialos, 2006). For example, studies have found both that vulnerable groups paid more often than other groups (Buch Mejsner & Eklund Karlsson, 2017) and that informal payments were more common for rich/wealthy individuals (Amiri et al., 2019).

The policy responses to reduce the prevalence of informal payments in a country will invariably depend on the national context, including the economic, social and political systems within which the health system is situated. Broadly the policy solutions will need to address the economic, institutional and health system factors that have been found to drive informal payments in the first place. Some theoretical drivers of informal payments may lend support to increasing private payments to both: (i) supplement provider salaries; and (ii) provide patients with an option to exit the public system and pay privately. However, the potential for new revenues and possible declines in informal payments need to be balanced against risks to equitable access and financial protection that come with increasing OOP payments. Where possible, collective or public financing could be used to increase wages, address workforce shortages and to reduce the need for informal payments. To address the lack of viable options for patients to express disappointment or concerns with quality of care in the publicly funded systems, potential policy responses include the establishment of formal options to address grievances, such as with a patient ombudsman, or patient complaints processes, while ensuring these are monitored and result in action. The institutional challenges such as government corruption, lack of oversight of the health system, informational asymmetry, and lack of trust among the population suggest a need to increase transparency and public communications about decision-making, including about the benefits package in the public system, and broader anticorruption measures could all help to address informal payments.

Overall, the policy actions should be informed by an understanding of the specific drivers of informal payments in a particular country, which may relate to some but not all of the factors described above. Moreover, since the existence of informal payments may not be the policy problem itself but rather a symptom or manifestation of broader health system and institutional challenges, the policy solutions may not directly target informal payments per se (e.g. tightening enforcement

mechanisms) but they may require much broader health system reforms. Policy options that target the problem of informal payments include: formalizing informal payments to ensure that exemptions can be introduced to protect vulnerable populations and that revenues can be invested in health system improvement; and clarifying the definition of and communication about a benefits package that is reasonable given the economic context of the country. The broader system-level policy options that address broader challenges that are driving informal payments include: increasing spending on health systems; supporting better monitoring and enforcement of the rules and any penalties for informal payments; and maintaining and expanding the scope, breadth and depth of insurance coverage.

On a final note, we leveraged internationally comparable data from the Global Corruption Barometer in this chapter to describe the prevalence of informal payments and the association with a selection of institutional factors. Our analysis highlights that informal payments are reported in most world regions and there is considerable within-region variability, which relate in part to health system expenditures, the role of OOP payments, and physician supply. Though analyses such as these have a number of limitations, Transparency International conducts these surveys with representative samples. Due to data limitations, we were only able to focus on systemic factors rather than the relationship between individual level characteristics and likelihood of paying informally. Furthermore, due to potential underreporting of informal payments by patients, we can presume that our results are conservative estimates of the actual prevalence. As with other illicit or stigmatized behaviours, respondents might be unlikely to share their true experiences. This issue could be mitigated through a more diverse set of methodologies. In addition to standard surveys, which are the primary method of data collection on the topic, the academic and policy literature would benefit from alternative approaches to information elicitation.

Reducing informal payments in health systems requires targeted responses specific to informal payments, as well as broader health systems reforms to address their underlying drivers. Importantly, the policy solutions proposed to address the specific problem of informal payments have the potential to not only reduce the prevalence of informal payments but also to yield positive impacts on health system performance and health outcomes. The COVID-19 pandemic has

further underscored the need to prioritize health workers and their adequate remuneration, and to ensure equitable access to essential services. However, the economic and health shocks of the pandemic, combined with high levels of distrust in governments in many jurisdictions, constitute a major obstacle both to prioritizing informal payments as a policy problem and implementing the needed health system reforms to address them.⁵

Additional resources

Fighting corruption in the health sector: methods, tools and good practices. New York: United Nations Development Programme; 2015 (www.undp.org/publications/fighting-corruption-health-sector).

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⁵ Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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3.4 *Paying for medicines*

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Key messages

Chapter 3.4 explores how pharmaceutical care is financed. Paying for medicines includes how the end-purchase of existing medicines is managed but also the way investment in R&D is handled. Key learning includes that:

- Pharmaceutical innovation draws on substantial public and private resources.
- The public sector primarily supports early-stage research, regulates the industry and incentivizes development.
- The private sector is typically central to development, commercialization, manufacture and marketing. It seeks high profit margins and is not always transparent or responsive to public policy priorities.
- Novel and specialized therapeutics as well as population ageing are likely to accelerate medicines expenditures. This requires careful management of pricing and reimbursement.
- Policy-makers can leverage a mix of push and pull strategies to align industry efforts with societal need.
- To optimize pharmaceutical policy policy-makers must consider:
 - clear communication of health system priorities;
 - transparent incentive and pricing systems and measures to enhance R&D efficiency;
 - payment mechanisms that foster equity and sustainability;
 - cross-country collaboration including on preparedness, procurement and pricing transparency.

Introduction

Pharmaceutical care is an important contributor to how health systems retain health gains and improve future outcomes. Pharmaceutical

spending is one of the largest items in health expenditures for most health systems, while patient cost-sharing for pharmaceuticals is one of the main contributors to health care-related financial hardship. The rate of pharmaceutical spending growth seems to have slowed primarily due to cost containment measures implemented in response to the global financial crisis and the concurrent patent expiry of many popular outpatient medicines (OECD & EU, 2022; Belloni, Morgan & Paris, 2016). However, the advent of specialized medicines and advanced therapy medicinal products (ATMPs) in conjunction with population ageing are likely accelerating spending again, a trend which is harder to track given that many of these newer therapies are used in inpatient settings, where data on pharmaceutical expenditure are harder to come by (Morgan & Xiang, 2022). What is clear is that new medicines are entering the market at increasingly high price tags, a phenomenon which progressively hampers governments' abilities to purchase the latest innovations for their citizens. Meanwhile, pharmaceutical companies are reaping significant financial benefits: 35 of the largest pharmaceutical companies generated a cumulative global revenue of US\$ 11.5 trillion between 2000 and 2018, with greater profitability margins than other large Standard and Poor's (S&P's) 500 index companies (Cutler, 2020; Ledley et al., 2020). Thus, rethinking the balance between ensuring access and incentivizing innovation is becoming increasingly important.

In addition to paying for medicines which are already on the market, societies also spend on medicines in other ways. The high risk of failure in drug development, the controlled nature of clinical trials and the long interval between medicine discovery and market authorization mean that every stage in the medicine development pipeline comes at a substantial cost (Wong, Siah & Lo, 2019). High prices for pharmaceuticals typically aim to offset pharmaceutical companies' R&D investment and cover production and distribution costs. However, substantial amounts of public funding also flow into medicines' discovery and development before consumer purchase (Galkina Cleary et al., 2018; Wizemann, Robinson & Giffin, 2009). To fuel innovation and subsequently ensure equitable access to affordable medicines, governments adopt a range of policies to try and steer pharmaceutical R&D towards unmet health care needs and to influence the prices at which new medicines can be purchased after market authorization. As well as leveraging policy instruments to negotiate prices, governments must

decide how best to allocate public funding and the level of co-payments, i.e. the extent to which they require their citizens to meet the cost of their own pharmaceutical care. These are decisions which may lead to considerable variation in pricing, coverage and access to medicines across different countries. Pricing and reimbursement decisions may be guided by evidence-based tools, including health technology assessment (HTA), to evaluate the clinical trial information submitted by manufacturers at the time of market authorization. Particularly for specialized medicines and biotechnology-based gene and cell therapies, repeated pricing and reimbursement assessments may be warranted over time, as further evidence on the cost-effectiveness of therapies becomes available.

This chapter explores how pharmaceutical care is financed, starting with investment in R&D for new medicines and then zooming in on the purchase of medicines by health systems, including the suitability of existing pricing and reimbursement models for novel types of therapeutics and the purchasing strategies adopted by different countries. Each of these two main sections follows a similar analytical structure and discusses the relative financial role of the public and private sectors (including patients), what the invested funds cover (particularly in terms of meeting patient needs), as well as the actual sums of money paid. Current pricing and reimbursement models and their suitability for novel types of therapeutics are also explored and we suggest potential ways the system could be improved.

Investing in R&D

R&D jointly make up the first stage in the pharmaceutical life-cycle and are concurrently the costliest and most failure prone. It can take several years for a new pharmaceutical target to become a real-world medicine and, on average, another eight years of clinical trials until marketing authorization and sales are underway (Wong, Siah & Lo, 2019). It is estimated that only around 10–14% of novel medicine candidates are approved for launch, with considerably lower success rates in specific medical subfields such as oncology (Hay et al., 2014; Thomas et al., 2016; Wong, Siah & Lo, 2019).

Most medicine development starts with basic research (preclinical phase) into disease mechanisms with the objective of identifying potential therapeutic candidates for later development and commercialization. If

a promising medicine candidate is selected for further advancement, its clinical efficacy and safety must be assessed under strictly controlled conditions in a sequence of clinical trials, which typically consist of three successive clinical trial phases (I–III) involving progressively larger participant groups (US FDA, 2018; Wong, Siah & Lo, 2019). Phase III is the most expensive of the trial phases, but it is typically associated with a high rate of success (50–60%) (Hay et al., 2014; Thomas et al., 2016; Wong, Siah & Lo, 2019). Manufacturers apply for intellectual property protection during this process, which encompasses different types of incentives to drive pharmaceutical innovation (see Box 3.4.1). To be considered for marketing authorization, new medicines generally must yield positive results at the end of phase III trials. To obtain a marketing authorization, manufacturers are required to submit an application to the competent authorities in different countries or to the European Medicines Agency (EMA) for the centralized marketing authorization in the EU (the latter is currently the principal pathway for new medicines). Clinical trials also encompass a fourth phase termed pharmacovigilance, which unfolds after a medicine's marketing authorization (phase IV) and serves to monitor its efficacy and safety under real-world conditions. Pharmacovigilance usually proceeds for several years after market entry and continues to inform policy processes on the pricing and reimbursement of medicines.

Efficiency gains made during the R&D process can shorten the passive patent protection period and bring forward the moment when manufacturers start to benefit from market exclusivity and can maximize investment returns through sales of the new medicine. For example, in a marketing authorization process, termed rolling review, medicines may be considered for authorization by regulatory agencies while evidence is still being generated during clinical trials, thereby accelerating market entry (as was seen with vaccine development during the COVID-19 pandemic) (EMA, n.d. a; Marinus et al., 2022).

In the EU, new pharmaceuticals are subject to both data and market exclusivities (EU, 2001; 2004). The former protects preclinical and clinical trial data for a duration of eight years and hinders generic competitors from applying for marketing authorization. Data exclusivity clauses foresee public disclosure of dossiers after expiry; however, generic competitors may not be marketed for another two years as part of the market exclusivity rights granted to reference products under European legislation (European Commission, 2019; EMA, n.d. b). At the time of writing, the EU's pharmaceutical legislation is currently

Box 3.4.1 Definition: intellectual property rights

Intellectual property rights are one of the most widely established incentives used by governments to propel innovation in the pharmaceutical sector. They comprise a range of different advantages and rewards, which secure the financial viability of pharmaceutical companies in a system characterized by high rates of failure, while also protecting inventions from competition (for a set number of years) and so, potentially, steering research into areas of unmet clinical needs, which may ultimately benefit patients. The main types of intellectual property rights are as follows.

Patents

Patents are classified as a type of industrial property and are typically granted for 20 years. They provide a period of exclusivity for new inventions (including processes, technologies or active substances), during which time they may not be marketed and profited from by anyone other than the patent owner. Medicines can carry numerous different patents at any given time. Competition from other developers is only possible once all patents have expired.

Supplementary protection certificates

Manufacturers are required to file patents for new medicine candidates early in the R&D process. Since patent protection only starts when marketing authorization is obtained, in practice the time during which the medicine is protected from competition is shorter than the 20-year patent period, because of lengthy clinical trials required to prove the safety and efficacy of new medicines. The protection until market authorization is considered as “passive”. Supplementary protection certificates can restore part of the protection that has been lost, up to a maximum of five years.

Regulatory data protection

This form of intellectual property rights is separate from patent rights and protects data pertaining to a new medicine, including all data that are collected during the clinical trials leading up to market authorization, rather than the invention per se. After marketing authorization is granted, pharmaceutical companies generally have exclusive rights to this data for a certain number of years (eight years in the EU).

Box 3.4.1 (cont.)**Market exclusivity/protection**

This is another type of regulatory protection scheme which may apply in addition to patent rights. Market exclusivity/protection grants protection from other generics or biosimilars with the same therapeutic indication from being placed on the market for a defined amount of time after data exclusivity expires.

Sources: EFPIA (2022); WTO (n.d.).

being reviewed as part of a broader strategy to strengthen crisis preparedness and access to affordable and innovative medicines in the Union, with new proposals for a Regulation and Directive published in April 2023 (European Commission, 2023a; 2023b). The proposed legislation envisions changes that may alter the conditions under which additional regulatory protection schemes (data and market protection) are granted to applicant manufacturers in upcoming years, including possible extensions to the duration of data protection. Among several planned changes, the introduction of transferable data exclusivity vouchers aims to incentivize the development of priority antimicrobials by prolonging the duration of data protection and enabling developers to either use or sell vouchers to other marketing authorization holders (European Commission, 2023b).

Who pays for R&D?

The pharmaceutical industry funds the development, commercialization and manufacture of medicines. The public sector regulates the industry and incentivizes the development and production of medicines it typically neglects. It also pays for most of the initial research, which is what we deal with first.

Early-stage research: predominantly public funding

Most early-stage (preclinical) research is funded by public means (usually pooled from taxpayers' money) and is typically conducted in academic institutions and research centres (Wizemann, Robinson & Giffin, 2009). Gaining an understanding of biological processes and

uncovering disease pathways lay the foundation for pharmaceutical innovation and the discovery of new medicine candidates. Investment in basic research comprises a large share of overall R&D spending. In the USA, the National Institutes of Health dedicates 50% of its budget to this cause and, between 2010 and 2016, funded research underlying (both directly and indirectly) all 210 new medicines approved by the United States Food and Drug Administration during this period (Galkina Cleary et al., 2018). The EU is another crucial funder of fundamental research, having dedicated nearly €100 billion to its current research programme, Horizon Europe (European Commission Directorate-General for Research and Innovation, 2021). Under the previous research programme, Horizon 2020, one quarter of health-related projects were in the area of basic research (Gallo et al., 2021). Research that is publicly funded has been reported to generate a distinctive share of products with important clinical effects (see Box 3.4.2), particularly in areas of unmet medical need such as rare diseases (Stevens et al., 2011).

Box 3.4.2 The role of public funding: COVID-19 vaccines and therapeutics

The COVID-19 pandemic saw governments step out of their traditional roles as early-stage funders, contributing significantly to late-stage development and propelling the manufacture of COVID-19 counter-measures. Agarwal and Gaule (2022) estimate that close to 70% of COVID-19 trials were started by public institutions, including universities and hospitals. Governments worldwide invested in the expansion of infrastructure and facilities to scale up production capacities, even before the completion of clinical testing of the vaccine candidates in question (Wouters et al., 2021). In 2020, the United States government alone invested between US\$ 11 to US\$ 19.5 billion in late-stage vaccine research and supported vaccine manufacturing capacity-building to ensure production could be expanded adequately within the country (known as Operation Warp Speed). Most high-income countries (HICs) stipulated prepurchasing agreements with multiple vaccine developers to secure vaccine doses for their populations. Beyond vaccine procurement, monoclonal antibodies now approved for treatment were developed using therapeutic research platforms and technologies which benefited from public sector support prior to the pandemic. The

Box 3.4.2 (cont.)

adaptation of these technologies to commercialize and develop an effective COVID-19 treatment yielded substantial additional investment from governments globally (Robinson, 2021).

Development: predominantly private funding with public sector incentives

In contrast to early research, the brunt of the cost for medicines' development, commercialization and manufacture is borne by the private sector (Kalindjian et al., 2022). Additionally, the pharmaceutical industry spends substantial amounts on buying back shares and on marketing to ensure successful market penetration by newly developed medicines. These activities can surpass expenditure on R&D itself (Mazzucato et al., 2018) (Box 3.4.3).

Governments can try to regulate and incentivize the medicine development process to some extent to steer development to areas of unmet need. This includes leveraging so-called push and pull mechanisms (see chapters 3.9 and 3.10). These approaches incentivize private R&D investment at the entry and exit points of the pipeline, respectively. Box 3.4.4 showcases examples of how these tools work using the case of antibiotic development.

Push financing consists of R&D subsidies in the form of direct funding (e.g. project grants, fellowships and scholarships for researchers, funding for small and medium-sized enterprises (SMEs)), which can be conditional on research in specific domains or aimed at stimulating translational research along the entire medicine supply chain and so lower the risks of loss for private investors (Panteli & Edwards, 2018). Push financing can also take the shape of indirect support such as tax benefits to encourage the participation of SMEs in the R&D process. While this lowers the risk of failure for the private sector, it can be a burden to public funders and does not guarantee delivery of the required output at the end of the pipeline. Similarly, it is frequently implemented on a national scale, limiting the potential global level benefits.

Conversely, pull mechanisms provide financial incentives once specific development milestones have been achieved. These must

Box 3.4.3 Industry spending on lobbying, marketing and consolidation

The industry engages heavily in lobbying activities to propel its interests at policy level to ensure outputs surpass the R&D stage and successfully enter the market (EMA, 2022; Wouters, 2020). It also funds patient advocacy organizations working on indications in which they have marketed products and provides financial incentives to health care professionals, whose prescribing decisions have shown to be directly influenced by such industry payments (Mitchell et al., 2021). The fact that the work of regulatory agencies is also funded through user fees paid for by the industry has led to discussions around the potential for regulatory capture (Wouters, 2020).

Over time, the industry's structure has evolved to rely strongly on the commercialization of scientific discoveries and the entrepreneurial potential of scientific research, resulting in closer partnerships with academic institutions and strategic mergers with biotechnology firms through the financial support of private equity and venture capital (Malerba & Orsenigo, 2015). However, the increased dependency on shareholder expectations and a stable performance in stock markets has largely favoured R&D investments with short-term returns and high profit margins. With a vision to sustain and increase its revenues, the industry has grown to become a skilled political and economic player in the health care arena.

sufficiently offset the risk for SMEs to partake in the development process, while also requiring a longstanding political commitment given the protracted timeline of R&D for a new medicine. Such output-based financing tools can comprise lump sum or milestone prizes, advanced purchasing agreements, which entail committing to the acquisition of a new medicine at a specified price and/or volume prior to the completion of the R&D process (advanced market commitment). Alternatively, rewards-based tools can rely on performance indicators (pay for performance) such as medicine consumption levels or be awarded in exchange for intellectual property rights (patent buyouts) and unlimited patient access (payer licenses) (Panteli & Edwards, 2018). These mechanisms reward the achievement of specific goals but are also susceptible to shifting political agendas. At the same

Box 3.4.4 How do push and pull mechanisms work? Examples in the area of antimicrobial resistance (AMR)

Push mechanisms: Feeding the preclinical antibiotic pipeline

It has been estimated that over two thirds of the financial incentives to develop new antibiotics are provided in the form of push incentives (Simpkin et al., 2017). In recent years, many national and transnational programmes have been initiated across the USA and EU (Wasan et al., 2023). For example, the United States Biomedical Advanced Research and Development Authority (BARDA) launched a dedicated initiative in 2010 and established public–private partnerships aimed at developing new antibiotics and diagnostics. Between 2010–2019, nearly US\$ 1 billion in grants, agreements and contracts were awarded by BARDA through these channels for the development of antibiotics (Wasan et al., 2023). At the EU level, the Innovative Medicines Initiative (predecessor of the Innovative Health Initiative), a public–private partnership co-funded by the EU and involving a range of stakeholders, including from academia and industry, established the New Drugs for Bad Bugs programme. With a budget of €650 million, the programme supported projects working towards solutions to overcome challenges impeding the development of new antibiotic treatments (Innovative Medicines Initiative, n.d.). For example, one of these projects (TRANSLOCATION) focused on finding new pathways for the delivery of antibiotics into bacteria (with a focus on Gram-negative pathogens such as *Escherichia coli*, which are subject to high rates of resistance and particularly challenging to penetrate for drugs) (Innovative Medicines Initiative, n.d.).

Pull mechanisms: The Longitude Prize

The Longitude Prize, a prize co-funded by Innovate United Kingdom (the United Kingdom’s national innovation agency) and a range of public and private entities including the BBC, Amazon and Glaxo Smith Kline, offers substantial financial rewards, up to several million pounds, to teams of innovators who develop novel solutions to address pressing societal problems. In the area of health, these so-called “challenge” prizes have addressed priority issues including dementia (i.e. how to help conserve the independence of affected individuals in their everyday lives) and antibiotics (i.e. how to halt the rise in resistance to antibiotics). For example, one prize, offered £8 million for the development of rapid diagnostic tests, which could be used by clinicians to identify the most suitable antibiotic therapies at the point-of-care and thereby promote better antibiotic stewardship in the clinical setting (Longitude Prize, <https://amr.longitudeprize.org/>).

For further information on the underlying issues of the antibiotics market and some of the initiatives operating to incentivize antibiotic R&D and tackle AMR, see Chapter 3.9.

time, the risk is borne entirely by the developer, which can deter smaller enterprises from participating in the R&D process. Pull mechanisms may require the pooling of resources across multiple countries to offer meaningful financial rewards for the delivery of a specific output without compromising cost-effectiveness (Panteli & Edwards, 2018).

Beyond push and pull mechanisms, there are also important examples of initiatives blurring the traditional public and private sector roles and transcending the barriers to establish fruitful collaborations across sectors, including public-private partnerships such as the Innovative Medicine Initiative (now Innovative Health Initiative) and the Drugs for Neglected Diseases initiative (DNDi).

Investment in R&D: does it produce the medicines we need?

As the primary proponent and cost carrier of medicines' commercialization and manufacture, the pharmaceutical industry largely determines which medicine candidates enter the development pipeline. Private R&D investment choices have shown that expected profits and market growth are more important factors in pharmaceutical company decisions than unmet societal needs (Kalindjian et al., 2022). Risk of failure does not seem to be a prominent determinant of medicine development decisions, as particularly risky domains like oncology have experienced an important investment surge in recent years (Huang & Nambudiri, 2020).

As of late, the pharmaceutical sector has experienced a fall in numbers of new medicines brought to market, as medicine development has become increasingly specialized, complex and lengthy with the advent of biologicals and biotechnology-based gene and cell therapies (also known as ATMPs) (Hay et al., 2014). R&D investment is increasingly concentrated in areas protected from competition, such as medicines for rare or neglected diseases and ATMPs. The area of oncology has seen a particular peak in authorizations over the last decade, with close to 50% of the global pipeline focused on oncology and immunology (Shimmings, 2017). While cancer is a major public health issue, other chronic diseases such as cardiovascular conditions which cause millions of deaths each year have experienced a decline in investment and medicine development (Fordyce et al., 2015). Moreover, evidence suggests at least one in five new cancer medicines do not bring any improvement to patients in terms of quality of life, overall survival, or safety

benefits (Davis et al., 2017; Salas-Vega, Iliopoulos & Mossialos, 2017; Vokinger et al., 2020; 2022). Neglected and antimicrobial-resistant diseases are another area of public health concern, which is underrepresented in medicine development efforts, likely due to the limited scope for returns on investment (see chapters 3.9 and 3.10). Overall, R&D efforts do not appear to correlate with global disease burden (Cottingham, Kalbaugh & Fisher, 2014). Relatedly, incentives originally introduced to propel the development of medicines to cater for the unmet needs of rare disease patients have also had unexpected effects, oversteering investment in this area and contributing to the emergence of “niche” blockbuster products (Kumar Kakkar & Dahiya, 2014). The Pharmaceutical Strategy for Europe and ongoing revisions of the EU’s general pharmaceutical legislation aim to address and correct some of these possible misincentives in the European context (European Commission, 2023a; 2023b).

Even in areas with substantial R&D investment like cancer, there is a disproportionate focus on projects of shorter duration, such as late-stage cancer, due to the immediacy of financial rewards and the limited profitability stemming from fixed patent duration (Budish, Roin & Williams, 2015). The system’s reliance on patents as one of the primary incentives of innovation actively influences industry practices and hampers medicine innovation. In particular, it has created a market for new medicines which form part of the same therapeutic class as existing medicines (known as “me-too” medicines) and provide limited or no added clinical benefits due to their closely related molecular structures and modes of action. Me-too medicines build on existing knowledge and are hence faster to develop and commercialize. In addition, being subject to conventional intellectual property protection, they can represent profitable ventures for medicine developers once patents for other members of the same class expire (Gagne, 2011). These and similar approaches adopted by industry to extend the market protection and profitability of their products impede the introduction of generic alternatives which would improve the affordability of medicines for patients.

Research duplication and waste represent other important sources of costs, which can be challenging to fully ascertain. Evidence suggests that up to 80% of clinical trials produce redundant findings and approximately 50% never publish full reports of performed research and results (Glasziou & Chalmers, 2016). The failure to disclose full

records and clinical effectiveness information from clinical trials is accompanied by a reporting bias towards positive clinical outcomes (Mitra-Majumdar & Kesselheim, 2022). As a result, a substantial proportion of medical research funding risks being misspent as research efforts are duplicated even when they have demonstrably yielded meaningless results. In addition, there are ethical implications of failing to report negative results of clinical trials. If these results were reported, it could prevent and protect future trial participants and patients from receiving therapies which are unlikely to generate clinical benefits (Nygaard, 2017). Additionally, without full disclosure of all clinical trial results, public payers risk overpaying for medicines if they lack and cannot avail themselves of the full picture of clinical trial outcomes when entering pricing negotiations (Vogler, 2022a).

To enable fast access to medicines addressing unmet patient needs, the EMA provides manufacturers with the option of obtaining early scientific advice and accelerated assessments. This was systematized in its PRIME scheme, a voluntary scheme providing guidance on data and clinical trial requirements to participating medicines at early stages of development (EMA, n.d. c). Approaches such as this one are more permissive with regards to the standards of evidence required than traditional marketing authorization procedures and have shown to reduce average approval time by a few years (Panteli & Edwards, 2018). This may result in efficiency gains in the R&D process leading up to authorization, although safety and efficacy should continuously be monitored as well as missing evidence substantiated to comply with post-marketing requirements. Concerns have been raised, however, that accelerated assessments may expose patients to safety risks and progressively lower evidentiary requirements if used inadequately, instead of effectively managing unmet needs (Panteli & Edwards, 2018). Box 3.4.5 describes an additional way to accelerate the development of medicines to meet medical needs currently uncatered for, by repurposing existing medicines.

How much money is spent on R&D?

Despite fewer new products being commercialized, the sector has experienced continued increases in investment with substantial incentives provided by public and private entities to spur innovation (Huang & Nambudiri, 2020). The pharmaceutical industry is characterized by

Box 3.4.5 Addressing R&D shortages: repurposing of medicines

There are different ways in which a drug candidate or a marketed medicine can be repurposed to serve a new therapeutic use in addition to the one for which it was originally approved or developed. The development of repurposed medicines is associated with lower costs and shorter timelines for the developing entity than traditional clinical trials and can revive research on partially developed molecules which were never approved for use (Pushpakom et al., 2019); as a result, repurposing has been used as a commercial strategy for years (Botella, 2022).

However, for conditions with unmet clinical needs and/or without viable treatment options, developing other clinical indications for administering and combining existing products can also present new effective treatment solutions and enhance patient access to them (Frail et al., 2015). Numerous initiatives have been launched in this direction. For example, building on the work of the European Commission's Expert Group on the Safe and Timely Access to Medicines for Patients, the EMA launched a repurposing pilot project to support academia and non-profit organizations in studying the use of existing medicines for new indications in 2021 (EMA, 2021a). Within the scope of the project, beneficiaries can obtain regulatory and scientific advice to support the development of an application for regulatory approval (EMA, 2021a).

elevated fixed R&D and marketing costs and a low marginal production cost. As explained above, it takes substantial investment to discover and launch a new medicine, while the cost of producing an extra unit is usually comparatively small (Cutler, 2020; Rennane, Baker & Mulcahy, 2021). Several studies have deployed different methodologies and sources to attempt cost estimations of the R&D process, which range between US\$ 314 million and US\$ 2.8 billion for the development of new molecular entities (DiMasi, Grabowski & Hansen, 2016; Wouters, McKee & Lutyen, 2020). Other publications report even broader ranges. Rennane and colleagues detected gaps of US\$ 113 million to US\$ 6 billion accounting for all new medicines, including those developed in specific cost-intensive therapeutic areas such as Alzheimer's disease (Rennane, Baker & Mulcahy, 2021). Similarly,

a 2016 report by the United Nations Secretary-General's High-Level Panel on Access to Medicines (2016) described estimates ranging between US\$ 100 million to US\$ 4.2 billion.

The costliest of the R&D stages are phase III clinical trials, with USA estimates suggesting that the cost of a pivotal trial alone lies somewhere between US\$ 12 to US\$ 53 million depending on therapeutic area studied. In the same study, cost estimates for phase II trials and phase I trials also varied importantly by therapeutic area being examined, with ranges of US\$ 7 to US\$ 20 million and US\$ 1 to US\$ 7 million, respectively (Sertkaya et al., 2016). Figures in a similar ballpark were reported by other USA-based investigations (Moore et al., 2018; 2020). The question remains whether pharmaceutical companies' overall R&D investments are truly reflective of the high pharmaceutical prices charged at the end-users' side. A few initiatives have been pressing for more transparency in this regard. For example, DNDi, the public-private partnership working towards treatment solutions for neglected diseases, has pledged to disclose the R&D costs of its products (DNDi, n.d. a; n.d. b; 2022), which as some evidence suggests, have been lower than those reported by pharmaceutical companies (Junod Moser et al., 2023; Moon, 2017; Moon, Bermudez & 't Hoen, 2012).

Pharmaceutical companies argue that the elevated failure rate and high costs incurred in the early stages of a medicine's life-cycle necessitate the observed high prices of newly marketed products. However, the industry's resistance to disclosing the full costs of medicine development undermines this argument and has prompted multiple investigations into the true costs of the R&D pipeline. Moreover, this argument fails to account for the substantial public investment in basic research as stated above. Going forward, enhancing the system's transparency is key and could potentially support R&D priority-setting based primarily on societal needs rather than commercial viability (Panteli & Edwards, 2018).

In this first half of the chapter, we have looked at the financing of medicines' R&D. In the next half, we turn to look at how their purchase is funded and some of the processes involved.

Purchasing medicines

Once medicines have received marketing authorization and commercial production can begin, they are registered with relevant regulatory

agencies who serve as intermediaries between pharmaceutical companies, prescribing health care professionals and patients, and ensure continued data collection and pharmacovigilance. Different payers are responsible for purchasing medicines depending on the organizational set-up of the health system. Against the backdrop of their budgetary constraints, payers face the challenge of providing comprehensive access to effective medicines while also providing appropriate incentives to continue fuelling the system with innovations. Health systems employ different mechanisms to determine reimbursement and pricing of medicines. At the early stage of marketing, evidence on the effectiveness and safety of medicines is usually limited, hampering payers' abilities to robustly determine willingness to pay. Exclusivity rights and the resulting lack of competition (see Box 3.4.1) contribute to high pharmaceutical prices and expenditures (Kesselheim, Avorn & Sarpatwari, 2016; Vincent Rajkumar, 2020). According to 2020 estimations, pharmaceutical spending was approaching 20% of net health expenditure in several European countries (OECD, 2020). Furthermore, official estimates of pharmaceutical expenditure commonly exclude the costs of medicines purchased and dispensed within hospitals and sometimes also those incurred by private households in the form of co-payments and out-of-pocket (OOP) payments. Since the majority of specialized and expensive medicines are used in hospital settings, current approximations of pharmaceutical expenditure are likely to gravely underestimate the true costs of medicines for health systems worldwide.

Who pays for the purchase of medicines?

Generally, pharmaceutical expenditure is covered by a mix of public and private funds. Solidarity-based health systems, which represent the most common model in Europe, leverage public funds to ensure access to essential health services, including essential medicines, for their populations. Primarily, this entails coverage via social health insurance models or a national health service, which rely on diverse revenue streams, including forms of taxation, employment and social security contributions (see Chapter 1.1). On average, 58% of pharmaceuticals are funded by government/compulsory schemes (39% are paid OOP and 3% through voluntary health insurance (VHI) schemes (see Chapter 1.3)) across Organisation for Economic Co-operation and

Development countries, although there is considerable cross-country variation; at the two ends of the spectrum, over 80% of retail pharmaceuticals are funded publicly in France (83%), Ireland (82%), Germany (81%) and Croatia (80%) and fewer than 40% in Poland (35%), Bulgaria (24%) and Chile (20%) (OECD, 2023).

Although publicly funded and organized systems are designed to provide universal access, financial protection does not necessarily cover all pharmaceuticals, and patients are typically required to cover a part of the expenses for reimbursed (i.e. publicly funded) medicines in the community (i.e. outpatient sector). In countries with more limited progress towards universal health coverage, most medicines (in both outpatient and hospital sectors) are to be paid fully OOP by the patients. This may lead to a high financial burden for patients and their carers and can even result in catastrophic spending.

There are different types of co-payments (e.g. fixed prescription fee, percentage co-payments of the medicine price, and deductibles), with variable effects on the amount paid by the patients, and by the public payer (see Chapter 2.4). In solidarity-based health systems, vulnerable population groups may be fully or partially exempt from co-payments for outpatient reimbursable medicines (Panteli et al., 2016; Vogler, Zimmermann & Haasis, 2018; Vogler, Haasis & Zimmermann, 2021; WHO Regional Office for Europe, 2018). Evidence shows that patients in low- and middle-income countries (LMICs) are more frequently exposed to high OOP payments for pharmaceuticals with over 90% of the 150 million individuals incurring catastrophic health expenditure globally residing in these countries (WHO & IBRD, 2020). Even in the World Health Organization (WHO) European Region, estimates from 24 countries¹ comprising 18 HICs and six middle-income countries) suggest that up to 9% of households are impoverished and unable to pay for basic needs due to health spending, although large differences are observed among EU countries (estimates ranging between 0.3% to 5.9%) and non-EU countries (estimates ranging between 3.6% to 9.0%) (Thomson, Cylus & Evetovits, 2019). Importantly, OOP payments for medicines are a key driver for

¹ Albania, Austria, Croatia, Cyprus, Czechia, Estonia, France, Georgia, Germany, Greece, Hungary, Ireland, Kyrgyzstan, Latvia, Lithuania, Moldova, Poland, Portugal, Slovakia, Slovenia, Sweden, Türkiye, Ukraine, United Kingdom.

this catastrophic and impoverishing health spending in Europe (Thomson, Cylus & Evetovits, 2019; WHO & IBRD, 2020).

Purchasing medicines: what is covered?

Funding medicines implies compensating the actors in the supply chain for their services related to the product: the pharmaceutical manufacturer for the development, production and launch of the product; importers, wholesalers and other distributors for their logistics services; and pharmacies for services around dispensing the medicine. Usually, in price-regulated settings of solidarity-based systems, these services are remunerated through the different components of the medicine price: the ex-factory price to reward the manufacturer, the wholesale markup for the distributor, and the pharmacy markup for the pharmacy.² The costs attributable to medicines' distribution can be considerable, but are beyond the scope of this chapter. The following paragraphs discuss which medicines are reimbursed by public payers, and how this is determined.

Which medicines are reimbursed by public payers?

In principle, all medicines that have been granted marketing authorization can be paid for by public payers. In practice, however, to ensure responsible use of public money and eventual sustainability for the health systems, not all medicines are included in public spending. Reimbursed medicines are mainly prescription medicines, but several countries also include at least some nonprescription medicines in their benefit baskets (see Chapter 2.2). In the EU, out of every €4 spent on outpatient medicines, €3 are used to pay for prescription medicines and the rest mainly cover nonprescription medicines (OECD & EU, 2022). In the next few paragraphs, we look at the differences in pharmaceutical benefits baskets across countries and outline the underlying decision-making processes, including those for high-cost novel therapeutics.

In the outpatient sector, selected medicines are included in reimbursement, following an evaluation process as described below. Most

² In several European countries, pharmacies are no longer (solely) remunerated for dispensing medicines via a price-related pharmacy markup or margin, but through a dispensing fee (Vogler, Zimmermann & Haasis, 2018).

European countries apply the concept of a positive list, which compiles medicines that are considered eligible for public funding, whereas negative lists which explicitly specify medicines excluded from reimbursement are rare (WHO Regional Office for Europe, 2018; Vogler, Haasis & Zimmermann, 2019). HICs tend to have large benefit baskets since they usually have more resources they can spend on medicines. In general, medicines that are considered essential are included in public funding. While WHO's model essential medicines list, which has grown from 208 medicines in 1977 to 460 medicines in 2021 (WHO, n.d.), aims to guide decision-makers in defining which medicines are considered essential, the essential medicines concept has deliberately been designed to be flexible so as to allow consideration of national particularities and priorities. Adjustments to specific situations (e.g. different needs resulting from the country's geographical area, such as tropical versus Nordic zones) are encouraged. Policy-makers are urged to ensure that essential medicines are "available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford" (Quick et al., 2002).

The range of medicines included in reimbursement lists thus varies significantly across countries and regions. For instance, within the EU context, Spain included 21 703 medicines in its reimbursement list in 2020 (including different pharmaceutical forms and dosages) compared to 11 845 medicines in Italy (in 2020), 7399 medicines in Austria (in 2019) and 1733 medicines in Cyprus (in 2020) (Vogler, 2021b; Vogler, Haasis & Zimmermann, 2019; 2020; Zimmermann & Haasis, 2021). Differences in reimbursement are even more striking in and compared to other central and eastern European countries outside the EU where the number of medicines included in reimbursement lists in 2018 (information provided for the outpatient sector and per active substance) ranged from 460 International Nonproprietary Names (INNs) in Belarus to 399 INNs in Kazakhstan, 148 INNs in Moldova, 50 INNs in Kyrgyzstan and 23 INNs in Ukraine (Vogler et al., 2020).

In addition, public funding may also be provided through additional programmes or funds, outside the regular reimbursement systems (e.g. alternative funding sources, alternative inclusion criteria and processes) to cover specific groups of medicines. In some countries, including some in central Asia, so-called vertical programmes fund

medications for diseases such as cancer, diabetes, hepatitis C, HIV/AIDS, tuberculosis (TB) and multiple sclerosis (Vogler et al., 2020). In HICs, dedicated funds offer patients access to medicines with high price tags, such as ATMPs, other cancer medicines and/or medicines for rare/neglected diseases. A well-known example is the English Cancer Drug Fund which finances, for a maximum of two years, cancer medicines which have not yet been deemed as cost-effective. In 2021, the creation of another similar fund called Innovative Medicines Fund for potentially life-saving new treatments (for example, in the areas of spinal muscular atrophy and cystic fibrosis) was announced in the English National Health Service. Since 2017, Italy has been operating two innovation funds (one for innovative cancer medicines and one for innovative non-cancer medicines, each worth €500 million) which were merged into a single fund in 2022 (Vogler, 2022b).

How do public payers decide which medicines to pay for?

Policy-makers leverage a range of policies to ensure that medicines covered by statutory money will be carefully selected (reimbursement policies) and that publicly funded medicines are purchased at affordable prices (pricing and procurement policies) to reduce waste, curb pharmaceutical spending and enable equitable patient access. In practice, there is, to a large extent, interlinkage between reimbursement and pricing policies, since whether or not a medicine is included in public funding frequently also depends on its price.

Criteria that countries in the WHO European Region apply when they decide on the inclusion of medicines in reimbursement comprise the (added) therapeutic benefit of a medicine, medical necessity/priority, safety, cost-effectiveness and budget impact (WHO Regional Office for Europe, 2018). The main tool which supports policy-makers in taking more evidence-based decisions about which medicines to cover is HTA, which is defined as “a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its life cycle” (O’Rourke et al., 2020) (see Chapter 2.2 for more information on health benefits packages and HTA).

The way in which assessment of pharmaceuticals is built into coverage decision-making varies across countries (Fontrier, Visintin & Kanavos, 2022; Panteli et al., 2016). While most European countries use HTA, or components of it, for reimbursement (and pricing)

decisions (37 of 53 countries of the WHO European Region), only some countries (including Denmark, Germany, Norway, Sweden, United Kingdom) apply HTA systematically (Vogler, 2022b). In addition, different assessment methodologies can be applied (Panteli et al., 2016; Robinson, Panteli & Ex, 2019; Emanuel et al., 2020; The Kings Fund, 2020). An outcome of HTA may be that a medicine shows only limited or no added (therapeutic) value. This does not automatically equate to exclusion from reimbursement, but the medicine is usually covered at a lower price. For instance, statutory health insurers in France reimburse new medicines which are deemed to offer no additional clinical benefits at 5–10% lower prices than comparator medicines on the market (Emanuel et al., 2020). In Australia, both clinical effectiveness and cost-effectiveness considerations play a role. If therapeutic potential is deemed equivalent to standard treatment options, a new medicine is priced to match the least expensive medicine in the medicine comparison group (Emanuel et al., 2020). When there are high degrees of uncertainty, HTA can result in a recommendation for a conditional reimbursement, or a managed-entry agreement can be put in place (see pricing mechanisms in the *How are purchase prices determined?* section).

Several European countries also apply such a policy to cluster therapeutically equivalent or similar medicines into a reference group, within which the same amount is reimbursed for all medicines. This can reflect the price of the least expensive medicine within the group or may be calculated based on more complicated processes. If patients wish to access a higher-priced medicine from the same reference group, they must usually cover the difference themselves; thus, this policy, called a reference price system, incentivizes the use of lower-priced alternatives (usually generics) whenever they are available. With such systems, often manufacturers price medicines below or just in line with the chosen reference price limit to ensure their product is covered by the insurance funds and is consequently chosen by health care providers and patients; the majority of these medicines are generics (Robinson, Panteli & Ex, 2019). The underlying idea of including medicines of same or similar therapeutic value within the scope of reimbursement is to enhance competition and thus to offer medicines at affordable prices (for payers and patients). However, it is important that these lower-priced medicines are actually prescribed, dispensed and used; this can be supported by demand-side measures targeted at prescribers (e.g.

prescribing by the INN), pharmacists (e.g. generic substitution), and consumers (e.g. financial incentives for requesting lower-priced equivalent in pharmacies, information campaigns to inform and build trust in generic and biosimilar medicines) (Vogler et al., 2021b).

Below, as with R&D, we set out the actual sums of money involved in the purchase of medicines, as well as the share of it paid by patients. We then go on to examine how the purchase prices for medicines are determined, and in particular how public payers decide what they are willing and able to pay, and the resultant national variations in purchase price.

How much money is spent on the purchase of medicines?

Pharmaceutical expenditure is the product of the volume of medicines consumed and their price (Fig. 3.4.1). For comparative purposes, pharmaceutical expenditure is usually expressed in one of three ways: per capita, as a share of national gross domestic product (GDP), or as a component of total health spending. Per capita annual spending for outpatient pharmaceuticals in the EU was estimated at €462 in 2020,

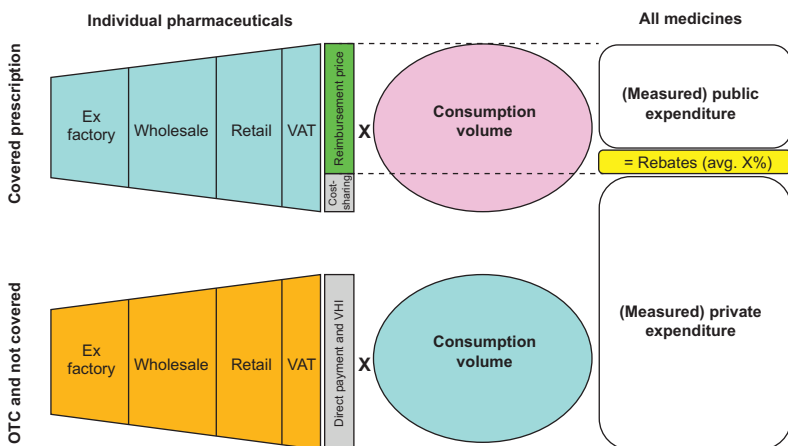


Fig. 3.4.1 Pharmaceutical expenditures are composed of the volume of medicines consumed times their prices

OTC: over the counter; VAT: value-added tax; VHI: voluntary health insurance.

Source: Adapted from Busse & Panteli (2019).

with considerable variation detected across Member States (OECD & EU, 2022). At €660 per capita, Germany was the highest spender, while Denmark lay well below the EU average at €258 per capita (see Panteli et al. (2016) on the relevant context for these figures). In the wider European Region, disparities in spending are even more extreme. Adjusted for purchasing power parity, current expenditure on medical goods ranged from €1281 per capita in Germany to €221 per capita in Moldova in 2020 (WHO, 2020). Lastly, if measured as a share of GDP, pharmaceutical expenditure usually corresponds to current health expenditure (as a share of GDP) times the share of health expenditure spent on outpatient pharmaceuticals, and in the EU ranged from 0.6% (of GDP) in Luxembourg to 2.87% (of GDP) in Greece in 2020 (OECD, n.d.; Panteli et al., 2016). As explained above, there is a lack of data on the costs incurred from hospital pharmaceuticals in health systems and sometimes also from private households, making it challenging to paint a comprehensive picture of total pharmaceutical expenditure. Generally, the share of pharmaceutical expenditure out of total health expenditure tends to correlate negatively with national income level. This is observed in many LMICs, where spending on pharmaceuticals can reach up to 60% of health care spending (Milne & Kaitin, 2019). One reason for this is that HICs have a stronger price negotiating power.

At the EU level, 29% of outpatient medicines were financed by private households in 2020 (OECD, 2022), while public expenditure accounted for 70% and VHI for 1% of total expenditure on outpatient pharmaceuticals. The shares of public and private expenditure vary significantly across different Member States, with particularly high public shares observed in Cyprus (85%), Germany (82%) and France (82%) and low shares in Bulgaria (24%), Poland (35%), and Latvia (41%). About half of what is spent OOP by patients in the EU went towards medical goods (including outpatient pharmaceuticals and therapeutic appliances) in 2020 (OECD, n.d.). The comprehensiveness of the benefit basket, the level of prices as well as the type of co-payments impact actual patient expenditure.

How are purchase prices determined?

Payers employ a range of mechanisms to determine the prices they are willing and able to pay for pharmaceuticals, against the backdrop of balancing necessary considerations of cost containment with the need

Box 3.4.6 What shapes manufacturers' prices?

Pharmaceutical manufacturers frequently argue that it is high R&D costs that render high medicine prices necessary to sustain future investment in innovation. However, evidence suggests that even larger proportion of pharmaceutical company budgets is spent on advertising and stakeholder awareness-raising activities to increase market share in the later stages of the pharmaceutical lifecycle (as mentioned above) and that manufacturer prices are determined based on what the market is willing or likely to bear.

In the US market, total annual spending on advertising and marketing was estimated at \$29.9 billion in 2016. Marketing to medical professionals makes up the largest proportion, yet direct-to-consumer advertising has rapidly increased over the past 20 years, making up one third of the total marketing costs in 2016 (Schawartz & Woloshin, 2019). While direct-to-consumer advertising of prescription medicines is not permitted in Europe, payments to health professionals and organizations advocating for patient rights are common practice and still poorly regulated across many European countries (Fabbri et al., 2018). Several countries, including the UK, have opted for a self-regulatory mechanism in which pharmaceutical companies disclose financial support provided to health professionals in public databases (e.g. Disclosure UK). This is one of few means to estimate the extent of payments, which amounted to an annual £50 million in 2015 and 2016 in the UK alone (Mulinari & Ozieranski, 2018).

to retain a healthy R&D pipeline (Box 3.4.6). Approaches include value-based pricing, managed-entry agreements, external reference pricing, internal price referencing and centralized procurement. We explain each of these briefly below.

While most countries only regulate prices for reimbursed medicines, some (e.g. Lithuania, Türkiye) statutorily determine (or negotiate) the prices of all medicines (Vogler, Zimmermann & Haasis, 2018). The rationale for this scope of price regulation is to protect patients from excessive prices even if they pay for their medicines OOP.

Value-based pricing

Increasingly used to determine what health systems are prepared to pay, this approach entails setting medicine prices on the basis of

evaluations of clinical and economic benefits. For instance, new medicines with additional benefit compared to available alternatives may be awarded with premium prices (Panteli et al., 2016). Pricing approaches that consider the comparative effectiveness of new medicines struggle with new therapeutics that offer curative options where only symptomatic treatment was available before. A well-known example is that of hepatitis C therapies based on direct-acting antivirals such as sofosbuvir (Sovaldi®), which started entering pharmaceutical markets in 2014. These medicines have evident clinical benefits and improved cost-effectiveness compared to interferon-based treatment, but given their high prices and sizeable target populations, providing access had important budgetary implications for health systems. Indeed, the total cost of treating every patient affected by hepatitis C was estimated to represent a potential threat to the sustainability of national pharmaceutical budgets in many countries (Iyengar et al., 2016). In order to mitigate the effect on public expenditure, some countries initially restricted access to certain patient groups, but this obviously poses an ethical dilemma in the long run. For ATMPs with the potential to cure complex medical conditions that have so far been treated symptomatically, target populations are usually smaller, but prices for these too have the potential to be so high that the budget impact will be considerable (Gonçalves, 2022) (Box 3.4.7).

Box 3.4.7 Zolgensma® – worth the high price tag?

At a price of around €2 million per dose, Zolgensma® was the most expensive medicine on the market at the time of its launch (Nuijten, 2022). It is a single-dose gene therapy medication used to treat spinal muscular atrophy in children, a disease which causes life-threatening muscle wasting and weakness leading to a very short life expectancy (EMA, 2021b). After being shown to improve survival and reduce the need for artificial ventilation, Zolgensma® received a conditional marketing authorization from the EMA in 2020 (EMA, 2021b). Due to the rarity of the condition and lack of comparator treatments, most of the studies conducted prior to authorization have been single-arm clinical trials comprising small patient groups, as is the case for many gene therapies. Additional evidence on the therapy's benefits and risk profile is continuously collected and shared with marketing authorization agencies in an effort to fill remaining knowledge gaps, including on the long-term outcomes and curative potential of this treatment.

Governments worldwide are struggling to balance the potential benefit for these patients with the staggering costs for health systems and concerns for equity. Within Europe, countries have limited access to specific patient age groups and types of spinal muscular atrophy based on the quality of available clinical evidence, while also adopting differing price negotiation and reimbursement approaches to secure access to Zolgensma®. Italy has approved its reimbursement using a “payment at results” contract with payments due at checkpoints of 12, 24, 36 and 48 months of treatment and confidential discounts on the ex-factory price applied for public health facilities and facilities accredited by the Italian national health system (Agenzia Italiana del Farmaco, 2021). Belgium, Ireland and the Netherlands participated in a joint HTA process through the Beneluxa Initiative and subsequently joined forces to negotiate a mutual agreement on pricing in late 2021 (Beneluxa, n.d.; Besley et al., 2022).

Managed-entry agreements

Related to value-based pricing are managed-entry agreements. These allow payers to mitigate the risks of purchasing new medicines whose benefits to patients remain highly uncertain by stipulating contractual agreements with manufacturers which set out specific conditions for their reimbursement. Commonly, managed-entry agreements constitute two types of agreement: performance-based (also called outcome-based), whose public funding is conditional on achieving specific health outcomes, or finance-based, which are not subject to these conditions. The scope of managed-entry agreements varies, but they always have confidential features, for instance negotiated discounted prices are always kept secret (Webb et al., 2022). This type of agreement is commonly employed in specialties where new pharmaceuticals with limited evidence but high expected value are marketed at high prices, such as oncology, immunology or rheumatology. Performance-based pricing models have been successfully negotiated between payers from several countries and the manufacturers of the first two approved CAR-T cell therapies for treatment of cancer. Although the specific clinical indicators considered are not always disclosed, the reimbursement of CAR-T therapies is conditional on clinical outcomes in several European countries, including France, Germany, Italy, Spain and the United Kingdom; some are also subject to future reassessments based on longer-term follow-up data as part of managed-entry agreements (Jørgensen, Hanna & Kefalas, 2020).

Although many countries use these agreements, the extent to which they deliver on their promise in different health care systems is still unclear. Evaluations are difficult to perform, given the confidential data that are required (Gerken et al., 2017). It is accepted that their administrative burden is considerable. Italy is one of the earliest adopters of performance-based agreements, investing millions of euros into an infrastructure to follow up on real-world outcomes in individual patients treated with expensive medicines, such as acetylcholinesterase inhibitors for Alzheimer's disease. Despite substantial investment, the Italian system of managed-entry agreements has been shown to be expensive and slow at generating the evidence required to track meaningful clinical outcomes. It is burdensome in practical terms, as health care professionals are exposed to additional administrative tasks, such as filing the required forms on clinical outcomes. Evidence suggests that finance-based agreements have generated some savings in the Italian setting (Dabbous et al., 2020).

External reference pricing

External reference pricing consists of setting the price of a new medicine according to a benchmark determined based on prices charged for the same medicine in other countries (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, n.d.). This approach is commonly applied to new medicines, either as the sole method of determining the maximum price statutory systems will pay or serving as a starting point for negotiating pricing and reimbursement conditions with pharmaceutical companies. For instance, in Norway the maximum price for a new medicine is set by averaging the lowest three prices applied among nine other European countries (Austria, Belgium, Denmark, Finland, Germany, Ireland, Netherlands, Sweden, United Kingdom) (Emanuel et al., 2020; Weise, Festoy & Hagen, 2018). Several European countries use external reference pricing as the main mechanism for medicine pricing. Others, including Belgium, Finland, Germany, Italy, Poland and Spain, use it as a supportive mechanism (European Commission Directorate-General for Health and Food Safety, et al., 2015; Schneider & Vogler, 2019; Toumi et al., 2014). The widespread use of this method of pricing incentivizes pharmaceutical manufacturers to keep high the official list prices used for it and then offer confidential discounts on the list price to payers. This creates an overall lack of transparency and concerns that the

actual prices paid for pharmaceuticals are not in line with what different health systems can afford (see Webb et al., 2022).

Internal price referencing

For pharmaceuticals with one or more therapeutic alternatives already on the market, internal price referencing is applied by several countries (Panteli et al., 2016; WHO Regional Office for Europe, 2018), intended as both a cost containment and competition-stimulating measure. Internal price referencing has two variants: the first features the reference price system in which medicines are classified into a reference group, within which all medicines are reimbursed at the same price by public payers. This can be understood as a reimbursement policy (more than a pricing policy), as described previously. A second type of internal price referencing is exercised in the form of a so-called price link (generic price link or biosimilar price link), by which the price of a generic or a biosimilar medicine is set in relation to the price of the originator or biological originator medicine (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, n.d.). In some countries, price link approaches also affect the price of the originator medicine. Generic and biosimilar price links are used in several European countries (Vogler et al., 2021b).

(Centralized) tendering

The procurement of medicines in the inpatient sector usually involves tendering for competitive offers. In European countries, hospital procurement is conducted by individual hospitals or through group purchasing. However, an increasing number of countries have started to introduce centralized procurement which can take place at national and regional levels (European Health and Digital Executive Agency et al., 2022). Different variants of centralized procurement through tendering can be found in countries such as Denmark, Norway, Portugal or Serbia (Bartels, 2016; Vogler, Bauer & Habimana, 2022). In 1990, Denmark established the public sector organization AmgroS owned by the country's five regional authorities. AmgroS is tasked with procuring all medicines for public hospitals in Denmark. It conducts cost-effective purchasing using different types of tendering contracts to attract bids from diverse suppliers and identifies which expensive medicines to acquire with the support of treatment recommendations issued

by another competent body, the Danish Council for the Use of Expensive Hospital Medicines (Bartels, 2016).

A study on public procurement of medicines has shown that countries with strategic approaches in medicines procurement were able to generate lower purchase prices. Their approaches involve applying a mix of policies and procedures such as pooling volumes and capacity (e.g. through centralized procurement and targeted procurement techniques (e.g. framework agreements)) which are aligned to their medicine procurement objectives; awarding the most economically advantageous tender and not the lowest-priced one; multiple-winner bids; and making use of supplementary tools such as HTA or horizon scanning. In addition, procurement can be used strategically to achieve other policy objectives such as security of supply, environmental protection, or crisis preparedness (European Health and Digital Executive Agency et al., 2022). There are also tendering-like procedures in the outpatient sector in a few European countries (e.g. Denmark, Germany, Netherlands) in which reimbursement is granted to the medicine out of a group of comparable medicines (e.g. the same active substances or therapeutic equivalents) for which the lowest price was offered; this is often supported by demand-side measures such as generic substitution. It has also been shown to effectively contain costs (Vogler, Gombocz & Zimmermann, 2017).

National variations in purchase price

The mix of different mechanisms employed by countries along with factors such as purchasing power and market size contribute to a considerable price variation across health systems globally. For example, studies examining the costs of new hepatitis C medicines based on direct-acting antivirals sofosbuvir (Sovaldi®) and ledipasvir/sofosbuvir (see the *Value-based pricing* section) show considerable variation in originator prices across countries (e.g. the median list price for a 12-week treatment course was of US\$ 40 502 in 2020 with a range from US\$ 10 730 in Argentina to US\$ 91 461 in Italy (Barber et al., 2020).

Evidence suggests that national income levels correlate negatively with prices – at least with official list ones. Although evidence on medicine prices in LMICs remains limited, over the past few years higher prices in LMICs compared to HICs have been documented for

the same treatments (Moyer-Holz & Vogler, 2022). This pattern is not limited to territories outside Europe, as similar discrepancies have been demonstrated between EU Member States of different income levels (Moyer-Holz & Vogler, 2022; Vogler, Vitry & Babar. 2016). This appears to be linked to lower health care budgets and less power to negotiate discounts with manufacturers, who are attracted to markets in wealthy countries amenable to purchasing expensive specialty medicines, such as oncology medicines. Evidence from Latin American countries suggests ineffective or lack of pricing regulation in these countries may result in higher prices in comparison to prices paid in HICs for these products (Moyer-Holz & Vogler, 2022).

International price comparisons face a number of methodological challenges (Panteli et al., 2016), not least in terms of meaningfulness of results due to the widespread use of confidential discounts. One of the few studies that has published confidential price data (for cancer medicines) highlighted differences of up to 58% in discounted prices across 15 European countries (van Harten et al., 2016). Countries with large markets such as Italy and Spain are more likely to be granted higher discounts for medicines than other countries, for instance in central and eastern Europe (Vogler, 2021a). Furthermore, there is no explicit and generally accepted definition of what constitutes an “affordable” or a “fair” price for a medicine; this means that while comparisons can highlight differences, they cannot automatically guide policy decisions.

Policy relevance and conclusions

The previous sections have described the financing of pharmaceutical care, focusing on the R&D investment required to create new products and the purchasing process that makes them available to patients. We have also highlighted the challenges budget-constrained health systems face when trying to provide sufficient financial means to stimulate innovation and make the resultant new products available to patients. An ideal pharmaceutical system building on the current model would simultaneously: allow industry to maintain a profit margin to cover the expenses and risks incurred when bringing a new medicine to the market; meet the expectations of shareholders and investors providing the necessary capital for R&D; continuously spur the development of novel medicine candidates attuned to unmet needs; and enable the

marketing of effective products that are affordable to public purchasers and accessible to patients. This is easier said than done.

On the side of R&D funding, clear communication of priorities on behalf of health systems and transparent and aligned incentive systems combining push and pull elements as described earlier in the chapter are crucial for addressing the commercial unattractiveness of certain medicines and steering efforts in their direction (see Anderson, Panteli & Mossialos, 2023). At the same time, measures to ensure efficiency in R&D practices should be strengthened (Panteli & Edwards, 2018). For instance, a large proportion of research on new pharmaceutical candidates is discarded before it is ever published or shared with the scientific community (Glasziou & Chalmers, 2016). This often causes inconclusive research or negative research findings to be excluded from public databases and official communication channels, and results in substantial duplication and consequent waste of research in the system. According to a Transparimed report from 2017, medical research that is wasted amounts to US\$ 170 billion each year (Bruckner, 2017). Research registration systems and the development of reporting guidelines have started to spur transparent research practices; however, this needs to be further sustained to ensure knowledge generated from research is openly disclosed and fewer resources are wasted in the early stages of the pharmaceutical pipeline. The EU Clinical Trials Regulation, which will be fully implemented after a transition period lasting until 2025, aims to increase transparency of trial information through a new portal and database (Vogler, 2022a). Nondisclosure of R&D costs complicates public payers' understanding of how to best invest in supporting innovation and the extent to which high pharmaceutical prices are justified. There are many who argue for more explicit ways to account for public "return on investment" for medicines that have been developed with substantial support from public funds (Mazzucato et al., 2018; McKee et al., 2021; Torreele, Mazzucato & Li, 2021).

On the spending side, we have shown the high variability across countries and the related impact on equity. Overall, countries with less advanced regulatory systems, lack of HTA capacities, and lower price negotiating power are susceptible to high pharmaceutical expenditure which frequently translates into higher OOP contributions and an elevated financial burden for the general population. However, even where there are well-established pricing and reimbursement systems,

payers face acute sustainability concerns, particularly in the light of the increasing number of new medicines with extremely high price tags. Reviewing current payment mechanisms is essential. For example, managed-entry agreements where financial compensation is contingent on the provision of additional evidence on clinical outcomes over time can have direct influence on how the medicine's price evolves. This can, in theory, relieve the initial costs of medicines, while also ensuring that public money is allocated to medicines with a genuine added value for the patient and the health system involved. However, the evidence on the impacts of managed-entry agreements in terms of actually boosting affordability and access to innovative medicines is still limited (Vogler, 2022b), and their administrative burden is high. External reference pricing, while prevalent, is limited by both the lack of transparency due to confidential discounts and the lack of consideration of the "appropriateness" of referenced prices.

To mitigate these limitations, newer approaches need to be considered and piloted further. A range of different approaches including those which aim to reduce the upfront costs of treatment have already been discussed or tested. For instance, payment models that delink manufacturer revenue from the price and volume of medicines used entail agreements between payers and manufacturers that foresee a regular pre-set payment for (a range of) medicines. This procurement approach is known as the subscription or Netflix model. Such models can be used for costly therapies which should be given to all patients who need them, as in the case of hepatitis C medicines (Dore, 2021; Vogler, 2022b). They can also be suitable for medicines with larger target populations, or where the goal is to retain alternatives but limit unnecessary use (such as in the case of antibiotics, Vogler, 2022b). In this sense, subscription models can also function as pull mechanisms to incentivize manufacturers to engage in R&D efforts for medicines that are needed but would otherwise be financially unattractive (see Anderson, Panteli & Mossialos, 2023). Subscription models can be combined with other provisions (e.g. with managed-entry agreements in the case of the hepatitis C in Australia, or updated HTA methodology to assess novel antibiotics in England) to strengthen their effectiveness. However, due to their novelty, evidence on the effectiveness of these models is still limited. Other suggested options entail paying in instalments and reclassifying costs for the procurement of ATMPs as investments rather than current expenditure (Active Citizenship

Network, 2022); while these options would potentially improve access, they would not necessarily contribute to the sustainability of health budgets.

Even though their health systems have both important budgetary constraints and less elaborate price regulation options, LMICs have more limited access to new medicines and are exposed to higher prices than HICs. Equity-based tiered pricing is a mechanism that has the potential to mitigate these disparities. Such approaches entail setting differential prices based on countries' economic abilities to pay for medicines working off a benchmark determined by involved governments. While equity-based tiered pricing could substantially improve access to innovative medicines in LMICs, its effective adoption requires careful design and, most importantly, solidarity and political will from leaders in HICs (Nemeth et al., 2022). A further prerequisite is the reconsideration of the current practice of confidential discounts: an equity-based official price for a HIC that gets an ex post discount to a level below the equity-based price for a lower-income country would defeat the purpose of the initiative.

Strengthening cross-country collaboration in general is another potential avenue for improving access to innovative medicines. Collaborative approaches and pooling scientific expertise and negotiation capacities can reduce the number of resources that individual countries must invest. At the same time, this can create economies of scale and strengthen smaller and/or lower-income countries' abilities to access pharmaceutical products at affordable prices. In recent years, several voluntary collaborations between governments in different geographical constellations have emerged, such as the Beneluxa Initiative, the Nordic Pharmaceutical Forum or the Valletta Declaration. Within these initiatives, countries aim to collaborate on a range of activities, including joint horizon scanning activities, HTA, joint pricing negotiations with industry and, in some cases, joint procurement of medicines (WHO Regional Office for Europe, 2020). Due to differences in national legal and organizational policy frameworks and the need for new working structures and governance processes, such collaborations can be resource-intensive and challenging, particularly at the start. As such, the success of joint negotiations and procurements is not guaranteed (WHO Regional Office for Europe, 2020). Nevertheless, there are some first positive outcomes of joint tenders and negotiations

(Vogler, Haasis & Zimmermann, 2021). The potential of joint purchasing initiatives at the EU level was demonstrated by the procurement of over 4 billion COVID-19 vaccines on behalf of all Member States (European Commission, 2022b) as well as COVID-19 therapeutics (European Commission, 2022a). This EU experience also demonstrated the importance of the design of such mechanisms, as the advance purchase agreements for vaccines were considered less constrained by unilateral priorities compared to tenders under the Joint Procurement Agreement. Furthermore, EU-level collaboration on HTA has been ongoing for many years and was cemented in the 2021 Health Technology Agreement Regulation which foresees joint assessments for new medicines starting in 2025. Next to the described benefits for payers, streamlining HTA, pricing negotiations and procurement can also benefit industry by simplifying the processes involved and accelerating the entry of novel therapies to markets.

Finally, strengthening the preparedness and improving the transparency of the pharmaceutical system can have important benefits for equitable and affordable access to medicines. Horizon scanning activities entail active collection of information on medicines (and other health technologies) in development to enable and facilitate priority-setting and long-term planning and shape pricing and reimbursement decisions. Few countries in the WHO European Region have introduced horizon scanning systems at the national level (Vogler, 2022c), though collaborative approaches like the International Horizon Scanning Initiative are starting to operate (Vogler, 2022b). The lack of transparency around pharmaceutical prices discussed in this chapter contributes to inequities and reduces accountability and trust; however, evidence on the potential effects of introducing measures to improve price transparency is very limited. Efforts to establish platforms for exchanging price information, such as the European Integrated Price Information Database (EURIPID), and clearing-house approaches demonstrate potential for further expansion and consideration, respectively. Similarly, clearing houses managed by trusted third-party actors may be best suited to collect pricing information anonymously from payers, including details on confidential discounts (Webb et al., 2022).

The selection of policy actions described in this section is by no means exhaustive. No single one of the approaches is a magic remedy

to the complex issues emerging in the pharmaceutical and innovation sector if implemented on its own. Payers at different levels need to consider these options according to their context, and cross-country collaboration can strengthen action to address these global issues with local specificities.³

Additional resources

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³ Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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3.5 *Paying for integrated care*

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Key messages

Chapter 3.5 reflects on how to use payment mechanisms to support the integration of care. Integrated care is about better management of the care patients receive in different settings (primary, secondary) and from different specialists and teams. It is particularly important for patients with multimorbidity and chronic long-term needs, and as populations age. Key learning includes that:

- Health systems' payment models can play an important role in incentivizing integrated care.
- Purchasers are now testing innovative payment models (e.g. pay for coordination (P4C)) which explore how to foster better coordination. These models include:
 - bundling payments to single providers so that the multiple services a patient uses are better linked; and
 - bundling payments for patients being treated by multiple providers, creating joint budget responsibility and a need to work together and avoid duplication.
- Policy-makers would do well to focus on careful design of information systems to underpin payment schemes because:
 - information sharing supports clinical effectiveness;
 - quality indicators allow purchasers to tie bonuses or penalties to integration and guard against inappropriate cost-cutting;
 - monitoring activity and health outcomes helps assess value for money;
 - tracking the distributional consequences of incentive schemes is crucial in protecting equity;
 - robust evaluation alongside payment reform allow immediate lessons to be shared and will capture changes over time and across the health care system.

- Health systems need to embed financial incentives as part of a broader system approach. Critical elements include:
 - committed leadership;
 - effective communication among providers;
 - structural integration, either through coordinating mechanisms that link provider roles or by the formation of new entities with single management teams.

Introduction

In this introduction, we set out the need for integrated care, and the role that payment models might play in delivering it. Across high-income countries (HICs), the increased burden of chronic disease associated with rising life expectancy has led to a call for health systems to extend their focus beyond the treatment of acute illnesses to the provision of long-term care (LTC) for patients who may require inputs from primary, secondary and social/community care providers (OECD, 2016; WHO, 2015). The growing prevalence of individuals with multiple chronic diseases (multimorbidity) increasingly requires models of care delivery that focus on the multiple care needs of the patient rather than separate treatment of single diseases. Indeed, without action, the increasing burden of multimorbidity poses a fundamental challenge to the sustainability of health systems worldwide (Bloom et al., 2012; European Commission, 2011; Nolte & Pitchforth, 2014).

There is a broad consensus that this rising need for care inputs from multiple providers and the fundamental concerns for the long-term sustainability of health systems require the provision of care that is better coordinated and less fragmented – commonly referred to as integrated care.

Definition of integrated care

Using Struckmann and colleagues' (2018) definition, integrated care can be understood as:

structured efforts to provide coordinated, proactive, person-centred, multidisciplinary care by two or more communicating and collaborating care providers. Providers may work at the same organization or different organizations, either within the health care sector or across

the health care, social care, or community care sectors (including informal care).

This definition encompasses both a system and a patient perspective, where integrated services are those that are experienced by the patient as coordinated (Goodwin, 2016).

The goal of care integration can be achieved through multiple means – of which payments, the focus of this chapter, are one. According to Poku, Kagan and Yehia (2019), there is an inverse relationship between care that is truly integrated and the need for care coordination: the more integrated care services are, the less need there is for coordination. The delivery of integrated care may, but need not, involve the formation of new vertically integrated organizations and it is important to note that organizational integration does not automatically solve the need for internal coordination (Williamson, 2002).

The role of payment models

In the same way that health systems may require reform to meet the changing needs of the population, there is a need for new payment methods that better align with current policy goals (Leijten et al., 2018; Struckmann et al., 2017). This chapter discusses payment models that can support the delivery of integrated care by non-integrated organizations, as well as models intended to incentivize the delivery of integrated care by vertically integrated organizations. The current ways of paying for primary and secondary care (Box 3.5.1) do not fit well with the provision of integrated care. For example, fee-for-service (FFS) and prospective payments based on diagnosis-related groups (DRGs) are based on activity, and primarily incentivize a high throughput of discrete units of care, rather than a long-term, well-coordinated, holistic care effort that ensures quality and cost-effectiveness for the chronically ill and multimorbid across the spectrum of care (Busse & Mays, 2008).

The redesign of payment models to enable more efficient care for patients with one or more chronic diseases requires providers to recognize the interdependency of care delivered across multiple sectors. Although this goal cannot be met by changes to the payment system alone, it is clear that most existing payment models are designed with a single sector in mind, and do not encourage providers to better

Box 3.5.1 Common payment mechanisms in health care systems

There are three main payment mechanisms for physicians (i.e. general practitioners (GPs), ambulatory specialists):

1. **FFS:** each individual service (unit of care) provided is reimbursed.
2. **Capitation payment:** providers receive a fixed amount for providing services to a patient (e.g. per registered patient on a practice list) for a specified period of time, regardless of the volume of services consumed by individual patients.
3. **Salary:** a payment per time period that depends on the characteristics of the physician, e.g. their years of experience or position in the hierarchy. Salaries are administratively simple but provide limited incentives for productivity (Rechel, Maresso & van Ginneken, 2019).

There are also three main payment mechanisms in hospitals:

1. **Global budgets:** a type of broad capitation in which a provider, typically a hospital, is paid a fixed amount, based on hospital characteristics or expected activity.
2. **DRG case payment systems:** hospitals are paid a fixed amount of money per inpatient stay depending on the characteristics of the patient and the treatment provided.
3. **Per diem fees:** payments per day of an inpatient's stay (Bell, Charlesworth & Lewis, 2021; Rechel, Maresso & van Ginneken, 2019).

The payment mechanisms may be used in combination.

coordinate their care or consider the implications of care in one sector on the expected cost and benefits of care in other sectors (Mason et al., 2015). Although more than 100 integrated care programmes for people with multimorbidity have been implemented in Europe, these challenges are rarely addressed by new innovative payment methods (Struckmann et al., 2017). However, such methods do exist and are worthy of consideration, as we shall show in what follows.

We begin by outlining a set of criteria by which we can benchmark payment models with respect to their ability to meet the policy goal of greater care integration across sectors; we provide a comparative example to illustrate the need for system change. We then use the criteria to examine traditional provider payment models and their

failure to meet the health system challenges of today. Next, we consider the options available for policy-makers looking for new payment models that can encourage integrated care, and the models' potential to incentivize integrated care, in theory and in practice, including three case studies, from Germany, the Netherlands and the USA, respectively. Finally, we draw policy lessons from the foregoing and highlight where the evidence base still needs further strengthening.

Setting performance objectives for incentives for integrated care

We begin by defining the challenges a payment model needs to address with respect to integration, and the criteria by which its performance should be measured. When providing integrated care, to achieve system-level efficiency from the perspective of a third-party payer, the interconnectivity of care and needs across sectors is a priority. Likewise, the definition of quality has evolved from a narrow focus on clinical processes and outcomes to incorporate patient-reported outcomes and health-related quality of life. At the same time, the increasing prevalence of an ageing and multimorbid patient population means that the care inputs needed from across the system have changed, and therefore the requirements for payment models also need reformulating.

The so-called triple aim of improving patients' experience of care, improving population health and reducing per capita costs of care (Berwick, Nolan & Whittington, 2008) is often proposed as the target for efforts to integrate care. The implications from the perspective of payment model design are that provider payment methods should create incentives for health care providers to internalize the impact their care decisions have on (i) patients' future care needs; and (ii) the expected costs and benefits incurred and delivered by other health care providers. The key requirements for payment mechanisms that are specific to integrated care are therefore:

- internalization of the impact of current care on future care needs/costs in the same sector;
- internalization of the impact of current care on current and future care needs/costs in other sectors;
- delivering care in the most efficient setting and without duplication.

Payment models that meet these requirements will help achieve the stated triple aim of higher levels of patient satisfaction, better population health and lower per capita costs. In what follows, we use these three requirements as a measuring rod for both traditional payment methods and the emerging alternative payment models.

First, though, we underline the need for change with a comparative example. If a patient develops acute appendicitis, the key objectives from a health system perspective are that the patient is treated quickly, cost-effectively and receives good quality care with a minimum of complications and a minimum need for post-treatment care. There is no uncertainty about where the patient is best treated, whether the patient will need care from multiple sectors, or what the impact on future care needs may be. The traditional health system goals of appropriate activity, quality and efficiency are therefore adequate to set requirements for and evaluate the effectiveness of the payment model. Likewise, traditional activity-based payment methods, possibly with an adjustment to incentivize quality in the delivery, are adequate to support these goals.

In comparison, for a patient with one or more chronic diseases, such as diabetes or chronic obstructive pulmonary disease (COPD), the picture is less clear. There is likely expertise available in both primary and secondary care that could treat the patient, and depending on the severity of the condition, there might also be a need for inputs from social care. Considered in isolation, these care needs could potentially be supported by traditional payment methods. However, the chronic nature of the condition means that care for the patient will be needed throughout the patient's remaining lifetime. Therefore, there is a need to incentivize the performance of each care activity with the impact on future care needs (and costs) in mind.

In addition, it is necessary for each sector to recognize that the care delivered in one sector affects the need for care in others. The typical example is "avoidable" emergency admissions. With the appropriate levels of ambulatory and social care, it is believed that acute emergency admissions can be avoided. Clarity about how emergency hospital visits might be avoided is critical, however, whether clinically unnecessary, clinically divertible or clinically preventable (Parkinson et al., 2021). Nonetheless, the potential for improvements in primary care quality and scope to reduce emergency hospital visits should not be overestimated (Parkinson et al., 2020).

Why traditional payment methods fail to support integration

Traditional payment methods such as cost-reimbursement, global budgets, capitation, FFS or activity-based payment based on DRGs do not encourage providers to take care interdependency into account (see Box 3.5.1).

FFS and DRG payments

FFS payments are mostly used in primary or ambulatory care and involve paying for each service unit provided. The fee level usually relates to the type and complexity of the provided service. This generally gives providers the financial incentive to provide as many reimbursable services as possible (Busse & Mays, 2008; Gosden et al., 2000). Therefore, FFS systems may stimulate inappropriate or unnecessary use of services and offer little or no incentive for (macro level) expenditure control (Ellis & Miller, 2008). Particularly for patients living with multiple chronic conditions, this may result in having to make more doctor visits with a greater number of doctors, which could also have repercussions on the quality of the care they receive (Rijken et al., 2017).

DRG-based case payments are frequently used in hospitals. If based on average costs, they provide strong incentives for efficiency (Shleifer, 1985), but bring the same challenges as FFS payments and equally come with the risk of disregarding patient needs and appropriateness of care (Busse et al., 2011).

With regard to care integration, neither FFS nor DRG-based payments offer providers incentives to coordinate care or consider in which setting care will be provided with greater efficiency as this could lower the number of reimbursable services/episodes (Struckmann et al., 2017).

Global budgets and capitation payments

Global budgets and capitation payments involve paying providers a fixed amount to provide services to patients for a particular time, regardless of the volume of services provided to individual patients. Both payment methods are administratively simple and control macro level expenditure well but they create few financial incentives for

providing care proactively and therefore do not incentivize figuring in the expected impact of care on future care needs. Providers may respond by providing as little care as possible to each patient (care-skimping) as the providers bear the financial risk. This in turn may create the potential for undersupply of services, lower quality of service provided, increased referrals and the adverse selection of low-risk patients (Busse & Mays, 2008; Ellis & Miller, 2008; Nolte & Knai, 2015). The latter particularly threatens access to appropriate care for people with multiple chronic diseases.

Traditional payment models' inadequacy: summary

In practice, most countries have implemented combinations of these payment methods (blended payments) based on different types of information (about the service, the provider or the patient) in order to mitigate the adverse incentives of the methods individually and create a more balanced set of incentives.

Generally, these payment mechanisms do not sustain a LTC effort, are focused on a single specialty or sector, and do not recognize the interdependency of care delivered across the care spectrum. This particularly affects the appropriateness and quality of care for patients with multiple chronic diseases. In terms of factoring in the impact of care on future needs and therefore costs, only capitation and global budgets give some incentive for reducing future care needs, but only in the same sector and within the current budget period. Providers paid by FFS and DRG could even be seen to benefit financially from maintaining or increasing patients' future care needs, although altruistic provider motives would be expected to limit the extent of perverse responses to these incentives.

In addition to incentivizing the goals for integrating care, payment models should also support, or at least not work against, other policy goals such as access to care, equality and transparency/accountability, and avoidance of unintended consequences. One of the important benefits of basing payments on provider activity has been that it gives purchasers and regulators access to clear information about activity in the health sectors. If new payment models move away from being activity based, it is important to ensure that information of similar richness and accuracy can still be obtained – a point to bear in mind, when considering new, alternative models.

Paying for integrated care: what are the alternative models?

As the focus on integrated care has increased, a range of new payment methods to support care integration are being considered. Below we present the options available to health systems wishing to deliver better integrated care. These range from simple add-on payments to support coordination and integration for individual providers of primary, secondary or social care that are not organizationally integrated, to models that require financial integration, whether via a new integrated care organization formed vertically or horizontally by care providers, or by individual care providers assuming joint financial responsibility.

Struckmann et al. (2017) provided a summary of various options for the adjustment of traditional payment models, illustrating that existing payment mechanisms can be adjusted to promote coordination and ultimately integration of care. That summary formed the starting point for the framework we present in Table 3.5.1 and the alternative payment models we set out below. We look briefly at P4C then in more detail at bundled payment schemes and the different means of financial integration when payments are bundled, in particular the shared-savings model. We also examine how the payment mechanisms can be adjusted to ensure quality of care.

P4C

At the most basic level, existing payment methods can be adjusted to promote better coordination of care with a payment type known as P4C (Tsiachristas et al., 2013). The adjustment can be made by: (i) adjusting the care provider's budget to cover; for example, the cost of employing a case manager tasked with ensuring coordinated care; (ii) increasing capitation payments for each registered patient with a provider that employs case managers or multidisciplinary teams; or (iii) providing additional fees for coordination activities such as case review and participation in meetings. Combinations of the three are also possible.

Bundled payments

Bundled payments is the term used for payments covering more than one episode of care for the same patient. As shown by Stokes and

Table 3.5.1 *Payment methods to support coordinated and integrated care*

Basis of payment	Provider	Patient/population	Service
Traditional payment mechanism	Global budgets/salary	Capitation	FFS/DRGs
Incentivizing coordination ↓	P4C		
	Budgets for multidisciplinary teams (e.g. case manager)	Higher capitations for providers with multidisciplinary teams	P4C activities (e.g. case review, documentation, participation in meetings)
	Bundled payments to one provider		
		Bundled payment per patient in target population for multiple providers	Bundled payment for multiple services performed by one provider
	Financial integration		
Incentivizing integration	Pooled budgets or shared savings for (joint budget responsibility between multiple providers)	Bundled payment per patient in target population for multiple providers	Bundled payment for multiple services performed by multiple providers
	Organizational integration (horizontal or vertical mergers) New organizational forms, e.g. accountable care organization		
Supplementary incentives	Bonus/penalty in relation to meeting structural quality indicators	Bonus/penalty in relation to risk-adjusted mortality, readmissions, complications or patient satisfaction	Bonus/penalty for proportion of patients treated in line with guidelines
	Monitoring structural, process or outcome quality		

DRG: diagnosis-related group; FFS: fee for service; P4 C: pay for coordination.

Source: Adapted from Struckmann et al. (2017).

colleagues (2018), what is included in the care bundle can vary greatly, from payments covering all episodes of care for a given condition from a single provider to payments covering all care for a patient from multiple providers.

The effect of a bundled payment on care integration depends on the exact scope of the payment in terms of the target population, time perspective, how many sectors are included, how many providers are

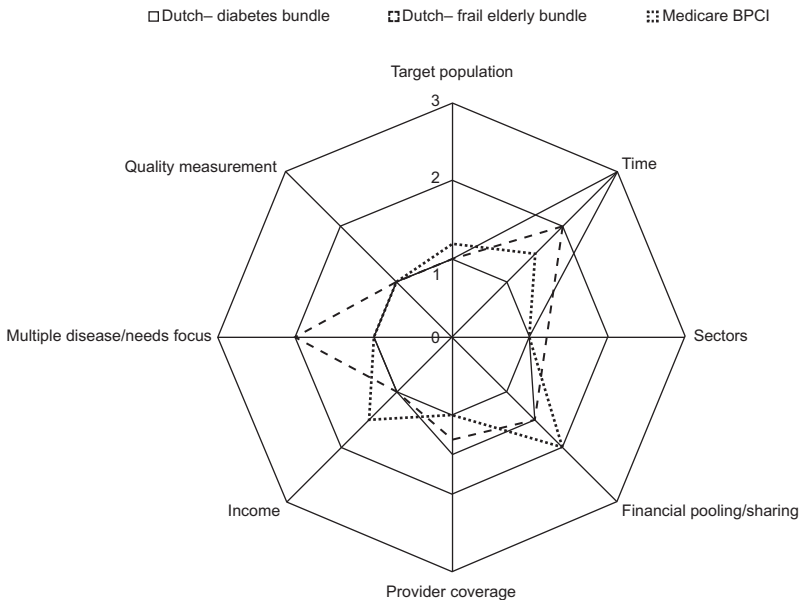


Fig. 3.5.1 Three bundled payment schemes and how they vary on key dimensions

Source: Stokes et al. (2018).

covered, the number of diseases/activities covered for the population, supporting levers in the form of quality measurement, the proportion of income affected and whether there is additional financial integration or risk sharing in place (Stokes et al., 2018). Fig. 3.5.1 gives an example of how three existing bundled payment systems vary on these dimensions, two from the Netherlands (for diabetes and elderly care, respectively) and one from the USA (Medicare BCPI).

In general, the broader the scope of the payment, the greater the incentive for integration of care but also the greater the financial risk transferred to the provider (Struckmann et al., 2017). Therefore, the introduction of a bundled payment model must always consider the existing provision structure and the availability of suitable contractors to accept the financial risks involved with the introduction of bundled payments.

When the payment bundle covers more than one provider, the contractual arrangement required increases in complexity as the

mechanism necessitates financial integration between the two or more providers who become jointly responsible for the care of a patient. Such arrangements are much harder to implement than P4C because they require changes that go beyond simply modifying the payment system and imply a transfer of financial risk from the payer(s) to the provider(s). The multiple providers may be from within the same sector (e.g. primary care) or across sectors (e.g. primary and secondary care providers). They may choose to form a new integrated care provision organization, often referred to as an accountable care organization (ACO). But even without forming a new organization, multiple providers can assume joint financial responsibility.

A review by Mason and colleagues (2015) identified eight types of financial integration, including: (i) transfer payments and cross-charging, where one provider either makes contributions to or pays fees to compensate the other entity; (ii) pooled funds, where multiple providers contribute to a common fund that can be spent on shared patients; and (iii) structural integration, where a new entity is formed with a single management team.

The difference to the add-on payment methods previously discussed is that financial integration offers a greater incentive to providers to recognize their joint impact on patient outcomes, by creating a financial interdependency between providers across sectors and assuming a mutual financial risk.

Theoretically, the broadest bundled payment would cover all care provided to all patients living in an area over a defined period of time. However, this type of payment would be usually called a broad capitation payment or a population-based budget. This implies that the question of how to pay providers and how to assure coordination of care is simply transferred from the purchaser to another organization, which then becomes the payer for individual providers (Struckmann et al., 2017). In this situation, purchasers arguably have less capacity to act as strategic purchasers and influence service provision without supporting collection of information about activity and quality, and care provision under such a payment bundle becomes opaque for the payer and the public.

Shared-savings model

One of the most common models of financial integration designed to promote integrated care is shared-savings. In this model, participating

providers agree to cooperate in a network and to collaborate with the aim of achieving joint savings for the care provided to participating patients. If such savings are made, a share is distributed to providers. Of course, the providers, patients and services eligible for participation in the programme have to be explicitly defined before the start of the programme (Hayen et al., 2015). Within the model, each individual provider continues to be paid according to the established payment system, but all costs for patients participating in the integrated care programme are registered and retrospectively compared to previous figures or a benchmark set to ensure that random fluctuations are not rewarded or punished. The payer is thus able to determine if any savings have been made, a share of which can then be shared among the collaborating providers.

Usually, shared-savings models require a new organizational structure to coordinate the roles of the participating providers, (re)distribute savings between them, help with the coordination of care, and facilitate the development of joint clinical pathways or joint electronic medical records. The (re)distribution mechanism is very important as it may well determine the success of the programme and the extent to which all providers gain from the reorganization of care (Struckmann et al., 2017). Payers will likely want to specify reporting requirements about activity and quality to ensure transparency.

Ensuring quality of care

Finally, payment systems can be adjusted to incorporate incentives for quality. This is often called pay for performance (P4P) or pay for quality (P4Q) and can be based on structures, processes and/or outcomes (Donabedian, 1988; McManus et al., 2021). P4P can be used to achieve agreed quality targets, for which payment to providers (professionals or institutions) is modified upwards or downwards. Within a provider network, target achievements can be recorded electronically and compared among participating providers, for example, with respect to patient experience (Struckmann et al., 2017).

Measuring and incentivizing quality of care is particularly important when payments allow providers to interpret patients' care needs broadly, as is the case with shared-savings models, bundled payments and capitation payments made to integrated care structures. This is because broader payments provide larger incentives and room for providers to reduce costs – and, in the absence of adequate mechanisms

to monitor and reward quality, providers may attempt to cut costs by reducing the provision of services, disregarding patient needs and providing lower quality care.

Table 3.5.1 also provides examples of these monitoring and rewarding mechanisms. For example, providers could be given penalties or bonuses for having appropriate structures in place for the care of people with chronic diseases (e.g. employing personnel with special training in multimorbidity, case managers) calculated as a percentage of their usual income. Furthermore, bonuses could be given for achieved outcomes of care (e.g. lower than average rates of mortality or hospital admissions, high patient satisfaction). Lastly, providers could receive a bonus if care is delivered in line with recommended treatment pathways and guidelines (e.g. if they perform a biannual polypharmacy review) (Struckmann et al., 2017).

Designing appropriate P4P programmes is a complicated task because of the many issues surrounding the measurement of quality (e.g. which indicators to use and how), the definition of targets (e.g. absolute targets or relative targets), the level of the payment adjustment (e.g. individuals, groups, institutions), the form of the incentive (bonus or penalty), the use of risk adjustment and so on (Eijkenaar, 2013).

How the new payment models incentivize integrated care: in theory

P4C is the least likely to incentivize providers to figure in the temporal and cross-sectoral consequences of their care, and thus lead to cost-effective care across the pathway. This is because the coordination payment is simply an add-on payment intended to incentivize providers to engage in a coordinating process, but other than signalling the need to coordinate to the provider, it does not give the provider a financial incentive to do so. Moreover, coordination effort is difficult to make contractible because the details of what is needed will vary greatly from patient to patient. It is also difficult to monitor compliance (Kristensen, Bech & Lauridsen, 2016), and there is no incentive for providing cost-effective care across the pathway.

Bundled payments are in principle able to incentivize the figuring in of the impact of current care on future needs in the same sector and the impact of care needs in other sectors, but it is difficult to imagine a cross-sector blended payment without a joint organization or a

collaboration between providers from different sectors. To deliver care in the most efficient setting would likely require some form of financial integration.

For example, cross-charging could be used to incentivize the figuring in of care in one sector on care need in other sectors. However, as financial integration moves towards organizational integration, there is a risk of recreating the coordination problems facing payers/purchasers. Joining up entities from across sectors does not guarantee that the coordination problem goes away (Williamson, 2002). In fact, by removing the explicit transaction from the equation, new internal coordination problems may arise (Struckmann et al., 2017) and benefits from specialization may be lost (Baicker & Chandra, 2004, cited in Mason et al., 2015) and the payer has effectively transferred the question of how to ensure coordination of care to the providers. In addition, larger budgets across more complex organizations are less transparent and may be more difficult to monitor and control.

Thus, from a theoretical perspective, financial integration without organizational integration (for example, in the form of shared-savings) may be thought to have the greatest likelihood of achieving the goals of integrated care but require careful incentive design which in itself is a complex task.

How the new payment models incentivize integrated care: in practice

Overall, the empirical literature on payments for care integration does not provide very strong evidence that introducing financial incentives alone will incentivize integrated care. On a side note, the same can be said about integrated care interventions in general (Kumpunen et al., 2020). This raises a general point about the literature on the effectiveness of payments for care integration – that it is rare to have evidence on interventions that changed the payment system only. Most often, the changes to provider payments are part of a larger system change to stimulate care integration. It can therefore be difficult to separate out the impact of the changes to payment mechanisms from other changes to the organization of care occurring at the same time.

Because the specific payment mechanisms to support integrated care differ widely, the challenge for the literature in terms of condensing the empirical evidence is similar to that facing the literature on P4P (which

is another example of an intervention that is not as uniform as the name would suggest). One study that does try to generate generalizable knowledge is Tsiachristas et al. (2015). The authors used longitudinal variation across 25 countries from 1996 to 2013 to examine the impact of national payment schemes to support integration classified as either P4P, P4C or bundled payments. Nine countries introduced at least one of the three payment schemes to incentivize care integration. The authors examined the impact on total health care expenditure, and outpatient care, hospital care, medication and administration expenses individually. They found that introducing P4C and bundled payments was associated with reductions in outpatient care expenditure, while P4P was associated with reductions in hospital and administration expenditure.

Hayes and colleagues (2021) used a similar approach to examine the impact on health and health care utilization, analysing patient-reported data from 20 countries from 2011 to 2015; eight countries introduced payments for integration, with a particular focus on the impact of payment reform on patients with multiple chronic conditions. The health outcomes examined were self-assessed health, limitations to day-to-day living and quality of life. To measure health care utilization, the authors focused on the total number of times respondents had seen or talked to a medical doctor in the past 12 months, the total number of GP contacts (a subset of the previous variable) and the proportion of GP contacts in relation to overall doctor contacts. The authors found that in countries that introduced P4C, multimorbid patients had proportionately more contacts with a GP, suggesting a shift to the primary care level where this payment method was introduced. In countries that introduced bundled payments, there was a relative increase in the number of times multimorbid patients were in contact with a doctor in comparison to patients who were not multimorbid. For both payment schemes, there was no measurable differential impact on health outcomes for multimorbid patients associated with the change. In countries that introduced P4P, multimorbid patients experienced a relative decrease in quality of life and greater limitations to their day-to-day living than other patients, while no measurable changes were detected in their pattern of care seeking.

When interpreting the findings from the studies by Tsiachristas et al. (2015) and Hayes et al. (2020), it should be kept in mind that they both group specific national payment schemes under broader headings, at

the cost of reducing potentially important institutional differences across countries. On the other hand, this is a common issue in empirical work and, if nothing else, the results can point interested policy-makers and practitioners in the direction of payment changes that were effective in their respective settings, and dive into detail that might need translation to their own context.

A review of integration of funds for health and social care (Mason et al., 2015) looked at 38 examples of financial integration from eight countries. Out of 34 studies that evaluated the impact of financial integration on health care costs and utilization, only three found a reduction in the cost or use of care, while the remaining 31 either found no, mixed or negative results (greater care use or costs after financial integration). Twenty-four studies examined the impact on patients' health and, here, just five found an improvement, and half of the studies found no effect at all. The authors found that the primary barrier for integration was practical challenges in communicating and exchanging information across sectors. One lesson from this review is therefore that it often takes more than financial integration to integrate care.

Case study 1: Bundled payment scheme for chronic diseases, Netherlands

A pilot of this bundled payment scheme with a focus on diabetes care began in 2007 and the scheme was fully operational from 2010. The scheme is voluntary, and allows health care providers to form care groups consisting of multiple providers that take joint clinical and financial responsibility for the patients covered by the scheme; for example, patients with diabetes, COPD or vascular disease. Participating care groups receive a fixed payment to cover disease-specific care, while other care is still reimbursed separately. The amount is set through negotiation between the payer and the care group. The group participants can then either provide care for patients themselves or subcontract to other providers (Llano, 2013). The aim of the scheme is to improve the quality of care, and the contracts specify the care process and outcome quality standards of care that providers must adhere to under the scheme.

An evaluation by the Dutch National Institute for Public Health and the Environment (Struijs et al., 2012) found modest improvements in

most process indicators of quality, including foot examinations, kidney function testing and cholesterol testing, while numbers of eye examination declined. Nevertheless, the variation in the quality of care between care groups was considerable. It should be noted, however, that the analysis did not use a control group, and it is therefore possible that the improvements in process quality would have occurred in the absence of the payment change regardless. We have not been able to locate stronger or more recent empirical evidence on the impact of the Dutch bundled payments on the quality of care.

Early empirical evidence suggested that expenditure increased in the short run for patients covered by the scheme (Mohnen, Baan & Struijs, 2015) and a recent study (Karimi et al., 2021) confirmed that this was also the result in the long run. According to a recent evidence scan (Struijs et al., 2020) the Dutch bundled payment scheme seems to be an outlier in this respect. Summarizing evidence on 11 bundled payment models, the authors found modest savings or modest reductions in spending growth reported in 20 of 32 studies; 18 of the studies reported quality improvements.

Case study 2: Medicare Shared Savings Program, USA

The Medicare Shared Savings Program is a voluntary scheme that enables health care providers (e.g. hospitals and/or primary care physicians (PCPs)) to form ACOs which take population responsibility for the quality, costs and care of their patient population (CMS, 2021). Launched in 2012, the scheme offers participating ACOs a menu of risk-sharing contracts between Medicare and the ACO. ACOs taking on larger financial risk may also receive greater shares of the savings. A one-sided option is the most popular, where only savings – not losses – are shared; this option was taken up by 99% of the participating ACOs in 2015 (McWilliams et al., 2018). The participating providers are paid by FFS. A prerequisite for accessing the shared savings is that the quality of care meets agreed performance standards. In addition, only savings above a certain level, known as the minimum savings rate, qualify for sharing. As pointed out by Pope and Kautter (2012), the minimum savings requirement can be seen as an attempt by Medicare to distinguish random variation in expenditure from expenditure reductions due to the ACO's "true" cost-control effort.

An evaluation by McWilliams and colleagues (2016) after the first year of the programme found that in the 32 participating ACOs spending per beneficiary was about 1% lower for beneficiaries enrolled in an ACO participating in the Medicare Shared Savings Program. ACOs with higher baseline spending generated larger savings, but there was no difference in the savings generated by ACOs whose providers integrated financially, compared with those that did not. In a follow-up study, McWilliams et al. (2018) found that shared-savings contracts entered into by groups of PCPs were on average associated with greater savings, and that the savings were higher the longer the groups had been participating in the scheme. The spending reductions generated by physician ACOs in 2015 amounted to US\$ 256 million in net savings to Medicare, the payer. Hospital-integrated ACOs, which have weaker incentives to generate savings due to the implications for other revenue streams not covered by the ACO contract, did not on average generate statistically significant spending reductions, and the reductions that were generated were offset by bonus payments. Subsequently, concern about whether savings had been generated by providers selecting patients with lower risk was not supported by empirical evidence (McWilliams et al., 2020).

Case study 3: Gesundes Kinzigtal, Germany

An example of a European-type ACO is provided by the *Gesundes Kinzigtal* (“Healthy Kinzigtal”) programme in Germany (Hildebrandt, Schulte & Stunder, 2012). The programme started in 2005 and targets the entire population of the city of Kinzigtal, regardless of disease or age. The guiding principle of the programme is the triple aim concept – improving patients’ experience of care, improving population health and reducing per capita costs of care – and the main elements of the programme comprise self-management support, prevention, patient-centred care and an electronic networking system (Struckmann, Boerma & van Ginneken, 2015).

The *Gesundes Kinzigtal* programme also aims to improve the financial margin for the purchaser, which in the German context are sickness funds, and in this specific case two sickness funds: AOK and LKK. The programme aims to generate savings within the Kinzigtal region as compared to German “standardized” costs, which are average costs across all sickness funds, and a reference period prior to the intervention. These standardized costs are calculated in the German risk

adjustment mechanism, which allocates money from a central allocation pool to purchasers. Since 2009, allocations for each individual are based on age, sex and marginal expenditures for one of 80 diseases as coded the previous year (Buchner, Goepffarth & Wasem, 2013). The contracts between *Gesundes Kinzigtal GmbH* (i.e. the company) and the two sickness funds are based on the virtual budget of each fund's total allocation from the central allocation pool – the budget is “virtual” because the money is not actually passed through to providers, who continue to receive their reimbursements from the sickness funds as usual. The financial result is measured by the total expenditure for the insured *Kinzigtal* population both within and outside partner institutions compared to the allocation from the pool. If the sickness fund spends less than it receives, the gain is shared between the fund and *Gesundes Kinzigtal* (Busse & Stahl, 2014).

Over the years the programme has managed to achieve savings. By 2010 the per capita expenditures of an LKK policy holder in the *Gesundes Kinzigtal* programme relative to those in the control group had decreased about 16.9% since 2005 (Hildebrandt, Schulte & Stunder, 2012). An internal evaluation of the AOK and *Gesundes Kinzigtal* over the period 2006 to 2013 found that the programme had led to a net annual saving for the sickness funds of close to 3% (after sharing the 6.5% surplus difference with *Gesundes Kinzigtal*). In 2012, the relative cost reduction that could be allocated to the activities of the programme amounted to around 7.9%.

Policy relevance and conclusions

This chapter has shown why existing arrangements may be seen as failing to deliver appropriate care and has outlined the options for payers wishing to use the payment model to incentivize improvements in care coordination and integration. We then reviewed the available evidence for the effectiveness of these payment methods.

Improving care coordination and integration is, however, a complex task, and payment reform is unlikely to solve all problems of coordination. Rather, changes to the payment system should be seen as one (key) element in supporting the transition to coordinated and integrated services, but as emphasized by the review by Mason and colleagues (2015), leadership and communication across providers remain crucial facilitators for care integration.

Despite the criticisms raised against traditional payment systems such as FFS or payments based on DRGs, one benefit is that they require data to be collected on the activities undertaken by health care providers, making care processes more transparent. If payers change to a system of payment bundles that include multiple services delivered over a longer time period and across settings, it is important to consider how information about providers' activities will then be collected. Even if new payment systems are supported by the monitoring of health outcomes or other indicators of care quality (which matters), information about providers' activities remains essential for payers to assess the content of the care bundle that is delivered, and to assess the efficiency of care. Beyond monitoring the impact on health outcomes and activity, it is also crucial for payers to be mindful that payment changes can have distributional consequences and ensure that the equity consequences of reform are either monitored or explicitly addressed by the payment change.

Likewise, payers would do well to consider how to evaluate the impact of payment changes. For example, changes could initially be introduced to just a few providers (ideally randomly chosen), or gradually rolled out (again in a random order) to facilitate a controlled or stepped-wedge design, so allowing a comparison of key outcomes before and after the change, between an intervention and a control group. Moreover, policy-makers should be open to the possibility that some changes will not work out as hoped for, and in that case be prepared to seek explanations for why the change did not generate the desired impact, with the aim of revising the scheme and trying again.

With a key aim for new payment methods being the consideration of the impact of care by one provider on the need for care from another, facilitating the availability and integration of information enables providers to review the changes experienced in care provision. Still, it should be acknowledged that demand for health care is fundamentally uncertain – both for patients and providers. In light of this, new payment methods should not excessively assign risk to providers for outcomes that are beyond their control.

Nevertheless, many new payment methods do include shifting risk from payer to provider. Consequently, payers must redefine their role as one of setting objectives and ensuring that payment systems facilitate the achievement of these objectives. There is also a question of how to deal with changes in patterns of care that ensue from payment reform,

which may result in some providers required to undertake fewer activities than previously.

Finally, payers should be mindful that, although demographic changes have created a need to rethink the way care is delivered which may be particularly relevant for patients with one or more chronic conditions, there is still a need for health care providers to respond swiftly to acute illness.

While the combined theoretical and empirical evidence suggests that financial integration such as shared-savings arrangements with careful design of incentives and information collection is a promising policy option for achieving the goals of integrated care, more empirical evidence is required before conclusions can be confidently drawn. Policy-makers are advised to have the need for further research in this area in mind when experimenting with new payment models, and to introduce new policies in a way that allows robust evaluation.¹

Additional resources

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¹ Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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3.6 *Balancing incentives to promote quality of care and improve long-term care*

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Key messages

Chapter 3.6 addresses how payment mechanisms can foster value for money and quality in long-term care (LTC). As populations continue to age with multimorbidity and the supply of informal care declines, expenditures in LTC are expected to increase significantly. However, better value for money can be achieved in LTC. Resource allocation mechanisms for LTC and payments to providers are distinct from those for health care for a number of reasons. Key learning includes that:

- LTC is particularly prone to poor quality or inadequate care, under provision, overmedicalization and to delivery in suboptimal settings.
- The challenges for LTC reflect its differences from health care markets, including that:
 - In health care the focus is on improving health whereas, once an individual needs LTC, that need for care is permanent and the emphasis shifts to maintaining quality of life;
 - LTC is often provided by low-paid or informal (often unpaid) caregivers rather than highly-trained professionals;
 - LTC markets are generally fragmented, with a multitude of funding sources and payers involved;
 - Collecting data on LTC quality, defining indicators and setting targets are difficult and make value-based payments particularly challenging.
- Payments for formal LTC provision should be adjusted based on risk and inevitable cost variation between patients, and then combined with other payment types that incentivize additional aspects, including quality of care and cost containment.
- Informal caregivers may be compensated either with cash or non-monetary benefits. Although these do not normally cover the full

costs of providing care, they acknowledge carers' contributions and to some extent address issues such as working hours lost.

Introduction

LTC is required by patients who are dependent on others on a daily basis because they are limited in the activities they can undertake for themselves. Since dependency on and demand for LTC are mainly associated with age and its concomitant comorbidities, the growing numbers of people living longer ensure that the demand for LTC will continue to increase. In 2018, about 25% of individuals aged more than 65 years in Organisation for Economic Co-operation and Development (OECD) countries had at least one limitation in instrumental activities of daily living (IADL), i.e. those activities that enable a person to live independently, such as shopping, laundry, cooking, the ability not to put oneself at risk by getting lost, and turning off electric appliances. Another 17% were limited in at least one of the activities of daily living (ADL), such as eating, washing and going to the toilet. An average of 11% of the OECD population aged more than 65 years received LTC in 2019, of whom 68% received LTC in the community, at home,¹ even though institutional care represented about 50% of LTC expenditures (OECD, 2021) (see Chapter 2.5).

Community care is provided by low skilled caregivers (meaning untrained or with lower level qualifications), predominantly informally by family members – most of them women. In formal LTC the gender of the caregiver often depends on that of the beneficiary. Since most beneficiaries are women, so too are their formal caregivers. Countries vary in scope of formal LTC, but it is estimated that just 10% to 30% of LTC caregivers in OECD countries are formal, i.e. paid workers (Colombo et al., 2011). Changes in family composition – for example, as a result of lower fertility rates – are projected to reduce the availability of informal caregivers (Brimblecombe et al., 2018; Gragnolati et al., 2011). Formal caregivers often work part time, are low-paid, low skilled (with lower

¹ Though nursing homes were the traditional setting for LTC provision, these institutions are expensive, and the added value of institutional care compared to home care is not clear. Governments that fund LTC have thus been trying to incentivize LTC at home through both in-kind services (formal care) and cash benefits accompanied by counselling on how to use the funds to receive the best home care possible (Norton, 2016).

level qualifications) and have a high turnover (see Chapter 2.5 for more on the differences between formal and informal LTC workers). Formal LTC is typically seen as a rather unattractive profession due to factors such as low pay or difficult working conditions, and supply has been constantly decreasing. Therefore, in many high-income countries (HICs), the LTC workforce relies particularly on immigrants. Even when wage increases are implemented in an attempt to retain the formal LTC workforce, results are modest (OECD, 2020b).

The limited supply of both formal and informal care, along with the growing demand for LTC, results in increases in total expenditures on LTC (Cravo Oliveira Hashiguchi & Llana-Nozal, 2020). Per capita expenditures are projected to rise even further (Bakx, 2015). LTC financial pressures on families and the state require LTC systems to improve their efficiency by mitigating market failures. Payment mechanisms are one of the tools available to achieve this (Charlesworth, Or & Spence, 2016), and this chapter presents our analysis of how best to deploy them.

First, we outline the conceptual framework for our analysis on the flow of LTC funds across the agencies. We then step outside it to argue caution: payment mechanisms cannot always be used in the same way in LTC markets as in those for health care, and we highlight the ways in which the LTC providers, markets and failures are different. Next, returning to our framework, we look first at the pooling and allocation of funds for LTC, and then at the payment methods used to purchase LTC services and the different incentives the various methods create. Finally, we draw conclusions and make suggestions for policy.

Our framework: conceptualizing LTC and financial flows

In this section we set out the terms and concepts on which our analysis relies and the framework within which we conduct it (Fig. 3.6.1). We define the services which make up LTC (personal and social, in kind or in cash), the settings in which the care takes place (community/at home, or institutional) and the workers who provide the care (formal or informal, skilled or unskilled).

The arrows shown in Fig. 3.6.1 represent the flow of funds which is central to our analysis. Within the framework, public LTC systems collect funds either nationally or locally (grey arrow “Raise funds: LTC contributions or general taxes”; see also Chapter 2.5). In systems with multiple payer agencies, the collected funds may be pooled and

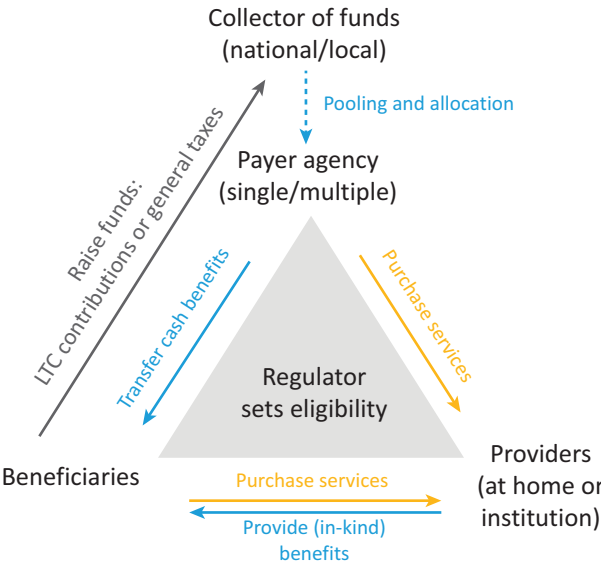


Fig. 3.6.1 Framework to analyse financial flows in LTC and payments for providers

LTC: long-term care.

Source: Based on Kutzin (2001), Busse, Schreyögg & Stargadt (2017) and Waitzberg et al. (2020b).

allocated to the payer agencies (e.g. local governments, health plans, ministries or national insurance systems; see the vertical blue dotted arrow “Pooling and allocation”). In systems with a single payer, funds are not allocated, therefore the arrow is dotted. Ideally, funds are allocated based on predicted risks or costs of the beneficiaries under responsibility of the payers, through a risk-adjustment/allocation formula. Payer agencies subsequently purchase LTC services on behalf of their beneficiaries by paying LTC providers (yellow arrow on the right hand side “Purchase services”). Alternatively, agencies can also “pay” beneficiaries directly with cash benefits (blue arrow “Transfer cash benefits”), giving them the option to use this money as they wish; for example, to pay for formal home care. Private funding exists in all LTC systems, and users often pay for LTC either entirely through out-of-pocket payments or partially, via user charges (yellow arrow at the bottom of the triangle). Voluntary LTC insurance plays a modest role in funding LTC in most

countries due to many market failures (Brown & Finkelstein, 2007), and thus we do not analyse this source of funding in this chapter.

LTC: its services

LTC comprises a range of services aimed at slowing down and managing the decline in functional capacity among beneficiaries with a high degree of long-term dependency (Colombo et al., 2011; OECD, 2018). LTC services are provided to dependent people, such as older adults (aged more than 65 years) or people with physical or mental disabilities suffering from chronic conditions with functional or cognitive limitations over an extended period.² LTC services cover various forms of care. In this chapter, we include: (i) personal care and help with ADL, such as eating, bathing and toileting; and (ii) social care, which deals with assistance services that enable a person to live independently and help them with IADL, such as shopping, laundry, cooking, not putting oneself at risk (e.g. getting lost), or forgetting to turn off an electric device (Gori, Fernandez & Wittenberg, 2016; OECD, 2018). We include cash benefits to buy the aforementioned services (i.e. monetary benefits for people needing ADL and/or IADL), as these payments are taken as a proxy for a paid transaction. However, we exclude medical or nursing LTC, such as wound dressing, administering medication, health counselling, palliative care, pain relief and medical diagnosis with relation to a long-term condition, as this type of service is usually funded by health systems.

LTC: its settings and caregivers

The severity of beneficiaries' dependency determines not only the type and number of hours and services, but also the setting where LTC is provided.

Community care

LTC is predominantly provided at home – referred to as community or home care in this chapter – by low skilled caregivers, whether paid workers (formal care) or family members (informal care). While the number of care hours are determined by the level of dependency (Colombo et al., 2011).

² While Chapter 2.5 in this volume focuses on LTC for older people specifically, this chapter covers LTC in its broad form.

Institutional care

If LTC beneficiaries' functional capacity continues to deteriorate, they may be treated in institutions with permanent nursing staff and rehabilitation-allied health professionals, such as LTC nursing homes, geriatric wards in care homes, or separate geriatric institutions (Cafagna et al., 2019; OECD, 2018). Our analysis takes account of two types of LTC institutions: day care centres and nursing/care homes.

Day care centres

In day care centres, beneficiaries receive several hours of care on a daily basis, particularly preventive care. The centres include nursing and rehabilitation services such as physiotherapy, occupational therapy and mental health support, provided by skilled and unskilled caregivers. These formal caregivers are part of community care although working in an institution (the day care centre), as beneficiaries live in their own homes.

Nursing/care homes

Recipients of care in nursing/care homes are those who require LTC due to physical or mental disability/dementia, but are not in need of complex medical care. Caregivers include skilled and unskilled caregivers (such as nurses and allied health professionals). Patients admitted to nursing homes for a short period following an acute-care hospitalization to recover before being able to return to their homes are excluded from this analysis. We also exclude geriatric/LTC wards in hospitals, because the care provided in these wards is medical and the costs are typically captured in health expenditure data. Sheltered housing is also absent in our analysis, as this type of institution is designed for independent residents. Residents of sheltered housing who receive help with ADL are considered community-based care beneficiaries and are mentioned under "community care".

Such, then, are the conceptual underpinnings and context for our analysis of the use of payment mechanisms in LTC markets, but first we need to see why caution is needed, if thinking simply to replicate the way they function in health care markets.

How LTC markets differ from health care markets

In health care markets, policy-makers use payment mechanisms as a tool at their disposal to influence providers' behaviour and decision-making through the economic incentives created. The ultimate objective of payment mechanisms is to compensate providers fairly for services rendered and promote efficiency: to achieve more with a given number of resources without undermining quality of care; or improve quality of care while controlling expenditures (Cylus, Papanicolas & Smith, 2016a; 2016b). Payment mechanisms can accomplish this by incentivizing the provision of the adequate number and types of services based on need, i.e. avoiding unnecessary treatment or selection of patients (Frank, Glazer & McGuire, 2000; Geissler et al., 2011). Likewise, payment mechanisms could potentially be used in LTC markets to balance economic incentives related to provision of LTC in a way that promotes desired objectives such as equity in access and high-quality care. However, the payment mechanisms required for LTC are not necessarily the same as those for health care, given some crucial differences between the two markets in terms of the type of care needed and the workers providing it; levels of market fragmentation; questions concerning the quality of care; moral hazard and excess demands. Here, we outline these differences and, briefly, some of the payment mechanisms which relate to them. We go into more detail about the various mechanisms in the *Payment methods and the incentives they create* section.

LTC versus health care: type of care

While in health care the aim is to cure or improve a patient's condition, in LTC it is about improving quality of life, where conditions are either longstanding or permanent (Bakx, 2015). There is also the question of the duration of an "episode of care" and the subsequent distributions of costs. Health costs are usually unpredicted and are very high for very few people, and the demand for care is usually not known in advance. For LTC, once an individual becomes disabled, costs are usually permanent and likely to increase gradually, though the duration of care varies. While only a small fraction of the population is responsible for most expenditures in health markets, funds in LTC are dispersed over a broader percentage of those aged more than

65 years (Berk & Monheit, 2001; Mitchell, 2019; Zuvekas & Cohen, 2007). In LTC it can be challenging to predict longer-term expenditures because it is difficult to foresee: (i) the probability of need (Costa-Font, Courbage & Swartz, 2015); (ii) the duration of care; and (iii) the future costs of the LTC services (Barr, 2010). For LTC it is challenging to define a clear episode of care that can be costed and priced in advance. Thus, prospective, activity-based payments are difficult to apply, and diagnosis-related group (DRG) payments are rare in LTC (Cots et al., 2011) (see Chapter 3.2 for more on DRGs).

LTC versus health care: type of provider

While health care is provided by highly skilled professionals, most LTC is provided by low-paid, low skilled (low or untrained) formal caregivers or informal (i.e. unpaid) caregivers (see Chapter 2.5). Informal caregivers typically face high opportunity costs in terms of time spent providing care and income lost due to reduced participation in the formal labour market, as well as a loss of personal time. To compensate informal caregivers, some countries offer incentives, such as tax exemptions, work leave days or other allowances. These have important impacts on caregivers' well-being, income, willingness to provide LTC and the interplay between formal and informal care. However, the incentives given do not compensate for the full cost of care, and there is no formal contractual relation between provider/informal caregiver and the beneficiary. Implicit contracts are mainly based on altruism or exchange motivation that might be influenced by the level and availability of supply of formal care (Costa-Font, Jiménez-Martín & Vilaplana-Prieto, 2022). Controlling for or incentivizing quality of informal care remains a challenge (OECD, 2020b).

LTC versus health care: level of fragmentation

Compared to health care markets, LTC markets are highly fragmented, with various sources of funds coexisting, and many payer agencies responsible for the different settings and types of care (see Box 3.6.1). Inadequate (re)allocation of funds may create incentives for cost shifting by LTC payers, resulting in attempts to shift unattractive (i.e. labour-intensive or high-risk) beneficiaries and costs to other care settings or payers. Shifting beneficiaries to less optimal care settings is

Box 3.6.1 Fragmentation within LTC financing systems

Due to historical development of LTC systems, countries often have multiple LTC programmes, correspondent to the care setting; for example, institutional versus community care, or type of benefit (in-kind versus cash). The different settings or types of care may have different methods of collecting funds, different budgets, different payer agencies, different pooling and redistribution systems, and sometimes also provide care for different types of beneficiaries. For example, Austria has different systems for cash and in-kind benefits. For cash benefits, the central government is the single payer, while for in-kind benefits the local governments are the multiple payers. Funds for cash benefits are transferred directly from the payer agency (the central government) to the beneficiaries, while funds for in-kind benefits are pooled and redistributed to the payer agencies through an allocation formula, and subsequently provided to the beneficiaries (Schmidt, Waitzberg & Blümel, 2021). Similarly, Czechia and Italy have different LTC systems for cash and in-kind benefits. Croatia, France, Poland and the Netherlands have different LTC systems for community and institutional care. The Netherlands also has different systems for community care based on type of care (one for ADL services, and another one for IADL) (Waitzberg et al., 2020b).

exacerbated when different payers are responsible for different types of care settings. In the Netherlands, for example, regional care offices pay for institutional and intensive home care (ADL), while community IADL care is paid for by local government. Since local government funds are not earmarked for LTC, those with greater budgetary pressures tend not to invest in preventive, less intensive care and instead have an incentive to shift beneficiaries to more intensive care settings paid for by the regional care offices (Alders & Schut, 2021). Beneficiaries may not only forgo IADL care, which can result in increased dependency levels, but they might end up receiving unsuitable (more intensive) care. Shifting beneficiaries to more intensive care settings may thus increase expenditures without added benefit. The undertreatment of patients, and the accompanying increase in their levels of dependency, in order to move them to other care settings and payers, has also been reported in Italy, Spain (Arlotti & Aguilar-Hendrickson, 2018) and Portugal (Lopes, Mateus & Hernández-Quevedo, 2018).

Two payment mechanisms used to mitigate this type of cost shifting and to promote continuity of care are bundled payments and pay for performance (P4P) (see Chapter 3.1). In health care markets, their effects have been modest (Eckhardt et al., 2019). The experience with these payments for LTC is less extensive, and outcomes are even less pronounced. The ability to reduce excess demand or total expenditures in LTC is lower than in health care, when each care setting is funded by a different payer (Kattenberg & Bakx, 2021). To mitigate cost shifting related to LTC's fragmentation of payers, it would be more effective to combine policy tools such as merging budgets, integrating providers or integrating LTC within health payers, rather than rely on payments as a single solution (McClellan et al., 2017). Experiences from England and Sweden show that pooling budgets for health care and LTC for older adults reduced duplication and fragmentation of care, improved coordination of care and collaboration between the sectors. However, no clear evidence of an improvement of quality of care was found (Hultberg et al., 2005). In addition, in the short term, there was no evidence of reduced costs. In the *Pooling and allocation of funds* section, we describe in more detail countries' LTC payer agencies, and how pooled funds are redistributed among payers to improve equity in financing.

LTC versus health care: quality of care

Concerns about how to incentivize high-quality care is core to the design of payments for LTC providers (Barber et al., 2021), while those paying for health care are balancing a greater range of payment objectives (see chapters 3.1 and 3.2). In the context of LTC, poor quality care by formal (paid) providers may exist in the form of neglect, overmedicalization or provision of services in the wrong setting; for example, not providing enough hours of care at home or treating a non-severely disabled person in a nursing home (National Academies of Sciences, Engineering, and Medicine, 2022). In addition to P4P and bundled payments, already mentioned, pay for coordination, pay for quality (P4Q) and shared-savings models have also been implemented to promote quality of care with mixed results, and without evidence for positive effects in the long run (Wieczorek et al., 2022). One of the main challenges of applying value-based payments is the difficulty in defining, measuring and collecting data on quality in LTC. It is also clear that payments and their impacts are context specific, and financial

incentives should be developed and tailored to each local setting (Struckmann et al., 2017).

Overmedicalization is more common in nursing homes than in home care, and is a further instance of service distortion, as institutionalized beneficiaries of LTC consume more or inappropriate medication, particularly opioids and psychiatric drugs, compared to those non-institutionalized (Fog et al., 2017; García-Gollarte et al., 2014; Jensen-Dahm et al., 2015). Keeping beneficiaries at home might reduce the phenomenon of overmedicalization, as it is less prevalent in this setting. One way to ensure more beneficiaries are cared for at home may be to set higher or more accessible benefits for home care than for institutional care.

LTC versus health care: moral hazard and excess demand

In health economics, moral hazard is a phenomenon where, in theory, patients consume more services or technologies because they are insured and do not see real prices (see Chapter 2.4) (Stone, 2011; van de Ven & Ellis, 2000); but in LTC this is different since beneficiaries are not typically insured and much of their care is unremunerated. Yet, moral hazard can still occur in LTC when publicly paid-for beneficiaries create an excess demand for: (i) LTC at an earlier stage of disability; (ii) more hours of care than needed; or (iii) more costly services, such as nursing homes (without real need), or replacing informal care with formal care too soon, thus potentially increasing public expenditures (Bakx et al., 2015a; Konetzka, 2006).

Countries typically reduce the risk of this market failure by imposing cost-sharing or limiting eligibility for benefits, but this raises risk of creating barriers to accessing basic LTC (Bakx et al., 2015a). A better strategy to mitigate excess demand is setting clear eligibility criteria at the national level, based on need (Bakx, Douven & Schut, 2021; Waitzberg et al., 2020b). For example, the Netherlands publicly funds both home care and nursing home care in similar scope. Beneficiaries are allocated to the setting (home or nursing home) and intensity of care (number of hours) with clear eligibility criteria based on level of need. There is little room for choice of care setting, and thus for preferring institutional care over home care (Bakx et al., 2020). In Spain too, needs tests based on severity of IADL and ADL limitation allocate beneficiaries into one of four tiers of care, leaving little room for excess demand (Costa-Font, Jiménez-Martín & Vilaplana-Prieto,

Box 3.6.2 Summary of potential market failures in LTC and possible policy tools to mitigate them

1. Difficulty in defining and costing a clear “episode of care”: once an individual becomes disabled, costs are permanent and likely to increase gradually, though the duration of care varies. DRG payments are infrequent.
2. Most care is provided by informal (unpaid) workers, who face high opportunity costs. Rather than formal contracts, there are implicit contracts based on altruism, which can pose difficulties in controlling or incentivizing quality of care.
3. LTC markets are highly fragmented, with multiple sources of funds coexisting and many payer agencies each responsible for the different settings and types of care. Risk selection by LTC payers can occur when they face incentives to shift unattractive (i.e. labour-intensive or high-risk) beneficiaries and costs to other care settings and payers. Beneficiaries may receive unsuitable care. By bundling sources of funds, payers and budgets may mitigate this inefficiency. In addition, funds should be pooled at the central level, and distributed among payers according to needs-based allocation formulae.
4. Quality of care and service distortion are key concerns. Over- and underprovision of care may exist in the form of neglect, overmedicalization or provision of services in the wrong setting. For formal (paid) providers, P4P payments may promote quality, yet evidence on their effectiveness remains limited and inconclusive.
5. Moral hazard (or excess demand) can occur when demand rises for LTC in an earlier disability stage, more hours of care than needed, or more costly services, such as nursing home care without real need. Cost-sharing is a suboptimal option to mitigate excess demand, but a better alternative is setting need-based eligibility criteria, frequently reassessed.

2022). Eligibility should be frequently reassessed with needs tests, to allocate patients to the proper care setting. Box 3.6.2 contains a summary of LTC market failures and policy options.

Pooling and allocation of LTC funds

Returning now to the framework set out in Fig. 3.6.1, in this section we look at the actions and processes represented by the horizontal arrow at

the top of the triangle. First, we describe the “who” of pooling and allocation – the collectors and the payer agencies, and then move on to “how” – the process of and criteria for allocating LTC funds.

Collectors and payer agencies

Payer agencies receive public LTC funds from national or local collectors of funds and commission or purchase LTC services from providers on behalf of beneficiaries (Busse, Schreyögg & Stargadt, 2017). Alternatively, payer agencies provide cash benefits to beneficiaries (see Fig. 3.6.1). In countries with multiple payers, payer agencies can be either local governments or health/LTC insurance plans, while countries with a single payer task the central government itself or another agency (such as a national insurance institute) as the payer agency. As such, in single-payer systems, the agency that collects funds, usually the central government, is also the payer agency since it purchases services from providers and/or transfers cash benefits to beneficiaries directly. Such agencies thus have an important role in purchasing LTC services and ensuring their supply for those in need, according to eligibility, in an equal and efficient way (Thomson, Foubister & Mossialos, 2009). Frequently, countries have different payers for the different LTC settings, i.e. a payer responsible for institutional care, and another payer for community care (as described in Box 3.6.1).

Collectors – mostly single, sometime multiple

In many countries, LTC funds are collected by the central government, or a combination of the central government with subnational (regional or local) governments. When funds are collected by multiple agencies, such as regional or local governments, they are usually pooled at the central level, and redistributed to the payer agencies. Canada and Germany are exceptions in the sense that most of the funds are collected in a decentralized manner and are not pooled and redistributed. In Germany, the LTC plans associated with the specific sickness funds collect contributions from their members, yet funds are pooled and redistributed ex post according to the de facto expenses of each sickness fund. In Canada, each province or territory has its own LTC system, and roughly 75% of the funds are collected by the provinces and territories, which are also the payer agencies. The other 25% comes from federal

transfers to the provinces and territories to fund their health care systems. These funds are not earmarked and are not pooled or redistributed across provinces and territories (Waitzberg et al., 2020b).

Payer agencies – mostly multiple

In contrast to the stark dominance of countries with central collectors of funds, most LTC systems have multiple payers. In these systems, funds are pooled at the central level and allocated to the payer agencies.

How are allocation decisions made?

Similar to mechanisms for allocating pooled funds to health care payers, allocation mechanisms for LTC should be based on predicted need of LTC, through a risk-adjusted capitation formula to ensure equity in financing (van de Ven & Ellis, 2000). Yet, contrary to health care, in LTC, multiple payer agencies are each responsible for different care settings, and may receive funds from different sources, and through different allocation mechanisms. LTC funds can be allocated to multiple payer agencies based on government decisions, automatic updates of past budgets or past use, or the predicted needs of the population they serve calculated via a risk/needs-based allocation formula. The more the distribution of funds is done based on objective and transparent criteria that reflect LTC needs, the higher the equity of funding. However, it is important to note that distribution of funds according to a needs-based formula alone does not ensure equity of distribution to a certain population if each region or payer agency commissions a different set of services for populations with the same need, or does so according to different eligibility criteria. Therefore, eligibility criteria should be set at the national level (Waitzberg et.al, 2020b).

In systems with single-payer agencies, funds do not need to be pooled and allocated. This is the case in Israel, where the National Insurance Institute is a single collector of funds and is a single payer for home-based LTC public provision (Asiskovitch, 2013).

In a study that analysed 25 LTC systems in 17 countries, only seven systems had a single payer, with the central government also functioning as the payer agency (Austria, Czechia and Italy for cash benefits; Croatia and Cyprus for institutional and community care; and Israel, as mentioned in the previous paragraph). Out of the remaining 18 systems, eight distributed funds according to past budgets, government

decisions or a general needs formula for public services (Waitzberg et al., 2020b). The other 10 countries did so based on a specific risk/needs-based formula for LTC, including Austria (for in-kind benefits), Czechia (for 15% of its budget), England, France, Germany, Lithuania, the Netherlands (for institutional care and community intensive ADL care), Norway, Portugal and Sweden (Table 3.6.1). Norway and Sweden applied demographic risk adjusters such as marital status to consider the existence of alternative informal care. They also used information about spoken language and residence in sparsely populated areas to reflect special caregiver needs. A few countries considered further risk adjusters such as disability, dependency level or chronic diseases (England, the Netherlands) and/or previous years' expenditures (Austria, France, Norway). France further considered socioeconomic risk adjusters such as the number of allowance claimants and income of older people in the area overseen by the respective local authority. In England up to 2020, needs-based allocation formulae accounted for differences in wages across areas and to recognize differences in costs driven by factors outside the control of payers (local authorities) and providers.

Compared to allocation formulae for health care, those used for LTC are simpler (Bryndová, Hroboň & Tulejová, 2019; Cylus et al., 2018; van de Ven et al., 2007). Maybe, due to the nature of LTC markets, where age and other demographic characteristics are strong predictors of need, these adjusters are good enough to allocate funds in an equitable manner. Future studies could test this hypothesis. LTC funds could also be adjusted retrospectively to account for unpredicted expenditures. That is even more important for LTC than for health care, because LTC is a social service and, as already discussed, can be challenging to insure.

With the funds now allocated to the payer agencies, we turn to the downward yellow arrow on the right hand side of the triangle in Fig. 3.6.1: the purchase of services from the providers of LTC – in particular, the payment methods used and their associated incentives.

Payment methods and the incentives they create

As already shown, different payment mechanisms can incentivize the provision of LTC in different ways. Broadly speaking, payments that vary according to activity and that are retrospective, fine and narrow,

Table 3.6.1 Risk adjusters used in needs-based formulae for allocating pooled funds, 2018

	Demographic (age, gender, marital status, household composition)	Socioeconomic (income, education, allowance claimants)	Health/disability condition (number of ADL limitations, chronic conditions, level of help needed)	LTC costs (previous year, and expected)
Austria (in kind)				x
Czechia (15%)	x		x	
France	x	x		x
Germany				x
Lithuania	x			
Netherlands (institutional)			x	
Netherlands (community)	x	x	x	
Norway	x	x		x
Sweden	x			
United Kingdom (England)	x	x	x	x

ADL: activities of daily living; LTC: long-term care.

Source: Waitzberg et al. (2020b).

such as fee for service (FFS), create incentives to increase productivity (i.e. the number of services or patients) and reduce the costs per unit of care. Prospective payments that are coarse, broad and fixed, such as budgets, salaries and capitation, can also create incentives to reduce the cost per unit (Ellis, Martins & Miller, 2017; Ellis & McGuire, 1996; Jegers et al., 2002; Newhouse, 1996; OECD, 2016; Quinn, 2015). Per diem and activity-based payments such as DRGs may create different incentives depending on the context. The challenge for policy-makers is to balance trade-offs between incentives to increase productivity and control expenditures and manage the different risks of unintended consequences that these incentives pose (e.g. overprovision of care, risk selection of beneficiaries, underprovision of care, provision of unsuitable care) (Chaix-Couturier et al., 2000; Geruso & McGuire, 2014; van Barneveld et al., 2001). Selection may occur if LTC providers prefer less labour-intensive beneficiaries and attempt to shift unattractive beneficiaries to other providers or other care settings. As in health care markets, prospective payments that incentivize cost containment (such as budgets, salaries, capitations and sometimes per diem) may aggravate this inefficiency. Cost containment may also undermine the supply of LTC beds in institutions or supply of formal workers.

One strategy to achieve this balance in economic incentives is to apply risk-sharing mechanisms that combine types of payments to distribute the risks of unpredictable costs between payers and providers in different ways (Newhouse, 1996; Quentin et al., 2018). This is done by combining payments with different characteristics, also called “add-on payments”. For example, in the health care market, providers are paid with a blend of prospective and retrospective payments, such as budgets or capitations combined with FFS, or salaries combined with FFS or P4P (Brammli-Greenberg, Glazer & Waitzberg, 2019; Quentin et al., 2018). Another strategy employed in health markets to balance incentives is to include other mechanisms of risk offset, such as the addition of risk adjusters into capitation formulae or including case mix in payment mechanisms (van de Ven & Ellis, 2000). For example, DRG-based payments adjust the tariff of episodes of care by accounting for case mix, comorbidity and severity of case (Street et al., 2011).

In LTC, adjusting payments based on risk is particularly necessary (and common) in countries where prices are set unilaterally or negotiated collectively, as providers do not set their own prices based on their own costs. Risk-adjusted prices avoid underpricing and mitigate

incentives for providers to skimp or reduce quality of care (Barber et al., 2021). Prices are commonly adjusted based on geographical location, the degree of dependency of beneficiaries and the type and setting of services. These adjustments recognize the legitimate and unavoidable cost differences among providers. For example, in Australia, the Netherlands and the USA, geographical price adjustments are made for facilities in rural areas, while Japan uses increased tariffs in the metropolitan Tokyo area to account for higher wages and higher costs of living. Adjustments for specific conditions that require more intense labour are done for beneficiaries with dementia (Australia) or Huntington's disease (Netherlands). Finally, some adjustments are done to incentivize provision of care to specific populations, such as for indigenous communities in Australia (Barber et al., 2021).

In what follows below we describe the most common methods to pay LTC providers and what is known about the economic incentives the different methods create. We consider institutional care separately from community care because of the differences in type and duration of care, caregivers and cost.

Payments to institutional care (nursing or care homes)

In nursing homes, beneficiaries may receive some specialized services, such as pain and psychiatric medications, rehabilitation and other allied health services (physiotherapy, speech and occupational therapy, diet and pharmacy counselling), and receive accommodation services for each overnight stay. Like hospitals (see chapter 3.2, for more on paying for hospitals), nursing homes have fixed costs such as infrastructure and personnel and, to a lesser extent, variable costs, such as consumables and payments to independent professionals. Variable costs in nursing homes, however, are proportionally small compared to hospitals, making it easier to work out a daily LTC tariff (per diem).

Payment method 1: per diem

Most care homes are paid by day of stay (per diem), complemented by FFS schemes (Table 3.6.2), with some countries setting global budgets (Barber et al., 2021). Such payments are often negotiated prospectively or based on a prefixed share of high-need users (Colombo et al., 2011). Examples of public LTC systems that pay care homes on a per diem basis are France (Le Bihan, 2018), Greece and Estonia (European

Table 3.6.2 *Types of payment for nursing/care homes used in different countries*

Type of payment	Nursing/care homes
Fee for service	Australia, Bulgaria, China, Czechia, Germany, Japan, Lithuania
Per diem	Australia, Estonia, Germany, Greece, Netherlands, Korea, Portugal, Spain, Sweden
Case mix-adjusted per diem	Canada, Italy, Switzerland, USA (Medicare)
Flat capitation	Argentina, Uruguay
Risk-adjusted capitation	France, Chile
Budgets	Czechia, Netherlands
Pay for performance	Germany

Source: Authors.

Box 3.6.3 Day care

Although day care is considered to be community care, the framework to analyse payments to and incentives for day care facilities is similar to that used for nursing homes, because unskilled care is provided along with some skilled care – mainly by allied health professionals. Prices for such services are often freely set by providers. Day care is also paid predominantly via the per diem system, in many countries adjusted to the severity of cases; for example, in France and Spain (Barber et al., 2021). In Italy, per diem payments are adjusted by diagnosis, and are higher for Alzheimer centres (Hohnerlein, 2018).

Commission, 2019), and Sweden and Spain (Barber et al., 2021). Day care institutions are also commonly paid per diem (Box 3.6.3).

As in health markets, flat per diem payments create incentives for LTC providers to contain costs, which can result in underprovision of care, neglect or the selection of lower-need beneficiaries. To mitigate these perverse incentives and promote proper and high-quality care, countries commonly adjust per diem rates to account for the variable costs of beneficiaries. For example, per diem rates are adjusted by the

risks of beneficiaries in the USA and Canada (Colombo et al., 2011) or, as in Portugal, according to the case mix of the institution, measured by the levels set by the eligibility criteria to qualify for public funding (Barber, Lorenzoni & Ong, 2019). Adjusting per diem rates for case mix mitigates the incentives for care providers to select beneficiaries, without significantly negating incentives for cost containment. This, though, comes at the risk of reducing incentives to prevent health deterioration: the more severe the case, the higher the payment (Wunderlich & Kohler, 2001).

The USA's experience with Medicaid's per diem rates showed that the system incentivized nursing homes to contain costs by decreasing levels of staffing and preferring less labour-intensive beneficiaries. Adjusting per diem rates to case mix reduced these perverse incentives both in the USA and Canada (Norton, 2016; Wilkinson et al., 2019). Since 2019, Medicaid sorts LTC beneficiaries in nursing homes into a patient-driven payment model based on the type of services they need: physical therapy, occupational therapy, speech–language pathology, non-therapy ancillary and nursing. Each resident is classified into one group of services, and per diem rates are adjusted accordingly (Barber, Lorenzoni & Ong, 2019). Early evidence shows that this patient-driven payment model may have resulted in a reduction in therapy staff levels and services (National Academies of Sciences, Engineering, and Medicine, 2022). Switzerland also has LTC needs-adjusted per diem payment structures for nursing homes (Bischofberger & Landolt, 2018).

Per diem rates can also be adjusted based on the facility's features or costs (up to a ceiling). However, this blurs the economic incentives of cost containment as rates can be adjusted for increased costs. For example, Portugal has four types of nursing homes to account for different care needs, and each type is paid with a different per diem tariff (Lopes, Mateus & Hernández-Quevedo, 2018).

Alternatively, per diem payments can be combined with payments that create incentives to increase productivity (FFS) or quality (P4P/P4Q). Germany has chosen to balance the economic incentives of payments to nursing homes by combining per diem payments with FFS if additional services are provided, such as allied health care, and P4P for rehabilitation services (Blümel et al., 2020). These add-ons may promote prevention of deterioration of patients' functioning. These add-on retrospective payments need to be accompanied by a proof of the service provided, to avoid fraud.

Payment method 2: FFS

FFS payments create incentives to increase productivity, which creates a risk of overprovision. This type of payment is therefore usually capped and combined with other payment methods. For example, Czechia pays nursing homes primarily via budgets to cover the operational costs, combined with FFS for certain services; the FFS component is capped to mitigate incentives for overprovision of care (Koldinská & Štefko, 2018). Australia, Germany and Japan combine their per diem schemes with FFS to incentivize nursing homes to provide appropriate care (Barber, Lorenzoni & Ong, 2019). Denmark's main payment method for institutional care settings is FFS (WHO Regional Office for Europe, 2019), which may partially explain why Denmark spent almost twice the European Union average on LTC in 2016. Lithuania and Bulgaria pay FFS for additional medical services in nursing homes (Barber et al., 2021; OECD, 2020a).

Payment method 3: capitation

Capitation bundles the payment for all services projected for each beneficiary during a period, usually one year. However, this payment is not very frequently applied, as it is challenging to cost and price an episode or a period of care. In Argentina and Uruguay, nursing homes are paid based on the number of beneficiaries they serve during a certain year (Cafagna et al., 2019). As with per diem payments, capitation creates incentives to contain costs; for example, by improving preventive care or quality of care, but also by skimping on care or selecting low-cost beneficiaries. It is therefore usually adjusted for the beneficiary characteristics that influence variation of costs. For example, Chile adjusts capitation rates according to beneficiaries' level of dependence, their age, medical status and socioeconomic status (Matus-Lopez & Cid Pedraza, 2015). In the USA, Medicare nursing homes that participated in the Evercare project and started receiving capitation-based payments (instead of FFS) invested in primary care to avoid hospitalizations, which reduced (unnecessary) hospitalizations (Konetzka, 2006).

Capitation payments can be used to promote integrated LTC (see Chapter 3.5 for more on integrated care). The Program for All-Inclusive Care for the Elderly (PACE), and the Institutional Special Needs Plan (I-SNP), are examples from the USA. In the PACE programme, day care was paid by capitation to provide all social and

health services in one single space during the day so the patient could keep living in their home (Konetzka, 2006). In the I-SNP programme, nursing homes were paid by capitation to provide onsite integrated care (McGarry & Grabowski, 2019). In both cases the integration of payments supported integrated care and reduced hospitalizations. This kind of incentive can be used only in a structure that enables the integration of social and medical LTC and primary and institutional care (see Chapter 3.5).

Payment method 4: P4P

Since most LTC is provided by low-paid, low skilled caregivers and some beneficiaries lack the cognitive capacity to complain, it is crucial to supervise and promote quality of care. Failures in LTC markets can result in low-quality or improper care, so maintaining quality is a key concern. Payments such as P4P can incentivize providers to improve quality, but it is not the only tool available to achieve this; Box 3.6.4 lists some of the others, both financial and nonfinancial.

Box 3.6.4 Other tools to incentivize quality of LTC

Apart from payment mechanisms designed to promote quality of care, other financial incentives can be implemented:

Quality-related subsidies

- In Austria, LTC providers must meet certain quality thresholds and adhere to quality management schemes to be eligible for public funding.
- In England, quality-related subsidies are given to providers that invest in and increase their nursing homes' workforce.

Quality-related public procurement

Australia and England give greater weight to predefined quality criteria (Malley, Trukeschitz & Trigg, 2015).

In addition, nonfinancial tools may also promote quality of LTC such as publicly publishing information about prices and quality.

Regulation is justified in any market with failures or distortions that are not naturally resolved and especially in markets that have social importance (Selznick, 1985). In LTC, regulation plays a major role in promoting quality of care, and yet there is still room for improvement (Mor, Miller & Clark, 2010). Ideally, payment mechanisms should be used as tools to enforce quality-promoting regulation (Ullmann, 1987).

P4P has been widely implemented in health markets, but to a lesser extent in LTC (Li & Norton, 2019). Its use in LTC markets is different, for two main reasons. First, “performance” is defined differently, and quality measures frequently used for health are not suitable for LTC. For example, mortality rates are unsuitable to assess quality of LTC because mortality rates are high among all providers, even high-quality nursing homes and the objective of LTC is not good health, but rather managing well-being. Second, perceived quality measured by satisfaction of beneficiaries may also be unsuitable for LTC settings because some beneficiaries may not be responsive to quality of care, particularly those with cognitive impairment such as dementia (Norton, 2016; 2018).

However, if P4P payments are effective, provision of higher quality of care potentially reduces the costs and burden on both the LTC and health care systems by reducing hospital (re)admissions and improving health outcomes. This is the reason why P4P is being increasingly implemented in nursing homes, despite the difficulty in measuring “performance” in LTC.

In 2010, about 14 states in the USA had P4P programmes for LTC through government-funded Medicaid. Programmes differed in how to measure and reward “quality”. Some used traditional measures, such as customer satisfaction with care provided, rates of staffing and regulatory deficiencies, while others used clinical outcomes, such as number of urinary infections or pressure ulcers.³ The rates of bonuses for performance were modest and varied between 2% and 6% of the per diem rate (Dyer et al., 2020; Konetzka, 2006). Germany applies P4P payment schemes for institutional LTC whenever rehabilitation interventions can lower the level of needed care (Blümel et al., 2020). Japan pays an add-on payment for nursing homes that exceed the minimum standards of staffing, a measure of quality of LTC (Malley, Trukeschitz & Trigg, 2015). Korean nursing homes can receive 1–2% additional P4P bonuses if they score highly in five domains of quality of care, namely management of institutions, environment and safety, guarantee of rights of beneficiaries, process and outcome. Evaluation scores are disseminated through an official LTC insurance website (Barber et al., 2021).

³ It is important to note that medical indicators may incentivize overmedicalization, therefore these should be used with caution.

Evaluations of P4P schemes in Iowa and Minnesota showed improvements in resident satisfaction with care provided, employee retention rate and nursing hours to beneficiaries. However, these very same P4P schemes resulted in the selection of beneficiaries, as they created incentives to admit beneficiaries that increased the probability of performing well (Colombo et al., 2011). In addition, P4P schemes have raised concerns that institutions with fewer resources have less chance of scoring high in performance. This potentially leads to a vicious circle where worse-funded institutions receive fewer payments for performance and have even less opportunities to improve performance or quality (Konetzka, 2006). Other recent evaluation studies from the USA found that P4P schemes had little effect on the quality of LTC and suggest that there is room for improvement in designing these payments (Grabowski et al., 2017; Li & Norton, 2019).

Given the above, policy-makers should be cautious in their enthusiasm for P4P payments. There is little reliable evidence, much of which is inconclusive, on whether these types of payments improve the quality of care. P4P payments are often technically and politically difficult to implement, and their cost-effectiveness remains unclear (Eckhardt et.al, 2019). To improve quality of care in practice, P4P payments should be carefully designed and combined with other tools (see Box 3.6.4).

Payment method 5: budgets

Budgets may be combined with other activity-based payments to balance economic incentives. In LTC, budgets are often negotiated prospectively or based on a prefixed share of high-need users. This poses a financial risk for providers, as they may face budget overruns, since public budgets are rarely adjusted later to reflect the changing disability status of care beneficiaries in institutions (Colombo et al., 2011). Budgets are not commonly used to pay for nursing homes, but some countries combine budgets with other activity-based payments to balance the economic incentives. In Czechia, as mentioned above, nursing homes' budgets cover the operational costs and fees for service for allied health services, which are capped (Koldinská & Štefko, 2018). The Netherlands combines a per diem system with overall budgets for residential care (Barber et al., 2021).

Community care

The key cost in community care is the labour of its formal caregivers. As in institutional care, most are low-skilled (see Chapter 2.5). In many countries, they are paid based on the number of hours they work. Elsewhere, caregivers are paid a global monthly wage or a fraction, corresponding to the worked hours. Usually, salaries are accompanied by quality norms and constant measurements. Current wages for personal home care in many countries are the minimum wage per hour and sometimes even lower, primarily due to unpaid time (i.e. unpaid travel time and “on-call” hours) (OECD, 2020b; Cravo Oliveira Hashiguchi & Llana-Nozal, 2020). Since the publicly financed hours are often not enough to cover the needs of the LTC beneficiary, the caregiver might receive payments from two payers: one being the public payer, and the other being the beneficiary or their family as private funding directly paid to the caregiver to ensure the beneficiary receives the number of hours of care they need.

The caregiver’s characteristics and the way a home care beneficiary receives the payment (in kind or in cash) can impact the level of expenditure, regardless of whether the care is formal or informal. In Germany, for example, LTC beneficiaries are free to choose between cash or in-kind benefits for home care. In-kind benefits are more than double the amount of cash benefits for the same care level assessed. Cash benefits are mostly chosen when the caregiver is an informal one, usually a relative, while in-kind benefits are the preferred choice for those contracting a formal caregiver (OECD, 2020b).

Informal caregivers can be rewarded by receiving allowances (cash benefits) or non-monetary benefits (extra care leave or paid leave from their regular work to care for relatives, tax benefits, respite care services and more, to incentivize informal caregiving). Both methods increase the willingness of informal carers to provide LTC and may promote home care instead of nursing home care (Brimblecombe et.al, 2018). Notably, in countries where the employer is not reimbursed for the paid sick leave or paid leave that an employee uses to help care for a relative, the costs of such legislation shift to the private/commercial sector. In some countries, such as Germany, LTC beneficiaries receiving cash benefits can use this money to pay their informal caregivers (Blümel et al., 2020). The monetary and non-monetary benefits usually do not cover the full costs of care, such as foregone working hours, and are

rather simply an acknowledgement that providing care involves costs (OECD, 2020b). For example, in Spain, caregiving allowances are unconditional (paid directly to the caregiver's bank account) but are lower than the minimum wage (Costa-Font, Jiménez-Martín & Vilaplana-Prieto, 2022). High benefits may disincentivize carers to participate in the formal labour market, particularly for low-skilled workers and especially if they are means tested (Colombo et al., 2011). In Spain, caregiving allowances incentivized informal care, while the effects of public funding of home care on informal care was mixed, with no clear pattern of substitution or complementarity of informal and formal home care (Costa-Font, Jiménez-Martín & Vilaplana-Prieto, 2022).

Policy relevance and conclusions

Compared to health care, LTC has unique characteristics when it comes to the type of care provided (by low/untrained caregivers, in formal and informal care settings, for an unknown duration) and the beneficiaries it serves (older people and others with impaired abilities' whose health situation is not expected to improve). Therefore, funding and payments for LTC should be regarded as social care rather than health care. Public and private expenditures in LTC are likely to keep increasing given population ageing, declining supply of informal (unpaid) care, and the introduction of new care technologies, but better value for money can be achieved. Public funds should be allocated efficiently to payer agencies, providers and beneficiaries. Payment methods are tools that can potentially be used to change provider behaviour to provide quality LTC according to need (not too much and not too little), in the most cost-effective setting. Payment types for LTC providers are largely the same as those for health care providers, and the incentives that each payment type generates are similar. The same two guiding principles to balance economic incentives apply: payments can be adjusted based on risk or on inevitable cost variations and then combined with other types of add-on payments to incentivize additional aspects such as quality and cost containment.

However, there are important differences between the health care and LTC markets.

First, the duration of LTC is unknown, which makes case-based payments such as DRGs difficult to price. Second, selection of less labour-intensive beneficiaries can occur when payments are not

adjusted to variation of risks or costs. Negative selection by payer agencies can manifest as shifting unattractive (i.e. labour-intensive or high-risk) beneficiaries and costs to less optimal care settings. Improper costing of payment fees, or prospective payments such as budgets, capitations or per diem payments can create incentives to service distortion such as underprovision of care, which usually means fewer hours of care, but also poor quality, neglect and understaffing. In extreme cases, improper costing may result in closure of nursing homes if they are not financially sustainable. Nursing homes are paid primarily per diem, which incentivizes cost control, but also service distortion. To balance economic incentives, per diem tariffs are either adjusted for severity of dependency, high costs, geographical region, or beneficiary characteristics; or combined with other types of payment such as FFS, budgets and P4P. Capitations are used to pay for day centres and nursing homes and can be used to promote integrated care. Capitations, too, are adjusted to account for variable costs and reduce incentives for selection or service distortion.

Home care is mostly provided by informal (unpaid) caregivers, who have no formal contracts, and provide quality of care dependent on their altruism, free time and opportunity costs. Formal caregivers are typically paid prospectively, by the hour or via a monthly salary, as there are few specific services that can be paid for with a specific fee. Informal caregivers can go unpaid, be paid from the cash benefits received by the care beneficiary, or receive non-monetary allowances, such as additional paid leave to provide care from the state or their regular employer, and tax exemptions. Neither the cash benefits nor the allowances fully cover the costs of care or loss of alternative income, which represent an increasing burden on informal caregivers.

Third, since LTC beneficiaries are not always able to complain, and many of the market failures may undermine quality of care, assessing and promoting quality of care is crucial for all care settings. However, quality- or performance-related payments in LTC are not yet widespread and the existing experience shows inconclusive results, with no clear evidence of benefit in the long run. Multiple coexisting policies may promote quality of care, if applied in a coordinated manner: (i) regulation that sets standards of care, promotes transparency and publicly publishes information on quality indicators; (ii) financial mechanisms such as payments to balance economic incentives and subsidies to enforce regulation; and (iii) reducing the fragmentation of LTC payer agencies and providers.

Fourth, moral hazard problems are less common in LTC than in health care due to rigorous eligibility criteria and assessment of need for services. Moral hazard is reduced with clear and objective eligibility criteria set at the national level, and detached from payers. Eligibility assessment should be done on a regular basis to account for changes in level of disability. These are better tools than cost-sharing to mitigate moral hazard, as they do not exacerbate financial access barriers. In addition, overprovision of LTC does not necessarily mean more hours of care and can result in overmedicalization.

Fifth, due to the fragmentation of LTC markets by type of care, payers may face incentives to negatively select unattractive beneficiaries, by shifting them to other care settings (and payers). Earmarked budgets or integration of payers might mitigate these perverse incentives. Equity in funding payer agencies may also reduce/end this market distortion. Equity in funding can be improved if funds are allocated to payers according to the needs of the populations they serve; this can be achieved by means of allocation formulae with clear and objective risk adjusters.

Since health care and LTC are interconnected, the effects of payments to providers in each area should be better explored. Investments in health care can prevent or delay the need of LTC. High-quality LTC and rehabilitation can save the costs of unnecessary hospitalizations. However, the systems are often fragmented, which may result in inefficiencies, and these interplays should be better understood – in particular, the incentives of payers and providers to shift beneficiaries to other settings by underproviding preventive care, or by upcoding severity of dependency. From the literature we have reviewed, it is not yet clear whether providers of LTC are more or less sensitive than health providers to changes in economic incentives created by payments. This could also be explored in future research.

Finally, payments are an important tool that influence provider behaviour, but are not the only ones. Policy-makers should bear in mind that health care and LTC providers are not motivated solely by remuneration. Other considerations often outbalance or prevail over the economic ones, such as the needs of beneficiaries, empathy or altruism, particularly among informal caregivers, who are usually relatives or friends of the person they are caring for (Berenson & Rice, 2015; Busse & Mays, 2008; Waitzberg et al., 2020a). It is key to receive the full value of LTC payments, and there is still a need to scrutinize the

effects of payment mechanisms on LTC market failures. Health economics provides a starting point to define frameworks to analyse the particularities of LTC.⁴

Additional resources

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⁴ Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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3.7 *From vertical to horizontal priority-setting: funding and procurement mechanisms*

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Key messages

Chapter 3.7 reviews priority-setting. Priority-setting is about taking explicit decisions on where limited public resources should be allocated. Vertical priority-setting focuses on choices for particular sets of health conditions or population groups whereas horizontal priority-setting looks more broadly across types of care, such as primary or secondary care, and broader investments. Key learning includes that:

- Defining a health benefits package (HBP) that is affordable and accessible by all implies a horizontal approach to priority-setting.
- Countries cannot progress towards universal health coverage (UHC) without horizontal priority-setting and without some form of collective funding and procurement mechanisms.
- Horizontal priority-setting is highly context specific. Countries may need to reorganize financing and procurement mechanisms to overcome barriers to progress.
- Increasing the total resources for HBP can help with the introduction of more horizontal approaches.
- Improving procurement can also support the move towards horizontal priority-setting whether through national efforts (such as better data gathering and use) or international initiatives (i.e. harmonizing regulation across countries or global investment in health security).
- Local capacity is key in supporting the pooling mechanisms, HBP design and regulation which enable horizontal priority-setting. Donors can usefully support health systems strengthening by investing in capacity-building and information sharing.
- Strong political will and cooperation between stakeholders is critical in progressing towards appropriate priority-setting for UHC and in designing, financing and implementing a comprehensive HBP.

Introduction

Following the 2012 United Nations resolution on UHC, in September 2015 all United Nations Member States reinforced their commitment to UHC by subscribing to Sustainable Development Goal 3.8 – achieving UHC. Moving towards UHC requires investment across three key dimensions identified by the World Health Organization (WHO): (i) extension of health coverage to populations not covered; (ii) improvement in quality and the number of services in the health package provided; and (iii) financial risk protection for poor and vulnerable populations. But, in most countries, scarce resources imply trade-offs between these dimensions, and not everyone in a country may have access to all beneficial health services at affordable prices. Trade-offs mean choices on what and how health care interventions are provided by a health system, for which population groups, in what quantity and at whose expense. Such choices must be made in health care systems in both high and low- and middle-income countries (LMICs) – i.e. some form of rationing of health services takes place in all health systems. A process of priority-setting is therefore essential to ensure that policy-makers align the HBP with both the goals and capacities of their country's health system.

Priority-setting: definition and role in developing an HBP

Without an explicit priority-setting process, rationing may still happen within a health system at multiple levels. For example, prices faced by patients may limit demand; long travel distances and delays in accessing services (such as waiting lists) may also lead to a reduction in demand. Eligibility rules based on citizenship, population groups or packages of services covered are all forms of rationing within a health system. Priority-setting in health care is the process of making explicit the decisions about allocations of resources in a health system, given that resources are limited – i.e. rationing always takes place. In the context of UHC, priority-setting is required to develop a comprehensive package of health services – an HBP that is aligned with social goals to which all individuals have access (Chalkidou et al., 2016). Such HBPs include “the set of health services and products that can be feasibly financed and provided for everyone, given a particular country's actual circumstances” (Glassman, Giedion & Smith, 2017). Establishing an HBP requires difficult political

choices and finding a balance between different suppliers of technologies and services, and claims from patient groups and regions (Savedoff et al., 2012). Making the process of defining an HBP transparent and based on scientific evidence for the cost–effectiveness of different interventions and products can help mitigate some of the political challenges associated with priority-setting for UHC. However, priority-setting using cost–effectiveness alone focuses only on the maximization of health within a population. Other criteria beyond cost–effectiveness, such as equity and financial protection, can have significant implications for which products and services are included and who has access to the HBP (Norheim et al., 2014).

Many high-income countries (HICs) that have UHC also already have some form of priority-setting process in place (Ham, 1997; Seixas et al., 2021). This chapter is primarily concerned with LMICs looking to make the transition to UHC. Decision-makers in LMICs often face severe resource limitations compared to decision-makers in HICs; the challenge is choosing affordable health care products and services to include in an HBP from a wide array of available options (see Chapter 2.2 for more on setting HBPs).

Vertical and horizontal priority-setting: definitions

In the priority-setting process, distinction can be made between vertical and horizontal priority-setting. In vertical priority-setting, the choice typically concerns which health care interventions and services to offer for the same or similar set of health conditions (Ham, 1997) or to specific population groups. In contrast, horizontal priority-setting involves choices between health care interventions and services for different diseases, across types of care (primary or secondary care) and broader investments in health system strengthening. But the definitional boundaries between the two are hardly clear cut when it comes to actual implementation. If we take HIV/AIDS prevention and treatment, for example, these occur across different care settings, making a programme focused on treatment with antiretroviral therapies (ARTs) more vertical than one that deals with the whole spectrum of the disease. Disease-specific donors often cover prevention and treatment for multiple diseases and may practise horizontal priority-setting within their portfolio of services. For example, the Global Fund to Fight AIDS, Tuberculosis and Malaria covers three diseases and,

recently, COVID-19. The Global Fund's investment has also been shown in large part to support pandemic preparedness and health system strengthening (Boyce et al., 2021). The same applies for Gavi, the Vaccine Alliance, as investment in vaccines also helps strengthen national procurement systems. However, as we discuss later in this chapter, a recipient country may face significant challenges in incorporating these donor-funded services within a more integrated (horizontal) priority-setting exercise. On the other hand, a health insurance package which caters mostly to the wealthy or urban population or a health care fund which is predominantly noncommunicable disease-focused, such as a cancer treatment fund as proposed in Nigeria (Onyejia & Adebowale, 2019) or the Indian dialysis programme (NHSRC, 2018), is more vertical, and in some cases may be less pro-poor than a broader HIV or malaria programme. Another form of verticalization can occur where federal states devolve financing and delivery of care to provinces/regions with inequity across states in terms of access and outcomes.

Horizontal priority-setting and UHC

Within the UHC framework, defining an HBP that is affordable and accessible to all implies a primarily horizontal approach to priority-setting. For countries which may already have several, often large, vertically set priority programmes, moving towards an HBP which takes a more integrated, horizontal approach will require reorganization of existing financing and procurement mechanisms.

Most countries that have horizontal priority-setting processes in place (regardless of explicitly stated or implicitly defined HBPs) have some form of collective funding and procurement mechanisms – for example, centralized tax financing as in Denmark, New Zealand, Sweden and the United Kingdom – while others, such as Germany or the Netherlands, rely on forms of compulsory health insurance (see Chapter 2.1). In contrast, countries looking to move to UHC through horizontal priority-setting have limited collective funding and are financed by a wide range of sources, including taxes (income or value-added tax (VAT)), international donors and a large share of out-of-pocket (OOP) payments (see Chapters 1.4 and 2.4). The two groups also differ in their health product procurement strategies. Those that have horizontal priority-setting processes in place typically have a national procurement strategy with well-established supply chain

mechanisms, enabling market-shaping power due to volume of purchasing. Countries pursuing UHC through horizontal priority-setting tend to have highly decentralized and fragmented procurement and supply chain systems with poor demand forecasting and supply management abilities (Silverman et al., 2019).

The definition of procurement in this chapter encompasses product (not service) selection, regulation, price negotiation and purchasing. It begins with a discussion of prevalent funding and procurement arrangements that pose a challenge for countries looking to move towards horizontal priority-setting for UHC. It then discusses potential ways forward, highlighting successes from countries making this transition. Emphasis is also placed on limitations and unintended consequences that have occurred during the transition. The chapter concludes with policy recommendations for donors and countries working towards a transition from vertical to horizontal priority-setting.

Challenges in moving to horizontal priority-setting

The role of financing arrangements

As organization and funding arrangements within a health system are built up over time, the nature of the health financing system has practical implications for horizontal priority-setting. Horizontal priority-setting assumes that there is some form of collective financing mechanism (general taxation/social insurance/employer scheme) where utilization is independent of funding contribution. Moving towards a collective financing mechanism requires a health financing transition. The transition involves a rise in total health spending per person financed through pooled resources, accompanied by a gradual decrease in OOP spending (Fan & Savedoff, 2014). However, this delineation does not always exist in practice and most systems use some mixture of funding mechanisms. These funding mechanisms often affect social goals and can pose challenges to ensuring that prioritized services are provided. For example, certain types of financing arrangements can influence provider or patient behaviour by stimulating or suppressing demand for specific health services (e.g. curative services) or for services that may be of priority to specific population groups (e.g. the wealthy). They may also impact the size

of the revenue base. To illustrate these issues, we consider challenges to horizontal priority-setting with three types of internal funding mechanisms that coexist with collective financing: private insurance, complementary insurance and user charges.

In many countries that have collective health financing schemes, individuals can choose to also have voluntary (private) health insurance (see Chapter 1.3). For example, the United Kingdom has private health insurance alongside collectively financed health care; individuals can use private insurance to replace collective coverage with insurance premiums set by the private provider based on the individual's risk. Individuals choose private insurance if the benefits/services covered under private insurance are perceived as greater than those from the collective HBP given the cost of the premium. In this case, the collective HBP may receive less political support from wealthy individuals who prefer and obtain private insurance. To garner political support for the collective HBP, policy-makers may be forced to design packages that are attractive to wealthy individuals, which can result in trading off equity and limiting coverage for interventions that are deemed to represent the best value for money.

The existence of a large(r) private insurance sector (such as in the USA) can also have profound consequences for the horizontal priority-setting process. The existence of an opt-out option from the public system can mean significantly lower revenues for the collective HBP, limiting the services that can be provided and the population who can be covered. Private insurance tends to attract wealthier individuals, who are generally healthier and whose needs may not be covered by the collective HBP. Thus, the budget available for a collective HBP through horizontal priority-setting is intrinsically linked to the benefits being offered.

Alternative arrangements to private insurance are supplementary and complementary health insurance alongside a collective HBP. For example, in many Latin American and Caribbean countries, private health insurance is a secondary source of coverage for some of the population. Its role is supplementary, i.e. covering health goods and services not covered in the basic HBP in Belize, Ecuador, Guyana, Peru, Suriname and Uruguay. However, in others, such as Argentina, Brazil, Chile, Honduras and Peru, its role is complementary, i.e. covering cost-sharing for health goods and services covered in the basic HBP (Lorenzoni et al., 2019). In this scenario, establishing a comprehensive

package of services that is affordable and accessible to all may be challenged by a need to offer services which are not covered by supplementary or complementary health insurance or a package that predominantly meets the needs of those who are unable to afford private health insurance. The sustainability of such an offering may also be in question if the services covered by the collective HBP are those that are likely to result in catastrophic health expenditure.

A third type of funding mechanism may influence the success of a comprehensive collective HBP: user charges (see Chapter 2.4). User charges are OOP payments for services or contributions towards the cost of a service. Within a collective HBP, they can be used to try to regulate demand for health care and generate revenue for the health system. If user charges are implemented within the HBP without exemptions in place, they result in catastrophic payments for individuals who cannot afford the charges, exacerbating inequity within the health system. On the other hand, the removal of user charges or widespread exemptions may result in decreased revenue for the health system, limiting the ability to provide a wider range of services or cover a large population.

In many countries, the provision of public health interventions, mental health services and diagnosis and treatment of communicable disease has been vertically arranged, with corresponding vertical allocations of funding for these specific areas. This arrangement offers little flexibility for allocations across areas and can present significant challenges in incorporating these services within a more integrated priority-setting exercise. In LMICs, the vertical arrangement of certain services, particularly those for communicable diseases, are due to their reliance on external funding. External funding from bilateral, multilateral and philanthropic organizations have typically been targeted to specific disease areas or priority groups. Examples include the Global Fund, Gavi, the United States President's Emergency Plan for AIDS Relief (PEPFAR) and the Bill & Melinda Gates Foundation (Atun, Bennett & Duran, 2008).

Furthermore, the level and availability of external funding may dictate which health issues are placed high on national health agendas as well as the types of interventions that are selected to address them. Donors with disease-specific priorities may limit the extent to which health systems can leverage economies of scope in the delivery of services through a shared platform (horizontally). Such arrangements

also pose a challenge for setting a cost-effectiveness threshold that reflects the budget constraint across horizontal interventions. Cost-effectiveness thresholds set by national policy-makers will reflect the limited domestic budget. Interventions selected according to these cost-effectiveness criteria must be highly cost-effective (reflecting the narrow domestic budget), but the limited budget may also narrow the scope of services covered.

The role of procurement arrangements

Low-income and lower-middle-income countries are estimated to spend around US\$ 50 billion per year on global health products (Silverman et al., 2019, based on estimates from Rosen et al., 2017). Despite this, access to essential medicines and health products in these countries remains insufficient, leaving individuals and families to access them in the private sector from OOP payments (Ewen et al., 2017). Health product procurement in low-income countries is also highly dependent on donors or privately purchased in lower-middle-income countries. Moving towards a horizontally set HBP implies fundamental changes to how health products and medicines are financed, transitioning away from OOP payments towards pooled financing and procurement.

In implementing a package of services that will expand access and coverage, countries need to procure a wide range of products to meet the needs of horizontally set benefits plans. In doing so, countries must justify the selection of products that meet the goals of wider access to services and coverage within their budgets. Health technology assessments and cost-effectiveness analyses can play a useful role in product selection, but not all health-improving products will be locally cost-effective within highly constrained government budgets (Wirtz et al., 2017). Furthermore, problems may be compounded by transition away from donor aid as income levels rise. Public sector spending in LMICs accounts for around 50% of expenditure on health products. Global health institutions and nongovernmental organizations, however, account for a large share of this public sector funding (Silverman et al., 2019). These funding mechanisms are not guaranteed to persist, and their support is usually based on countries becoming self-reliant over time (Wirtz et al., 2017). As support from donors wanes, countries will not only have to make up for their share

but raise additional resources to expand services and products covered under the benefits plan.

Some countries have come together to use pooled procurement systems to aggregate demand for pharmaceutical products. Pooled procurement, sometimes also called group purchasing or group contracting, combines decentralized decision processes on required volumes with centrally negotiated prices (Dubois, Lefouili & Straub, 2021; Nemzoff, Chalkidou & Over, 2019). For example, the Organization of Eastern Caribbean States Pharmaceutical Procurement Scheme, established in the 1980s, aggregates demand for products on the essential medicines list of 10 Caribbean states. Similarly, the Pan American Health Organization Revolving Fund (for vaccines, syringes and related supplies) and the Strategic Fund (for vector control medicines, diagnostic kits and related equipment) aggregate demand across several Latin American and Caribbean countries. This approach has also been adopted by global health institutions such as the Global Fund, UNTAID and Gavi, who in some shape or form have adopted product “market-shaping” strategies aimed at lowering prices through volume guarantees, combining demand across countries or ensuring continuous supply by contracting multiple suppliers. Countries no longer eligible for or reliant on such organizations and arrangements for health products may be faced with higher prices for these products due to their limited negotiating power and smaller-scale purchases. Apart from facing higher transaction costs due to lower volumes, unorganized demand may also deter suppliers from low-volume markets and/or from offering preferential pricing arrangements. This lack of organization from the demand side may also discourage investment in development of new products or manufacturing capacity (Silverman et al., 2019). To be fit for purpose, procurement processes in a horizontally set plan will need to optimize for quality, price, supply security and efficiency. Many LMICs have fragmented supply chains with purchasing, distribution and delivery processes vertically arranged across funders or programme/disease areas. Silverman and colleagues (2019) provide the example of Nigeria, which has parallel funding, purchasing and distribution systems by commodity area, for example essential medicines, maternal and child health and HIV, tuberculosis (TB) and malaria. These duplications prevent the organization of demand and obstruct planning and delivery of a unified HBP. Further inefficiencies in procurement processes due to institutional and administrative challenges such as difficult tendering procedures or delayed payments to suppliers may result

in increased prices due to the higher transaction cost associated with operating in such markets.

Existing financing and procurement arrangements can pose challenges to successfully moving from vertical to horizontal priority-setting. In the next section, we discuss potential ways of addressing these challenges and highlight efforts already being made by international donors to assist countries transitioning from donor funds or those never eligible for funding for; for example, the Global Fund's Wambo platform for COVID-19 products, or Gavi's purchasing agreements for transitioning countries.

Moving towards horizontal priority-setting

Reducing fragmentation by integrating financing schemes

In countries with multiple financing streams, fragmentation of financing streams can be reduced by merging existing ones where possible, thus reducing overlaps and generating a wider risk pool, so improving equity (see Chapter 2.1 for more on pooling). Amalgamation of existing schemes requires strong political will and there is potential for resistance from existing beneficiaries of the different schemes. Such resistance may arise if a unified benefits package implies fewer services covered than any of the separate schemes or higher levels of contributions for the same or fewer services. To overcome resistance to the consolidation, sometimes new legislation may be required. Such legislation may place the management of financing of different schemes with a single institution while paving the way for eventual consolidation (Towse, Mills & Tangcharoensathien, 2004). Such an approach was implemented by Thailand when trying to consolidate four existing schemes in a move towards UHC (Box 3.7.1). However, full consolidation has not been achieved and three separate schemes still exist. Despite the extended coverage of Thailand's UHC scheme, its benefits package is still less generous than those offered by two of the existing schemes – civil servants and social security schemes – making consolidation unlikely to take place soon.

Expanding the fiscal space

Implementing a horizontally set benefits plan often requires an increase in resources. In general, with tax-financed health systems,

Box 3.7.1 Thailand's UHC scheme

Prior to the introduction of UHC in 2001, Thailand had four separate health coverage schemes:

1. a tax-financed scheme providing medical benefits for civil servants;
2. a tax-financed medical welfare card scheme for those with low incomes;
3. a voluntary health card scheme for households predominantly in rural areas; and
4. a contributory social security scheme, mandatory for all private employees.

Prior to UHC, these schemes benefited 43.5 million of Thailand's population of 62 million. In its attempt to merge the four schemes, the government met strong resistance from members of the civil servants' and social security scheme, who feared a reduction in their entitlements. To proceed with UHC, the government amalgamated the voluntary health card scheme and medical welfare schemes to give coverage to 47.8 million people (roughly 72% of the population). The UHC scheme established a unified benefits package covering essential services in preventive, curative and palliative care for all age groups. More recently, it has extended coverage to high-cost services, such as renal replacement therapy, cancer therapy and stem-cell transplants. Furthermore, the National Health Security Act, which was passed by Thailand's Parliament in 2002, created a new institution to regulate the quality and financial aspects of the UHC scheme. Under this legislation, while benefit entitlements of the civil service and social security schemes remained unchanged, the financing of these two schemes was placed with the National Health Security Office, which oversees the UHC scheme, thus paving the way for eventual consolidation when it becomes politically acceptable to do so.

Despite the successes of Thailand's UHC scheme it faces several challenges. As a noncontributory, predominantly tax-financed scheme, its sustainability is affected by the adequacy of tax revenues in the face of rising health care costs. Thailand continues to rely on funding from the Global Fund for specific programmes such as HIV prevention programmes because of the difficulties in getting certain interventions for key populations funded by government.

simply improving tax collection could generate more resources for health. However, such expansions, even if feasible, may not guarantee a larger allocation or more consistent support for health

care. One potential solution may be for governments to leverage OOP spending; for example, by enticing those paying OOPs to join a collective scheme for a small premium, through which certain frequently used services or purchased drugs could be accessed at better negotiated prices. Such an approach is an alternative to the more commonly used insurance for health financing approach and facilitates greater efficiency in spending. Health insurance for raising funds has been shown to be unlikely to raise revenues commensurate with the requirements of providing adequate coverage for financial risk protection in LMICs (Barasa et al., 2021; Gheorghe et al., 2019). Another option is the creation of new taxes or the earmarking of existing tax sources for health spending (Box 3.7.2).

Box 3.7.2 Ghana's National Health Insurance Scheme

Ghana was the first country in sub-Saharan Africa to introduce a National Health Insurance Scheme (NHIS). The NHIS was constituted in 2003 and all residents of Ghana are eligible for NHIS coverage, which has a generous benefits package covering 95% of diagnosed conditions including all outpatient, inpatient and emergency care. The scheme has no cost-sharing requirements, including for pharmaceuticals associated with the covered health conditions (Wang, Otoo & Dsane-Selby, 2017).

The NHIS is primarily funded from:

- VAT (70%);
- deductions from the Social Security and National Insurance Trust (SSNIT) (20%) which mainly includes formal sector workers;
- premium contributions (3%);
- and the remainder from donor funds (Wang, Otoo & Dsane-Selby, 2017).

Claims payments account for 77% of NHIS expenditure. By deriving funding for the NHIS from taxes on specific goods and services, Ghana's health insurance scheme is the only in the world that is funded by VAT. This ensures that revenues keep pace with economic growth, while risk and cost pooling occur at the national level. However, reliance on VAT funding means revenue does not rise with an expansion in coverage.

Box 3.7.2 (cont.)

Since its inception, the NHIS has faced several challenges to its financial sustainability. These include the small revenue base arising from high levels of premium exemptions. Over 60% of active NHIS members are exempt from premiums (Alhassan, Nketiah-Amponsah & Arhinful, 2016). Premium exemptions apply to SSNIT contributors, enrollees under age 18 or over age 70, indigent people, institutionalized people and beneficiaries of some social protection programmes. Adverse selection and enrollee turnover has also been a problem. Wang and colleagues (2017) report that NHIS members are more likely to be in high-risk age groups (under 5s and over 55s). Their analysis of membership data shows that only 42% of enrollees from January 2014 remained in the scheme in January 2015 with members aged 15–24 years (least likely to have high medical expenditures) being the least likely to remain enrolled for a full year. A further challenge is the increasing cost of health products and service delivery. Health care providers under the NHIS rely on reimbursements to cover their operational expenditures. Providers are reimbursed using capitation payments for primary care services while all inpatient care and speciality outpatient services are reimbursed using the Ghana Diagnosis-Related Group (G-DRG) tariff scheme. However, pharmaceuticals are reimbursed using a fee for service (FFS), encouraging the use of prescription drugs. While the capitation payment for primary services provides some incentive for providers to be cost-efficient, these outpatient services account for only one third of all claims expenditures. The G-DRG and pharmaceutical FFS account for the remainder, with little incentive for providers to be effective in their referrals for secondary care or to curb overprescribing of curative services and pharmaceutical products. Thus, the combined effects of a generous benefits package, small and inconsistent enrollee base along with weak provider incentives continue to threaten the financial sustainability of the NHIS in Ghana (Durairaj, D’Almeida & Kirigia, 2010).

Earmarking “involves separating all or a portion of total revenue – or revenue from a tax or group of taxes – and setting it aside for a designated purpose” (WHO, 2017a). Some obvious candidates include levying or increasing taxes on unhealthy products, such as tobacco and alcohol, or a reduction in subsidies for fossil fuels. The

use of this earmarked revenue can be channelled to specific health-related priorities rather than to general health spending. The main advantage of earmarking unhealthy products is that in the short-to-medium term they can be a source of continuous, regular funding that is not affected by budgetary reviews. There is also likely to be political support for tax increases on such products when the proceeds are channelled towards health care (WHO, 2016). Over the longer term, revenues may fall as consumption falls or a black market thrives. Such an approach may also generate small revenues in countries where certain unhealthy behaviours (such as smoking) are not dominant. One of the main criticisms of earmarking revenues is that they limit budgetary flexibility and earmarked funds could potentially have been channelled towards more deserving programmes or projects. In this case, soft earmarking for certain priorities may be an option. For example, Thailand's Health Promotion Foundation is funded directly through a 2% earmarked tax on alcohol and tobacco. Opponents also highlight the importance of determining public spending based on policy decisions rather than by the amount of revenue raised by an earmarked tax. Cases studies on earmarking tobacco tax revenues in nine countries have shown some evidence that when revenues are channelled directly into an autonomous fund dedicated to public health, such as into the overall pool of funds for a UHC benefits plan, then those revenues successfully add funding for health (WHO, 2017a).

Cooperation between donors and countries

Cooperation between countries and international donors is vital to successfully implementing horizontal priority-setting. Ochalek and colleagues (2018) suggest estimating the scale of the health opportunity costs associated with any restrictions and conditions on donor assistance to facilitate a more informed and accountable negotiation between stakeholders, including careful examination of the reasons for restrictions. However, a more pragmatic and sustainable approach may be a change in the role of donors in countries transitioning from donor-dependent to fully domestically funded. Such a role may include supporting interventions that are marginally cost-ineffective, i.e. subsidizing key cost-ineffective interventions to make them cost-effective for a country's threshold. Such an approach has been shown to be an equitable and sustainable model, especially for middle-income countries

(Morton, Arulselvan & Thomas, 2018). Kanpirom and colleagues (2017) also highlight the importance of not assuming value for money is a static property of interventions. Interventions implemented by a donor that are deemed initially cost-ineffective for a country due to their high start-up costs may become more cost-effective over time due to economies of scale, improvements in efficiency, etc. To ensure sustainability of donor-funded services after eligibility for donor funds ends, both countries and donors should monitor cost-effectiveness over time. This would enable countries to justify continued support for such cost-effective interventions within a horizontally set benefits package.

Donors also have a role alongside national health insurance schemes in ensuring equitable access to services. National schemes often do not prioritize the poorest, sickest or minority groups, resulting in unequal coverage (Schneider, Nakamura & Wu, 2019). Because of their emphasis on high-priority diseases and conditions by disease burden, national schemes and other UHC programmes may disregard important disease burdens in small populations (Kanpirom et al., 2017). For example, poor and marginalized groups living with HIV may not be able enrol in a national scheme as premiums may be unaffordable, or due to the limited regional coverage of the scheme (Global Fund, 2018). Donors supporting countries could focus their conditions or restrictions on requiring access for these groups, or where not feasible within the country's budget, support such access themselves. Donors such as the Global Fund who invest in specific diseases (HIV, TB and malaria in this case) could pay for the three diseases through insurance funds, as is currently done in Viet Nam, where the Global Fund pays the insurance premiums of people living with HIV through their social health insurance (SHI), with a commitment from the government to absorb these premiums over time under domestic resources. ART and HIV-related care and services became reimbursable under Viet Nam's SHI in late 2014. Over 70% of people living with HIV were due to receive ARTs via SHI by 2020 (Global Fund, 2020a). In Thailand, through a similar arrangement, migrant populations irrespective of registration status are covered by health insurance (Herberholz, 2020).

Improving procurement and supply chain management

Improving procurement and supply chain management is critical to making health systems fit for delivering a unified HBP. Such

improvements can reduce costs and limit supply shortages (WHO, 2015). Changes can include reducing fragmentation by centralizing procurement and improving data systems to monitor, manage and forecast demand for health products (Seidman & Atun, 2017). For example, the Nigeria Supply Chain Integration Project was established in 2015 with a mandate to coordinate product supply management across health programmes and funders with the aim of improving cost-efficiencies, reducing waste and minimizing stock-outs. The project created and continues to maintain a logistics database on health products and pharmaceuticals across all health programmes in Nigeria, using it to monitor stock levels. The process also involved the creation and coordination of warehousing and transportation systems for health products across local, state and federal levels. Dubois and colleagues (2021) further analysed the effect of centralized procurement on drug prices using data from seven LMICs. They found centralized procurement of drugs does lead to lower prices. However, if there are high levels of supply-side concentration, then the extent of price reduction is lower. In some cases, decentralization of financial management and procurement directly to the health facility level has been shown to be effective in improving the availability of medicines and medical equipment in health facilities (Kajuni & Mpenzi, 2021).

Any integration of vertical, particularly donor-financed services into a horizontal HBP requires a realignment of procurement arrangements. There are several possible actions for donors to facilitate such integration. For instance, donors can incorporate value-for-money assessments such as those for health technologies into their selection and price negotiation processes. Currently, many donors such as the Global Fund rely mainly on price negotiations based on bulk purchasing. In the longer term using value for money can help countries making the transition away from donor funding avoid the trap of investing in low-cost technologies that may have minimal impact or pay higher prices due to their inability to meet the bulk purchasing requirements for donor-negotiated prices (Kanpirom et al., 2017). Gavi, for example, assists countries transitioning away from its funding with access to multiyear supply agreement prices through manufacturer commitments via UNICEF or the Pan American Health Organization (Gavi's designated procurement agents). However, currently this arrangement only applies

to select vaccines, and is time-limited with varying lengths. Keller and Glassman (2019) discuss other strategies that Gavi might adopt, including offering incentives to manufacturers to ensure steady vaccine supply, or permitting buy-ins from non-eligible countries. The latter may enable Gavi to globally negotiate tiered pricing agreements for countries, based on local affordability and cost-effectiveness. Delivering on horizontal priority-setting also requires access to safe, effective, good quality and affordable health technologies, medicines and vaccines. WHO (2017b) estimates at least 10% of medicines in LMICs are substandard or falsified, costing approximately US \$ 31 billion annually. This is because many developing countries do not have the technical, institutional or financial capacities to regulate health product markets. Donors can facilitate alignment across countries and, where relevant, diseases, through the pooled procurement of products (such as vaccines or antiretrovirals) that meet World Health Organization requirements for international product safety and quality. Such market-shaping activities can benefit not just countries within the pool, but also those outside signalling good quality health products. One such example is the Wambo pilot for transactions not funded by the Global Fund, which was expanded to include COVID-19 products (Global Fund, 2020b).

Within a country, national regulatory authorities play a key role in selecting and approving health products. Thus, ensuring strong country regulatory systems is critical to ensuring countries are using good quality, safe and efficacious health products. Donors, in their efforts to strengthen health systems, could support investments in improving governance, technical competence, monitoring and evaluation capabilities. They could also make on-budget spending a key performance indicator for countries. Finally, donors can facilitate broader information sharing across countries, both within and outside pooled procurement arrangements, so addressing information asymmetry in product quality and safety. Countries, on the other hand, should lead the way in implementing regulatory reforms with donor support, resulting in less reliance on branding as a signal of quality and encourage high-quality generic suppliers (Silverman et al., 2019). They may also leverage models used by international donors such as organizing demand, volume guarantees and pooled procurement on a regional or global basis (Kim & Skordis-Worrall, 2017; Seidman & Atun, 2017).

Health system strengthening and global health security (GHS)

In recent years there has been a lot of debate around the extent of true dichotomy in global health between either prevention and treatment or primary versus specialized care or, specific to this chapter, vertical versus horizontal financing and delivery of health services (Frenk & Gómez-Dantés, 2017; Dhillon, Karen & Marten, 2019). The previous contention has been that vertical funding by donors for disease-based programmes could compromise the integrity and equity of recipient health systems (Daniels, 2006). However, evidence shows there are significant lessons and benefits to health systems from vertical programmes in how they strengthen, support and operationalize horizontal systems. For example, the response to the HIV/AIDS epidemic has shown vertical programmes can be effectively integrated into horizontal (in this case primary health care) systems. Such integration has enhanced the quality of the wider primary health care infrastructure, filled workforce gaps and improved patient flows between services (Pfeiffer et al., 2010). Morton and colleagues (2016) also demonstrate how investments in health system strengthening can be built into priority-setting exercises and highlight the complementarity between horizontal and vertical programmes.

Priority-setting implies difficult choices must be made. It also raises important ethical and equity considerations. In setting horizontal priorities and moving towards UHC, decision-makers are required to agree on criteria and establish transparent and fair priority-setting processes (WHO, 2014). As part of their priority-setting agenda, countries should invest in improving their GHS – preparedness for the prevention and management of outbreaks and epidemics, limiting the need to rely on external financing for emergencies and diversion of resources from horizontal priorities (see Chapter 3.8). Both priority-setting for UHC and GHS have intersecting agendas – both UHC and GHS aim at mitigating risk either to individuals (UHC) or populations (GHS) (Wenham et al., 2019). Low or no financial barriers to accessing health care improves access to services for infectious diseases while financial risk protection is an important social deterrent to the spread of infectious diseases. The recent Ebola outbreak in the Democratic Republic of the Congo and the COVID-19 pandemic have more than ever highlighted the importance of GHS and resilient health systems (Meyer et al., 2020). They have highlighted frailties in even the most

advanced health systems, reinforcing the importance of successfully functioning health systems to detect and respond to health crises. Recent evidence has also highlighted the extensive contribution by vertical disease-specific international donors such as the Global Fund towards health security efforts through their investments in health system strengthening (Boyce et al., 2021).

Linking UHC and GHS may also enhance leverage for financing UHC (Ooms et al., 2017). The COVID-19 pandemic resulted in simultaneous global health and economic shocks. To facilitate a sustainable and inclusive longer-term recovery, progress towards UHC and improvements in population health (beyond COVID-19) are essential. Countries need to overcome the immense health and economic opportunity costs of managing the COVID-19 crisis (Appleby, 2020) including setbacks in the progress made over decades in key health outcomes such as maternal and child health and malnutrition. For many countries, health recovery requires an expansion of the government health budget. For a substantial group of LMICs, external financing is essential to recovering from this health shock. But an increase in health spending needs to be accompanied by better spending – reflecting improvements in equity and efficiency (Kurowski et al., 2021). Such decisions inherently imply priority-setting across populations, diseases and services.

Conclusions and policy implications

Priority-setting involves decisions on the allocation of public resources. This naturally makes it a political issue subject to varying perspectives. For example, individuals may consider any reductions in their access to services as unacceptable, health product manufacturers may perceive priority-setting as a barrier to market access, or health care providers may perceive the exercise as restrictive of their autonomy. The ethical principles of priority-setting may not be easy to convey to the public, who may not also perceive the need for setting priorities.

When such political economy barriers are overcome at least to some extent, a move to horizontal priority-setting with the aim of UHC is possible. The long-term financial sustainability of existing national health insurance schemes, as in these countries, is, as such, unclear and potentially an issue. HBPs must be designed with the budget in mind, but also with consideration of the growth in overall health

Table 3.7.1 *Key policy recommendations for donors and countries*

Donors	Countries
• Engage proactively in local capacity-building for pooling mechanisms, whether through national health insurance schemes or single-payer models with an emphasis on: ◦ channelling funds through local country mechanisms (on-budget spend); ◦ strengthening strategic purchasing, procurement performance management and contractual mechanisms with an emphasis on outcome-based financing where possible; ◦ pooling with other donors where possible and aligning agendas. • Strengthen regulatory institutions through their investments in wider health systems strengthening. • Support and prioritize health benefits package design, including supporting global but also local efforts for local data on cost-effectiveness and equity. • Support and promote the use of global networks for capacity-building and information sharing.	• Increase the resources available for a health benefits plan through pooling of existing schemes, earmarking taxes or designing schemes to entice out-of-pocket spenders to join collective schemes. • Invest in improving procurement systems and processes by reducing fragmentation and improving data gathering and use of data. • Coordinate and organize demand, and explore pooled procurement on a regional or global basis. • Implement regulatory reforms, moving towards less reliance on branding as a signal of quality and encourage high-quality generic suppliers of drugs. • Harmonize regulation across countries, going beyond local legal protectionist approaches to commodity regulation. • Invest in improving GHS through preparedness for the prevention and management of outbreaks and epidemics.

Source: Authors.

expenditure. As discussed earlier, finding the correct balance between coverage and revenue is a difficult task.

The “best” approach to horizontal priority-setting is context specific. Each country will need to find its own solution to barriers before successfully designing, financing and implementing a comprehensive HBP. But information sharing across countries about their approach and lessons learned can be vital to helping other countries move towards undertaking priority-setting exercises. Global networks like the International Decision Support Initiative can facilitate such information sharing and capacity-building. As both donors and countries have a large role to play in realizing horizontal priority-setting, our key recommendations for policy implementation are given in Table 3.7.1.

In considering the role of vertical programmes and priorities, such vertical efforts can be an efficient way to achieve a time-limited target with explicit plans for future integration into a system-wide benefits plan. Large disease-specific health donors have a big role to play in supporting horizontal priority-setting through investments in building local capacity for its implementation, changing the way they support vertical programmes within a horizontally set benefits plan, and coordinating procurement across countries with lower purchasing power. In addition, more rigorous evaluations of procurement strategies (in addition to pooled procurement) are needed. Countries should also continue to gather and share information either on a regional or global level on health product pricing and quality. Platforms such as the Global Fund’s e-procurement hub (wambo.org) could provide a template for diseases beyond HIV, TB and malaria. It may be that donors can take on the role of coordinating and building or expanding existing platforms to offer global data on health products and market intelligence.¹

Additional resources

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Lal A et al. (2021). Fragmented health systems in COVID-19: rectifying the misalignment between global health security and universal health

¹ Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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3.8 *Financing pandemic preparedness*

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Key messages

Chapter 3.8 highlights the importance of financing as a tool for preparing for and responding to pandemics. A pandemic can wreak health, societal and economic havoc. Prioritizing common and global public goods for health and specifically for pandemic planning is complex and requires financing mechanisms at the national, regional and supra-national levels. Key learning, including from COVID-19, is that:

- Pandemic preparedness is subject to inherent market and collective action failures and is often underfunded.
- Governments need clear strategies for funding preparedness.
- Preparedness depends on strong health system foundations and contingency funding mechanisms that go beyond simply setting funds aside. It is crucial that funds can be mobilized quickly and in a coordinated fashion.
- Key steps for planning responses include:
 - assessing existing activities and mapping value for money;
 - agreeing on the need for public financing for population-based functions (i.e. common goods);
 - identifying appropriate types of financing that reflect the complexity of determining resource needs and allow for nuanced cost estimation;
 - developing context-specific financing tools that include flexible funds and address accountability;
 - holding transparent discussions about trade-offs;
 - improving budget transfer mechanisms;
 - integrating domestic finance into multiyear budgets; and
 - managing and strengthening international collaboration.

- International guidance and learning from COVID-19 can help inform preparations. Organizations including the World Health Organization (WHO) and the World Bank offer tools to help decision-makers. It is crucial that these are assessed for suitability to context and customized to the national and local setting.

Introduction

COVID-19 highlighted the catastrophic health, social and economic havoc that a pandemic can wreak. The widespread health and socioeconomic impacts of the COVID-19 pandemic devastated lives and livelihoods both directly and indirectly. Its impacts on health were not just the illness and deaths caused by the virus itself, but also its knock-on effects on noncommunicable diseases, mental health and health service delivery. Globally, COVID-19 caused major blows to the progress towards the Sustainable Development Goals (United Nations, n.d.) and disproportionately affected the poor and vulnerable groups in society. In 2020 alone, the global economy contracted by 3.6% (United Nations, 2021) and the pandemic further exaggerated disparities between individuals, groups, regions and countries (Blake & Wadhwa, 2020). Supranational/global plans for pandemic preparedness have proliferated and multilateral support for low- and middle-income countries (LMICs) is available in the form of soft loans (see Chapter 1.4). Yet, nationally, governments devote only a fraction of domestic resources to support national preparedness and capacity development. National pandemic preparedness strategies have often been unclear and have lacked realistic financial mobilization plans, as seen during the COVID-19 pandemic (The Independent Panel for Pandemic Preparedness & Response, 2021).

In terms of national health financing, there are specific aspects of funding pandemic preparedness that set it apart from the support required for personal health services. Supporting prevention and preparedness activities involves specific budgets and considerations of institutional capacity, including measurable costs with their own financing streams, as well as dedicated financing mechanisms (WHO, 2021a). Establishing adequate prevention and preparedness systems is a long-term process that varies country by country.

Critical prevention and preparedness activities go beyond the health sector and have implications for overall government, community and

global systems (for a global response that takes into account the reasons for the emergence of new viruses, see the summary of the One Health approach in Box 3.8.1). While health system foundations necessary for pandemic preparedness often sit under the purview of the health sector and ministries of health, preparedness and response-related activities are often financed and implemented by a larger range of agencies and government sectors at national and subnational levels (e.g. national centres for disease control, customs/border control, defence agencies, emergency services and various regulatory agencies) (Global Preparedness Monitoring Board, 2019; World Bank Group, 2019b; WHO, 2021b). Budget transfer mechanisms are often used to move funds that serve the entire population across sectors and levels of government, enabling coordination and efficiency.

Financing mechanisms for pandemic preparedness must be set up in a way that ensures that the necessary systems are already in place to respond when a pandemic (or other crisis) hits. Both nationally and globally, this requires proactive planning and mechanisms that can be quickly and flexibly activated. Due to the inherent uncertainty and fluid dynamics of such events, financing mechanisms that can be deployed rapidly and with strong systems of accountability are critical for an

Box 3.8.1 One Health approach

Established in response to the H5N1 highly pathogenic avian influenza, the One Health approach explicitly recognizes the influence of the human-animal interface and changing ecosystems on the spread of infectious disease. Various global bodies, including the WHO, the United Nations's Food and Agriculture Organization, the World Bank and UNICEF, together produced a strategic framework, One Health, that focuses on priority areas for financing and implementation in order to diminish the risk and minimize the impact of epidemics and pandemics caused by emerging infectious diseases, including those of animal origin (i.e. zoonotic diseases) (CDC, 2021). The priority areas comprise of intelligence, surveillance, emergency response systems, strong public and animal health services and effective communication. Implementing One Health explicitly requires multidisciplinary, multinational and multisectoral approaches, which has implications for both governance and financing mechanisms (Food and Agriculture Organization of the United Nations et al., 2008).

effective and timely response. This goes beyond setting funds aside, and rather comprises contingency funding mechanisms that can be quickly mobilized in ways that coordinate with and build upon other efforts.

This chapter focuses on those financing mechanisms that are distinct from and in addition to the general health system financing that relates to personal health services. These aspects of health financing are covered in other chapters in this volume. However, it is important to note that there are many aspects of personal health services that are critical to pandemic preparedness. In other words, the capacities required for effective pandemic prevention, preparedness and response generally rely on a strong health system foundation (WHO, 2021b).

In this chapter, we first define pandemic preparedness and set out the notions of common goods for health and market failures. We describe the particular challenges of financing pandemic preparedness, including high levels of uncertainty, limited resources and competing priorities, cross-border and cross-sectoral governance arrangements, and issues related to funding common goods for health. We outline how to decide what to finance and how to ensure value for money; we then examine the various financing mechanisms available. Throughout the chapter, we draw upon evidence from country examples to highlight lessons for health policy-makers.

What is pandemic preparedness?

Over the last few decades, there has been growing recognition that the world is unprepared for pandemics (Commission on a Global Health Risk Framework for the Future & National Academy of Medicine, Secretariat, 2016; Soucat, 2019). This was emphatically reinforced by the COVID-19 pandemic. Various national and international bodies have drawn up frameworks and strategic plans to anticipate and reduce the threat of new and existing hazards (Table 3.8.1). These instruments all share the common objective of setting countries, and the world, on a path towards a sustainable future, by introducing measures that minimize vulnerability and strengthen resilience. Generally, the instruments cover a broad remit across all-hazards and all-risks of public health concern as described in the WHO Health Emergency and Disaster Risk Management Framework (e.g. outbreaks of any disease or the occurrence of disasters due to natural hazards or chemical incidents (WHO Regional Office for Europe, n.d. a)). While the financing mechanisms and investment

Table 3.8.1 *International guiding instruments to frame public health threats and events and establish preparedness capacities*

Frameworks and strategic plans	Scope
International Health Regulations (2005) (WHO, 2016)	• A legally binding instrument of international law • Aims to prevent, detect and protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks and which avoid unnecessary interference with international traffic and trade
Sendai Framework for Disaster Risk Reduction (United Nations Office for Disaster Risk Reduction, 2015)	• Aims to guide the multisectoral management of disaster risk at all levels as well as within and across sectors to prevent and reduce hazard exposure and vulnerability to disaster, increase preparedness for response and recovery, and strengthen resilience
Health Emergency and Disaster Risk Management Framework (WHO, 2019a)	• Developed to consolidate different approaches and practices in a common language that can be adapted and applied by all sectors working to reduce health risks and consequences of emergencies and disasters

Sources: Authors, based on United Nations Office for Disaster Risk Reduction (2015); WHO (2016).

approaches are not necessarily distinct across all these risk domains, our focus is specifically on the financing for *pandemic* preparedness.

For the purposes of this chapter, we follow the Global Preparedness Monitoring Board (2019) (an independent monitoring and advocacy body) in defining preparedness as follows:

the ability (knowledge, capacities and organizational systems) of governments, professional response organizations, communities and

individuals to anticipate, detect and respond effectively to, and recover from, the impact of likely, imminent or current health emergencies, hazards, events or conditions. It means putting in place mechanisms that will enable national authorities, multilateral organizations and relief organizations to be aware of risks and deploy staff and resources quickly once a crisis strikes.

The definition thus encompasses both “prevention” and “response” as part of being prepared.

Common goods for health and market failures

The financing rationale for pandemic preparedness presented in this chapter is informed by WHO’s Common Goods for Health agenda.¹ This defines common goods for health as all population-based functions or interventions that require public financing (supplemented by donor funding in some cases), regardless of whether they are delivered by public or private sector providers, and that fulfil the following conditions:

- Common goods for health contribute to human health and sustained economic progress over the long-term.
- Provision or preservation of common goods for health are subject to specific market failures, typically because they are either public goods (meaning they are non-rival – so the consumption of the good by an individual does not affect the amount available for others – and non-exclusionary – available for all to use (Samuelson, 1954)), or they have large social externalities.

Despite their importance and the necessity of public financing to support them, common goods for health suffer from both market and collective action failures, and as a result are often underfunded and underprovided for relative to investments in personal, facility-based services (Gaudin et al., 2019). For many common goods for health expenditures, which can be either capital or recurrent in nature, it is impossible to charge a price (or a fine) to some or all users or consumers of the function. This can discourage private actors from financing common goods for health for fear that others will “free-ride” on their investments, and it limits optimal

¹ More details on Common Goods for Health can be found in WHO’s special issue of *Health Systems & Reform*, at: www.tandfonline.com/toc/khsr20/5/4.

production. Pandemic-related activities can be usefully classified as common goods for health (Yazbeck & Soucat, 2019). These activities are notable for their market and collective action failures, which lie at the heart of their underinvestment. This means that the predominant source of funding for pandemic preparedness activities will be through public revenues as described later in this chapter.

In the next section we look at how to decide what preparedness activities to finance at both national and global levels, and how to ensure value for money.

Financing pandemic preparedness: the challenges

Despite the resource gaps in their strategies for pandemic preparedness, many countries have yet to commit to firm plans for financial mobilization. This is partly related to the high levels of uncertainty in this area, the delayed and often difficult-to-measure benefits of preparedness financing and differing attitudes to risk among decision-makers. Governments' failure to commit is also because pandemic preparedness is only one of many competing priorities for health finances. Global institutions, too, must decide how best to fund crisis preparedness.

Challenge 1: How to decide how much and what to finance?

Deciding what to finance at the country level depends on first assessing the existing pandemic preparedness activities and resources and then identifying the gaps, in the context of total available resources. While the activities for prevention and preparedness are varied and many, guiding questions can be asked of each activity's cost estimate, such as:

- Which threats are being addressed (e.g. pandemic only, or broader emergency and disaster risks)?
- What stage of the pandemic do activities correspond to: acute, protracted or no one particular stage?
- Do they include animal health along with human health activities?
- Do they include health system-related activities that help to improve health even in times of no pandemic?
- Are they health-only or do they include non-health-related activities?

At the global level, there have only been a few attempts to understand the resource needs for preparedness. What is clear is that greater

investment is needed than has occurred traditionally. Pre-COVID-19, the World Bank estimated that global investments in preparedness need to be approximately US\$ 4.5 billion per year (World Bank, 2012). Others estimated even larger sums such as US\$ 12.3 billion in one-time capital costs, with US\$ 13.8 billion yearly recurrent costs (Peters et al., 2019). Estimates made after the onset of the COVID-19 pandemic by McKinsey and Co. put the figure at many more billions of dollars – US\$ 285 billion to US\$ 430 billion over 10 years, with many of the costs being incurred as start-up capital costs in the first few years, and sustained annual costs over the time frame (Craven et al., 2020).

Beyond estimating potential costs, there has also been an effort to track external assistance for common goods for health at the global, regional and country levels (Schaeferhoff et al., 2019). One study estimated that in 2017 there was US\$ 0.48 billion allocated to global functions for pandemic preparedness and an additional US\$ 1.36 billion for control of cross-border disease global functions (e.g. information exchange, early warning and response systems, risk assessment). Despite these efforts, there is a clear disconnect between the amounts committed as external assistance and the amounts needed (Yamey et al., 2019).

At the country level, the activities to be financed can be established as part of a pandemic risk management plan. When undertaking such plans, it is first useful to undertake a resource mapping exercise to understand where resources are currently being allocated, so that gaps and areas for improvements can be identified. Tools to conduct such mappings include the World Bank's Health Security Financing Assessment (HSFA) tool and WHO's REMAP tool (Osornprasop et al., 2020; WHO, 2019b). Once resources have been mapped, these can be integrated into planning for current and future preparedness activities, and also costed. WHO developed a National Action Plan for Health Security (NAPHS) framework, which provides a costing tool and has been implemented in several countries. The NAPHS plans conducted to date show high variation in cost distribution and estimates within NAPHS technical areas (World Bank Group, 2019b).

When using these costing tools, policy-makers must make careful consideration of cost drivers and the extent to which they are assessed in these models. For example, in Nigeria, three different pandemic costing tools were comparatively implemented and it was found that while in reality the high cost of developing and maintaining a strategic

stockpile of medical countermeasures was a very large cost driver, this was not included as a category in several of the tools. In a similar costing exercise undertaken in Tanzania, animal health activities, such as animal vaccination, were another potentially large cost driver, but did not always feature in costing exercises (Mghamba et al., 2018). Therefore, in decision-making when planning for pandemic preparedness, it is important to weigh the benefits and constraints of different tools and frameworks and consider how accurately they will estimate resource needs.

Challenge 2: How to ensure value for money?

To understand what constitutes a good investment in pandemic preparedness, it is necessary to look at the value for money of the different potential activities. The cost–benefit outcomes for pandemic preparedness are usually quite favourable due to the large impacts of catastrophic events compared to the costs of prevention, and the related co-benefits of tackling other health issues such as antimicrobial resistance (AMR) (Jonas, 2013). A key challenge, however, is to understand the probability of the catastrophic events occurring and to achieve the right balance of investment for preparedness without drawing resources from other essential activities. The assessment of value for money of activities for all health emergency preparedness also faces challenges such as high levels of uncertainty, uneven impacts and the differing perspectives (including attitude to risk) represented in the health system (Branch-Elliman, Safdar & Nelson, 2021).

Moreover, it is not a one-off decision. Policy-makers need to establish and maintain systems for ongoing assessments of the value for money of prevention and preparedness activities in order to continuously inform financing decisions based on the expected costs, the potential impacts from different risks, and overall budget availability. In addition, other elements besides cost may factor into decision-making. For example, the “rule of rescue” principle (when the perceived health needs of an individual or particular group override all other considerations) or wider societal priorities might lead policy-makers to invest in certain areas of preparedness regardless of their cost–effectiveness. The value-for-money considerations will also need to account for financial considerations of affordability and

understanding of where costs are incurred. For example, costs for a large vaccine development programme may be incurred at the global level, while the delivery costs for the subsequent vaccinations would be borne by health system budgets at national or subnational level.

Once resource needs are estimated and value for money is assessed, financing mechanisms need to be established to execute preparedness activities. The next sections provide understanding on *how* to finance the activities needed for pandemic preparedness.

What financing mechanisms are available?

Financing mechanisms for pandemic preparedness sit at the supranational/global, national and subnational levels. While this section focuses primarily on national and subnational mechanisms, it also provides a brief overview of supranational/global mechanisms. First, however, we look at the recommendations for preparedness actions made by a number of high-level global expert review panels,² which helps provide the strategic context for the financing mechanisms we then go on to describe.

High-level recommendations

Despite providing separate analyses and recommendations, there is convergence around several global and domestic financing priorities needed for preparedness – especially in the wake of the COVID-19 pandemic. In its report on *Improving Pandemic Preparedness by 2025*, the Wellcome Trust (2021) summarizes these as follows.

1. Pooled financing at the global level for global public goods

Funding should be pooled at the global level to finance global public health goods, such as global surveillance of major health threats, grant financing to regional or country-level investments, manufacturing and delivery of countermeasures and R&D (G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness

² The panels include: Independent Panel for Pandemic Preparedness and Response (IPPPR); United Kingdom G7 by the Pandemic Preparedness Partnership; G20 High-Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response (HLIP); and the Pan-European Commission on Health and Sustainable Development.

and Response, 2021; The Independent Panel for Pandemic Preparedness & Response, 2021; Pandemic Preparedness Partnership, 2021). Multilateral institutions, governments and nongovernmental organizations should provide contributions to these funds based on their ability to pay, amounting to approximately US\$ 10 billion per year (G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response, 2021; The Independent Panel for Pandemic Preparedness & Response, 2021). The governing bodies to allocate and monitor funding from these types of pools could be embedded in pre-existing agencies (e.g. the Investment Board of the World Bank), or set up as a new institution (e.g. an international pandemic financing facility) (G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response, 2021; The Independent Panel for Pandemic Preparedness & Response, 2021).

2. Recommendations for Multilateral Development Banks (MDBs)

MDBs should include pandemic preparedness in their core mandates and add it into their major assessment tools (e.g. International Monetary Fund's (IMF's) Article IV) (G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response, 2021; The Independent Panel for Pandemic Preparedness & Response, 2021; Pandemic Preparedness Partnership, 2021; McKee, 2021). Influential governments should raise pressure on these banks to ensure they increase lending for health and require health-related considerations to be incorporated into banks' and borrowers' business strategies, risk management frameworks and targets (G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response, 2021; McKee, 2021).

3. Domestic financing and preparedness

Governments should renew their focus on resilient domestic finances for preparedness (G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response, 2021). As part of this, each country should consider the cost implications of a NAPHS, including how it fits with overall health system financing, and ensure that any external financing for these objectives complements the domestic financing agenda (G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and

Response, 2021). Measurable targets and benchmarks for countries' pandemic preparedness and response capacities are an important element to monitor progress (The Independent Panel for Pandemic Preparedness & Response, 2021). As part of this, WHO should advise on how National Health Accounts systems can be used to define and track expenditure on preparedness activities to help monitor and incentivize investments in preventive services for health security (G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response, 2021; McKee, 2021).

It is the financing mechanisms available at the national level that we turn to first.

National-level mechanisms

As mentioned above, investments in pandemic preparedness activities are made in the context of competing demands for scarce budget resources. Countries face one or both of the following challenges: (i) fiscal, where they do not have enough resources; and (ii) prioritization, where they do not give high priority to investments in prevention and preparedness. The latter may be for several reasons, depending on preferences, incentives, politics or, as is likely, a mix of all of these.

At the national level, strategies to increase the investment base for pandemic preparedness include generating domestic resources from taxes or levies, introducing incentive mechanisms that increase awareness of the risks of infectious disease outbreaks to businesses, leveraging insurance models and pooling donor resources within specific prevention and preparedness and response funds or institutions (International Working Group on Financing Preparedness, 2017).

The precise form of the financing mechanism used not only depends on the level at which the prevention and preparedness activities reside, but also on the nature of what needs to be financed. Financing for pandemic preparedness can generally be differentiated into three types:

1. upfront capital investments for systems and infrastructure;
2. sustained, long-term financing for ongoing operations and recurrent costs; and
3. rapidly scalable surge financing that is, ideally, strategically identified in advance of an emergency, and able to be quickly deployed (Bill & Melinda Gates Foundation, 2021).

Here, we consider the available financing mechanisms in terms of revenue and the role of domestic resources; external assistance and loans; purchasing/payment mechanisms; incentivizing preparedness; and a variety of options for public financial management systems to enable both flexible and accountable financing arrangements.

Revenue and role of domestic resources

Domestic expenditure responsibility is often split between central (national) and state/local (subnational) budgets (International Working Group on Financing Preparedness, 2017). For example, in 2016 approximately 75% of all health security-related funding occurred at the provincial level in Viet Nam (see the *Evidence in practice* section) (Osornprasop et al., 2020). Given the need for a coordinated pandemic preparedness strategy, the dynamic between levels of government requires not only targeted governance platforms, but also financing mechanisms that can incentivize cooperation and joint approaches. For example, conditional transfers can influence and support allocation decisions by only allowing funding to be allocated when certain conditions and standards have been met (Jiménez Fernández de Palencia & Pérez-Foguet, 2011; Watabe et al., 2017). This approach is especially useful in devolved settings, where priority-setting and budget allocation decisions are made at subnational levels of government.

These explicit financing incentives also require regulatory, governance-related interventions and systems in place that allow for adaptation in the face of crisis. For example, in the face of COVID-19, the Brazilian intergovernmental transfer system was found to lack adaptability to transfer funds based on epidemiological need rather than on population size, and as a result funding for the pandemic response at the subnational level was insufficient (Fernandes & Pereira, 2020). Argentina, in contrast, successfully leveraged its pre-existing conditional grant system to enable fast and responsive funds to meet the needs created by COVID-19 (Barroy et al., 2020b; Sabignoso, 2021).

External assistance and loans

In many LMICs, domestic public resources are complemented by development assistance funding (see Chapter 1.4). This can include linking development assistance for capital or one-time expenses with domestic

budget funding for recurrent costs for ongoing operations and human resources (World Bank Group, 2019b). Development assistance can also supplement domestic budget allocations for preparedness with matching grants, or by converting debt to grants upon reaching agreed-upon performance benchmarks through “buy-down” approaches. When executed successfully, this type of complementarity and strategic pooling of resources can contribute to a domestically led and sustained preparedness system. The dominant role of domestic financing for national and subnational level preparedness activities is seen across a range of countries, including Indonesia, Kenya, Lao People’s Democratic Republic, the Philippines, Uganda, Viet Nam, to name a few (Barroy et al., 2020b; Development Initiatives, 2017; Hanvoravongchai et al., 2010; Osornprasop et al., 2020; Panelo, 2009).

Global mechanisms that support national-level financing of pandemic preparedness include emergency financial reserves; building contingency capacity for disasters into planning processes; emergency supply prepositioning and training; and forecast-based financing. While external assistance can play a critical supplementary role, it can also have unintended negative consequences. The delay between donor pledges and actual funding received can create inefficiencies in response activities. Such delays have obliged businesses and other stakeholders in recipient countries to use credit to meet their operating expenses. Procurement often requires money in the purchasing body’s bank before placing an order and manufacturing also takes time, which can delay the delivery of often critical goods and services. These delays are compounded by the weak health systems in many countries which are the true binding constraint to effective preparedness capacities (Board on Global Health et al., 2016). As a result, there are important considerations to be considered when utilizing these global funding mechanisms to ensure they achieve their end goals in the most effective and efficient way possible.

Flexible, accountable public financial management systems

Timely, agile and sustainable financing is critical to pandemic preparedness financing. Systems for managing public finances for pandemic preparedness therefore need to be flexible, yet still retain their accountability. Beyond revenue availability, the public financial management systems through which funds are allocated, expended and accounted for are central to meeting these objectives.

Public financial management objective 1: flexibility

Lessons from the Ebola epidemic in west and central Africa in 2014 highlight that flexible (unearmarked), rapidly disbursable funds are critical to meet the ever-changing needs of a public health emergency (World Bank Group, 2019a). The financing-related problems encountered in the epidemic included: delays in disbursement of funds, ineffective use of financing, bureaucratic delays, poor transparency and information sharing, lack of accountability and systems to track funds, low capacity to properly procure and enforce financing management – and all of these issues relate to the mechanics of financing rather than the overall resource envelope (World Bank Group, 2019a).

The need for financing mechanisms that are quick, easy to activate, flexible, and accounted for was seen again in the COVID-19 pandemic (Barroy et al., 2020b). Delayed and ad hoc funding is often at the heart of humanitarian agency concerns about their ability to effectively respond to crises (OECD, 2017). However, as discussed above, projecting how much to budget for preparedness activities in the face of resource constraints can be challenging due to the uncertainty of events (Board on Global Health et al., 2016). Still, the level of agility of fast and flexible spending can be enabled through prenegotiated plans delineating ex post and ex ante financing (Board on Global Health et al., 2016). Some countries may make public financial management adjustments to expand and reprioritize budgetary space to allow funds to flow to preparedness activities (Ndii, 2010).

Additional considerations are particularly necessary in fragile and conflict-affected settings where government capacity for intervention is severely limited. The collective action and consensus building essential for sustainable government action in favour of the commons is a special challenge in countries where societies have been fractured (Adulyanon, 2012). At the same time, investing in preparedness activities in these settings has particular urgency, given the potential deficits in the capacity, willingness and ability of the government to ensure provision of these goods. Actions to finance pandemic preparedness in these settings can include: targeted capacity-building efforts; coordination of external agencies' funding; or, in cases where government structures and processes are too weak, establishment of a substitute or shadow process that can be transitioned to domestic institutions as soon as possible.

In countries where governments have greater capacity to act, programme budgeting offers a way of managing public finances that can allow the flexibility that responding to a pandemic requires. The multi-sectoral nature of pandemic preparedness means that different parts of the public sector may be responsible for both financing and provision of these activities. From a budgetary perspective, the structure of a country's budget can place constraints on effectively matching financing with prevention and preparedness objectives (Barroy et al., 2018). For example, rigid line-items can be obstacles to the cross-cutting approaches needed to drive efficiency in organizing, delivering and rapidly deploying prevention and preparedness activities (Sparkes, Kutzin & Earle, 2019). Moving away from input-based budgets and towards budgets that are formulated and executed based on programmes can help strengthen the linkages between budget allocations and government priorities, as well as foster the flexibility to quickly adapt budgets in the face of crisis (Barroy et al., 2020a). Australia's experience of programme budgeting provides an example of how such arrangements can support cross-cutting investments in common goods for health (Australian Government, 2017) (Box 3.8.2).

The flexibility that programme budgeting affords was on display in the COVID-19 response, with New Zealand, Mexico and South Africa all adding a COVID-19 budgetary programme to the health budget where they were then able to redirect programme envelopes for the response (Barroy et al., 2020b).

Other countries have worked around budget inflexibility by introducing exceptional spending measures. These measures, often introduced by executive decree, can allow for rapid budget reallocation, activation of contingency funds, emergency spending authorization, simplified approvals and rapid fund disbursement to subnational levels (WHO, 2022). Having systems and plans in place in advance of a pandemic enables a faster response. This may also include the revision of finance laws to ensure that these sorts of flexibilities are baked into legislation for certain crisis circumstances.

Effectively integrating domestic financing for pandemic preparedness into annual and multiyear budgets requires targeted efforts. Funding for cross-cutting activities (such as laboratories, training, surveillance or information systems) requires pooled resources and coordination among the health sector and other relevant sectors (Sparkes, Kutzin & Earle, 2019). This coordination can be achieved

Box 3.8.2 Programme budgeting: Australia

Dedicated resources from general tax revenues finance Australia's programme budget for "health regulation, safety and protection". Its required outcome includes key performance indicators for:

- disease surveillance and information systems;
- immunizations;
- public health security response;
- AMR regulations;
- stockpiling of medicines.

The table shows these indicators do not sit within any specific departments or health programmes; they are all at the level of the "health portfolio" or sector. Additionally, the budget for these health sector activities is directly linked with other budgetary programmes, including some from outside the health sector. This budgeting approach recognizes the complementarity across sectors that is needed to achieve particular outcomes.

Coordinated multisectoral budgeting in Australia

Outcome 5. Regulation, Safety and Protection

Protection of the health and safety of the Australian community and preparedness to respond to national health emergencies and risks, including through immunizations, initiative and regulation of therapeutic goods, chemicals, gene technology and blood and organ products

Program 5.2: Health Protection and Emergency Response

Program 5.3: Immunization

Selected Linked Programs to Outcome 5 outside of Health Sector

Department of Agriculture and Water Resources	Program 2.1: Biosecurity and export services
Department of Education and Training	Program 1.2: Child care benefit
Department of the Environment and Energy	Program 1.6: Management of hazardous wastes, substances and pollutants
Department of Human Services	Program 1.2: Services to the community

Source: Australian Government (2017)

through a health sector medium-term expenditure framework (van Eden, Gentry & Gupta, 2017), public expenditure reviews (World Bank Group, 2017) or other processes that build on evidence-based, high-quality diagnostics of health challenges and policy effectiveness.

These processes provide clear priorities for spending over time, particularly in the face of both fiscal and political constraints, and involve focusing on strengthening national and subnational institutions to deliver cross-cutting activities. New Zealand, for example, has implemented a budgetary framework that enables cross-agency funding as a way to improve collaboration and reduce the transaction costs of working across agencies (The Treasury, 2015). The framework contains three possible funding models to determine both government and financing arrangements associated with delivering activities across agencies that contribute to shared outcomes: cost recovery charges, wherein one agency buys a service from another agency and recovers costs through a service fee; pooled funding, in which a group of agencies combine funds in order to share costs to achieve a common goal; and centrally determined funding, when ministers determine cross-agency collaboration is needed and then identify funding sources.

Public financial management objective 2: accountability

The expenditure flexibility required for pandemic preparedness must be matched with strong accountability mechanisms. Often opaque country financial management systems and outdated information systems make financial accountability difficult and a persistent problem (World Bank Group, 2019a). This dynamic not only lends itself to corruption and lack of transparency but also to inefficiencies and wasteful spending (Khasiani et al., 2020). Budget accountability mechanisms include ex post and/or risk-based controls, regular updates to public spending systems, developing performance frameworks, using programme envelopes for expenditure tracking and ensuring that finance authorities take a lead role (Barroy et al., 2020a). For example, both France and China have introduced and strengthened tracking procedures that take into account clearly defined policy goals and targets.

Purchasing/payment mechanisms

Pandemic scenarios likely require funding arrangements to pay health workers for working overtime and taking on additional responsibilities,

establishing diagnosis and treatment facilities, undertaking vaccine R&D and more. However, there can be financial obstacles that hinder a country's ability to pay. Countries require systems established in advance of a crisis which allow for budget flexibilities and reallocation to pay front-line health workers under pandemic conditions (Board on Global Health et al., 2016; Mathauer, Dkhimi & Townsend, 2020). Beyond reallocation mechanisms, these adaptations include lifting budget caps so that providers can actually receive the additional funds needed to respond to the pandemic. Facility accreditation changes (and established plans for flexibilities under crisis conditions) can also enable the emergency activation of certain services and providers. A survey of 31 LMICs during 2020 found that half had made this type of accreditation change in order to expand service provision related to COVID-19, particularly through private sector providers. These adaptations all have implications for information system management and governance mechanisms that similarly can be put in place in advance and facilitate coherence between the public and private sectors.

Incentivizing preparedness

Financing mechanisms for preparedness go beyond funding issues and extend to incentivizing investments into these critical activities. These mechanisms are put forward in recognition of the market and political failures until now associated with prioritizing investments in preparedness activities. These incentive approaches can include offsetting negative externalities from business activities by requiring appropriate investments from the private sector in risk mitigation, prevention and preparedness (International Working Group on Financing Preparedness, 2017). There are also calls to incorporate health security risks into macroeconomic bond ratings and investment criteria (International Working Group on Financing Preparedness, 2017; World Bank Group, 2019b). IMF Article IV consultations, which provide country surveillance to identify economic and financial risks, can also be extended to include infectious disease and health security risks. Similarly, the World Bank's Country Policy and Institutional Assessment and Systems Country Diagnostics are opportunities to integrate preparedness into economic risk and institutional assessments (Global Preparedness Monitoring Board, 2019).

None of these national-level financing mechanisms can ensure pandemic preparedness in isolation. However, they can be critical enablers when taken in conjunction with one another, along with effective

planning, political commitment and dedicated implementation capacities. They can also be complemented/supplemented by global and regional mechanisms, as we describe briefly below.

Global and regional mechanisms

Beyond the national-level mechanisms, global and regional mechanisms for pandemic preparedness financing also play important roles. After all, financing for pandemic preparedness represents a vital investment in global solidarity to avoid or mitigate catastrophic pandemic costs. As noted by the Global Preparedness Monitoring Board 2020 Report, “global preparedness is not simply the sum of national preparedness” (Global Monitoring Preparedness Board, 2020). Mechanisms for pathogen tracking, early alert systems, R&D, regulatory capacity-building and harmonization, allocation of countermeasures, stockpiles and supply chains are all necessary at the global and regional level and require dedicated funding. Regional networks and global coordination of funding and response, as well as sharing general best practices around financing preparedness, are all global prevention and preparedness activities. To establish each of these activities, a range of financing mechanisms to fund them should be considered (Global Monitoring Preparedness Board, 2020). Here, then, we consider the potential of pooled resources.

Pooled resources for pandemic preparedness

COVID-19 exposed clear limitations in pre-existing financing mechanisms that were not at a large enough scale to meet needs, and therefore new mechanisms and donor resources had to be mobilized rapidly for the response (Global Monitoring Preparedness Board, 2020). Pooling is the accumulation and management of prepaid financial resources on behalf of some or all of the population (Mathauer et al., 2020). Many global mechanisms focus on pooled funding, primarily from HICs, to support the response to pandemics and other emergencies (e.g. COVAX), as well as to incentivize investments in preparedness and prevention at the country level.

At the global level, existing financing mechanisms for pandemic response include the WHO Contingency Fund for Emergencies, which since its inception in 2015 has funded operational and response activities. As the scale of the COVID-19 pandemic and response grew, additional funding mechanisms were created or repurposed, including

the development of COVAX (Eccleston-Turner & Upton, 2021), and specific funding windows provided by the Global Fund and the World Bank (Bump, Friberg & Harper, 2021). Investments are also being made to build vaccine and other production capacities in LMICs. The pre-COVID-19 pooled global funding mechanisms often targeted specific functions, including vaccine and supply stockpiles, insurance systems, cross-border contagions or global coordination functions, including within WHO.³ For example, the World Bank's Pandemic Emergency Finance Facility is an insurance system established in the wake of the Ebola crisis in 2014 to enable the rapid mobilization and deployment of funds (Box 3.8.3).

In learning from the COVID-19 experience, there was a clear need for more coordinated action to strengthen health system foundations, as well as to rapidly mobilize needed resources for pandemic preparedness at a global level. In light of this, The Pandemic Fund⁴ was established in 2022 with the objective to provide additional, long-term financing and technical support to LMICs in the areas of health systems strengthening and pandemic preparedness (The Pandemic Fund, 2024). By the time of the first round of grant allocation, The Fund had already raised US\$ 2 billion in seed capital from governments, philanthropies and the private sector (The Pandemic Fund, 2023). The first round of funding awarded 37 country recipients with funds to strengthen disease surveillance and early warning systems, laboratory systems and human

³ Examples of global level mechanisms that implemented a pooled funding model pre-COVID-19 include: (i) global vaccine stockpiles, such as for oral cholera vaccines established by WHO; (ii) global mechanisms to develop medical products (e.g. medicines, vaccines, and diagnostics) to control neglected diseases and emerging infections, such as the Coalition for Epidemic Preparedness Innovations (CEPI), which in turn funds development of new vaccines to prevent and contain outbreaks; (iii) pandemic emergency response, such as the World Bank's Pandemic Emergency Finance Facility (PEF); (iv) reducing cross-border transmission of drug-resistant tuberculosis and other pathogens, pollution, harmful substances and counterfeit health products, such as through strengthening WHO and other global supranational efforts that work to reduce such transmission (e.g. the Global Health Security Agenda); (v) developing global norms and standards for safety and quality of care; (vi) generating a clearing house of global knowledge and a subsequent global surveillance function; (vii) WHO's Health Emergencies Programme; (viii) the WHO Global Health Emergency Workforce; (ix) WHO's Contingency Fund for Emergencies; and (x) WHO's Research and Development Blueprint.

⁴ The World Bank serves as The Pandemic Fund's trustee and hosts the Secretariat, which includes technical staff seconded by WHO.

Box 3.8.3 Pandemic Emergency Finance Facility (PEF)

Response to the Ebola crisis in 2014 was hampered by the inability to rapidly mobilize and deploy funds. To address this issue, the World Bank established its PEF insurance system which has been in operation since July 2017. It provides coverage for countries already deemed eligible for financial assistance from the International Development Association against the risk of pandemic outbreaks. The coverage consists of a combination of insurance bonds and derivatives and a donor-funded cash window for accessing loans. Importantly, the PEF does not provide funds for preparedness, and rather it is meant just for response needs. The facility has sought to create a market for pandemic risk insurance that draws on funds from the private sector through (catastrophe) bonds and swaps (a temporary agreement between two parties to exchange cash flows or liabilities from other financial instruments, often used to reduce financial risk) in return for highly lucrative interest rates. However, due to the relatively high threshold for countries to be able to access PEF funds, there are concerns about its functionality and utility (Brim & Wenham, 2019).

resources. Many of these country projects involve efforts that will have wider benefits to neighbouring countries through the One Health approach by building up cross-border and regional collaboration. There is a need to ensure, however, that the implementation arrangements and application of these projects and activities do not create new, parallel efforts or systems and are rather aligned with country systems.

As mentioned, global activities have transnational benefits that may extend regionally or globally. For this reason, both revenue mobilization and pooling mechanisms may also sit at regional levels. One such an initiative is Regional Disease Surveillance Systems Enhancement (REDISSE). Like the PEF, REDISSE was set up in the wake of the 2014 Ebola epidemic and is funded by the World Bank. Both a surveillance and response programme, it takes a regional approach across 11 countries in west Africa to strengthen routine systems to prevent and detect health threats, taking advantage of regional economies of scale (World Bank Group, 2019a).

Before setting out our conclusions, we present a case study of Viet Nam, as an example of a lower middle-income country that undertook a review of its health security financing in the light of recent experience of epidemics and pandemic.

Evidence in practice: financing pandemic preparedness in Viet Nam

Since 2000, Viet Nam has encountered several notable epidemics, such as avian influenza (H5N1) in 2003, influenza H5N6 and the pandemic of H1N1 in 2009. Given the history and the ever present threat of outbreaks and public health emergencies, Viet Nam conducted a HSFA (Osornprasop et al., 2020) using a tool developed by the World Bank to better understand the country's practices around health security financing based on data from the fiscal year 2016.⁵ Health security expenditures and activities were identified using the Joint External Evaluation structure.

From the analysis, the total health security expenditure, which included central and provincial levels, was estimated to be US\$ 181.2 million (0.09% of gross domestic product, and 0.29% of the total government expenditure), almost 75% of which was spent at the provincial level.⁶

The government funded the largest share of health security activities in the country (77%), followed by external aid (12%), which was spent primarily at the central level. In order to transfer government funds to the implementing agencies, they used annual budget allocations for recurrent, investment and national target programmes, where recurrent budget allocations accounted for 66% of total health security expenditure. Additionally, their systems allowed for contingency funds and budget, financial and national reserves to be triggered at a time of public health emergency.

Differences in health expenditure at the provincial level were found, where provinces on the country border as well as those provinces that were empowered to mobilize their own revenues, where sufficient, to cover health security spent a higher amount on health security activities. At both the central and provincial level combined, spending on preparedness activities was the highest proportion of expenditure (16%), followed by food safety, zoonotic diseases and workforce development (all between 12% and 15%).

⁵ To read the whole report and access the HSFA tool, see: <https://pubdocs.worldbank.org/en/942051579589669565/Vietnam-Health-Security-Financing-Assessment.pdf>.

⁶ Due to fiscal decentralization, little disaggregated budget and expenditure data at local levels, and the private sector's undetermined contribution, these figures should be taken as estimates.

During the 2003–2006 avian influenza outbreak, most domestic funds came from a contingency fund within the recurrent budget allocated to ministries and localities. This was already in place: once the necessary authorities declared an epidemic of public health concern, a contingency fund could be activated for the use of prevention and response activities. The central level fund was allocated to provinces to cover 50% of expenses relating to prevention and response of the epidemic, such as culling of infected poultry, while the remaining 50% was covered by the local level contingency fund. Supplementary budgets were also approved through the Prime Minister, which came from the contingency fund from the central budget, budget surplus revenues and loans from the credit balance.

The analysis identified significant challenges in the planning and financing of epidemic and pandemic preparedness. Viet Nam is working to improve and enforce close cooperation and effective coordination across sectors and levels of government for the accountability and funding of these interdisciplinary activities. However, at the time of the study, there was clear duplication in mandates and mechanisms for information sharing across agencies. Without clear coordination, activities such as disease surveillance lack integration, especially across geographical areas. Additionally, important sectors such as agriculture and tourism were rarely accounted for in planning and coordination activities. These deficiencies highlight the importance of establishing and implementing governance arrangements to enable the coordination and collaboration required across different levels of government and between sectors.

Another challenge lies with the planning efficiency and budgeting processes in the country. Recurrent and nonrecurrent funding for pandemic preparedness is based on the previous year's amount rather than projected need. Reserve budget is allocated on a per capita basis, and additional amounts are specified by an input-based budget structure, which does not account for the cross-sectoral nature of the activities. Proposed budgets are often higher than the approved funding, which is dependent on the amount of external aid and local budget capacity. This often results in lower funding allocations in poorer areas, thus exacerbating existing inequalities.

The report provided a call to action to improve and efficiently plan and allocate necessary funding for preparedness activities. The actions identified included improved information sharing, shared planning across sectors, integrated disease surveillance, increased understanding

of actual workload and a budget for these activities across the central level of government.

Policy relevance and conclusions

Evidence-based principles for establishing pandemic preparedness imply actions that strengthen existing systems, ensure business continuity plans with continuous learning to refine systems and strategies and are supported by adequate and appropriate financing mechanisms. This involves a continuous process of planning, exercising, revising and translating into action national and subnational pandemic preparedness and response plans (WHO Regional Office for Europe, n.d. b).

Establishing pandemic preparedness capacities requires targeted financing mechanisms to ensure funding commitments are translated into activities and interventions. Despite the recognized importance of pandemic preparedness, investments have often been limited or lacking due in part to the uncertain nature of preparedness and risk. As exemplified by the Viet Nam case study, the countries that have taken action to dedicate resources and establish financing mechanisms tend to be those spurred into action by their own particular experience of a health crisis. In the context of COVID-19, however, all countries have now experienced such a crisis. Financing pandemic preparedness must be a core government and global function.

The lessons from countries that have worked both to establish preparedness capacity and to respond to crisis show that effective financing goes beyond resource commitments and considers public financial management mechanisms and incentive structures. These financing mechanisms go beyond health budget allocations and consider transfer mechanisms to ensure coordination across multiple sectors (including the health sector) and multiple levels of government. Good governance and stewardship of preparedness, national and multisectoral coordination, political will and previous experience with pandemics have been found to be predictors of better mobilization and allocation of funds for prevention and preparedness (Hanvoravongchai et al., 2010).

Financing mechanisms that support preparedness activities require budgetary space and institutional capacities that include funding for both the capital and recurrent expenditures required. These are measurable, annualized costs that require dedicated financing streams. Financing for activities that support preparedness requires proactive planning,

systems and mechanisms that can be quickly and flexibly activated. Due to the inherent uncertainty of these events, the prepositioning of financing mechanisms that can be deployed quickly and with strong accountability systems is critical for an effective and timely response. Prepositioning goes beyond setting funds aside, and rather considers contingency funding mechanisms that can be quickly mobilized.

Importantly, financing pandemic preparedness should not be viewed in isolation, separate from the overall health system or other public financing priorities. For the purposes of this chapter, we have focused on distinct characteristics of pandemic preparedness. However, in practice these financing mechanisms need to be well-coordinated and integrated within overall public investments that promote and protect health and well-being and those that protect against emergencies more broadly. Furthermore, these investments can either leverage existing systems, or can have beneficial spillover effects on non-disease control measures, for example through improved information systems for health care or additional hospital capacity. Therefore, the societal gains from investments and sustainable financing of pandemic preparedness are not limited to the cost savings related to averting or being prepared for a pandemic, but also in relation to strengthening the foundations of the system for other health needs.⁷

Additional resources

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⁷ Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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3.9 *Antibiotics as global public goods*

MATTHEW RENWICK

Key messages

Chapter 3.9 explains how payment mechanisms should respond to the notion of antibiotics as global public goods. Global public goods are goods and services whose benefits are universal in scope. Antimicrobial resistance (AMR) poses a major health and economic threat worldwide, making novel antibiotics a global public good. Payment mechanisms have an important part to play in encouraging crucial R&D. Key learning includes that:

- Antibiotics are essential global public goods, but rising antimicrobial resistance is rapidly undermining their effectiveness worldwide.
- The antibiotic development pipeline has collapsed, as traditional patent-based market incentives fail to generate sufficient returns for industry.
- Antibiotic R&D faces high scientific risk, long timelines, high costs, and weak commercial viability, particularly at clinical and market-entry stages.
- Numerous global and national incentive programmes have been established to support, fund, and coordinate antibiotic R&D.
- Existing efforts rely mainly on push incentives, such as grants, which support early research but do not ensure successful commercialization.
- Pull incentives, such as market entry rewards and subscription payment models, are essential to correct market failure by delinking revenues from sales volume while supporting antimicrobial stewardship and patient access.
- Sustainable solutions require coordinated global action integrating push–pull incentives, regulatory harmonization, and One Health principles.

Introduction

Alexander Fleming famously discovered the first modern antibiotic, penicillin, in 1928 – revolutionizing the practice of medicine. Although penicillin was not mass produced until the early 1940s, the subsequent decades saw a boom in new antibiotics and antibacterial classes (Silver, 2011). By 1990, 31 new antibiotic classes had been discovered or patented (Pew, 2016; Silver, 2011). Today, antibiotics are indispensable to routine medical practice for the treatment of mild to severe antimicrobial infections, such as urinary tract infections, tuberculosis (TB), pneumonias and blood stream infections; preventing post-surgical infections; and managing immune-compromised individuals, such as cancer patients receiving chemotherapy.

AMR: causes and effects

However, growing AMR is rapidly pushing our existing antibiotic arsenal into obsolescence. AMR is a biologic process whereby bacteria develop mechanisms over time to escape or buffer antibiotics, making the drugs ineffective. Constant overuse and poor regulation over antibiotic consumption in human and agricultural settings has accelerated AMR in recent years. Between 2000 and 2015, global antibiotic consumption increased by 65%. This can largely be attributed to unregulated use in low- and middle-income countries (LMICs) (Klein et al., 2018). The World Health Organization's (WHO's) Global Antimicrobial Resistance and Use Surveillance (GLASS) Report for 2021 revealed growing resistance rates to key antibiotics used for common infections (WHO, 2021a). For instance, first-line drugs for urinary tract infections including co-trimoxazole and ciprofloxacin are reaching average resistance rates of 50% and 30%, respectively, for common urinary pathogens.

Today, the impacts of AMR are already high, and they are growing rapidly. Currently, more than 700 000 people die worldwide from drug-resistant pathogens annually (Review on Antimicrobial Resistance, 2016).

AMR and its associated mortality disproportionately affect LMICs but high-income countries are also significantly impacted. In the USA, an estimated 35 000 people die from the >2.8 million antibiotic-resistant infections that occur each year (CDC, 2019). Similarly, AMR is responsible for approximately 33 000 deaths annually in the EU (OECD & ECDC, 2019). At the current rate of advancement, AMR is expected to be responsible for 10 million annual deaths globally by 2050, overtaking the annual mortality of cancer (Review on Antimicrobial Resistance, 2016). The cumulative economic cost of growing AMR is predicted to be US\$ 100 trillion between 2014 and 2050 (Review on Antimicrobial Resistance, 2016). This equates to an approximate 2–3.5% drop in predicted global gross domestic product (GDP).

A frighteningly thin antibiotics pipeline

In the past, developing new antibiotics appeared to be the easiest mechanism to overcome emerging resistant pathogens. As certain antibiotics became less effective against evolving bacteria, treatment for infections could be supplemented or replaced by newer generations of the same antibiotic or by a new, more effective class of antibiotic. Pharmaceutical companies leveraged scientific breakthroughs and were rewarded with high-value patents. But, due to a combination of financial, regulatory and scientific barriers to continued development of new antibiotics, the focus of R&D has shifted away to other therapeutic areas such as oncology and cardiovascular disease. As a result, the antibiotic development pipeline has dwindled to almost a complete standstill, leading to increasing challenges in the market, and ultimately to poorer health outcomes.

In 1990, there were 18 large-capital pharmaceutical companies actively developing antibiotics, but as of 2020 there were only eight (Butler, Blaskovich & Cooper, 2013; AMF, 2020). Of these, only two companies ranked within the top 50 drug companies by sales in the world. Over the 25-year period from 1990 to 2015, there were no approvals of novel antibiotic drugs with unique chemical structures for clinical use (WHO, 2017a) (Fig. 3.9.1). Developers had relied on reformulating existing antibiotic drugs or combining two different

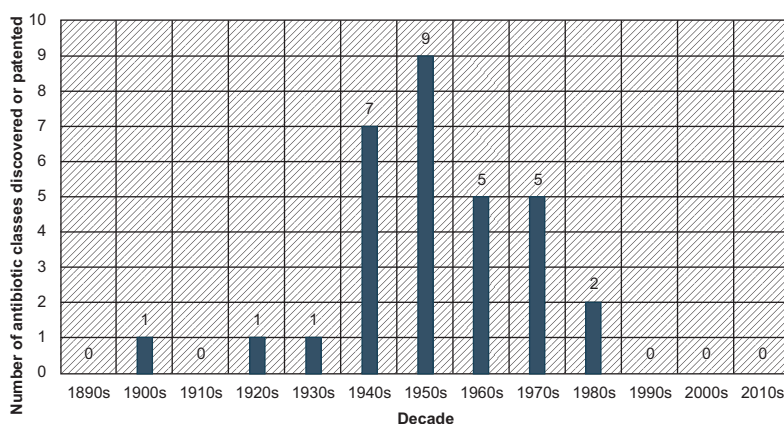


Fig. 3.9.1 Number of new classes of antibiotics discovered or patented each decade

Sources: Adapted from Pew Charitable Trusts (2016); originally from Silver (2011).

classes of antibiotic. This void in discovery and development has meant that the antibiotic pipeline is frighteningly thin relative to the unrelenting advance of AMR.

This chapter looks at how to fill this void in the discovery and development of new antibiotics. In particular, we describe the barriers to development and examine the policy and funding tools that can overcome them, in terms of the push and pull incentives available to policy-makers. We outline the various initiatives underway – multilateral, international, national and regulatory. We assess the state of progress in antibiotic development up to 2021 and the performance of the various incentive mechanisms, and suggest other measures that are required.

Barriers to antibiotic development

Low success rates, scientific difficulties and overall costs create a lot of uncertainties in the antibiotic development process.

From the initial process of molecular research right up until regulatory approval and distribution of the finished product, barriers to antibiotic development permeate the entire value chain (Renwick &

Mossialos, 2018). The success rate of moving an antibiotic from basic research to market approval is estimated to lie between 1.5% and 3.5% and can typically take 15 years or more (Review on Antimicrobial Resistance, 2015). Towse et al. (2017) estimate that it costs approximately US\$ 1.5 billion to bring an antibiotic to the market. The economic, regulatory and scientific barriers to antibiotic R&D can best be categorized based on the steps of the antibiotic value chain: basic research, preclinical trials, clinical trials, market approval and, finally, commercialization (Fig. 3.9.2) (Stern et al., 2017, and see also Chapter 3.4). These barriers are important to consider when designing and targeting future incentives to support antibiotic R&D.

Barriers in basic research and product trials

Research efforts to understand and identify new molecules for candidate drugs present scientific difficulties. Bacteria, particularly Gram-negative varieties, are highly resilient to recent experimental mechanisms of destruction (WHO, 2017b). In addition, scientific expertise in this area is currently lacking and still recovering from the discovery void that began around 1990 (Silver, 2011). Thus, the preclinical stage of antibiotic research is often ominously referred to as the “valley of death” (So et al., 2012). As discussed in Chapter 3.4, basic research has predominantly been tackled by academics funded by the public sector, while clinical trials have been the domain of private pharmaceutical companies, thus leaving a gap in funding and appropriate actors to move from molecular discovery to clinical trials.

It costs roughly US\$ 130 million to take a drug candidate through clinical trial phases I to III (Review on Antimicrobial Resistance, 2015) and many drug candidates will be discarded along the way, at a financial loss. Additionally, recruiting patients with acute bacterial infections for antibiotics clinical trials poses logistic challenges due to short treatment windows and lack of rapid point-of-care diagnostic tools to identify potential participants. Post-approval follow-on trials, which build further evidence for effectiveness, amount to an additional US\$ 146 million costs on average (Review on Antimicrobial Resistance, 2015a). These expenses and uncertainties are often prohibitively high for small and medium-sized enterprises (SMEs) (Renwick, Brogan & Mossialos, 2016). Despite these challenges of economies of scale, SMEs represent over 95% of the share of antibiotics in the current antibiotic pipeline and

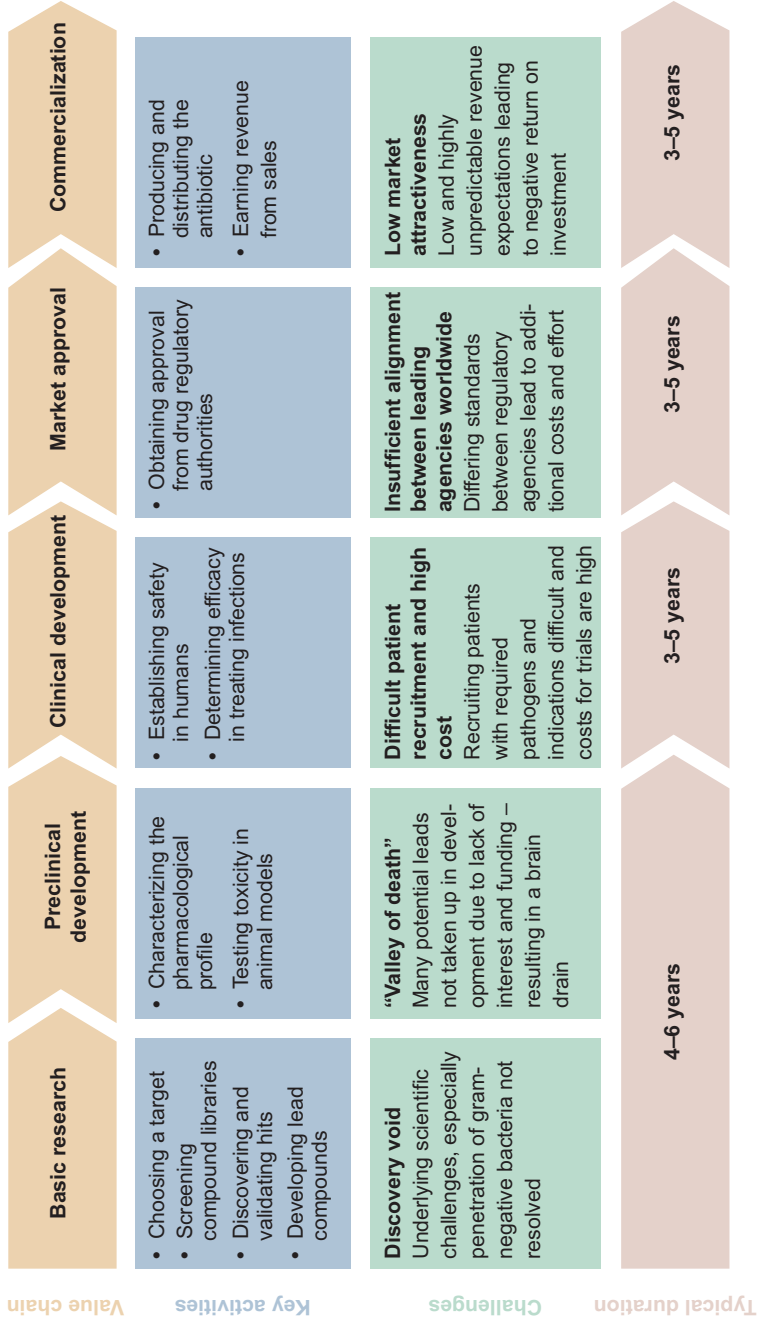


Fig. 3.9.2 Antibiotic value chain and the barriers to R&D progression
 Source: Adapted from Renwick, Simpkin & Mossialos (2016).

roughly 70% of the companies active in the antibiotic R&D pipeline have never developed, commercialized or marketed a drug product before.

Barriers in market approval and commercialization

Procedural differences in antibiotic approval processes between drug regulatory agencies can make global licensing time-consuming and expensive (Renwick, Simpkin & Mossialos, 2016). These differences relate to patient selection criteria, definitions of clinical end-points, specification of statistical parameters and rules regarding expedited approvals (Stern et al., 2017; and see Chapter 3.4).

An additional challenge is that despite their public health value, antibiotics offer minimal (or even negative) commercial reward compared to other therapeutic areas (So et al., 2011; and see Chapter 3.4). Potential sales volumes are restricted by short treatment durations and hospital stewardship programmes that limit access to novel drugs, both of which are critical practices to thwart the advance of resistance rates. In addition, the large overlap in clinical application of newly patented antibiotics with existing generic alternatives places downward pressure on prices (Renwick, Simpkin & Mossialos, 2016).

A 2003 study calculated that investment in musculoskeletal, neurologic and cancer medications were 11.5, 7.2 and 3.0 times more profitable, respectively, than developing an intravenous antibiotic targeting Gram-positive bacteria (Projan, 2003). This type of analysis has not been replicated with more current figures, but large-capital pharmaceutical companies have continued to exit the antibiotic R&D space due to profitability. Most recently, Novartis closed its antibiotic development department in 2018 citing plans to focus on oncology projects (Plackett, 2020). The oncology sector is by far the largest drug market, comprising approximately 20% of global pharmaceutical sales with a total market value of US\$ 199.5 billion in 2021 (Business Wire, 2022). In comparison, the total global market value of antibiotics in 2021 was estimated at US\$ 47.2 billion (Research and Markets, 2023). Furthermore, a 2017 study showed that the median R&D cost per drug, including opportunity cost, for 10 new cancer drugs was US \$ 648 million and significantly lower than previously estimated (Prasad & Mailankody, 2017). After a median duration of four years

on the market, these cancer drugs had accrued revenues that were almost 10 times the total R&D cost.

Overcoming the barriers to antibiotic development?

Policy and funding tools are needed to augment the current drug financing system as it is applied to antibiotics, with push and pull incentives being the main levers available to policy-makers.

Financing of drug R&D has traditionally been the purview of private pharmaceutical companies that allocate resources based on profit potential. National governments incentivize companies to carry the full burden of R&D costs with the promise of lucrative patents for marketable drugs whereby the developer is the sole supplier for a limited time, pricing the drug at their discretion. Basic supply and demand economics states that revenue potential is greatest where there is the highest demand and R&D money tends to flow to areas of public need. This system works well for most therapeutic areas and has resulted in revolutionary developments in medicine. Pharmaceutical companies have greatly benefited with profit margins that are significantly higher than those obtained by other large, public companies (Ledley et al., 2020).

However, the patent-centric system does not work well in every scenario to meet public need and has now failed in the case of antibiotics as outlined above. A significant amount of research has explored the policy proposals for minimizing R&D barriers and incentivizing companies to invest in the antibiotic field. Push and pull incentives are broadly used to classify the two main types of mechanisms for supporting antibiotic R&D (Mossialos et al., 2010; and see chapters 3.4 and 3.10).

Push and pull incentives: overview

Push incentives reduce the cost of researching and developing new antibiotics, while pull mechanisms increase the potential revenue of a successfully marketed antibiotic. Examples of push incentives include research grants, access to shared resources and product development partnerships to split R&D costs (Dutescu & Hillie, 2021). Pull mechanisms include outcome-based rewards that directly increase revenue such as monetary prizes, reimbursement premiums, advanced market

commitments to purchase the drug and patent buyouts by governments (Dutescu & Hillie, 2021). If large enough, outcome-based pull rewards can replace the traditional revenue stream generated by the sales volumes of a licensed antibiotic. This concept is referred to as “delinkage” since the antibiotic’s revenue is delinked or uncoupled from its sales, thus removing the commercial incentive to promote the drug’s use (Rex & Outterson, 2016). Alternatively, pull mechanisms may be legal or regulatory, providing incentives such as accelerated procedures for marketing approval or extensions to the patent period. As of 2015, there were 47 different core incentives available or proposed for antibiotic developers that ranged from simple push or pull mechanisms to complex hybrid models (Table 3.9.1) (Renwick, Brogan & Mossialos, 2016).

Table 3.9.1 *A selection of push and pull mechanisms available or proposed for incentivizing antibiotic R&D*

Push incentive strategies	
• Supporting open access to research • Grants for scientific personnel • Direct funding • Conditional grants	• Funding translational research • Tax incentives • Refundable tax credits • Product development partnership
Outcome-based pull incentive strategies	
• End prize • Milestone prize • Pay-for-performance payments • Patent buyout • Payer licence	• Research tournament • Advanced market commitment • Strategic antibiotic reserve • Service-availability premium
Lego-regulatory pull incentive strategies	
• Accelerated assessment and approval • Market exclusivity extensions • Transferable intellectual property rights • Conservation-based market exclusivity • Liability protection	• Anti-trust waivers • Sui generis rights • Value-based reimbursement • Targeted approval specifications • Priority review vouchers

Source: Renwick, Brogan & Mossialos (2016).



Fig. 3.9.3 Framework for developing a holistic incentive package for antibiotic development

NPV: net present value; SME: small and medium-sized enterprise.

Source: Simpkin et al. (2017).

Designing a global incentive package for stimulating antibiotic innovation is a complex task with numerous variables. Policy-makers need a methodology for selecting a complete and realistic set of incentives from the surplus of options that takes account of their unique circumstances and contexts. In 2015, the author of this chapter published a conceptual framework to guide policy-makers with this challenge (Fig. 3.9.3) (Renwick, Brogan & Mossialos, 2016). The framework breaks the strategy down into three steps or phases. The first phase involves fashioning a core incentive package targeting the economic criteria necessary for rebalancing the market. According to the framework, this core incentive package must:

- improve the profitability of developing and commercializing a novel antibiotic;

- make market participation feasible for SMEs;
- encourage investment by large pharmaceutical companies;
- facilitate cooperation across all stakeholders including patients, academics, policy-makers, regulators and industry.

The second step requires adjusting the core incentive package to address public health goals pertaining to sustainability and patient access to new antibiotics. The final step considers the implementation and operational practicalities that are specific to national context.

Current initiatives incentivizing antibiotic R&D

At both the national and international levels, many programmes have been established in recent years to help fund, coordinate and incentivize antibiotic R&D.

By 2016, there were 58 active initiatives directly incentivizing the development of antibiotics at global, EU, and national levels, including in Canada, France, Germany, the Netherlands, Sweden, the United Kingdom and the USA (Renwick, Simpkin & Mossialos, 2016). These initiatives employ one or more push or pull incentive mechanisms and are financed through a combination of public health care budgets, non-profit donations and private pharmaceutical investments. These initiatives provide targeted pathways for public and private money to flow towards the antibiotic market and share the financial risk across all stakeholders. Additionally, nine initiatives were identified as offering indirect incentives through economic and policy research or the coordination of strategic actions on AMR.

The number of active initiatives in this field continues to rise. The Global AMR R&D Hub provides an up-to-date summary of the latest global and national initiatives supporting antibiotic R&D (<https://globalamrhub.org/>). The following section highlights some of the largest antibiotic R&D initiatives at multilateral and EU levels, as well as key initiatives from the United Kingdom and the USA, which are national leaders in this field (Table 3.9.2).

Multilateral initiatives

National health systems alone cannot correct the global market for antibiotics or contain the transborder threat of AMR. The

Table 3.9.2 *Summary of initiatives incentivizing R&D*

Initiative	Value chain target	Incentive type
Multilateral initiatives		
JPIAMR	Research, preclinical	Push
GARDP	Research, preclinical, clinical, commercialization	Push, outcome-based pull
CARB-X	Research, preclinical	Push
EDCTP	Research, preclinical, clinical, commercialization	Push
GAMRIF	Research, preclinical	Push
AMR Action Fund	Clinical	Push
EU initiatives		
DG-RTD	Research, preclinical, clinical	Push
IMI – ND4BB	Research, preclinical, clinical	Push
InnovFin ID	Preclinical, clinical	Push
US initiatives		
NIAID	Research, preclinical, clinical	Push
BARDA	Research, preclinical, clinical, commercialization	Push, outcome-based pull
United Kingdom initiatives		
NIHR	Research, preclinical, clinical	Push
MRC	Research, preclinical	Push
Netflix	Commercialization	Outcome-based pull
Regulatory initiatives		
EMA	Market approval, commercialization	Lego-regulatory pull
FDA	Market approval, commercialization	Lego-regulatory pull
TATFAR	Market approval	Lego-regulatory pull

AMR: antimicrobial resistance; BARDA: Biomedical Advanced Research and Development Authority; CARB-X: Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator; DG-RTD: Directorate-General for Research and Innovation; EDCTP: European and Developing Countries Clinical Trial Partnership; EMA: European Medicines Agency; EU: European Union; FDA: Food & Drug Administration; GAMRIF: Global Antimicrobial Resistance Innovation Fund; GARDP: Global Antibiotic Research and Development Partnership; IMI: Innovative Medicines Initiative; JPIAMR: Joint Programming Initiative on Antimicrobial Resistance; MRC: Medical Research Council; ND4BB: New Drugs for Bad Bugs; NIAID: National Institute for Allergy and Infectious Diseases; NIHR: National Institute for Health Research; TATFAR: Transatlantic Task Force on Antimicrobial Resistance; UK: United Kingdom; US: United States.

Source: Authors.

international community has come together to create several multilateral initiatives including the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR), the Global Antibiotic Research and Development Partnership (GARDP), the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), the European and Developing Countries Clinical Trial Partnership (EDCTP), the Global Antimicrobial Resistance Innovation Fund (GAMRIF) and the AMR Action Fund.

Joint Programming Initiative on Antimicrobial Resistance (JPIAMR)

The JPIAMR is a collaborative organization engaging 28 countries with the purpose of coordinating the national funding of its members towards six priority fields related to AMR: diagnostics, environment, interventions, surveillance, therapeutics and transmission. As of December 2022, the JPIAMR has funded 112 projects and created 44 research networks with €141 million in funding (JPIAMR, 2021). Their incentivization is push-based and is mostly directed towards academic research of basic and preclinical science (Renwick, Simpkin & Mossialos, 2016; Kelly et al., 2016).

Global Antibiotic Research and Development Partnership (GARDP)

Founded in 2016, GARDP is a not-for-profit initiative that is jointly led by the Drugs for Neglected Diseases initiative (DNDi) and WHO with the objective of developing treatments that target priority pathogens, address diseases and syndromes with the greatest medical need and help neglected patient populations (Piddock, 2018). GARDP plans to develop five new treatments in the following core areas: sexually transmitted infections, neonatal sepsis, paediatric infections and serious bacterial infections. By the end of 2020, GARDP had secured €91 million in commitments from several countries including Germany, Japan, the Netherlands and the United Kingdom, as well as charitable organizations such as the Wellcome Trust and the Bill & Melinda Gates Foundation (GARDP, 2021a). This initiative is unique in its offering of both push and pull incentives to antibiotic R&D projects, with the possibility of delinking antibiotics that are developed and marketed with the help of GARDP. As of September 2021, the programme had 10 drugs in its pipeline at various stages of development (GARDP, 2021b).

Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X)

CARB-X is a transatlantic public–private partnership started in 2016 aimed at accelerating early-stage R&D for antibiotics, rapid diagnostic tools, vaccines and other antimicrobial products. CARB-X projects receive push funding along with scientific and business guidance for projects in preclinical and early clinical phases, with particular focus on targeting high-priority resistant pathogens (Renwick, Simpkin & Mossialos, 2016). As of July 2021, CARB-X had awarded US\$ 361 million to 92 different projects with funding support from large governmental and nongovernmental organizations (NGOs) in Germany, the United Kingdom and the USA (CARB-X, 2021). Successful projects can unlock additional funding by reaching certain development milestones or can attract external financing from other public and private investors. Nine projects have graduated from the programme to later stages of development, several of which are new antibiotic drug formulations or combinations (CARB-X, 2021).

European and Developing Countries Clinical Trial Partnership (EDCTP)

The EDCTP is a public–private partnership that brings together the EU, 14 European countries, 16 sub-Saharan African countries and the pharmaceutical industry to facilitate clinical trials on therapies treating poverty-related communicable diseases that bear the greatest health burden in sub-Saharan Africa (Olesen, 2017; EDCTP, 2020). These infections include HIV/AIDS, malaria, TB and many neglected infectious diseases. The EDCTP is now in its second decade of operation (2014–2024). The organization operates using pooled push funding from its partners with total funding of €814 million across 431 projects as of December 2022 (EDCTP, 2020). Fifty-one grants totalling €282 million are for drug development, with several large antimicrobial clinical trials currently running. In addition, vaccine development is a major aspect of their funding with 26 active projects and €243 million in funding.

Global Antimicrobial Resistance Innovation Fund (GAMRIF)

Following recommendations from the United Kingdom Review on AMR, GAMRIF was established in 2017 as an investment fund to support

underfunded and neglected areas of AMR research for the particular benefit of LMICs. GAMRIF is primarily funded by the United Kingdom's Department of Health and Social Care with additional funding provided by the Chinese Ministry of Science and Technology. GAMRIF has a £57 million portfolio of seven core work packages including InnoVet AMR (innovative veterinary solutions for AMR with the International Development Research Centre), the United Kingdom–Argentina project on tackling AMR in the environment, and innovation in AMR diagnostic tools with the Foundation for Innovative New Diagnostics (Department of Health & Social Care, 2020). In addition, the fund also supports projects within CARB-X and GARDP.

AMR Action Fund

Established in 2020, the AMR Action Fund is a public–private partnership pooling investment and leadership from over 20 pharmaceutical companies through the International Federation of Pharmaceutical Manufacturers and Associations, the Boehringer Ingelheim Foundation, the European Investment Bank (EIB) and the Wellcome Trust. The fund expects to invest US\$ 1 billion to help bring two to four new antibiotics to the market by 2030 (AMR Action Fund, 2021). The AMR Action Fund provides push funding specifically to drug candidates in phase II and III clinical trials to help bridge the gap between early clinical R&D, which has funding support through programmes such as CARB-X and JPIAMR, and the market approval phase (Clancy & Hong Nguyen, 2020).

EU initiatives

The EU has been a leader in initiating policy action to revitalize the antibiotic market. The key EU organizations fostering antibiotic R&D are the European Commission's Directorate-General for Research and Innovation (DG-RTD), the Innovative Medicines Initiative (IMI), the InnovFin Infectious Diseases Facility (InnovFin ID) and the European Health Preparedness and Response Authority (HERA).

European Commission's Directorate-General for Research and Innovation (DG-RTD)

The DG-RTD partially administers and funds the largest European antibiotic R&D funding programmes including the EDCTP, the IMI

and HERA. Beyond these specific programmes, it provides funding support to numerous smaller R&D projects. Between 2007 and 2013, the DG-RTD gave €235.6 million in direct funding for European antibiotics and diagnostics R&D projects, which were separate from the IMI and EDCTP (Kelly et al., 2016). This funding is primarily push-based via direct project funding, research grants and fellowships. It specifically offers funding opportunities to SMEs undertaking antibiotic R&D through the SME Instrument (Renwick, Simpkin & Mossialos, 2016). As part of the 2020 Pharmaceutical Strategy for Europe, the EU has committed to helping pilot pull incentive programmes (EU-JAMIRAI & Global AMR R&D Hub, 2020).

Innovative Medicines Initiative (IMI)

The IMI is a public–private partnership between the EU and the European Federation of Pharmaceutical Industries and Associations (EFPIA). It has a subsidiary public–private partnership called the New Drugs for Bad Bugs (ND4BB) programme, which is dedicated to the discovery and development of novel antibiotics for humans. Funding for the ND4BB programme is split between the EU and EFPIA and totals over €660 million (Kostyanov et al., 2016). There are four core projects, which offer push-based support to most aspects of the antibiotic value chain: TRANSLOCATION and ENABLE assist early drug discovery; iABC and COMBACTE with its subsidiary programmes COMBACTE-NET, -MAGNET, -CARE and -CDI support clinical development of novel antibiotics particularly against Gram-negative bacteria; and DRIVE-AB explores economic solutions to stimulating antibiotic R&D in a sustainable manner (Innovative Medicine Initiative, n.d.). DRIVE-AB's final report with specific recommendations was published in 2018 (Årdal et al., 2018a).

InnovFin Infectious Diseases Facility (InnovFin ID)

InnovFin ID was a financial risk-sharing programme for ventures in the clinical development phase for a novel drug, vaccine or diagnostic device that tackles an infectious disease. It was jointly governed by the European Commission and EIB. InnovFin ID offered loans ranging from €7.5 million to €75 million, which will only be repaid if the project successfully results in a marketable product (EIB, 2017). These loans were available to non-profit and for-profit ventures alike. The programme ended in 2022.

European Health Preparedness and Response Authority (HERA)

In response to the SARS-CoV-2 pandemic, the European Commission announced the launch of the HERA in September 2021 (EC, 2021). HERA has been tasked with identifying, preparing and tackling current and future health emergencies including AMR. Funding for HERA totals €30 billion sourced from various EU programmes and economic packages. HERA is still in its infancy and undergoing feasibility studies for how the agency can support drug procurement and stockpiling as well as bring AMR counter measures such as antibiotics and vaccines to market (HaDEA, 2022).

Initiatives in the USA

There are two key governmental bodies in the USA that run programmes to incentivize antibiotic R&D: the National Institute for Allergy and Infectious Diseases (NIAID) and the Biomedical Advanced Research and Development Authority (BARDA).

National Institute for Allergy and Infectious Diseases (NIAID)

The NIAID is a research institute within the NIH responsible for conducting basic science and applied research in the field of infectious, immunological and allergic diseases. The NIAID's large, push-based AMR portfolio runs from basic science projects to clinical trials for antibiotic therapies, rapid point-of-care diagnostic tools and vaccines for resistant bacterial infections. The NIH-wide funding for combating AMR in 2020 was US\$ 638 million (NIH, 2025). NIAID supports the Antibiotic Resistant Leadership Group (ARLG), which is an academic team that prioritizes, designs and executes clinical research on antibiotic resistance. The NIH renewed funding for the ARLG in 2019 with a US\$ 102.5 million grant over seven years (NIH, 2019). Additionally, the NIAID is a partner of CARB-X (2021).

Biomedical Advanced Research and Development Authority (BARDA)

BARDA is an organization within the Office of the Assistant Secretary for Preparedness and Response in the Department of Health and Human Services (Department of Human & Health Services, 2021a). BARDA is responsible for facilitating R&D and public purchasing of critical drugs, vaccines and diagnostic tools intended for public health emergencies. BARDA is a founder and key funder of CARB-X,

manages Project BioShield¹ and supports numerous public–private partnerships through its Broad-Spectrum Antimicrobials Program (Department of Health & Human Services, 2021a; 2021b). Since its inception in 2010, BARDA has invested over US\$ 1.5 billion into antibiotic R&D through these programmes. As of 2021, BARDA had supported 28 public–private partnerships ranging from SMEs to multinational pharmaceutical firms, including AstraZeneca and GSK, and had 16 products in various development phases (Department of Health & Human Services, 2021b). BARDA offers push funding and guidance to all its partners, as well as the possibility for pull-based purchasing commitments for select marketable antibiotics (Renwick, Simpkin & Mossialos, 2016).

United Kingdom initiatives

The United Kingdom Government offers a variety of programmes with push-based funding to support antibiotic R&D, primarily at the basic science and preclinical stages. The National Institute for Health Research's (NIHR) Biomedical Research Centres and Health Protection Research Units have started a variety of programmes conducting basic science research that is laying the groundwork for antibiotic development (NIHR, 2023).

Medical Research Council (MRC)-supported initiatives

The United Kingdom's MRC supports antibiotic R&D through the AMR Cross-Council Initiative, the Newton Fund and the Global Challenge for Research Fund. The Cross-Research Council AMR Initiative promotes a multidisciplinary approach to tackling AMR and offers a range of individual and collaborative grants to academic institutions (UKRI, 2022a). The Initiative aims to break down research silos and involve LMICs in AMR research. The Newton Fund aims to strengthen scientific research partnerships between the United Kingdom and LMICs (UKRI, 2022b). The MRC, alongside government agencies from China, India and South Africa, had pooled approximately £13.5 million by 2017 in the Newton Fund for

¹ Project BioShield is a programme that supports late-stage development and procurement of medical countermeasures, such as novel antibiotics, for the Strategic National Stockpile.

collaborative academic research on AMR (Simpkin et al., 2017). The Global Challenge Research Fund is a £1.5 billion fund that strives to address a multitude of challenges faced by LMICs, including AMR (UKRI, 2023). However, antibiotic R&D has played only a small role in this Fund's mission to date.

“Netflix model”

Finally, NHS England and NHS Improvement, along with support from the Department for Health and Social Care and National Institute for Health and Care Excellence (NICE), are implementing a pilot project for a subscription-type payment model for novel antibiotics – a first of its kind (Anderson & Mossialos, 2020; Perkin & Glover, 2020). The programme, nicknamed the Netflix model, pays eligible companies a set annual fee for access to a novel antibiotic, regardless of the volume used. The scheme will be trialled with Pfizer's Zavicefta (ceftazidime avibactam) and Shionogi's Fetcroja (cefiderocol), two antibiotics that have efficacy against priority pathogens identified by WHO (Mullard, 2020). The pilot is expected to begin in April 2022 and will see that drug developers receive an annual fee of £10 million for 10 years.

Regulatory initiatives

European Medicines Agency (EMA)

EMA authorizes most antimicrobial agents in Europe through its centralized licensing procedure. EMA promotes antibiotic innovation through several lego-regulatory mechanisms that facilitate faster market authorization, lower costs associated with obtaining regulatory approval and potentially increase a drug's effective patent period (EMA, 2016; Renwick, Simpkin & Mossialos, 2016). For innovative medications that have high-priority for public health and address an unmet medical need, EMA offers an accelerated approval pathway that shortens the assessment period for its marketing authorization application. In addition, EMA can provide scientific advice and protocol assistance with the authorization process. Certain medications may qualify for conditional market authorization whereby a drug is approved under weaker criteria for quality, safety and efficacy, to hasten patient access. These products have much narrower indications

for use, must participate in post-market evidence generation, and are reserved for those individuals without other treatment options. Some antibiotics against rare pathogens may also be eligible to receive orphan drug designation and an associated patent extension. EMA recently introduced the PRIME scheme for priority medications to help guide SMEs and academics through the complicated process of market authorization and ensure that these developers take advantage of the offered lego-regulatory mechanisms (EMA & CHMP, 2018).

United States Food & Drug Administration (FDA)

The United States FDA offers similar incentives to antibiotic developers through the Qualified Infectious Diseases Products designation and the Limited Population Antibacterial Drug designation (FDA, 2020; Renwick, Simpkin & Mossialos, 2016). Novel antibiotics that qualify for Qualified Infectious Diseases Products status receive regulatory guidance from the FDA, priority review and fast-track consideration when being assessed for market approval. Certain Qualified Infectious Diseases Products antibiotics may also be eligible for a market exclusivity extension of five years. Antibiotics that target rare and deadly pathogens could be eligible for Limited Population Antibacterial Drug designation, which permits a streamlined and conditional approval process so that patients lacking appropriate treatment can receive early access to a promising novel antibiotic. Analogous to the EMA's conditional market authorization process, antibiotics with Limited Population Antibacterial Drug designation are studied using smaller clinical populations and would only be approved for a narrow indication limited to the in-need patient cohort. The FDA also has an orphan drug licensing programme that offers market exclusivity extensions among some other benefits (Mossialos et al., 2010; Renwick, Simpkin & Mossialos, 2016).

Transatlantic Task Force on Antimicrobial Resistance (TATFAR)

TATFAR is an international partnership bringing together health policy and regulatory agencies from Canada, the EU, Norway and the USA (TATFAR, 2021). TATFAR's key goal is knowledge exchange and coordination across the various partner agencies as well as promotion of innovative global strategies to tackle AMR. The regulatory agencies within TATFAR have been working collaboratively to improve and align the market authorization processes for antibiotics among member nations.

What is the state of progress in the antibiotic pipeline?

A new approach now aims to guide antibiotic R&D based on medical need as opposed to the economic factors that have traditionally directed antibiotic investment.

In 2017, WHO published a priority pathogens list (PPL) which outlines the antibiotic-resistant bacteria that pose the greatest threat to global public health (WHO, 2017b) (Table 3.9.3). At the top of this list, categorized as “critical”, are the Gram-negative, carbapenem-resistant strains of *Acinetobacter baumannii*, *Pseudomonas aeruginosa* and the Enterobacteriaceae family. In 2013, the United States Centers for Disease Control and Prevention published a USA-focused urgent threats list for antibiotic resistance, which highlighted many of the same pathogens (CDC, 2013).

Table 3.9.3 WHO priority pathogens list

Priority level	Pathogens
Critical	<i>Acinetobacter baumannii</i> , carbapenem-resistant <i>Pseudomonas aeruginosa</i> , carbapenem-resistant <i>Enterobacteriaceae</i> , carbapenem-resistant & 3rd generation cephalosporin-resistant
High	<i>Enterococcus faecium</i> , vancomycin-resistant <i>Staphylococcus aureus</i> , methicillin-resistant, vancomycin intermediate and resistant <i>Helicobacter pylori</i> , clarithromycin-resistant <i>Campylobacter</i> , fluoroquinolone-resistant <i>Salmonella spp.</i> , fluoroquinolone-resistant <i>Neisseria gonorrhoeae</i> , 3rd generation cephalosporin-resistant, fluoroquinolone-resistant
Medium	<i>Streptococcus pneumoniae</i> , penicillin-non-susceptible <i>Haemophilus influenzae</i> , ampicillin-resistant <i>Shigella spp.</i> , fluoroquinolone-resistant

Source: Authors.

Traditional antibiotics

WHO and the Pew Charitable Trust keep close track of the antibacterial agents in clinical development. Between 2014 and 2020, 14 antibiotics had been developed and approved for use by the FDA, EMA or other national drug regulatory agencies (Pew, 2021). Of these 14 approvals, 11 occurred in the last four years between 2017 and 2020 (WHO, 2021b). During the same 2014–2020 period, 19 antibiotic drug candidates were discontinued at various stages of development (Pew, 2021).

As of March 2021, there were 43 drugs in clinical development: 15 in phase I, 13 in phase II, 13 in phase III and two applying for regulatory approval (Pew, 2021) (Fig. 3.9.4). Of these drugs in development, approximately half (26) target a WHO priority pathogen (WHO, 2021b). As with most drug developments, the R&D and market approval process is lengthy. The phase III antibiotics are three to five years from potentially reaching the market. However, the phase I and II antibiotics have development timelines of at least five to 10 years and successful progression to marketing approval is far from certain. Antibiotics in phase I clinical trials have only a 14% likelihood of

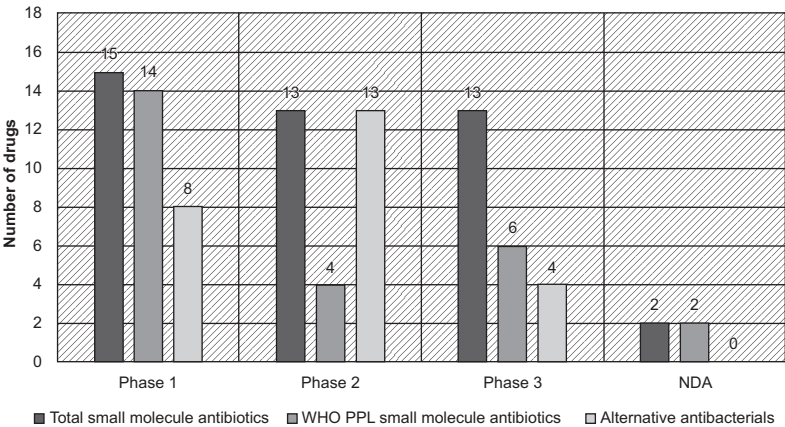


Fig. 3.9.4 Antibiotic drugs and alternative antibacterial therapies in clinical development

NDA: new drug application; PPL: priority pathogens list; WHO: World Health Organization.

Source: WHO (2021b).

reaching the market. This means that of the 10 phase I antibiotics targeting resistant Gram-negative bacteria only one or two are likely to succeed.

A compounding problem is that most of the pipeline drugs are redevelopments of classic antibiotic compounds or are combination therapies of existing antibiotic molecules.

These types of less original antibiotics are at higher risk of quickly losing effectiveness in clinical practice because of cross-resistance and therefore offer less clinical benefit over existing options. Of the 11 drugs approved from 2017 to 2020, only two drugs represent a novel antibiotic class with new pathogen target (meropenem/vabrobactam and lefamulin) (WHO, 2021b). Furthermore, of the 26 antibiotics in the pipeline targeting a WHO PPL pathogen, only seven (27%) meet at least one criteria for innovation: (i) absence of cross-resistance to existing antibiotics; (ii) new chemical class; (iii) new target; or (iv) new mechanism of action. The recent 2021 WHO analysis concluded that the current antibacterial pipeline is inadequate for the soaring resistance rates. This sentiment was echoed in the Access to Medicine Foundation's 2021 AMR Benchmark Report, an independent assessment of key industry players across a spectrum of AMR priorities related to R&D, production and manufacturing and appropriate access and stewardship (AMR, 2021).

Alternative antibacterial therapies

A burgeoning portfolio of alternative antibacterial therapies in addition to antibiotics is now emerging and includes antibodies, bacteriophages, immunomodulating agents, microbiome-modulating agents and various peptides (Fig. 3.9.5). These products would likely supplement typical antibiotic regimens as adjunct or preventive therapies. WHO's pipeline analysis found that there are 27 alternative therapies in development targeting PPL bacteria: eight in phase I, 14 in phase II, four in phase III and one not in a defined clinical trial phase (WHO, 2021b) (Fig. 3.9.4). Most of these alternative therapies are in the early phase of clinical trials and target specific pathogens, namely *Staphylococcus aureus* and *Clostridium difficile*. This specificity limits clinical applicability when there is diagnostic uncertainty about the exact pathogen causing infection, which is a common issue in LMICs. Furthermore, a significant challenge will be later-stage clinical trials as

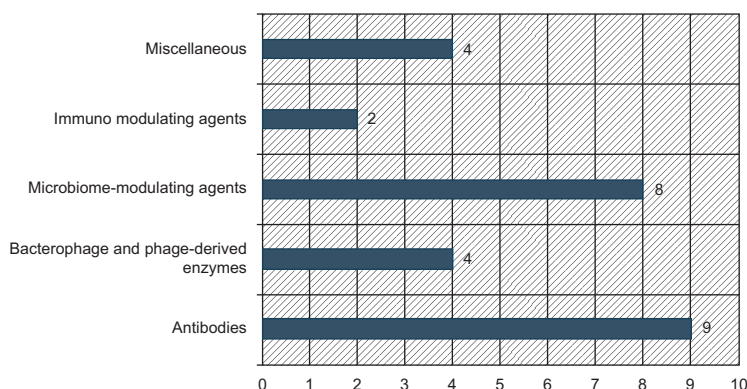


Fig. 3.9.5 Types of alternative antibacterial therapies in development

Source: WHO (2021b).

well as regulatory hurdles, as regulatory agencies have minimal experience with many of these drugs.

Antibiotic development incentivization: is it working?

The current incentive package still has major gaps and deficiencies that inhibit the transition from basic science research all the way to patient access, and incentivization needs to be adjusted accordingly.

Though the extensive array of antibiotic R&D incentives is commendable, and incredible strides have been made towards reviving the antibiotics pipeline over the past several years, the end goal should be a continuum of incentivization that reflects the economic need, cost distribution and blockages of the entire antibiotic value chain. Different types of incentives are better suited for tackling different stages of this value chain (Fig. 3.9.6). To achieve this continuum, there is a need to adjust push incentivization to increase funding of clinical development, support global regulatory harmonization and provide added legal or regulatory incentives to facilitate market approval. There is also a need to introduce a variety of outcome-based pull incentives to help with commercialization and distribution of licensed antibiotics. These incentive changes must involve inter-initiative coordination and be made within the context of broader public health and health system goals related to sustainability, patient access, care quality and access and medical need.

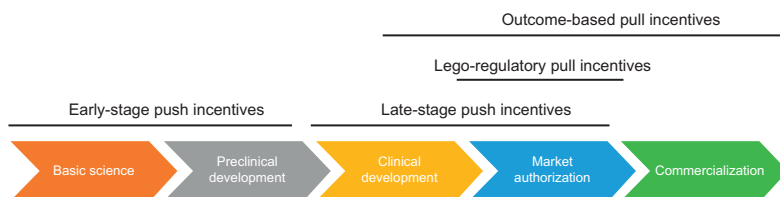


Fig. 3.9.6 Continuum of incentivization across the antibiotic value chain

Source: Adapted from Renwick, Simpkin & Mossialos (2016).

Early-stage push incentives

Push incentives, such as grants for researchers and direct project funding, are best used to facilitate the earlier stages of R&D from basic science up to clinical development. Most push funding for antibiotic R&D is directed towards basic antimicrobial science and less so towards clinical development. An estimated 86% of European national-level public funding of antibiotics was in this category (Kelly et al., 2016). The JPIAMR, DG-RTD, CARB-X, United States NIAID, United Kingdom MRC and United Kingdom NIHR preferentially fund antimicrobial basic science and preclinical development. While early-stage push funding of antimicrobial science is integral to the R&D process, there is a need for more late-stage push funding of clinical trials to help translate scientific innovation into marketable products. The overemphasis on early-stage push funding reflects the fact that basic science and preclinical development lends itself to being partitioned into projects requiring smaller individual monetary commitments than clinical trials. In addition, public funders can more easily justify supporting non-profit academic work. Basic science is largely the domain of academia and, as a result, private companies often do not benefit from early-stage push funding. Yet, clinical trials, which are usually operated by private companies, are by far the most expensive aspect of R&D (Review on Antimicrobial Resistance, 2015). SMEs are the most impacted by the lack of late-stage push funding as they often struggle to raise the capital necessary for clinical trials (Renwick, Simpkin & Mossialos, 2016).

As more drug candidates transition to clinical development, early-stage push funding could be pooled and reallocated to late-stage push funding to ensure viable antibiotics make it to the market approval

stage. In addition, existing programmes, such as BARDA and the IMI's COMBACTE, which specifically fund clinical trials could be further expanded. The AMR Action Fund is another promising new initiative that specifically addresses the lack of push funding in the latter half of the clinical development pipeline (i.e. phase II and III). Public and regulatory organizations could bolster this initiative by offering further funding and clinical trial guidance, respectively. Public–private partnerships naturally lend themselves to facilitating early- and late-stage clinical development by pooling investment and expertise from industry and governmental organizations while also dispersing financial risk. Many major incentive programmes such as BARDA, IMI and CARB-X rely on public–private partnerships and have been successful in adding promising drugs to the pipeline.

Lego-regulatory incentives

Lego-regulatory pull incentives, such as those offered by the EMA and FDA, are most effective at facilitating progress through the market approval stage.

Both the EMA and FDA offer several incentives that decrease the approval timeline for antibiotics: regulatory guidance, expedited pathways and conditional market authorization. The primary value of these incentives comes from indirectly increasing the effective patent period of the antibiotic since it reaches the market earlier (Mossialos et al., 2010). But there is a balance to be struck between speeding up the approval process and ensuring that licensed drugs meet standards for quality, safety and efficacy (Renwick, Simpkin & Mossialos, 2016). It is unlikely that these regulatory processes can be shortened any further without sacrificing regulatory standards. It remains to be seen how these lego-regulatory incentives may be applied to the variety of alternative antibacterial therapies in the pipeline. In addition, many of the pipeline antibiotics are not expected to be high-volume products and therefore adding to their effective patent period does not translate into meaningful revenue. Market exclusivity extensions suffer from this same problem. Therefore, it may be worthwhile to explore alternative incentives that allow priority review (e.g. priority review vouchers) or market exclusivity extensions (e.g. transferable intellectual property rights (TIPR)) to be transferred from an approved antibiotic to another product in the developer's portfolio that would benefit more from the

longer effective patent period (Ferraro, Towse & Mestre-Ferrandiz, 2017). Incentives such as priority review vouchers and TIPR could provide a market incentive to license new antibiotics without requiring upfront government funding. However, it is important to be aware that priority review vouchers and TIPR do not incentivize antibiotic commercialization or access and they could have broader pharmaceutical market consequences (Ferraro, Towse & Mestre-Ferrandiz, 2017; Mossialos et al., 2010).

Harmonization between the EMA and FDA's market approval requirements has been a step towards lowering market approval costs and time. However, the EMA and FDA regulatory processes are relatively similar, unlike the Japanese Pharmaceuticals and Medical Devices Agency or the Chinese Food and Drug Administration. Harmonization efforts among these agencies will prove more challenging but could further relieve companies of duplicative regulatory approval costs. Including the Japanese Pharmaceuticals and Medical Devices Agency in TATFAR discussions was a laudable starting point.

The need for outcome-based pull incentives

Push funding and legal or regulatory incentives can drive viable antibiotics to licensing; however, they are weak incentives for the commercialization and distribution of the product. Net profits from sales of an innovative new antibiotic are perceived to be limited for several reasons, especially when compared to therapeutic areas with the highest sales revenues; for example, oncology, immunology and musculoskeletal medicine (EvaluatePharma, 2021). A novel antibiotic would be reserved as a treatment of last resort or may only target a rare resistant pathogen, which restricts potential sales revenue. High product prices are unlikely to compensate for low sales volume because of the considerable overlap in effectiveness between existing antibiotics. Also, future rapid-point-of-care diagnostic tools could cut into the revenue potential for newly marketed antibiotics (Outtersson et al., 2015). Therefore, large outcome-based pull incentives are necessary in the absence of a viable market. Pull incentives have the added benefit of potentially allowing SMEs to secure venture capital for clinical trials. However, pull incentives for antibiotics have been mostly absent from current funding initiatives. The only established outcome-based pull incentives currently available are relatively limited advanced market

commitments offered by BARDA and GARDP for certain low-volume antibiotics (Simpkin et al., 2017).

Market entry rewards

Market entry rewards have repeatedly been recommended by major reports and journal articles as an effective pull incentive for antibiotic commercialization (Stern et al., 2017; Årdal et al., 2018a; Rex & Outtersson, 2016; Outtersson et al., 2015; Renwick, Simpkin & Mossialos, 2016; Simpkin et al., 2017; Ferraro, Towse & Mestre-Ferrandiz, 2017). A market entry reward is a financial prize for the successful development and licensure of an innovative antibiotic. To receive the prize, a developer must ensure that the antibiotic meets predefined product criteria and adheres to post-market authorization conditions related to sustainability and patient access as specified by the payer. The DRIVE-AB group, as well as other major reports, expect that an effective reward would need to be approximately US\$ 1–2 billion per first-entrant novel antibiotic to entice developers to invest in R&D and gamble on inventive antibiotic projects (Årdal et al., 2018a). In a more recent journal article, Outtersson (2021) estimates that a more accurate price for a standalone market entry reward would be in the range of US\$ 1.5–4.8 billion. A prize of this magnitude might be paid out in instalments over five to 10 years. This would create a guaranteed revenue stream for the developer, spread out payer expenditures and provide the payer with leverage if the developer chose to deviate from the agreed reward conditions.

Market entry rewards can also be designed to have varying degrees of delinkage. Delinkage, in the context of a reward, refers to how much of the winner's revenue can be generated from sales volume (Rex & Outtersson, 2016). A fully delinked market entry reward would pay for the antibiotic patent or licence in return for access to the drug at the cost of production. A partially delinked reward would still allow developers to generate some revenue from antibiotic sales. A fully delinked reward would thus need to be much larger than a partially delinked one.

Numerous other design variations, stipulations and augmentations can be applied to the basic market entry reward model to achieve various market goals. One such variation is a sustainability bonus that rewards developers for maintaining low resistance rates for their drugs (Morel et al., 2020). Both the 2018

DRIVE-AB final report and the 2017 OHE Report offer in-depth discussion of and recommendations for market entry reward design and costing (Årdal et al., 2018b; Ferraro, Towse & Mestre-Ferrandiz, 2017).

The key barrier to implementing a reward programme is the cost. With the 10-year goal of bringing 10 to 15 novel antibiotics to market, a market entry reward programme is estimated to cost between US\$ 10 and US\$ 30 billion (Årdal et al., 2018a; Ferraro, Towse & Mestre-Ferrandiz, 2017; Review on Antimicrobial Resistance, 2016). Such a programme would provide large payouts of US\$ 1–2 billion for first entrants and increasingly smaller prizes for follow-up therapeutic products. A fund of this scale can only be practically achieved by pooling financial commitments from numerous countries and institutions into a secure endowment. For a market entry reward programme to effectively pull antibiotics to the market, it is important that developers perceive this fund to be guaranteed by participating governments and protected from other public expenditures. This type of international fund for market entry rewards has been recommended by various journal articles and international reports, such as the United Kingdom's AMR Review, Boston Consulting Group's report for the GUARD initiative and DRIVE-AB (Stern et al., 2017; Review on Antimicrobial Resistance, 2016; Renwick, Simpkin & Mossialos, 2016; Rex & Outtersen, 2016).

In lieu of a global market entry reward scheme, alternative outcome-based pull incentives could be applied such as corporate tax incentives, value-based pricing and reimbursement strategies, and national advanced market commitments for bulk purchasing (Renwick, Simpkin & Mossialos, 2016). These strategies are generally weaker incentives, but do not require the same upfront financial commitment as a market entry reward programme and thus may be more politically palatable.

Further developments

Subscription models

Subscription models in Sweden and the United Kingdom

Both Sweden and the United Kingdom have pilot programmes that offer payment subscriptions for access to antibiotics regardless of volume

acquired (Global AMR R&D Hub, 2020). Sweden started its programme in 2020, securing access to five products, and will run until 2022. The United Kingdom announced its “Netflix” programme will start in early 2022 and offer subscription payments of £10 million annually to four antibiotics for 10 years. These two pilot programmes are an exciting initial step towards creating a global delinked pull mechanism. Rex and Outtersen (2020) estimate that if the United Kingdom’s subscription programme was scaled up to a G20-financed programme, reflecting individual national contributions to total G20 GDP, the G20 could offer a global delinked pull incentive of US\$ 2–4 billion per novel antibiotic. Therefore, if other countries within the G20 offered similar subscription payment schemes adjusted for their overall GDP or national drug sales then a global pull incentive is feasible.

Subscription model in the USA

Another promising development is the reintroduction of the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act to United States Congress previously submitted in September 2020 (Bennet et al., 2023; Global AMR R&D Hub, 2020). The PASTEUR Act would create a delinked subscription scheme for priority antibiotics available to the United States Centers for Medicare and Medicaid Services. Like the United Kingdom’s programme, PASTEUR would offer eligible antibiotics annual payments of US\$ 750 million to US\$ 3 billion for 10 years along with stipulations regarding access, appropriate use and post-market evidence generation. The entire package would total US\$ 6 billion.

The need for a global coordinating body for antibiotic R&D investment

Coordinating antibiotic incentivization is a complex task, but essential to creating an efficient and effective continuum of antibiotic incentivization. National governments, global institutions, NGOs and industry often independently invest their resources in antibiotic R&D projects and funding programmes. This has partially been responsible for mismatched and incomplete global incentive packages (Renwick, Simpkin & Mossialos, 2016). In addition, many of the antibiotic R&D initiatives operate in isolation from one another despite their commonalities. There is a clear risk of duplicating efforts with initiatives that have

similar mandates and receive interweaving funding from different payers.

The Global AMR R&D Hub was established in 2018 by the German government to provide a knowledge sharing platform about current incentive programmes, the antibiotic clinical pipeline and R&D financing to guide policy-makers, organizations and funders towards evidence-based, collaborative decisions about antibiotic investment. Ideally, this hub could be taken a step further to become a global governing body that can take a more active role in coordinating antibiotic R&D incentive programmes at an international level and direct their operation at national levels. This global governing body could establish a unified direction for international antibiotic R&D incentives and guide incentive programmes towards achieving a more balanced global R&D incentive profile.

Such an entity would also help ensure that broader AMR goals related to a global One Health approach are reinforced by the individual incentives. The concept of One Health recognizes that AMR reaches all edges of the world and impacts humans, livestock, wildlife and our broader environment, and, therefore, a holistic strategy addressing all areas of the issue is needed for a long-term solution. Issues such as veterinary antibiotic use, rapid diagnostic tools for identifying pathogens, vaccinations, antibiotic stewardship and antibiotic access all play vital roles in tackling AMR. Fixing the antibiotic pipeline will be wasted if the root causes of AMR itself are not addressed.

Policy relevance and conclusions

Health systems traditionally rely on private industry to finance the discovery and development of novel medical therapies in exchange for patents that provide developers with market exclusivity and freedom to choose their price. However, in the field of antibiotics, a multitude of unique scientific, regulatory and economic barriers prevent this arrangement from working sufficiently. Consequently, the antibiotic discovery and development pipeline severely lags behind the critical public health need for novel antibiotics. Innovative incentives and funding mechanisms are necessary to fix this broken market and overcome the barriers that impede progress through the entire antibiotic value chain.

Over recent years, many multilateral, European and national-level incentive programmes have been implemented to repair the antibiotic value chain. These have lifted the clinical pipeline out of dormancy. Promising antibiotic drugs and alternative therapies are on the horizon. However, with few truly innovative drugs targeting high-priority pathogens, the present pipeline is not sufficient to overcome the relentless advancement of resistance rates. We must capitalize on global momentum to tackle AMR by bolstering and calibrating existing push funding and expand pilot programmes for pull mechanisms. The United Kingdom's subscription programme and the United State's PASTEUR Act are encouraging steps towards addressing the serious lack of pull financing and commercial incentivization. A global governing body that provides overarching guidance to international and national-level incentive programmes could be an asset to achieving an effective continuum of antibiotic R&D incentivization.²

Additional resources

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² Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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3.10 *Financing innovation for neglected diseases*

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Key messages

Chapter 3.10 evaluates innovative financing for neglected diseases. Neglected diseases account for about a fifth of the global burden of disease and affect over 1 billion people. They are neglected because the pharmaceutical sector does not consider it profitable to develop treatments for them. This reflects the fact that neglected diseases are most prevalent in low- and middle-income countries (LMICs) with relatively low purchasing potential. Key learning includes that:

- Global pharmaceutical R&D invests a disproportionate share of innovation and activity in diseases that affect high income countries, something which fosters significant inequities.
- A range of push and pull incentive mechanisms have been developed to delink the cost of research from market profitability and promote innovation in areas of need. These include measures to:
 - reduce the upfront costs by subsidizing R&D pre-discovery (push incentives); and
 - offer a reward post-discovery (pull incentives).
- The evidence on the effectiveness and reach of incentive schemes is scant and more needs to be done to understand the relative cost-effectiveness of the different incentive mechanisms and the extent to which they mitigate inequalities in innovation and access to new medicines.
- A global, unified governance framework for needs assessment and resource allocation could usefully:
 - carry out systematic comparisons of the relative needs associated with neglected diseases globally;
 - assess the costs and benefits of addressing these;

- set priorities for the coordinated global allocation of funding and targeted incentive mechanisms; and
- consider payment mechanisms that will translate research into market launches.

Introduction

Neglected diseases (NDs) comprise a diverse set of around 20 diseases and disease groups, depending on the classification used. Typically considered to offer little scope for profitability to the pharmaceutical industry, these diseases are known as neglected diseases either because their prevalence is proportionally small (rare diseases) or because they are endemic in LMICs that cannot afford to buy either treatment or prevention therapies at market prices. As a result, market incentives for R&D to develop therapies for these conditions are weak (Maurer, 2005).

Neglected diseases include several parasitic, viral and bacterial diseases that cause substantial illness globally (Table 3.10.1). Neglected disease products were only 4% of all therapeutic products registered between 2000 and 2011 (Belen et al., 2013). Despite these diseases affecting more than 1 billion people, causing around 19% of global burden of disease, with devastating health, social and economic consequences (Fitzpatrick et al., 2017; IHME, 2019), there is substantial inertia in the development of treatments and prevention targeting these diseases. Fig. 3.10.1 illustrates the wide geographical distribution of disability-adjusted life years (DALYs) from neglected diseases between 1990 and 2010 for both sexes and all ages.

Table 3.10.1 *Neglected diseases affect more than 1 billion people globally*

Disease categories
1. HIV/AIDS
2. TB
3. Malaria
4. Diarrhoeal disease (rotavirus, cholera, shigella, cryptosporidiosis, enterotoxigenic <i>Escherichia coli</i> , enteroaggregative <i>E. coli</i> and giardiasis)
5. Kinetoplastid disease (sleeping sickness or HAT, Leishmaniasis, Chagas disease (American trypanosomiasis))

Table 3.10.1 (cont.)

6. Bacterial pneumonia and meningitis (<i>Streptococcus pneumoniae</i> , <i>Neisseria meningitidis</i>)
7. Salmonella infections (typhoid and paratyphoid, non-typhoidal <i>Salmonella enterica</i>)
8. Helminths infections (schistosomiasis, onchocerciasis, lymphatic filariasis, tapeworm, hookworm, whipworm, roundworm, strongloidiasis)
9. Dengue
10. Hepatitis B
11. Hepatitis C
12. Leprosy
13. Cryptococcal meningitis
14. Snakebite envenoming
15. Buruli ulcer
16. Trachoma
17. Leptospirosis
18. Rheumatic fever
19. Mycetoma
20. Other diseases (rare diseases, chikungunya, dracunculiasis, rabies, scabies, yaws)

HAT: human African trypanosomiasis; TB: tuberculosis.

Note: Definitions of neglected diseases vary widely; this table combines definitions in G-Finder in addition to other diseases from the World Health Organization’s neglected disease list.

Sources: WHO (2010); 2023; Policy Cures Research (2021b).

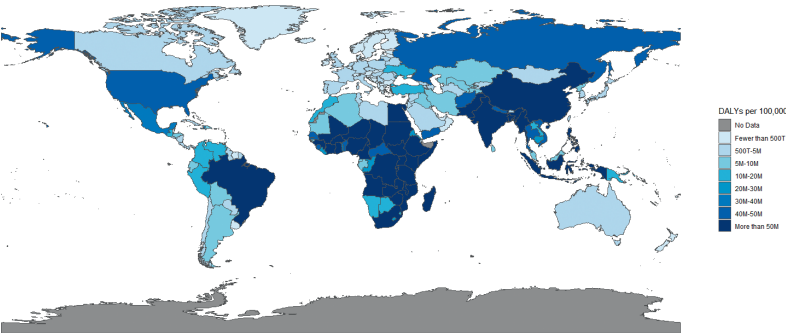


Fig. 3.10.1 Neglected diseases disproportionately affect LMICs
DALYs: disability-adjusted life-years.

Source: IHME (2019).

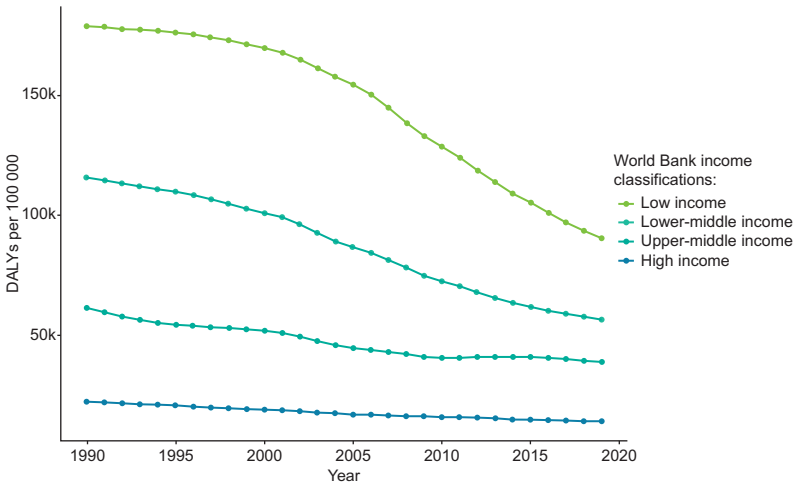


Fig. 3.10.2 Neglected diseases have declined in richer countries but remain constant in LMICs

B: billion; DALYs: disability-adjusted life-years; M: million.

Source: IHME (2019).

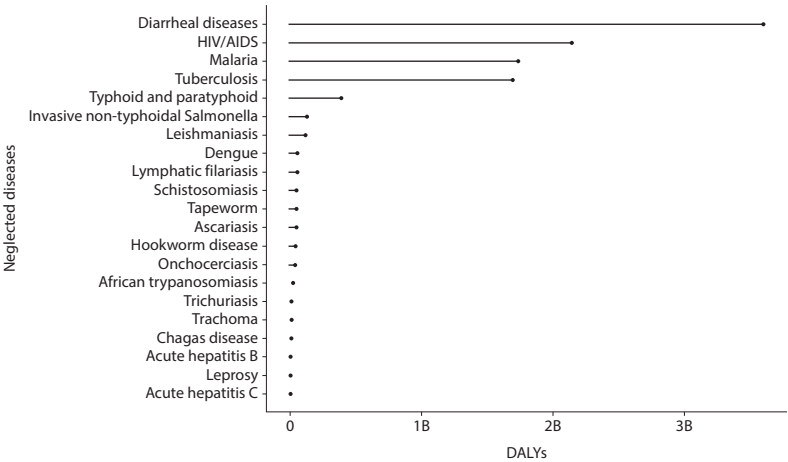


Fig. 3.10.3 Top five neglected diseases: diarrhoeal diseases, HIV/AIDS, malaria, TB, and typhoid and paratyphoid

B: billion; DALYs: disability-adjusted life-years.

Source: IHME (2019).

While over time there has been a decline in the global burden of disease associated with neglected diseases, they still disproportionately affect LMICs (Fig. 3.10.2).

Diarrhoeal diseases, HIV/AIDS, malaria, tuberculosis (TB) and typhoid and paratyphoid are the top five diseases that contribute the highest burden of DALYs (Fig. 3.10.3). The bottom five diseases that contribute the lowest burden of DALYs are trachoma, Chagas disease, acute hepatitis B, leprosy and acute hepatitis C (Fig. 3.10.3).

World Health Organization's (WHO's) neglected diseases roadmap, 2021–2030

The WHO Road Map for Neglected Tropical Diseases 2021–2030 sets out global targets and milestones for 2030, including 90% reduction in cases requiring interventions, 75% reduction in DALYs lost to neglected diseases, working to eliminate at least one neglected disease in 100 countries, and eradicating two neglected diseases globally. The roadmap highlights research, development and innovation as “fundamental enablers of programmatic progress for all neglected diseases” (WHO, 2021a). To achieve this endeavour, the WHO Council highlights the need for a systematic approach to innovation and the elimination of unacceptable inequities in access to treatment and prevention (WHO, 2021b).

Delinking the costs of R&D from the cost of new therapies: financing incentive mechanisms

The eradication of neglected diseases or the mitigation of their impacts requires greater pharmaceutical innovation. The report on financing and coordination by WHO's consultative expert working group on R&D (WHO, 2012) highlights that novel financing incentive mechanisms are required to address these challenges. The World Health Assembly passed a resolution in 2006 that highlighted the importance of “incentive mechanisms . . . addressing the linkage between the cost of R&D and the price of medicines, vaccines, diagnostic kits and other health care products” in addressing unmet needs for neglected diseases (WHO, 2007). The design of financing incentive mechanisms is

important to ensure not only sustained investment in R&D but also an efficient targeting of effort and resources towards key areas of need.

In this chapter, we quantify some of the systemic gaps with regards to the distribution of pharmaceutical R&D activity and funding across neglected diseases, and describe some of the underlying reasons for these gaps. We then discuss the financial incentive mechanisms in use since 2007 in terms of pre-discovery push (public–private partnerships, in particular product development partnerships, R&D grants and subsidies, fiscal measures) and post-discovery pull (transferable patent extensions, patent buyouts, priority review vouchers (PRVs), advance market commitments (AMCs), prizes). We examine the evidence for their effectiveness levels, noting their relative advantages and disadvantages. We conclude with insights into the overall state of R&D funding for neglected diseases.¹

Trends in funding, 2007–2019

Fig. 3.10.4 illustrates total spending in US dollars by source of spending on R&D for new products and technologies to address challenges in public health caused by neglected diseases between 2007 and 2019. Total spending is around US\$ 3.25 billion per year and was highest in 2009, 2017, 2018 and 2019 and lowest in 2007 and 2015. Between 2015 and 2018 spending on R&D for neglected diseases amounted to US\$ 17.9 billion, 2.7% of global pharmaceutical R&D spending (US \$ 660 billion) (Statista, 2021), signalling underinvestment in neglected disease R&D, considering that neglected diseases account for 19% of the total global burden of disease (IHME, 2019).

Between 2007 and 2019, on average, the three areas that accounted for the highest proportion of spending, in descending order, were vaccines, drugs and basic research (Fig. 3.10.5). The year 2014 saw the highest spending, with vaccines, drugs and basic research accounting for about 37.5%, 22.5% and 20% of total spending, respectively, when compared to other products such as diagnostics and core funding and other R&D products. Cumulatively, between 2015 and 2019, there was a gradual decline in total spending across all the different types of products.

¹ Please note that this chapter focuses on the financing of medicines and vaccines in relation to neglected diseases rather than access; while access issues are important, we do not assess them here. We also do not comprehensively cover preventive technology such as diagnostics or medical devices.

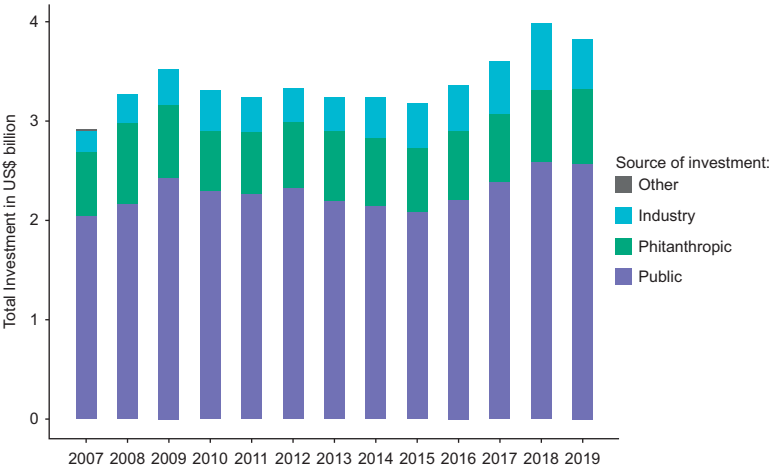


Fig. 3.10.4 Global pharmaceutical companies are underinvesting in neglected disease R&D, 2019
B: billion.

Note: Authors' analyses
Data source: Policy Cures Research (2021b).

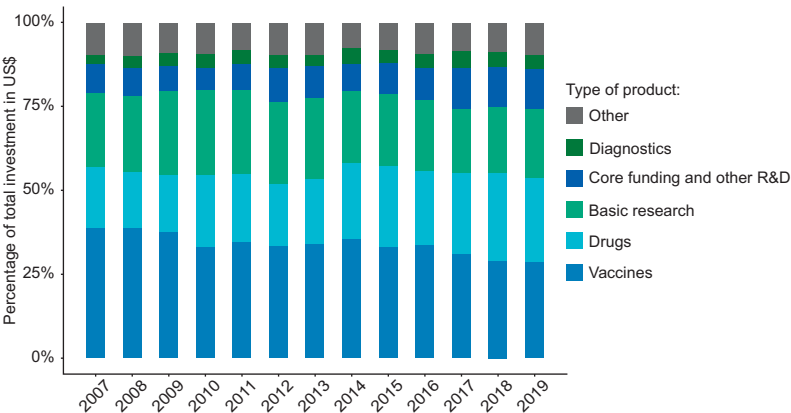


Fig. 3.10.5 Most money is spent on vaccines, drugs and basic research R&D: research and development.

Note: Authors' analyses
Data source: Policy Cures Research (2021b).

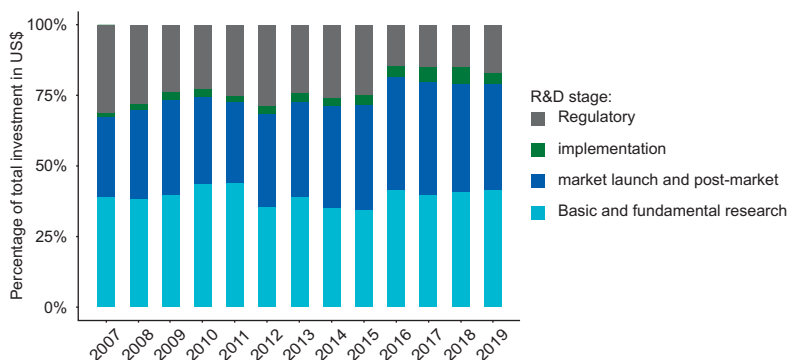


Fig. 3.10.6 Most R&D spending to address neglected disease challenges goes on just two stages

R&D: research and development.

Note: Authors' analyses

Data source: Policy Cures Research (2021b).

Between 2007 and 2019, although around 30% of total spending was unspecified, the majority (approximately 70%) of spending was shared between two stages, namely the clinical and the basic and fundamental research stages (Fig. 3.10.6). The regulatory, implementation, market launch and post-market stages received the smallest proportions of the total funding. Even though the proportion of total funding invested in clinical research has remained constant at around 35% during the period 2015 to 2019 (Fig. 3.10.6), the increased funding in clinical and preclinical R&D over the years could be translated into further innovation for neglected diseases in the years to come.

Sources of funding

The three most common sources of funding were industry, philanthropic and public sources. Between 2007 and 2019, public and philanthropic sources accounted for more than 70% and 20% of total expenditure, respectively, while industry sources accounted for about 10%.

The United States of America (USA) consistently ranks as the top funder, funding on average 65% of total spending between 2007 and 2019. Apart from the EU, which funds on average 3% of the total

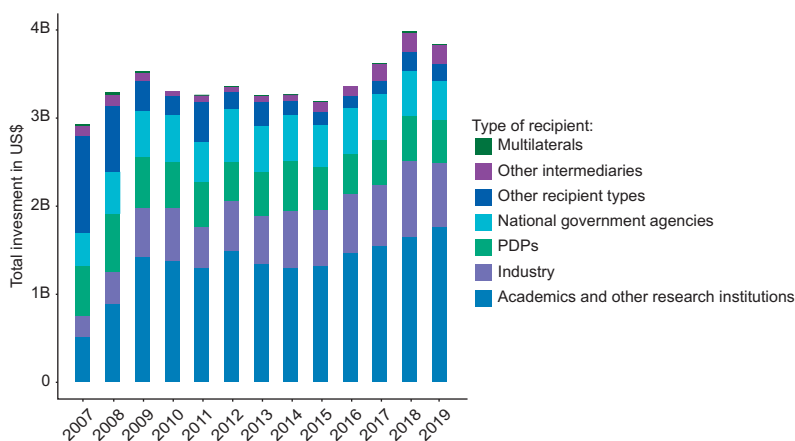


Fig. 3.10.7 Academics and research institutions receive the biggest proportion of investment

PDP: product development partnership.

Note: Authors' analyses

Data source: Policy Cures Research (2021b).

expenditure, other top funding countries include the United Kingdom and France, which fund on average 6% and 2%, respectively. However, it is important to note that over the same period, about 13% of the total spending came from countries that were not specified.

Fig. 3.10.7 shows total neglected disease R&D spending by type of recipient. On average academics and other research institutions receive the highest amount of investment followed by industry, whereas “other intermediaries”² receive the lowest amount of funding.

Inequities and inequalities in R&D activity and funding

When we compare the distributions of pharmaceutical R&D activity and global DALYs across neglected diseases (Fig. 3.10.8), for the

² Intermediaries are organizations that receive funding for R&D and allocate it as onward funding to product developers. There are two types of intermediaries: product development partnerships (PDPs) and “other intermediaries”. The latter are coordinating entities where money flows to them as well as from them. The former, beyond coordination, engagement and advocacy activities, also conduct their own R&D. Further information can be found at: <https://gfinderdata.policycuresresearch.org/assets/media/pdf/Glossary.pdf>.

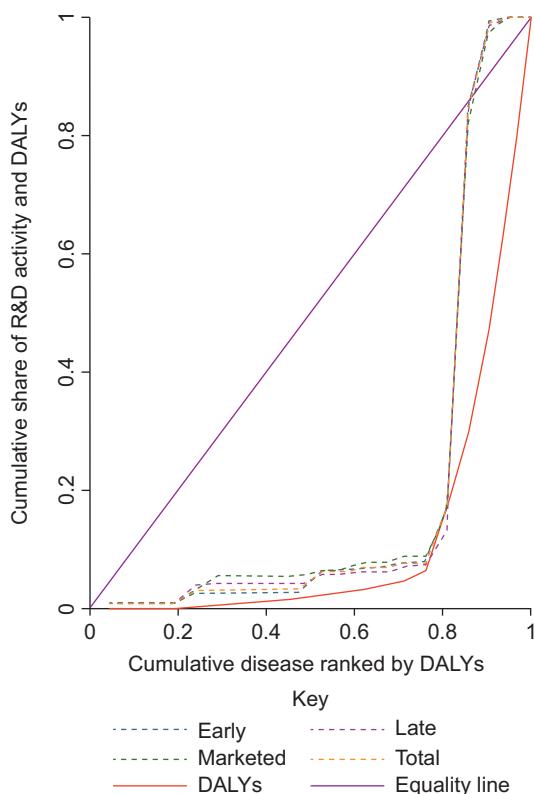


Fig. 3.10.8 Low-burden diseases receive more than their fair share of R&D
 DALYs: disability-adjusted life-years; R&D: research and development.
Note: Authors' analyses.

Sources: DALYs data from IHME (2019); R&D data from IQVIA (2019).

diseases at the top of the distribution of DALYs there is a disproportionate concentration of innovation in low-burden diseases, meaning that low-burden diseases receive more than the fair share of R&D activity when we consider their need relative to other diseases (inequity pro-low burden). This inequity is even more pronounced once we consider market launches in LMICs where we see low-burden diseases experience more market launches than their relative need would warrant when compared to high burden diseases (Fig. 3.10.9).

These inequities can be attributed to inequalities in the distribution of R&D funding across neglected diseases and/or the fact that most

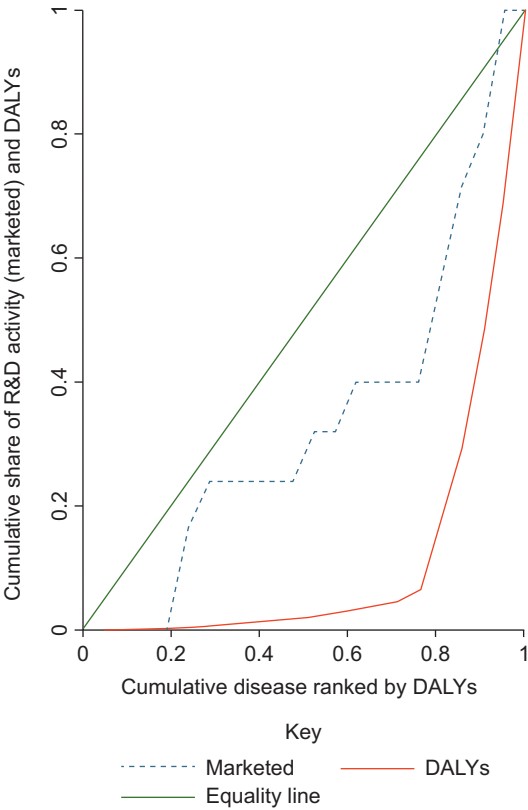


Fig. 3.10.9 LMICs receive few market launches for new pharmaceutical products

DALYs: disability-adjusted life-years; R&D: research and development.

Note: Authors' analyses.

Sources: DALYs data from IHME (2019); R&D data from IQVIA (2019).

LMICs lack the resources and research infrastructure to develop their own medicines (Mrazek & Mossialos, 2003).

The 10 neglected diseases that received the highest R&D investment in US dollars between 2007 and 2019 for new products and technologies to address challenges in public health are shown in Fig. 3.10.10. HIV/AIDS received the highest investment by about US\$ 16.9 billion, followed by malaria and TB, with US\$ 7.9 billion and US\$ 7.8 billion, respectively. Mycetoma, leptospirosis and hepatitis B received the

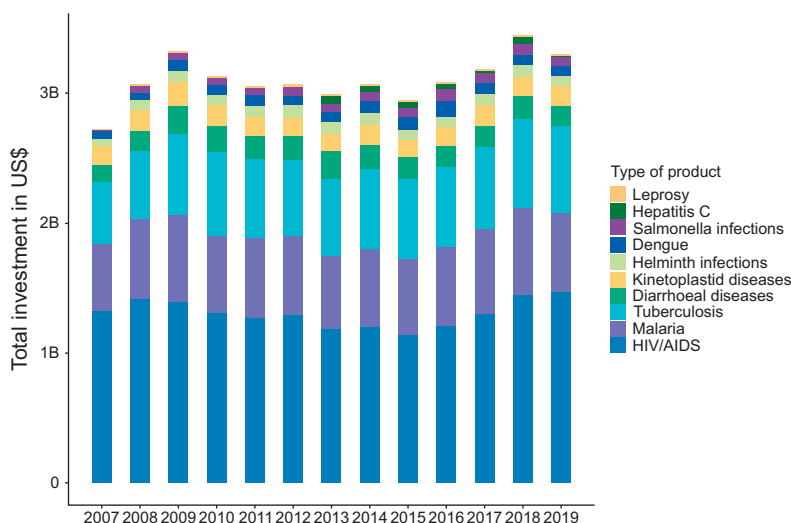


Fig. 3.10.10 HIV/AIDS, malaria and TB receive most investment
B: billion.

Note: Authors' analyses

Data source: Policy Cures Research (2021b).

lowest investment, which cumulatively in the last five years (2015 to 2019), was around US\$ 1.5 million, US\$ 9.3 million and US\$ 16.5 million, respectively (Policy Cures Research, 2021a).

Between 2015 and 2018 the cumulative spending has seen a steady increase, albeit remaining concentrated on HIV/AIDS, malaria and TB. Looking at global spending for R&D activity for neglected diseases, we observe a disproportionate concentration on low-burden neglected diseases.

Fig. 3.10.11 (the concentration curve of global R&D activity (1980–2019) and DALYs in LMICs (2018–2019)) and Fig. 3.10.12 (the concentration curve of market launches in LMICs (1980–2019) and DALYs (2018–2019) in LMICs (2018–2019)) show that low-burden diseases receive more than their fair share of funding given their relative disease burden. With the exception of spending on regulatory, implementation, market and post-market launch activities, this inequity is more pronounced when one considers funding allocated only to LMICs.

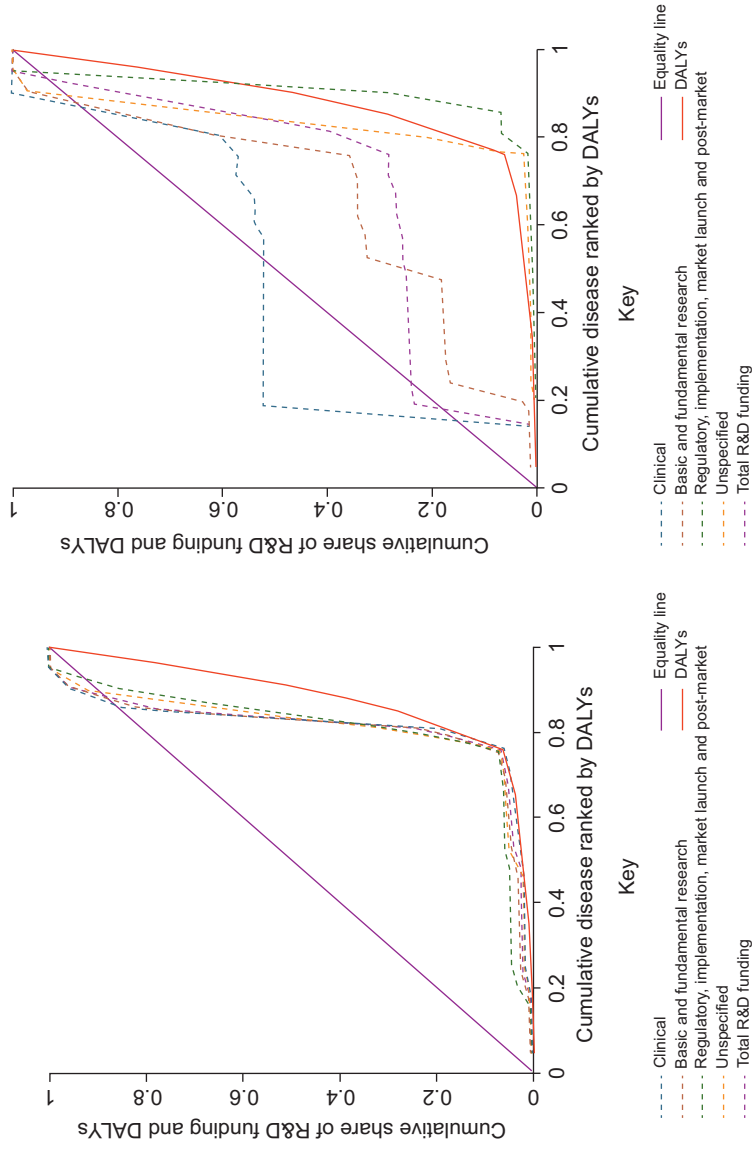


Fig. 3.10.11 and 3.10.12 Low-burden diseases received more than their fair share of funding

DALYs: disability-adjusted life-years R&D; research and development.

Note: Authors' analyses.

Sources: DALYs data from IHME (2019); R&D data from IQVIA (2019).

Reasons for inequities and inequalities

Several mechanisms may explain these inequities in innovation that impact differential access to treatment for neglected diseases to the detriment of health and well-being in LMICs. Concerns around pricing, affordability and the low potential for profit of those treatments in LMICs implies that firms have little incentive to develop innovations for these populations. This is aggravated by HICs giving priority to fund R&D for diseases that impact their own populations and the lack of international coordination in pooling and allocating resources to innovation taking account of health needs across all disease areas and geographies, as well as affordability.

These inequities are also intrinsically related to market failures and the effectiveness of mitigating strategies, including financing and incentive mechanisms.

Market failures in R&D: misalignment between private incentives and health need

There are several features of the R&D sector in the context of pharmaceutical innovation that are associated with market failures as a result of which the resource allocation for R&D efforts is not socially optimal (Arrow, 1962), thus justifying government intervention. Most notably there is imperfect appropriability, with significant knowledge spillovers implying that firms will not fully recoup the benefits of their investment in R&D (Henderson & Cockburn, 1996; Bloom, Schankerman & Van Reenen, 2013). Research shows social rates of return to R&D (i.e. returns to the innovator, benefits to other firms and to society) to be up to five times higher than private rates of return (Salter et al., 2000). These may lead to underinvestment (Romer, 1990), in particular in risky areas where prospects of profitability are uncertain, such as neglected diseases.

There is also information asymmetry between pharmaceutical firms and funders because several aspects of innovation and its processes are difficult to describe contractually and there are often no incentives for private firms to disclose them. Asymmetry of information between firms and funders typically leads funders to underinvest in R&D in the light of risk and uncertainty (Czarnitzki & Toole, 2007). This underinvestment may be more accentuated in markets with high levels of uncertainty such as those for neglected diseases. It also

disproportionately impacts firms that may lack the financial resources to self-fund their activities; thus, decreasing prospects of breakthrough innovation by smaller but innovation-agile firms that play a crucial role in neglected disease markets (BVGH & BIO, 2012). Small and medium-sized enterprises (SMEs) play an important role in the development of innovation for neglected diseases being engaged in 41% of drug and vaccine R&D activity (BVGH & BIO, 2012), but they face severe funding constraints and often bear the risks and uncertainty associated with therapy development.

Infectious diseases do not have borders, thus eradication and to some extent herd immunity is a public good, which implies that some countries will free-ride on others' efforts to invest in control and prevention measures. At an individual level there are externalities, implying that the social marginal benefits of infection control are higher than the marginal private benefits, leading to under provision of preventive and infectious control measures.

These factors, combined with the fact that pharmaceutical innovation is costly, lengthy and risky, result in firms focusing on markets that maximize the return on investment and therefore the level of innovation for neglected diseases is suboptimal.

These issues are often used as the rationale for intellectual property rights. Beyond the standard drawbacks of patent systems (e.g. costly patent races, incentives for incremental rather than breakthrough innovation, barriers to entry, pre-emptive patenting, etc.; see Gallini and Scotchmer (2002) for a review), patent systems bring additional challenges in the context of neglected diseases. Patents are associated with lack of affordability in low-income settings where neglected diseases are endemic. And importantly, since markets for neglected diseases are therefore small, the incentives inherent in patent systems are reduced in the context of these diseases.

As a result, market incentives reinforced through a patent system alone are insufficient to stimulate innovation for neglected diseases and should, therefore, be coupled with other incentive mechanisms. In particular, policies related to public and donor financing have an important role to play. These financing policies can aim to build research capacity through the direct funding of innovation, or they can be designed to steer R&D and ensure equity and affordability through the implementation of a set of incentive mechanisms that directly or indirectly affect investment in R&D.

Using incentive mechanisms to stimulate innovation for neglected diseases: an overview

The underlying principle behind these mechanisms is the “delinkage” of the cost of research from market profitability so that the incentive to enter the market is not (or is less) contingent on the ability to charge high prices and recover costs through sales. Push mechanisms reduce upfront costs inherent to R&D activities by subsidizing R&D activities prior to product discoveries (i.e. *ex ante*). Pull mechanisms, on the contrary, offer a reward contingent on successful product discoveries (i.e. *ex post*). Hybrid mechanisms combine pull and push incentives.

Push mechanisms work better in settings where developers are capital constrained and risk averse. By subsidizing R&D costs push mechanisms also stimulate competition in innovation by enabling small companies and start-ups that lack capital to develop R&D activities. However, when effort is difficult to monitor and contracts are incomplete with research outcomes not contractable, push incentives lead to moral hazard, resulting in suboptimal levels and scope of innovation (Kremer, 2002).

Adverse selection may also arise. Payers have little insight into the relative chances of success of different R&D targets and the effort exerted in each project. Therefore, push mechanisms may incentivize projects with small chances of success (Kremer, 2002).

Under pull incentives, on the other hand, the risk lies with the innovator, with incentives accruing only when innovation occurs and targets key public health priorities. Innovators are better informed about the risk of investment but also, bearing the risk of development, have a strong incentive to prioritize projects with a higher chance of success and better prospects of social and financial impact. If public health needs are well defined, these pull mechanisms enable the funder to direct incentives to key priority areas as the reward is attributed after the innovation has occurred.

However, these mechanisms benefit larger companies that can leverage capital for R&D. Smaller firms (e.g. biotech companies) that are capital constrained and more risk averse are less likely to benefit from pull incentives. This is particularly relevant in markets where the prospects of profitability are weak or uncertain such as in the case of neglected diseases.

The extent to which push and pull incentives are effective also depends on the stage of the R&D process they target, given that the costs and risk vary considerably during the R&D process.

Pull incentives require the desired innovation to be specified in advance, so are less likely to encourage basic and fundamental research (Moran et al., 2005; Grace & Kyle, 2009). Push mechanisms, on the contrary, incentivize R&D by decreasing the marginal cost of development and/or by ensuring access to key research inputs through collaboration with key stakeholders, thus favouring the invention phase of the R&D process when compared to pull. The facilitated collaboration with other stakeholders that is inherent to some forms of push mechanism (e.g. public-private partnerships) implies that they are also useful in supporting advanced stages of the R&D process, including regulatory hurdles and market launch.

The effectiveness of pull and push incentives is also likely to vary depending on the type of technology. Drug therapies that target treatment or management of chronic conditions offer a broader prospect for recouping R&D investments than prevention therapies or vaccines. Therapies and vaccines that target larger markets with high willingness and ability to pay for therapies (e.g. HIV) are less risky than smaller markets (e.g. schistosomiasis). Therapeutic areas also differ on scientific challenges and development times and costs. One could expect incentive mechanisms that enable collaboration among different stakeholders with different expertise and inputs to therefore perform better in areas where it is scientifically more challenging to innovate than those mechanisms that bring only R&D subsidization.

In what follows we present an overview of the main types of push and pull incentives. A full discussion of the advantages and disadvantages can be found in Table 3.10.2. Note that, in addition to push and pull mechanisms, pool mechanisms can be seen as indirect mechanisms to incentivize R&D. In pool mechanisms intellectual property and knowledge is “pooled” to enable collaboration in research, technology and knowledge sharing to fast-track R&D (Gold et al., 2007). While these mechanisms relate to intellectual property and knowledge sharing rather than financing mechanisms, they have the potential to substantially decrease the costs and thus incentivize innovation. AMCs, one of the pull mechanisms discussed below, also involves pooling, but in terms of purchasing, rather than intellectual property and knowledge.

Table 3.10.2 Advantages and disadvantages of incentive mechanisms for innovation and access to innovation

Type	Mechanism	Commitment timing	Payment timing	Mechanism focus	Monitoring challenges	Intellectual property appropriability	Incentives for access	Disease focus (general versus targeted/scope for innovation)	Time inconsistency	Risks sharing (borne mostly by funder, by developer, shared)	Knowledge sharing/pooling of expertise
Push	Research grants	Pre- and during innovation	Pre-innovation	Advance lump sum funding (despite the grant where some may cover initial R&D costs while others may not)	Funders are unable to perfectly monitor the use of the funds. Moral hazard and misdirection of resources towards other activities is possible	Retained by: Originator/less desirable if price conditions	Pricing or access conditions are not met. If price/benefit may neither enable nor hinder access	Can be general but can also target investment towards specific areas of huge social benefits, if funder specifies conditions of award around breakthrough innovation, otherwise firms can apply for grants with any project so long as private marginal cost is covered	Not an issue since grant is not contingent on successful innovation	Mostly borne by funders since grants are awarded on the premise of a potential product, not on an actual delivery	Both possible if multiple partners involved in funding and on a precondition for award
	PPPs (PDAs)	Pre- and during innovation	Pre-innovation since funding is provided to alleviate capital constraints	Funding from public or philanthropic donors (covers upfront R&D costs)	Significant monitoring challenges due to large information asymmetries between funders and developers	Varies. IP and pricing conditions may be set	High (variable) IP arrangements but most set price or accessibility conditions	Both possible: funding by government tends to have unrestrictive use while private funding tends to be restricted, although better prioritization of neglected diseases since collaborative agreements are normally independent of market size	Not an issue since funding is not contingent on successful innovation	Borne by funder i.e. public sector bears most of the financial risk	High between collaborating partners, reduces duplication of efforts and increases scale and scope of activities
	Fiscal incentives	All stages of innovation	All stages of innovation	Tax credits, tax exemptions, tax deductions, tax allowances, e.g. depreciation allowances once realized (covers R&D costs)	Vary across mechanisms. When inputs are rewarded monitoring is difficult if firms use incentives to increase claims. If incentives are pre-innovation, monitoring may be difficult	Retained by: Originator but IP and price conditions may be set for selected markets	Ultimately depends on whether there is pass-through of tax credits onto consumers. Do not generally ensure provisions ensuring accessibility or affordability but in some cases may require companies to donate licenses to foreign government or not-for-profit entity (see NTDs, HR 3136)	Can target specific disease area or groups of diseases/R&D targets normally at the discretion of private developers and may be misaligned with social priorities	Limited scope for time-inconsistency issue since incentives are applicable for actual product development	Shared between developer and funder. The extent to which risk is shared varies by specific fiscal incentives, the timing of the incentives and the R&D process and the financial value of the incentive. Fiscal incentives on NTDs tend to reduce expenses on early R&D activities and therefore risk sharing of the developer of costs sharing	Some mechanism (e.g. tax credits) require dominating licenses to not-for-profit entities enabling knowledge sharing/target different types of incentives allowing pooling from diversified sources of knowledge and expertise, including small firms for whom financial incentives may be crucial for survival in the market
Pull	Transferable Patent Extensions	Pre-innovation	Post-innovation	Reward (ring fences revenues)	Generally irrelevant but rent-seeking behaviour may occur if qualification criteria for an extension are incomplete and non-specific	Retained by: Originator	Hinders access if innovator applies extension to another blockbuster drug, can limit generic entry of that drug and limit its access and affordability	Targeted towards innovation in critically needed but less profitable areas/High	Not an issue since there is no commitment of pre-innovation	Borne by the developer since no upfront funding is involved	Does not enable knowledge sharing/Low since collaboration between different firms is unlikely

Priority review vouchers	Pre-innovation	Post-innovation	Reward (ring-fences revenues)	Irrelevant since voucher is granted conditional on the innovation of ND-specific drugs	Retained by: Originator	Early market entry in high-income countries. Market based nature of the scheme, however, depends on firms' pricing strategies, and the government must ensure access to deprived populations where neglected disease may be endemic	Targeted at key areas of need/High since PRV will be used for drugs with highest expected return for society	Limited scope for time inconsistency since PRVs are rewarded post-innovation	Borne by the developer since voucher is conditional on innovation for a specific neglected disease being delivered	Low
Advanced market commitments	Pre-innovation	Post-innovation	Reward (ring-fences revenues)	Irrelevant since buyer commits to purchase only upon successful innovation	Retained by: Originator	High (award conditional on negotiated low prices) – attempts to provide short and long-term incentives to firms in low-income countries but depends on complexity of intervention and facility to scale up production	Targeted/reward output rather than input so less prone to moral hazard allowing effort allocation to socially desired outcome	Time-inconsistency problems can occur in that the government may not comply with commitment ex post	Developer bears risk entirely during development phase. Post development though there is no commitment by payers mitigating risk for developers	Low since scheme fosters more competition – several companies compete simultaneously to develop the product faster
Prizes	Pre-innovation	Post-innovation	Reward (prize)	Irrelevant if prize awarded for finished product. However, if prize is awarded to encourage early-stage research, then monitoring of effort may be difficult	Variable: patent expropriation in some cases, in others IP is retained by originator	Low unless IP is expropriated	Targeting specific diseases/High	Time-inconsistency problem with uncertainty on whether government commits to agreed size of reward post-innovation	Borne by the developer since prize awarded is fixed and awarded only upon successful innovation	Low scope of collaboration due to the “winner takes it all” nature of the scheme
Patent buyouts (proposal)	During and post-innovation	Post-innovation	Reward in the form of a prize or premium paid by the government	Generally irrelevant since reward is contingent on successful innovation	Government can acquire patent directly from the innovator and place it in the public domain in exchange for a payment	If patent is bought, it is proposed to be made available publicly so it enables lower prices and increases access to innovation once bought out	Targeted/encourages sequential and complementary innovation if the government buys the patent and places it in the public domain, then need for contracting or licensing	Limited scope for time inconsistency since there is no commitment pre-innovation	Developer bears complete risk of innovation in the development phase	High since the patent is placed in the public domain

IP: intellectual property; ND: neglected disease; NTD: neglected tropical disease; PPP: public–public partnership; PRV: priority review voucher; R&D: research and development.

Source: Authors.

Push mechanisms

Product development partnerships (PDPs)

PDPs are the most common type of public–private partnerships for neglected diseases (Aerts et al., 2017; Widdus, 2005). PDPs may exist as voluntary collaborations between private companies and public funders, but may also involve contract-based stakeholders such as academic centres that provide scientific expertise in drug development (Moran, 2005; Moran et al., 2005; Widdus, 2005). More recently, along with public and private partners (e.g. academia, public funding organizations and pharmaceutical companies) PDPs, and public–private partnerships more broadly, include diverse stakeholders such as regulators, insurers and patient organizations (de Vruhm, de Vlieger & Crommelin, 2019).

In 2017, there were around two dozen PDPs for neglected diseases, most created around 2000 (Borrás, 2017), with most focusing on malaria, HIV/AIDS and tuberculosis (TB). Notable examples are shown in Table 3.10.3 (Munoz et al., 2015; Borrás, 2017).

While focusing on all R&D stages, PDPs are particularly relevant in incentivizing early-stage innovation when firms may not have easy access to capital (Grace & Kyle, 2009) by financing the large upfront R&D cost through public or private funding, or a combination of both (Chapman et al., 2020; Sloan & Hsieh, 2017).

External financing (mainly through the public sector and multiple philanthropic organizations) and amounting to 16% of total “external” R&D funding for neglected diseases (Chapman et al., 2020) reduces the cost of failure for collaborating partners by sharing the risk of failure early on between them, thus incentivizing private R&D (Moran et al., 2005; WHO, 2013). In exchange for funding and research inputs, the developer commits to invest in less profitable products at early R&D stages of basic research and to a reduction in eventual profits. The public sector contributes to the development and/or clinical trial stages that require most of the investment (Moran, 2005). In most cases, PDPs channel funding through pharma partners, who own the rights to the product. In return for those rights, the partner commits to ensuring global access to the product at a reasonable price for those in developing countries (NBR, 2014). Notably in some product development schemes intellectual property rights (IPR) are owned by the partnership, so enabling some pricing control once the innovation is developed and thus promoting affordability and access (Buse

Table 3.10.3 *PDPs have increased overall investment in R&D and innovation for neglected diseases*

Name of PDP	About/purpose of PDP	Funding amount	Stakeholders involved	Disease focus	Type of technology	Targeted R&D stage	Intellectual property rights implications
Drugs for Neglected Disease Initiative (DNDi)	Collaborative PDP Non-profit R&D organization established in 2003 to fund and manage R&D development for medicines across over 200 partners. DNDi has already delivered eight field adapted and affordable treatments for five deadly diseases, and aims to have delivered 25 new treatments by 2028	€615.5 million (raised by end of 2019). Funding source: 57% public 43% private	Founding partners: WHO TDR, MSF, Malaysian Ministry of Health, Kenya Medical Research Institute, Indian Council of Medical Research, Oswaldo Cruz Foundation and Institute Pasteur. Donors: 1.Public: Australian Trade and Investment Commission, United Kingdom Department of Health and Social Care, Dutch Ministry of Foreign Affairs, French Development Agency, GIZ, European Commission, etc. 2.Private: BMGF, MSF, Takeda pharmaceuticals, Wellcome Trust, etc.	Visceral Leishmaniasis, Human African trypanosomiasis (sleeping sickness), Chagas, paediatric HIV, filarial infections, mycetoma and hepatitis C	Treatment (drugs)	Drug discovery, translational research, clinical trials and registration and access	Variable per drug DNDi adheres to basic principles stated in its intellectual property rights policy. The overarching theme is that it will ensure that the results of the work carried out under its auspices are disseminated as widely as possible and its products made readily available and affordable in developing countries

Table 3.10.3 (cont.)

Name of PDP	About/purpose of PDP	Funding amount	Stakeholders involved	Disease focus	Type of technology	Targeted R&D stage	Intellectual property rights implications
Medicines for Malaria Venture (MMV)	Collaborative PDP Non-profit product development partnership established in 1999 to fund and manage R&D development and access to antimalarial medicines across around 400 partners in 50 countries (donors and clinical centres in endemic countries)	US\$ 350 million (raised by the end of 2018) Funding source: More than 60% private	Founding partners: Launched with initial seed finance of US\$ 4 million from Government of Switzerland, United Kingdom Department for International Development, the Government of the Netherlands, the World Bank and The Rockefeller Foundation. Clinical centre partners: 50 clinical trial sites in sub-Saharan Africa, South-East Asia and South America. Donors:	Malaria	Treatment (drugs)	Drug discovery, translational research, clinical trials and registration and access	MMV retains rights to any Intellectual property rights that is essential in allowing them to develop and launch drugs for the benefit of MMV target group. Principles include: exclusivity, royalty-free, transferable Intellectual property rights

MMV has validated more than 19 new malaria drug targets since 1999	1.Public: United States government (USAID, NIH), Australian Government Development of Foreign Affairs and Trade, United Kingdom Government (DFID and DoH), Netherlands Ministry for Development Cooperation, etc. 2.Private: BMGF, Wellcome Trust, GSK, Sanofi, etc.						
TB Alliance	Collaborative PDP Non-profit product development partnership of around 38 partners established in 2000 to fund and manage R&D development and access to TB medicines.	Around US \$ 184 million (raised by end of 2019)	Founding partners: Launched with issuance of Cape Town Declaration by around 28 partners including BMGF, European Commission, MSF, WHO, World Bank, Wellcome Trust, etc. Donors: 1.Public: Australian Aid, United Kingdom FCDO & MRC, USAID,	Tuberculosis	Treatment (drugs)	Drug discovery, translational research, clinical trials and registration and access	TB Alliance's mission includes an explicit commitment to "AAA Mandate" – that all new products will be adopted, available and affordable to those with TB.

Table 3.10.3 (cont.)

Name of PDP	About/purpose of PDP	Funding amount	Stakeholders involved	Disease focus	Type of technology	Targeted R&D stage	Intellectual property rights implications
	TB Alliance has more than 30 projects of medical products in the pipeline		Germany Federal Ministry of Education and Research, Netherlands Ministry of Foreign Affairs, Ministry of Foreign Affairs (Republic of Korea), etc. 2.Private: BMGF, The Rockefeller Foundation, EDCTP, Global Health Innovative Technology Fund (Japan), UNITAID, etc.				No further information on Intellectual property rights implications

BMGF: Bill & Melinda Gates Foundation; DFID: Department for International Development; DNDi: Drugs for Neglected Disease Initiative; DoH: Department of Health; EDCTP: European and Developing Countries Clinical Trials Partnership; FCDO: Foreign, Commonwealth and Development Office; GLZ: German International Cooperation Society; MMV: Medicines for Malaria Venture; MRC: Medical Research Council; MSF: Médecins sans Frontières; NIH: US National Institute of Health; PDP: product development partnership; TB: tuberculosis; TDR: Special Programme for Research and Training in Tropical Diseases; WHO: World Health Organization.

Sources: DNDi (2004; 2019a; 2019b; 2023); MMV (2018; 2023a; 2023b; 2023c; 2023d); TB Alliance (2019; 2020; 2023).

& Walt, 2000). Box 3.10.1 provides a case study of a PDP and Table 3.10.3 provides selected examples to show PDPs' common features and differences with regard to IPR.

Box 3.10.1 PDP case study: Medicines for Malaria Venture and Coartem

Who are Medicines for Malaria Venture (MMV)?

A collaborative non-profit product development partnership established in 1999 to fund and manage R&D and access to antimalarial medicines for 400 partners in 50 countries. This includes clinical centres in endemic countries across sub-Saharan Africa, South-East Asia and South America. The mission of MMV is to support specific, targeted interventions to reduce the burden of malaria in disease-endemic countries by discovering, developing and facilitating the delivery of new, effective and affordable anti-malarial drugs.

Funding

US\$ 350 million, funding source more than 60% private.

How does the PDP model work?

With financial support from donors including government agencies, private foundations, international organizations, corporations, corporate foundations and private individuals, MMV operates a virtual R&D model bringing together partners from academia and the public and private sectors and uses funds to establish a portfolio of R&D projects for developing antimalarial medicines.

The PDP does not itself have the capacity or infrastructure to undertake early-stage development projects in-house; instead, it relies on its partners for financing and other in-kind contributions (i.e. laboratories and expertise) and then allocates resources to the most promising projects, coordinates partner activities for various stages of the R&D process and manages the project portfolio. The PDP acts as a facilitator, bringing dedicated sources of funding and know-how to committed researchers so they can collaborate on the right projects to fulfil the objectives of the PDP's mission.

Box 3.10.1 (cont.)**IPR and access**

When MMV enters into contractual relationships with partners, they encourage partners to work with them to guarantee that malaria drugs that they develop and launch will be accessible to those most in need in malaria endemic countries. This means ensuring first and foremost that agreements made within the PDP meet this public health mission. MMV negotiates for new medicines to be made available at an affordable price – typically with no profit and no loss – through public sector channels.

To achieve this, MMV must retain the rights to any intellectual property arising from the R&D undertaken by their partners. This is essential in allowing them to develop and launch drugs for the benefit of target patient groups. The following principles are applicable to all MMV contracts.

Exclusivity: If MMV does not own the necessary IPR outright, it insists on being granted an exclusive licence to use the “programme intellectual property rights” and any necessary “background intellectual property rights” to develop a drug for malaria and bring it to market. That licence must be worldwide, to ensure maximum flexibility for later-stage activities such as manufacturing and distribution.

Royalty-free: Any such licenses are preferably royalty-free, at least in malaria endemic countries, to help keep costs to a minimum and ensure that the drug will be sold at the lowest price possible in these countries.

Transferable: MMV does not conduct any R&D in-house or any manufacturing and, therefore, requires IPR that can be transferred to other partners – especially manufacturing partners – if necessary.

Portfolio

MMV and partners manage a portfolio of over 65 projects, the largest portfolio of antimalarial R&D and access projects ever assembled. The 2021 portfolio includes 11 compounds in clinical development addressing unmet medical needs in malaria, including medicines for children, pregnant women and relapsing malaria and drugs that could support the elimination/eradication agenda.

Box 3.10.1 (cont.)**Notable successful products – Coartem Dispersible**

Coartem is an antimalarial paediatric formulation that was developed by Novartis and gained approval by securing a United States Food & Drug Administration (FDA) priority review voucher (“fast-track voucher”) in 2009. It is approved in over 80 countries and by several regulatory agencies in Africa, Swissmedic and the EMA, and it is the only artemisinin-based combination therapy which has been approved by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use regulatory authorities. The Coartem combination of artemether and lumefantrine reduces the risk of resistance developing to either agent, and is therefore useful for the treatment of chloroquine-resistant *Plasmodium falciparum* cases.

Despite the wide proliferation of public–private partnerships in recent years, in particular those focused on product development, a systematic review by Aerts et al. (2017) did not find a single impact evaluation related to them, barring one analysis that compared the cost–effectiveness of the PDP model against AMCs and a hybrid scheme (PDP until phase II trials, followed by AMCs later) in the context of immunizations for malaria. While costs were lowest for the PDP scheme, DALYs averted were also the lowest, rendering PDPs a non-cost-effective approach. Most descriptive evidence, however, suggests that PDPs have led to a substantial increase in investment in R&D and innovation for neglected diseases. Between 2009 and 2013, 57% of new approvals in WHO’s list of essential medicines were developed through PDPs. PDPs have been particularly successful in vaccine development, with more than 400 PDP-led vaccines under development (Breitstein & Spigelman, 2013); and over half of the vaccines for neglected diseases during the period 2009 to 2013 resulting from PDPs (Cohen, Sturgeon & Cohen, 2014). Despite these promising results, impact evaluations are seriously lacking and consistent data collection and availability of data to analyse cost–effectiveness of PDPs are necessary.

R&D grants and subsidies

Grants and subsidies are normally in-advance lump sums awarded to fund R&D. They tend to focus on key priority areas identified by funders and cover the initiation of discovery or early stage research. Grants and subsidies constitute the main means to fund R&D adopted by public funders and third parties, contributing to 77% of total R&D funding for neglected diseases (Chapman et al., 2020). They specifically focus on early basic research, preclinical and clinical development stages, but tend to cover a wide range of neglected diseases (WIPO, 2014) and are primarily provided by public and philanthropic sources. This includes, for example, governments that allocate a proportion of their gross domestic product (GDP) such as the USA through the United States National Institute of Health and USAID, or the United Kingdom through the Department for International Development (DFID)³ and Medical Research Council (MRC), as well as philanthropic organizations such as the Bill & Melinda Gates Foundation (BMGF) and the Wellcome Trust (Chapman et al., 2016). Grant funds are channelled either directly to researchers and developers or through a conduit (20% of research grants) such as public-private partnerships/PDPs with some private sector participation (Pugatch Consilium, 2017), or through non-PDP intermediaries such as the Global Health Innovative Technology Fund (GHIT) and the European and Developing Countries Clinical Trial Partnership. Non-PDP intermediaries generally have a broader funding base than PDPs, supported by science and technology organizations, aid agencies and philanthropic foundations, making them less vulnerable to changes from one donor funding stream (Table 3.10.4).

Evidence of the impact of grants and subsidies on neglected disease-specific R&D is lacking. However, general pharmaceutical industry research suggests that grants and subsidies have a positive effect on R&D investment, and the innovation of new molecules and patent applications (Toole, 2012; Azoulay et al., 2019; Kourouklis, 2021). These effects vary across different stages of drug development – in the case of orphan drugs, they are most pronounced in phase I and phase II of the drug development process (Kourouklis, 2021).

³ Following a merger in 2020, DFID is now the Foreign, Commonwealth & Development Office (FCDO) in the UK.

Table 3.10.4 *Selected examples of grants intermediaries*

Name of intermediary	About/purpose of intermediary	Funding amount	Stakeholders involved	Disease focus	Type of technology	Targeted R&D stage	Intellectual property rights approach
Global Health Innovative Technology Fund (GHIT)	GHIT fund is a general incorporated association in Japan (PPP), founded in 2012 to facilitate and invest in global partnerships (including PDPs) for the discovery and development of new health technology for infectious diseases prevalent in developing countries	More than US \$ 260 million invested at the time of writing	Japanese Government, BMGF and 6 Japanese pharmaceutical companies, and foundations such as the BMGF and Wellcome Trust	Malaria, TB and the 17 WHO defined NTDs	Drugs, vaccines and diagnostics	Discovery, preclinical and clinical stages and registration	Supports open access innovations through its access policy. When product development partners and/or participants are successfully granted a patent deriving from projects invested by the GHIT Fund, product development partners and/or participants will grant royalty-free licenses to users operating in least developed countries as categorized by the United Nations classification and low-income countries categorized by the World Bank classification

Table 3.10.4 (cont.)

Name of intermediary	About/purpose of intermediary	Funding amount	Stakeholders involved	Disease focus	Type of technology	Targeted R&D stage	Intellectual property rights approach
European and Developing Countries Clinical Trials Partnership (EDCTP 1 &2)	EDCTP is an EU funded PPP established in 2014 between countries in Europe and sub-Saharan Africa to enhance research capacity, collaboration and accelerate the development of new or improved medical interventions for the identification, treatment and prevention of poverty-related infectious diseases.	Total fund around € 752.7 million at the time of writing	14 European and 16 sub-Saharan African countries, supported by the European Union, third parties and participating states	TB, HIV, malaria, diarrhoeal diseases, lower respiratory tract infections, other neglected infectious diseases, including emerging and re-emerging infections of particular relevance in sub-Saharan Africa	Drugs, vaccines and diagnostics	Phase I to IV clinical trials, with an emphasis on phase II and III trials and access (product focused implementation research). EDCTP also funds capacity development and international networking	No specific information on Intellectual property rights implications was detected
	EDCTP 1 (2003–2015).						
	EDCTP 2 (2014–2024)						

BMGF: Bill & Melinda Gates Foundation; EDCTP: European and Developing Countries Clinical Trials Partnership; EU: European Union; GHIT: Global Health Innovative Technology Fund; NTDs: neglected tropical disease; PDPs: product development partnership; PPP: public–public partnership; TB: tuberculosis; WHO: World Health Organization.

Sources: GHIT (2013; 2022; 2023a; 2023b), EDCTP (2020; 2022a; 2022b; 2022c).

Fiscal incentives

Fiscal incentives focus on reducing the cost of R&D, raising the long-term rate of return on R&D investments, and include: tax exemptions, tax deferrals, tax allowances and tax credits (OECD, 2016).⁴ Some apply to current expenditures, others to capital or revenues. Tax allowance, exemption and deduction consist of reducing the taxable amount by reducing the tax base before the tax liability is computed. With tax credits, in contrast, the tax liability is reduced by subtracting the credit after the liability has been determined. Tax deferrals do not reduce tax liability but defer tax payment. These incentives can be used to target single firms or foster collaboration across firms, with some schemes designed to support SMEs, and they can also be used to target a specific disease area or groups of diseases.

In practice, fiscal incentives for neglected diseases are mostly in the form of tax credits, exemptions and reliefs. Although the R&D phases targeted by fiscal incentives may vary across initiatives, tax incentives for neglected disease R&D have often been considered for encouraging basic and non-clinical research for vaccines or medicinal products (Rao, 2011). By reducing the R&D cost, these incentives encourage innovation in areas of high risk and smaller returns on investment – such as neglected diseases. These particularly benefit SMEs that, while financially constrained, are often agile and innovative in neglected disease innovation (BVGH & BIO, 2012), thus increasing the prospects of breakthrough innovation.

There are two main tax incentive initiatives highlighted in literature (Monroe, Greenberg & Basey, 2015; Pugatch Consilium, 2017). These are the United States Neglected Disease Tax Credit Proposal (HR3156) which mandates a transfer of IPR, and the United Kingdom Vaccine Research Relief which is not necessarily limited to a neglected disease focus, but rather extends to orphan drugs and humanitarian driven innovations (Monroe, Greenberg & Basey, 2015; UK Government, 2016; US Congress, 2009a) (Table 3.10.5).

Given the reduced number of fiscal incentives for neglected diseases, their effectiveness in spurring research for neglected diseases is difficult to ascertain. Rao (2011) argues that tax credits in the United Kingdom did not attract new firms to invest in R&D for neglected diseases and alone

⁴ Most fiscal incentives implemented to date subsidize R&D costs and are therefore categorized as “push” incentives. However, fiscal incentives can also be used as “pull” incentive by applying to sales (Webber & Kremer, 2001).

Table 3.10.5 *Fiscal incentives' effectiveness in stimulating neglected disease research is unclear*

Fiscal incentive	About the scheme/incentive nature	Eligibility criteria/ disease focus	Targeted companies	Benefits claimed	Intellectual property rights implications
United Kingdom Vaccine Research Relief (VRR)	Proposed and introduced in 2003, implemented and expired in 2017. In the United Kingdom R&D tax credits were introduced for SMEs in 2000 and extended to large companies from 2002. This is normally done through SME scheme and Research and Development Expenditure Credits (RDEC) (non-neglected disease specific). VRR was introduced as an additional "top-up" relief for vaccines research. All companies may deduct a standard 100% of their R&D expenditure from their taxable income under SME scheme and RDEC. While VRR allows 50% deduction on top for eligible R&D expenditure	HIV/AIDS, TB and Malaria. Expenditures on activities ranging from identification of a chemical entity, or a potential vaccine through completion of Phase III clinical trials	All companies. Large companies claiming VRR can only use the deduction option; they cannot claim payable credits for VRR	Number of claims under the VRR scheme remained at about 10 a year with support claimed of less than £5 million each year between 2003–2004 and on average around £20 million each year in the period up to 2012–2013	No information detected on intellectual property rights implications

United States neglected disease tax credit proposal (HR 3156)	Proposed in 2009, no information detected on introduction or implementation. This proposal was put forward by the biotechnology company (“biotech”) Genzyme with the sponsorship of Representative Donald Payne and others”. 50% tax credit for non- clinical expenses for research on neglected disease treatments	All NTDs (see Table 3.10.1) and any infectious disease with unmet need or disproportionately affecting the poor. Qualified research: Only preclinical or basic research. Companies could not use the credit for expenses incurred from clinical trials or regulatory review. This includes expenses for in-house or contracted research activities undertaken for the purpose of non-clinical basic research only. With this specific criteria of discovering information – which is (i) technological in	All companies. In-house or contracted research services	No information detected on implementation	Mandates a transfer of intellectual property rights and could only apply for the credit if they have donated a royalty-free licence to a foreign government or a non-profit research organization for the claimed research in that year

Table 3.10.5 (*cont.*)

Fiscal incentive	About the scheme/incentive nature	Eligibility criteria/ disease focus	Targeted companies	Benefits claimed	Intellectual property rights implications
		nature, and (ii) the application of which is intended to be useful in the devel- opment of a new or improved business component of the taxpayer			

NTD: neglected tropical disease; SME: small and medium-sized enterprise; TB: tuberculosis; VRR: Vaccine Research Relief.

Sources: US Congress (2009a; 2009b), UK Government (2016; 2020) and European Commission (2008).

are insufficient to increase R&D spending in global health. In contrast, the tax credits created in the Orphan Drug Act (P.L. 97–414) in 1983 have had a significant impact on orphan drug development, leading to 201 new orphan drugs in the market and this trend has been particularly strong in recent years; for example, 18 new drugs gained approval in 2014 (EY, 2015). Yin (2008) shows that the Orphan Drug Act-led income tax credit (equal to 50% of clinical trial expenses) increased the annual flow of clinical trials for drugs for rare diseases by 69%.

Pull mechanisms

Transferable patent extensions

Transferable patent extensions (TPEs) or wildcard patent extensions are a form of supply-side production response intended to encourage R&D for critically needed drugs in less attractive disease areas (Sonderholm, 2009). A successful innovator of a new drug is granted a one-time patent extension (ranging from six months to two years in the USA and five years in Europe) that can be applied to one of the innovator's other drugs or sold to another firm. Such an extension is worthwhile for companies with a drug in their portfolio whose patent is near to expiry, and provide a source of return on investment (Moran, 2005; Sonderholm, 2009; Seabury & Sood, 2017). These incentives can be particularly important for attracting companies to undertake R&D for neglected diseases because the return on investment in neglected disease markets remains insufficient due to limited market size and affordability (Seabury & Sood, 2017). Our review did not yield notable examples of TPEs granted for neglected diseases, but they have been proposed as a potential incentive in the context of developing new antimicrobials to tackle the problem of antimicrobial resistance (AMR) (Spellberg et al., 2007; Spellberg et al., 2008; Outtersson, Samora & Keller-Cuda, 2007). Within this context, Outtersson and McDonnell (2016) calculate the potential costs of a 12-month extension and conclude that such an extension would cost the USA's health system more than US\$ 4.8 billion, making such an extension extremely inefficient.

Patent buyouts

A patent buyout is an outcome-based pull mechanism aimed at delinking returns from price and volume-based sales by acquiring the patent

directly from the innovator in exchange for a payment (Batista et al., 2019). The government offers to buy the rights to the patent to encourage innovation and subsequently places the patent in the public domain for unrestricted access. The scheme may specify criteria *ex ante* to run a prize-like competition or may engage in *ex post* identification of a suitable patent candidate (Robinson, Ritchie & Kenny, 2020). Patent buyouts add a markup to private market valuations and internalize the social returns to innovation, which in the context of limited market size for neglected diseases, assures innovators a satisfactory return on investment. By abolishing private patent rights, it also fosters access to innovation through lower prices.

Despite the theoretical applicability of buyouts, there is a lack of real-world application and empirical evidence on its effectiveness in the context of neglected diseases. In the context of neglected diseases, patent buyouts have only been proposed within the Medical Innovation Prize Fund (S.2210) as an end-product prize (US Congress, 2007). Theoretical evidence on welfare effects concludes that buyouts rewarding innovators based on observed market outcomes are an effective tool to improve social welfare (Galasso, Mitchell & Virag, 2016; Radhakrishnan, 2016). Outterson (2006) argues that by recovering lost R&D costs, buyouts are a cost-effective method to improve access and health outcomes in LMICs. For example, the lost R&D cost recovery for GlaxoSmithKline's Cervarix human papillomavirus vaccine is as little as US\$ 29.2 million. Therefore, for a patent buyout that would cost as little as US\$ 30 million, the medicine could be immediately available for millions in LMICs in its generic form.

Priority review vouchers (PRVs)

The PRV scheme enables firms with drugs approved for certain tropical diseases to apply for a voucher that can be used to obtain priority review for an unrelated drug application, so shortening the regulatory agency review time from a standard average of 10 months to a maximum of 6 months (Ridley, Grabowski & Moe, 2006; Gaffney, Mezher & Brennan, 2019; Aerts et al., 2022). Alternatively, the firm can sell the voucher to another firm.

The innovator retains IPR and prices may be unaffordable if this mechanism is not complemented by differential (tier) pricing, donation or a drug access programme.

At the time of writing, PRV initiatives are primarily offered through the United States FDA's scheme (FDA, 2020). To be eligible, products need to satisfy certain criteria including: approval by the FDA or the EMA; recognition as a product for serious conditions where there is unmet medical need; adequate and well-controlled trials have established that the drug influences a surrogate end-point and there is clinical superiority to other existing therapies. PRVs mostly focus on late-stage clinical development, registration and post-marketing and delivery stages of the R&D model and are commonly awarded to drugs. For a potential blockbuster drug, the value of PRV has been estimated by some experts to be worth anywhere between US\$ 50 million to US\$ 500 million (Robertson et al., 2012). As of late 2018, seven PRVs had been awarded for neglected/tropical diseases – in malaria, tuberculosis, leishmaniasis, cholera, onchocerciasis (river blindness) and Chagas disease (US FDA, 2017; Cohen, 2018). Since then, the PRV programmes have expanded substantially, with many more vouchers issued across tropical disease, rare paediatric disease and medical countermeasure indications).

Notable examples include: Coartem, which is now a first-line treatment for malaria across Africa and South-East Asia; benznidazole indicated for Chagas disease (in use as early as the 1970s, approved by FDA in 2017); Krintafel, the first new antimalarial in over 18 years (approved in 2018); and Moxidectin, a treatment for onchocerciasis (approved in 2018) (MDGH, 2018; Cohen, 2018) (Table 3.10.6).

Evidence on the impact of PRVs on R&D is hampered by a lack of data; sample sizes are small due to the low number of vouchers issued. PRVs have been found to not significantly impact clinical trial activity for neglected tropical disease (Aerts et al., 2022; Jain et al., 2017) nor for rare paediatric conditions (Hwang et al., 2019) but have been found to increase the likelihood of initiation of large patient trials for paediatric rare disease (Hwang et al., 2019).

Advance market commitments (AMCs)

In AMCs the funder/donor commits to (fully or partially) subsidize the initial purchases of innovative medicines at an agreed price, for an established maximum threshold, to be provided to a specified set of countries. The subsidy is normally only triggered when countries purchase the innovation. The binding agreement is signed before the medicine is developed and contains a full specification of the desired product and use. They also often involve a commitment by the firm to

Table 3.10.6 PRVs' impact on R&D is unclear because of a lack of data

Drug name	Supplier(s)	Year PRV granted	Disease focus	How was the voucher redeemed/traded?	Approach to IPR transfer
Coartem (artemether/ lumefantrine)	Novartis	2008	Malaria	First PRV so market value of PRV was unknown. In 2011, Novartis redeemed the voucher on a BLA for Ilaris (canakinumab) to treat gouty arthritis. FDA declined the application	Innovator retains IPR
Benznidazole	Chemo Research	2017	Chagas		Innovator retains IPR
Krintafel	GSK	2018	<i>P. vivax</i> malaria		Innovator retains IPR
Moxidectin	Medicines Development for Global health	2018	Onchocerciasis (river blindness)	No information found or anonymously redeemed	Innovator retains IPR

BLA: biologics licence application; FDA: Food & Drug Administration; IPR: intellectual property rights; PRV: priority review voucher.

Sources: FDA (2008; 2017; 2018; 2020) and Wang (2018).

sell at an affordable price (close to marginal cost and below the AMC price) all quantities beyond the agreed subsidization threshold in the agreed countries (Levine, Kremer & Albright, 2005).

By “pooling” purchase commitments across many countries the scheme creates a profitable and less risky market for the developer by establishing volume guarantees. By pooling funding from several donors and negotiating a low price it enables LMICs to access the medicine. The risk is shared by the developer and the funder: while in the development phase costs are born entirely by the developer who still bears fully the risks associated with the scientific challenges of R&D, when innovation occurs the funder commits to a level of demand in participating countries, thus minimizing for the developer the risk associated with low demand and reduced affordability in LMICs (including international advocacy for low prices of novel treatments) (Berndt et al., 2007). For the funder/sponsor the scheme is beneficial as the financial commitment only occurs if a medicine with social value targeting key areas of need is developed and launched in the market.

AMC is intended to focus on clinical development, registration and post-marketing and delivery stages of the R&D model (Pugatch Consilium, 2017). At the time of writing, only two AMCs have been implemented. In 2007, BMGF initiated the first AMC pilot programme targeting the development of pneumococcal conjugate vaccine (PCV) (Gavi-run pilot Pneumococcal AMC) and in June 2020, Gavi launched the second AMC, COVID-19 Vaccines AMC (COVAX AMC) to accelerate access to 1.8 billion COVID-19 vaccine doses for 92 lower-income countries (Gavi, 2022). Price details of the most recent Gavi supply agreement are provided in Table 3.10.7.

With only two AMCs fully implemented, evidence is either descriptive due to a lack of appropriate counterfactuals or based on simulations. For the PCV AMC, Médecins sans Frontières (MSF) indicated that for over 12 years donors have granted more than US\$ 1 billion in subsidies to two vaccine producers, GSK and Pfizer (main producers of the vaccine in the market) (MSF, 2020). Although in principle both manufacturers were obliged to cut the price after a predetermined level of doses was sold, or to license their technology to other manufacturers, prices were only marginally reduced and the transfer of technological know-how was not adequate to expand the manufacturer base into LMICs (MSF, 2020). COVAX AMC has also gathered more than US \$ 6 billion in funds from governments, foundations and the private sector (WHO, 2021c). Further evidence suggests that the AMC for

Table 3.10.7 *Selected example of advanced market commitments*

Name	About/purpose of AMC	Funding amount	Stakeholders involved	Eligibility criteria and disease focus	How is AMC awarded?	Type of technology	Targeted R&D stage	IPR implications
PneumoAMC 2009	It was launched by donors in 2009 to accelerate the development of vaccines that meet country needs, scale production and accelerate vaccine uptake, while testing the AMC concept for future applications.	US\$ 1.5 billion to the Pneumococcal AMC (as of January 2021).	AMC donors: BMGF, Governments of Canada, Italy, Norway, the Russian Federation and United Kingdom. Vaccines rolled out in 45 countries across 3 continents by 2015. Manufacturers: GSK, Pfizer and SII	Pneumococcal disease Target product profile required to be prequalified by WHO.	The AMC is delivered through supply agreements with manufacturers where donors make a financial commitment through Gavi alliance to fully or partially finance the purchase of treatments meeting pre-established criteria at a specified price to be distributed on Gavi countries. Specific supply agreements are available on the Gavi Pneumo AMC.^a Latest AMC was awarded in June 2020 by UNICEF in its capacity as Gavi's procurement agency to SII for its recently WHO prequalified PCV10 product.	Vaccines	Focused mainly on late-stage R&D and launch	Innovator retains IPR

SII received an award of 10 million doses annually (Annual Supply Commitment) from 2020 for a period of 10 years, for a cumulative total of 100 million doses.

5% of the AMC funds are allocated to SII according to the AMC terms and conditions, representing US\$ 75 million. The Tail Price for this agreement is US\$ 2.00 per dose (for the 5-dose vial presentation) from 2020 onwards, a reduction of over 30% from the previous lowest Tail Price of US \$ 2.90 per dose

^a Gavi: Supply agreements, <https://www.gavi.org/investing-gavi/innovative-financing/pneumococcal-amc/manufacturers/supply-agreements>AMC: advance market commitment; BMGF: Bill & Melinda Gates Foundation; IPR: intellectual property rights; R&D: research and development; SII: Serum Institute of India. WHO: World Health Organization
Sources: Gavi (2020a; 2020b; 2021).

PCV has increased vaccination coverage across 60 countries immunizing over 49 million children and saving 14 to 17 million DALYs through to 2015 (Kremer, Levin & Snyder, 2020; BCG, 2015). Both the PCV AMC as well as a vaccine AMC for malaria, TB and HIV/AIDS have been shown to be cost-effective in modelling studies (Berndt et al., 2007; Tasslimi et al., 2011).

Prizes

Prizes are rewards for innovations that may focus either on the technical specifications of a product or on the desired outcomes it delivers. Prizes may adopt different models but essentially are a pay for performance scheme where the developer receives a lump sum amount if a certain innovation with social impact is achieved (Hollis, 2005a; 2005b; Love & Hubbard, 2007), with the risk borne by the developer. Prizes thus incentivize innovations where social marginal benefits outweigh (or are equal to) marginal costs of development, thus promoting an efficient allocation of innovation effort. Some propose that this mechanism be voluntary, and complement the patent system by imposing structure on market rewards defined on the basis of incremental benefits (Hollis, 2005a; Pogge, 2005); for example, the Health Impact Fund prize scheme proposed by Hollis and Pogge (2008). Others recommend that such schemes be compulsory, with companies forgoing IPR so the developed drug could be made available globally, i.e. also in economically deprived populations (Love & Hubbard, 2009; Syed, 2009; Shavell & Van Ypersele, 1999).

In the context of neglected diseases, prize schemes have mostly been used to reward innovation in relation to a specific disease; however, there have been some schemes that encompass any innovation for neglected diseases (Pugatch Consilium, 2017).

To date, only five of the 11 prize schemes in health targeted neglected diseases (Monroe, Greenberg & Basey, 2015; Pugatch Consilium, 2017), including the Qualcomm Tricorder XPRIZE (run by the XPRIZE Foundation and sponsored by the Qualcomm Foundation), the Health Impact Fund, the EU vaccine prize led by the European Research Council, the Longitude Prize led by Nesta (a United Kingdom innovation foundation) and a combined initiative proposed by Bangladesh, Barbados, Bolivia and Suriname. With a combined funding purse of roughly US\$ 130 million, these prizes mostly focus on basic

R&D research, preclinical development and post-marketing and delivery stages of the R&D model. Disease fields included treatments for TB, AMR and vaccine cold chain development, with some prizes allowing companies to maintain IPR and others replacing IPR rights with respective prize awards (Table 3.10.8).

Different prize schemes focusing on specific disease areas and sometimes on unmet needs have spurred innovative activity in early stages of R&D. For instance, the Gotham Prize for Cancer research has led to the development of novel approaches to treat cancer (Bernstein, 2008). Similarly, the Dr Paul Janssen Award, aimed at solving unmet medical needs and rewarding scientists for basic or clinical research, has advanced innovation in the treatment of rare diseases such as mosaicism (Johnson & Johnson, 2020). The Prize4Life organization has accelerated discovery of treatment of amyotrophic lateral sclerosis (ALS) through its ALS Prediction Prize scheme (Leone, 2012). While such awards have increased early-stage discovery in critical areas as described above, systematic evidence on the impact of prizes on stimulating R&D for neglected diseases is virtually non-existent.

Policy relevance and conclusions

Since the early 2000s there has been a considerable amount of effort to tackle the global burden associated with neglected diseases by fostering innovation in safe, effective and affordable medicines and prevention. To stimulate R&D investment a complex range of innovative financing mechanisms have been proposed, with most of the funding provided by public, philanthropic and private industry sources. Over the course of the last decade total R&D funding grew by 14%, rising from US\$ 3 410 billion in 2010 to US\$ 3 876 billion in 2019 (Chapman et al., 2020). And although progress has been made, control of neglected diseases is still largely inadequate and extremely difficult to monitor or evaluate. There is little evidence on the effectiveness of the current mix of innovative financing mechanisms, either at the individual or the collective level.

At the disaggregated level the prospect for effective delinkage of R&D from market considerations varies across schemes and specificities of initiatives (in particular, schemes that only partly fund R&D costs only enable partial delinkage; for example, in the case of prizes it can be difficult to measure the expected effects of a registered health product in order to estimate a suitable prize amount). The heterogeneity and lack

Table 3.10.8 Selected examples of prizes

Name	About/purpose of prize	Prize amount	Stakeholders involved	Eligibility criteria and disease focus	How is prize awarded?	Who was awarded?	Type of technology	Targeted R&D stage	IPR implications
XPRIZE F foundation	Milestone inducement prize.	US\$ 10 million	Prize partners: BMGF	TB	Any company can enter	Pennsylvania-based team,	Diagnostics	Clinical testing and registration.	No information found
	Non-profit organization that designs and hosts public competitions intended to encourage technological development to benefit humanity. Many of the prize competitions are not global health or neglected disease specific.		Qualcomm Foundation, ANA, American, Telemedicine Association, Arthur Clarke Center for Human Imagination, Continua Health 2.0, HIMSS, IEEE, Mems Industry Group, Point Clear Solutions, Open Photonics Inc., Quest, Shimmer, US San Diego Clinical and Translational Research Institute, Wireless Life Sciences Alliance and Xamarin	The winning team was required to develop a tricorder device that: (i) accurately diagnose 13 health conditions; (ii) capture five real-time health vital signs; (iii) provide a compelling consumer experience	a competition style prize, with awards to 1st and 2nd place among competing teams from various companies	Final Frontier Medical Devices (1st place), Taiwan-based finalist, Dynamical Biomarkers Group (2nd place)	Diagnostics	The foundation conducts consumer testing at the Altman Clinical and Translational Research Institute. This testing included the same rigour and protocols as a clinical trial but focused on the objectives of the XPRIZE competition	

EU Vaccine Prize	Inducement prize competition launched in 2012 by European Commission with more prizes to be offered via the Horizon 2020 Research Funding programme. The prizes intend to accelerate development of vaccines and solve common issues of vaccine access	€2 million	Donors: EU Research Council	Cold chain development for vaccines. Competition criteria, includes alternative ways of formulating, preserving or transporting vaccines	Competition cash prize with a jury (2014) appraising submissions and deciding on winner. No particular approach was prescribed and competitors were invited to convince the jury that their solution could respond best to the competition criteria, including alternative ways of formulating, preserving or transporting vaccines	CureVac GmbH	Vaccines	Discovery, preclinical and clinical stages, and registration	Owner maintains IPR
Health Imp act Fund (proposal)	A new proposal by Incentives for Global Health to provide a complementary or alternative to the patent system for development of	A reasonable minimum required is US\$ 6 billion per year	Founding partner: Incentives for Global Health. Potential funding partners: Governments, charitable	Pharmaceutical innovations intended for poor patients	The product is supplied at a generic price with a potential mark up for increment health gains, and the developer is	–	Drugs	Discovery, preclinical and clinical stages, and registration	Developer making IPR available for competing manufacturers

Table 3.10.8 (cont.)

Name	About/purpose of prize	Prize amount	Stakeholders involved	Eligibility criteria and disease focus	How is prize awarded?	Who was awarded?	Type of technology	Targeted R&D stage	IPR implications
Longitude Prize	pharmaceutical innovations intended for poor patients		foundations or international taxes		not rewarded for the R&D element until it can demonstrate that the resulting product has health value for the intended patients. A 10-year fixed payment contingent on developer making IPR available for competing manufacturers, and calculated according to health impact of developed product				
	An ex ante inducement prize launched in 2014 awarded to the submission considered most impactful and feasible, currently for a competitive AMR innovation	£10 million fund	Lead by: Nesta (United Kingdom). Funding partners: Innovate United Kingdom and Biotechnology Industry	AMR. Any team of innovators from anywhere in the world that can invent an affordable, accurate, fast	Competition style prize, with £8 million pay-out to winner, judged by a Prize Advisory Panel	The first challenge is ongoing with around 50 registered teams	Diagnostics	n/a Testing will take place over the six months following the Prize Advisory	Developer maintains IPR

[illegible]

Table 3.10.8 (cont.)

Name	About/purpose of prize	Prize amount	Stakeholders involved	Eligibility criteria and disease focus	How is prize awarded?	Who was awarded?	Type of technology	Targeted R&D stage	IPR implications
	open, reasonable and non-discriminatory licenses to patent pools (such as the UNITAID patent pool)				with those who openly, freely share knowledge materials and technology. Example: The 2015 Development of Low-Cost Rapid Diagnostic Test for Tuberculosis Proposal suggests endowing a \$100 million for an entrant TB diagnostic that satisfies criteria set by WHO committee.				

A licensing pool
would manage
the intellectual
property and
guarantee that
the diagnostic
would be made
available at an
accessible price

AMR: antimicrobial resistance; ANA: All Nippon Airways; BBBS: Bangladesh, Barbados, Bolivia and Suriname; BBC: British Broadcasting Corporation; BMGF: Bill & Melinda Gates Foundation; EU: European Union; HIMSS: Healthcare Information and Management Systems Society; IEEE: Institute of Electrical and Electronics Engineers; IP: intellectual property; IPR: intellectual property rights; TB: tuberculosis; WHO: World Health Organization.

Sources: For XPRIZE: XPRIZE Foundation (2020; 2023), Philanthropy News Digest (2008); for EU Vaccine Prize: European Commission (2014); Health impact fund (Incentives for Global Health (2021)); Longitude prize (Longitude Prize, n.d. a; n.d. b; n.d. c); BBBS: WHO (2011; 2015a; 2015b).

of widespread implementation of these schemes means there is little evidence on whether they succeed in stimulating innovation in key areas of need and the extent to which they may lead to crowding-out of private investment.

From a policy perspective, it is important to assess the extent to which these different funding incentive mechanisms work, as well as their relative cost-effectiveness. This can be achieved by international collaboration in devising and implementing pilot schemes designed to allow an assessment of the factors that hinder or enable a particular mechanism's effectiveness. Yet, to date, the rolling out of these schemes seems to be linked to political will and the strength of their proponents' advocacy rather than the need to gather and examine evidence. For example, tax credits have been considered to have a low uptake as an incentivizing mechanism for R&D in the United Kingdom. The tax credit-based vaccine research relief initiative came to an end in 2017, with United Kingdom assessors having found evidence for minimal or negligible impact on incentivizing R&D uptake (UK Government, 2016). Meanwhile, in the USA, pharmaceutical companies can receive a 20% R&D tax credit (that can be increased to 50% if the neglected disease is low burden), reflecting a contrasting view of the potential effectiveness of this approach (Mueller-Langer, 2013).

Another issue that can be observed among innovative financing mechanisms is their primary focus on "innovation" as an objective rather than "access and affordability". The ultimate desirability of each of these mechanisms relies on the extent to which they either embed or are complemented by provisions to ensure innovation is affordable and supplied in LMICs. Such provisions include knowledge and technology transfer, pricing and financing policies. In their absence, some of the incentives may further widen existing health inequalities, for example by enabling high prices through extending the effects of IPR arrangements. Schemes that combine incentives to foster innovation coupled with specific provisions with regard to weakening IPR and/or pricing arrangements (e.g. AMCs and the Health Impact Fund) are therefore more likely to contribute effectively to tackling neglected diseases in LMICs.

On the collective level, the current push and pull mechanisms remain fragmented and consistently lack a governing overarching framework. Most schemes implemented to date target one or few disease areas, with allocation of resources across neglected diseases

largely depending on donors' views of need or particular remit of action. There is no needs assessment that systematically compares the relative needs associated with neglected diseases globally, assesses the costs and benefits of addressing them, and defines guidance on priority-setting for the coordinated global allocation of funding and targeted incentive mechanisms. This state of affairs risks a suboptimal allocation of funding as well as negative spillover effects across initiatives. The relationship between push mechanisms (such as R&D tax credits or PDPs) and pull mechanisms (such as the prizes, patent system, patent pools, AMCs or wildcard extension) is a good example. The Medical Innovation Prize Act (US Congress, 2007) was proposed as a replacement for the patent system, while others such as the earlier United States Orphan Drug act (US Congress, 1983) aim to complement or augment existing patency jurisdictions.

A governance and resource allocation framework that embeds incentive schemes would need to assess their relative ability to generate valuable innovations across the different disease areas, how they interplay with intellectual property regulations, and consequently their implications for affordability. Given that the R&D landscape is not comprehensively mapped or supranationally governed, it is challenging to produce such a framework, hindering the ability to make informed decisions to allocate resources efficiently across key priority areas. As a result, considerable systemic gaps in funding exist across different R&D stages and disease areas. The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property drawn up by WHO's consultative expert working group (WHO, 2012) highlights the key elements desirable in such a framework as being: needs assessment and prioritization; promoting R&D and R&D capacity; transfer of technology; application and management of intellectual property to contribute to innovation and promote public health; improving delivery and access; promoting sustainable financing mechanisms; and establishing and monitoring reporting systems.

Finally, WHO recognizes that the way research is currently funded is integral to the perceived need for better coordination. There are many funders in both public and private sectors, as well as many research organizations in public and private sectors and in partnership between them. Coordination among these actors is strongly needed to identify

and manage research priorities. Not only will coordination provide opportunities for pooling resources for donors to fund a multiplicity of research institutions in developing country neglected diseases, but it will also enable the strategic governance of initiatives and inputs made in priority-setting, monitoring and evaluation, coordination and advocacy, and impact assessment (WHO, 2012).⁵

Additional resources

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⁵ Unless noted otherwise in the chapter text, the book covers developments up until the end of 2023.

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Index

- activity-based funding. *See* diagnosis-related group (DRG) funding
- advance market commitments (AMCs), 647–9, 652
- adverse selection principle of health insurance, 5, 12, 74, 92–4, 102
- Afghanistan, 68
- African Development Bank, 123
- ageing populations, 44, 52–5, 246, 479, *See also* long-term care (LTC)
- Albania, 371
- alcohol, taxes on, 48–9, 50–1, 55, 526–8
- AMCs (advance market commitments), 647–9, 652
- AMR Action Fund, 586, 597
- antibiotics, R&D funding
 - additional resources, 603–4
 - alternative antibacterial therapies, 594–5
 - antimicrobial resistance (AMR), causes and effects, 573–4
 - barriers to, 576–9
 - European initiatives, 586–8
 - global coordinating body, need for, 601–2
 - incentivizing, 579–82, 595, 596–600
 - key messages, xlix–l, 19, 572, 602–3
 - lack of innovation concern, 574–5, 593–4
 - multilateral initiatives, 582–6
 - national initiatives, 588–90
 - over-prescription disincentives, 205, 206, 207–8
 - overview of initiatives, 582
 - regulatory initiatives, 590–1, 597–8
 - subscription payment models, 436, 590, 600–1
 - WHO priority pathogens list, 592
 - See also* medicines procurement; pharmaceutical industry's R&D
- Argentina, 498, 520–1, 552
- Armenia, 43, 49, 69
- Asian Development Bank, 119, 123, 125–7
- ATMPs (gene therapies), 407, 415, 424, 436
- Australia
 - hospital care funding, 337, 343–4
 - long-term care, 275, 495, 498
 - low-value care decommissioning, 199, 201
 - medicines procurement, 425
 - pharmacist services, 296
 - programme budgeting, 555–6
 - public financing of healthcare, 38
 - VHI schemes, 101, 103
- Austria
 - long-term care, 254–7, 268, 269
 - medicine payments, 423
 - user charges, 237
- Bangladesh
 - CBHI schemes, 68, 72
 - old-age dependency ratios, 54
 - public financing of healthcare, 39, 45, 49
- BBBS open-source dividend, 657
- Belarus, 423
- Belgium
 - long-term care, 254, 268, 269
 - pharmacist services, 296
 - public financing of healthcare, 38, 48
 - user charges, 237
- Belize, 520
- benefits packages. *See* health benefits package (HBP) setting

- Benelux Initiative, 437
 Benin, 68, 70
 Bill & Melinda Gates Foundation, 521, 584, 638
 block contracts for hospital care, 332–4, 340
 Blue Cross Blue Shield Association, 207
 Bosnia and Herzegovina, 371
 Brazil
 ageing population challenge, 52, 53
 COVID-19 pandemic response, 552
 health benefits package, 520–1
 public financing of healthcare, 39, 44
 VHI schemes, 108
 bribes. *See* informal payments
 Bulgaria, 118, 427, 498
 bundled payments
 for integrated care, 301–2, 460–3, 465–6, 468–9
 for long-term care, 486–7, 498–9
 Burkina Faso, 68, 69, 70, 73, 74, 146
 Burundi, 38

 Cambodia, 46, 73
 Cameroon, 49
 Canada
 long-term care, 269, 490–1, 496–7
 low-value care decommissioning, 200, 201, 202
 pharmacist services, 296
 primary care commissioning, 299, 302–3
 public financing of healthcare, 38
 VHI schemes, 95, 101, 103, 109
 cancer drug investments, 415–16, 430
 capitation mechanisms
 bundled types. *See* bundled payments
 generally, xliii
 global or pooled types. *See* global or pooled payments
 for hospital care, 333
 for long-term care, 498–9
 for pharmacists, 296, 297
 for primary care, 18, 288, 290–1, 298
 rationing incentives, 15
 for risk sharing, 206–7
 CARB-X (Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator), 585, 596, 597
 carers, informal. *See* informal carers

 case mix funding for hospital care, 175–6, 334–7, 339, 341
 CBHI. *See* community-based health insurance (CBHI)
 Chile
 health benefits package, 179–83, 191
 long-term care, 498
 VHI schemes, 109, 111, 179–80, 520–1
 China
 ageing population challenge, 52, 53
 CBHI schemes, 68, 70
 informal payments in, 369, 370, 386
 medical savings accounts, 5
 pharmacist services, 296
 public financing of healthcare, 38
 user charges abolition, 231
 clinical decision support tools, 207–8
 clinical trials, concerns over, 416–17
 Cochrane Library, 199
 Colombia, 149
 Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), 585, 596, 597
 community pharmacists, 296–7
 community-based care for older people, 252–3, 479, 483, 502–3, *See also* long-term care (LTC)
 community-based health insurance (CBHI)
 additional resources, 80
 arguments supporting, 64–5, 66–7
 challenges, 70–1
 definition and characteristics, 5, 63–4, 65, 67
 externally sponsored schemes, 67–9
 impact, mixed evidence on, 69–70
 key messages, xxxv–xxxvi, 9, 63, 79–80
 preconditions for success, 75–8
 UHC delivery via, 78–9
 See also voluntary health insurance (VHI)
 complementary and supplementary health insurance, 5, 31, 93–5, 105–7, 110–11, 145
 consumption taxes. *See* indirect taxation
 coordinated care. *See* integrated care, payment mechanisms

- co-payments. *See* user charges
- Costa Rica, 33, 38, 49
- cost-sharing arrangements. *See* user charges
- Côte d'Ivoire, 68
- COVID-19 pandemic
 - health spending in, 20, 100–1
 - health-related inequities in, 130, 541
 - informal payments in, 369, 395, 397–8
 - lessons from. *See* pandemic preparedness
 - LTC sector deficiencies exposed in, 276–7
 - ODA in. *See* official development assistance (ODA) for health
 - vaccines developed in, 408, 438, 559–60
- 'cream-skimming'. *See* moral hazard problems
- Croatia
 - long-term care, 263, 268
 - public financing of healthcare, 38
 - VHI schemes, 95, 105–6
- Cyprus, 101, 237, 423, 427
- Czechia
 - long-term care, 254–7, 498, 501
 - low-value care decommissioning, 205
- daily fees, 495–7
- data protection, regulatory, 409
- day care for older persons, 497, *See also* long-term care (LTC)
- decentralized administrations, 146, 174–6, 189–90
- decommissioning decisions. *See* low-value care decommissioning
- Democratic Republic of the Congo
 - CBHI schemes, 68, 71–2, 73
 - Ebola epidemic in, 532
 - health spending, 38, 45
 - tax revenues, 46
- demographic trends
 - ageing populations, 44, 52–5, 246, 479
 - long-term care recipients, 271–2
 - single-adult households, 246–7
 - See also* long-term care (LTC)
- Denmark
 - ageing population challenge, 55
 - health benefits package, 190, 427
 - long-term care, 269, 498
 - low-value care decommissioning, 205, 208
 - medicines procurement, 432–3
 - pharmacist services, 296
 - primary care commissioning, 299
 - public financing of healthcare, 36, 38
- developed countries. *See* high-income countries (HICs); upper-middle-income countries (UMICs)
- developing countries. *See* low- and middle-income countries (LICs and LMICs)
- development assistance. *See* official development assistance (ODA) for health
- devolved administrations, 146, 174–6, 189–90
- diagnosis-related group (DRG) funding
 - generally, 455
 - German case study, 175–6
 - for hospital care, 334–7, 339, 341
 - for integrated care, 458, 471–2
 - for long-term care, 485, 494
- disinvestment decisions. *See* low-value care decommissioning
- donations. *See* external health financing
- Drugs for Neglected Diseases initiative, 415
- drugs, payments for. *See* medicines procurement
- Ebola epidemic (2014), 532, 554, 560, *See also* pandemic preparedness
- Ecuador, 520
- EDCTP (European and Developing Countries Clinical Trial Partnership), 585
- efficiency concept, 35
- Egypt, 39, 51
- elderly persons, LTC needs. *See* long-term care (LTC)
- EMA (European Medicines Agency), 408, 590–1, 597–8
- employment-based risk pools, 145–6
- England. *See* United Kingdom
- equitable healthcare provision
 - CBHI schemes and, 69, 78

- COVID-19 pandemic affecting, 130, 541
- definition, 3
- financial exclusion categories, 66–7
- long-term care, challenges affecting, 275–8, 505
- medicine price disparities, 433–4, 437
- moral hazard problems affecting. *See* moral hazard problems
- neglected diseases and. *See* neglected diseases, R&D funding
- OOP payments, equity concerns, 7, 22, 65–6
 - informal payments, 394
 - user charges. *See* user charges, unintended effects
- patient decision-making support, 205–6, 209–10
- population groups covered by risk pools, 11
- regressive v. progressive revenue raising, 7, 34–5, 92–4
- risk pooling deficiencies affecting, 139, 140
- UHC goal. *See* universal health coverage (UHC)
- VHI, equity concerns. *See under* voluntary health insurance (VHI)
- Estonia, 36, 264, 269, 495
- Ethiopia
 - CBHI schemes, 69, 70, 74, 77, 78–9
 - old-age dependency ratios, 53
 - public financing of healthcare, 39, 45, 46
- European and Developing Countries Clinical Trial Partnership (EDCTP), 585
- European Health Preparedness and Response Authority (HERA), 588
- European Medicines Agency (EMA), 408, 590–1, 597–8
- European Union
 - access to drugs initiatives, 415, 417, 438
 - antibiotics initiatives, 586–8, 596
 - health financing, 7
 - long-term care needs studies, 270
 - medicines expenditure in, 426–7, 434
 - neglected diseases, R&D funding, 618
 - pharmaceuticals legislation, 410, 416
 - Vaccine Prize, 652
- Evidence-Based Interventions programme (NHS England), 211–14
- external health financing
 - CBHI schemes, externally sponsored, 67–9
 - generally, 7, 20
 - horizontal priority-setting and, 528–9, 535
 - neglected diseases R&D, grants and subsidies, 638
 - from NGOs, 521, 522–3
 - ODA. *See* official development assistance (ODA) for health
 - procurement systems of donors, 530–1
 - risk pooling approaches for, 150–1, 159
- external reference pricing for medicines, 431–2
- fee-for-service (FFS) mechanisms
 - generally
 - for hospital care, 331–2, 335, 338–9, 340
 - for integrated care, 458, 469, 471–2
 - for long-term care, 492–4, 498
 - over-provision incentives, 15, 170, 192, 211
 - for pharmacists, 296
 - for primary care, 18, 288, 291–2, 298–9, 302–3
- financial hardship. *See* poverty
- Finland
 - ageing population challenge, 55
 - long-term care, 262, 269
 - user charges, 236
- fixed co-payments, 226, *See also* user charges
- foreign direct investment, 123
- France
 - Common Classification of Medical Procedures, 192
 - long-term care, 260
 - funding, 254, 262, 265, 274, 495
 - needs assessment, 269
 - low-value care decommissioning, 206

- France (cont.)
 medicines procurement, 425, 427
 public financing of healthcare, 38, 48, 55
 VHI schemes, 95, 98
- Gabon, 149
- GAMRIF (Global Antimicrobial Resistance Innovation Fund), 585–6
- GARDP (Global Antibiotic Research and Development Partnership), 584, 599
- Gavi, the Vaccine Alliance, 518, 521, 523, 530–1
- gene therapies (ATMPs), 407, 415, 424, 436
- general taxation. *See* taxes and social health insurance (SHI)
- Georgia, 46
- Germany
 health benefits package, 169, 174–6, 191, 192, 427
 integrated care case study, 470–1
 long-term care, 260, 269
 funding, 262, 490, 497, 498, 500, 502–3
 needs assessment, 268, 269
 low-value care decommissioning, 201
 pharmacist services, 296
 public financing of healthcare, 38
 user charges, 239
 VHI schemes, 98–100, 103–4, 109, 111, 145
- Ghana
 CBHI schemes, 65, 68, 70, 78–9
 pharmacist services, 296
 public financing of healthcare, 48, 50–2, 144, 528
 risk pooling approaches, 159
 gifts. *See* informal payments
- Global Antibiotic Research and Development Partnership (GARDP), 584, 599
- Global Antimicrobial Resistance Innovation Fund (GAMRIF), 585–6
- global financial crisis (2007–08), 100
- Global Fund
 financing and procurement strategies, 523, 524, 530, 535
 role, 517–18, 521
 specific programmes, 529, 560
- Global Health Innovative Technology Fund, 638
- global or pooled payments
 for LTC. *See* long-term care (LTC), payment mechanisms
 generally, 455
 for hospital care, 333
 for integrated care, 458–9
 for pandemic preparedness, 549–50, 559–61
 for primary care, 301
See also risk pooling
- Great Britain. *See* United Kingdom
- Greece
 informal payments case study, 391–5
 long term care, 249, 495
 medicines procurement, 427
 public financing of healthcare, 36, 391
 user charges, 227
- Guinea, 68, 70
- Guyana, 46, 520
- health benefits package (HBP) setting
 additional resources, 193
 decision-making framework, 188–93
 disinvestment decisions. *See* low-value care decommissioning
 explicit HBPs, case for and against, 168–70
 explicit HBPs, examples, 170–1, 188
 Chile, 179–83, 191
 Germany, 174–6, 191, 192
 Italy, 171–4, 190, 191
 Malawi, 183–8, 190–1
 Premera Blue Cross (US health insurer), 176–9
 HBPs generally, 11, 166–8, 516–17
 horizontal priority-setting for. *See* horizontal priority-setting
 HTA for. *See* health technology assessment (HTA)
 key messages, xxxix, 13, 165, 193
 medicine choices. *See* medicines procurement
- health financing
 concept, xxxiii, 1
 ethical concerns. *See* equitable healthcare provision

- functions overview, 2
- horizontal priority-setting. *See*
 - horizontal priority-setting
- informal payments linked to, 386–7
- key challenges, li–lii, 21–3
- national comparisons, 19–21, 37–43
- pooling function. *See* risk pooling
- purchasing function, xlii, 13–15, 160,
 - See also* payment mechanisms;
 - strategic resource allocation
- revenue raising function, xxxiv, 4–7,
 - See also* community-based health insurance (CBHI); official development assistance (ODA)
 - for health; taxes and social health insurance (SHI); voluntary health insurance (VHI)
- UHC goal. *See* universal health coverage (UHC)
- Health Impact Fund, 652
- health insurance. *See* community-based health insurance (CBHI); voluntary health insurance (VHI)
- health system efficiency concept, 35
- health technology assessment (HTA)
 - for health benefits package setting, xxxix, 173, 190–1, 424–5
 - for identifying low-value care, xl, 199–200, 211
 - for medical devices, 173–4
 - for price control and regulation, 238, 407
 - for primary care payments, 292
- healthcare as human right, 170
- HERA (European Health Preparedness and Response Authority), 588
- high-income countries (HICs)
 - health benefits packages (HBPs) in, 166, 167, 170, 191, 192
 - health financing, comparative data, 20–1
 - health spending in, 37–8, 49
 - informal payments in. *See* informal payments, prevalence
 - long-term care, spending on, 259–61
 - medicines expenditure in, 426–7
 - revenue raising challenges in, 31, 48–9, 52–5
 - VHI revenue in, 96
- Honduras, 520–1
- horizontal priority-setting
 - additional resources, 535–6
 - characteristics, 518–19
 - donor and country cooperation for, 528–9, 535
 - financing scheme integration for, 524–5
 - fiscal space expansion for, 524–8
 - funding arrangements affecting, 519–22
 - global health security linked to, 532–3
 - key messages, xlvii–xlviii, 18–19, 515–16
 - priority-setting generally, 516–18
 - procurement arrangements
 - affecting, 522–4
 - procurement improvement for, 529–31
 - See also* medicines procurement; pharmaceutical industry's R&D
- hospital care, payment mechanisms
 - additional resources, 352
 - block contracts, 332–4, 340
 - choice factors
 - administrative effort, 340–2
 - number of hospitals, 338–9
 - number of payers, 338
 - relative importance of payer objectives, 339–40
 - compared, 328
 - diagnosis-related group (DRG), 334–7, 339, 341
 - fee-for-service (FFS), 331–2, 335, 338–9, 340
 - funding policy, key design elements, 323, 328
 - hospital objectives, 327
 - key messages, xliii–xliv, 15–18, 320–1, 351–2
 - line-item budgeting, 328–31, 339, 341
 - NHS England case study, 347–51
 - payer objectives
 - efficiency, 325–6
 - number and type of patients, 324
 - quality of care, 324–5
 - simplicity, 326
 - payer–hospital relationship, 321–3, 327
 - pay-for-performance (P4P), 345–6

- hospital care (cont.)
 - transitioning between, 342–5
- HTA. *See* health technology assessment (HTA)
- human right to healthcare, 170
- Hungary, 48, 55
- Iceland, 269, 336
- IMF (International Monetary Fund), 45, 118, 119, 123
- India
 - CBHI schemes, 68, 70, 73, 78–9
 - health spending, 49
 - informal payments in, 387
 - old-age dependency ratios, 54
 - public financing of healthcare, 36, 39, 44, 48
- indirect taxation
 - alcohol and tobacco taxes, 48–9, 50–1, 55, 526–8
 - generally, 33, 35
 - VAT funding in Ghana, 528
- Indonesia, 45, 146, 148–9, 296
- ineffective care. *See* low-value care
- decommissioning
- inequitable healthcare provision. *See* equitable healthcare provision
- informal carers
 - cash and in-kind benefits for, 254–9, 502–3
 - concerns over, 250–2, 479
 - definition, 250
 - generally, xlvii, 485, 504
 - See also* long-term care (LTC)
- informal economic activity, 46–7, 144
- informal payments
 - additional resources, 398
 - adverse effects on health systems, 363–4
 - data on, 20, 250
 - definitions, 362–3
 - drivers, empirical evidence, 367–71
 - drivers, theories, 365–7
 - generally, 5–6, 361–2
 - Greece case study, 391–5
 - key messages, xliv–xlv, 18, 360–1
 - motivations for, 363, 364–5
 - policy responses, 395–8
 - See also* out-of-pocket (OOP) payments; user charges
- informal payments, prevalence
 - Asia-Pacific region, 386
 - cross-sectional surveys, 372, 397
 - Europe, 368, 372–86
 - formal OOP payments and, 387–9
 - health financing levels and, 386–7
 - physician density and, 389–90
 - summary, 390–1
 - systematic review findings, 371–2
- informed choice for patients, 205–6, 209–10
- Innovative Medicines Fund, 424
- Innovative Medicines Initiative, 414, 415, 587, 597
- InnovFin Infectious Diseases Facility, 587
- integrated care, payment mechanisms
 - additional resources, 473
 - bundled payments, 301–2, 460–3, 465–6, 468–9
 - Dutch case study, 468–9
 - German case study, 470–1
 - ‘integrated care’ definition, 453–4
 - key messages, xlv–xlvii, 18, 452–3
 - operation in practice, 466–8
 - operation in theory, 465–6
 - overview of, 454–6
 - pay-for-coordination (P4C), 460, 465
 - performance objectives setting, 456–7
 - policy responses, 471–3
 - quality of care incentives, 464–5
 - shared-savings models, 463–4, 466, 469–70
 - traditional models, limitations, 458–9
 - US case study, 469–70
 - See also* long-term care (LTC)
- Inter-American Development Bank, 123
- internal price referencing for medicines, 432
- International Horizon Scanning Initiative, 438

- International Monetary Fund (IMF), 45, 118, 119, 123
- Iran, 371
- Ireland
- long-term care, 268, 275
 - user charges, 236
 - VHI schemes, 94, 109
- Israel, 94, 491
- Italy
- ageing population challenge, 55
 - health benefits package, 171–4, 190, 191, 423, 424, 431
 - long-term care, 268, 269, 486
 - low-value care decommissioning, 205
 - public financing of healthcare, 36, 38
- Ivory Coast, 68
- Japan
- ageing population challenge, 53,
 - health spending, 49
 - hospital care funding, 337
 - informal payments in, 387
 - long-term care, 257, 260, 269, 495, 498, 500
 - pharmacist services, 296
 - public financing of healthcare, 38
 - user charges, 234
- Joint Programming Initiative on Antimicrobial Resistance (JPIAMR), 584, 596
- Jordan, 100
- Kazakhstan, 423
- Kenya, 68, 109, 146, 231
- Kiribati, 43
- Korea, Republic of
- hospital care funding, 337
 - long-term care, 257, 500
 - pharmacist services, 296
 - public financing of healthcare, 39
 - risk pooling approaches, 148–9, 157
- Kosovo, 371
- Kyrgyzstan, 146, 336, 423
- Lao People's Democratic Republic, 68, 73
- Latvia, 238–9, 263, 269, 427
- Lebanon, 101
- Liberia, 46, 101, 103
- LICs and LMICs. *See* low- and middle-income countries (LICs and LMICs)
- line-item budgeting for hospital care, 328–31, 339, 341
- Lithuania, 227, 268–9, 498
- lobbying by pharmaceutical industry, 412–13
- Longitude Prize, 652
- long-term care (LTC)
- additional resources, 279, 506
 - decisions to apply for, 265–7, 272
 - definition, 247–8
 - formal carers, 248–50, 479–80
 - funding 'carve outs' for, 11, 12, 262
 - increasing demand for, 246–7, 479
 - informal carers. *See* informal carers
 - integrated care, payment mechanisms
 - key messages, xli–xlii, 18, 245–6
 - moral hazard problems, 504–5
 - needs assessments
 - national variations, 267–9
 - reports on, 270
 - within countries, 269–70 - OOP payments for, 261–5
 - payment mechanisms. *See* long-term care (LTC), payment mechanisms
 - public v. private provision, 253–4
 - quality and value concerns, 275–8, 487–8, 504
 - recipients, data on, 271–3
 - services, 482
 - settings for, 252–3, 482–3
 - spending on, 259–61
- long-term care (LTC), payment mechanisms
- budgets, 501
 - bundled payments, 486–7, 498–9
 - for community care, 502–3
 - for day care, 497
 - experimental schemes, 273–5, 487
 - fee-for-service (FFS), 492–4, 498
 - financial flows, 259, 480–1
 - health care and LTC markets
 - compared, 484–9, 503–6 - incentives created by, 492–5
 - for institutional care, 495–501

- long-term care (LTC) (cont.)
 - key messages, xlvii–xlviii, 478–80, 503–6
 - pay-for-performance (P4P), 486–7, 499–501
 - per diem payments, 495–7
 - pooled payments, 487
 - allocation decisions, 491–2
 - collectors and payer agencies, 490–1
- low- and middle-income countries (LICs and LMICs)
 - antibiotics overuse in, 573
 - CBHI systems advocated for. *See* community-based health insurance (CBHI)
 - external health financing for. *See* external health financing; official development assistance (ODA) for health
 - health benefits packages (HBPs) in, 166, 167, 183, 191
 - health financing, comparative data, 20–1, 38
 - health spending in, 37–8, 49, 427, 433–4, 437, 522
 - horizontal priority setting goal for. *See* horizontal priority-setting
 - neglected diseases in, 612
 - OOP payments levied in, 41–3, 65–6, 239, 367–8, 421
 - informal payments. *See* informal payments, prevalence
 - P4P mechanisms, potential benefits in, 306, 309, 311
 - pandemic preparedness planning by. *See* pandemic preparedness
 - revenue raising challenges in, 21–2, 31, 43–7, 53–4
 - risk pooling deficiencies in, 139, 142–3, 151, 157
 - VHI revenue in, 96
- low-value care decommissioning
 - additional resources, 215
 - barriers to, 209–11
 - conceptual framework, 197–8
 - demand-side interventions, 202
 - financial, 203–5
 - nonfinancial, 205–6
 - identifying candidates for
 - disinvestment, 198–201
 - key messages, xxxix–xl, 196–7, 214–15
 - multicomponent interventions, 208–9
 - NHS England case study, 211–14
 - prioritizing candidates for
 - disinvestment, 201–2
 - supply-side interventions, 202
 - financial, 206–7
 - nonfinancial, 207–8
 - user charges as strategy, 203–5, 229–30
 - See also* health technology assessment (HTA)
- LTC. *See* long-term care (LTC)
- Luxembourg, 262, 269, 427
- Madagascar, 38
- Malawi, 183–8, 190–1
- Maldives, 387
- Mali, 68, 69, 73, 79
- managed-entry agreements for
 - medicines, 430–1
- market exclusivity/protection, 410
- market failures. *See* moral hazard problems
- marketing by pharmaceutical industry, 412–13
- medical devices evaluations, 173–4
- medical research, concerns over, 416–17
- medical savings accounts (MSAs), 5
- Medicare Shared Savings Program (US), 469–70
- Medicines for Malaria Venture, 635–7
- medicines procurement
 - additional resources, 439
 - antibiotics. *See* antibiotics, R&D funding
 - ATMPs (gene therapies), 407, 415, 424, 436
 - centralized tendering, 432–3
 - co-payments, 421–2
 - decision-making mechanisms, 173, 424–6
 - expenditure, comparative data, 426–7, 433–4
 - expenditure, composition of, 426
 - generally, 419–20
 - key messages, xlv, 18, 405–7
 - negative lists, 191

- over-prescription disincentives, 205–6, 207–8
- payment mechanisms, 422, 427–9, 430–2, 436–7
- policy responses, 435–9
- Premiera Blue Cross formulary, 176–9
- prescription charges. *See* user charges
- public funds, 420–1, 422–4
- R&D investments. *See*
 - pharmaceutical industry's R&D
- repurposing of medicines, 418
- safety controls, 531
- subscription ('Netflix') model, 436, 590, 600–1
- mental health services, 11, 146, 521
- Mexico
 - ageing population challenge, 52
 - COVID-19 pandemic response, 556
 - public financing of healthcare, 44
 - risk pooling approaches, 147, 149, 157, 158
- migrant workers in LTC sector, 250, 479–80
- Moldova, 146, 423, 427
- Monaco, 101
- moral hazard problems
 - of CBHI schemes, 74
 - of DRG funding, 337
 - of long-term care, 504–5
 - neglected diseases R&D affected by, 624–5
 - pandemic preparedness affected by, 545–6
 - of user charges, 229–30
 - of VHI schemes, 101–2
- Morocco, 49, 100
- Mozambique, 146
- MSAs (medical savings accounts), 5
- multidisciplinary care. *See* integrated care, payment mechanisms
- multilateral development bank finance. *See* official development assistance (ODA) for health
- Myanmar, 36, 43
- Namibia, 103
- National Health Accounts, comparative data from, 19–21
- National Health Service (NHS). *See* United Kingdom
- neglected diseases, R&D funding
 - additional resources, 662
 - advance market commitments (AMCs), 647–9, 652
 - data on, 616
 - fiscal incentives, 641–5, 660
 - grants and subsidies, 638
 - inequities of, 619–20, 622, 624
 - key messages, I–li, 19, 611–12, 653–62
 - market failures affecting, 624–5
 - neglected diseases generally, 612, 615
 - patent buyouts, 645–6
 - priority review vouchers (PRVs), 646–7
 - prizes, 652–3
 - product development partnerships (PDPs) for, 630–5, 637
 - push and pull incentive mechanisms, 413–15, 626–7, 660–1
 - recipients, 619
 - sources of, 618–19
 - transferable patent extensions, 645
 - WHO initiatives, 615–16, 661–2
 - See also* pharmaceutical industry's R&D
- Nepal, 68
- 'Netflix' model of medicines
 - procurement, 436, 590, 600–1
- Netherlands
 - ageing population challenge, 55
 - compulsory health insurance, 34
 - integrated care case study, 468–9
 - long-term care, 260
 - funding, 257–9, 486–7, 501
 - needs assessment, 268, 488
 - low-value care decommissioning, 201, 205
 - pharmacist services, 296
 - primary care commissioning, 302
 - public financing of healthcare, 100, 147–8
 - VHI schemes, 95, 109, 111, 145
- New Zealand, 201, 296, 337, 556,
- NGO health financing. *See* external health financing
- NHS. *See* United Kingdom

- Nigeria
 - old-age dependency ratios, 53
 - public financing of healthcare, 36, 39, 44, 45, 47, 51
 - risk pooling approaches, 146, 523
 - supply chain management, 530, 547–8
- Nordic Pharmaceutical Forum, 437
- Norway
 - health spending, 38, 431
 - long-term care, 249, 269
 - primary care commissioning, 299
 - public financing of healthcare, 36, 38
- OECD Development Assistance Committee (DAC), 118, 119, 123, 131
- official development assistance (ODA)
 - for health
 - additional resources, 131
 - Asian Development Bank's COVID response, 125–7
 - critical role played by, 122–3
 - definition, 118
 - key messages, xxxvi–xxxvii, 10, 116–18, 130–1
 - multilateral development banks' role, 123–5, 550
 - for pandemic preparedness, 122, 129–30, 550, 552–3
 - quality and impact assessments, 127–9
 - recipients, COVID impact, 120–1
 - volumes and donors, COVID impact, 118–20, 121–2
 - See also* external health financing; pandemic preparedness
- old-age dependency ratios, 52–5, 246
- older persons, LTC needs. *See* long-term care (LTC)
- One Health framework, 561, *See also* pandemic preparedness
- out-of-pocket (OOP) payments
 - CBHI schemes, impact on, 70
 - equity concerns, 7, 22, 65–6
 - informal payments, 394
 - user charges. *See* user charges, unintended effects
- as horizontal priority-setting strategy, 526
- for long-term care, 261–5
- P4P mechanisms to reduce, 306
- private health sector and, 370
- public finance increases, effects on, 40–1, 103, 111
- revenue from, national comparisons, 41–3
- risk pooling implications, 139–40, 142–3
- types. *See* informal payments; user charges
- VHI schemes compared with, 94
- P4C (pay-for-coordination)
 - mechanisms, 460, 465, 487–8, *See also* integrated care, payment mechanisms
- P4P. *See* pay-for-performance (P4P) mechanisms
- Pakistan, 39, 45, 49
- Panama, 49
- Pandemic Emergency Finance Facility (World Bank), 561
- pandemic preparedness
 - accountability goal, 557
 - additional resources, 565
 - definition, 543–5
 - domestic resources and national mechanisms, 550–2, 557–9
 - European Union agency (HERA), 588
 - external assistance, 122, 129–30, 550, 552–3
 - financing challenges, 546–9
 - flexible financial management goal, 553–7
 - horizontal priority-setting and, 532–3
 - international guidance, xlix, 547, 551
 - introduction, 541–3
 - key messages, xlviii–xlix, 19, 540–1, 564–5
 - moral hazard problems, 545–6
 - pooled financing at global level for, 549–50, 559–61
 - Viet Nam case study, 562–4

- World Bank mechanisms, 560
- See also* COVID-19 pandemic; official development assistance (ODA) for health
- patents for medicines, 645–6
- patients
 - decision-making support, 205–6, 209–10
 - older persons. *See* long-term care (LTC)
 - payments by. *See* informal payments; out-of-pocket (OOP) payments; user charges
- pay-for-coordination (P4C)
 - mechanisms, 460, 465, 487–8, *See also* integrated care, payment mechanisms
- pay-for-performance (P4P) mechanisms
 - for hospital care, 345–6
 - for integrated care, 464–5, 467
 - LMICs, potential benefits in, 306, 309, 311
 - for long-term care, 486–7, 499–501
 - low-value care decommissioning and, 206
 - for primary care
 - generally, 288, 292–4
 - quality improvement, 304–9, 310
 - secondary care reduction, 299–300, 302–3
 - UK QOF case study, 299–300
- payment mechanisms
 - bundled. *See* bundled payments
 - co-payments. *See* user charges
 - generally, 484
 - global or pooled. *See* global or pooled payments
 - for integrated care. *See* integrated care, payment mechanisms
 - key principles for, lii
 - for LTC. *See* long-term care (LTC), payment mechanisms
 - for medicines, 422, 427–9, 430–2, 436–7
 - mixed methods, 18, 294, 310
 - overview of, 17
 - for primary care services. *See* primary care commissioning
 - for secondary care services. *See* hospital care, payment mechanisms
 - transitioning between, 342–5
 - See also* capitation mechanisms; diagnosis-related group (DRG) funding; fee-for-service (FFS) mechanisms; pay-for-performance (P4P) mechanisms
- per diem fees, 495–7
- percentage-based co-payments, 226–7, *See also* user charges
- personal care for older persons. *See* long-term care (LTC)
- Peru, 149, 520–1
- pharmaceutical industry's R&D
 - antibiotics research. *See* antibiotics, R&D funding
 - cost of, 417–19
 - in COVID-19 pandemic, 408, 411–12
 - early stage, public funding, 410–11
 - intellectual property rights, 410
 - lobbying and marketing activity, 412–13
 - neglected diseases. *See* neglected diseases, R&D funding
 - overview of phases, 407–8
 - policy responses, 434–5
 - push and pull incentive mechanisms, 413–15, 626–7
 - unmet patient needs concern, 415–17, 624–5
 - See also* medicines procurement
- pharmacists, remuneration of, 296–7
- Philippines
 - CBHI schemes, 68
 - old-age dependency ratios, 54
 - public financing of healthcare, 39, 49, 50–1
 - risk pooling approaches, 146
- Poland, 249, 272, 427
- pooled payments. *See* global or pooled payments
- pooling concept, xxxvii, 10, 138–9, *See also* risk pooling
- population trends. *See* demographic trends

- Portugal
 - ageing population challenge, 54
 - long-term care, 249, 269, 486, 497
 - pharmacist services, 296
 - public financing of healthcare, 36
- poverty
 - low CBHI uptake due to, 71
 - OOP payments contributing to, 231–4, 236, 261–5, 332, 394, 421–2, 521
 - as revenue raising challenge, 44, 123
 - rural areas, 142
- Premiera Blue Cross (US health insurer), 176–9
- prescription charges. *See* user charges
- price control and regulation, 238, 407
- primary care commissioning
 - additional resources, 311
 - generally, 286–7
 - information technology for, 292
 - integrated care. *See* integrated care, payment mechanisms
 - key messages, xliii, 15, 285, 309–11
 - organization of primary care, 286
 - payment models
 - compared, 290–4
 - mixed, 18, 294, 310
 - overview and effects of, 288–90
 - pharmacists' remuneration, 296–7
 - quality of care, effects of payment models, 303–9, 310
 - UK QOF case study, 299–300
 - for secondary care reduction
 - background, 294–8
 - effects of payment models, 298–303, 309–10
- priority review vouchers, 646–7
- priority-setting, horizontal. *See* horizontal priority-setting
- private health insurance. *See* voluntary health insurance (VHI)
- prizes for R&D innovation, 652–3
- programme budgeting, 202, 326, 554–5, 556–7
- public financing. *See* taxes and social health insurance (SHI)
- public health emergency funding. *See* pandemic preparedness
- purchasing healthcare services, xlii, 13–15, 160, *See also* payment mechanisms; strategic resource allocation
- quality of care
 - definition, 3
 - disinvestment decisions. *See* low-value care decommissioning
 - hospital care, 324–5, 340, 345–6
 - integrated care, 464–5
 - long-term care, 275–8, 487–8, 504
 - moral hazard problems affecting. *See* moral hazard problems
 - primary care, effects of payment models, 303–9, 310
 - UK QOF case study, 299–300
- QuODA index, 127–8, *See also* official development assistance (ODA) for health
- R&D investments. *See* pharmaceutical industry's R&D
- Regional Disease Surveillance Systems Enhancement (World Bank), 561
- regional risk pools, 146
- regulatory data protection, 409
- Republic of Korea. *See* Korea, Republic of
- research and development investments. *See* pharmaceutical industry's R&D
- revenue raising, xxxiv, 4–7, *See also* community-based health insurance (CBHI); official development assistance (ODA) for health; taxes and social health insurance (SHI); voluntary health insurance (VHI)
- right to health, 170
- risk pooling
 - additional resources, 161
 - by communities. *See* community-based health insurance (CBHI)
 - employment-based pools, 145–6
 - fragmentation prevention strategies, 147–51
 - generally, 10–11, 22, 138–40
 - good system design, 140–1

- horizontal priority-setting,
 - implications for, 523–4
- key messages, xxxviii–xxxix, 12–13, 137–40, 159–61
- one-pool systems, 145
- overview of types, 143–5
- pooling concept, xxxvii, 10, 138–9
- poor system design, 142–3
- reforms, political economy of, 156–9
- reforms, Thailand case study, 147, 149, 151–6, 158
- region-based pools, 146
- services covered. *See* health benefits package (HBP) setting
- for specialist services, 12, 146–7, 262
- user charges. *See* user charges
- See also* global or pooled payments
- Romania, 240
- Russian Federation, 39, 44, 53, 54
- Rwanda, 65, 69, 70, 78–9, 309
- salary payments
 - generally, 455
 - in pandemics, 557–8
 - for primary care, 288, 290, 298
- SDGs (Sustainable Development Goals), 64, 68, 117, 183, 516, 541
- secondary care, payment for. *See* hospital care, payment mechanisms
- Semashko model health service, 32
- Senegal, CBHI schemes
 - administration, 75–6, 77
 - impact, 69, 70, 77
 - introduction, 68
 - state support, 68–9, 73, 75
- Serbia, 371
- shared-savings payment models, 463–4, 466, 469–70, 487–8, *See also* integrated care, payment mechanisms
- SHI. *See* taxes and social health insurance (SHI)
- Singapore, 5, 337
- Slovakia
- Slovenia, 95, 105–6, 238, 264
- social care for older persons. *See* long-term care (LTC)
- social health insurance. *See* taxes and social health insurance (SHI)
- Solomon Islands, 43
- South Africa
 - COVID-19 pandemic response, 556
 - medical savings accounts, 5
 - public financing of healthcare, 51
 - risk pooling approaches, 150, 157
 - VHI schemes, 94, 100, 103, 109, 148
- South Korea. *See* Korea, Republic of
- South Sudan, 38, 49
- Spain
 - health benefits package, 190, 191, 423
 - long-term care, 486, 488, 496, 503
 - low-value care decommissioning, 201
 - public financing of healthcare, 36
 - user charges, 240
- Sri Lanka, 49
- strategic resource allocation
 - future challenges, 23
 - HBP setting. *See* health benefits package (HBP) setting
 - horizontal priority-setting. *See* horizontal priority-setting
 - pandemic preparedness. *See* pandemic preparedness
 - programme budgeting, 202, 326, 554–5, 556–7
 - transparent policies, 169–70
- subscription model of medicines
 - procurement, 436, 590, 600–1
- substitutive health insurance, 96, 111
- supplementary and complementary health insurance, 5, 31, 93–5, 105–7, 110–11, 145
- supplementary protection certificates, 409
- Suriname, 520
- Sustainable Development Goals (SDGs), 64, 68, 117, 183, 516, 541
- Sweden
 - antibiotics initiatives, 600–1
 - long-term care, 269, 487, 496
- Switzerland
 - compulsory health insurance, 34
 - health spending, 38
 - long-term care, 272, 497

- Switzerland (cont.)
 - low-value care decommissioning, 208
 - pharmacist services, 296
 - user charges, 237
 - VHI schemes, 109, 145
- Taiwan, 302
- Tanzania, 68, 70, 73, 548
- taxes and social health insurance (SHI)
 - additional resources, 57
 - ageing populations challenge, 44, 52–5, 246
 - conflicting budget priorities challenge, 49–52
 - defined and compared, 32–3, 35–7
 - equity, regressive v. progressive systems, 7, 34–5
 - fiscal incentives for R&D, 641–5, 660
 - generally, 30–2
 - increases, effects on OOP payments and VHI, 40–1, 103, 111
 - indirect taxation. *See* indirect taxation
 - informal economic activity challenge, 46–7
 - key messages, xxxiv–xxxv, 9, 29, 55–6
 - for long-term care, 259
 - low economic growth/poverty challenge, 44
 - medicine payments from. *See* medicines procurement
 - resistance to SHI contributions challenge, 47–9
 - revenue, national comparisons, 37–8, 39
 - variations between schemes, 4, 34
 - weak revenue generation challenge, 44–6
- TB Alliance, 633
- Thailand
 - alcohol and tobacco taxes, 528
 - health benefits package, 524–5
 - hospital care funding, 337
 - pharmacist services, 296
 - risk pooling reforms, 147, 149, 151–6, 158
 - VHI schemes, 100, 529
- Tinbergen Rule, 343
- tobacco, taxes on, 48–9, 50–1, 55, 526–8
- Togo, 73
- Transatlantic Task Force on Antimicrobial Resistance, 591
- Turkey, 148–9, 157–8
- Uganda, 49, 69, 146, 159
- UHC. *See* universal health coverage (UHC)
- Ukraine, 46, 423
- UMICs. *See* upper-middle-income countries (UMICs)
- United Arab Emirates, 101, 118
- United Kingdom
 - access problems, 101
 - antibiotics initiatives, 585–6, 589–90, 596, 600–1
 - health and social care global budgets, 301
 - health benefits package, 168, 169, 190
 - hospital care funding, 347–51
 - long-term care, 260
 - funding, 275, 487
 - needs assessment, 269
 - low-value care decommissioning, 200, 201, 202, 206, 208, 211–14
 - medicines procurement, 424
 - neglected diseases, R&D incentives, 641–5, 660
 - NHS introduction, 32, 35
 - patient safety scandals, 346
 - pharmacist services, 296
 - prescription charges, 226
 - primary care commissioning, 299–300, 301
 - public financing of healthcare, 38, 48, 347
 - VHI schemes, 104, 520
- United Nations
 - Development Programme (UNDP), 118, 123
 - pandemic preparedness guidance, 542
 - Sustainable Development Goals (SDGs), 64, 68, 117, 183, 516, 541
- United States of America
 - ageing population challenge, 38, 53

- antibiotics initiatives, 588–9, 591, 596, 597–8, 601
- compulsory health insurance, 100
- health spending, 49, 197
- long-term care
 - funding, 275, 496–7, 498–9, 500–1
 - needs assessment, 269
 - OOP payments, 264, 265
- low-value care decommissioning, 201, 206, 207
- medical savings accounts, 5
- Medicare Shared Savings Program, 469–70
- neglected diseases, R&D funding, 618, 638, 641, 645, 646–7, 660
- pharmacist services, 296
- Premiera Blue Cross (health insurer), 176–9
- primary care commissioning, 301, 302, 303
- risk pooling approaches, 146
- vaccine research in COVID-19 pandemic, 411
- VHI schemes, 103, 109, 520
- universal health coverage (UHC)
 - CBHI schemes for, 78–9
 - definition, 1
 - horizontal priority-setting for. *See* horizontal priority-setting
 - key financing challenges, li–lii, 21–3
 - optimal financing models for, 32, 40
 - policy designs for, 10–11
 - risk pooling design for. *See* risk pooling
- Sustainable Development Goal 3.8
 - on, 64, 68, 183, 516
- VHI and. *See* voluntary health insurance (VHI)
- WHO guidelines on, 516
- See also* equitable healthcare provision
- upper-middle-income countries (UMICs)
 - health financing, comparative data, 21
 - health spending in, 37–8
 - OOP payments levied in, 43
 - revenue raising challenges in, 52–5
 - VHI revenue in, 96
- Uruguay, 49, 100, 498, 520
- user charges
 - additional resources, 241
 - co-payments, 421–2
 - data on, 20
 - direct and indirect types, 13
 - examples of schemes, 238–9
 - fixed, percentage-based and mixed types, 226–7
 - generally, 5–6, 11–12, 421
 - key messages, xl–xli, 13, 224–6, 239–40
 - as low-value care disincentive, 203–5, 229–30
 - for primary care, 292
 - protective mechanisms, 234–8
 - revenue from, 230–1
 - See also* informal payments; medicines procurement; out-of-pocket (OOP) payments; risk pooling
- user charges, unintended effects
 - drug regimen nonadherence, 228–9
 - poverty, 231–4, 332, 421–2, 521
 - preventive care discouragement, 230
 - unmet health needs, 234
 - See also* equitable healthcare provision
- vaccines in COVID-19 pandemic, 408, 438, 559–60
- Valletta Declaration, 437
- value-added tax. *See* indirect taxation
- value-based pricing for medicines, 428–9
- value-for-money decisions
 - disinvestment decisions. *See* low-value care decommissioning
 - by donors, 530–1
 - HBP setting. *See* health benefits package (HBP) setting
 - for hospital care, 325–6
 - HTA for. *See* health technology assessment (HTA)
 - in long-term care sector, 277–8
 - for pandemic preparedness, 548–9
 - See also* quality of care
- Vanuatu, 43
- VAT. *See* indirect taxation
- Venezuela, 100
- vertical priority-setting, 517–18, 532, *See also* horizontal priority-setting

- Viet Nam, 529, 562–4
- voluntary health insurance (VHI)
 additional resources, 112–13
 adverse selection concern, 5, 12, 92–4, 102
 CBHI. *See* community-based health insurance (CBHI)
 complementary and supplementary types, 5, 31, 93–5, 105–7, 110–11, 145
 distorted use of resources concern, 148
 early forms, 102–3
 horizontal priority-setting, implications for, 520–1
 key messages, xxxvi, 91–2, 112
 medical savings accounts (MSAs), 5
 OOP payments compared with, 94
 policy responses, 110–12
 public finance increases, effects on, 103, 111
 resistance to regulation concern, 109–10
 revenue from
 changes over time, 96–101
 general data, 20, 38
 national comparisons, 96, 98,
 substitutive type, 96, 111
 UHC delivery via, overview of challenges, 9–10, 101
 unaffordability concern, 103–7
 for user charges reimbursement, 238
- Wellcome Trust, 549, 584, 586, 638
- WHO. *See* World Health Organization (WHO)
- women
 formal workers in LTC sector, 250, 479–80
 informal workers in LTC sector. *See* informal carers
 long-term care (LTC) recipients, 271–2
- World Bank
 ODA provision by, 119, 123
 pandemic preparedness guidance, xlix, 547
 pandemic preparedness mechanisms, 560, 561
See also official development assistance (ODA) for health
- World Health Organization (WHO)
 antibiotics work, 573, 592
 Contingency Fund for Emergencies, 559
 essential medicines guidelines, 423
 long-term care needs estimate, 270
 neglected diseases initiatives, 615–16, 661–2
 OOP threshold recommendation, 40
 pandemic preparedness guidance, xlix, 547, 551
 poverty definition, 232–3
 risk pooling guidance, 140–1, 154, 156, 160
 universal health coverage guidelines, 516
- XPRIZE Foundation, 652
- Zimbabwe, 74

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