

WHAT'S IN, WHAT'S OUT?

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WHAT'S IN, WHAT'S OUT?

Designing Benefits for Universal Health Coverage

Edited by
Amanda Glassman,
Ursula Giedion *and*
Peter C. Smith



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FOREWORD

Lord Darzi of Denham
Kalipso Chalkidou

This book, a multiyear effort by leading applied academics, frontline practitioners, and policy-makers from around the world, is the first-ever “how-to” guide to addressing one of the most overlooked practical, methodological, and moral questions in nations’ journeys to universal health coverage (UHC): *What do we pay for in our healthcare systems and how do we decide to pay for it?*

This guide comes at the right time. With the current squeeze on aid budgets in high-income countries and a persistent skepticism in emerging economies about the return of investing in healthcare compared with other priorities such as education or the environment, policymakers need guidance on how to design affordable, equitable, good-quality packages of care for their populations. These packages of care must address specific needs, be able to be delivered in a realistic framework, and be costed and shown to be feasible within available resources. To be relevant and useful to healthcare policy creators and drivers—the politicians, budget holders, and regulators in developing countries that are committed to UHC—such

guidance must be both methodologically rigorous and grounded in the practical challenges that they likely will face.

This book was developed for and to a large extent with these audiences in mind. It distills practical experiences and in-depth understanding of the theory and the realities of evidence-informed policy-making. Alongside chapters on economic evaluation methods and ethical, legal, and governance frameworks, it features case studies and testimonials from national treasuries and health insurance funds, think tanks, and university groups working closely with governments such as those of Malawi, South Africa, and Vietnam.

The book has been developed under the auspices of the International Decision Support Initiative (iDSI), which was launched in 2012 following the publication of a report by the Center for Global Development on priority-setting institutions for better spending on health. Led by the Institute of Global Health Innovation at Imperial College London, iDSI stands for “better decisions for better

health.” Because UHC can be a unique mechanism for redistribution of health resources, and such redistribution is more readily achieved through locally relevant, fair, and evidence-informed processes, iDSI has been designed as a multicountry, multidisciplinary partnership of practitioners and researchers from around the world. It is supported by the United Kingdom Department for International Development and the Bill & Melinda Gates Foundation, with lead partners in Thailand’s Ministry of Public Health and its Health Intervention and Technology Assessment Program, South Africa’s Wits University, China’s National Health Development Research Center, and the Center for Global Development in Washington, DC.

iDSI has supported the government of India in its assessment of the value of medical technology for its national and state health insurance schemes, and advised China’s National Health and Family Planning Commission on setting up a network for health policy research and technology evaluation comprising 30 universities and more than 10 provincial health bureaus. It has worked with the South African National Department of Health to implement the UHC vision in a financially sustainable and equitable fashion; and with the Vietnamese authorities to review and rationalize the country’s health benefits package. It also has helped the Indonesian national health insurer decide whether to fund preventative interventions and determine how to cover off-label medications. All of these efforts, of course, have required evidence to build successful approaches,

whether in the form of clinical and economic evidence; evidence on feasibility, including the total bill with regard to available funds; assessments of cultural acceptability; evidence on government priorities, and an awareness of opportunities to make things happen on the ground.

The work is hardly over. The iDSI team is planning to use the material for courses, including massive open online courses, or for simulation games using hypothetical and real budgets; for real-time links to GEAR, an innovative database for sourcing and addressing policymakers’ questions on the economic evaluation of healthcare interventions; and for postings to F1000 Research’s iDSI gateway, a new open-access knowledge-sharing platform. Information from this book has made it possible to deliver training in South Africa to colleagues from six sub-Saharan Africa countries, including policymakers from the Republic of South Africa, and the team is planning to do more in India and West Africa. Team members also will develop a case study compendium using real country examples of the good and the bad, contributing to a live document that will be able to grow and adapt to accumulate experience and drive research as much as it can to inform practice.

We hope that the Institute of Global Health Innovation can be a catalyst in these efforts, and we look forward to learning from our partners and taking the lessons that we learn back to our own National Health Service—which more often than not faces the same challenges of maintaining high levels of quality, affordability, and access.

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ABOUT THIS BOOK

Vaccinate children against deadly pneumococcal disease, or pay for cardiac patients to undergo lifesaving surgery? Cover the costs of dialysis for kidney patients, or channel the money toward preventing the conditions that lead to renal failure in the first place? How much to do of each? Policymakers who deal with the realities of limited healthcare budgets face tough decisions like these regularly. And for many individuals, their personal healthcare choices are equally stark: paying for medical treatment may be infeasible, or could push them into poverty.

Many low- and middle-income countries (LMICs) now aspire to universal health coverage (UHC), where governments ensure that all people have access to the quality health services they need without risk of impoverishment. But for UHC to become reality, the health services offered must be consistent with the funds available—and this implies tough everyday choices for policymakers, choices that could be the difference between life and death for those affected by any given condition or disease. The situation is particularly acute in LMICs, where public spending on health is on the rise but is still extremely low, and where demand for expanded services is growing rapidly.

This book, *What's In, What's Out: Designing Benefits for Universal Health Coverage*, argues that an

explicit health benefits package (HBP)—a defined list of services that will be funded with public monies—is an essential element of a sustainable and effective health system. Contributions from leading analytic and policy experts consider the many dimensions of governance, budgets, methods, political economy, and ethics that are needed to decide “what’s in and what’s out”—what services are critical to a successful HBP, and what services are desirable but not essential—in a way that is fair, evidence-based, and sustainable over time. As a result, this book aims to reach out directly to LMIC policy audiences—policymakers and their advisors who have been tasked with “designing the package” or “updating the package” as part of UHC reforms, who are looking for an overview of basic principles and what has been done elsewhere, and who are considering options for their own next steps in consolidating an effective HBP-based UHC policy.

External global health funders and advocates are also key audiences for this work. People often talk about health systems and UHC as something outside the realm of global health, where the concept of “global health” itself is understood here as the policies and interventions that are intended to reduce vaccine-preventable diseases or HIV/AIDS and are heavily supported by external funders in the form

of aid. Yet public money priorities matter greatly for global health outcomes, and will matter more than the amount of aid, which is a declining share of total spending on health. Too often, aid funding for mostly cost-effective healthcare such as vaccines and antiretroviral therapy happens outside public budgets and outside the health benefits package. As middle-income countries lose their aid eligibility or as donors change policies, there is a risk that these key services will fall off the list of public subsidy, with potentially disastrous and immediate consequences for health.

Global health advocates themselves are stakeholders and competitors in global and domestic resource allocation decisions. This book aims to show how important fair process and rigorous methods are to maximizing health in LMICs, where tough prioritization decisions must be made.

Finally, the book may also be useful to the healthcare industry more broadly as it deepens investment in new markets. To this audience, the book argues that the clearer the decisionmaking process and criteria for obtaining public reimbursement for a product, procedure, or device, the more level the playing field for competing firms and the clearer the incentives to develop products that meet the cost-effectiveness criteria of a country's health system.

We believe that this work makes a unique contribution to a field that for several decades has been more art than science. Private health insurers in high-income markets have long understood that the definition of benefits is at the heart of their business sustainability. Public insurers and payers need to take this same view of the issue to make the best use of public funds; unlike private insurers who respond to shareholders and clients, public insurers and payers are accountable to the public at every step of the process.

Yet this book is far from comprehensive and should be viewed as a first effort to understand and analyze the options that LMIC health systems face.

Aspects that it does not cover include greater analysis of the range of institutional arrangements that underpin the governance and resource allocation process, a deeper dive on how existing plans cover specific disease burdens and related interventions and technologies, more information on how a cost-effective HBP design can help with price negotiation and purchasing more broadly, and a broader assessment of emerging legal and rights issues in health systems around the world. We provide as many country examples as possible without field-based original research, but strongly believe that more documentation, original research and analysis, and experiencing-sharing on how different health systems operate their HBP policies are all needed.

The book is not intended to be a technical manual for conducting health technology assessments or cost-effectiveness analyses; there are other comprehensive resources on these topics. Instead, the goal is to put HBP development and design methods into a broader context and consider how they might be applied practically to coverage decisions in LMIC settings.

Finally, the book is a collection of views of different authors, experts, and disciplinary perspectives; as a result, each chapter is written and approaches the topic in different ways. We believe that this diversity is helpful in nurturing debate about the emerging scientific, ethical, and governance issues that arise in setting health system priorities.

The book is organized in four parts, each followed by short commentaries by policymakers engaged in developing HBP policies. The first part is an overview for the rest of the book, describing why an explicit statement of the benefits to be publicly funded is core to the UHC mandate and providing a framework to help think through the necessary steps involved in setting up a HBP. The second part lays out the governance arrangements, budget issues, and monitoring and evaluation functions that an effective HBP

policy will consider. The third part focuses on the methods, criteria, and evidence that can be and have been used to design and adjust HBPs, and touches on how to deal with constraints to analyses, from limited data to supply-side inadequacies. The final part

discusses some of the political economy, ethics, and rights issues involved in HBP design and adjustment.

An accompanying set of learning resources is available on our website: cgdev.org/health-benefits.



Credit: Athit Perawongmetha / World Bank

INTRODUCTION

The Health Benefits Package

Bringing Universal Health Coverage from Rhetoric to Reality

Amanda Glassman

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At a glance: Universal health coverage promises health coverage for all. A health benefits package defines what the government can deliver—and what citizens can demand—given budget realities.

There is immense interest worldwide in the notion of universal health coverage (UHC): the idea of providing a core set of good-quality health services to which all citizens are entitled regardless of their circumstances. After the political commitments are made, however, many policymakers are left to grapple with the central issue: what services should be made available, and under what conditions? This book aims to provide a framework and implementation options for UHC, and will give examples of how a health benefits package (HBP)—the set of health services and products that can be feasibly financed and provided for everyone, given a particular country’s actual circumstances—can work in the real world.

This introductory chapter sets out the policy background for current interest in HBP. It starts with a brief discussion of UHC and the pool of public funds available to fund the HBP. It then explains the role of the HBP and the importance of making explicit choices regarding its contents. The chapter concludes with a framework that presents the important processes that should be undertaken if a sustainable HBP is to be specified and delivered to the population, within financial and other constraints. The framework does not seek to be prescriptive about how the processes are organized; rather, it asserts that these processes must be implemented in some form, whatever the institutional context.

Universal Health Coverage

The worldwide interest in UHC culminated in the publication of the World Health Organization's (WHO) World Health Report 2010 on the topic,¹ and was given further momentum when the United Nations (UN) General Assembly adopted Resolution A/67/L.36 on UHC in December 2012. In January 2016, the UN adopted the pursuit of UHC as one of its 17 Sustainable Development Goals. The WHO defines UHC as “ensuring that all people can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.”² In practice, UHC aims to ensure that certain health services or products are delivered free of charge, or at a subsidized fee, to the entire population.

It is easy to understand the international interest in moving toward UHC. Done well, UHC improves access to health services for many people who otherwise would be unable to use those services, and can improve the use of services designed to prevent future ill-health.³ It can reduce the incidence of serious impoverishment caused by health shocks. And, by making access to health services unrelated to ability to pay, it satisfies a widely held concept of fairness.⁴ Further, as well as promoting financial security, progress toward UHC can improve health outcomes for the population.⁵ Most high-income countries have had a comprehensive form of UHC in place for several decades, and an increasing number of low- and middle-income countries (LMICs) are seeking to make a transition toward these same outcomes.

A central requirement of any UHC system is that the range of services made available to the population is consistent with the available resources. This book argues that the creation of an explicit HBP is an essential policy tool to meet that requirement. This chapter describes the functions needed to design and adjust a HBP over time, in a “framework” for setting

and adjusting what is included in and excluded from the package. It sets out the salient features of the health system needed to implement UHC, and explains why an explicit package is desirable. After establishing the framework, which comprises 10 core elements, the chapter concludes with some brief observations on implementation.

The UHC Funding Pool

UHC systems require the establishment of a pool of finance with which to fund the health services to be made available. Whatever the precise source of such finance, in order to maintain the universal principle of UHC, it is essential that a citizen's financial contributions are mandatory, and that they are unrelated to the individual's medical circumstances, risks, or ability to pay.⁶ If these basic requirements are not met, then both economic theory and practical experience show that the health insurance mechanism breaks down, or progress toward UHC stagnates.⁷ Therefore, a defining feature of UHC is its reliance on public finance, in the form of taxation or pseudo-taxation, such as social health insurance. In most systems that have adopted UHC, financial contributions are related to ability to pay, and so have the effect of ensuring that healthy and wealthy people to some extent cross-subsidize the health service utilization of poor and sick people.

A serious limiting factor in any progress toward UHC is the size of the funding pool that a country is willing and able to make available for “needed” medical services. High-income countries can claim that their available funds enable them to cover most mainstream medical services. Even in high-income countries, however, there are increasing debates about the ability to subsidize certain high-cost drug therapies, and more general concerns about the future sustainability of existing systems. This trend reflects more general long-standing debates about

the “rationing” of health services.⁸ Such debates are in many ways like those in low-income settings that consider “prioritizing” only a limited number of treatments for public funding. Although the nature of the binding constraints facing low-income settings is much more dramatic—in 2013, low-income countries spent an average of US\$37 per capita on health versus US\$4,456 in high-income countries—the political economy of different interest and patient groups seeking to expand coverage without regard to resource constraints and trade-offs is broadly similar.

To some extent the effective size of the funding pool can be enlarged by expanding the scope of the taxation base and improving the efficiency with which services are delivered. However, no country can possibly offer access to all available medical treatments. Serious questions therefore need to be addressed on how best to use the limited funds available, especially in LMICs. Thus, in making a transition toward UHC, three fundamental policy questions arise: what services should be available under UHC, to whom should they be made available, and what (if any) user charges or other arrangements should be attached to services that are not considered priorities given current circumstances?

In practice, the imposition of user charges, even if they are below market prices, is bureaucratically complex and (if poorly designed) can frustrate the objectives of UHC.⁹ Likewise, restricting UHC or charging different prices to different socioeconomic groups or certain subsets of the population can be ethically and administratively questionable. In many countries, for example, the administrative expense related to the collection of user charges can be greater than the sum of the charges themselves, defeating the purpose of expanded revenue collection. Further, the practice of excluding informal sector workers with some ability to pay from public healthcare subsidies has been largely unsuccessful.¹⁰ Some have argued that UHC might be limited to certain disadvantaged groups, such as poor households;¹¹ and several of

these targeted schemes have successfully enhanced utilization and outcomes among these groups. However, such policies run the risk of alienating the broader population, who fund the scheme, and in any case the need to equalize benefits among different groups generally grows over time, and these targets and restrictions compromise the universal principle of UHC.

Therefore, in practice, a major policy focus in moving toward UHC has been on what services should be made available and under what conditions—or, as the title of this book puts it, “what’s in and what’s out?”

The Health Benefits Package

The set of health services to be made available can be determined implicitly or explicitly, but the simple accounting requirement means that its total size will be constrained by the available funds. This may seem obvious, but the discontinuity between aspirational health plans and actually available financial and other resources is the single most common failing of existing benefits plans in LMICs.¹² Furthermore, it is important to distinguish the *de jure* set of treatments offered in theory (perhaps defined in grandiose terms such as “all necessary services”) from the *de facto* set of treatments that patients actually receive, which may be severely restricted by factors such as budget, infrastructure, human resources, geographical, cultural, and other constraints. The chapters in this book are concerned with how a feasible set of UHC services can be explicitly defined to create what is commonly known as a HBP, a set of services that can be feasibly financed and provided in each country’s actual circumstances.¹³

An important characteristic of the HBP as defined is that the services included are made explicit, so that citizens can be made aware of what services are (and, equally important, are not) available and so

that payers may assess year-to-year resource requirements. It should then represent an explicit statement of the services to be made available that secure the maximum value (however defined) from the limited funds available. Nevertheless, explicit HBP specifications create political and practical difficulties for several reasons:

- Countries may lack the analytic and administrative capacity to set a HBP with any assurance.
- The data needed to establish the HBP may be absent or subject to serious distortions and bias.
- Service delivery constraints may preclude changing the current pattern of services.
- Legal statutes may appear to proscribe any limits on access to publicly funded services.
- The need to make the HBP explicit may create political tensions by alienating certain patient or provider interest groups.
- From a financial ministry perspective, explicit entitlements to treatment may create uncertain budgetary implications that could be resolved if arbitrary restrictions on access (like budget caps, or long waiting lists) were imposed.
- 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.
- It facilitates orderly adherence to budget limits, which might otherwise be attained only through arbitrary restrictions on access and services.
- It reduces the risk that providers will require “informal” payments from patients to secure access to high value services.
- The entitlements created empower poor and marginalized groups, who cannot be made aware of any specific entitlement without an explicit HBP.
- It creates the preconditions for a market in complementary health insurance for services not covered, with several potential benefits for the health system as a whole.

The importance of such considerations should not be underestimated. However, an explicit statement of funded and provided services also has numerous benefits:

- 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.
- It helps to identify whether funds are being spent wisely, on services that create the maximum benefit for society.

By contrast, many inefficient and unethical consequences may result from the absence of a clear statement of the contents of the HBP. For example, in the past, a commonly used resource allocation method was to fund local district hospitals with a fixed budget but without an explicit HBP statement.¹⁴ Doing so secured strict expenditure control without a need for a statement of services to be delivered. However, this approach left the choice of who should secure access to services to the local hospitals or local governments, and was liable to result in arbitrary decisions as to who secures that access, with obviously adverse consequences for efficiency (poor use of funds) and equity. Furthermore, this disconnect between the explicit hospital budget and the nonexplicit HBP was likely to increase the risk that local providers (either explicitly or implicitly) might demand informal payments from patients to secure access, further exacerbating inequities. Therefore, although it is difficult

to secure unequivocal evidence, progress toward UHC nevertheless seems to be better managed with explicit HBP specifications.¹⁵

This chapter documents the processes that will be needed to pursue such an objective. Establishing a HBP involves hard political choices, balancing the claims of various patient groupings, localities, and suppliers of technologies and services.¹⁶ However, such allocation decisions will always occur when resources are limited, as they are in every country of the world, and making these decisions transparent—and, to the extent possible, based on the best scientific evidence on benefits and costs—is an important requirement for mitigating the political difficulties that arise when setting priorities for UHC.

Compared to their counterparts in high-income settings, decision-makers in LMICs face especially severe challenges in implementing UHC systems. The profound resource limits in LMICs intensify the pressures on priority-setting processes. High-income countries could develop the HBPs in their health systems organically, being able to provide a generous package by adding new technologies incrementally as they emerged, and funding them through regular increases in the health budget alongside their economic growth. By contrast, LMICs are confronted by a huge array of technologies and services that they cannot possibly fund with their existing (or planned) funding levels. This disparity gives rise to especially difficult choices, and makes it particularly important that the interventions included in the HBP yield high value, in line with the health system objectives.

Reliance on donor funds in low-income settings can also create challenges for the HBP. Available funding levels may fluctuate from year to year,¹⁷ complicating the long-term planning process needed to select a HBP and move toward UHC. Some aid may have conditions attached that place restrictions on the diseases and services that can be covered. In the same vein, LMICs may come under pressure to adopt recommendations made by international agencies,

even if those recommendations would not otherwise be a priority or even cost-effective for their setting.¹⁸ Such recommendations may “preempt” use of funds and restrict the size of the pool available for the remainder of the HBP, potentially resulting in opportunity costs in the form of disease burden—costs that might have been averted if the entire budget was allocated jointly with an eye to maximizing health system objectives.

Choosing the Health Benefits Package

It is important to recognize that HBP specifications can take many forms and vary greatly in detail and specificity. At one extreme, a HBP could contain a detailed list of specific treatments and the criteria under which patients become entitled to that treatment, such as clinical indications or age. At another extreme, the HBP could merely comprise a general specification, such as any treatment normally occurring in a primary care setting. Both extremes create risks, in the first case of unmanageable complexity, and in the second case of vagueness and possible provision of unnecessary or inappropriate services and implicit rationing. In practice, a useful HBP is usually likely to take an intermediate form; for instance, a 2014 analysis finds a varying degree of explicitness and detail in seven Latin American countries.¹⁹

So far as is feasible, the contents of a HBP should be selected based on consistent and transparent criteria that are aligned with a health system’s objectives. It is perfectly possible to create a HBP without consistency or transparency. However, such an approach will always be vulnerable to criticisms that it unduly favors the interests of particular patient groups, service providers, or health technology industries. Setting explicit criteria makes it possible to explain the reasons for adopting or rejecting specific products and services, and can allow health systems to set up

agencies with explicit terms of reference for assessing technologies and services. Setting out a clear system and set of criteria for decisionmaking and reconsideration of evidence can also make it possible to revisit HBP decisions when more money or new evidence comes along. These are important approaches for alleviating some of the profound political difficulties that can arise when setting up a HBP, and help ensure a sustainable transition toward UHC.

Furthermore, setting transparent criteria for assessing treatments and services allows a debate to take place about what the health system's objectives should be, how priorities are to be set, and how performance should be assessed. In short, transparency is part of good health system governance. The speed of progress toward UHC will largely be constrained by the taxes that citizens are prepared to make available to fund HBP services. Their willingness to contribute to funding the health system may be strongly influenced by their confidence that the money will be spent wisely, requiring both efficient and fair choices.²⁰

Toward a Framework

The principle underlying the selection of the HBP should be to select services according to the “value” they offer, in terms of satisfying social objectives, given the costs of providing the services. Economists have pursued this principle in the development of cost-effectiveness analysis (CEA), which ranks treatments according to their costs relative to the additional health benefits they confer. CEA has become widely used and influential, and offers a practical approach to the priority-setting problem. However, it is by no means the only possible approach, and individual health systems may choose to augment CEA (for example, by including additional equity objectives) or to replace it with other analytic devices. These different methods are discussed in detail in the

second section of the book. The important requirement, however, is that any method should seek to secure for society the greatest “value for money” in setting the contents of the HBP, however “value” is defined.

The need to target the interventions that yield the highest value will become even more pressing in the future. Globally, demands on health systems will increase as life expectancy rises and new technologies emerge. These developments may promise major future improvements in citizen welfare, but they also place major responsibilities on governments and their agencies to ensure that the limited funds available are spent wisely. This will require reconciling competing claims from numerous interest groups, an intensely political process. The requirements for that process go far beyond narrow technical concerns of analytic coherence. It requires consideration of a wide range of functions that are necessary to ensure that the HBP has widespread support and real impact. (Section 1 of this book describes HBP governance and processes in greater detail, while section 3 focuses on the ethical, rights, and political economy dimensions of HBP policy.)

Further, the HBP does not exist in isolation. As signaled above, if it is to be more than a *de jure* “wish list” of services, HBP must inform health system functions like payment, provision, performance measurement, and accountability. If these conditions are not fulfilled, the HBP will be little more than a tokenistic process that has no real impact on *de facto* services that citizens can use. In this sense, an intrinsic characteristic of the transition toward UHC should be that it is “sustainable,” meaning that (1) the process of setting the HBP is practical and secures broad support from providers, politicians, citizens, and other stakeholders; (2) the HBP offered can be afforded from available resources; (3) the HBP has a real impact on services received; (4) similar (or improved) coverage can be offered over future periods, given reasonable projections of future needs, technologies,

and resources; and (5) citizens continue to support the principle of UHC and are prepared to contribute taxes and other funds to pay for it.

Any sustainable HBP will have four attributes that distinguish it from other priority-setting strategies.

1. *A HBP comprises a portfolio of multiple services, rather than single services or categories of services or technologies.* Unlike other priority-setting policy instruments characterized by discrete analyses that focus on one disease or one category of technology (such as medicines), HBP design and adjustment may (though does not always) require an assessment of the whole set of services covered when deciding on initial or ongoing inclusions and exclusions of new or existing services, given the available budget. The portfolio of services allows for a more integral costing of the package, the link with budgeting and payment, and a conceptualization of care from the perspective of the patients themselves. A portfolio does not mean that discrete analysis will not be part of the process, but that for the purposes of moving toward UHC the full complement of services and products needs to be considered. This portfolio approach is crucial because it will reflect the full set of services that the health system needs to manage. The HBP is not a program or project; instead, it is the basis on which other health systems policies and tools are used to deliver and be accountable for services.

2. *A sustainable HBP portfolio of services will be properly costed using actuarially informed estimates of supply and demand, based on realistic projections of current and future utilization.* This requirement is essential, and is a characteristic of the HBP seen in countries like Chile, Colombia,²¹ Liberia (prior to the 2014–15 Ebola outbreak),²² and Thailand.²³ In contrast, in countries such as Ghana,²⁴ Uganda,²⁵ and Peru,²⁶ the HBP has not been linked to resource availability and budgeting to the payer agency, resulting in fiscal imbalances and likely implicit rationing.

3. *A sustainable HBP will completely or partially constrain the products and services that will be made*

available through the publicly funded health system, or will serve as a guarantee that “at least” the HBP-listed services will be available. The Chilean HBP is an example of an “at least” HBP, where the set of prioritized services is made available to the entire population under prespecified cost-effective clinical guidelines, timeliness standards, and full subsidy. In Chile, non-prioritized services are still offered but are subject to implicit rationing via waiting lists, service availability, and other implicit mechanisms. A HBP might also be complemented by a negative list—a list of interventions, services, and products that will not be publicly funded under any circumstances. For example, in the past, Colombia used a negative list alongside a positive list as a strategy to limit outside-of-HBP special request loopholes for certain medicines and procedures known to be ineffective or unsafe.

4. *A sustainable HBP is a living, evolving policy instrument that should adapt as new evidence and capabilities emerge.* Processes should be in place that lead to a relatively consistent and predictable process of inclusions and exclusions over time. Most health systems continue to lack these kinds of processes.²⁷

The 10 Core Elements of Setting a HBP

If a coherent and sustainable process for setting the HBP is to be established, in line with the requirements outlined in the previous section, then 10 core elements are indispensable. It is important to underline that there is no single “correct” way of organizing these functions; their precise nature and locus may vary substantially depending on the political framework, policy choices, and nature of the health system. What is important is that structures to undertake the functions are in place, that they operate efficiently and effectively, and that the functions are aligned according to the common purpose of setting a HBP that secures the maximum value for society.

FIGURE 1. The Core Elements of HBP Design

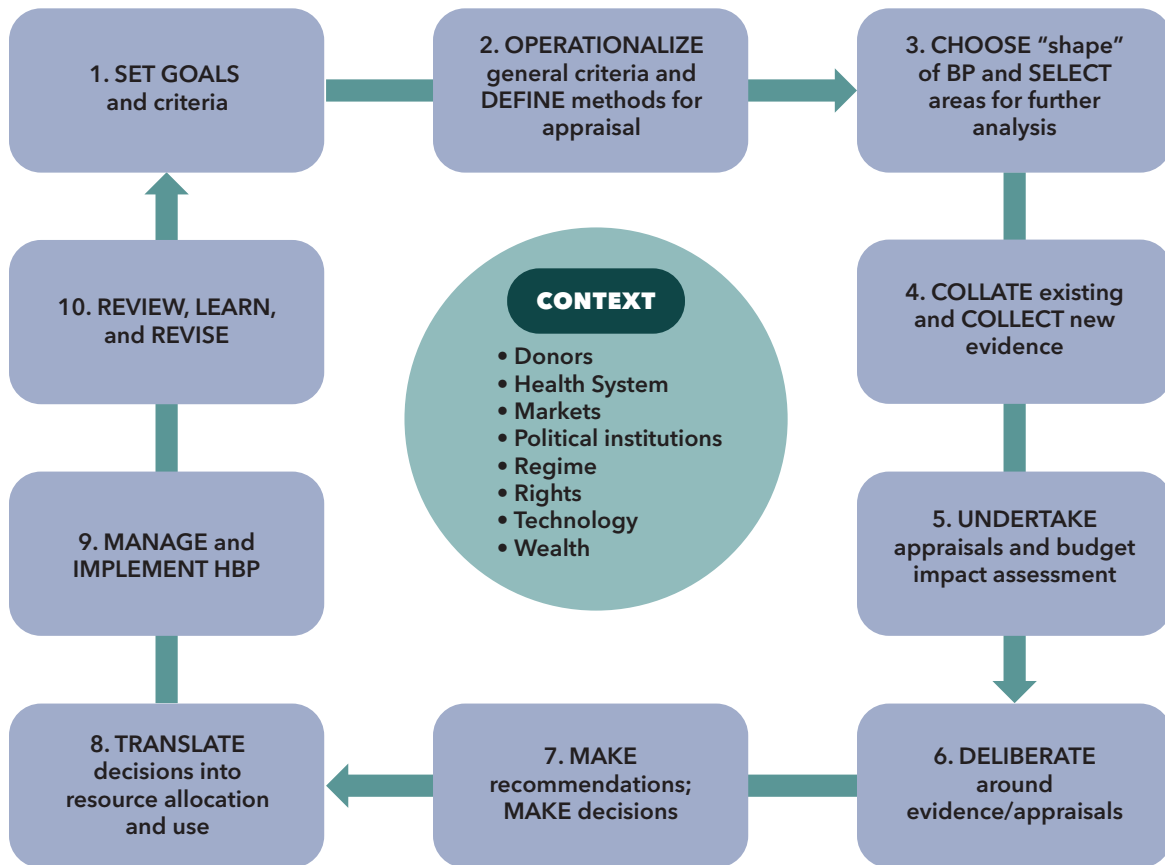


Figure 1 presents a diagram that illustrates the functions and indicates how they are likely to be ordered. In practice, their operation likely will not be so neatly sequential; rather, the ordering is intended to underline how the functions are interdependent. In practice, many functions will occur simultaneously and implementers may need to cycle back to preceding functions before undertaking later ones. Moreover, illustrating the process as a cycle highlights the fact that setting the HBP must be a continuous process, one that requires constant review and refinement as new evidence, new technologies, and even new preferences emerge. The reason for describing the inevitably messy real-world process of setting the HBP as a set of 10 discrete functions is to aid discussion and

help policymakers examine the effectiveness of the arrangements in their own health system.

This description of the HBP elements gives examples from health systems that are grappling with these issues in the context of difficult resource and other kinds of constraints. It emphasizes that HBP design is a dynamic multistep process that goes well beyond using the evidence to make decisions about what is to be covered under UHC, and thereby seeks to add value to the literature and guidance in this area.

1. Set goals and criteria. A first step in HBP design is a simple yet crucial and often forgotten one: setting clear goals and general criteria for the selection of disease control priorities and, subsequently, services

and products within each priority. At core, this step asks policymakers and politicians to clearly state the intended impact or use of the HBP. In Argentina, for example, the goal was to protect uninsured mothers and their infants from preventable morbidity and mortality.²⁸ In Vietnam, the existing HBP—initially set up to reimburse providers—is to be updated to reflect reduced donor funding for vertical public health programs such as HIV/AIDS as well as ambitions to scale up insurance coverage.²⁹ In other countries, HBPs are mainly used to define allowable reimbursement for medicines (Uruguay) or to regulate insurers (Colombia, United States). Explicit goal setting is a *sine qua non* condition to ensure coherence in all subsequent steps, and it is the basis for implementing accountability mechanisms to check whether the HBP responds both on paper and in practice to what it originally was meant to achieve. Once goals have been set, defining general (not technical) criteria for inclusion or exclusion of disease control priorities and/or services comes next. Here, policymakers and (in some cases, with appropriate process) citizen and advocacy groups can set out the list of general criteria to guide subsequent technical staff and analyses. For example, in the recently initiated HBP update in the Dominican Republic, general criteria of geographic and socioeconomic equity, severity, number of people affected, and other criteria were agreed as the basis on which to select disease control priorities and services for inclusion, while nonprioritized diseases and related interventions would be rationed implicitly.³⁰

2. Operationalize general criteria and define methods for appraisal. After setting clear goals and criteria but before diving into any specific disease or service category, a next task—likely to be conducted by technical staff and analysts rather than policymakers themselves—is to operationalize general criteria into specific criteria that can be utilized in preagreed, technically rigorous appraisal methods so that each

disease-service pair is treated consistently from a methods perspective. Methods choices are closely related to goals; for example, if the goal is health maximization, then standard CEAs may be selected as the appraisal method, and general equity criteria can be operationalized into CEAs presenting disaggregated analyses by groups. In Thailand, for example, the Health Intervention and Technology Assessment Program (HITAP) has issued a methods manual that is used as the routine reference for CEAs.³¹ Likewise, Chile has established an algorithm consisting of several explicit criteria that are used to periodically update the number of health problems that are covered by its health plan, AUGE.³² Any appraisal method selected should meet four key principles: be technically robust and justifiable; reflect social values; be easy to understand; and have a relatively low cost of implementation.³³ Not every disease-service pair will be analyzed using such methods, but the idea is to clearly set out defensible methodological choices beforehand that will provide structure for the appraisal process where it is deemed to be feasible and necessary by means of a kind of triage (see the next element).

3. Choose the “shape” of the HBP and select areas for further analysis. Given the whole inventory of possible health services in the universe of potential candidates for inclusion, policymakers must grapple with how to classify services into different categories with some kind of rules to define priority inclusions or exclusions, or types of technologies. These choices will determine the “shape” of the HBP, or its structure, language, and granularity, choices that frequently depend on the planned uses for the package (budgeting, payment, accountability, or otherwise). Further, policymakers must set priorities for the priority-setting itself, and determine where to “start”—some sort of triage must be used to determine which disease-service pairs or comparators are priorities for appraisal and decision or for other

approaches that will meet HBP goals, or that can be postponed for later. A basic decision is whether a HBP is being developed *de novo* (from a zero-based scenario), or whether it includes all services currently being provided and the priority-setting problem is only incremental (such as deciding on the use of newly available resources from year to year). Whatever the case, for analysis to add value, it must reduce the decision-relevant uncertainty, where additional information will make a difference for whether a service is included in or excluded from the HBP. For example, a country like Vietnam, with a per capita gross domestic product of US\$5000 per year, might immediately exclude medicines not considered cost-effective by health technology assessment agencies in much wealthier countries like France, Germany, and the United Kingdom. This kind of informal benchmarking to exclude is a common first strategy in rationalizing benefits plans, and does not require in-depth appraisal. However, screening interventions for common noncommunicable diseases such as diabetes are likely in a gray area—perhaps cost-effective or perhaps not, with uncertain budget impact, not currently provided systematically, and worthy of further analysis.³⁴ Similarly, countries that are setting HBPs within certain disease goals can focus their attention on appraising the set of alternate interventions that will most efficiently reach disease control goals; this strategy has been undertaken as part of HIV/AIDS program planning in South Africa using mathematical programming, for example, and could be used to set an AIDS-specific HBP.³⁵ Other approaches include polling or consulting policymakers or stakeholders on key policy questions; in Thailand, for example, policy questions are nominated by stakeholder groups (such as “should the benefits package include the battery for hearing aids?”) and used as the basis for deciding which appraisals will be conducted.³⁶

4. Collate existing and collect new evidence. For those high-priority topics identified as part of an incremental inclusion or exclusion process and decision, a next step is to systematically collate existing and collect new evidence as input to appraisal. Systematic reviews, meta-analysis, literature reviews, and graded evidence quality are well-documented and tested strategies for collating, collecting, and analyzing existing and new evidence.³⁷ Alternatively, some countries have called for periodic wholesale HBP revisions, as in the Dominican Republic example mentioned earlier. Here, evidence collation and collection is essentially done by scanning guidelines and medicines lists from other countries—even those with very different resource constraints—and making a first-round decision to include wealthiest-country-in-the-world gold-standard cost-effective guidelines for priority diseases, while leaving any additional evidence gathering and analysis for a later time.

5. Undertake appraisals and budget impact assessment. Cost-effectiveness analysis has become a widely accepted approach to appraising technologies, as embodied in numerous health technology assessment agencies worldwide. However, use of CEA is by no means universally accepted or feasible. Implemented from scratch, CEA can require infeasible analytic demands, and the findings from other health systems may not be directly transferrable. Methods such as meta-analysis can be used to synthesize results from elsewhere, and regional collaboration may help reduce the analytic burden on single countries. A frequent criticism of CEA is its failure to address objectives other than health maximization, and other more general methods have emerged, although these can introduce new analytic complexities. Participatory methods such as program budgeting and marginal analysis are based on similar principles to CEA, but allow greater flexibility and participation of key stakeholders, although they are

demanding in terms of convening skills and expert facilitation.³⁸ A final key analytic step is to assess the budget impact of the proposed changes to the HBP as a whole (not only the part related to the appraisal) in current and future fiscal years. Here, too, there are widely accepted methods standards.³⁹ The lack of a robust budget impact analysis of the proposed change can lead to a lack of coherence between what is being promised in the HBP and what resources are allocated to implement it, and frequently compromises the package's sustainability.

6. Deliberate on evidence/appraisals. Once appraisals or proposals are prepared, a next step is to establish a mechanism that will allow for discussion and deliberation around evidence and appraisals/proposals as an input to recommending which components can be included or excluded (see step 7). In Organisation for Economic Co-operation and Development (OECD) countries, most notably in the case of the United Kingdom's NICE (National Institute for Health and Care Excellence) committees and citizens' councils, deliberation is more commonly applied as part of a health technology assessment, but there are good reasons to consider including a process of deliberation around the entire portfolio of HBP services and its subsequent adjustment. The information and methods available to make decisions on what components to include or exclude involve substantial uncertainty related to limited local information sources, variable strength of the evidence base, restricted empirical information on effectiveness, and the strengths and limitations of having and combining objective criteria. For example, LMICs often lack solid information on treatment costs and effectiveness in their own context.⁴⁰ Further, beyond incorporating specific criteria into the selected methods and appraisal approach, other values or considerations might be brought to bear in the selection of services. Under many circumstances, stakeholders can agree on a deliberation process that they consider

to be fair while acknowledging the uncertainties and constraints of the data and evidence.

7. Make recommendations and decisions. In many settings, deliberation ends with a recommendation to policymakers on the individual services or portfolio of services that are to be included in the HBP during either its initial design or later adjustment process, but fails to connect the recommendation with decisionmaking. In an ideal process, there is an obligation to consider the appraisal and its recommendations in decisionmaking on whether services are included or excluded for public subsidy. Such an obligation has been established in regulation in some countries (Thailand, Mexico), while in others recommendations are not binding for budget decisionmakers (United Kingdom, Colombia). The key issue is to lay out clearly how appraisals/recommendations will relate to decisionmaking bodies and individuals, whether payers or providers. There may be a need to first build confidence in the evidence/appraisal before setting up an explicit connection between recommendations and decisionmaking. Further, attention should be given to communicating recommendations and decisions to providers, the public, and policymakers at different levels of government.

8. Translate decisions into resource allocation and use. Decisions emanating from appraisals, budget impact analysis, and recommendations can be translated into resource allocation in binding or non-binding ways, but an effective HBP needs to have direct influence on resource allocation, whether through budgets, fiscal transfers, payment, reimbursements, or product procurement. Some health payers are legally required to consider recommendations in resource allocation. For example, as established in regulation, Mexico's Seguro Popular package CAUSES is the basis for budgeting the payment transferred by the federal government to state governments for the provision of CAUSES

services.⁴¹ Similarly, in Colombia and Uruguay, a medicine must be included in the published HBP regulations in order for insurers to reimburse or pay for it. However, in the absence of legislation or regulation, there may be other inducements for budget decisionmakers and providers to adopt recommendations. For example, reimbursement rates for non-included medications might be set at similar prices to included comparator medications, to avoid creating incentives for prescribing non-HBP medicines. Other nonfinancial strategies can induce adoption of included services, such as clinical guidelines with peer review or medical audits. Beyond these hardwired or inducement mechanisms to link decisions with resource allocation and use, there is an ongoing need to adjust HBP for resources available over time using inflation adjustments, price tracking/benchmarking, and other strategies (see step 9).

9. Manage and implement the HBP. Once resources are allocated, payers and providers of care delivery are involved in an ongoing process of HBP services implementation. But in the context of the HBP framing, HBP management and implementation denote the tasks that the HBP manager must perform to continuously update and monitor HBP payments and services using prescription and utilization data, to communicate with stakeholder groups on included and excluded services, to resolve disputes, to manage exclusions, to inform price negotiations with manufacturers,⁴² to prepare financial forecasts and plan needed adjustments, and so on. HBP implementation means ensuring that the benefits are delivered in practice, that the package is in line with its initial goals, and that it is both financially and institutionally sustainable. In short, implementation ensures that the HBP is coherent with available resources, policies, and context. This function or step is often forgotten and without an institutional home, but should lie at the heart of obtaining the value for money for UHC in the context of limited resources.

For example, an analysis of the coherence between Mexico's conditional cash transfers program and the availability of the infrastructure and inputs required to deliver the program's health benefits found that very few health posts had the capacity to provide the covered services.⁴³ Similarly, in Colombia there is no explicit alignment between the content of the HBP and the clinical practice guidelines, even though both are developed by the country's ministry of health.⁴⁴

10. Review, learn, and revise. Based on the management and implementation experience, the release of new technologies in the market, the emergence of new evidence on existing services, and changing amounts of resources available to finance the HBP, the HBP process should involve continuous learning, adjusting, and starting over. Often, countries do not have any systematic processes in place to update their HBPs, and a periodic updating process is rare.⁴⁵ Chile is an outlier in this context, as its normative framework mandates that its HBP be updated every two years.⁴⁶ A process for monitoring implementation, such as by measuring effective coverage of services and treatments included in the HBP, would be an ideal approach, but currently no country has such a process in place. The constraints to implementing desirable technologies should be assessed, and appropriate changes to the health system recommended as needed.

Cross-cutting and Contextual Issues That Influence HBP Policies

A set of cross-cutting and contextual issues need to be considered and managed when implementing the HBP framework.

Good governance across the cycle is an area that has received relatively limited attention, but can affect the rigor, fairness, and outcomes of the HBP; chapter 1 covers this issue in depth. Institutional

arrangements—placement, staffing, budget, extent of independence—are also critical to establish, and are discussed further in the introduction to the second section. The political economy, ethical dimensions, and rights of HBP and priority-setting are also fraught with challenge and complexity, and are covered in chapters 12, 13 and 14.

It is also essential to consider the specific context of each country and health system when developing HBP-related policies. HBP policies will operate differently depending on a health system's structure. For example, systems that separate payment and provision will need a greater level of specificity in “what we're buying,” as the HBP will be used to contract providers and regulate their performance. But even in decentralized or deconcentrated systems, such as the United Kingdom's National Health Service (NHS), there may still be care commissioning (as there has been between Primary Care Trusts and providers in the NHS) or there may be transfer and accountability arrangements (as in Mexico). In decentralized systems, fiscal experts may recommend leaving the definition of the HBP (and priority-setting in general) to subnational entities. However, given limited subnational capacities in healthcare resource allocation—reflected in low coverage of highly cost-effective basic healthcare alongside subsidies to less cost-effective interventions—experience suggests that it may make sense to first cost a basic HBP according to an aggregate assessment of resources available. Once the costs are established, subnational entities can then begin an iterative process of scaling the HBP according to resource availability, defined as states' capacities to finance themselves and the federal or central government's capacity to transfer funding to equalize public subnational spending to support the provision of the services specified in the HBP.

Conclusion

This introductory chapter has sketched the complex set of interconnected elements that ideally should be put in place to create a sustainable HBP. The HBP is the cornerstone of a modern health system that is seeking to make the transition toward UHC. This chapter has highlighted the numerous functions needed to develop a HBP, all of which should be aligned in pursuit of a coherent set of health system goals. Failure to attend to any of the functions jeopardizes the creation of a sustainable HBP, and may put at risk support for the principle of UHC.

Some sort of CEA will often form a crucial element of the evidence base for the HBP. However, explicit consideration of the 10 HBP design functions indicates that CEA and other quantitative evidence form only a part of the entire process. The process also embraces crucial elements such as political decisionmaking, stakeholder engagement, and implementation, which all involve different skills and mechanisms.

An important aspect of UHC that is rarely given adequate attention is the quality of services offered within the HBP. If certain population groups secure access to the included services at only low quality levels, the principle of universal coverage is breached. Therefore, for many services, it will be important to specify explicitly the level of quality that service users can expect, and to monitor adherence to those quality criteria. Where service capacity is inadequate, policies will be needed to bring the service up to the required level. The costs of such implementation issues should be included in the evidence when deciding whether to include the service in the HBP. Chile's AUGE guarantees—describing a set of highly cost-effective services that will be provided at a given and budgeted standard of quality and timelines, that can be tracked, and for which providers can be sanctioned for failure to provide under agreed conditions—are a good example.⁴⁷

A persistent theme in the discussion has been the need to ensure that all necessary functions—such as budgeting processes, clinical guidelines, or provider inspection regimes—are aligned to create and implement a HBP. How such alignment is to be secured will depend on the nature of the health system. A government-organized national health service may try to secure coherence through direct administrative rules and procedures. A more decentralized type of system may seek to set up regulators for which the terms of reference are carefully coordinated. In some circumstances, the coordinating mechanism might be a strong performance measurement system that monitors all parties' adherence to the HBP principles and contents.

The HBP should determine which services will be subsidized by public sources of finance. Although the costs of those services should be fully considered, a publicly funded HBP should not make assumptions about whether the services will be provided by public, not-for-profit, or private providers. The key issue is that the services should be provided efficiently and in line with intentions, which requires a properly functioning procurement function.

Services that are excluded from the HBP might still be provided and used within the health system; at minimum, a policy should be in place to manage exceptions. Excluded services might be funded privately (by out-of-pocket payments or voluntary health insurance) or by other parties, such as charities or municipalities. By definition, such services are likely to offer less value for money than those included in the HBP, but some might choose to use them nevertheless. This suggests, for example, that a properly functioning voluntary health insurance market, covering services not included in the HBP, might be an essential complement to the publicly funded HBP. However, the principle of universality embodied in UHC requires that HBP services should be provided to a level of quality that is satisfactory for all potential users. The publicly funded

package should not become a low-quality safety net for those on low incomes. Other strategies to manage exclusion include the adoption of implicit rationing and/or fees for nonprioritized services, partnerships that allow for cofinancing of poorer patients with pharmaceutical or device firms, or even rationing according to clinical quality standards. All of these strategies are problematic and politically challenging on different levels, but they are all preferable to *ad hoc* approaches. No matter what strategy is employed to cope with technologies that have been excluded from HBP coverage, exclusion is an area that requires specific attention and planning. The chapters in this book offer strategies to help policymakers manage exclusions, including ethical and legal challenges. Box 1 points the reader to specific chapters that discuss these strategies.

Again, a sustainable HBP requires constant review and revision, as new evidence emerges, new technologies are developed, and national circumstances evolve. It must be an ongoing process, and an important part of creating the HBP is to put in place well-governed institutions and processes that ensure that revisions are implemented in an orderly and coherent fashion.

Finally, the need to tailor the HBP process to local conditions and local systems must be stressed. Although the 10 elements described above will be important components of that process in any health system, the exact form they take, and the institutions involved, are likely to vary depending on local circumstances. For example, it is clearly infeasible for low-income systems to emulate the complex system of regulators and institutions found in high-income countries such as the Netherlands. However, all systems will need to ensure that the functions described above are undertaken satisfactorily, often in the context of the country's existing set of institutions. Failure to do so will make it difficult to establish a coherent HBP, and may compromise the transition toward UHC.

BOX 1. What's Out? Managing Exclusions

This book deals with both deciding “what’s in” the HBP (and ensuring that those services are provided effectively) and determining “what’s out.” The latter part of this framework—specifying the services that will be excluded or deprioritized—is often the most difficult and contentious dimension of HBP design. Specific chapters of this book focus on particular aspects of this problem.

In chapter 1, Ursula Giedion and Javier Guzmán suggest that adherence to good governance principles, including transparency, stakeholder participation, and consistency, can help sensitize the public to the need to set limits and lend legitimacy to subsequent exclusion decisions. By establishing a fair process for HBP decisionmaking, governments can ensure that citizens are better placed to understand the rationale behind exclusions and accept coverage decisions.

In chapter 3, Amanda Glassman describes how budget coding and allocation conventions should be made consistent with HBP contents, preventing funds from covering services or indications excluded from the HBP.

In their Policymaker Commentary in Part I, Mark Blecher and Yogan Pillay discuss South Africa’s initial steps toward development of a more explicit HBP. In the South African context, removing existing benefits was not seen as politically viable. Nonetheless, policymakers reached tentative agreements to assess new technologies based on cost-effectiveness and create protocols for benefit eligibility at different levels of care.

In chapter 13, Carleigh Krubiner and Ruth Faden examine the ethics of HBPs, with particular attention to exclusion decisions. Fair processes, they argue, can improve the probability that exclusions are ethically and politically acceptable. In addition, provision of palliative care can ease suffering when resource constraints prevent certain curative treatments from being included in the HBP. Monitoring and evaluation during implementation can also “rapidly identify any morally relevant harms” produced by prior exclusion decisions.

In chapter 14, Rebecca Dittrich and colleagues discuss how certain exclusion decisions are vulnerable to legal challenge, often by appealing to a legal “right to health.” She suggests four strategies to reduce legal exposure: using fair methods to underlie coverage decisions, setting HBP policy through legally minding mechanisms with an eye toward judicial precedent, instituting an appeals process prior to judicial review, and soliciting input from the judiciary early in the HBP design process.

In his Policymaker Commentary in Part III, Antonio Infante recounts the Chilean experience of the politics of priority-setting. Chile’s AUGE system—Universal Access with Explicit Guarantees (Acceso Universal de Garantías Explícitas)—does not explicitly exclude services from public subsidy; rather, it creates a list of “prioritized” services with guaranteed timeliness, quality, and financial protection. This approach helped to defuse ethical and political objections to priority-setting and increase public acceptability of the AUGE.

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POLICYMAKER COMMENTARY

Revisiting and Reformulating

How Explicit Benefit Packages Have Helped Mexico Move toward Universal Health Coverage

Eduardo González-Pier

At a glance: Mexico's Seguro Popular shows that guidance on reformulating existing health benefits packages is just as needed as guidance on creating new ones. This book collates countries' experiences with health benefits packages and gives policymakers a tool to sustainably advance their universal healthcare agendas.

For more than 20 years, defining explicit health benefits packages (HBPs) has been a core strategy to guide efforts to increase healthcare coverage in Mexico, especially for the poor. The landmark 1994 study *Economía y Salud*, led by the nonprofit healthcare organization Funsalud, introduced the concept of a national healthcare plan using what were then novel cost-effectiveness tools to choose interventions that would maximize health outcomes under a limited budget. By 1996 Mexico's Ministry of Health was implementing a World Bank–sponsored Coverage Expansion Program based on 32 highly cost-effective preventive and primary care–based interventions in rural poor communities. The program had encouraging results, and the following year this HBP became

the health component of the government's flagship conditional cash transfer program Progresa (Education, Health, and Nutrition Program).

Since these early efforts, progress toward universal health coverage (UHC) has been significant. Today, 56 million Mexicans not covered by social insurance—roughly half of the Mexican population—receive health insurance coverage through Seguro Popular, created in 2004. In contrast to the well-established large social security institutions such as the Mexican Social Security Institute (Instituto Mexicano del Seguro Social; IMSS) and the Institute for Social Security and Services for State Workers (Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado; ISSSTE), which over

time had followed a supply-driven coverage expansion plan, Seguro Popular followed the strategy of delivering care based on population health needs. Since its inception, Seguro Popular coverage has been pivoted on two explicit healthcare packages: a set of mainstream primary care and general hospitalization services (called CAUSES) and a set of high-cost/high-complexity healthcare interventions. CAUSES currently includes 284 interventions delivered and managed at the state level and financed through capitated payments to state governments. The high-cost/high-complexity package is centrally managed by the Catastrophic Health Expenditure Fund (Fondo para la Protección contra Gastos Catastróficos; FPGC), and it now reimburses 61 interventions directly to providers. Although results for the most part have been positively evaluated, Seguro Popular has not been without governance problems, design flaws, and budgetary and operational issues that warrant further policy revisions.

The Center for Global Development has made a formidable effort to document and analyze the growing pool of knowledge on HBPs across many countries and time periods in this current volume. For the first time, policymakers have access to a structured analytical framework to help understand what is and is not sound, evidence-based policymaking and translate these findings to each country's specific health system needs. Had this guide been available during Seguro Popular's design phase in 2003, the program undoubtedly would have been better structured and more in line with patients' evolving needs and expectations.

UHC has been and will remain a moving target. The need for insight into how best to revisit and reformulate an existing plan is just as relevant as the need for guidance on how to introduce a new HBP into an existing health system. It is often the case that as soon as new funds are made more available and accessible for healthcare uses, population growth, evolving health needs, technological change, and limited fiscal

space (especially in low- and middle-income countries) all keep changing the breadth, depth, and height of the UHC question, turning access into a continuous policy challenge. Policymakers need to understand what continuous "HBP maintenance" really means in this ever-changing context—which elements of the package need to be revisited and updated periodically, and which deliberative and technical processes should be put in place to accommodate such dynamics within the health system. This publication clarifies this distinction and presents policymakers with valuable case studies. The notion of explicit HBPs—alongside new insights on how to process difficult decisions, where to set limits, and how to increase health outcomes with a well-chosen and financially sustainable package of care—has made the quest for UHC a more feasible and less frustrating agenda.

In 1983, when the right to the protection of health was enshrined in the Mexican Constitution, the expectation was to achieve comprehensive and equitable access to healthcare sooner than later. However, in a fragmented healthcare system where unfair financing and access rules are the norm, the constitutional right remains an unfulfilled promise. More than ever, equity is at the center of the policy agenda. As long as half of the healthcare system remains funded without any alignment to an explicit set of benefits, health system performance will continue to be low. Explicit HBPs are, and will continue to be, the most powerful policy tool available to align health needs with health financing limitations to deliver sustainable access to care. This book will be a useful reference for countries that are exploring the use of packages to gradually reduce fragmentation among existing insurance schemes, even when it is not feasible or desirable to move to a single-payer system. To date, no other public health insurer in Mexico has a clearly defined benefits plan. As Mexico moves toward a more comprehensive unified health system, the introduction of a single HBP could be a cornerstone of a more unified healthcare system.

Along the way, HBPs need to guide decisions on how to invest and organize the supply response of UHC. Investments in new facilities and the development of human resources should be informed by HBP dynamics. As Antonio Infante discusses in his Policymaker Commentary on the AUGE experience in Chile later in this volume, having an explicit HBP in place should be considered a necessary (rather than merely sufficient) condition to ensure UHC. The supply response and quality standards required to ensure equitable access to the interventions covered also should be considered as part of package's cost, its operational management, and its accountability and responsiveness to beneficiaries.

Beyond the technical challenges of defining a HBP, policymakers constantly face the risk of failure when they do not have guidance on how to convey to the different stakeholders the key notions needed

to increase willingness to accept and participate in HBP reforms. In practice, an accurate assessment of the necessary mechanisms to ensure that reform processes and decisionmaking are institutionalized and legitimate is just as relevant as the technical design of the package itself. Until now, there was no one-stop reference to fully understand the political economy around HBPs, including the decisionmaking processes and bodies required to implement a package within a particular health system. In Mexico, as elsewhere, achieving UHC increasingly is becoming more feasible thanks to the availability of effective tools such as HBPs. However, because this publication also presents the rich experience of countries and explicitly considers key implementation issues, policymakers have a unique opportunity to move forward with their country's UHC agenda in a more sustainable, long-lasting effort.



PART I

GOVERNANCE AND PROCESS

The Foundation of a Health Benefits Package Policy

Introduction

Ursula Giedion

Creating a health benefits package (HBP) involves much more than a technical, evidence-based exercise that identifies the services that will be financed with available public resources while moving toward universal health coverage (UHC). It includes not only the work of designing a technically sound benefits package, but also updating, monitoring, evaluating, and implementing it. This HBP “production line” involves different tasks and processes carried out on a regular basis by different institutions that need to be established and coordinated and whose tasks need to be clearly defined and delimited. Also, the sustainability of a HBP depends on it being acknowledged by all stakeholders, and most important, by the beneficiaries it is meant to cover and by the physicians whose prescriptions it is intended to guide and circumscribe.

Likewise, the HBP design process itself needs to be consistent with the time, monetary, and human resources available. Further, a HBP policy should not be carried out in isolation. If it is to be more than a de jure wish list of services, it must inform health system functions such as the mobilization of resources, payment, provision, performance measurement, and accountability. If these links are not put in place, the HBP will be little more than a tokenistic process that will have little impact on de facto services that citizens can use.

In a nutshell, a HBP policy involves more than the use of methods and data to design a technically sound benefits package. Policymakers must also define and put into practice the HBP’s overarching governing principles; set up the necessary processes to monitor and evaluate the HBP policy design; and determine

its financing sources and allocation, processes, and results. These three key aspects, the foundation and architecture of the HBP policy, are the theme of this chapter. The words *foundation* and *architecture* are meant to convey that this chapter will address aspects of a HBP policy that grant a certain stability to its design, which in turn makes the policy more predictable and more likely to be consistent, reliable, and thereby trustworthy and, ultimately, sustainable.

The lack of such a foundation and clear architecture can decide the fate of a HBP policy, as many examples included in the chapters of the first part of this book illustrate. In Colombia, in the absence of clear and socially accepted rules and a strong political commitment, the limits set by its explicit HBP policy gradually vanished as patients and doctors increasingly resorted to administrative and judicial mechanisms that allowed them to request services beyond the limits of the package. In the end, 24 years after the HBP was first adopted, the original package was declared officially dead and the country started to operate with explicit benefits.¹ In the Dominican Republic, a benefits package adjustment proposal was abandoned when stakeholders asked for a more evidence-based, transparent, and participatory process. In Peru, the limited coherence between the package's cost and its financing has led many to ask whether effective HBP coverage can be granted under the current circumstances.² All of these examples indicate that not thinking about the institutional architecture can lead to the failure of a HBP policy and it is therefore worthwhile that policy makers spend time and resources carefully designing and implementing it.

The institutional architecture for a HBP policy is much more complex and wider in scope than what is usually discussed in the context of the institutional design related to health technology assessment-based coverage decisionmaking—an issue that has been dealt with elsewhere.³ The architecture does not begin with deciding what to evaluate, nor does it

stop with the evidence-based coverage decision itself. It involves many more processes and policy pieces as the HBP cycle presented in the introductory chapter shows and as Glassman and colleagues outlined in a 2016 paper.⁴

The chapters in this first part offer three perspectives on how to think about the institutional architecture of HBP policy, and identify key questions that policymakers should try to answer when implementing their policies. Unfortunately, and, maybe disappointingly, policymakers who are trying to answer these questions will not find many clear-cut answers; instead, they have a spectrum of highly context-specific options to choose from. At the same time, however, the chapters offer a series of best practice principles and lessons for reflection.

In chapter 1, which focuses on good governance, Ursula Giedion and Javier Guzmán make the case for using transparency, consistency, coherence, stability, and participation as guiding principles for all the processes that need to be put in place along the HBP policy cycle. Implementing these good governance principles probably matters more for benefits package policies than for most other public policy areas, given that explicitly delimiting the scope of benefits that qualify for public financing (not just an individual technology but the portfolio of services) and to which citizens have access is a sensitive political issue. No matter how technical and rational the approach, it will leave many without the optimal mix of benefits they would prefer as patients and individuals, or want to provide or promote as interested actors of the health system. As with any explicit priority-setting initiative, government programs that restrict the use of health technologies and make the available benefits explicit are “fraught with risk, and rarely increase the political capital of their architects.”⁵ In such a difficult policy context where there can be no consensus on the content of a HBP, an agreed-upon process based on good governance principles becomes paramount. As the literature has

highlighted, people often will not agree on results but can agree on a process.⁶

Chapter 1 uses examples from around the world to illustrate how the processes of defining, adjusting, and implementing a HBP are often fraught with governance problems. Goals are not explicitly established, stakeholders are too often involved only pro forma, participation may give effective voice only to the most powerful, and documentation on how decisions are made in practice tends to be scarce. Furthermore, those who make the recommendations for and decide on the content of the HBP are subject to conflicts of interest; processes to adjust the package are often ad hoc, infrequent, and erratic; and decisionmakers are rarely made accountable for their decisions. Not much is known about the effective coverage of prioritized services, and the time and money resources available to design, finance, and adjust HBPs are insufficient and tend not to be coherent with the size of the task. Deficient governance may create symptoms such as legal demands, indefensible decisions, erratic policy changes, inclusion of nonprioritized services or services without any clear benefit, financial unsustainability, and sometimes even the abandonment of the HBP policy itself.

Despite this rather bleak picture of governance of HBP policies, many countries have made important progress in introducing good governance principles for one or several steps in the HBP cycle, and provide sources for inspiration for other countries wishing to adopt a HBP policy. Chile is an example of how stability and consistency can be introduced by anchoring some of the key technical steps into a normative framework; the country's HBP states that the benefits policy must be adjusted every three years, that these adjustments must be accompanied by costing studies, that surveys must be carried out periodically to identify social preferences, and that HBP expansions and their expected budgetary impact must be in line with the finance ministry's information on the public resources available.⁷ Colombia's Ministry

of Health and Social Protection provides an online tool that helps citizens to identify which technologies are covered, and for several years it has been providing transparent information on its HBP adjustment policies, supporting its decisions with publicly available details on its topic selections, health technology assessments, and coverage decision processes.⁸ Likewise, Thailand has introduced a systematic participatory mechanism for its topic selection for health technology assessments consisting of several explicit steps and processes.

Even though they make the case for good governance, Giedion and Guzmán also highlight its cost and risks. Good governance has many positive connotations but its principles “frequently interfere with some other good things: speed, efficiency, effectiveness, flexibility, creativity, empowerment and innovation.”⁹ Introducing good governance principles becomes therefore a balancing act and, maybe most important, it should not be seen as an end in itself but rather as a means toward a sustainable HBP process and policy. Also, good governance is costly and requires a substantial amount of resources when it is carried out seriously. Finally, trying to implement good governance principles can also backfire in some circumstances. For example, the participation of key stakeholders may become, in practice, an effective vehicle to promote the interests of a few well-organized groups instead of helping to incorporate the views of all relevant stakeholders. Also, stakeholders opposing the exclusion of a certain technology from the HBP will often request the implementation of good governance principles to question the legitimacy of decisions in order to push their own agendas.

In chapter 2, Ricardo Bitrán offers several important inputs on monitoring and evaluation for policymakers participating in HBP policy design and implementation. First, HBP monitoring and evaluation involves evaluating whether the impact of the HBP policy is in line with its intended goals. As the chapter illustrates, it includes an ongoing endeavor

whereby processes and results are being permanently monitored. Are the goals of the HBP policy being met? Do beneficiaries actually receive effective coverage of services included in the HBP? Is quality up to expected standards? Are beneficiaries aware of their rights? Are incentives in place to promote the delivery of the prioritized benefits? What are the frequency and cost of the services that are being delivered? How are they changing? Are benefits clearly and unequivocally defined? Policymakers should ask questions about the HBP design and adjustment process itself. Have the objectives been clearly established? Are periodic adjustments being carried out? Are adjustments in line with the previously established goals of the HBP? Are criteria to include new services consistent with the goals? Are the institutions in charge of adjusting the HBP carrying out their functions in line with good governance principles and according to the established processes? Are there conflicts of interest that should be addressed? Is the HBP consistent with changing needs, demands, costs, and resources? Are available resources (money, human resources, infrastructure) coherent with the benefits that are being promised? And does the institutional design explicitly acknowledge the importance of monitoring and evaluating HBP policy? The chapter provides many examples illustrating why these monitoring and evaluation efforts are an important determinant of the success of a HBP policy. It also makes it clear that few countries have such ongoing monitoring and evaluation efforts in place. Finally, there is little evidence about the impact of HBP policies. Beyond the many methodological challenges involved in evaluating a HBP policy, the lack of evidence is surprising given that HBPs are often at the core of UHC policies around the world.

In chapter 3, Amanda Glassman presents many challenges related to the financing architecture supporting HBPs around the world. The cost of promised benefits packages and their adjustments are often well beyond the budgets available to deliver

them. Governments often graft the financing of HBPs on input-based budget structures, diluting the incentives to provide what is included in the package even before these incentives leave the finance ministry and reach the providers. The determination of the resources allocated to finance HBPs is frequently in the hands of finance ministries and subject to discretionary adjustments. Resources are allocated to providers with weak links to the benefits included in the packages. Often, different financing streams are used for different packages and programs without any clear overarching coordination or common priority-setting approach, and external financing may follow externally set global priorities. Perhaps the most prominent example in this context is the delivery of some disease-specific packages of services that are organized and financed parallel to local HBPs.

The results can be distressing: The financial equilibrium of those in charge of delivering the HBP becomes unpredictable and may be put at risk. Even worse, the mismatch between the cost and financing of the HBP can dilute what is being provided, and implicit rationing once again becomes common practice. The population becomes frustrated and the legitimacy of the HBP policy falls apart. The example of Peru illustrates these problems: the allocation made to providers is way below the cost of the HBP, and beneficiaries of Peru's universal health insurance system are increasingly turning to the private sector to access the health services that theoretically should be guaranteed by the explicit benefits package.¹⁰

The financing chapter puts forward concrete policy recommendations. Policymakers should dedicate regular time and effort to rigorously cost the HBP; anchor these efforts in a normative framework if possible; and use the cost information to mobilize resources, establish reserve or stabilization mechanisms to expand coverage or cover shortfalls, and establish financial arrangements that incentivize the provision of HBP services. The chapter gives numerous country examples to illustrate how these

strategies can be implemented. Perhaps the most important general recommendation that emerges from this chapter is the need for financial coherence: Budget allocations for the HBP must be coherent with cost (not a result of disconnected national finance ministry negotiations) and with the available fiscal space (not determined by a political promise of comprehensiveness). Provider payment mechanisms should be linked with the benefits (and not based on a budgeting structure and logic that delinks the content of the HBP and the amount that providers get from financing agents), and external financing should be aligned with HBP priorities.

The common denominator emerging from the three chapters in this section is the critical importance and extreme complexity of designing an institutional architecture. When designing a HBP policy, many questions need to be addressed beyond finding a technically robust way of choosing a set of benefits maximizing population welfare. The complexity of doing so is a lesson with practical implications and is a call for realism and pragmatism. Not everything can be put in place perfectly or in a short time. Thinking strategically about what is most important to the process and when it should be set in motion becomes important. Prioritizing processes and governance principles is paramount to a successful HBP policy. Also, as the discussions and examples included in this section indicate, challenges in setting up the institutional architecture of a HBP policy are country-, health system-, and time-specific. When designing a priority-setting architecture that articulates the needs of different health and geographic subsectors, for instance, highly decentralized and segmented health systems will have a greater struggle compared with that of centralized health systems. Similarly, governments in countries with a growing and increasingly demanding middle-income class, such as many in Latin America, will find it tougher than poorer countries to gain support for a (almost by definition unpopular) policy that explicitly limits

the services covered in a HBP. Ironically, the more access there is, the harder it may well be to set limits. Challenges are also time dependent. What might be right today may be unsustainable in the future; what might be unthinkable today may be possible in time. For example, a top-down approach to defining a HBP may be right at some point but may become unsustainable as the population becomes more aware of its rights. Likewise, at the beginning, only limited local information may be available to help design and cost a HBP, but as its implementation progresses stakeholders will ask for better information and technically robust designs will improve as new information becomes available—a sort of a virtuous cycle. This potential outcome is yet another indication that HBP policies should not be designed as one-off exercises, but rather as a dynamic, ever-evolving endeavor.

This section of the book does not address in detail important institutional design questions of HBP processes, which should be explored in future research. Aspects to consider include how these tasks are distributed among different institutions and actors; how each institution is set up in terms of its remit, its autonomy (technical, legal, and financial), its size, its financing sources, and its level of decentralization; and how actors interact with each other. An unpublished preliminary analysis by Manuel Espinoza and Anthony Culyer seems to indicate myriad options for each of these institutional design questions.¹¹ For example, in terms of decentralization, some countries have opted to concentrate most functions within a single institution (mostly health ministries), whereas others have preferred to create specialized entities in charge of different tasks, and still others outsource the technical work. There is no one-size-fits-all formula, and each country must tailor its institutional arrangement to local needs and context, but some lessons do emerge. First, the institutional arrangement should be anchored in an explicit normative framework. Doing so helps to avoid lack of clarity over task management, avoids duplications, and

grants a certain consistency and stability (both of which are important principles of good governance). This is especially important given that HBP adjustment is a politically sensitive effort and is vulnerable to calls for changing the institutional framework in order to respond to short-term political interests and pressures. It is no surprise that the stability of institutional design for explicit priority-setting is the exception rather than the norm.¹² Second, institutions need financial and qualified human resources to maintain an institutional structure for their HBP policy. Governments often underestimate the quantity of work required to adjust, monitor, evaluate, and implement HBPs. Frequently, they allocate these tasks to existing institutions, but in these cases the adequate functioning of HBP policy cycle tasks may increase workload and compete with prior tasks. Moreover, old structures may not be aligned with what is needed in terms of skills and capacities for a new HBP. Finally, because HBP adjustment is a highly complex issue that involves many processes, actors, and institutions, policymakers should explicitly articulate these dimensions and the incentives to move together to achieve the HBP policy goals.¹³ This is a key element of success, one that requires not only rules but also leadership and commitment from the highest level of government.

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3. Drummond and others (2008); Chalkidou and others (2013); and Menon and Stafinski (2009).
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6. Daniels (1996, 2000).
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CHAPTER 1

Defining the Rules of the Game

Good Governance Principles for the Design and Revision of the Health Benefits Package

Ursula Giedion

Javier Guzmán

At a glance: To sustain your health benefits package policy, lean on tested principles for good governance: transparency, consistency, and stakeholder participation.

Designing and adjusting a health benefits package (HBP) not only requires the use of robust methods and high-quality data (as outlined by Katharina Hauck, Ranjeeta Thomas, and Peter C. Smith in chapter 9) but also sound processes and adequate institutional and legal frameworks to be sustainable. The term “governance” describes the process and structure by which the benefits package is designed and adjusted. In essence, “governance” sets out “the rules of the game”—it refers to how organizations, institutions, businesses, and governments manage their affairs. Well-designed and -implemented rules lead to good governance. As the HBP design and adjustment process is both a political (see Jesse Bump and Angela Chang’s assessment of the political economy of HBP design in chapter 12) and a technical

undertaking, good governance principles such as transparency, stakeholder participation, coherent decisionmaking structures, and consistency and stability are essential concepts that should be understood and put into practice.

Good governance underlying the HBP policy generates many benefits. It has an intrinsic value—a value it itself, for its own sake—in that it allows for citizens and stakeholders to understand how decisions are made, how they may participate in the HBP policy, and how they may hold policymakers accountable, thereby enriching the lives of citizens and strengthening democracy. It also has a constructive value—one that establishes a process that provides information about values and limits—because applying good governance principles to HBP design

allows citizens and stakeholders to learn from each other by participating in discussions and exchanging information, views, and analyses. Finally, good governance has an instrumental value—one that enables it to achieve something beyond itself—because it makes the HBP more legitimate, acceptable, and defensible, and therefore better from a political and managerial point of view.

The instrumental value of good governance is of key relevance in the context of the HBP design and adjustment and, more generally, explicit priority-setting, for a number of reasons. First, deciding what healthcare will be financed and provided under which circumstances is a very sensitive issue, because it affects people's health, a domain central to human happiness and well-being. In general, people care more about health and access to healthcare than most other aspects of public policy, in part because good health is a prerequisite for most other aspects of well-being. Second, benefits packages involve (by definition) limitations, which will always negatively affect a subset of people, actors, and/or institutions—and those limitations inevitably will be larger in low- and middle-income countries (LMICs) given the much smaller resource envelopes available. Those who need or provide services not covered by the HBP will want to understand, at the very least, how decisions were made and whether they were based on understandable and reasonable criteria.¹ Third, there is no single right answer for the optimal composition of the plan, as different people may place different weights on potentially conflicting inclusion criteria—for example, the balance of health maximization, equity, and the rule of rescue. Deciding “what's in and what's out” thus requires HBP designers to rank the relevant values and preferences despite differing values. (Chapter 9 discusses possible coexisting criteria in the context of multicriteria decisionmaking.) Finally, the information and methods available to make inclusion or exclusion decisions involve substantial uncertainty. Combining different criteria to establish priorities is

a process fraught with methodological limitations, and local information sources are often limited and/or unreliable (also discussed in chapter 9). Stakeholders often do not know, for example, how existing resources are used and how their allocation would change if a HBP were to be adopted or adjusted. LMICs more often than not lack solid information on the effectiveness and costs of treatment in their own context, or ways in which to combine different types of evidence on different priority-setting criteria such as cost effectiveness, equity, and financial protection when selecting services. Yet despite these political and methodological challenges in HBP design and adjustment, stakeholders can often agree to a process that is considered to be fair even if as they acknowledge the difficulty of setting limits and the evidence uncertainties and constraints. Working toward good governance and a fair, transparent, participatory, consistent, and technically sound process is a key strategy to reach a legitimate, accepted, and defensible HBP.

This chapter first deals with the definition of governance and good governance in the context of HBP design and adjustment. It then looks at three key good governance attributes that policymakers should take into account when setting up processes to design and adjust benefits packages: transparency, consistency and stability, and stakeholder participation. It provides a description of what these principles mean in the context of HBP policy, explains why the criteria are important when designing and adjusting HBPs, and uses examples of how different countries have implemented them. Each section also includes a practical toolkit for policymakers, including links to some useful resources.

Governance and Good Governance Applied to Benefits Policy

Governance refers to the structure of policymaking in a system.² It therefore responds to the question

of how decisions are made and implemented and includes aspects of patterns and routinization. As Scott Greer and colleagues put it, governance is the systematic, patterned way in which decisions are made and implemented.³ Governance relates to the different ways that organizations, institutions, businesses, and governments manage their affairs. It refers to the act of governing, and thus involves the application of laws and regulations, but also of customs, ethical standards, and norms.⁴ Governance comprises the mechanisms, processes, and institutions through which citizens and groups articulate their interests, exercise their legal rights, meet their obligations, and mediate their differences.⁵ Several key aspects of governance emerge from these descriptions when applied to health benefits policy, specifically with regard to how the policy is *normally* designed and implemented and how governments *usually* define and adjust their HBPs: what processes are carried out, how these processes are carried out and by whom, and how different actors and institutions affected by or participating in the HBP policy interact to make decisions.

Good governance means doing the business of governance well. If certain good governance attributes are met, it is expected that policies will be fairer, more effective, and more legitimate and accepted. In contrast, bad governance leads to high levels of corruption, misaligned incentives, regulatory capture, incompetence, lack of trust, difficulties with long-term planning, or failed implementation. Yet despite growing consensus on the importance of good governance for explicit priority-setting and HBP design and adjustment, the world is fraught with examples of less-than-optimal governance in this regard.⁶ Often, processes are not explicitly stated and stakeholders are involved only *pro forma*; documentation on how decisions were reached tends to be scarce; HBP adjustment processes are often ad hoc, infrequent, and erratically changing; decisionmakers are rarely made accountable for their decisions;

and the available time and monetary resources tend to be insufficient for the size and scope of the task. In the HBP context, visible symbols of bad governance include lack public distrust of the package and its underlying restrictions, legal challenges, indefensible decisions, erratic policy changes, inclusion of services with no clear benefit, and financial unsustainability. (Box 1 presents country examples illustrating these symptoms of bad governance.) There is room to improve the legitimacy and sustainability of benefits policies by enhancing their governance arrangements. Unsustainable policies may result as a consequence of bad governance even when rigorous methods are used, as illustrated by the example from Colombia below.

Different authors consider different elements as essential to governance, both in general and for the health sector.⁷ This chapter uses an adapted version of the framework produced by William Savedoff and Pablo Gottret to analyze the governance of mandatory health insurance systems.⁸ It looks specifically at the principles of transparency; consistent, stable, and coherent decisionmaking structures; and stakeholder participation as the three key elements of good governance that can improve HBP design results.

Transparency

Although there are many different definitions, transparency generally refers to the extent to which an entity reveals information about its own decision processes, procedures, functioning, and performance.⁹ According to a more metaphorical understanding, transparency refers to the ability to look clearly through “the windows of an institution” or “lift the veil of secrecy.”¹⁰ Transparency is an attribute of governance intended to enhance participation and accountability in government. When organizations and institutions act visibly, predictably, and understandably—all attributes of transparency—citizens

BOX 1. The Consequences of Bad Governance in Benefits Policy

Failed implementation. In some cases, disrespect for some or all good governance principles can lead policymakers to drop a HBP proposal or abandon a HBP policy altogether.

Colombia. When Colombia introduced its universal health insurance scheme in 1993, the government commissioned a team of world-class experts to design a HBP based on cost-effectiveness criteria. After one year of intense technical work, the proposal was submitted to the government and other stakeholders. The proposal was technically sound but was not perceived as the product of a transparent, participatory, and valid process. It also met with fierce political opposition from the largest public health insurance entity at that time, the Social Security Institute, which already offered a much larger benefits package than the one suggested by the experts.^a As a result, the 1993 technical proposal was dropped, and the government decided instead to use the Social Security Institute's own tariff manual as the HBP for its newly created universal health insurance system.^b The new HBP was called the POS (Plan Obligatorio de Salud; Mandatory Health Plan).

This comprehensive but explicitly limited benefits package was in place until 2017. In January 2015 Colombia's Constitutional Court adopted a Statutory Law requiring the government to finance all services prescribed by physicians except for experimental treatments, treatments provided abroad, cosmetic treatments, and treatments without any proven effectiveness. As a result, the government now has almost no margin to limit the HBP based on cost-effectiveness or other economic considerations. The adoption of this law emerged, in part, from two decades of a largely ad hoc benefits policy, where explicit rules and a corresponding institutional framework for priority-setting were weak, or only rolled out slowly and with great hesitation. Physicians in particular resisted the idea of a bureaucratically updated HBP that limited their medical autonomy.^c

Dominican Republic. The Dominican Republic's universal health insurance system covers roughly 65 percent of the country's population (as of 2016) with a standard benefits package. In 2012, the entity in charge of updating the package presented an adjustment proposal to the public but met with strong opposition from several different stakeholders. Specifically, opponents cited the lack of information about the criteria and process underlying the proposal as one key reason for their opposition.^d As a result, the Dominican Republic had to start from scratch. Based on this experience, the country undertook a new and far more transparent and participatory process to thoroughly update its HBP in 2015-16.

Limited credibility, lack of trust, unsustainable decisions, legal problems. In some cases, insufficient attention to good governance principles during HBP design or adjustment can undermine public trust in the package and lead to legal challenges of its content.

Peru. Peru designed a HBP called PEAS (Plan Esencial de Aseguramiento de Salud; Essential Health Insurance Plan) when it adopted its universal health insurance system, AUS (Aseguramiento Universal en Salud) in 2009. During the design process, however, the technical team had only limited interaction with the other public sector actors who had worked on earlier iterations of the benefits package. Importantly, the designers did not consider the content of previous main benefits package, the LPIS (Listado Priorizado de Intervenciones en Salud; Prioritized List of Health Interventions). LPIS was more comprehensive in scope than PEAS, leading to a public perception that benefits had been reduced. As a result, PEAS was later expanded to include all LPIS-eligible services.^e

Inclusion of services that are without a shown benefit and/or not in line with stated HBP policy goals. When there are no clear criteria for adjusting a HBP, services included may not contribute to HBP goals, particularly health improvement through the provision of cost-effective services.

(continued)

BOX 1. The Consequences of Bad Governance in Benefits Policy (*continued*)

Colombia. Before 2012, the comprehensive HBP described above (POS) was available only to the formal sector population affiliated with the contributory system. The informal sector and the poor were covered by a subsidized system that started out by covering only parts of the services (about 50 percent) covered in the contributory regime. The law mandated a gradual convergence of the two packages (which happened in 2012). Colombia had no clear vision to guide the convergence of its subsidized HBP for the poor with the more expansive HBP for members of the contributory scheme. For example, photon external-beam radiation therapy and laparoscopic cholecystectomy were added to the more limited package before it included coverage for basic cancer services such as a consultation with a specialist or a mammogram.^f

Ghana. Ghana has committed politically, legislatively, and fiscally to providing universal health insurance coverage for its population in an effort to reduce financial barriers to the utilization of healthcare. In 2005, Ghana launched a publicly financed comprehensive health benefits package with preventive care and treatment for communicable and noncommunicable diseases, but some highly cost-effective services were not covered. In general, the benefit package is biased in favor of curative rather than preventive care. For example, in principle, the Ministry of Health provides for family planning, but this commodity is not part of the NHIS (National Health Insurance Scheme) basic HBP and remains chronically underfunded.^g

Mexico. The Seguro Popular (SP) consists of two HBPs. The first, currently known as CAUSES (Catálogo Universal de Servicios de Salud; Catalogue of Universal Health Services), covers services with relatively low costs and high incidence. The second is the FPGC (Fondo de Protección contra Gastos Catastróficos; Fund for Protection from Catastrophic Expenses), which covers a small list of diseases with lower incidence but high costs. As of the end of 2015, the FPGC covered 56 high-cost interventions. A case study of the FPGC found that inclusion decisions often were made on the basis of political criteria and pressures, and not through a fair, participatory, and transparent process intended to cover the conditions most important to the population.^h

Financially unsustainable benefits packages. Often, poor governance leads to HBP policies that do not account for the plan's costs/fiscal implications, leading to a mismatch between the generosity of coverage on paper and the resources allocated to operationalize the package in practice.

Ghana. Ghana has had problems financing of its benefits package due to rapidly increasing utilization rates. Out-patient visits increased from 0.4 per capita in 2005 to about 1 in 2009; inpatient utilization during the same period increased from 22 to 58 per thousand without making any substantial adjustments in its financing.ⁱ As a result, the HBP policy may not be sustainable under NHIS's current financing and provider payment arrangements. This indicates a clear lack of coherence between the size of the package and the actual financing available.

Peru. According to estimates from Prieto and colleagues, the per capita resources allocated to finance the benefits package (PEAS) amounted to just 25.5 percent of its variable cost.^j

a. Giedion, Panopoulou, and Gómez-Fraga (2009).

b. Until that point, the Social Security Institute had used its tariff manual to buy services from the existing healthcare provider network, and it described a comprehensive list of all the services that could be bought and their agreed-upon tariffs.

c. Giedion and Cañón (2014).

d. *Ibid.*

e. Prieto, Cid, and Montañez (2014).

f. Giedion and Cañón (2014).

g. Saleh (2013).

h. Lakin and Daniels (2007).

i. Saleh (2013).

j. Prieto, Cid, and Montañez (2014).

and stakeholders can track public spending and its uses and use this information to inform voting or other kinds of democratic participation.¹¹

Based on this definition, under a transparent HBP policy, citizens and stakeholders have access to the information they need to form their views on the policy cycle and its results (see the introduction for more on the process cycle). All interested parties should be able to look at and understand what is covered, how the policy was designed, how and why decisions were made, and whether the policy goals were reached. It is the opposite of a “black box” policy where people do not fully grasp their entitlements under the benefits package, much less the process that led to its definition and adjustment. Transparency should not only involve passive information-sharing but also active communication during the design and implementation process, including the implications for all relevant stakeholders. It means that the information is actually spread to and taken in by the people who will be affected.¹² In the specific HBP context, it means that people not only have access to information on the process and the package content but also actually understand its implications for them personally and for the country and health system as a whole.

In many countries where HBP policies have been formulated, transparency has been limited. In Latin America and the Caribbean, for example, seven country case studies suggest that there is great scope to improve the transparency and publicity of their HBP policies. Beneficiaries tend to have limited knowledge of the benefits package, and governments rarely disseminate information on how and why coverage decisions are made.¹³

Why is transparency important in the context of a HBP policy?

Transparency is desirable as a value in itself (intrinsic value) but it is also an input for good HBP policy

(instrumental value). It has intrinsic value because transparency is seen as a cornerstone of democratic governance, which requires general openness of governmental organizations.¹⁴ From this perspective, citizens have an intrinsic *right* to know about the operations of the government and to participate in them. A paper from Tanzania helps illustrate this idea; the author evaluates stakeholder views on different aspects of good governance related to explicit priority-setting.¹⁵ It finds that all stakeholders believe that transparency can enhance the democratic process by helping members of the community learn how to allocate healthcare resources thoughtfully and fairly. From an instrumental standpoint, transparency allows scrutiny and encourages actors to make better decisions.

It is difficult to hold those in charge of the HBP policy *accountable* for their decisions unless there is information and thereby room for scrutiny. In the terminology of the principal-agent theory, transparency is a means by which the “principal” ensures that its “agent” does not engage in “agency-shirking” (effectively, pursuing policies that promote its own interests rather than the interests of the principal).¹⁶ Translated into HBP policy, this means that those affected (the principal) should have access to information on the HBP process and decisions carried out by those in charge (the agent, usually one or several government bodies involved in defining the HBP). This allows citizens to check whether the government is acting on behalf of the beneficiaries’ interests or on behalf of their own, or pursuant to the interests of any other particular stakeholder or interest group. In other words, transparency in HBP policy reduces the margin for capture, bias, and corruption by allowing stakeholders to gather information that may be critical to uncover abuses or inappropriate practice and defend their interests. It enables citizens to exert a disciplinary role with regard to the state in charge of implementing the HBP policy. Indeed, the notion of transparency lies at the very heart of

the HBP rationale: defining an explicit set of priority health services helps to increase the accountability of the health system by explicitly stating what the government is committing to guarantee. Whether the commitment to an explicitly defined benefits package is just another void promise or, to the contrary, a tool that helps to establish the population's right to health, depends on many factors, including government capacity to check whether those in charge of insuring and providing the health benefits are

complying with their responsibilities. It also involves an effort to monitor what is happening with the services included in the benefits policy and to evaluate whether it is leading to the expected results. Some examples illustrating the link between transparency and accountability in HBP design and adjustment are included in box 2.

Transparency also raises *awareness* of the HBP policy itself and the basic rationale for placing explicit limits on the coverage of health services, a

BOX 2. Transparency to Increase Accountability in HBP Policy Design and Adjustment

Dominican Republic. The Dominican Republic originally adopted a HBP called PDSS (Plan de Servicios de Salud; Health Services Plan) in the context of its universal health insurance scheme. In 2013 the entity responsible for updating the HBP, SISARIL (Superintendencia de Salud y Riesgos Laborales; Superintendent of Health and Labor Risks), proposed a revision; its proposal was widely disseminated and discussed in national media, before its eventual rejection by stakeholders. One rationale for its rejection was the lack of credible information used in the updating exercise—an issue discussed extensively in the media coverage. For example, one newspaper article argued that the SISARIL proposal did not reveal data on the cost-effectiveness or expected health impact of the adjusted HBP; this was contrary to the health insurance law, which mandated that the HBP prioritize cost effective services and those most relevant to improve the health status of the Dominicans.^a

Iran. A 2008 World Bank Health Sector Review found that many different publicly financed health benefits packages coexist in Iran; their contents are often unclear, potentially contributing to the persistence and frequency of informal payments. The review recommended that standardization of the packages would improve equity and help make the scope of benefits more transparent for consumers and providers, which could help reduce informal payments.^b

Colombia. The Colombian Ombudsman Office (Defensoría del Pueblo) is a national government agency charged with overseeing the protection of the country's civil and human rights. It produces a widely disseminated yearly report on writs of protection filed by the population to access health services, including those explicitly included in the mandatory benefits package.^c

Chile. The Superintendence of Health systematically monitors compliance with the AUGÉ (access, quality, timeliness, and financial protection) benefits package guarantees and penalize any entities that shirk their legal responsibility.

a. See Pimentel (2013). Article 13 of the CNSSS resolution No. 48-13 of 2002 stipulates that the HBP should prioritize activities, interventions, procedures, and practice guidelines with a higher cost-effectiveness targeting illnesses of most importance to the community and according to the epidemiologic profile taking the National Health Plan, the existing technologies, and the current and future resources as a starting point. See SISALRIL (2002).

b. World Bank (2008).

c. The *tutela* system allows citizens to initiate court proceedings to obtain treatments (including particular medications) in cases where these have been denied by insurers whenever their human right to health is involved. This includes instances where patients have been denied treatments included in the mandatory HBP and situations in which they demand the provision of other treatments not included in the package.

prerequisite for making the HBP acceptable. Box 3 provides some examples illustrating this idea.

Transparency also contributes to trust-building, and thereby to the *legitimacy* of a HBP policy. When government organizations open up and show what coverage decisions are made, how they are made, and what the results are, people will likely have more *trust* in the HBP policy. As Norman Daniels has put

it, people affected by painful decisions want to know the grounds on which decisions that may harm them were made.¹⁷ It is difficult to find examples illustrating how a transparent HBP policy *improved* trust, but the following provide some cases where the lack of transparency led to mistrust. Some country cases illustrating the link between transparency and trust in the benefits policy are given in box 4.

BOX 3. Transparency to Raise Awareness on the Importance of Setting Limits

Colombia. In 2014 a 25-year-old patient requested the government pay for experimental treatment abroad through a mechanism called *tutela*, a legal constitutional writ intended to protect and guarantee fundamental rights.^a The media extensively reported on the story, creating strong public support for the patient and substantial pressure on the government to pay. Nonetheless, the minister of health publicly declared that the government would not finance the treatment abroad, arguing that equivalent solutions were available in Colombia at far lower cost and that the law excluded coverage with public resources for experimental treatments abroad. More important, he explained that such a decision would imply unequal protection of Colombians' right to health by taking resources away from other patients in need; it was his responsibility to care for them as well.^b His public statements helped open a constructive but very difficult public debate about priority-setting in Colombia and generated support for the government's position from the public and physician groups.^c

South Africa. In 2011 a patient with chronic renal failure sued the Constitutional Court of South Africa. The patient had been denied dialysis by the state-provided public healthcare system. The state justified its decision by citing its limited resources and the need to prioritize those patients with a higher chance of treatment success; the patient argued that the Constitution guaranteed him the right to access healthcare. Ultimately, the court ruled that the patient's rights had not been violated, arguing that the state had only a limited budget and thus had to prioritize who could be treated; it had therefore fulfilled its duty to realize the right of access to healthcare.^d

United Kingdom. In 1995 a young patient with relapsing leukemia was denied treatment by the National Health Service.^e The case captured newspaper headlines and highlighted the profound dilemmas faced by governments confronted with limited resources and unlimited medical needs. The father was determined to seek the treatment he believed was best for his daughter, doctors who disagreed about which treatment was appropriate, health service managers were prepared to take a stand over the use of resources for services of questionable effectiveness, lawyers were willing to test the decision of the health authority in court, and journalists saw the case as exemplifying the dilemmas of health service decisionmaking. The case helped to raise awareness of the need for resource allocation to balance the needs of the whole population against the urge to respond to the needs of individuals; the importance of a fair and rigorous decisionmaking process; and the need for decisionmakers to explain the rationale behind decisions, offer the opportunity for appeal, and ensure that the process is regulated. Yet not all of these conditions were fulfilled—health authorities and primary care groups should thus learn from this experience.

a. By using *tutela* action, constitutional judges are able to take relatively fast and unobstructed action to order the protection of fundamental rights that are being violated or threatened.

b. "Con el costo de un trasplante de médula en EE. UU. se Hacen 'diez de Colombia': Oncóloga" (2014).

c. See, for example, "Magistrados no entendieron Ley Estatutaria que aprobaron: Minsalud" (2014).

d. World Bank (2013).

e. Ham (1999).

BOX 4. Transparency to Increase Trust in and Legitimacy of the HBP Policy

Uruguay. A World Bank review of adherence to good governance principles for HBP policy in Uruguay argues that transparency has helped to create support for and acceptance of the HBP policy. In particular, the normative framework for the HBP (PIAS; Plan Integral de Atención a la Salud) was widely publicized; however, there is still much room to improve the system's overall transparency.

Dominican Republic. As described above, lack of transparency and understanding of the decisionmaking process contributed to the rejection of a proposed HBP revision.

Colombia. Lack of transparency was the key challenge identified by Colombia's Constitutional Court in one of its groundbreaking decisions on the health benefits policy (T760).^a

a. Justice Manuel José Cepeda Espinosa (2008).

BOX 5. Transparency to Help Achieve Equity when Making Coverage Decisions

United Kingdom. The Cancer Drugs Fund, initially set up in 2010 with a budget of £50 million and increasing to £200 million in subsequent years, was designed to give certain NHS cancer patients access to drugs not approved by NICE, the British entity in charge of evaluating health technologies. Although this fund almost certainly has benefited some people, such NHS spending priorities have generated difficult ethical and equity questions. On a positive note, transparency on the purpose, functioning, and financing of the fund helped raise questions about whether patients who were not benefitting from the fund were treated equally to the fund's beneficiaries (a subset of cancer patients), whether differences in treatment could be justified, and whether differences were ethical.^a

a. Appleby (2014).

The availability of information on how and why decisions are made helps to check whether *similar cases are being treated similarly* and *different cases are treated in relevant different ways*. It therefore helps to ensure the consistency, stability, and, in the end, equity of decisions related to the HBP. This is what a recent World Health Organization (WHO) paper on universal health coverage (UHC) refers to as assuring horizontal and vertical equity through the process of explicit priority-setting.¹⁸ Examples of how transparency increases equity are provided in box 5.

Yet many of the potentially positive results of a transparent and publicized HBP policy will not materialize unless they are accompanied by other good governance principles such as the existence of specific accountability mechanisms or participation of stakeholders. For example, the population might have access to information on the content of the

HBP. The impact of this access, however, will be limited unless beneficiaries can voice their opinions and participate (for further detail see the section on participation below) and unless mechanisms exist that will sanction (by law, media, or other means) those in charge for not providing the promised benefits or following the agreed process. In other words, information may lead to scrutiny and scrutiny may lead to the revelation of problems, but participation and sanctions are needed to translate transparency into real impact. Likewise, transparency and participation are preconditions for accountability.

Transparency can also come at a cost, and it is possible to have too much transparency. Governments sometimes see transparency as carrying an important political risk, especially in the short run, and as restricting the discretionary power of governments. And at times, frank discussions behind closed

BOX 6. Challenges Related to Transparency and Its Related Resource Costs

Australia. Prior to the 2005 Australia/United States free trade agreement, widespread misunderstanding existed within Australia’s Pharmaceutical Benefits Scheme (PBS) about the extent of the government’s legal obligation to maintain the confidentiality of pharmaceutical company applications to include medicines on the PBS formulary. Applications would invariably arrive with every page stamped “commercial-in-confidence”; officials generally interpreted this to mean that nothing contained therein could be publicly disclosed without the consent of the applicant. As a consequence, the government treated the decisions of the Pharmaceutical Benefits Advisory Committee (PBAC)—the entity evaluating the evidence to recommend whether pharmaceuticals should be listed on the PBS—as confidential, as they were based on confidential information. For many years, this created a barrier to making the PBAC more transparent.

On closer examination during negotiations for the free trade agreement, the PBAC later realized that its obligations under the National Health Act had been widely misinterpreted. Specifically, “commercial-in-confidence” has no meaning under Australian law (although “confidential” has a very specific meaning). It is a privacy marking, though a document accepted as such is expected to be protected nonetheless. One of the key issues pursued (at the industry’s behest) by the U.S. trade representative under the Pharmaceuticals Annex to the Goods Chapter was “greater transparency.” In the Annex and accompanying Side Letter, negotiators included a number of transparency obligations for applicants, mostly reflecting the status quo but adding a provision requiring public transparency to the public. Through this treaty-level obligation, the PBAC was thereafter required to share decisionmaking details with the public, not just the applicants. This was put into effect in 2005 via the introduction of Public Summary Documents (PSD) for all decisions.^a Both the structure and content of these PSDs were heavily negotiated with the industry, but they were nevertheless a major step forward in explaining the rationale behind PBAC decisions. The PBAC agreed to exclude three key pieces of information: the proposed price, the actual cost-effectiveness ratio, and details of any as-yet unpublished data (which might influence the decision but cannot be disclosed in detail).

Improving transparency requires a lengthy process to determine which information can and should be revealed, and then substantial effort to regularly and systematically share this information with public. Each PBAC agenda includes about 30 major submissions; about 30 PSDs must be prepared after each meeting, at substantial cost and only after a back-and-forth negotiation between the PBAC and the applicant on the content and framing of the draft. The former PBAC secretary estimates that the work to prepare and publish PSDs is equal to at least one full-time employee.

Source: Ruth Lopert, personal communication.

a. See, for examples, Department of Health, Australia (2017).

doors are important to help move policy forward. Policymakers need candid interaction to float ideas and gauge their feasibility without revealing their raw thoughts and discussions to the general public. Transparency is also resource intensive. It requires people, expertise, money, and time, especially for leadership to communicate with all relevant actors across the full HBP cycle. In addition, staff resources for HBP

design and adjustment are often scarce, especially in LMICs, and they tend to be the same individuals who prepare for and participate in information-sharing activities. Getting clearance for communications can itself be a cumbersome, time-intensive effort that can slow down the process—a problematic feature when policymakers wish to move swiftly on the design or adjustment of their benefits packages. Box 6 provides

two examples from Australia on the challenges related to transparency in the context of a HBP policy.

Attributes of transparency

Having explained why transparency is important in the context of the HBP policy cycle and what it refers to in general, the attributes of transparency deserve closer attention (see table 1). Understanding these attributes will help policymakers understand the key components of a transparent HBP policy. The following paragraphs describe each of these attributes, illustrating that transparency refers to much more than to information dissemination.

Availability. Information is provided on the goals, process, decisions, rationale, and results of the HBP policy. In this sense, a transparent HBP policy requires that a government communicate its coverage decisions, the goals of the HBP policy, how these goals are being operationalized when choosing what to include in the HBP, the processes to make coverage decisions and their implementation, who participates and whether they hold potential conflicts of interest, the rationale to support the government's decisions, the content of the HBP and its adjustments, and,

most important, the effective coverage of services included. More generally, information needs to be available on the process and results across the *full* HBP policy cycle described in the introduction.

Country experiences tend to illustrate problems related to the communication of HBP content and coverage, but also problems related to communicating the underlying rationale, the processes for its creation and revision, potential conflicts of interest of those participating in the process, and the effective coverage of services promised in the HBP. Box 7 illustrates the existence or lack of availability of information related to the HBP policy cycle with concrete country examples.

Standardization. Information related to HBP decisions has to be understandable and standardized for the process to benefit from the advantages of transparency. Standardization is also crucial for the HBP design and adjustment process to be consistent and stable. Box 8 illustrates the importance of standardization in the HBP policy cycle with concrete country examples.

Timely and up-to-date information. Information should be made available with sufficient time to permit analysis, evaluation, and engagement by relevant

TABLE 1. Attributes of Transparency

Attribute	Description
Availability	Information on the process, division of responsibilities, and results is publicly available across the full HBP policy cycle. Potential conflicts of interest are revealed.
Standardization	Information is presented in a standardized way.
Timely and up-to-date information	Information is available on time and is regularly updated.
Understandable, sufficient, and relevant information	Information on process and results across the full HBP policy cycle is understandable to the public, sufficient (not piecemeal), and relevant for stakeholders (thereby enabling scrutiny, participation, and accountability).

Note: Standardization of processes is an additional attribute of transparency that is dealt with extensively in the section on the consistency and stability attribute of good governance.

BOX 7. The Availability Attribute of Transparency**Available information on HBP content, coverage decisions, and results**

Chile. Since 2006, the Chilean Superintendency of Health has been commissioning population surveys to assess public knowledge about the AUGE benefits plan. In 2006 the survey found that 53 percent of respondents knew about “some” health conditions covered by the HBP. In 2009 an equivalent assessment showed that between 28 percent and 38 percent of the population claimed to know “all” of the health problems covered by the HBP. A 2010 survey conducted with FONASA, the public insurer, showed that 57 percent of beneficiaries under treatment for cervical cancer were unaware that their health condition was part of the package.^a

Africa. A study by Carapinha and others^b evaluated the program structure, characteristics, and availability of routine data for decisionmaking related to medicines benefits packages in 33 health insurance programs operating in Ghana, Kenya, Nigeria, Tanzania, and Uganda. The authors identified a lack of comprehensive information on medicines benefits and very limited information on the design, implementation, and outcomes of medicines benefit policies.

United States. In 2014, the Affordable Care Act (ACA) established, for the first time, a package of essential health benefits (EHB) for nearly all health plans. The EHB provision requires balanced coverage across 10 categories of care. A citizens’ advocacy group, Community Catalyst, has stated that it is important for ACA beneficiaries to understand what is covered, but also to advocate for collecting and releasing information on consumer experiences, access to care, and coverage limitations that will help shape future decisions about the EHB.^c A truly transparent HBP policy must reveal both the scope of a package and beneficiaries’ actual access to covered benefits.

Colombia. From 1993 to 2015, Colombia’s universal health insurance scheme operated with an explicit benefits package (POS), consisting of a detailed positive list of services that were covered with public resources. The government designed a user-friendly app, POS Pópuli, that allowed people to search for covered services and drugs. The app won many awards, including a prize for best web and mobile-based government application.^d

Lack of available information on processes

Uruguay. According to one analysis, a key challenge for Uruguay’s HBP policy is the limited availability of public documentation on the benefits selection process.^e

Colombia. No public information is available on how the Colombian benefits package (POS) was originally designed, nor on the process by which it was adjusted during its first decade of implementation (1993–2003). There was substantial uncertainty about the scope of the package, which, in turn, led to many discussions between the insurers in charge of providing the package and the government in charge of its financing. The lack of clarity was highlighted by the Constitutional Court in a landmark decision that ordered the government to clarify the scope and content of the HBP.^f The situation has improved substantially, but there are still important gaps in the publicly available information on the HBP adjustment process. For example, there is still no public information on how the ministry of health evaluates the evidence provided by the Colombian Health Technology Institution and others to make decisions on whether new technologies should be included.^g

Argentina. The criteria used to define the mandatory HBP available through social security (Obras Sociales) were not outlined in any public document.^h

Australia. Until 2005 both the existence and content of PBAC submissions were treated as confidential and only limited information about PBAC recommendations was released. In October 2005 the first detailed accounts of

(continued)

BOX 7. The Availability Attribute of Transparency (*continued*)

the PBAC's deliberations, including descriptions of the evidence considered by the committee, were published on the Department of Health and Ageing's website in the form of Public Summary Documents. These are developed from the PBAC minutes, presented in a standardized format, with some limited redactions. In September 2008 the PBAC agenda for the forthcoming November 2008 meeting was published for the first time, with an invitation for public comment.ⁱ

European regulatory agencies. In the case of the European Medicines Agency (EMA), the scientific evaluation system operates through a network of external experts. Those experts serve as members of the agency's scientific committees, working parties, or scientific evaluation teams. In 2012 the European Court of Auditors released an audit report on the management of conflicts of interest within four European Union agencies, including the EMA, concluded that "none of the selected Agencies adequately manages conflict of interest situations." At the end of November 2014 the EMA announced the adoption of a more balanced policy on managing conflicts of interest, which came into effect on January 30, 2015.^j

- a. Giedion and Cañón (2014).
- b. Carapinha and others (2011).
- c. Stahl (2012).
- d. Ministry of Health, Colombia. (2017).
- e. Molins, Alonso, and Fernández (2014).
- f. Justice Manuel José Cepeda Espinosa, Decision T-760 of 2008 at 76.
- g. Giedion and Cañón (2014).
- h. Bergallo (2005).
- i. Lopert (2009).
- j. Parliamentary Assembly (2015).

stakeholders. This may sound reasonable but information is often only shared very late in the design and adjustment process. Box 9 illustrates the importance of providing timely, up-to-date information in the HBP policy cycle with concrete country examples.

Understandable, sufficient, and relevant information. The information provided on the HBP process and decisionmaking needs to be understandable, sufficient, and relevant. For example, the complex and technical health technology assessment (HTA) reports used to define and adjust the HBP might not be relevant or understandable to most stakeholders, and therefore not helpful in allowing them to understand whether decisions were made using reasonable methods and criteria. The information provided must be sufficient for interested persons to make an assessment and thereby create trust or sanction. This

"quality of the information" aspect is not trivial in the context of a HBP policy given the methodological complexities involved in reviewing the evidence and making recommendations. How, for example, could a lay person understand whether the services included in the benefit package were adequately costed, judge whether an HTA is carried out in line with some minimum quality standards.¹⁹ Also, the provision of information is only useful insofar as it helps to *empower* those concerned by the policy. For example, a broad benefits package with vague categories might not help users to understand the scope of the benefits being offered. Box 10 illustrates the existence or lack of comprehensive information related to the HBP policy cycle with concrete country examples.

Table 2 presents a list of some important transparency "dos" and "do nots" to take into account when designing a HBP policy.

BOX 8. The Standardization Attribute of Transparency

Latin America and the Caribbean. A study carried out by the Inter-American Development Bank (IADB) examining and comparing coverage decisions for 20 high-cost drugs in six Latin American and Caribbean countries (Argentina, Brazil, Chile, Colombia, Costa Rica, and Uruguay) and four high-income countries (Australia, the Netherlands, the United Kingdom, and the United States [Oregon]) found very limited publicly available and accessible information in Latin American and Caribbean countries on the coverage decisions for these drugs, including the rationale behind coverage decisions and the process by which the decisions were made.^a In contrast, it was much easier to find the corresponding information in some high-income countries such as the United Kingdom or Australia.

Estonia. Since 2002 Estonia has had clearer and more explicit rules for the inclusion of HBP services and pharmaceuticals and for the level of cost-sharing; in addition, the process for adjusting the HBP has become more standardized. The government established the Estonian Health Insurance Fund (EHIF) as an independent public body responsible for defining the benefits package, in collaboration with other stakeholders. The EHIF and the Ministry of Social Affairs agree on the package, after which the government makes the final decision by endorsing the list of services and giving each item on the list a reimbursement price.^b

Iran. A 2015 study of how a national priority-setting program works in the centralized health system of Iran concludes that the process in that country is nonsystematic, leading to many inadequacies in developing HBPs.^c

Europe. The lack of systematic processes for HBP design and adjustment extends far beyond LMICs. Despite claims that cost-effectiveness is an important rationale for developing HBPs, one comparative 2005 study of nine European countries (Denmark, France, Germany, Hungary, Italy, the Netherlands, Poland, Spain, and the United Kingdom) found that many had no rational process for reviewing the available evidence on specific procedures or technologies as the basis for updating their HBP. Instead, the decisionmaking process was frequently guided by lobbying activities of some actors in the system. Even some countries with explicit benefits baskets, such as Poland, were found to lack transparency of decisionmaking criteria.^d

a. IADB (2012).

b. Lai and others (2013).

c. Chapman, Forman, and Lamprea (2015).

d. Schreyögg and others (2005).

BOX 9. The Timeliness Attribute of Transparency

Colombia. Colombia has recently constituted a benefits package advisory committee to review proposals for HBP policies made by the Ministry of Health. Committee members include one delegate each from the ministries of health, finance, and planning; one delegate from Colombia's health technology assessment institute (IETS; Instituto de Evaluación Tecnológica en Salud), and one delegate from the presidency.^a Within the last year, the committee received this proposal and the supporting evidence on very short notice, without sufficient time to thoroughly and seriously review the submitted information. This experience is one reason why Colombia is currently reviewing its institutional process to review the benefits package

Source: Conversation with officials from Colombia's Ministry of Health.

a. Ministerio de Salud y Protección Social, Decreto Número 2562.

BOX 10. The Importance of Providing Understandable, Sufficient, and Relevant Information on HBP Design, Adjustment and Results

Chile. The Chilean experience illustrates some challenges in making the scope of the benefits package understandable to both providers and beneficiaries. Until 2005 the lack of a common set of benefits for those affiliated with either the public insurer (FONASA) or one of the private insurance companies (ISAPREs) meant that beneficiaries were often misinformed about their rights and only poorly understood the scope of their respective benefits packages. ISAPREs offered several thousand medical plans to potential clients, making comparison of plans difficult or impractical. This led to limited transparency and competition. In response, starting in 2005 the AUGE reform mandated that all health insurers cover 56 specific medical conditions, thus defining for the first time a floor of uniform benefits across all insurers in the system, both public and private.^a The exact content of the HBP is described in an easy-to-understand and complete way.

Russia. An analysis of the HBP policy in Russia found that it was hard for consumers to understand the details of an insurance contract and thus compare the offerings of different companies. To increase transparency and thereby increase competition in the health insurance market, the paper recommended that the health insurance benefits should be more standardized to help consumers understand and compare them.^b

a. Savedoff and Gottret (2008).

b. Xu and others (2011).

TABLE 2. Dos and Don'ts Regarding Transparency

	Dos	Don'ts
Available information	<ul style="list-style-type: none"> ■ Keep written track of your processes. ■ Explicitly communicate the goals of your benefits package. ■ Provide clear information on benefits package content, targeted for prescribers and citizens. ■ Make sure that conflicts of interest are openly and systematically declared. Ensure that patient groups declare the source of their financial support and their own conflicts of interest. ■ Decide strategically what information is most important to share given your limited resources. 	<ul style="list-style-type: none"> ■ Do not make decisions on the benefits package behind closed doors. ■ Do not flood key stakeholders with information without prioritizing what is most important to share. Large amounts of raw information in the public domain may breed opacity rather than transparency.
Timely information	<ul style="list-style-type: none"> ■ Maintain updated information on services covered by the HBP and effective coverage of those services. ■ Submit your proposals to relevant key stakeholders with sufficient time for them to make meaningful suggestions for adjustment. 	<ul style="list-style-type: none"> ■ Do not disseminate information that is no longer relevant.
Understandable information	<ul style="list-style-type: none"> ■ Put resources aside to translate your technical documents into documents tailored to the needs of the target audience. 	<ul style="list-style-type: none"> ■ Do not disseminate unintelligible technical reports.

Consistent, Stable, and Coherent Decisionmaking Structures

Consistency literally means that something exhibits harmony, regularity, and continuity, and is free *from arbitrary variation* or contradiction. Stability means that something is not easily changed or, alternatively, likely to change. Coherence means that something is logically ordered, clear, and intelligible.²⁰ A consistent, stable, and coherent HBP policy means that processes, rules, and decisions related to coverage are applied systematically and do not change arbitrarily or every time leadership changes. It also means that the policy follows explicit rules and regulations (as opposed to ad hoc procedures) and that those responsible for particular decisions have the managerial discretion, authority, capacity, tools, and resources required to fulfill their responsibilities.²¹ Consistent, stable, and coherent HBP policies are backed by a legal framework to support this stability and coherence, with laws establishing the objectives of the system, the roles and responsibilities of all stakeholders, the checks and balances, and the procedures for making changes to the law. Finally, a consistent, stable, and coherent HPB policy has standardized and formalized processes which leads to traceable decisions.²²

By contrast, an inconsistent and incoherent HBP policy is subject to erratic and incongruous changes with respect to how it makes decisions to include medicines or services in the package. It might also change the objectives it pursues, the goals it sets, the criteria it uses, processes it follows, or the roles and responsibilities given to stakeholders. This inconsistency and incoherence make the HBP policy vulnerable to capture by interest groups, political expediency, or especially strong-minded individuals. In these cases, decisions and processes tend to be made on a case-by-case basis, often with regard for to politic advantage rather than what is right or just. For example, a seven-country study on benefits packages

in Latin America identified the lack of consistently applied rules as a key challenge in the region. In some countries like Mexico, “the process has yet to be formalized and documented.”²³

Consistent and stable HBP policy processes do not mean that the content, rules, and institutional HBP frameworks remain unchanged. To the contrary, the packages should be updated periodically to adjust to constant changes in medical technology, evidence, budgets, demand, prices, and national priorities. Indeed, the lack of periodic adjustments has emerged as a key weakness of HBP policies in many countries.²⁴ Increasingly, benefits packages are reviewed not just to include new technologies, but also to scrutinize and potentially delist those already covered. France and New Zealand are forerunners on this issue.²⁵ In France, existing technologies are reassessed every five years, a process which has resulted in delisting of hundreds of ineffective pharmaceuticals.

Even the rules of the game for adjusting the benefits package need not be written in stone; indeed, the way of thinking about explicit priority-setting may evolve over time. For example, seminal work by Angela Coulter and Chris Ham shows how countries have evolved over time in how they select health services, from previous frameworks based primarily on technical criteria to far more deliberative processes using different types of evidence.²⁶ This evolution has brought about a new set of actors, roles, responsibilities, and interactions with a new set of advantages, disadvantages, and challenges. In short, national priority-setting frameworks do need to change over time, but rules should exist on how to make changes to them to avoid erratic, incongruent processes. It is possible and desirable to implement a consistent, stable, and coherent HBP policy without stifling creativity and adaptation. Consistency, coherence, and flexibility are not mutually exclusive; a country can continuously adjust and improve its benefits package and underlying processes while staying true to the key goals and principles of its HBP policy.

Why are consistent, stable, and coherent decisionmaking structures important for a HBP policy?

A consistent, stable, and coherent HBP policy is important for the following reasons, which will be discussed in greater detail below:

1. It helps to ensure long-term commitments.
2. It promotes equity.
3. It improves coordination.
4. It improves legitimacy and reputation.
5. It reduces the influence of interest groups on decisions and makes the attainment of HBP goals more likely.
6. It allows for better and more accurate measurement.
7. It gives the right incentives to all stakeholders and ensures a viable system.
8. It makes the HBP decision process more efficient.
9. It may have positive external effects on the innovation system.

It helps to ensure long term commitments. Since the impact of a HBP on societal goals, such as improving population health status, is not immediate, long-term commitments are required from those in charge of designing, adjusting, and providing the package. When a HBP's goals and the ensuring processes, methods, and decisions are not coherent or change continuously, it is difficult to ensure long-term commitments to participate in the system. In Colombia, for example, there has been substantial discussion about HBP's exact scope of coverage. In general, insurers have a narrower interpretation of coverage than the government. Further, interpretation by the

Colombian Ministry of Health has changed over time, generating legal, financial, and reputational risks for those providing the package and having an impact on their long-term commitment to the system.²⁷

It promotes equity. A consistent and coherent HBP policy helps ensure that similar cases are being treated similarly and different cases are treated in relevant different ways. A 2014 WHO paper on UHC refers to this as assuring horizontal and vertical equity in the process of explicit priority-setting.²⁸ Experiences from some countries demonstrate how lack of consistency, stability, and coherence undermines the horizontal and vertical equity of HBP and priority-setting systems.

A consistent and coherent HBP policy is closely linked to a transparent one. If all interested parties are not able to look at and understand how the policy was designed, how decisions were made, and the rationale behind them, there is no way to guarantee consistency, coherence, and stability. For example, in 2014 the Colombian HTA institute, IETS (Instituto de Evaluación Tecnológica en Salud; Institute of Health Technology Assessment) published the list of technologies that would be evaluated; some medical specialists voiced confusion about why certain technologies were being evaluated while other technologies were not. In this case, the published information was not sufficient for stakeholders to feel that the system was consistent, stable, and coherent.

It improves coordination. A consistent and coherent HBP policy helps stakeholders to align their activities and responsibilities, avoiding duplication, inefficiencies, and disarticulation. For example, in Iran, the two main benefit packages are decided by different bodies—the Ministry of Health and Medical Education and the Ministry of Welfare and Social Security—without coordination between them.²⁹ In Uganda, the government and development assistance partners conduct parallel processes of prioritization,

sometimes resulting in certain interventions receiving both donor and government funding.

It improves legitimacy and reputation. When HBP policies do not seem to follow a consistent and coherent pattern, stakeholders and the population in general might feel that decisions are arbitrary and possibly a result of vested interests, compromising the legitimacy of the HBP policy. For example, the Peruvian government ignored the LPIS (Listado Priorizado de Intervenciones Sanitarias; Prioritized List of Health Interventions), an explicit health insurance benefits package started in 2007 for the poor, when designing the PEAS (Plan Esencial de Aseguramiento en Salud; Essential Health Insurance Plan) benefits package for UHC in 2009. As a result, PEAS excluded benefits that had previously been included in the LPIS, generating significant resistance and a perceived lack of legitimacy. Finally, the government had to accept the inclusion of all LPIS benefits that had not been originally included in PEAS.³⁰

It reduces the influence of interest groups on decisions and makes the attainment of HBP goals more likely. Consistent and coherent rules with predictable consequences help the influence of particular interest groups, or at the very least, help detect undue influences on decisionmaking. A consistent and coherent HBP policy also may ensure better alignment between the goals of a benefits package (e.g. maximizing health status with given resources) and the actual coverage decisions over time. For example, Sitaporn Youngkong and colleagues illustrate how prior to the current systematic, coherent, and consistent process of explicit priority-setting in Thailand, coverage decisions were typically ad hoc and opaque, with certain interest groups (politicians, health professionals, or industries) selectively advocating that new interventions receive public reimbursement.³¹ Similarly, Colombia is gradually making its coverage decision process more explicit, consistent, and

systematic. For example, IETS, its HTA institute, informs coverage decisions, and different stakeholders can participate in the decisionmaking process. This is an important improvement from a process considered “erratic, non-transparent and without any clear orientation and goals” during the first decade of its implementation.³² A comparison of the priority-setting criteria used to adjust the benefits packages between 1994 and 2002 showed that criteria changed constantly and in a nonsystematic manner.³³

Interest groups are not only from within the country but also include aid agencies and global civil society groups from abroad. In Uganda, for example, external assistance from the Global Fund to Fight AIDS, Tuberculosis, and Malaria and other HIV/AIDS funding agencies has led to these conditions being prioritized despite potentially differing health needs at the population level. Provision of antiretrovirals now tops the list of health system concerns and the Ugandan health ministry has committed to provide universal free access to antiretrovirals despite statements to the contrary in its Health Sector Strategic Plan. This example illustrates how the lack of strong local capacity and institutions to set national priorities in a consistent and stable manner makes countries vulnerable to external pressure.³⁴

It allows for better and more accurate measurement. Until you have tried something new for a period of time in a consistent and coherent manner, it is difficult to judge whether or not it works. How, for example, can countries measure whether HBP decisions are in line with stated goals if coverage criteria are not consistently used? How can a country judge whether a policy meant to disseminate knowledge on the package works unless it has been consistently used?

It gives the right incentives to all stakeholders and ensures a viable system. Consistent and coherent rules allow stakeholders to carry out their roles in full alignment with the objectives of the entire system.

They know their responsibilities and the consequences they will face for their decisions.³⁵ Governments should not only provide adequate capacity and resources for stakeholders to deliver on their mandates but should also have consistent instruments to adjust the system and maintain its viability. In the Netherlands, for example, the government has the authority to regulate the HBP, but insurers can complement packages and the supervisory authority periodically assesses the risk borne by insurers.

Unfortunately, HBPs are often incoherent. For example, there are mismatches between the legally mandated benefits and the actual ability of insurers to pay for these services, or between the benefits and the ability of providers to deliver them. For instance, the Mexican government did not adjust the capitation payment for the HBP CAUSES (Catálogo Universal de Servicios de Salud; Universal Catalog of Health Services) despite growth in the number of interventions covered between 2004 and 2008.³⁶

It makes the HBP decision process more efficient. All stakeholders must be clear on who makes decisions and how decisions are made; they also require authority, capacity, tools, and resources to fulfill their responsibilities. For instance, government departments should be able to cost the HBP properly and assess its affordability and fiscal impact prior to implementation, HTA agencies should have the budget, time, and capacity to conduct transparent, participatory, and robust assessments, and patient representatives and laypersons should understand their roles and have the means to make their voices heard.

Lack of clear rules, reduced timeframes, low budgets, and unviable expectations lead to low morale and misalignments.³⁷ Unfortunately, the absence of consistent and coherent decisionmaking structures is very common. For instance, the Dominican Republic asked the Inter-American Development Bank to provide technical assistance to completely redesign and update its benefits packages in less than a year.³⁸

Similarly, in 2011 the Colombian Health Regulatory Commission, an autonomous, special unit created to update the Colombian HBP, commissioned 248 health technology assessments within just a three-month period.

It may have positive external effects on the innovation system. Consistent and stable rules might be strong market signals for the pharmaceutical market. Pharmaceutical companies might align research and development choices with the criteria used to make coverage decisions when developing new products, making the process more focused and effective. This positive effect is likely to be related to market size and also to the degree of alignment between coverage criteria in different geographies. Finally, by repeatedly applying the same stable, consistent, and coherent rules, all those involved in designing and adjusting the HBP will undergo a learning process, with information sources, methods, and processes improving as a result. For example, information sources on unitary costs used in the HBP adjustment process may gradually improve due to a virtuous circle of information use, scrutiny, fine-tuning, and enhancement. The more the basic operations related to the adjustment of a HBP are repeated, the more they can be standardized. In Chile, for example, the law mandates that the AUGE (Acceso Universal con Garantías Explícitas; Universal Access with Explicit Guarantees) benefits package be updated every three years, with adjustments including updated costings and social preference studies. As a result, both the costings and the social preference studies have improved over the years. Similarly, Colombia has routinely reevaluated the cost of its benefits package as the main input to decide on the capitation payment paid to insurers (Unidad de Pago por Capitación; UPC). Initially, information sources for this exercise were scattered and scarce; over the years, however, an increasingly robust methodology has emerged. Government authorities now collect and use detailed

information on how much is paid by each of 25-plus insurance companies for each service in the HBP. In contrast, reinventing HBP processes every time there is a change in leadership is complicated, inefficient, time-consuming, and even unviable. Creating new institutions, normative frameworks, methods, and processes result in substantial expenditure and an unstable environment around the HBP policy.

Consistent, stable, and coherent decisionmaking structures: Checklist for policymakers and links to useful resources

The following is a checklist of enabling factors that might help to establish a stable, consistent, and coherent HBP policy:

Do

- Be explicit about the goals and criteria used to choose and adjust the HBP.
- Anchor the goals and criteria used to define and adjust the HBP in legal frameworks.
- Be explicit on the institutional arrangements, indicating specific responsibilities for making coverage decisions (define who does what and how different entities interact).
- Be explicit on how the priority-setting framework can be modified.
- Monitor and evaluate to make sure actual decisions are in line with existing rules.
- Have an appeals mechanism in place so actors can question decisions not in line with established rules.
- Earmark resources to allow the adequate functioning of the existing institutional framework.
- Isolate key participants within the priority-setting process from political bodies.

Don't

- Have ad hoc rules and regulations.
- Give managerial discretion to any institution without the authority, capacity, tools, and resources required to fulfill this responsibility.
- Change periodically the objectives the HBP pursues, the goals it sets, the criteria it uses, and the processes it follows.
- Make decisions on a case-by-case basis.
- Be afraid to adjust the HBP when needed—just make sure the adjustment follows established rules.

Stakeholder Participation

Participation has been defined as everything that enables people to influence the decisionmaking process and its outcomes and get involved in the actions that affect their lives.³⁹ Participation is not only a tool to engage the public, support implementation, and improve overall decisionmaking quality,⁴⁰ but is also a right in a democratic society, one increasingly demanded as citizens become more educated and less deferential.

In the context of HBP design and adjustment, participation entails the systematic involvement of all interested parties (health professionals, insurers, providers, academics, patients, civil society, the pharmaceutical industry) in the different stages of the decisionmaking process—from scope definition (that is, which diseases, which patient groups, and which types of interventions) to final inclusion and exclusion decisions. Unfortunately, many HBP policies have been formulated with only limited or nonexistent participation. For instance, a review of medicine benefits packages offered by 33 health insurance programs in Ghana, Kenya, Nigeria, Tanzania, and

Uganda showed that only 8 HBPs (18%) considered stakeholder preferences in the package design.⁴¹

A participatory HBP policy is the opposite of an exercise conducted by government officials, experts, and/or consultants behind closed doors. Note, however, that a participatory policy does not imply that decisions will be made by consensus, or that all stakeholders will participate to the same degree and in the same way throughout the entire process. Instead, it simply means that stakeholders have clearly defined spaces where they can raise their concerns, share viewpoints, and otherwise participate effectively. As Sir Michael Rawlins always reminds: “We want everyone to have their say, but it’s impossible for everyone to have their way.”⁴²

Why is participation important for a HBP policy?

Participation is an important HBP policy element for several theoretical reasons (see figure 1). Participation is often described by words like “informing,”

FIGURE 1. Key Theoretical Benefits of Participation in HBP Policy Cycle

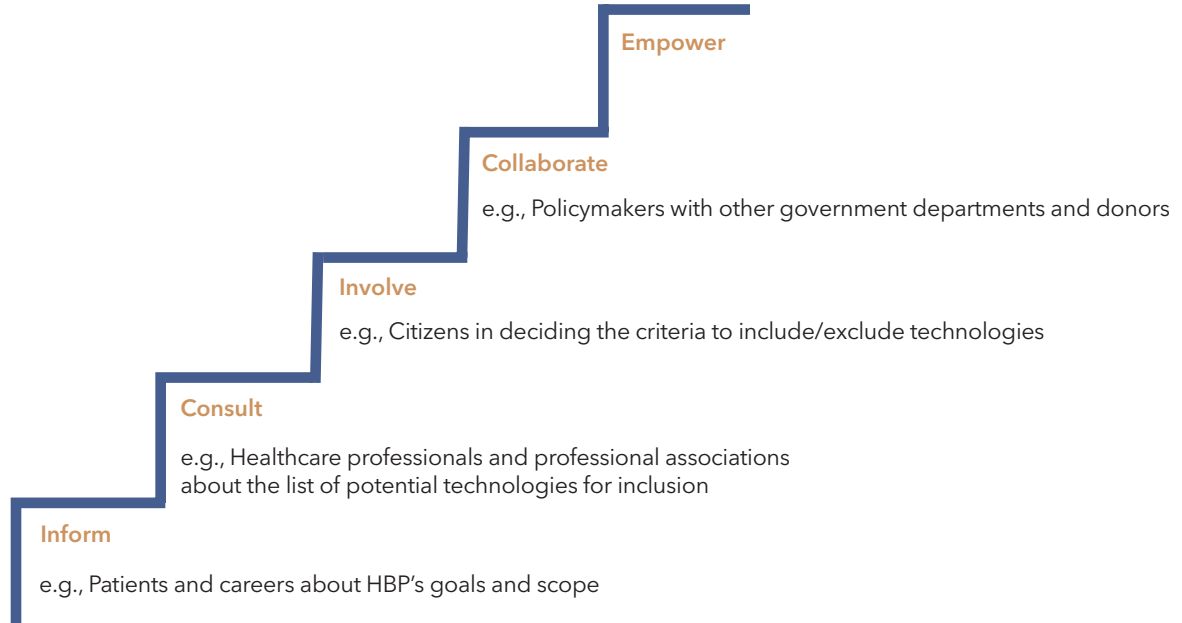


“consulting,” “involving,” “collaborating,” and “empowering.” These terms describe different levels of participation and the degree of power devolved to participants (see figure 2). The following sections will clarify what these words mean in the context of the HBP design and adjustment process.

Legitimacy and accountability. Participation provides legitimacy and accountability to the HBP decisionmaking processes.⁴³ For example, in Argentina, public awareness campaigns and direct work with Plan Nacer beneficiaries (mainly women and children) about their rights and the services available as part of the plan, have empowered consumers, and have helped create a sense of social accountability that complements the formal accountability obtained through official audits.⁴⁴

Experiences from some countries also demonstrate that lack of transparency and participation undermine the legitimacy of the HBP and contribute to its failure. In Colombia, for instance, the Constitutional Court, an entity charged with protecting the rights enshrined in the constitution, ordered comprehensive updates and the equalization of HBPs (Plan Obligatorio de Salud; POS) in 2008 in response to thousands of *tutelas* (special constitutional writs where any citizen can go to the judicial system to protect the right to health). The mandate to the government also included the need to introduce an explicit, clear, and participatory methodology in future HBP adjustment processes.

Quality of decisions. Participation improves the quality of HBP decisions by allowing people to make choices based on better information, including societies’ preferences and values. For instance, the Chilean AUGE reflects the preferences of many stakeholders, including civil society, academia, health service providers, insurers, trade organizations, and the general public. Consultation suggested that many stakeholders prioritized two population groups (children and

FIGURE 2. Levels of Participation with Examples

the elderly) and several diseases (diabetes, cancer, cardiovascular conditions, and mental and dental health) as especially deserving of coverage.⁴⁵ By contrast, the Israeli process to design and update the HBP has been criticized for not incorporating the priorities, values, views, and preferences of the general public.⁴⁶

Discipline of decisionmakers. Participation makes decisionmakers more careful and disciplined, and promotes consistency across decisions.⁴⁷ Policymakers face increasing pressure from all stakeholders, including the public, to be explicit on how decisions were made—through which mechanisms, with whose input and with what outcomes—and also on how they can actively engage and influence these processes. They will understand that a lack of discipline or inconsistency will lead to criticism and loss of legitimacy and trust in the system.

Awareness raising. Participation plays an educative role as it strengthens the knowledge and capacity of

interest groups and society as a whole in a virtuous cycle, where individuals, organizations, and society can grow and develop.⁴⁸ Stakeholders learn about the need for the plan to have limits and make fair decisions under resource constraints. Also, they learn about concepts such as equity, burden of disease, cost-effectiveness, and budget impact. In the United Kingdom, for instance, the participatory processes led by the National Institute for Health and Clinical Excellence (NICE) have made people understand why the agency will not supply the inclusion of a particular technology.⁴⁹

Ownership, and mitigating risk of legal action. Participation helps parties understand decisions which might increase ownership, decrease the likelihood of abuse and judicial challenge, and facilitate implementation. For example, a World Bank report from Uruguay suggested that the development of technical and social validation mechanisms for periodic redefinition of the HBP (PIAS) are needed to improve governability and prevent legal action challenging

covered or noncovered benefits.⁵⁰ (Current adjustment processes there do not allow for the systematic application of health technology evaluation or for a social validation processes.) A WHO report also notes that “successful implementation involves dialogue on purpose and design; decisions on financing and delivery arrangements, and adaptation over time. Without adequate national ownership, a HBP is unlikely to be implemented.”⁵¹

Despite the potential benefits, stakeholder participation might not lead to a satisfactory outcome. It can carry some risks—for instance, nonexpert members of the public might distort the deliberative process with biased or self-interested reasoning—or even, if handled poorly, be counterproductive.⁵² In 2006, for example, the Dominican Republic had to pass legislation authorizing the Safety and Labor Risks Superintendence (SISALRIL), an autonomous public entity, to make decisions on the contents of the benefits package. This emergency measure resulted from deadlock within the National Social Security Council, a multistakeholder body of 17 members representing several government departments, the central bank, health professionals, insurers, providers, and trade unions, which normally responsible for defining the HBP content. Consensus was a mandatory requisite for the body’s decisionmaking.⁵³ In Israel, participation of patient groups has been a double-edged sword; several decisions have been reversed due to their pressure. Finally, unsuccessful participatory exercises might result in mistrust, waste people’s time and money, and undermine future attempts to seriously engaged stakeholders in public policy.

Attributes of participation

Some attributes have been suggested for effective participation in public policymaking.⁵⁴ These attributes also apply to HBP design and adjustment and

can be used as an aspirational guide for policymakers who want to strengthen stakeholder participation and governance in their HBP adjustments or by those who are putting together a HBP for the first time.

Participation should make a difference. Participation should not be seen as another box for government officials to tick or another hurdle for politicians to jump through. As outlined earlier in this chapter, getting stakeholders, including the public, to explicitly articulate their values (maximization of population health, equity, rule of rescue, and the like), their preferences (what population groups should and should not be prioritized, for instance), and their views on the inclusion and exclusion criteria (such as cost effectiveness, equity, severity of the disease, or financial protection) will improve the ownership, acceptability, appropriateness, and legitimacy of the HBP.

Giving participants sufficient power and effective tools is essential for participation to make a difference. It is not enough to have the right participants seated at the table; participants should be able to contribute effectively to the process. The heterogeneity of stakeholders, from large, professionally run organizations such as industry groups to volunteer-led groups such as patient organizations, can make this a difficult endeavor, owing to implicit power hierarchies, unequal skill sets and powers of persuasion, and even unequal confidence levels. For example, in a qualitative study evaluating how the Cardiac Care Network of Ontario, a Canadian expert committee, made priority-setting recommendations to the ministry of health, researchers documented how committee members had different perceptions about the power they had during the process. The lay member of the committee questioned his effectiveness: “I’m a businessperson, and to walk into a medical panel where they’re talking a great deal of medical topics that I knew very little about, it’s very hard for me to have the confidence to question what

they were doing. You try to some extent but, if there was a matter of conflict it would be very easy for me to defer to their expertise.”⁵⁵ Even among laypersons, politically active citizens tend to be relatively wealthy and highly educated.⁵⁶ To give participants sufficient power, agencies such as NICE have a Patient and Public Involvement Unit (or similar) in charge of recruiting members of the public through patient organizations and then providing them with training, designed to give them confidence so they feel capable of making a contribution. As Professor Sir Michael Rawlins said, “it can be very daunting if you are a patient sitting around a table with some very distinguished professors.”⁵⁷

Participation should be transparent, honest, and clear. Participants should understand the purpose, mechanisms, and limits of the participatory processes for these to be effective and fulfill everyone’s expectations. For instance, if stakeholders are invited to participate in meetings to define the scope of a HBP, they should understand who will be involved, what their roles will be, what can and cannot be changed, and what will happen as a result of the meetings. A good example of a transparent, honest, and clear participatory process is the topic selection for HTA conducted by HITAP in Thailand. Each year, representatives of key stakeholder groups (four each of policymakers, health professionals, academics, patient associations, civic groups, and lay citizens, and three for the healthcare industry group) can propose up to six topics for HTA each. Then, a panel comprising representatives of four stakeholder groups (health professionals, academics, patients, and civic groups) selects at least 10 topics a year for assessment according to six prioritization criteria (size of population affected, severity of disease, effectiveness of health intervention, variation in practice, economic impact on household expenditure, and equity/ethical and social implications).⁵⁸

Participation should be planned and funded appropriately. Participation comes at a cost, and sufficient resources should be allocated to manage the process and deliver on the results. Policymakers often allocate resources to quantify the burden of disease, estimate the cost-effectiveness of potential interventions, cost the HBP, and the like without appropriately funding the participatory processes; many implicitly believe that either the “technical” components are more valuable than the “political” components or that participation is something to add once the technical process is complete. For instance, after seven years of establishing the PIAS in Uruguay, policymakers are considering the introduction of social validation processes to adjust the plan as a mechanism to prevent judicial challenge by beneficiaries who demand non-covered interventions.⁵⁹

The right participants should be included at different stages of the HBP cycle with the right level of participation. It is difficult to give clear guidelines as to who should participate at what points within the HBP process. The right mix of stakeholders will depend on many elements, including the context, the purpose of each HBP stage, the type of decision to be made, and the ability to contribute. However, at least in theory, all relevant stakeholders (all those who will be affected, may be affected, are interested in the HBP policy, or have the ability to affect its design, adjustment or implementation)⁶⁰ should be included in different stages of the HBP policymaking process. If this exercise is not properly conducted, there are risks that only the powerful or those close to the government are invited to participate.

With regard to the *level* of participation, different levels are appropriate for different stakeholders in different circumstances. For example, understanding citizens’ values and preferences is essential to define the goals and objectives; pharmaceutical industry input at that stage might be unnecessary or even

inappropriate. Levels of participations range from informing (providing balanced, objective information to assist in understanding the problem, alternatives, opportunities, and solutions, as discussed in the transparency section) to empowering (placing final decisionmaking authority in the hands of the participants).⁶¹ Other authors suggest that participation ranges from having a voice (where stakeholder views are articulated through, for example, surveys and citizens' juries), through having representation (such as a formal governance role on boards and other structures) to having a choice, whereby participants are given the ability to make decisions through, for example, coproduction.⁶² Regardless of how levels of participation are defined, higher levels might need more capacity and experience and different levels are appropriate for different stakeholders in different circumstances. For example, patients and providers should be involved in defining the most relevant outcomes for any HTA, but it may only be necessary to inform them of the overall HBP goals.

In summary, there is no right formula for policymakers to decide which participants should be included at each phase of the HBP design and adjustment process or what level of participation they should have. This is because the right mix of participants is context-specific, and thus likely to be different in different settings; in addition, there is scant evidence from which to draw conclusions. (Few countries have experience at large with participatory mechanisms in the context of HBP, and even fewer have documented their experiences.) Overall, it is policymakers who decide on the right participants and levels of participation for each HBP stage. In Israel, for example, the parliament is the decisionmaking body; a multistakeholder public committee made up of health and finance ministry officials, physicians, health policy and health economics experts, an ethicist, and health insurance representatives plays an advisory role. By contrast, the German system's Federal Joint Committee, composed of doctors, dentists, patients, and representatives from

hospitals and sickness funds, issues legally binding directives regarding coverage of treatments (though patients do not have voting rights). Participation at certain stages, such as HTA exercises, and by certain groups, such as patients and the general public, has been better researched than others, and therefore it is more plausible to draw conclusions or good practice principles. For example, Drummond and colleagues included stakeholder participation as one of 14 good practice principles of any HTA.⁶³

Finally, three elements should be considered when selecting participants for any participatory process: (1) legitimacy, (2) potential biases/conflicts of interests, and (3) inclusion of traditionally excluded groups. Legitimacy denotes the extent to which selected groups of individuals can accurately and validly represent certain constituencies. For example, government officials will have to decide how representatives from the public will be selected—will the public be represented by randomly selected citizens, elected representatives, nongovernmental organizations, or local activists?⁶⁴ Some groups might be prone to bias by financial interests, for example by funding received from industry or other interest groups. Declaring conflicts of interest can help counteract these biases and strengthens the integrity and transparency of any participatory process. Finally, groups that traditionally have been excluded from HBP discussions, such as patient groups or ordinary citizens, should be invited and should receive special support and encouragement for their participation to be effective. Experiences from some countries demonstrate that there is still a long way to go to get the public to participate in HBP design and adjustment, with only four Organisation for Economic Co-operation and Development countries (Australia, Denmark, Norway, and the United Kingdom) involving the public in coverage decisions.⁶⁵

Participatory processes need to be accountable. This accountability—or the obligation of individuals

and organizations participating in the design and adjustment process to account for their activities, accept responsibility for them, and disclose the results in transparent manner⁶⁶—is owed to each constituency but, more important, to the wider community. This requires good recordkeeping and reporting of both processes and outcomes. Participation also involves the ability to review the results when parties identify errors in the process. Limitations on participation may be one of the reasons why countries fail to successfully manage political pressure.

Participatory processes should provide mutual learning and development. Participatory processes should be designed to educate all stakeholders about fair decisions under resource constraints and about limits. It should also connect decisionmaking in healthcare to broader, more fundamental democratic deliberative processes. If this is achieved, learning will not be limited to only the general public or certain constituencies but also may expand to government officials, who might not have had experience with HBP design. In Vietnam, for example, a workshop conducted in 2014 found that policymakers saw the HBP design as a challenging task and had no relevant practical experience.⁶⁷

The right participatory vehicle should be used. Policymakers can use ad hoc initiatives to make case-by-case decisions about who should be invited to participate in HBP design, and for what purpose; can institutionalize stakeholder participation by integrating participatory processes in the decision-making structures; or can combine both strategies. Ad hoc initiatives are often used for HBPs conceived as one-off exercises, with no arrangements in place to update their contents. These initiatives are not very expensive but are not very useful, either. By contrast, institutionalized approaches have been the preferred route for systems keen to foster more sustained relationships; these require organizational resources but

facilitate clear and transparent dialogue on these difficult decisions. For instance, the United Kingdom's NICE has a Citizens' Council, a panel of citizens who provide input into decisions on new drugs. Likewise, in Australia, the committee in charge of making recommendations on what drugs are subsidized with public funds has representatives for patients, doctors, health professionals, health economists, consumer advocacy groups and the wider public. The Israeli Public Committee, the body in charge of recommending which technologies the Israeli health system should adopt, is made up of representatives from the health and finance ministries, the Israeli Medical Association, insurers, health economics and health policy experts, and public figures from outside the healthcare system.⁶⁸ Despite the benefits of institutional approaches, some have criticized them for being tokenistic and not giving adequate support to the committee members, since it is hard for one individual to hold his or her own opinion against experts without adequate training.⁶⁹

Stakeholder participation: Checklist for policymakers and links to useful resources

Do

- Ensure that participation is carried out properly, not merely because it is politically correct to have some sort of participation. Bad practice can be worse than no practice.
- Make the purpose of the participatory process explicit and clear.
- Make sure that participants' needs are fully aired and considered and that their level of influence is clear from the start.
- Incorporate stakeholder participation from the beginning rather than at the end *after* decisions have been made.

- Minimize the power imbalance between the public and patients on the one hand and clinicians and policymaking experts on the other.⁷⁰
- Take the time to plan and conduct an appropriate participatory process. If the necessary time to obtain genuine input from stakeholders is not spent upfront, a greater amount of time may be spent later addressing objections to both the process and its outcomes. Remember that sometimes “you save time by taking time.”⁷¹
- Actively involve those who have the least say in decisionmaking.

Don't

- Try to legitimize a decision that has already been made behind closed doors.
- Use participation to avoid responsibility for difficult decisions.
- Plan participation poorly: no one wins from situations where anger, distrust, frustration, and a sense of utter powerlessness taints stakeholder participation.
- See participation as another hoop for officials and politicians to jump through, instead of an enhancement to current practice.
- Let advocacy groups overtake the request for public participation.
- Include more than 15 members when setting up committees.⁷²

Conclusion

Governance is the systematic, patterned way in which decisions are made and implemented. Good governance principles applied to the HBP generate many benefits, including intrinsic value, as citizens and stakeholders are able to understand how

decisions are made, how they may participate, and how they may hold policymakers accountable; constructive value, as citizens and stakeholders are able to learn from each other by participating in discussions and by exchanging information, views, and analyses; and instrumental value, as HBP policy is made more legitimate, more acceptable, and more defensible. Transparency; consistent, stable, and coherent decisionmaking structures; and participation are three key elements of good governance that have the potential to improve the HBP decisionmaking process. Good governance can also come at a cost. It can carry risks, and, if handled poorly, it can be counterproductive.

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CHAPTER 2

Tracking the Benefits Package from Paper to Practice

Monitoring and Evaluation

Ricardo Bitrán

At a glance: Is your health benefits package helping to achieve your health policy objectives? Monitoring and evaluation—from design through implementation—lets you learn and tweak as you go.

Low- and middle-income countries are increasingly adopting health benefits packages (HBPs) as core elements of their national policies to achieve universal health coverage (UHC). For example, Mexico's Seguro Popular (Popular Insurance), which offers coverage to low-income citizens without social health insurance, has two HBPs: one for common ambulatory and hospital services and another for infrequent and high-cost services.¹ Vietnam has implemented a mandatory HBP for all citizens, including outpatient and inpatient services, screening, and medicines.² And Ghana's National Health Insurance Scheme offers a broad HBP, with interventions addressing 95 percent of the causes of the country's burden of disease.³

The prominence of HBPs in countries' UHC strategies necessitates monitoring and evaluating (M&E) of their construction, implementation,

operation, and revision, and their consequences for health system performance—yet few developing countries have adopted HBP-specific M&E systems.⁴ This chapter thus seeks to fill a gap in knowledge. It reviews the areas that should be the subject of M&E efforts, the types of M&E that should be undertaken during each stage of the policy cycle, and the associated information needs. It also offers existing examples of HBP-related M&E efforts from low-, middle-, and high-income countries.

This chapter first defines the concepts of monitoring and evaluation. Next, it establishes the difference between M&E of UHC at the global level and M&E of HBP-related policies at the country level. It then considers the role of M&E during HBP design and revision, during HBP implementation, and for assessing the consequences that the HBP has had on health system performance (or *results*).

Monitoring and Evaluation

Monitoring refers to a family of methods for data collection and analysis. It is a systematic effort undertaken during the implementation and operation of a project or a policy that is intended to help improve its design and adoption, with the ultimate goal of improving health system performance. Monitoring provides early indications of progress toward the development of project or policy activities, resulting outputs, and achievement of overall project or policy objectives. It is undertaken more frequently than evaluation.

Evaluation is concerned with the outcome of a project or policy, and is conducted with the aim of fine-tuning design or informing future projects or policies. Evaluation examines longer-term results and identifies how and why activities succeeded or failed. The resource intensive nature of evaluation efforts, in terms of data collection needs and analysis, means that evaluations are conducted sporadically—generally every few years, sometimes at regular intervals. Further, evaluations generally focus on phenomena that change slowly over time, meaning that changes will only be statistically detectable over a longer time horizon, hence their lower frequency.⁵

M&E of UHC versus M&E of HBP

The recent focus on UHC has led policymakers, project managers, donors, and academics to develop M&E methods to track progress toward that goal. An important distinction is made here, however, between M&E for UHC with M&E for a specific country's efforts to design, update, and implement its HBP.

A significant body of literature considers the former topic: M&E for UHC. For example, a 2014 series in *PLOS Medicine* reviews methods to measure progress along the three dimensions of the UHC cube (see chapter 6) and offers applied case studies from several countries. The World Health Organization (WHO) and World Bank also shared guidance

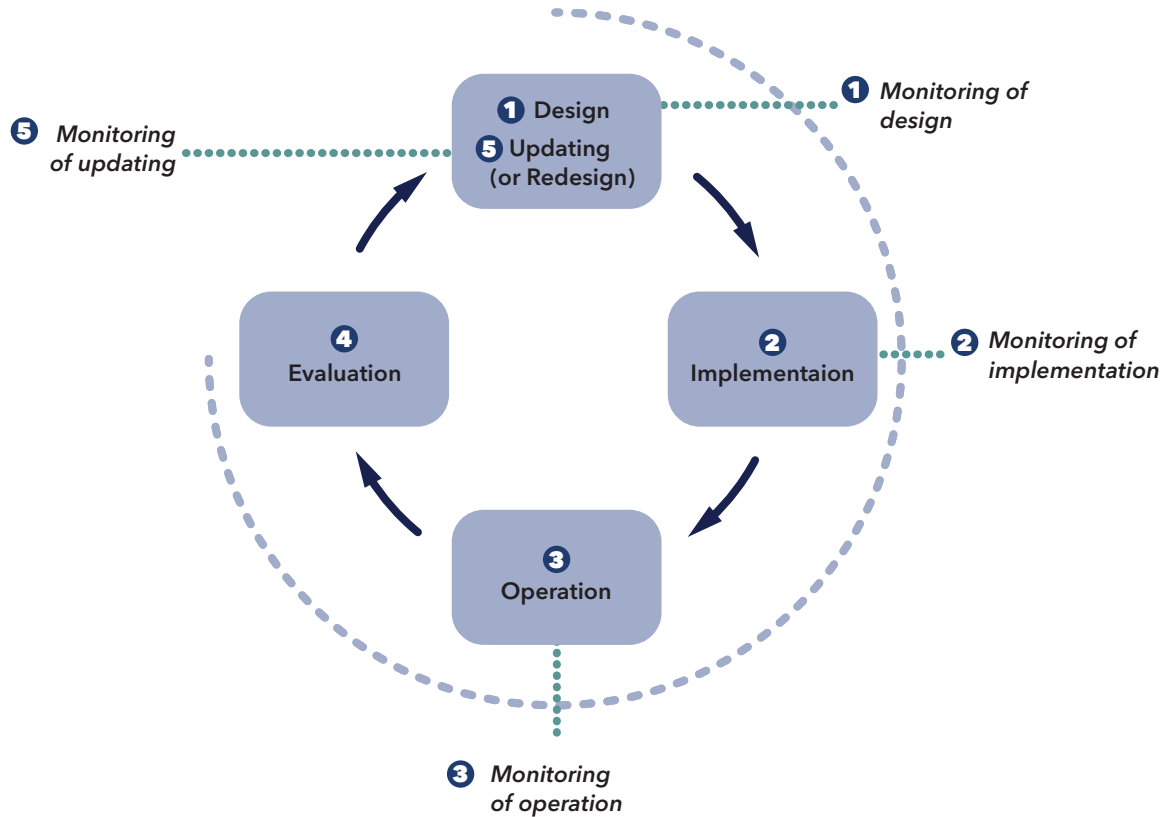
on the measurement of progress toward UHC in their 2013 report,⁶ and the Organisation for Economic Co-operation and Development (OECD) has disseminated methods for its member countries.⁷

However, these efforts pay only limited attention to the important differences that exist across countries in the content, per capita cost, policies, and implementation modalities of country-specific HBPs—a point noted by Amanda Glassman and María-Luisa Escobar.⁸ They also largely ignore differences in the UHC coverage objectives adopted by different countries. For example, the WHO and World Bank seem to assume that progress toward UHC would be identical in two countries if they exhibited the same gains in health status and financial protection, or if both achieved the same coverage or delivery level for some specific intervention. Their aim is to identify unique and globally comparable indicators that can determine each country's progress toward some universal UHC goal. They state that “in order to facilitate global UHC tracking, it is recommended that countries focus on a common and comparable set of tracer indicators, covering health promotion, illness prevention, treatment, rehabilitation and palliative care.”⁹ Different countries, however, have different HBPs and policy objectives. Progress toward UHC in each country should thus be measured against country-specific policies and objectives in addition to universal UHC goals.

What should be monitored and evaluated?

A new HBP-based policy involves four distinct phases, each of which must be the subject of monitoring, evaluation, or both. They are shown in figure 1 as a circular diagram intended to symbolize the cyclical nature of the health policy process. The activities that the figure represents, however, evolve over time in a continuum. The numbers that precede each element in the figure denote the sequence in which activities occur over time.¹⁰

FIGURE 1. The HBP Monitoring and Evaluation Cycle



The first phase is HBP *design*, where policymakers and technical experts construct a HBP and conceive of the requisite arrangements for its delivery. Those arrangements may include collection of additional financing to pay for HBP delivery, criteria and methods to identify and enroll HBP beneficiaries, strengthening of health services physical infrastructure so that providers will be capable of delivering HBP services, hiring and training for clinical and administrative health staff, adoption of contracts and payment methods to compensate providers, instruments to ensure that HBP services are of acceptable quality, and M&E systems to assess the performance of the HBP policy. The design phase ends once the first steps are taken to turn the new policy into action.

Design is followed by *implementation*, or the period during which all HBP-related arrangements,

such as those just listed, are put in place. During implementation, the financing entity will begin to collect its needed revenue, HBP beneficiary identification and enrollment will begin, HBP services will be offered to beneficiaries, and so forth.

Implementation gives way to *operation*, or a period in which the new policy, with its associated arrangements, is fully functional. It may be argued that implementation never ends, and there is thus no recognizable moment when all policy arrangements are functional and stable. From this perspective, implementation and operation may be viewed as a single continuous phase. For operational purposes, implementation ends at the point when new mechanisms, such as beneficiary identification and enrollment, quality assurance, and resolution of beneficiary grievances, are functional, even though they

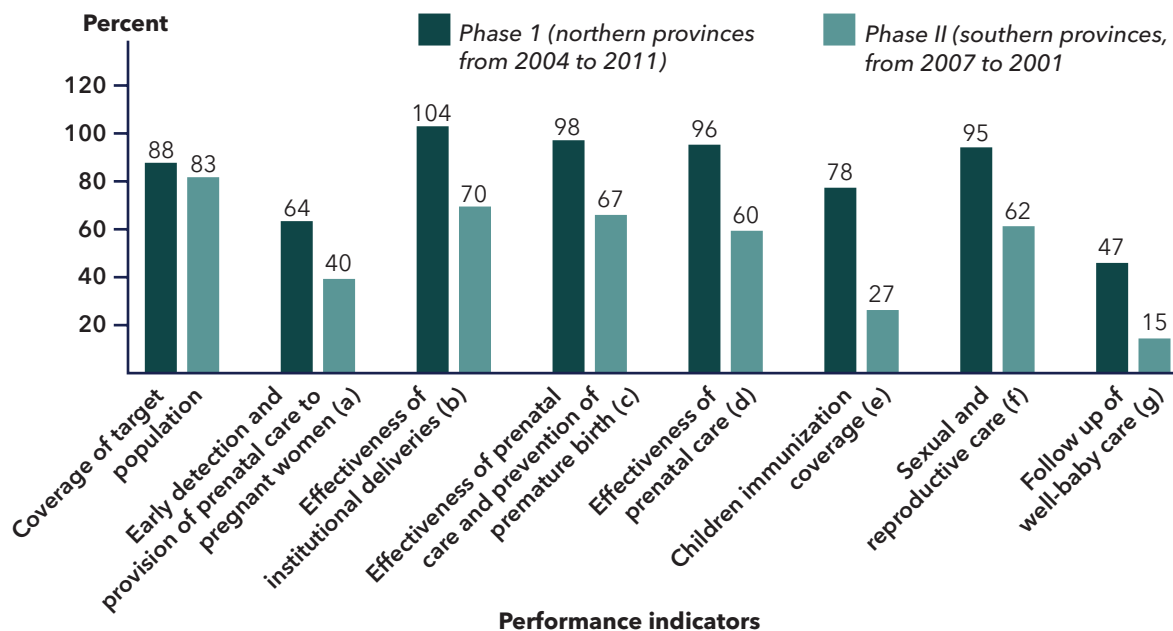
may not yet apply to all intended subjects. For example, if a new system of provider accreditation is fully functional, then the implementation of accreditation is considered to have ended even if some providers are not yet accredited. Likewise, implementation of a beneficiary identification and enrollment system ends when the system is functional even if not all target beneficiaries have been identified and enrolled in it. During operation, the accreditation system expands its geographic scope to reach a growing number of providers, and the identification and enrollment system reaches new beneficiaries.

The fourth phase is *evaluation*, a process through which information is collected and analyzed to assess the performance of the HBP policy. To be useful, the evaluation can occur only when sufficient time has elapsed since the beginning of implementation, such that the system being assessed closely represents the state of current operation. Typically, implementation may take one to two years. Further, some of the

phenomena being evaluated, such as morbidity and mortality indicators, out-of-pocket spending, and beneficiary health service consumption patterns, take several years to change in a way that can be statistically established with confidence. Hence, the evaluation of a new HBP reform may only be carried out three to five years into the reform.

Monitoring efforts carried out during project implementation by those responsible for Argentina's Plan Nacer helped them detect problems and search for causes and solutions. Plan Nacer was first implemented in 2004 in the country's poor northern provinces (phase 1), and in 2007 it was expanded to the remainder of the country (phase 2). For example, monitoring results from 2011 showed that coverage of the target population in phase 2 provinces was nearly as high as in phase 1 provinces—but all other performance indicators were lagging (as shown in figure 2). Plan Nacer's implementation unit concluded that although there had been sufficient numbers of staff

FIGURE 2. Argentina's Plan Nacer: Evaluation of Selected Performance Indicators in Northern and Southern Provinces, 2011



Source: Silva (2011).

in place during the smaller phase 1, human resources were being spread too thin under the phase 2 expansion. Additional staff were needed to strengthen implementation efforts in the remaining provinces.

Evaluation results help determine whether a new policy is achieving its expected results. For example, an evaluation of Plan Nacer showed that infant mortality rate (IMR) had dropped by 15.4 percent nationwide between 2004 and 2009, but it had fallen by a far greater 23 percent in the northern (phase 1) provinces. Consequently, as shown in figure 3, the IMR gap between the northern provinces and the entire country narrowed, an effect attributed to Plan Nacer.¹¹

The timing of M&E efforts for a HBP depends on the duration of each of the above phases, from design to operation. It will also vary from country to country, depending on local circumstances. In general, the design phase takes between one and two years, a period during which design efforts should be monitored to ensure that they are progressing according to plan (see figure 4). Implementation may also take a year or two, followed by a period of steady state

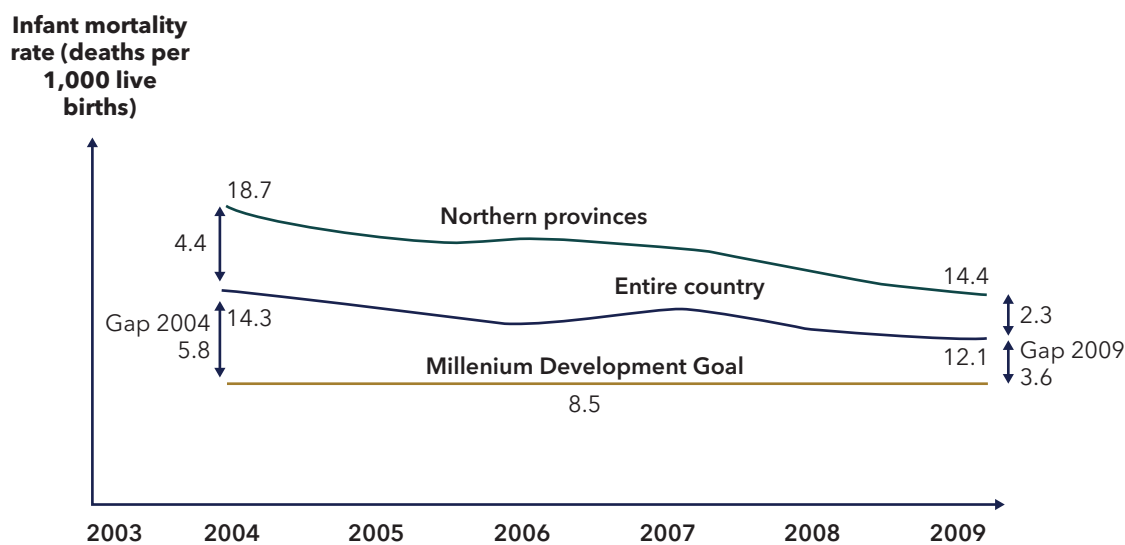
operations. Monitoring efforts should also accompany implementation and operation. Evaluation may occur after the project has been in operation for three to five years. The evaluation effort itself may take between one and two years, because designing and implementing evaluation methods and instruments, including field data collection, is time consuming. Evaluation results may lead to revisions of the HBP policy, a process that may take up to a year.

HBP Design and Revision

Designing a HBP is a one-time event that generally takes place in the context of structural policy changes. In contrast, the revision of a HBP should be a recurring activity. For this reason, the M&E efforts associated with design and revision differ.

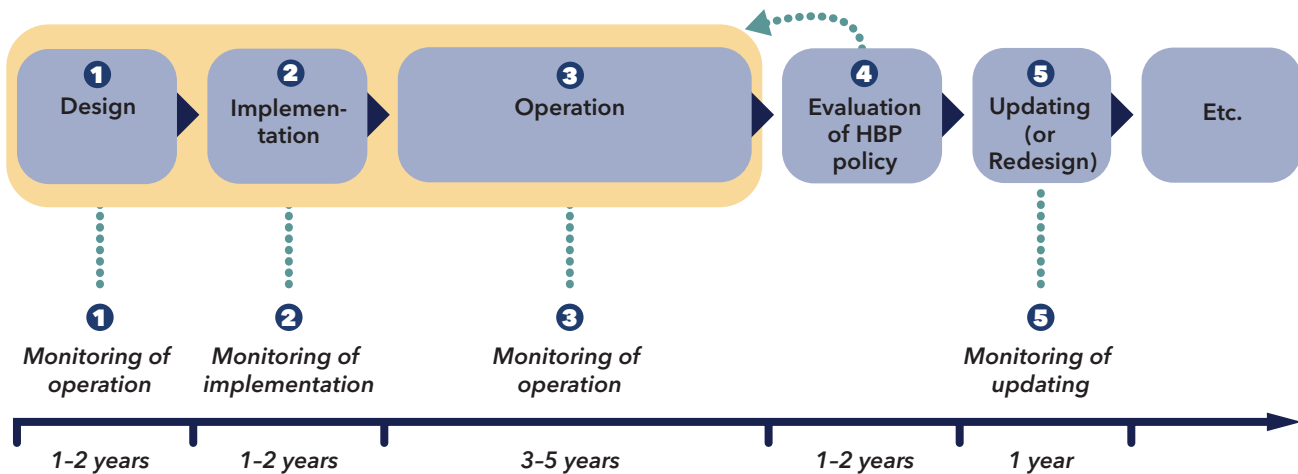
Policy design is a process whose intermediate activities and products include consultations, debates, studies, and designs, and whose end result is the formulation of laws and regulations. This section proposes a

FIGURE 3. Argentina’s Plan Nacer: Evolution of Infant Mortality Rate in Northern Provinces and in Country, 2004–09



Source: Sabignoso (2011).

FIGURE 4. Hypothetical Timeframe: From Design to Evaluation of a HBP Policy



framework for the monitoring of HBP design. It outlines key elements related to the logic, processes, and products involved in design. It is intended to be of use for technicians involved in policymaking as well as development agencies involved in technical assistance for UHC- and HBP-related policies.

Design

In any given country, HBP design is driven by specific policy objectives. Thus, the health services to be contained in the package and the conditions under which those services are to be provided are based on their expected contributions to those objectives.

Countries adopt a wide variety of policy objectives. Before discussing an approach to evaluate the performance of the HBP design process, it is necessary to define what “good” performance means in this context. Many authors and development agencies endorse a normative conceptual model, which states that the ultimate objectives of any health system should be those shown on the right-hand side of figure 5: improving health status, protecting households financially against catastrophic and impoverishing health expenditures, and responding

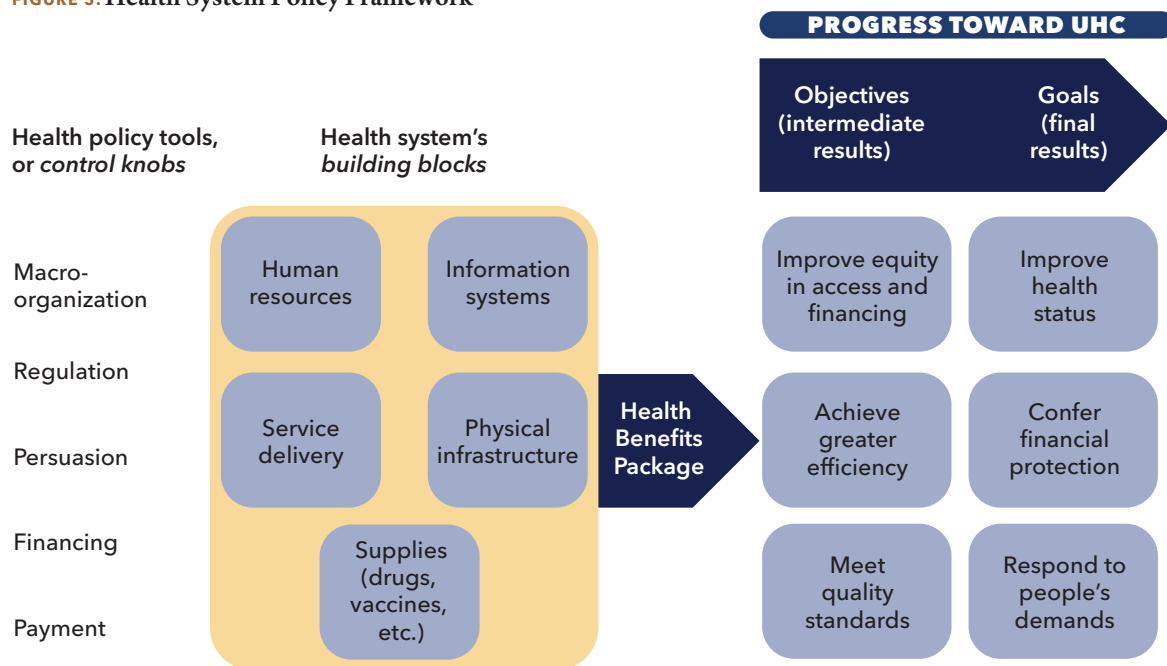
to citizens’ health expectations.¹² This framework also considers intermediate objectives, such as the improvement of equity in access to health services, the increase in health system efficiency, and the enhancement of service quality.

M&E of a HBP design process should at least inquire as to whether those three policy objectives were considered and, if not, should assess the rationale for their exclusion. After all, a HBP is the core of a health insurance system and, as such, it is to be expected that its aims include financial protection of beneficiaries against health shocks.

Whether improving health status should be the aim of all HBPs, however, is less clear. For example, Mexico’s Seguro Popular is built around two HBPs, one of which is designed exclusively to offer financial protection to its beneficiaries. Health status improvement did not inform the definition of its contents; instead, its contents were based on the expected cost of treatment. Therefore, it would be incorrect in this case to evaluate HBP design with respect to its impact on health status improvement.

The inclusion of citizen preferences as a key design objective to be evaluated also varies. For political or other reasons, not all policymakers will

FIGURE 5. Health System Policy Framework



Source: Adapted from Hsiao and Sparkes (2012).

want to lead a citizen consultation process to assess preferences that could be used to formulate a HBP's contents; whether or not they do will depend on the kind of government that exists and the value that policymakers ascribe to popular participation in policy formulation. Some governments may choose (and have chosen) to adopt a purely technocratic approach to formulate their HBP without any public consultation; the pros and cons of this approach are discussed at greater length in chapter 1.

The focus of the assessment is on the coherence between design and objectives, not on the merits of the objectives. More specifically, it proposes six key principles for a template for the evaluation of HBP design: (1) conduct of a sound assessment of health system performance, (2) existence of explicit objectives guiding design, (3) coherence between objectives and design, (4) clarity in the enunciation of benefits included in the HBP, (5) financial feasibility

of the HBP, and (6) supply sufficiency to meet the demand for HBP services (see figure 6).

Sound assessment or diagnosis. A sound assessment of health system performance must be the point of departure of any health policy effort. A sound assessment is one in which the most important performance variables (or desirable results) have been identified, in accordance with local values; those variables have been measured; and a correct conceptual framework has been formulated linking policy action with performance. A sound diagnosis is indispensable to achieve improved health system results, but it will lead to better results only if followed by good implementation. A well-implemented but poorly designed health policy is also undesirable.

Further detail on the components of a sound health policy assessment is beyond the scope of this chapter.¹³ Still, the evaluation of a HBP design should

FIGURE 6. Potential Principles Against Which to Evaluate HBP Design



not accept any policy objective or causal theory at face value. Instead, it should verify that the design was supported by a sound diagnosis and an appropriate causal theory about the determinants of health system performance.

Explicit objectives. A first evaluation principle that, without controversy, should be observed in any HBP formulation process is that design should be driven by a set of explicit objectives. Those objectives generally vary among countries. Yet, as part of the assessment of HBP design, it is useful to verify whether the three ultimate objectives given above (figure 5) were among the drivers of the design. HBP design may even omit certain desirable policy objectives. For example, consider a country or region whose population is greatly dissatisfied with the services offered in its health system. Policymakers could mistakenly disregard this dissatisfaction when formulating a new HBP, thus missing an opportunity to address an important social problem.

Three examples that illustrate the diversity of policy objectives in HBP design are those of Medicaid in Oregon (United States), Norway, and Israel. In Oregon, the public health insurer (Medicaid) sought to formulate a HBP with the dual objectives of covering the entire state population falling below the federal poverty line and maximizing the population's health status. Making the HBP publicly affordable would require a trade-off between access and benefits, as the breadth of the existing package would have to be reduced to make a less expensive (and smaller scope) package available for the entire target population.¹⁴ Initially, Oregon constructed a HBP that would maximize health status by identifying priority health problems and available health interventions, and then ranking the latter based on their health impact. Thus, from a M&E perspective, Oregon met the first principle of HBP design: making its objectives explicit and using a design method consistent with those objectives.

In Norway, the commission set up in 1987 to formulate health policy priorities decided to use severity of a health condition as the exclusive basis for prioritization, outlining five groups with descending levels of priority: emergency care for life-threatening diseases; treatment that prevents catastrophic or very serious long-term consequences, such as cancer treatments; treatment that prevents less serious long-term consequences, such as medication for hypertension; treatment with some beneficial effects, such as medication for common colds; and treatment with no documented effects.¹⁵ In Israel, the National Health Insurance (NHI) law passed in 1995 guaranteed health insurance coverage to all citizens and created a need to define an associated HBP. When the law was first adopted, government decided that the current package of the largest existing sick fund would also be covered under the new HBP, a “grandfathering” of preexisting benefits plans under the new insurance scheme. Thus no explicit process for deciding on the HBP was undertaken at the time, though it was recognized that a process was needed for updating the HBP in the future.¹⁶

How can a country reconcile its own objectives associated with its HBP with the general objectives formulated in the above models? Should all countries' health systems seek to improve health status, financial protection, and responsiveness, in addition to any other specific objectives that they may have? Should HBP design be evaluated against these general objectives, even if they are not included among a country's explicit policy objectives?

Coherence. A second principle in the formulation of any HBP, and therefore its evaluation, is that of coherence between the HBP objectives and the actual criteria used to construct it. Oregon exhibited this coherence when redesigning its Medicaid HBP (see above): it formulated a package whose estimated total cost (cost per capita × number of target beneficiaries) was within its available budget, and

it adopted cost-effectiveness criteria so the package would maximize health status.¹⁷

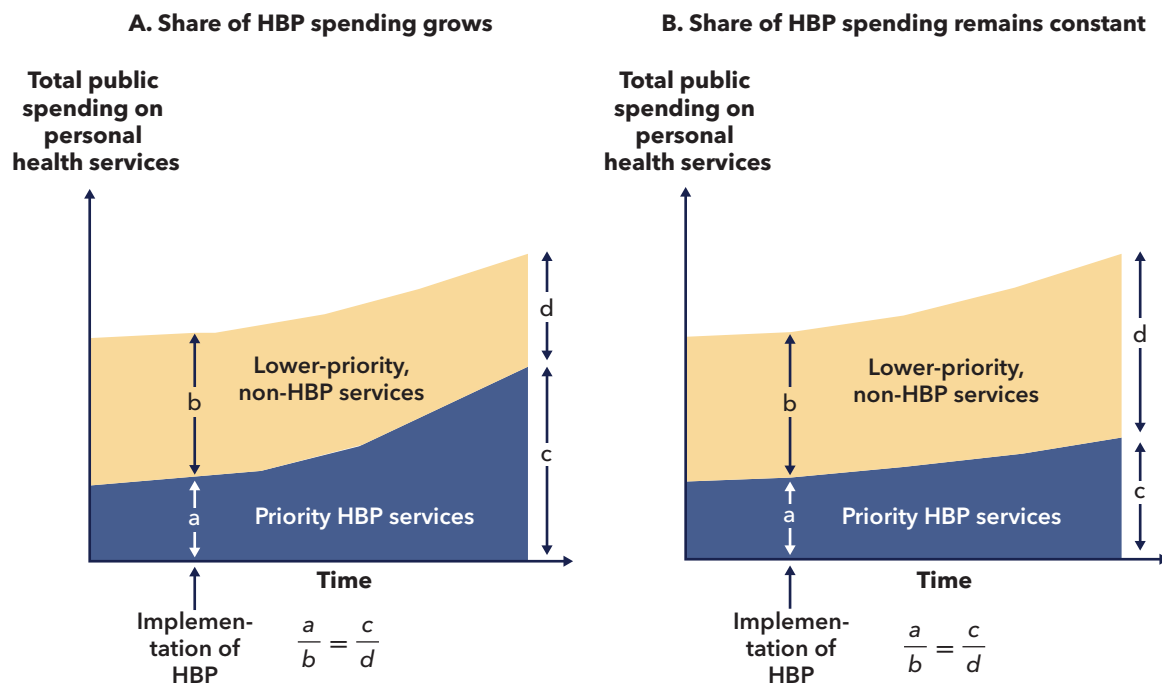
The need to undertake a health reform with a HBP at its core is often driven by general policy objectives, whose coherence with the resulting HBP may be overlooked and thus the subject of assessment. For example, Peru motivated its adoption of a new HBP, the Essential Health Insurance Plan (Plan Esencial de Aseguramiento en Salud; PEAS), by stating that the new policy should guarantee the right to promptly access quality healthcare, protect families against the impoverishing effects of illness, and improve overall health status to boost economic productivity. An assessment of PEAS should include an evaluation of the extent to which it contributes to these three policy objectives.

Clarity. A third principle related to the formulation of a HBP, and therefore its evaluation, is clarity: which services are included in the HBP, which services are

excluded, and what is the meaning of inclusion and exclusion? Of the five principles suggested here, this is probably the one most often overlooked. In most low- and middle-income countries, adoption of a publicly financed and explicit HBP does not imply discontinuation of public financing for excluded services. Instead, it generally means that higher priority will be given to HBP services than to services excluded from the package. For example, if emergency treatment for myocardial infarction is among the HBP benefits but coronary bypass surgery is not, it will not always follow that the latter will be discontinued in government health facilities or that public funding for it will stop. Publicly financed bypass surgery may still be offered but with rationing mechanisms, such as queues and quality deficiencies, that should not occur for HBP services.

Figure 7 presents two possible but hypothetical trajectories for the evolution of public financing for priority and nonpriority health services. Diagram

FIGURE 7. Hypothetical Evolution of Public Spending on HBP and Non-HBP Services



A (left) represents a situation in which the share of public spending allocated to HBP services grows over time, consistent with the goal of increasing consumption for these services. In contrast, diagram B (right) depicts a scenario in which public financing for HBP services increases in absolute terms, but its share remains constant over time. Case A unambiguously represents a situation where the pattern of public spending is coherent with the priorities, whereas case B does not; this is true even though public financing for HBP services, in absolute terms, is growing in both scenarios. Of course, several other spending patterns can be envisioned, including one where the growth rate of HBP spending is lower than that of expenditure on nonprioritized health services.

It is important to consider these scenarios beforehand, when the HBP policy is being designed. Doing so helps policymakers to create clarity about policy priorities and negotiate with budget holders in the ministry of finance. A study commissioned by Chile's Ministry of Health sought to assess how government health spending had been allocated between the priority health services contained in that country's AUGE (for its Spanish acronym for Universal Access with Explicit Guarantees) benefits package and other nonpriority services. Its methods and findings are summarized in box 1.

Financial feasibility. A fourth principle is financial feasibility, or fiscal affordability. The general question here is whether sufficient funds will be available in the future to pay for the publicly financed share of HBP services.

In the above example from Oregon state, affordability was an explicit principle driving the design process—but that is not always the case. For example, Peru's Ministry of Health designed its PEAS as part of its 2009 health system reform under the Universal Health Insurance Law. PEAS was envisioned as a universal HBP for all Peruvians, yet the package was so generous that public financing has proved

largely insufficient to pay for its costs. Available public resources allocated to the country's Comprehensive Health Insurance represent only about one-fourth of the total financing required to pay for PEAS for its target population.¹⁸

In Chile, the policymakers who designed the AUGE HBP considered the financial feasibility principle as follows. First, they conducted an actuarial study to estimate the future annual cost per beneficiary of AUGE health services. Second, they determined that there would be future gaps in public financing to pay for those services. Third, they carried out a fiscal space analysis to assess alternative ways of bridging the expected financing gaps. Fourth, they selected a politically feasible mechanism to generate additional public resources: a one percentage point increase in the value-added tax (VAT). Fifth, they passed a law to increase the VAT. Additionally, to minimize the risk of large, abrupt future imbalances in public financing, they planned the implementation of the AUGE HBP in phases over three years, starting with guaranteed health treatments for 25 AUGE priority health problems in year one (2005), an additional 15 in year two, and another 16 in year three. Additional policy measures to prevent fiscal imbalances included a mandatory actuarial study each time the Chilean Ministry of Health considered expanding AUGE beyond the initial 56 priority diseases and a cap on the per capita annual cost of AUGE, with annual growth tied according to the country's real remunerations index. Since the cost of AUGE would be financed partly through mandatory social health insurance contributions by workers (a fixed percentage of their pay), and partly through a 1 percent increase in the country's VAT, the rationale was that the cost of AUGE should not increase faster than workers' incomes. By 2013, the AUGE HBP had grown to include guaranteed treatments for 80 priority diseases. A new actuarial study conducted in 2016 concluded that no additional public financing would be available to expand AUGE beyond the existing 80 priority diseases, and therefore

BOX 1. Chile: Allocation of Public Financing for Personal Health Services before and after Adoption of AUGE Policy

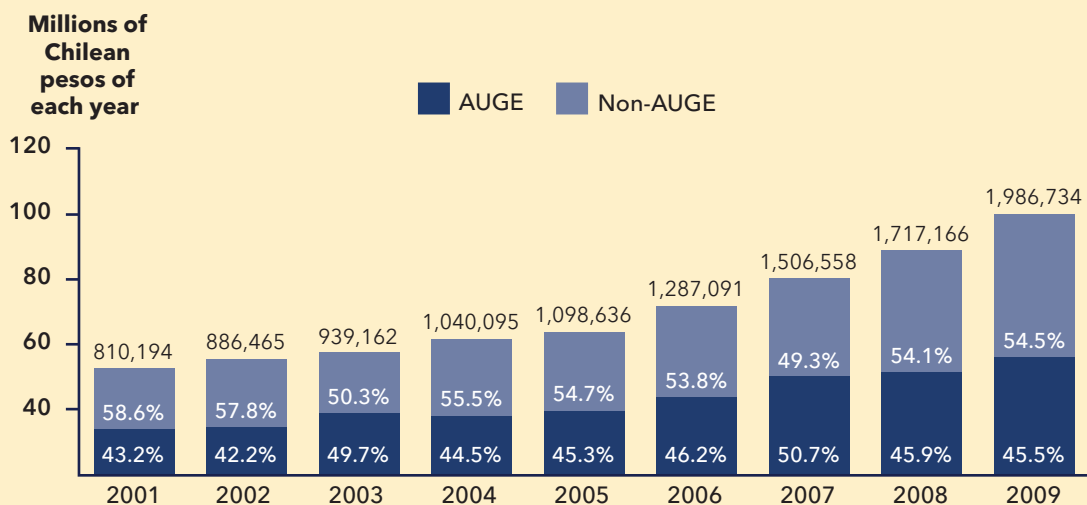
Implementation of Chile's AUGE HBP began in 2005 with coverage for 25 priority health problems. Coverage grew to 40 health problems in 2006 and 56 in 2007. As of July 2016, the AUGE HBP covered 80 priority health problems. These have been added progressively, approximately every three years, following a legally mandated actuarial study and confirmation from the country's Ministry of Finance that sufficient public financing would be available to support to the expansion. With each modification, the ministry of health passes a decree explicitly defining the new coverage.

To track the pattern of spending by FONASA, the large public insurer, covering 80 percent of Chile's population, the Chilean Ministry of Health commissioned a study that estimated its spending on AUGE and non-AUGE services before and after the 2005 passage of the AUGE law. The study assessed the effect of the AUGE law on FONASA spending patterns for prioritized AUGE services and all others.

Many of the interventions included in the AUGE package were delivered by FONASA before AUGE law was passed, and therefore it was possible to estimate how much the public insurer spent on AUGE services even before AUGE become a policy. Using the same method, it was also possible to estimate AUGE and non-AUGE spending after the law passed (figure 8).

As the figure shows, the share of FONASA spending on AUGE services began to increase well before the actual passage of the law with the same name. This may be explained by the early implementation of AUGE pilots. Further, as Chileans became acquainted with the concept of explicit guarantees for prioritized health services—the core of the AUGE reform—they began to demand from FONASA equal promptness in the delivery of non-AUGE care. Consequently, the share of spending going to the prioritized AUGE package did not increase after reform implementation as non-AUGE services kept their share of the total budget more or less constant, as in the case depicted in panel b of figure 7.

FIGURE 8. Chile: Breakdown of AUGE and Non-AUGE Spending by FONASA, 2001–09



the health ministry decided to delay further expansion of AUGE until at least 2019, when a new actuarial study will be conducted.

Colombia's 1994 health reform devised two separate HBPs: a larger self-financed one known as the Mandatory Health Plan (Plan Obligatorio de Salud; POS), for the contributing members of the country's social health insurance system; and a smaller publicly subsidized HBP, known as POS-S (Plan Obligatorio de Salud-Subsidiado), for the lower-income social health insurance population. During the design phase, policymakers conducted a financial feasibility analysis of their proposed reform. They estimated that future growth in public revenue would make it possible to progressively expand the breath of POS-S, such that by the 2000 it would be equal to the POS health package. Regrettably, an economic recession hit Colombia in the mid-1990s and reduced growth in public revenue relative to what health reformers had envisioned; this resulted in their inability to implement the originally planned expansion of the POS-S package. Additionally, unforeseen evasion of social health insurance contributions following the 1994 reform constrained growth in the financing base, thus limiting the magnitude of the cross-subsidy that contributing members granted to subsidized members. Further, successful legal claims by social health insurance beneficiaries forced their insurers to pay for health services not included in the POS or POS-S packages, which also constrained growth in the range of benefits offered under POS-S. In sum, while Colombian policymakers did conduct a fiscal impact analysis of their reform and devised a financing plan, some of their key financing assumptions did not hold and unexpected events undermined its fiscal viability. By 2010, Colombia's new administration set out to overhaul the country's health system through a major reform process.

Supply sufficiency. A fifth and final principle is availability of sufficient human and physical resources

within the country, and within each of its regions, to deliver the services contained in the package. This means that those responsible for HBP design should verify that the required human resources, equipment, drugs, and infrastructure will be available in sufficient quantities to meet the expected demand for services.

This principle was initially observed in the case of Chile's AUGE.¹⁹ For example, in its initial formulation, AUGE included emergency treatment for myocardial infarction but excluded the implantation of a stent among its covered benefits because designers were aware that Chile did not have many cardiac surgeons spread throughout the country. Subsequent revisions of AUGE, however, failed to observe the principle of supply availability. By mid-2015, 10 years into the AUGE reform, several thousand beneficiaries of the public insurer, FONASA (Fondo Nacional de Salud; National Health Fund), were on waiting lists because of unlimited capacity among public providers (table 1). Political preferences and fiscal constraints kept FONASA from purchasing these services from private providers, whose prices for some guaranteed AUGE services tend to exceed those that the public insurer would pay to public facilities.

Revising a HBP

As new health technologies emerge and new health problems develop, public health authorities must determine whether it would be socially beneficial to update a HBP by incorporating new interventions or removing old ones. More generally, HBP revision is a periodic process that may occur annually or every few years in response to changing resource constraints, preferences, technological innovations, epidemiological conditions, and other factors. Ideally, the five key principles proposed to assess a HBP design process should also apply to the HBP revision process.

Monitoring and evaluating the HBP revision matters because some countries may simply fail to do it, or they may update it in a way that is inconsistent

TABLE 1. Chile: Number of Individuals Facing Unmet Guarantees for Health Treatments Contained in AUGE Health Benefits Package as of June 2015 (quantity of patients on a waiting list)

Health problem with guaranteed coverage under AUGE	Less than 30 days	Between 31 and 60 days	Between 61 and 90 days	More than 90 days	Total unmet time guarantees
Cataract	401	804	482	416	2,103
Diabetic retinopathy	249	323	234	525	1,331
Oral health for pregnant women	154	106	89,134	439	788
Secondary prevention of end-stage chronic renal failure	108	133	351	n6	726
Cancer of the cervix	236	136	5968	165	596
Breast cancer	173	140	110	491	491
Bladder cancer preventive cholecystectomy	135	104	6,957	121	429
(36-Órtesis)—Orthosis	163	110	57	79	409
Visual impairment	222	139	28	10	399
Use of hearing aid for adults bilateral hearing loss	98	11	3	107	219
Prostatic hyperplasia	38	41	2,627	90	195
Hip arthrosis	27	30	189	105	189
Depression	30	37	29	87	183
Hip dysplasia luxating	66	40	18	149	149
Herniated nucleus pulposus	32	32	20	64	148
Pacemaker	43	38	16	2,248	119
Adult lymphoma	28	29	11	116	116
Squint	68	24	11	9	112
Primary tumors of the central nervous system	23	22	21	41	107
End-stage chronic renal failure	49	17	9	25	100

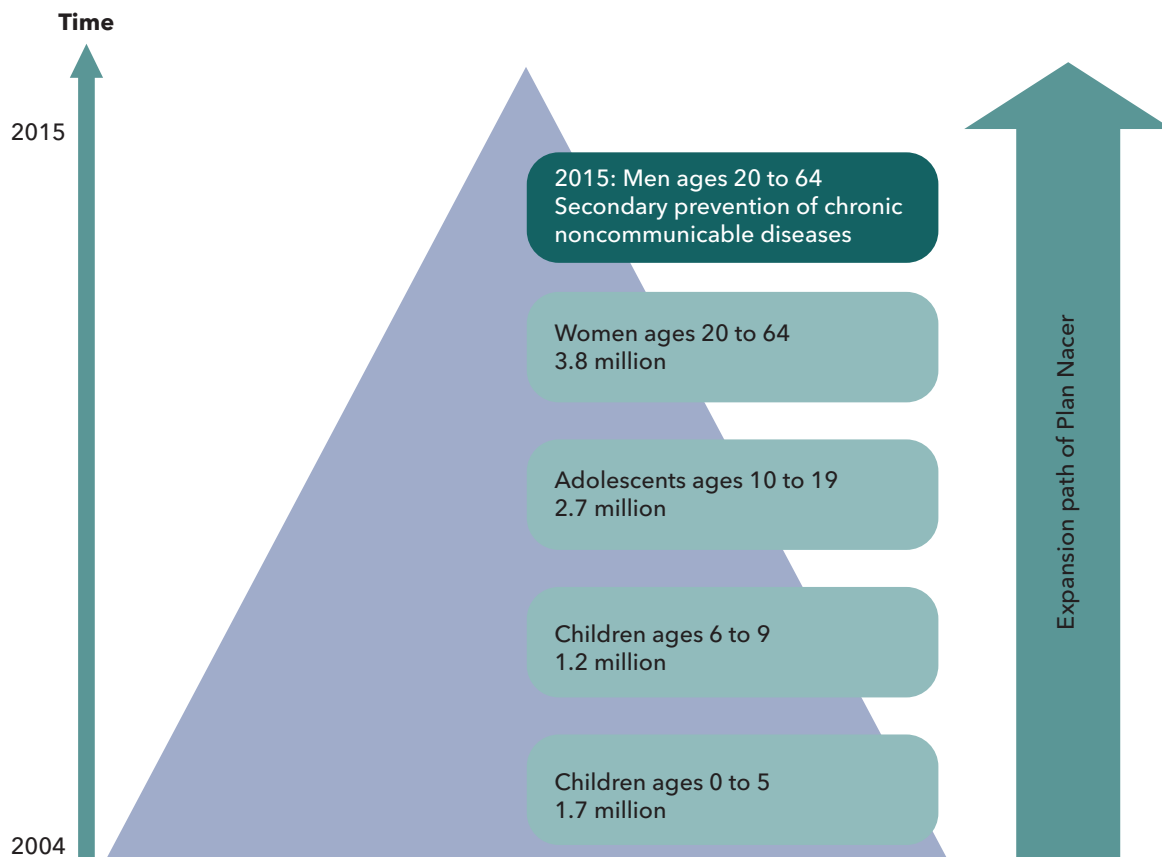
Source: Subsecretaría de Redes Asistenciales del Ministerio de Salud (2015).

Note: Only unmet guarantees with 100 or more beneficiaries are reported in the table.

with policy objectives or with resources constraints. Argentina's Plan Nacer (subsequently renamed as SUMAR) is an example of the latter. Plan Nacer emerged as a federal health policy initiative in the aftermath of a deep economic and political crisis that occurred in 2001. A prioritization process to define the initial contents of the HBP was guided by

evidence of deteriorating health indicators among low-income children in the nine provinces of the country's northeast and northwest. Accordingly, the initial contents of Plan Nacer's HBP comprised a narrow set of health interventions to treat and prevent child diseases and deaths. Concrete evidence of success in these initial regions led to the expansion

FIGURE 9. Argentina: Beneficiary Population and Health Services Expansion Path of Plan Nacer



Source: Giedion, Bitrán, and Tristao (2014).

of Plan Nacer to the remaining 15 provinces (figure 9). Despite Plan Nacer's inability to demonstrate improvements in mothers' and children's health status in the remaining 15 provinces, and notwithstanding significant federal budget constraints and meager provincial financial contributions, policy-makers continued to enlarge the HBP's set of interventions and its beneficiary groups. By 2015, several hundred interventions were included in Plan Nacer's HBP, contrasting with the handful in its original iteration.²⁰ This suggests that the revision may not have responded to rational policy criteria such as financial feasibility and supply sufficiency.

Some European countries systematically carry out studies of incremental cost-effectiveness to compare the expected health gains from covering a new health intervention with the intervention's cost. In other words, they seek to answer the question *does the intervention offer good value for money?* Some countries have implicit or explicit cost-effectiveness thresholds to decide whether or not to include a new intervention in the publicly financed HBP. For example, the United Kingdom's National Institute for Health and Clinical Excellence uses a threshold value of £20,000 to £30,000 (about €24,000 to 36,000) per quality-adjusted life-years (QALY) gained. In

the Netherlands, a frequently cited threshold value is €20,000 per QALY.²¹

The existence of explicit and clear criteria to update HBPs is rare in developing countries. For example, in Honduras, the agency responsible for contracting the general practitioners who deliver HBP services seems to lack explicit criteria for deciding when and how to update its HBP. For example, new additions over the past five years include distribution of micronutrient powders, nutrition counseling (comprehensive care for children in the community), and zinc for treatment of diarrhea. The motivation behind these updates has not been clearly documented.²²

In Chile, the AUGE HBP is reviewed and revised every three years. A special institution operating within the Chilean Ministry of Health, known as the AUGE Consultative Council, is responsible for deciding on revisions to the HBP. The council uses information from the most recent actuarial study about the expected annual cost per beneficiary of potential interventions, but it also uses other criteria that increase the complexity and ambiguity of the process, at least relative to the simpler processes adopted by European countries (see above) where cost-effectiveness analysis provides a clear-cut decisionmaking tool.

In sum, this section has presented a rationale for assessing the design and revision of HBPs in developing countries. It proposed five key principles to assess a HBP design and revision process. The principles include the existence of explicit objectives, the coherence between HBP objectives and its design or revision, clarity in the enunciation of benefits included, financial feasibility, and supply sufficiency to meet the demand for HBP services.

HBP Implementation and Operation

Although formulating and implementing policy are both difficult challenges, they are of a very different nature. Implementation is the process of turning

policy into practice. Implementation of HBPs typically occurs in what can be characterized as a top-down approach, which sees policy formulation and policy execution as distinct activities. HBP design and related policies are set at higher levels in a political process and are then communicated to subordinate levels responsible for the technical, managerial, and administrative tasks of putting policy into practice.

Political scientists have theorized that the top-down approach requires that certain conditions be in place for policy implementation to be effective, including the following:

- Clear and logically consistent objectives
- Adequate causal theory (to how particular actions would lead to desired outcomes)
- An implementation process structured to enhance compliance by implementers (incentives and sanctions)
- Committed, skillful implementing officials
- Support from interest groups and legislature
- No changes in socioeconomic conditions that undermine political support or the causal theory underlying the policy
- Adequate time and sufficient resources available
- Good coordination and communication.

The above points are relevant in the context of HBPs. The first two bullets highlight the importance of a good diagnosis about health system performance. Health system problems must be identified and their causes understood. The construction and implementation of a HBP may be among the desirable policy actions to improve equity and efficiency. The causal link between the delivery of prioritized services and improved performance must be clearly established, to ensure that the policy is indeed necessary and that it will achieve

improved results. The points also highlight the importance of committed implementers and stakeholders, ample time for implementation and for additional resources, and good coordination and communication.

The following are frequent problems associated with the top-down approach to implementation:

- It is very unlikely that all preconditions would be present at the same time.
- It adopts the perspective of only those in higher levels of government and neglects the role of other actors.
- It risks overestimating the impact of government action (neglects other factors).
- It is difficult to apply where no single, dominant policy or agency is involved.
- Policies change as they are being implemented.²³

The above general conditions or enabling factors related to health policy implementation, as well as the potential implementation problems, apply well in the context of HBPs. However, it is important to list all enabling factors that are specific to the successful implementation of HBPs (see also figure 10). Implementation can and must be the subject of M&E. Deficiencies in implementation will weaken the HBP-based initiative and limit its impact. At the end of this section, an instrument in the form of a checklist is proposed for use in the M&E of HBP implementation.

Demand for HBP services. In some situations, the lack of consumption of a specific health intervention stems not from a lack of supply but from insufficient demand. Simply including services that the population does not want in the HBP will not change the root cause of the problem; demand, and therefore utilization, will remain unchanged. Other policy measures, such as public and patient education, may be effective in promoting demand for services with low

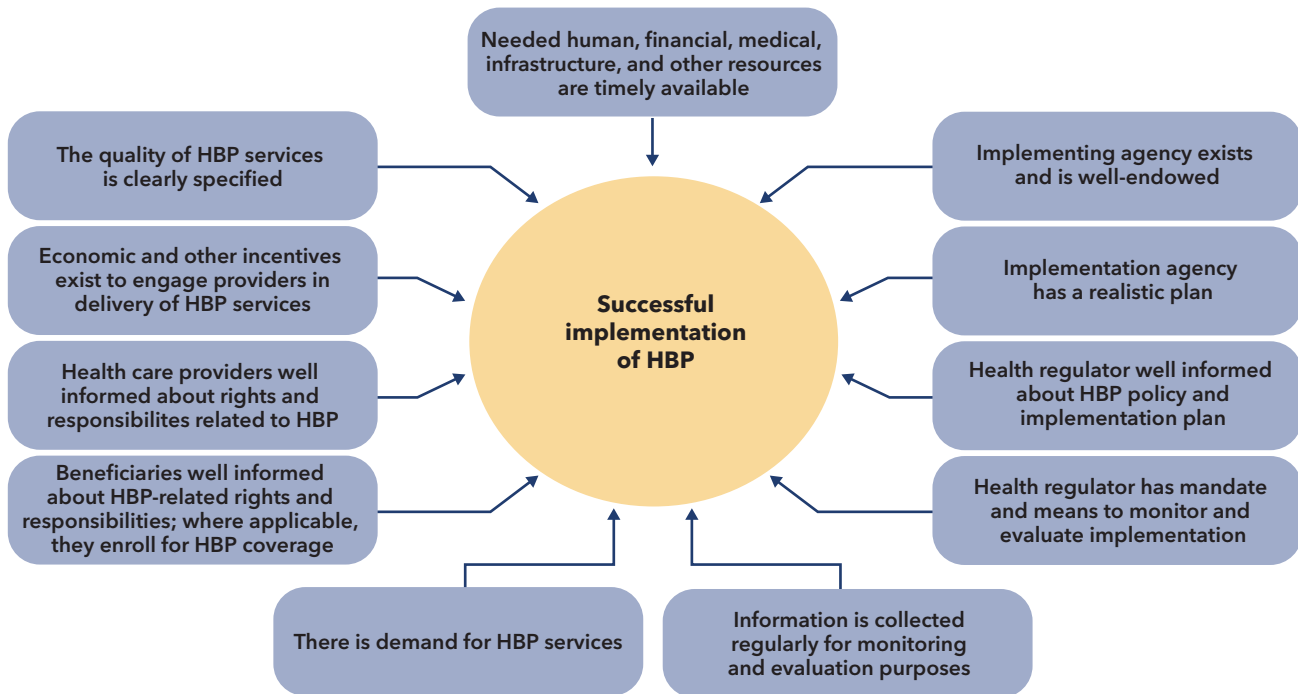
perceived value for individuals that nonetheless are cost-effective or have high social benefits, including some preventive services and institutional deliveries. Only once those complementary policies are adopted to promote demand does it make sense to devote public resources to the supply of those services in a HBP. In Chile, for example, policymakers mandated inclusion of preventive health interventions for adults in the AUGE benefits package. Demand for these services has always been very low, however, because beneficiaries do not perceive those services as sufficiently beneficial, even if offered at no direct cost.

Informed beneficiaries. The beneficiary population of a HBP must be well informed about its contents, the circumstances under which they can obtain its services, and their responsibilities with regard to the HBP. Anecdotal evidence suggests that the population often has limited information about the services offered under the HBP and the right to demand and obtain HBP services. Therefore, health authorities must make a concurrent effort to relay this information to the public through mass communication campaigns, with the help of healthcare providers, or through other means.

An example of the importance of educating beneficiaries comes from Chile's AUGE. There, individuals enrolled with a private social health insurer face a trade-off between their ability to select any health provider and the size of their copayment. To make an informed choice, they must understand that they can receive AUGE coverage for any of the 80 priority diseases and their copayments will be smaller, but their choice of provider will be restricted to the network of providers for that specific disease (for example, the network of oncologists). If, instead, the patient decides to forego AUGE coverage, he or she is free to go to the medical doctor of his or her choice under the regular health plan, but copayments will be higher.

Provider information. Healthcare institutions and professionals must also be informed about the new

FIGURE 10. Enabling Factors for Successful Implementation of a HBP Policy



Source: Author.

policy and their respective new roles. Specifically, managers and health staff should be well acquainted with the services they are expected to deliver, including their quality, and should become familiar with the administrative or patient education actions required to successfully deliver the prioritized services.

In Uruguay, for example, the adoption of the Comprehensive Health Care Plan (PIAS) benefits package called for the establishment of clinical management standards defined in handbooks, along with technical guidelines and corresponding protocols to aid in the selection of prioritized procedures. This led to the standardization of medical practice for interventions contained in PIAS and meant that medical doctors had to become acquainted with and modify their medical practice to comply with the official protocols.

Another example about required changes in provider behavior comes from Chile. Under the AUGE law medical doctors are required to inform the patient,

when applicable, that their medical condition is covered by AUGE, and must give the patient a signed written certificate with this information. Patients covered by private insurers can then decide to seek treatment and financial coverage under AUGE, or to obtain care under their regular health plan.

Provider incentives. Defining certain services as social priorities and including them in a HBP will not always result in increased provision of those interventions. Commonly, economic and other incentives will be required to induce appropriate provider participation in the delivery of HBP services. Those incentives are paid in recognition of the additional effort that providers sometimes must make to induce demand for services that the population undervalues or to purchase the additional resources needed for provision.

For example, Peru's Comprehensive Health Insurance decided to adopt fee-for-service payment to

induce government healthcare providers to engage in the provision of priority services. Government providers receive most of their financing through a budget, but since many of them are close to full capacity, they need incremental resources to pay for the additional inputs required to deliver PEAS services, including doctors' time, drugs, and medical supplies.

Mexico's Seguro Popular offers another example of how financial incentives to providers may be required to promote their participation in service delivery for priority interventions. The state of Hidalgo adopted a system of financial rewards to promote delivery of underutilized preventive health services for diabetes, cardiovascular health, prenatal care, breast cancer screening, oral health, family planning, chronic disease prevention, and reduction of preventable surgery and hospital readmissions. Indicators related to delivery or coverage were formulated and initially measured to establish the baseline. A monitoring system was put in place to measure the evolution of the indicators, and a system of rewards established wherein providers received a bonus equal to 10 percent of their budget if they met target delivery indicators.²⁴

The designers of Plan Nacer in Argentina were aware of the need for additional financial and economic incentives to promote delivery of prioritized health services in government health centers around the country. Accordingly, they devised a performance-based financing scheme through which provinces would receive additional federal financing if they met certain healthcare delivery targets (figure 11). Provinces, in turn, were encouraged to set up a fee schedule and to pay their providers fee-for-service. Evaluations of Plan Nacer showed that delivery targets were generally met and that the health status of mothers and children improved accordingly.

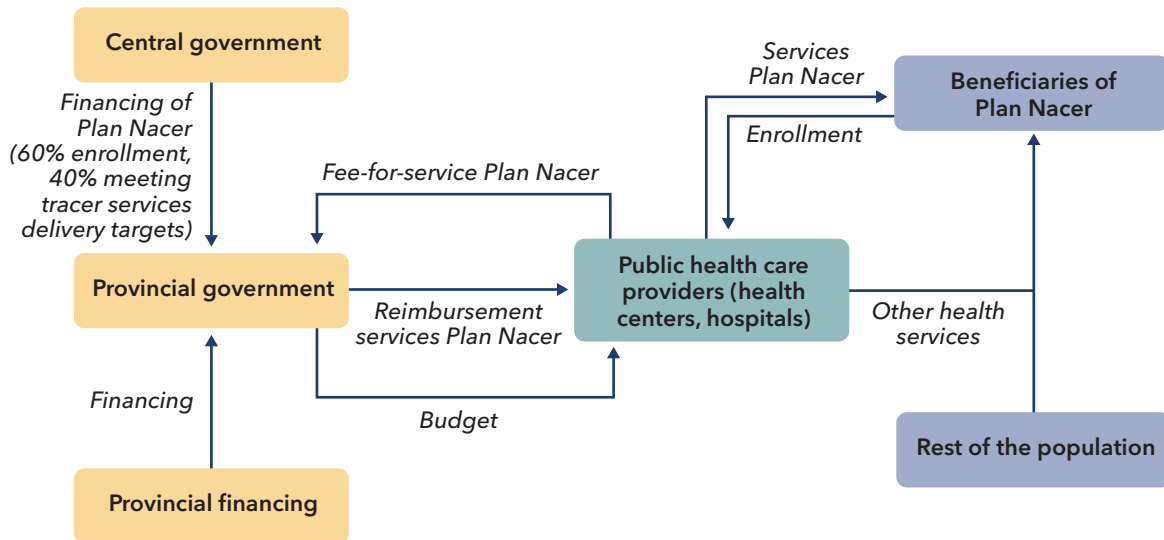
Explicit quality. Delivering quality healthcare is a main objective of reforms based on HBPs. Ensuring appropriate and uniform service quality improves

health system efficiency (service delivery effectively improves health status) and equity (all HBP beneficiaries have access to services of homogenous quality). For this reason, HBP construction and delivery policies typically include mechanisms to ensure quality of care. These may consist of the development and use of explicit treatment protocols, the training of health staff in the compliance with those protocols, the adoption of monitoring systems to assess quality, the licensing and accreditation of health professionals and institutions, and the operation of a quality assurance entity.

In Mexico, quality assurance was a pillar of the Seguro Popular policy initiative, with its central managerial reform under the so-called National Crusade for Quality in Health Care. This reform sought to enhance patient safety, improve responsiveness, manage facility accreditation and provider certification, implement quality improvement initiatives, measure technical and interpersonal quality, and undertake performance benchmarking among states and other organizations.²⁵ The considerable increase in public funding for Seguro Popular resulted in significant improvements in access to care and in financial protection for the beneficiary population. However, household out-of-pocket spending did not drop significantly as a share of total health financing among beneficiaries.

The importance of achieving effective and lasting gains in health service quality became evident in the context of Mexico's reform. Felicia Knaul and colleagues concluded that while additional financing is generally necessary to improve access, financial protection, and health status for the poor, it may not be a sufficient condition to improve all dimensions of health system performance. They noted that "until universal access includes a guaranteed, acceptable level of quality, the egalitarian exercise of the right to protection of health will remain an elusive goal and inefficient out-of-pocket spending will grow. Further, without efficient use of current resources, generating

FIGURE 11. Financial and Service Flows in Argentina's Plan Nacer



the additional fiscal space required to face the burden of chronic diseases is politically unfeasible.”²⁶

Chile’s health regulator took nearly a decade after the implementation of the AUGE reform until it could launch a system of provider accreditation. Further, most government hospitals were not ready to be accredited and had to be given an extended period to make the required infrastructure investments and operational changes needed to pass the accreditation.

Available inputs. The effective delivery of HBP services general calls for additional resources in the form of health and administrative staff, buildings, vehicles and equipment, pharmaceutical product information technology, and new management systems. Additional financing therefore is needed to make HBP-based reforms successful. In the absence of these investments, HBP implementation may be ineffective, as deficiencies in supply of services are among the main causes of underperforming health systems.

In Honduras, the evaluation of the feasibility of the HBP in remote rural areas led to a supply adjustment in some situations. However, in many cases, policymakers fail to see a link between their plan to

deliver HBP services to a defined beneficiary population and the consequent need to reinforce the supply side of the health system to enable it to meet the demand for priority services.²⁷

In Chile, policymakers responsible for the AUGE reform’s design and implementation did anticipate the need to strengthen the supply of government health services and carried out a national assessment, followed by the implementation of an investment plan, to endow providers with the needed resources. Yet public providers maintained resource deficits and management deficiencies, which kept them from meeting AUGE demand. This was compounded by a continued exit of government system medical specialists to the private sector, lured by higher wages. This led to the appearance of waiting lines for services that were outside of the AUGE benefits package, and for AUGE priority services as well (see table 1).

Implementing agency. Implementing a HBP requires that various actors in several parts of the health system take many diverse actions. Ensuring that these changes occur as planned is a major logistical challenge and therefore calls for the existence of an

implementing agency and an appropriate implementation plan. This agency ought to be well acquainted with the blueprint of the HBP-based reform and it should be endowed with sufficient human, financial, and physical resources to lead the implementation process. In the absence of this institutional figure, changes may not occur, may differ from plans, or may not take place within the necessary time frame.

Capable health regulator with appropriate means. Regulating the policy involving the HBP is as necessary to its success as is appropriate implementation. The regulatory role, however, may fall in the hands of a different entity than that charged with implementation.

Monitoring and evaluation mandate. The health regulator has the mandate and means to monitor and evaluate its implementation.

Evaluation of HBP Results

In the preceding sections, it was argued that sound policy design and successful implementation are indispensable to achieve desired improvements

in health system performance. Monitoring these activities helps to detect any problems and offers designers and implementers an opportunity to take any necessary corrective actions. Yet, sound design and implementation will not guarantee a successful reform. Success will occur only if the reform achieves desired results in terms of expected improvements in health system performance. The guiding light of evaluation, therefore, must be the set of objectives that motivated the reform. For example, if achieving reductions in maternal and child mortality in rural areas was a main reform objective associated with the construction and delivery of a HBP, as in Argentina’s Plan Nacer, then an evaluation to determine the reform’s achievements should focus on those health status indicators. If, instead, the chief reform objective was to reduce impoverishing and catastrophic health spending on prioritized services, then the evaluation should focus on assessing the financial burden of household health spending.

Generally, health reform objectives sought through HBP design and implementation may be formulated in relation to performance variables that belong to different conceptual domains, as shown in figure 12 and table 2. Thus, some reforms may seek

FIGURE 12. Indicators in M&E Efforts for HBP policy

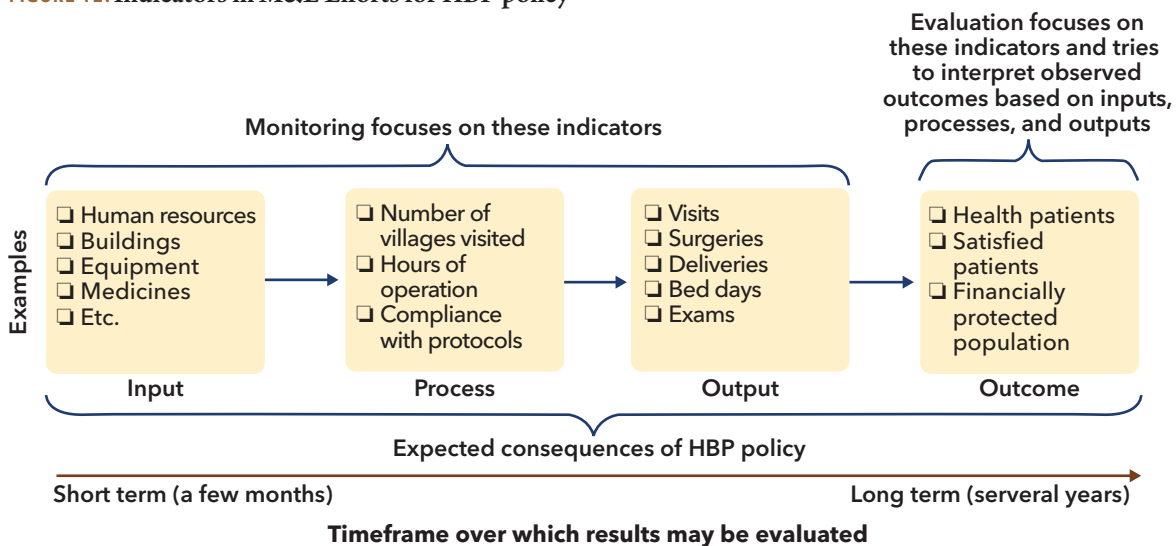


TABLE 2. Domains and Examples of Indicators to Be Measured and Methods Used for HBP Policy Monitoring and Evaluation

Domains	Indicators	How to measure
Inputs	Human resources	<ul style="list-style-type: none"> ■ Analysis of staffing using central or regional payroll information. ■ Field visits to a sample of facilities to assess actual staffing and hours worked. ■ Interviews or focus groups of a sample of health facility staff, including administrators and health workers, to assess their perception of pay and incentives in place to engage in the delivery of HBP services.
	Buildings	<ul style="list-style-type: none"> ■ Analyses of executed investment budget at central or regional levels of government. ■ Field visits to a sample of new or renovated health facilities to determine quality of construction, degree of completion, and other aspects. ■ Review of bidding processes for construction and renovation contracts. Interviews of staff responsible for implementing contracts and of staff in construction companies.
	Equipment	<ul style="list-style-type: none"> ■ Field visits to a sample of new or renovated health facilities to determine progress, quality of construction, and the like. ■ Review of bidding processes for construction and renovation contracts. Interviews of staff responsible for implementing contracts and of staff in medical equipment companies.
	Medicines	<ul style="list-style-type: none"> ■ Assessment of existence of drugs policy and law, if applicable. ■ Assessment of procurement and distribution processes at central and regional levels. ■ Field visits to central and regional distribution centers. ■ Field visits to a sample of health facilities at different levels of delivery system (pharmacies, rural health stations, health posts, health centers, hospitals) to assess existence, stock levels, stockouts, brand, packaging, conservation, and quality of drugs available.
Processes	Number of villages visited	<ul style="list-style-type: none"> ■ Staff interviews at a sample of health facility and mobile health teams to assess frequency of visits, achievements, challenges, proposed solutions. ■ Interviews of village and other local informants to assess compliance of health staff with schedule of visits to villages.
	Hours of operation	<ul style="list-style-type: none"> ■ Field visits to a sample of health facilities to assess actual hours of operation. Interviews of health staff to determine existence of compliance problems with work schedule. ■ National or regional survey to a randomly selected (and possibly stratified) sample of households to inquire about their actual experience accessing health services.
	Compliance with treatment protocols	<ul style="list-style-type: none"> ■ Assessment of the existence of treatment protocols as a national or regional policy. ■ Review of training efforts undertaken by Ministry of Health to disseminate protocols and to promote their appropriate use. ■ Survey of sample of health facilities to assess whether health staff are aware and regularly use HBP-related treatment protocols, and to identify any problems that they view in the contents of the protocols or in their use. ■ Exit surveys of a sample of patients in a sample of health facilities to inquire about the services received.

Domains	Indicators	How to measure
Outputs	Visits	<ul style="list-style-type: none"> ■ Analysis of administrative electronic records of service delivery information. National or regional survey to a randomly selected (and possibly stratified) sample of households to inquire about their actual use of various health services.
	Surgeries	
	Deliveries	
	Bed days	
	Exams	
	Other indicators	
Outcomes	Healthy patients	<ul style="list-style-type: none"> ■ National household survey of health status, including self-perception and anthropometric measurements (height and weight, blood pressure, blood samples for lab exams). The Demographic and Health Survey is a good example.
	Satisfied patients	<ul style="list-style-type: none"> ■ Exit polls of a random sample of patients in a sample of health facilities to gather their satisfaction with the services received. ■ National or regional survey to a randomly selected (and possibly stratified) sample of households to inquire about their self/perceived health status and need for healthcare, their actual experience accessing health services, including their satisfaction with the services received, healthcare-seeking patterns, and out-of-pocket spending on healthcare, medicines, transportation, and related expenditures.
	Financially protected population	<ul style="list-style-type: none"> ■ National or regional survey to a randomly selected (and possibly stratified) sample of households to inquire about their self/perceived health status and need for healthcare, their actual experience accessing health services, including their satisfaction with the services received, healthcare-seeking patterns, and out-of-pocket spending on healthcare, medicines, transportation, and related expenditures.

to improve the availability of certain production *inputs*, such as human resources, through new hiring and training, or essential drugs, via improvements in procurement and distribution systems. Those promoting these reforms may not make explicit reference to expected health system outputs or outcomes, even though they may expect that both outputs and outcomes will increase or improve if the availability of key production inputs improved. Other policymakers may attempt to improve *processes*, such as the technical quality of services through compliance with standard treatment protocols. Here too, their underlying expectation is that strengthened health-care delivery processes eventually will result in more

and better outputs and outcomes. Other reforms may set out to expand health service *output*, or the volume of services provided to the whole population or to certain target groups—for example, the proportion of deliveries taking place in accredited health facilities or the percentage of children fully immunized. The expectation may be that higher volumes of outputs will result in improvements in health status. Finally, some reforms may hope to improve health *outcomes*, such as health status, or patient satisfaction, of financial protection.

The further one moves to the right along the policy domain diagram in figure 12, the longer the time period required to be able to detect performance

improvements through an evaluation. For example, if the reform's objective is improved availability of certain inputs, then a few weeks or months may suffice to assess whether or not the policy was successful. If the policy's objectives are formulated in terms of improvements in outcomes, however, then it may take several years to determine whether the reform succeeded. Intermediate time frames of several months to a year or two may be required to evaluate reforms that aim to improve processes or outputs.

Reforms that have a HBP at their core tend to pursue multiple policy objectives, some of which may belong to different domains. Therefore, evaluations should encompass indicators of success related to all those objectives, or to the most important ones. Further, HBP-based reforms will generally aim to improve health outcomes, such as mortality or morbidity, and policymakers may view the achievement of indicators in other domains solely as intermediate results that do not guarantee overall success of the reform. In Colombia, for example, policymakers viewed the establishment of social health insurers and the enrollment of individuals as intermediate objectives, with improved access to healthcare, reduced reliance on out-of-pocket spending and better health status as the ultimate objectives.

Table 3 lists the reform objectives of a selected set of developed and developing countries that undertook a reform consisting to deliver a prioritized set of health services.

Ideally, the performance variables and expected achievements related to a reform, in terms of outputs and outcomes, should be made explicit from the moment the reform is conceived.

Often, health reforms produce unanticipated consequences within the health system. If evaluations focus only on expected consequences, they

may overlook unexpected consequences, thus under- or overestimating the reform's impact. For example, the AUGE reform in Chile was successful in promoting awareness among the population about the existence of explicit legal rights related to their access to healthcare. Ten years into the reform, Chileans are now aware that if they suffer from any of the 80 priority diseases covered by AUGE, they can demand prompt and quality treatment with modest copayments. An unanticipated consequence of AUGE, however, was that citizens became so familiar with their empowerment to demand and obtain AUGE treatments that they began demanding prompt treatment for non-AUGE conditions as well. The public insurer and public healthcare providers have been unable to meet this demand, as they were striving to meet the growing demand for priority AUGE services. For the past several years, the Chilean Ministry of Health has been keeping an electronic information system that records waiting lines for non-AUGE treatments. They contain millions of specialty visits and hundreds of thousands of surgeries, all excluded by AUGE. These waiting lists are the subject of contentious policy debates and exert upward pressure on the public budget. Measuring them must be part of the effort to evaluate the AUGE reform.

To avoid omitting important issues to be assessed through an evaluation, those writing the evaluation's terms of reference must reflect on what has occurred as a consequence of the reform. This reflection must follow field observations about what seems to have happened during the HBP implementation, and may be enriched by including the opinions of various health system actors and experts. Their combined reports may broaden the understanding of those designing the scope of the evaluation.

TABLE 3. Reform Objectives and Evaluation Variables in Selected Countries

Country	Reform objectives	Variables that should be the focus of an evaluation
Argentina	Reduce infant and maternal mortality for low-income rural populations not covered by social or private health insurance	<ul style="list-style-type: none"> ■ <i>Process</i>: Percentage of provincial health authorities that have set up a price schedule with public health providers for prioritized health services under Plan Nacer ■ <i>Output</i>: Target population covered for prioritized preventive services; percentage of the population receiving those services ■ <i>Outcomes</i>: Reductions in infant and maternal mortality
Chile	Guarantee access to treatment for priority diseases, included in the AUGE HBP, for all Chileans covered by the country's social health insurance	<ul style="list-style-type: none"> ■ <i>Process</i>: Public and private insurers have set up networks of healthcare providers that are acquainted with the treatment protocols of AUGE ■ <i>Output</i>: There is an increase in the percentage of fertile age women who get their Pap smears done, and in the time it takes women with anomalous Pap smears to undergo further testing ■ <i>Outcomes</i>: There is a reduction in hospital case fatality for childhood epilepsy and HIV/AIDS^a
Colombia	Offer a broad and explicit HBP of standard quality to all Colombians, through a competitive system of public and private social health insurers, with formal workers conferring cross-subsidies to the poor, and with public and private healthcare providers competing for insurers' business.	<ul style="list-style-type: none"> ■ <i>Process</i>: Private and public insurers have been created and they have started to affiliate their covered population. Public and private providers are celebrating delivery contracts with insurers. A beneficiary identification system is put in place to conduct means tests in order to identify the low-income population of the subsidized regime. An equity fund is set up and collecting and distributing public and cross-subsidies for the low-income population. ■ <i>Output</i>: Access to services contained in the HBP is growing among all those insured. Gaps in access to HBP services are narrowing between beneficiaries of the subsidized and contributory regimes. ■ <i>Outcomes</i>: Health status of all Colombians has improved and inequalities in health status among socioeconomic groups have narrowed. Financial protection has improved so that fewer Colombians experience catastrophic and impoverishing health expenditures.

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11. Sabignoso (2011); and Gertler, Giovagnoli, and Martinez (2014).
12. WHO (2007); Roberts and others (2008); and Hsiao and Sparkes (2012).
13. For more on policy formulation, see Roberts and others (2008).
14. Wong (1998).
15. Sabik and Lie (2008).
16. Ibid. A *propos* of the M&E framework, in these HBP cases, while explicit objectives are established for future iterations of HBP (the “update”), the initial version of the HBP (the “design”) does not follow these explicit objectives, and an evaluation of the design of the HBP would reflect that appreciation.
17. These criteria were measured through a metric known as Quality of Well Being.
18. Prieto, Cid, and Montañez (2014).
19. This package was subsequently renamed GES for the Spanish acronym for Explicit Health Guarantees.
20. Giedion, Bitrán, and Tristao (2014).
21. Polinder and others (2011).
22. Dinarte and Prado (2014).
23. The above paragraphs of this section draw on Steinbach (2010).
24. Srivastava, Mueller, and Hewlett (2016).
25. Knaul and others (2012).
26. Ibid., p. 13.
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3. Durairaj, D’Almeida, and Kirigia (2010).
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CHAPTER 3

Managing the Money

Fiscal and Budgetary Considerations for the Benefits Package

Amanda Glassman

At a glance: It's not all about the money—but for a successful health benefits package, live within your means, link payments systems to the plan, and account for donor earmarks.

Once the decision to adopt a health benefits package (HBP) has been made, four key finance-related challenges must be considered and aligned if the plan is to be an effective instrument for setting and delivering on health priorities: fiscal space, budgetary structures, provider payment arrangements, and external funding sources. These cross-cutting finance issues touch on steps 7 (make recommendations and decisions), 8 (translate decisions into resource allocation and use), 9 (manage and implement the HBP), and 10 (review, learn, and revise) of the core elements of setting a HBP, as described in the introduction, as well as the overall governance (chapter 1) and institutional arrangements (chapter 2) of the HBP. They are singled out in this chapter because of their centrality to the effectiveness of the HBP enterprise as a whole.

Four Common Challenges

First, if a HBP is intended to effectively set priorities, the fiscal space available necessarily determines the size of the package over time. Put another way, the budget available to the plan in every fiscal year is what determines the scope, number or depth of services included, and their associated financial coverage for the population. While a self-evident point, many HBPs have been enshrined in law or regulation by low- and middle-income country (LMIC) governments or insurance agencies but remain unconnected to the amount of financial resources available, thereby limiting or nullifying the utility and sustainability of HBP as a tool for setting explicit priorities. In the case of Ghana's National Health Insurance Fund, for example, Director of Insurance Vivian

Addo-Cobiah has noted: “The [insurance] law establishes a list of benefits, but that list has nothing to do with the amount budgeted or contributions made to the insurance fund in each year, with the result that finances are not in balance.”¹ Another example comes from Peru: the country’s legally-mandated PEAS (Plan Esencial de Aseguramiento de Salud; Essential Health Security Plan) had an annual average cost per beneficiary 2.5 times higher than the total annual spending on health per person in Peru.² Other common pitfalls include failing to account for the budget impact of new technology adoption in future fiscal periods or not adjusting for changes in input costs, demand for services, purchasing power and demographic changes. In the Dominican Republic, for example, the value of the HBP was eroded over time by a failure to update for price, utilization, and cost changes.³ This example further illustrates a common thread of this volume: HBPs are dynamic policy tools that must be adjusted and revised regularly.

A related challenge is connected to “grandfathering,” or rolling over historical per capita spending into a capitation or premium associated with the HBP as part of a health reform. Israel, Germany, the Netherlands and Uruguay are all examples of this phenomenon.⁴ While grandfathering is practical in a short-term sense, the approach quickly falls apart as an effective priority-setting tool if the funding shortfalls vis-à-vis benefits to be provided is too large.⁵

Finally, attention must be given to how to adjust the HBP in case of external shocks that can affect healthcare budgets; recent experience in some European countries highlights how unprepared some countries were to adjust benefits to new resource realities, or to save or reallocate anticyclically to cover shortfalls.⁶

Second, the budget structure in each health system has implications for the effectiveness of the HBP. Even if adequate fiscal space is allocated to a plan, the way resources are budgeted and transferred

to local governments or health provider organizations affects the extent to which HBP can be effective in practice. Often, LMIC governments graft a HBP onto an input-based budget; in Mexico’s Seguro Popular reform, for example, a HBP was defined and a fixed budget per person was allocated from the federal government to each state. However, once the HBP-per-person budget reached the state government treasury, the monies are allocated to health providers through traditional input-based budgets, with a corresponding lack of tracking, accountability, and feedback around whether those monies produce the prioritized services. In Mexico, then Sub-Secretary of Health Eduardo González-Pier noted that “HBP priorities sometimes stop at the state line.”⁷ An even more extreme example can be found in Peru, where one of the benefits plans (PEAS) is financed through different input-based budgeting streams (human resources, results-based budgeting, and others), without much attention to coordination and coherence. A shift to HBP capita cost-based budgeting and/or output-based, diagnosis-related group (DRG)-based, or guideline-based budgeting can also be useful in structuring payment and claims/billing systems, and ideally can be used to structure the HBP itself.

Third, provider payment arrangements have enormous implications for the effectiveness of the HBP. Ideally, the HBP is used to structure payment or commissioning processes, with the goal of creating direct financial incentives for providers to deliver the highest-priority prevention and care services. A mix of payment methods will likely be needed to effectively deliver the HBP; the HBP’s effectiveness will in turn depend on existing health system characteristics and risk-sharing practices. There is an already large literature on the advantages and limitations of different healthcare payment approaches in both high-income and LMIC settings; generally, these discussions have been agnostic on “what” is to be paid—the main focus of this book—while providing excellent guidance on “how” to pay, including incentives and other

approaches.⁸ There is no need to revisit the discussion here, but only to emphasize that the incentives generated through provider contracts and payments should support the effective, appropriate, and quality delivery of the care included in the HBP.

There are, of course, nonfinancial policy tools that can create incentives for providers to implement the HBP, such as benchmarking, performance monitoring, audit, supervision, and other enhanced accountability strategies. These are beyond the scope of this chapter, but should be kept in mind. Also, certain mechanisms can directly empower beneficiaries, thereby increasing the likelihood that effective health services will be delivered. Chile's AUGÉ (Acceso Universal con Garantías Explícitas; Universal Access to Explicit Guarantees) guarantees are an important example in this context: beneficiaries have an explicit and legally enforceable right not only to receive the benefits enshrined in the package but also to receive high-quality services, enjoy reasonable waiting times, and be financially protected.

Fourth and finally, in many of the lowest-income countries, some highly cost-effective services—vaccination, communicable disease treatment (HIV/AIDS, tuberculosis, malaria), and family planning—are funded partially or entirely from external bilateral or multilateral aid earmarked for those uses. Ideally, the HBP would prioritize these services based on cost-effectiveness and related criteria, and aid monies could flow alongside public monies to ensure payment for and provision of the entire package of care. In practice, several low-income countries have developed HBPs that exclude these services precisely because they are funded from external sources, leading to fragmentation and (perhaps) lack of sustainability. In Vietnam, for example, Phuong Nguyen Khanh says that “HIV/AIDS programs have historically been funded separately by donors, and apart from Vietnam’s social health insurance basic health services package.”⁹

The reasons behind the ubiquity of these challenges are clear—the institutional arrangements in

place simply are not aligned with the need to consider the health system as whole. In addition, there is often a lack of policy coherence between ministries of finance and ministries of health or social security institutes; for example, finance ministries might fail to include needed HBP adjustments in medium-term expenditure frameworks. Misaligned policies or interests between different levels of government, or between payers and providers, may also explain these phenomena, as would the use of HBP as political rhetoric but without enabling context and connected financial policies. Addressing some of these underlying reasons, as well as the symptoms themselves, is a central concern for policymakers engaged in designing and operationalizing HBP policy.

There may also be a simple story related to each country’s capacity and economic development. Most health systems, for example, seem to evolve toward better billing and reporting systems over time.¹⁰ This book suggests that the HBP can be used as the starting point to establish and improve these other routine health sector systems, perhaps leapfrogging more developed countries that have done this process in reverse. (In the United States, for example, the introduction of DRGs for payment/claims/billing, followed by quality improvement processes, predates the establishment of essential minimum benefits by about 20 years).

This chapter will examine how some health systems have dealt with these challenges in practice: how to fit HBP benefits within available resources over time, how to make budget coding and allocation conventions consistent with HBP goals, and how to manage earmarked donor funding within HBP policies. Discussion of the role of payment systems is not included, given its ample coverage elsewhere.

Strategies to Address Challenges

The literature explicitly related to these topics is scarce and derivative of other subjects, so the material

presented draws heavily from the gray literature and expert interviews. In addition, literature searches were conducted using the *Red Criteria* virtual library, Cochrane and Campbell collaborations, EconLit, and others.

Challenge 1: Fitting HBP benefits to available resources over time

Fitting the HBP within the available resource envelope is a well-known accounting imperative for all healthcare payers and commissioners, especially for health insurers in the private sector. Revenues must necessarily equal expenditures for the enterprise to survive and, more important, to ensure that sufficient resources are available to provide the HBP services. The macro-strategies deployed are also common and intuitive (see table 1). The main difference with a HBP is the intention to shift away from ad hoc strategies to expand coverage, contain cost, or rationalize spending, toward a more systematic strategy of coverage expansion and inclusion or exclusion of benefits, per resource availability in every fiscal period, conducted in cooperation and consultation with fiscal and finance authorities.

While the key imperative is to ensure coherence between available funding and benefits, these same strategies also can be used to define and plan for future budget and resource mobilization needs. As Felicia Marie Knaul and others write: “by establishing the content and cost of the [Mexican] Seguro Popular benefits package, it was possible to make the resource requirements evident; this in turn helped to mobilize additional resources.”¹¹

This chapter is mainly concerned with understanding how HBP managers in different kinds of health systems detect and assure (or detect period-by-period) that the HBP is consistent with available resources.

A few health systems hardwire the imperative to fit benefits to available budgets into their legal

frameworks. Oregon’s Medicaid plan establishes the budget limit as the total size of the HBP, for example. Another interesting example is New Zealand’s PHARMAC, the organization charged with managing total medicines expenditure in the country’s health system. Its 2000 legislative mandate charges the agency with securing “for eligible people in need of pharmaceuticals the best health outcomes that are reasonably achievable and from *within the amount of funding provided*” (emphasis added).¹² PHARMAC is given a fixed budget for medicines, usually 7–8 percent of total public spending on health. It then prioritizes spending and negotiates prices based on that budget constraint, using its market power in the context of New Zealand’s universal coverage health system.¹³ Both systems have indeed “lived within their means” over time, but both are based in health systems where cost control is widely understood as a policy imperative. In LMICs, by contrast, the issue is more the coherence between available resources and benefits to ensure adequate financing of prioritized services, rather than cost control as a policy objective. However, the imperative to balance benefits with available resources remains. These kinds of analyses and adjustments can be used for multiple purposes beyond budget-benefit coherence, including planning, forecasting, premium calculation, and resource mobilization.

A first step therefore is to calculate HBP funding requirements and then to estimate the size of the resource mismatch, if one exists. In so doing, policy-makers are trying to figure out how much money is likely to be needed to provide a set of services for a given population in each geographic area or among the population group to be covered. Approaches differ across countries. In Chile, for example, micro-costing¹⁴ of the entire plan is done periodically within a regulatory framework, while in Colombia annual actuarial calculations are made to determine and adjust the premiums paid to insurers that will in turn pay healthcare providers to guarantee

TABLE 1. Macro-Strategies Commonly Used to Adjust Benefits to Available Resources

Strategy	Specific Strategies	Examples
Mobilize additional resources to expand coverage, equalize coverage across insurers, or cover shortfalls	<p>Identify new general revenue sources or reallocation opportunities across budget</p> <p>Increase insurance premium annually based on costs or inflation</p> <p>Establish reserve or stabilization mechanisms to expand coverage or cover shortfalls</p> <p>Advocacy</p>	<p>Mexico's Seguro Popular reform compares benefits plans between social security and ministry of health, calculates additional DALY associated with equalizing package, convinces president/finance ministry to fund the equalization^a</p> <p>Chile's AUGE enshrines alignment between the AUGE plan and available resources in legislation^b</p> <p>Estonia health insurance agency has a reserve fund intended to be used when revenues associated with premiums and contributions fall in order to meet the obligations of the service package^c</p> <p>Mexico Fondo de Prevision Presupuestal (Budget Forecasting Fund) to cover unforeseen expenses including budget shortfalls related to excess demand or state budget crunches^d</p>
Adjust benefits	<p>Health technology assessment (HTA) for inclusion/exclusion</p> <p>HTA for price negotiation of products</p> <p>Rollout of medicines policies (generics; reimbursement pricing based on comparative cost-effectiveness or therapeutic value; price regulation)</p>	<p>Thailand National Health Security Office universal health coverage package informed by HTA, used for price negotiation^e</p> <p>Brazil's CMED (Câmara de Regulação do Mercado de Medicamentos; Office of Pharmaceutical Market Regulation) sets prices to be used for the purchase of medicines, and adjusts these prices annually^f</p> <p>17 of 38 Organisation for Economic Co-operation and Development countries use HTA systematically to make coverage decisions or set reimbursement price^g</p> <p>Romania revises medicines list that is part of Basic Package of Health Services and Technologies to omit off-label, cost-ineffective, nonapproved uses^h</p>
Adopt cost-sharing strategies for lower-priority services or products; modify payment incentives	<p>Modifying reimbursement or payment policies</p> <p>User charges and co-pays</p>	<p>China plans to decrease reimbursement price for selected medicines and procedures to reduce incentives for nontherapeutic overutilizationⁱ</p> <p>The Dominican Republic includes financial caps for nonpreventive services in its benefits package (PDSS)^j</p> <p>Peru has established financial caps for most health conditions covered by PEAS^k</p>
Improve efficiency	<p>Use data on empirically observed production function of set of services to adjust HBP-related capitation or other payments over time</p> <p>Use contracting, payment or accountability strategies to create incentives for greater efficiency in the production of services (risk sharing, pay-for-performance, etc.)</p>	

Note to table: Discussion of the macro-strategy of restricting population eligibility for certain sets of benefits is omitted from this list with the understanding that the HBP is intended to serve the goals of UHC. However, many countries have in fact limited benefits to certain populations to "fit" benefits to the available budget. Further, efficiency improvements related to benefits included in the HBP are omitted, as those actions fall outside the scope of the benefits management activity.

a. Frenk and others (2006).

b. Bitrán (2013).

c. Lai and others (2013).

d. Giedion, Panopoulou, and Gómez-Fraga (2009).

e. Suchonwanich (2017).

f. Vianna (2013).

g. Aaraaen and others (2016).

h. Ruiz, Lopert, and Chalkidou (2012).

i. Zhao (2012).

j. Cañon and others (2014).

k. Prieto, Cid, and Montañez (2016).

the services in the HBP to the covered population.¹⁵ The results of these annual micro-costing exercises are fed directly into the budget negotiation process. Mexico's initial plan undertook two approaches: a bottom-up micro-costing using production functions for each intervention, and a top-down macro-costing based on the budget ceiling. The total financial envelope in which to conduct the micro-costing is given by the top-down macro-costing. However, the mechanism for adjusting on the micro side in response to the macro-envelope is not clear, at least from the perspective of the public, nor are any arrangements made for revisiting costing of the plan in subsequent years.¹⁶ (Chapter 8 on costing in the methods section provides more detail on how different countries handle these choices.)

Routine adjustments for changes in costs and purchasing power are also essential to prevent erosion of the HBP's value and utility. Some countries have established legal regulations requiring adjustment according to inflation or medical cost indices (see table 2). Regular adjustment, and ideally projections into the future, are also required to reflect current and anticipated changes in the demographic

composition or population aging that will affect HBP service and product utilization; this is done routinely in high-income countries but almost never considered in LMICs, perhaps because LMIC information systems are generally inadequate in their current incarnations to carry out these tasks.¹⁷

An equally important issue is to understand and reflect the budget impact of new technology introductions or disinvestment choices within the capitation or premium attached to a HBP, on an ongoing basis. The purpose of a budget impact analysis (BIA) is "to predict how a change in the mix of drugs and other therapies used to treat a particular health condition will impact the trajectory of spending on that condition."¹⁸ A BIA is complementary to a cost-effectiveness analysis (CEA), covered in part II; it is not a substitute. Whereas a CEA evaluates the costs and outcomes of alternative technologies over a specified time horizon to estimate their economic efficiency, a BIA addresses the financial consequences related to the adoption and diffusion of technologies to assess their affordability. In European countries and Canada, a BIA is commonly submitted alongside a CEA to support national or local formulary approval or reimbursement;

TABLE 2. Approaches to Adjusting Capitated Benefits Plans for Changes in Prices and Utilization

Country	Approach	Frequency	Issues
Israel ^a	Health cost index intended to adjust for changes in prices of inputs, composed of other indices (consumer price index [CPI], average wage of healthcare providers, average wage of public servants), published methodology and evaluation	Annual	Did not reflect changes in hospital costs (such as per diem rate) when inpatient care represented 40% of all spending
Mexico	Financial and actuarial valuation of CAUSES and high-cost interventions packages (FPGC), established by law	Annual	No published methodology, no published evaluations
Uruguay ^b	Formula that reflects price changes in inputs using CPI, exchange rates and wages	Biannual	Changes in actual utilization and expenses not fed into formula, no published methodology, no published evaluations

a. Rosen, Waitzberg, and Merkur (2015).

b. Giedion, Bitrán, and Tristao (2014); and World Bank (2012).

country-specific guidelines are available.¹⁹ The International Society for Pharmacoeconomics and Outcomes Research has also developed guidelines for overall study design, decisionmaker perspectives, scenarios to be compared, populations to be considered, time horizons to be used, costing methodologies, the need for sensitivity analyses and quantification of uncertainties, use of discounting, empirical validation, and standard reporting principles;²⁰ some of these issues are also covered in the chapters on CEA and methods in part II.

Private or not-for-profit health insurers represent an important but not well documented source of experiences and approaches to the calculation and adjustment of cost-efficient premiums (or capitations on the public side), particularly when both public and private providers will be reimbursed for care. For example, the PharmAccess Foundation, a Dutch not-for-profit financing subsidized health insurance in five sub-Saharan African countries, has briefly described lessons learned in the calculation of premiums for an insurance scheme that reimburses both public and private providers for services given to enrollees.²¹ This work notes the importance of accurately reflecting the full set of costs in a premium to ensure sustainability; in Tanzania, for example, government providers' fixed costs were covered by government while the external insurer was only liable for variable costs. That same external insurer was responsible for full costs when reimbursing private providers, thereby requiring the size of the premium to be adjusted depending on the amount of utilization in each sector. As noted earlier, using what data exists to estimate a premium is important, but creating ongoing systems to enhance accuracy of data on costs, utilization, and household size are needed to ensure sustainability of any insurance or coverage scheme over time.

A challenge arises when the resource envelope for the HBP shrinks over time. In this respect, there is much to learn from European government policies

following the 2007–9 global economic crisis.²² Much effort was made to increase or reallocate resources for health, but given that cuts had to be made despite these efforts, the benefits subsidized and prices paid by end users had to be adjusted. Several countries were obliged to completely overhaul their respective HBPs (Greece, Portugal) or to establish minimum benefits (Cyprus, Spain). Other countries applied cost-effectiveness criteria to existing or new medications before their adoption to limit spending growth; these were countries that had planned to adopt such measures before the crisis began, pointing to the importance of setting up mechanisms ahead of time. Ad hoc measures were also taken and have had adverse effects on population health; Romania and Bulgaria, for example, limited primary care visits or restricted population coverage of some key interventions. Disinvesting from drugs was “easiest,” but adjusting medications alone may not be best from a patient care standpoint.²³ A worse strategy for coping with budget reductions is to simply ignore that cuts are happening and assume that those in charge of healthcare provision will somehow adapt. As the HBP's “purchasing power” erodes, implicit rationing in the form of waiting times, informal payments, or other barriers will increase. Yet the reduction of implicit rationing is one of the key motivations behind adopting a HBP in the first place. This is, alas, a path often chosen by LMICs undergoing fiscal pressures.

Challenge 2: Making budget coding and allocation conventions consistent with HBP goals

HBPs as a budgetary construct differ enormously from status quo approaches in most LMICs. Many LMIC systems continue to rely on historical, input-based budgets, with generic budget codes for salaries, medicines, and equipment. Other systems—particularly those that have split the payment function from provision, such as Peru's subsidized coverage scheme

(Seguro Integral de Salud; SIS)—have deployed fee-for-service or per diem payments with coding by type of service. For example, Brazil, China, and Iran have introduced budget coding and payment reform to hospitals using the DRG approach.²⁴ Still other systems, usually in highly decentralized or federal countries like India or Nigeria, merely divide up revenues among states or provinces and transfer this amount as a lump sum, frequently without any specified use. In other federal countries, like South Africa, provincial health budgets are coded by type of healthcare facility.²⁵ Some countries are experimenting with “output-based budgets” in the health sector, where some of the budget is reserved for release against progress on health coverage or outcomes.²⁶ Sometimes countries have line items for priority interventions like vaccination or family planning, but everything else remains input-based. Frequently, all of these budgetary conventions co-exist within a single health system.

The HBP, in theory, should direct most (though not necessarily all) resources to providing those priority services that have been identified as contributing most to UHC objectives.²⁷ But for the HBP prioritization to be realized in practice, budgets must be coded and allocated in a way that links the budget to the tracking and provision of the interventions or products included in the plan. It will be evident that—except for the fee-for-service payment, case payment (like DRG), or output-based budget examples provided above—many existing budgeting and allocation conventions have very different rationales and will not be effective in providing a standard level of service or entitlements as described by the HBP. For example, a capitated transfer from federal to state level based on a share of revenues in each fiscal year may have no relationship to the costs of providing a standard set of services, even if the amount is risk-adjusted (at the family, group, or plan level, as is commonly done by actuaries using occupational and demographic averages) for some measure of need such as poverty or age composition. This may

seem a self-evident point, but it is a ubiquitous challenge; countries as diverse as Spain and the United States define some essential health benefits (in Spain known as the “common basic package”) but either do not know or do not use the baseline costs in each state for providing the package, or do not equalize financial resources available to each state, leading to inequities and care variation in service provision, quality, and outcomes. (That said, inequities may well be considered legitimate in a federal system so long as the nationally mandated HBP is respected in every jurisdiction.) Thus, the main issue is to ensure that the budget accurately reflects expected local expenditure requirements associated with the HBP. Once the standard set of services is defined in the HBP, that definition implies a certain level of expected expenditure for a given population or locality that depends on specific demographic, social and economic characteristics, as well as the assumption of a given level of productive efficiency in health services. That level of expenditure is defined by the probability of use of the services included in the HBP and the intensity of that use (see chapter 8).

In these circumstances, the goal is then to allocate funds among riskholding entities—whatever the health system pooling and payment arrangements—to allow each entity to deliver the standard level of service embodied in the HBP. (Since localities may differ in terms of their baseline access to revenues, local jurisdictions may be allowed freedom to vary some elements of the package of services; however, if such a choice is made, the entire burden of any extra expenditure falls on the locality.) To get this done, there are two main reforms to consider.

First, budget coding reforms may be required ahead of both HBP and payment reform. For example, DRGs are part of a classification system that groups patients according to principal diagnosis, type of treatment, age, surgery, and discharge status, and this system is used to bill payers and reimburse hospitals in most developed countries, such as Australia,

Germany, and the United States.²⁸ Although DRGs generally are described as a payment or quality measurement system, they are also a way to structure and code budgets and billing, and some variant of DRG and its equivalent for primary care is needed to effectively plan for, implement, and monitor a HBP. Medicines budgets are generally easy to incorporate into a HBP because they are already organized by product; however, products will need to be linked to indications, clinical guidelines, or DRGs in order to track their appropriate use, quality of care, health outcomes, and related considerations. The budget coding example of Chile's AUGE, based on clinical guidelines with associated products and procedures, is a useful reference.²⁹

Second, reform of allocation conventions may be needed to ensure expenditure adequacy for HBP provision: minimizing budgetary risk, preventing risk selection, and maximizing equity across different covered populations.³⁰ Budgetary risk is the likelihood that actual expenditure varies from predicted expenditure; this risk arises from weaknesses in the underlying costing, demand/utilization, and disease data based on which the HBP has been costed, as well as clinical practice variations among different providers and random variation among the covered population. With regard to the HBP, the budget riskholder will be the entity that will financially manage and absorb the results of any higher or lower utilization, or disease incidence or prevalence, than those anticipated during calculation of the HBP capitation.³¹ Different health systems place the allocation function and management of budgetary risk within different kinds of institutional settings; some send funding to subnational governments, others to insurers, still others to commissioning agencies of different kinds, and still others pay provider groups directly (see table 3).

The extent of the budget risk faced by riskholders therefore depends on the size of the budget holder (all other things equal, covering large populations

reduces risk), the quality of the underlying costing of the HBP and its year-to-year adjustments (discussed in previous sections), and the formula used to adjust the HBP capitation based on the characteristics of the covered population or locality (generally known as "risk adjustment" in the literature; see the fourth column of table 3).

Most capitation payment adjustments based on formulae are generated from historical data that serve as an input to regression analyses, generating a predicted level of expenditure for people with a given set of characteristics. The same model can then be used to adjust actual capitation for the next year. There are several challenges to this approach (as discussed in Smith (2008)), including the difficulty of accommodating unmet need, since using empirical spending patterns to infer needs will perpetuate inequity; the possibility that a characteristic may empirically influence expenditure but also create a perverse incentive to do more of something undesirable (for instance, low-vaccination-rate localities receive more money, thereby creating a perverse incentive to keep vaccination low); and the difficulty of choosing indicators that accurately reflect needs. Smith (2008) also draws attention to the difficulty of distinguishing between "legitimate" drivers of budget risk (baseline poverty or age structure, for example) and "illegitimate" drivers of budget risk that are related to the policy or management actions of the budget riskholder (baseline obesity or smoking levels, for example). Ideally, formulas should adjust for legitimate but not illegitimate drivers of budget risk. In LMICs with HBP policies, risk adjustment is generally still at its most basic, focused on age, sex, and sometimes poverty or number of welfare recipients. However, the need to obtain greater predictive power for future healthcare expenditure may drive countries to more accurate methods; in Colombia, for example, there is increasing interest in better risk adjustment.³²

Different allocation and related risk-adjustment methods can generate stronger or weaker incentives

TABLE 3. Budget Riskholding and HBP Allocation Practice in Different Health Systems

Example Countries	Allocating Entity	Budget Riskholding Entity	Allocation Approach
Mexico (Seguro Popular)	Ministry of Finance	State governments	Formula-based capitation based on macro-costing with risk adjustment according to state population and age structure, transferred as a global budget at start of fiscal year
Colombia, Israel, Netherlands	Ministry of Health	Public or private insurers	Formula-based capitation based on average micro-costs with risk adjustment according to selected characteristics of the insured population, with a portion transferred prospectively and a portion transferred retrospectively
Chile, Estonia, Thailand, Mexico (Instituto Mexicano del Seguro Social)	Government general revenues, earmarked taxes	National government or single public or social security payer agency	Global budget based notionally but not explicitly on annual costing studies differentiated by region
Medicare (United States)	Government general revenues including earmarked taxes	Federal public payer agency (Center for Medicare and Medicaid Services)	Global budgets divided by type of care: inpatient hospital (Hospital Insurance trust fund); physician and outpatient hospital (Supplemental Medical Insurance trust fund); prescription drugs (Part D), transferred based on case payment rates with benefits determined in legislation
Germany ^a		Sickness funds (quasi-public insurers)	Formula-based capitation based on average predicted expenditure of standard benefit package with risk adjustment according to age/gender and the existence of 80 morbidities (Morbi-RSA) ^b among the covered population
U.S. non-Medicaid/Medicare	Individuals, households	Private insurers	Risk-rated actuarially calculated individual premiums, sometimes regulated, transferred in lump sum

a. Buchner, Goepffarth, and Wasem (2013).

b. Based on the Hierarchical Condition Categories model introduced into U.S. Medicare in 2004.

for effective delivery of HBP services. Budget riskholders that receive HBP-based capitations packaged as a global budget will have clear incentives for expenditure control but little incentive to produce more, reduce care variations, or enhance quality; in

Mexico, for example, states had an incentive to enroll additional people to increase the number of capitations received via the global budget, but there was no explicit supply-side incentive to increase productivity, efficiency, or effectiveness, or even to produce

the services included in the HBP. Other instruments, such as performance measurement/benchmarking or efficiency audits, can be used to create these incentives, and performance-based payments might usefully accompany block transfers.³³ These issues will be relevant only in systems where allocation is separate from payment. Where single budget riskholders are also payer agencies, this is a single exercise better addressed through payment strategies.

Some health systems also have reinsurance mechanisms to cover unexpectedly large numbers of cases or particularly high-cost individuals. Such high-cost funds are increasingly common; many Latin American countries, for instance, have created funds whose criteria for selecting benefits depends on their cost, including Chile's Ricarte Soto fund (covering 11 high-cost diseases), Peru's FISSAL and the Plan Esperanza (covering cancer care), Mexico's catastrophic care fund, or the Dominican Republic's SIAP high-cost drug program. However, attention should be paid to ensuring that this kind of mechanism does not create perverse incentives by covering additional and different interventions to those specified in the HBP, or by generating incentives for overproduction or excess demand (beyond medical need) of certain high-cost products and services within the HBP.³⁴ Instead, the reinsurance mechanism should narrowly address the "legitimate" budget risk once it exceeds a certain dollar amount.

A related issue is how HBP allocation will interact with other existing allocation methods. Some funders will cover only a portion of the costs associated with the HBP and will pay the remainder of costs through other methods; in Peru, for example, salaries are funded through lump-sum transfers to provinces, variable costs associated with primary care benefits are paid via capitation, and hospital care is paid on a case payment approach.³⁵ Pure case payment can inhibit access for some high-need service users, but could be augmented by cost-sharing between payer

and locality above some cost threshold (preferably in lieu of separate "high-cost" packages or funds).³⁶

Challenge 4: Managing earmarked donor funds in the context of HBP policies

Donor funding for health is a diminishing share of total spending on health in most LMICs.³⁷ Yet in many of the lowest-income countries, donor funding still represents a large share of total spending on the highest-priority public health programs. For example, external funding for HIV/AIDS ranged from a low of 40 percent of total HIV/AIDS spending in Mozambique to a high of 80 percent in Rwanda and Tanzania.³⁸ In Ethiopia, prevention and public health is 92 percent financed by donor spending.³⁹ Similar dynamics are observed in malaria, family planning, and vaccination programs. Because these programs are majority-funded through external sources, many countries opt not to include these expenditure items in their HBPs. For example, a recent discussion paper by Marie Stopes International found that: "seven of ten [insurance schemes in] countries surveyed had opted to keep contraception out of the reimbursable package . . . insurance schemes in development in another seven countries surveyed had no explicit plans to reshape how contraception was financed due to its early exclusion from the insurance package."⁴⁰

The reasons why UHC schemes keep these cost-effective priorities outside a HBP are straightforward. First, only a small share of aid (2–5 percent, depending on the year) is channeled through the budgets of developing country governments,⁴¹ and HBPs tend to grow out of domestic spending for health. While multiple efforts have been made to move donors toward greater pooling and use of government channels,⁴² not much progress has happened in practice. Second, donor funds are earmarked to specific uses in health⁴³ and include accounting and tracking requirements that are not the same as recipient government accounting and tracking requirements.⁴⁴

Finally, policymakers may perceive that it is sometimes easier to “let the donors have their way” and simply fund “the rest” through the country’s HBP.⁴⁵ In Uganda, for example, donors not participating in pooled funds (known as sector-wide approaches, or SWAPs) decide and fund specific interventions outside the government HBP in what is described as “a concurrent priority-setting process.”⁴⁶

However, as countries grow economically and their own domestic funding dominates funding for health, the negative implications of leaving cost-effective benefits out of domestically funded HBP can be large, leading to neglect and underfunding. Even setting aside the unlikely prospect of greater donor pooling and budget support that could be used to fund the HBP, there are few examples of good practice to cite. Rwanda—where more than half of total spending on health comes from external funders⁴⁷—had historical success establishing a package of care and then channeling donor monies through a combination of cofinanced premiums and performance-based financing, both associated with package interventions.⁴⁸ Ethiopia’s “One Plan, One Budget and One Report” helped create the conditions to pool funding for the financing and provision of a primary healthcare package.⁴⁹ In more developed countries that were historically reliant on external donors, the experience is mixed. Mexico’s well-known diagonal approach⁵⁰ basically packaged the relevant vertical programs together and began to pay states and providers based on the package. In the less encouraging examples of Colombia and Peru, donor funding receded alongside vertical programs, resulting in a lost decade of child health programs until reforms initiated new package-based payment and accountability systems targeted to worst-off areas.⁵¹ Although more systematic study of country experiences is needed, lessons to date suggest that donor-dependent countries scaling down aid funding for vertical programs should pay early attention to ensure that these programs are included in HBPs and

payment mechanisms. With a well-designed HBP policy and process, low-income governments may even be able to use the HBP to coordinate donors’ efforts and contributions.

Conclusion

This chapter has laid out four main fiscal and budgetary challenges facing HBP policies, and three sets of strategies to address these challenges.

As in the introductory chapter, a central recommendation is to ensure alignment between HBP contents and costs and available funding across current and future budget cycles, from budgeting through allocation through transfers and payments, spending tracking, reporting, and accountability. At each step of this cycle, different agencies need to be engaged and to act coherently with one another, including the ministry of finance, the ministry of health, national-subnational payers, providers, and insurers (if applicable); for coherent and active engagement, each agency’s roles and responsibilities must be set out over time and dedicated staffing and budget must be provided.

Donor funding is a particular challenge in low-income countries considering HBP in the context of UHC; many countries may be omitting cost-effective, donor-financed interventions already. Both recipient governments and donors themselves must pay early attention to wrapping relevant vertical programs into HBP policies, perhaps employing the strategies of some of the more successful health system efforts in Ethiopia, Mexico, and Rwanda.

In general, the intersection of fiscal policy, budgetary practices, and HBP policy is poorly understood and studied, and much more of a practical art than a science. More work is required to fully understand the issues and provide fuller guidance to health systems undertaking HBP reforms.

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27. A study of seven Latin American countries' HBP found that the amount of public expenditure channeled through the HBP varied from less than 2 percent in Honduras to more than 70 percent in Colombia. See Giedion, Bitrán, and Tristao (2014). The rationale for maintaining a portion of spending outside the HBP framework varies—public goods such as vector spraying are not included, or salaries are managed separately, or contingency funds are set aside, or political pressures may play a role as the result of special pleading (see chapter 12 on political economy).
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29. Giedion, Bitrán, and Tristao (2014).
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32. Riascos Villegas, Quantil, and Romero (2013).
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POLICYMAKER COMMENTARY

Aspiring to National Health Insurance, South Africa Considers Its Health Service Benefits

Mark Blecher
Yogan Pillay

At a glance: In South Africa, policymakers take their first, cautious steps toward guidelines-based health service benefits for national health insurance.

When South Africa first endeavored to develop its National Health Insurance (NHI) system, the Department of Health and the National Treasury struggled to find common ground on an approach to defining the health benefits package. The National Treasury believed that leaving the benefits largely undefined would lead to low-value but high-cost interventions being included in the package; the overall system thus would be difficult to cost actuarially and could become very expensive. Certain categories of services, such as maternal and child health or oncology, would be too broad to answer specific questions about coverage of expensive interventions, such as medication options like trastuzumab for breast cancer treatment or sofosbuvir for hepatitis C. In contrast, the Department of Health initially believed that benefits should be comprehensive

and based on the services currently provided by the public health sector. The Department of Health was firmly opposed to inclusive (positive) lists, arguing that it would be near-impossible to include all conditions and treatments that citizens might require, and that anything excluded might be needed but denied. Even negative lists were seen as unacceptable beyond the most basic limitations, such as cosmetic surgery and designer (vs. standard) eyeglass frames. Prioritization of benefits was seen as an attempt to introduce exclusions and inclusive lists through the back door. Even the term “benefits package” was discouraged, as it implied a defined list of benefits.

In part, these negative perceptions were the historical legacy of South Africa’s previous experience with a package of prescribed minimum benefits for medical schemes (provided by private health

insurance). For various reasons, public-sector decisionmakers perceived such packages as limited, exclusionary, and difficult to understand from a patient perspective; for instance, they excluded primary care. In contrast, the public sector was seen as offering a wide range of benefits, albeit according to level of care and with varying quality of care; some argued it would be unconstitutional to remove benefits already available through the public sector. Even opponents, however, recognized that benefits could be tiered by level of care.

By the time the initial White Paper on National Health Insurance was published in 2015, policymakers had made some limited progress toward accepting the principle that services to be subsidized with public monies should be assessed on the basis of cost-effectiveness, efficacy and health technology assessment (HTA). As the White Paper stated:

130. The NHI Benefits Advisory Committee will develop the service entitlements for all levels of care (primary, secondary, tertiary and quaternary). The range of services will be regularly reviewed using the best available evidence on cost-effectiveness, efficacy and health technology assessments. The service entitlements will be specified in terms of the type of services that will be delivered by different kinds of accredited and contracted providers.¹

Although these principles were useful, questions remained about how this would be achieved and what the NHI benefits would be. The minister of health thus established a work stream on benefits; after several meetings, some progress was made:

- It was recognized that the public sector, at baseline, already had an essential medicines list, diagnostic and treatment protocols for many conditions, and a set of standard treatment

guidelines. However, some of these protocols and guidelines were nonstandardized or incomplete, and various different protocols had been issued by different bodies, including national vertical programs, for a single intervention. Understanding these differences helped to build buy-in for a more standardized national approach.

- It was recognized that the public sector already had some processes for deciding whether or not to introduce a new medicine, and that all new medicines and medical equipment were not necessarily adopted. These processes were not standardized or consistent, but they did tend to involve considerations of affordability and effectiveness; it was recognized that these processes could be standardized and otherwise improved. International HTA agencies such as Thailand's Health Intervention and Technology Assessment Program (HITAP) and the United Kingdom's National Institute for Health and Care Excellence (NICE) were seen as providing some positive lessons in building HTA systems and capacity. Discussions about where such capacity should be established in South Africa are ongoing.
- It was recognized that some forms of improved national decision analysis, economic evaluation, and priority setting would be worthwhile.

On the basis of the above points, it was decided:

- To begin to build an "encyclopaedia" of existing "benefits" by level of care, building on existing locally accepted diagnostic and treatment protocols, standard treatment guidelines, and essential drug lists. In time, this approach would require some standardization in cases of multiple protocols for the same disease or illness, a clearer process of formal approvals, greater

formalization of the committee, and an appropriate institutional location for this function.

- To cost as many of the existing “benefits” as possible. This process has already begun.
- To support the development of HTA capacity as a more standardized mechanism to assess new benefits (and reassess old ones where necessary).

The road toward a full and formal health benefits package is still long, and greater attention needs to be placed on where the formal institutional capacity for such decision analysis and recommendations will be located and how to set up this capacity. Rather than a single decision on whether a benefit is “in” or “out,” a more complex protocol-based approach may be taken to outline at what level of care, and under which circumstances, a given intervention would or would not be appropriate. The forms of reimbursement to be

used in the NHI system are also likely to inform the detail with which benefits are specified. For example, diagnosis-related groups for hospital reimbursement are likely to require a more detailed system of diagnostic and procedural classification and information collection than capitation for primary care.

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Credit: Asian Development Bank

PART II

PUTTING PEN TO PAPER

Methods to Select a Health Benefits Package That Works

Introduction

Peter Smith

In the first chapter of this book, Amanda Glassman, Ursula Giedion, and Peter Smith explain the powerful reasons for setting a health benefits package (HBP) as a key foundation for moving toward universal health coverage. A key question then arises: how is this to be done? It is important to distinguish between explicitness in stating the contents of the benefits package and consistency and rigor in selecting the contents. A package may be made explicit, but the process for selecting the contents may be opaque and inconsistent. Some of the virtues of setting an explicit package are evident regardless of the selection process. However, most packages can have full effect only if their components are selected by consistently applying an explicit set of criteria. HBP design choices have proved to be a fertile ground for the development of decisionmaking methodologies, as the contributors

to this part of the book will show. The chapters that follow describe methodologies that have been developed to help set up HBPs based on a comprehensive and consistent assessment of the available evidence.

Various forms of cost-effectiveness analysis (CEA) lie at the center of most HBP methodology, although CEA is by no means the only possible approach. The principle of CEA is that (subject to a number of important assumptions) healthcare interventions can be ranked on the basis of their incremental costs relative to their incremental benefits. Benefits are usually measured in terms of expected health gain, although alternative formulations can be envisaged. This approach leads to a policy prescription of including treatments in the HBP in order of decreasing cost-effectiveness until the available budget is exhausted. An equivalent formulation is

to accept for inclusion only interventions that lie below some cost-effectiveness threshold, the value of which depends on the size of the budget available. The CEA principle seeks to maximize “value” (usually expressed in the form of expected health gain) secured by the available budget. A “marginal” treatment, one that is only just included in the package, determines the system’s cost-effectiveness threshold.¹

This simple theory has proved robust to methodological challenge, and forms the basis of a great deal of health technology assessment undertaken around the world. Although there are alternative formulations, the standard approach to a HBP seeks to maximize the social value secured from the limited budget available. The CEA threshold offers a consistent benchmark for assessing the competing claims of patients when the health system has a limited budget, and applies a widely accepted principle of fairness—that those who can benefit the most from health service spending should have priority.

Furthermore, the use of a threshold obviates the need to consider simultaneously all treatments that may be included in the HBP. In practice, HBP decisions proceed incrementally in most health systems. The set of existing services is often accepted as a starting point and is not formally assessed or challenged at first. A small number of potential new candidates for inclusion are then assessed as evidence and analytic capacity permit. (Less frequently, candidates for exclusion may be assessed.) The natural benchmark for deciding whether to accept a new treatment is the system-wide cost-effectiveness threshold. Of course the level at which the threshold should be set is often a matter for conjecture and may be subject to trial and error, although international evidence of the likely threshold ranges for countries at different income levels is beginning to emerge.² Thus the widespread pragmatic approach of developing the HBP by sequentially subjecting a limited number of treatments to the cost-effectiveness test is not necessarily inconsistent with the CEA philosophy.

Mark Sculpher and colleagues set out the current state of CEA development in chapter 4. They show that the theory derives from a concept of maximizing an objective (usually health improvement) subject to a budget constraint. This has given rise to the widely used concept of the incremental cost-effectiveness ratio (ICER) as the principal metric of whether an intervention is likely to be included in the HBP. Treatments in vastly different therapeutic areas can then be compared in a common analytic framework. The principles of constrained optimization remain valid even when the scope of the objectives broadens or the range of constraints increases. However, under such circumstances it may be necessary to sacrifice the simplicity of the ranking of ICERs.

The inevitable uncertainty involved in all cost-effectiveness estimates has led to widespread use of sensitivity analyses, both formal and informal, to inform coverage decisions. Furthermore, CEA practitioners have stressed the need for CEA evidence to be embedded within a broader deliberative process that enables legitimate decisionmakers to consider factors that could not be included in the analysis, and to account for the inevitable uncertainty of the models and evidence used. Increasing attention is being paid to innovative approaches to setting the HBP, including provisional acceptance of treatments contingent on factors such as the health outcomes they actually yield in practice.

From humble beginnings, the methods of CEA have developed into a powerful suite of analytic tools. Although most CEA studies conform to the principles set out by Sculpher and colleagues, the literature now contains a wide range of approaches to implementing CEA, which often makes it difficult to assess research on a consistent basis. Consequently, calls for improved standardization have led to the development of an International Reference Case that sets out best-practice principles for CEA studies, and the Disease Control Priorities Project has sought to summarize the best available CEA

evidence across all therapeutic areas, with a particular emphasis on the needs of low- and middle-income countries (LMICs). Although numerous practical and methodological challenges have yet to be resolved, CEA has become firmly entrenched as the most widely accepted principle on which to base a HBP selection process.^{3,4}

A fundamental concern with CEA as conventionally implemented is that it assumes that the sole objective of the HBP is to maximize health improvement. This assumption undoubtedly reflects a central mission of all health systems, but it does not consider other important objectives. In particular, the drive toward universal health coverage underlines the importance of protecting individuals from the financial consequences of ill-health. Specifically, user fees for health services could have two types of adverse effects: patients may be deterred from using needed services, or they may secure access but at the cost of impoverishing themselves or their families. An associated issue is the extent to which CEA should place a higher weight on gains for disadvantaged groups compared to those for the general population. In its simple form, CEA makes no distinction between health gains for rich or poor, old or young, or healthy or sick people. Yet there are powerful arguments for placing a higher weight on gains for more disadvantaged groups. Such equity weighting is in principle straightforward, but in practice it places very high demands on data availability for different population groups and requires policymakers to make judgments about how much more to value the gains for disadvantaged groups.

In light of these additional considerations, extended cost-effectiveness analysis (ECEA) has been developed as a methodological extension of the CEA model. Through ECEA, financial protection and equity can be formally integrated into conventional CEA methods. Stéphane Verguet and Dean Jamison (chapter 5) set out the principles of ECEA, emphasizing that it represents a supplement to rather

than an alternative to conventional CEA. They also show how ECEA has been applied in the Ethiopian context. The approach yields a wealth of evidence to supplement the stark simplicity of the usual cost-effectiveness ratio, yet it is agnostic about how the relative importance of the different objectives should be quantified. The authors present the disaggregated results of the analysis, but leave priority judgments to policymakers. The case study also underlines the constraints to extending conventional CEA imposed by data limitations.

The ECEA model illustrates that the need for additional information and policy judgments quickly expands when seeking to relax any of the simplifying assumptions made in conventional CEA. This has led to the development of a range of alternative formulations of the HBP decision problem that seek to reduce the demands on the decisionmaking machinery. These alternative options do not always exhibit the internal consistency and intellectual coherence offered by CEA, but they can provide hard-pressed decisionmakers with pragmatic solutions to what otherwise would be infeasibly complex problems. In short, because analytic resources are often limited, analysts may need to sacrifice some accuracy and comprehensiveness in how they formulate the problem in order to come up with timely and practical recommendations.

An example of less-formal approaches toward priority-setting (not explored further in this book) is the collection of approaches known as program budgeting and marginal analysis. Program budgeting and marginal analysis emphasizes stakeholder engagement and problem formulation rather than rigorous and comprehensive analysis. However, in most applications the principles followed are consistent with the sort of incremental CEA described above. Other examples include various approaches to multicriteria decision analysis (MCDA) that seek to integrate the objectives placed on the HBP within a coherent decision-analytic framework. MCDA usually requires

decisionmakers and other stakeholders to assess the values placed on the different objectives.

In chapter 6, Alec Morton and Jeremy Lauer summarize the state of knowledge on incorporating social values other than health into the HBP, underlining the need to base choices on explicit social values. As highlighted by ECEA, the challenges include selecting the dimensions of performance, measuring attainment, and combining the decisions into a single index. There also are fundamental questions about who to involve in such choices and how to elicit their values. Morton and Lauer argue that, whatever those choices, the associated methods should be technically robust and easy to understand, and should have low implementation costs. The principles of choosing, measuring, and weighting the various social dimensions are illustrated in the context of MCDA. In contrast to ECEA, this approach attaches social valuations to the criteria—a major undertaking, given the range of potential stakeholders and the heterogeneity of preferences.

Even if multiple objectives can be incorporated into the assessment of candidates for inclusion in the HBP, there will always be some interventions that cannot readily be included in any systematic comparison. In chapter 7, Rachel Silverman considers three important examples in this class: contraceptive services, palliative care, and reconstructive/aesthetic services. The common feature of such services is that even though each offers some benefits that can be captured by routine outcome measures, their main benefits lie outside the usual concept of health-related quality of life. Any conventional cost-effectiveness measure is likely to seriously understate their level of priority, and it is therefore vitally important that HBP process for assessing evidence is able to take account of such special cases. Silverman argues that transparent and participatory decisionmaking processes can help ensure that decisions on such services are acceptable to the population and appropriate to local context.

Information on the costs of delivering health services is fundamental to all forms of CEA. More generally, good costing information is an essential part of the evidence base needed to make HBP inclusion decisions, strategically purchase the covered services, and inform policies to promote efficient service delivery and utilization of cost-effective services. As Cheryl Cashin and Annette Özalın explain in chapter 8, costs inform three fundamental decisions related to HBP policy:

1. Estimates of the total expenditure required to align the HBP with available resources (namely, how generous a package can be, given a country's financial capacity)
2. Estimates of the costs of individual services in order to make decisions about inclusion in HBPs at the margin (specifically, what are the cost implications of adding individual services or medicines)
3. Estimates of individual health services or sets of services in order to set or negotiate provider payment systems and rates.

However, costing methodology is in general not very well developed or standardized, and wide variations exist in both the quality and availability of costing information. This weakness is especially troubling because cost structures can be highly dependent on resource availability and constraints in particular settings, and cost estimates therefore may not always be readily transferrable from country to country. Cashin and Özalın outline the current state of methodological advances and assess the priorities for future development, including improved standardization of methods and increased use of modeling and simulation.

Notwithstanding its widespread use, the recommendations arising from CEA often are not implemented as intended. A fundamental reason is that

conventional CEA assumes a single constraint, in the form of the budget constraint. In practice, decisionmakers may face other constraints, either real or illusory. In chapter 9, Katharina Hauck, Ranjeeta Thomas, and Peter Smith develop a typology of constraints that can act as barriers to implementing cost-effectiveness recommendations. They consider six categories of constraints: (1) the design of the health system, (2) the costs of implementing change, (3) system interactions between interventions, (4) uncertainty in cost and benefit estimates, (5) weak governance, and (6) political constraints. Where possible, the authors discuss ways in which decisionmakers who wish to pursue cost-effectiveness principles can take each type of constraint into account.

In principle, many of the constraints described in chapter 9 can be addressed using mathematical modeling techniques. In chapter 10, Marelize Gorgens and colleagues describe some recent advances in combining epidemiological and economic approaches to offer more realistic models of how policy objectives might be optimized. In contrast to conventional CEA, these models can embrace multiple objectives, accommodate economies of scale and scope in service delivery, map the dynamic progression of disease and service delivery over time, and recognize some of the nonlinearities in costs and benefits as interventions are scaled up (or scaled back). Although such optimization approaches are clearly feasible, the methods are at an early stage of development and their data and analytic capacity requirements can be demanding. Nevertheless, these approaches offer enormous potential for generalizing the principles of systematic and transparent optimization of the HBP.

Scientific evidence lies at the heart of methodical approaches to setting the HBP. The objectives of CEA and other systematic approaches can be fatally undermined if evidence is absent, ignored, used selectively, or otherwise distorted when assessing the relative merits of alternative candidates for inclusion in the HBP. Yet it is rarely feasible to undertake primary

data collection for the HBP. Instead, analysts must seek out existing evidence from a wide variety of sources to inform the priority-setting process. In principle, decisionmakers need to be sure that all relevant evidence for the HBP has been assessed and used appropriately.

As the volume of scientific evidence grows, data search and aggregation methods such as systematic reviews and meta-analysis are assuming increasing importance. An important question, especially in LMICs, is the extent to which it may be valid to compromise on the quality of the data, as reflected in factors such as their age, their institutional setting, or the scientific rigor with which they have been collected. What counts as “relevant” evidence is furthermore often a matter for debate, depending on factors such as geography, social and economic development, and the nature of the health system. Only recently have researchers started to apply scientific methods when assessing the selection and quality of the available evidence base.

In chapter 11, Neil Hawkins, Robert Heggie, and Olivia Wu describe the emerging science of evidence assessment and selection, stressing the balance that needs to be struck between the principled need for robust quality standards for evidence and the practical need to make decisions quickly with limited data and analytic capacity. They underline the distinction between internal validity (does the study answer the questions it set itself?) and external validity (does the study answer the real-world problem under consideration?), and argue that the selection of the HBP should be based on all available and relevant evidence. This of course opens up questions of how to assess relevance and how to weight evidence with imperfect relevance (for example, from different social, geographical, institutional or economic settings, or from dated studies).

However it is chosen, relevant evidence must then be synthesized into a single model of cost-effectiveness, which in a sense seeks as best it can to emulate the

“ideal” clinical and economic trial of the intervention that would be implemented in the country if research resources were infinite. In this context, modeling might include an assessment of all relevant future health and cost implications of the intervention in the health system under scrutiny, including the impact in different population subgroups. Uncertainty analysis should then reflect the imperfections in the evidence, including both the likely bias and the precision of estimates. The results of such modeling can also inform priorities for seeking out new evidence by identifying data gaps to which intervention inclusion and exclusion choices are especially sensitive.

This section is not meant to be a tutorial in the CEA methods and their extensions; several excellent texts are available to provide this information.⁵ Rather, the chapters that follow show how systematic, intellectually coherent analysis can support health systems that seek sound methodological principles as a basis for their HBPs. The authors present many advances that have been made in economic evaluation, costing, and evidence assessment methods. However, major gaps remain in both the methods and the underlying data needed for implementation. Furthermore, the use of evidence such as CEA is only a part of the entire HBP design process. Thus, those who promote an evidence-based approach in order to maximize the use of relevant evidence should also acknowledge the limitations of their craft, and embed their evidence within the broader process for setting the HBP.

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CHAPTER 4

How Much Health for the Money?

Using Cost-Effectiveness Analysis to Support Benefits Plan Decisions

Mark Sculpher

Paul Revall

Jessica M. Ochalek

Karl Claxton

At a glance: Cost-effectiveness analysis can help identify “best buys” in healthcare—the services that will produce the most health given available resources.

Any collective financial arrangement in health-care requires decisions to be made about which medical interventions and healthcare programs will be funded from the resources available, which inevitably are finite. Some low- and middle-income countries (LMICs) have made progress in defining those collectively funded interventions and programs to which particular individuals have access. Whether in high-income jurisdictions or LMICs, health benefits packages (HBPs) offer one means by which services can be defined as appropriate to attract collective funding of the sort required for any transition towards universal health coverage.

Determining and maintaining a HBP requires a number of decisions from policymakers. As well as which interventions and programs to include, policymakers will need to define what individuals will have access to them and in what circumstances (see the chapters in part III). In making these decisions, policymakers will have a series of social objectives they are seeking to meet, such as improving population health. They will also face a number of constraints in achieving those objectives. The most obvious constraint is that the resources available to fund HBP are not infinite; rather, there is likely to be a limited budget. This might be defined as an administrative

budget, but even when explicit budgets are not specified there will be restrictions on the growth in health-care expenditure.

Cost-effectiveness analysis (CEA) is a set of tools to inform decisions when there is an objective of improving some measure of benefit subject to constraints. CEA is useful when policymakers want to understand which services will lead to an increase in their objective function within specified constraints. Generally, CEA has been used in healthcare to establish the cost-effectiveness of specific interventions, assessing whether the intervention is able to make a greater contribution to the system's objectives from the funding it consumes (for example, gains in population health) than the other activities that could be funded from those same resources. Hence the concept of opportunity cost is central to the principles and practice of CEA—namely, what benefits are forgone when resources are used in one way rather than an alternative? This question highlights the strong ethical basis for ensuring that the interventions defined in the HBP are cost-effective.¹ If the HBP contains interventions that are not cost-effective, the individuals who receive them may experience less health benefit than could others who are denied more cost-effective interventions. The aim of this chapter is to outline CEA as a set of tools to guide decisions about resource allocation in healthcare in general, and the development of HBP in particular.

Constrained Maximization

The principles of CEA as applied to HBP design are intuitively attractive and relate to how everyday decisions are made about expenditures in all walks of life. Given available financial resources, CEA asks the question of how these resources should best be allocated to maximize the benefits of their use. In the context of HBP, it is concerned with maximizing the benefits obtained from the full range of activities

in the package that are funded while minimizing opportunity costs—namely, those activities that cannot be funded as a result of the financial limits. All kinds of resource allocation decisions by individuals, households, and private and public sector organizations reflect these principles, though most are applied informally.

In healthcare, CEA is increasingly used as a formal research tool to inform the decisions of health systems. In short, this involves estimating, compared to alternative approaches to managing given patient groups, the benefits gained from a new activity (such as a treatment or a diagnostic test) and any additional cost imposed. A crucial aspect is quantifying the opportunity costs to establish whether the cost of achieving the additional benefit can be justified—that is, are the additional benefits greater than the opportunity cost? In HBP design, CEA needs to be used across the full range of patient populations and subpopulations that have potential access to care. The principle of CEA, therefore, is to inform resource allocation decisions by indicating which options maximize an objective function subject to a series of constraints; that is, it is a method of constrained maximization. In doing so it applies a systematic and consistent approach for informing priorities. Although this chapter mainly considers a financial resource constraint, additional constraints may be relevant and can be incorporated (see chapter 9). To understand fully the value of these methods and some of the practical issues relating to their implementation, the building blocks of such analyses are now considered.

Objectives and constraints

One of the practical challenges of using CEA is the inevitable question of defining policymakers' objectives—what are they seeking to maximize subject to financial and other constraints? Most of the many examples of CEA in healthcare assume that the policy objective is to improve population

health. It seems reasonable to assume that such an objective will be a central concern to health systems internationally, particularly when a broad definition of “health” is used which includes both gains in survival duration and in health-related quality of life (HRQoL). However, other policy objectives inevitably play a role in shaping decisions about HBPs. For example, more importance may be attached to health improvement in particular types of individuals—perhaps those who are active in the formal or informal labor markets, or those with more severe diseases. It is often the case that any objectives other than gains in population health are considered in an informal way, as part of the decisionmaking process. Although CEAs generally focus on health outcomes, broader measures of benefit are possible. Chapter 6 discusses other methods that seek to reflect these wider considerations quantitatively, such as multicriteria decision analysis (MCDA).

The constraint that generally is considered formally in CEA is that relating to available financial resources. The nature of this constraint is that the health system’s financial limits can be expected to preclude the most effective option (the one offering the best health outcomes to the average patient in a given group) being made available to all groups. The exercise therefore becomes one of identifying options that maximize aggregate population health improvement, comparing across different patient groups, subject to the available financial resources. This will usually suggest that some patient groups will receive the most effective option available but, given limited resources, this will not be the case for others because greater gains in population health can be achieved elsewhere from using the additional resources that would be necessary.

Although rarely considered formally in CEA, many other types of constraint must be reflected in decisions (as discussed in chapter 9). An important consideration in LMIC relates to real resources as opposed to financial resources. Perhaps most notably, constraints can exist in the availability of

trained clinical staff. Therefore, a decision to fund, for example, a new medical device may not be feasible in practice (at least for the entire group of potential recipients) because there is insufficient staff to administer or to implant the device. Real resource constraints might also exist regarding capital equipment. For example, the treatment of HIV with antiretroviral drugs, with a strategy of testing viral load using plasma to ensure that the treatments remain effective, requires cold storage and timely access to a laboratory infrastructure that may not be available in many settings, particularly rural ones. Some real resource constraints are less specific and apply to the healthcare system more generally; this has been referred to as supply-side readiness, or the extent to which a healthcare system is able to implement a particular service that requires a range of real resources to be marshaled, such as the training of healthcare workers when new clinical guidelines are released. Over the longer term, it may be feasible to relax some of these nonfinancial constraints by using the available financial resources to invest in human capital, equipment, or other infrastructure. However, such constraints need to be respected in the shorter term and, particularly in low-income settings, some may be difficult or extremely costly to relax. There may also be noneconomic constraints such as political limits on the types of policies considered feasible.

Mutually exclusive and independent options

As generally used in healthcare, CEA focuses on identifying the best (cost-effective) option of a set of exhaustive and mutually exclusive alternatives for a particular group of individuals (these are often patients, but this is not necessarily the case, as in public health programs). For example, for patients with metastatic prostate cancer, what is the most cost-effective treatment of those that can be used? The specified options for the CEA should be exhaustive in that they are a complete set of interventions

and strategies that conceivably could be used for this group. For patients with specific diagnoses, this list could include discrete treatments, such as pharmaceuticals or surgical procedures; combinations of treatments; strategies involving sequences of treatments or the use of treatment starting or stopping rules; strategies involving diagnostic tests, such as watchful waiting; options that involve only care with no active treatment; or a “do nothing” option. For some options the scale of implementation across a patient group may have a nonlinear association with estimated costs and/or benefits. For example, particular levels of implementation may require new investments. In these situations, alternative scales of implementation become additional options in their own right. The key principle is that no feasible option, including doing nothing, should be left out of this set of alternatives. A failure to identify a complete list of options risks providing erroneous guidance to decisionmakers if the option identified as cost-effective is simply an artefact of a better option not having been included in the analysis. The list of alternatives should also be mutually exclusive in the sense that a given patient can only have one of these options (hence, for example, combination treatments are defined as single option strategies).

Resource allocation decisions inevitably need to be made across a range of patient groups. Even within a disease, there can be a number of distinct groups (such as early-stage, locally advanced, and metastatic prostate cancer). An exhaustive set of mutually exclusive options will exist for each patient group. When a decision is being considered about the cost-effective treatment among the options available for, say, metastatic prostate cancer, the options available for all other patient groups can be defined as independent. These independent options have no direct clinical relevance to patients with metastatic prostate cancer, but they have economic relevance because the financial resources available to fund independent options in other patient groups will depend in part on the

treatment funding decision made for patients with metastatic prostate cancer. For example, if the most effective treatment for metastatic prostate cancer is also the most costly available for these patients, other groups (such as patients with mild to moderate depression) may have to receive less-effective treatments or no treatment at all because fewer financial resources are available for their care.

This distinction between mutually exclusive and independent options is partly a function of how the patient group is defined. For example, if the group consists of all men with metastatic prostate cancer, interventions for all other groups are independent. However, there will be some different subgroups of men with metastatic prostate cancer between which the effectiveness or costs of alternative therapies may systematically vary. It may be the case, for example, that some treatments are more effective in men who have bone metastases rather than other forms. When this type of heterogeneity exists, the analysis needs to identify the cost-effective intervention for each subgroup. Decisionmakers may decide to fund different treatments for subgroups of patients with a particular disease or clinical need if there is a systematic difference between them in the cost-effective option.

Evidence

To quantify the costs and benefits of each mutually exclusive intervention for a given patient group (or subgroup) a range of evidence is needed (see chapter 11). In general this evidence relates, for each option being evaluated, to the resources used to deliver it (the activities that impose a financial cost associated with a given patient group), the prices and unit costs needed to value the financial cost of a resource, and changes in mortality risks and in HRQoL. A CEA requires an estimate of the expected (mean) cost of an option, which represents the cost of all the resource items that can be expected to be consumed for each

option being evaluation (see chapter 8 by Cashin and Özaltın). This is not just the cost of acquiring the particular intervention (such as a drug or device) being evaluated; rather, it includes all resources that could be consumed differentially between the options being compared. This could include visits to and from clinical staff, days in hospital, therapeutic and diagnostic procedures, and pharmaceuticals.

This list of resources that may be differentially consumed between mutually exclusive options will depend on the nature of the disease and the alternative options under evaluation, but also on what resources are funded by the budget relevant to the resource allocation decision. For example, if patients need to travel to a hospital clinic and, in doing so, take time away from their usual activities, this can impose travel and time costs on those individuals. A CEA undertaken from the perspective of the health system/payer's budget, however, will ignore these costs. It is possible to undertake CEA from broader perspectives, with the widest sometimes known as the societal perspective, but such analyses need to reflect the fact that different resources impose opportunity costs in different ways.² For example, the opportunity cost of any travel cost imposed on patients is likely to fall mainly on patients' consumption of other goods and services unrelated to health-care. Reflecting the different sources of opportunity costs can be analytically challenging, and is one reason why CEA is typically undertaken from the perspective of a single payer's budget.

The measure of effectiveness, benefit, or outcome used in CEA will be determined by the health system's objectives (the "objective function"). Assuming a focus on population health, the measure needs to be relevant to the range of patient groups covered by the budget. This is because it is necessary to be able to compare the expected health gained by one patient group from a more effective and costly intervention to the health that will be forgone by other groups because fewer resources will be available for their

care. For this reason, an outcome that is specific to a particular patient group or disease (such as HIV infection avoided) is unhelpful if resource allocation decisions need to extend to disease areas where such an outcome measure has no interpretation (for example, metastatic prostate cancer). A *generic* measure of health—one that includes any impact of an option on survival duration and on HRQoL—is, therefore, generally the focus in CEA. Two widely used CEA measures that satisfy these criteria are the quality-adjusted life-year (QALY) and disability-adjusted life-year (DALY) (see chapter 6).

The precise nature of evidence depends in part on how the study is conducted; in particular, on whether the CEA is undertaken alongside a primary study where sample data are available (as in a randomized trial), or using evidence synthesized from a number of sources within a decision analytic model. Regardless of how the study is conducted, however, an important principle applies: all relevant evidence should be incorporated into an analysis. It is not appropriate to select evidence on the basis of its convenience or the results it generates. So an important stage of any analysis is to identify evidence in a systematic way, to review the quality of the studies from which it is drawn, and to synthesize it to provide the best overall estimate of a given quantity with relevance to the analysis. These are the activities of systematic review,³ which has a key role alongside economic evaluation. Although collecting economic and health outcomes data as part of a primary study such as a randomized trial can be valuable, it is dangerous to base an economic evaluation solely on primary studies.⁴ In particular, a CEA needs to synthesize all relevant evidence, not just that collected in the primary study, and all options need to be compared even if they are not included in the primary study. Hence there is a key role for modeling and evidence synthesis in CEA even when data are available from a primary study.⁵

The term *relevant* in the context of evidence is important to consider further. This relates to the

appropriateness of the evidence for the decision that the analysis is seeking to inform. This is partly defined by the patient group for which the cost-effective option is being identified—ideally, the evidence should be drawn from studies that include this type of patient. This is often complicated by the heterogeneity referred to above in that certain endpoints or measurements will vary according to the characteristics of different types of patients in the group. Furthermore, the studies supplying the evidence may have different patient mixes from these different subgroups.

Understanding relevance also relates to the jurisdiction in which the decision is made. This is due to some quantities varying systematically between different jurisdictions, or even between different regions within a jurisdiction. Some of this variation may be explained by subgroup heterogeneity; for instance, one jurisdiction may have a greater proportion of metastatic prostate cancer patients with bone metastases than another. However, some variation may be due to other factors that differ between countries. These could include the relative prices of resources used in healthcare—one country may have a relative shortage of skilled HIV nurses, for instance—or the underlying prevalence of a disease (which may influence cost-effective screening or diagnostic options) or existing clinical practice for some types of patients (which may influence the cost of particular activities). Frameworks have been suggested that seek to provide a more generalizable estimate of cost-effectiveness: WHO-CHOICE is such an example, with a focus on low-income countries (see chapter 6).⁶

When evidence is being sought for a CEA informing a decision about a particular patient group in a given jurisdiction, therefore, the geographical source of that evidence may be important.⁷ For some types of evidence, its location of origin may not be considered important—that is, the estimate *generalizes* to various jurisdictions. This could be the case regarding the *relative* effectiveness of a given intervention. For example, a hazard ratio representing the impact

of one treatment, compared to another, on the rate of mortality, may show the same proportionate effect on the rate of death in all settings. For example, a hazard ratio of 1.5 indicates that the rate of the event is 50 percent higher with a given treatment compared to the rate with another (the baseline), this may be considered to generalize between jurisdictions even if the baseline rate of that event systematically varies between jurisdictions.

For other types of evidence, the geographical source may be more important. For example, as well as the baseline rate of the event above, the probability of hospitalization and the mean length of stay in hospital for the treatment of a given condition for a particular type of patient may systematically differ by location owing, perhaps, to standards of clinical practice. In this situation, the challenge is to try to identify evidence that is relevant to the jurisdiction in which the decision is being made. This could include the use of formal or informal adjustments based on data collected outside the jurisdiction.

Relevant evidence is not just that required to estimate the cost and benefit of each mutually exclusive option within the specific patient group of interest. As outlined in chapter 9, independent options that are (or could be) used for all other patient groups drawing on constrained resources are also relevant to any decision. In principle, therefore, estimates of the costs and benefits, or of all options available for each and every patient group (and subgroup), are required to implement fully a constrained maximization analysis. As discussed later in this chapter, this is a major challenge and is an important reason why a simplified form of CEA is generally used in practice.

Analytical Approach

In principle, CEA can be implemented using mathematical programming having specified an objective function, such as maximizing health gain, and

relevant constraints (for example, the specified budget). With such methods, the costs and benefits of all options (mutually exclusive and independent) are included in the model. The analysis indicates the cost-effective option for each patient group that, when taken together, maximizes the objective subject to the constraints. Mathematical programming has been available for many years,⁸ and there has been interest in these methods to support resource allocation decisions in healthcare.⁹

An example of such methods being used to inform a specific decision was in the context of HIV

treatments in South Africa.¹⁰ The study set out to establish appropriate levels of implementation of alternative treatments. Three mutually exclusive options were considered: (1) treatment and prophylaxis of opportunistic and HIV-related illnesses without antiretroviral therapy (ART); (2) treatment and prophylaxis of opportunistic and HIV-related illnesses with first-line ART only; and (3) the same option as the second one, but with both first-line and second-line ART. Box 1 shows how the programming was specified with the objective of maximizing health subject to the budget constraint. This implies

BOX 1. Mathematical Programming for CEA

- 1
$$\max_{x_1, \dots, x_n} \sum_{i=1}^n x_i E_i$$
- Maximizes health outcomes where:**
- i is an index relating to the options under consideration (where $i = 1, \dots, n$)
 - x_i is the percentage of those in need receiving option i
 - E_i is the present value of the outcomes of intervention i over the period of interest
- 2
$$\sum_{i=1}^n x_i C_i \leq C$$
- Subject to the budget constraint where additionally:**
- c_i is the present value of the cost of option i over the period of interest
 - C is the present value of the budget over the period of interest
- 3a $0 \leq x_i \leq 1$
- Constraints to implement health maximization:**
- The first expression indicates that the implementation level of each intervention lies between 0 and 1; the interventions are divisible and can be given to some patients in need but not all.
- 3b
$$\sum_{i=1}^n x_i \leq 1$$
- The second expression ensures that the sum of the proportions of options cannot exceed 1.
- 3c $x_i = 0 \dots \text{or} \dots x_j = 1$
- Constraints to implement "equal treatment":**
- Replaces the constraint 3a for health maximization showing that each option can either be implemented in all patients in need or none at all.
- 3d
$$\sum_{i=1}^n x_i = 1$$
- Constraint to implement "decent minimum":**
- Health is maximized subject to the sum of proportions of need covered by individual options equals 1, so all patients are treated but not necessarily with the same option.

Source: Cleary, Mooney, and McIntyre (2010).

that not all patients with the same clinical need will necessarily receive the same (or, indeed, any) intervention depending on the resources available. To address the likely equity concerns associated with this implication, the authors respecified their model to impose a further constraint that patients with the same clinical need all receive the same treatment, which may be no treatment if there are not enough resources to treat all (“equal treatment”). A third specification—“decent minimum”, where all patients are ensured a treatment even if there is variation in which treatment is received—was also modeled.

The authors estimated the lifetime costs and health effects (in terms of QALYs) of each option using available evidence. They then used mathematical programming to quantify, for a range of budgets, the percentage of the population in need that would be covered by the three options and the total impact on population health (QALYs), and compared the opportunity costs of the “equal treatment” and “decent minimum” equity constraints in terms of QALYs forgone compared with health maximization. Table 1 shows the results of the analysis. It indicates that, for five of the seven levels of budget considered, health maximization resulted in the greater impact on population health. Under “equal treatment” and “decent minimum,” no treatments are offered for budgets of \$2 billion, \$4 billion, and \$6 billion. For “equal treatment,” 100 percent of resources are allocated to one of the three options from budgets of \$8 billion upwards; and for “decent minimum” resources are used to distribute patients across the three treatments. Under health maximization a proportion of patients receive an option for all budget levels, but this is only, for example, 18 percent at the lowest budget of \$2 billion.

This HIV treatment example reveals some important strengths in mathematical programming as the analytical basis for implementing CEA. One is the need for explicitness in the options being specified, including variants such as the scale at which

they are being implemented; the objective to be maximized; and the relevant constraints. An important quantity that emerges from such an analysis is a measure of cost-effectiveness of the last option to be funded before the budget runs out or of the next option to be funded if the budget is increased. This is known as the “shadow price” of the budget constraint and can also be interpreted at the marginal efficiency of the system, which is made up of the all the options funded in all patient groups. This gives an estimate of the additional (reduction in) benefit that would follow a marginal increase (decrease) in the budget. Whether it is estimated as part of a mathematical model such as that given in box 1 and table 1, this quantity has an important role in CEA as a means of estimating a *cost-effectiveness threshold*, and this is considered further below.

The study’s interest in how equity considerations might be factored into mathematical modeling for CEA is important, and builds on earlier work that has been extended by others.¹¹ The South African HIV treatment study example has some limitations. One of these is the failure to reflect evidential uncertainty in the analysis and to consider strategies for how uncertainty should influence decisions in a budget-constrained health system. Appropriate methods for this purpose have been considered elsewhere.¹² A second weakness is the limited number of options considered in the analysis. In most healthcare systems, budgets must cover a number of diseases and many patient groups for whom numerous options potentially are available. In principle, this also would be the case for a system seeking to define a HBP. However, the use of a formal mathematical programming approach to cover the full list of potential options for all patient groups would require evidence on the costs and benefits of every option under consideration, and this evidence is unlikely to be available. The role of these methods to guide policy has been in the more limited context of a budget being allocated across a single disease or a small number of patient groups.

TABLE 1. Results of Mathematical Programming CEA for HIV Treatments in South Africa

	US \$2 billion	US \$4 billion	US \$6 billion	US \$8 billion	US \$10 billion	US \$12 billion	US \$14 billion
<i>Equal treatment</i>							
% need met on no-ART				100%	100%		
% need met on first-line ART						100%	
% need met on first & second-line ART							100%
Total QALYs (millions)				5.2	5.2	10.5	11.7
QALYs forgone versus health maximisation	-1.9	-3.9	-5.8	-2.5	-4.5	-0.8	0
<i>Decent minimum</i>							
% need met on no-ART				88%	27%		
% need met on first-line ART				12%	73%	31%	
% need met on first & second-line ART						69%	100%
Total QALYs (millions)				5.8	9.1	11.3	11.7
QALYs forgone versus health maximisation	-1.9	-3.9	-5.8	-1.9	-0.6	0	0
<i>Health maximisation</i>							
% need met on no-ART							
% need met on first-line ART	18%	37%	55%	74%	92%	31%	
% need met on first & second-line ART						69%	100%
Total QALYs (millions)	1.9	3.9	5.8	7.8	9.7	11.3	11.7
Unmet need (%)	82%	63%	45%	26%	8%	0%	0%

Source: Cleary, Mooney, and McIntyre (2010). Reproduced with permission.

Practical Implementation of CEA

The evidential burden associated with the formal use of mathematical programming modeling is the main reason why CEA has tended to focus on whether a particular intervention for specific patients ought to be included in a package. This approach focuses on

identifying the cost-effective option from among mutually exclusive and exhaustive alternatives for a particular patient group. It often considers the cost-effective option for subgroups to reflect patient heterogeneity, but it usually involves considering the same set of alternatives. In contrast with formal mathematical programming, there is no explicit consideration

of the resourcing of independent options for other patient groups, nor is the budget constraint formally modeled. Instead, a summary measure of the opportunity cost is used to represent the implications of funding a given option for the patient group of interest in terms of the benefits other patient groups forgo as a result of a constrained budget. This measure is generally known as the *cost-effectiveness threshold*. It can take the form of the shadow price of the budget constraint but, rather than being quantified as part of a mathematical programming analysis, it needs to be estimated in some other way.

CEA with two mutually exclusive options

To explain how CEA is generally used, start with the assumption that for a specific patient group, there are just two mutually exclusive options available to manage these patients: current practice is to provide no active intervention (Option A), and the alternative is to fund a drug therapy (Option B). For each option, the expected costs and health outcomes are estimated based on the relevant evidence, where the key considerations regarding suitable evidence are as outlined later in this chapter. These estimates can be denoted:

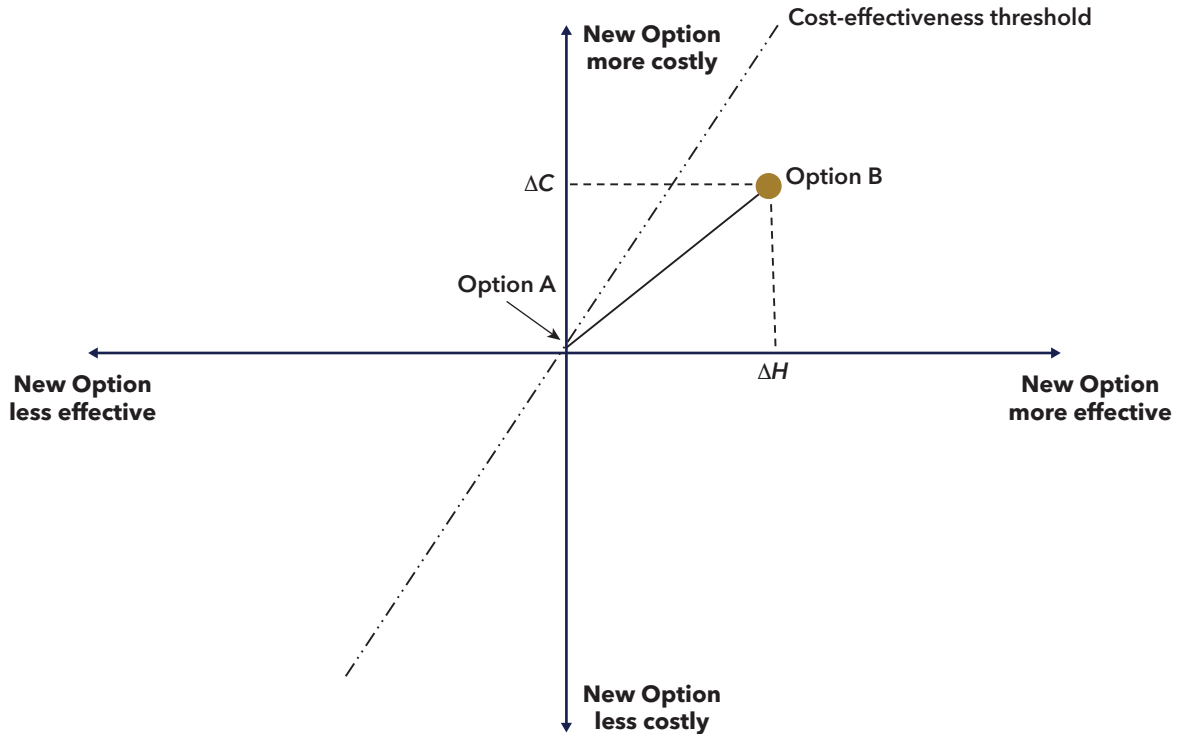
Expected cost of Option A:	C_A
Expected cost of Option B:	C_B
Expected health outcomes of Option A:	H_A
Expected health outcomes of Option B:	H_B
Difference in expected costs (Option B – Option A)	ΔC
Difference in expected health outcomes (Option B – Option A)	ΔH

The decision, therefore, is whether any additional health benefits from Option B justify any additional costs. This is centered on the comparison illustrated in figure 1. This shows a cost-effectiveness plane where one option—here the existing form of management (Option A) —is located at the origin. The second

option—here the new Option B—is located relative to the origin on the basis of its expected incremental costs and health outcomes. The horizontal axis shows the expected incremental effectiveness of Option B compared to Option A; and the vertical axis shows the expected incremental cost of Option B compared to Option A. In principle, Option B could be located in any part of the plane. If it is located in the bottom-right quadrant, it is expected (based on estimated means) to be more effective and less costly than Option A—that is, it is “dominant,” which indicates that it is unequivocally cost-effective subject to the available evidence and does not impose any opportunity costs on independent options. Conversely, if Option B is located in the top-left quadrant, it is expected to be more costly and less effective than Option A. This means that the latter is dominant and the CEA suggests that existing practice is unequivocally cost-effective with no opportunity costs imposed.

The more challenging situation for decisionmaking is where Option B imposes additional expected costs but also improves expected health outcomes in the relevant patient group—this is shown in figure 1 at a point in the top-right quadrant. In this quadrant the additional health outcomes offered by Option B come at an incremental cost. This is often presented in terms of an incremental cost-effectiveness ratio (ICER)— $\frac{\Delta C}{\Delta H}$ —the incremental cost per additional unit of health benefit. The ICER is also equal to the gradient of the line running from the Option A at the origin to the location of Option B. Option B remains a more costly investment for the health system than standard practice and, given constraints on expenditure, resources will need to be taken from independent options if Option B is to be funded. This imposes opportunity costs in terms of the health outcomes that other patients, probably with entirely different diseases, could have enjoyed if the same financial resources had been made available for their care. These opportunity costs are reflected in the cost-effectiveness threshold, which indicates

FIGURE 1. A Cost-Effectiveness Plane



the maximum affordable ICER. The threshold is an estimate of the additional cost of a new intervention that causes other patients to forgo one unit of health benefit because interventions are not funded. The threshold is the gradient of the dotted line shown in figure 1, passing through the origin and extending into the top-right and bottom-left quadrants. Based on expected costs and health outcomes, Option B falls below the threshold and therefore would be considered cost-effective. If the cost-effectiveness threshold is denoted k , one of the two mutually exclusive options can be considered cost-effective if:

$$\frac{\Delta C}{\Delta H} < K$$

The same logic applies if Option B were to be located in the bottom-left quadrant. The difference would be that Option A (standard care) would have higher

expected costs and outcomes, and an ICER would be calculated for that option compared to the new option—namely, the incremental cost per additional unit of benefit to retain Option A rather than move to the less costly Option B. To assess whether staying with Option A is cost-effective in this context, its ICER would again be compared to an appropriately estimated cost-effectiveness threshold. This comparison indicates the additional health outcomes that other types of patients with other diseases could expect to enjoy if the savings offered by moving from Option A to Option B were realized. In other words, the cost-effectiveness of Option B depends on comparing the health expected to be forgone by patients staying with Option A with the health expected to be gained by other patients from the savings made available by patients moving to Option B.

Therefore, CEA is the comparison of the health benefits gained or forgone by different patient groups. This is further demonstrated in the graph in figure 2, which focuses on the nature of the comparison when a new option is located in the top-right quadrant (more costly and more effective than a relevant comparator), and shows the implications of different prices. When the price of the new option is P1, the total additional cost per patient is \$2000 and two additional units of health benefit (here QALYs) are generated, so the ICER is $\$2000/2 = \1000 per QALY gained. If the cost-effectiveness threshold is estimated at \$2000 per QALY, this means that the new intervention generated two additional QALYs but, because it imposes \$2000 additional costs per patient on the budget, the funding of independent options in other disease areas is not possible and patients will forgo health. The threshold indicates that this opportunity cost will be $\frac{\Delta C}{k} = \$2000/2000 = 1$ QALY. As the additional QALYs generated by the new intervention are greater than the opportunity costs (2 vs. 1 QALY), the new option is cost-effective at price P1, below the cost-effectiveness threshold in figure 2. The gains from implementing the new option can also be expressed in terms of an alternative measure of cost-effectiveness, the net health benefit (NHB) which is denoted:

$$\text{NHB:} \quad \Delta H - \frac{\Delta C}{k}$$

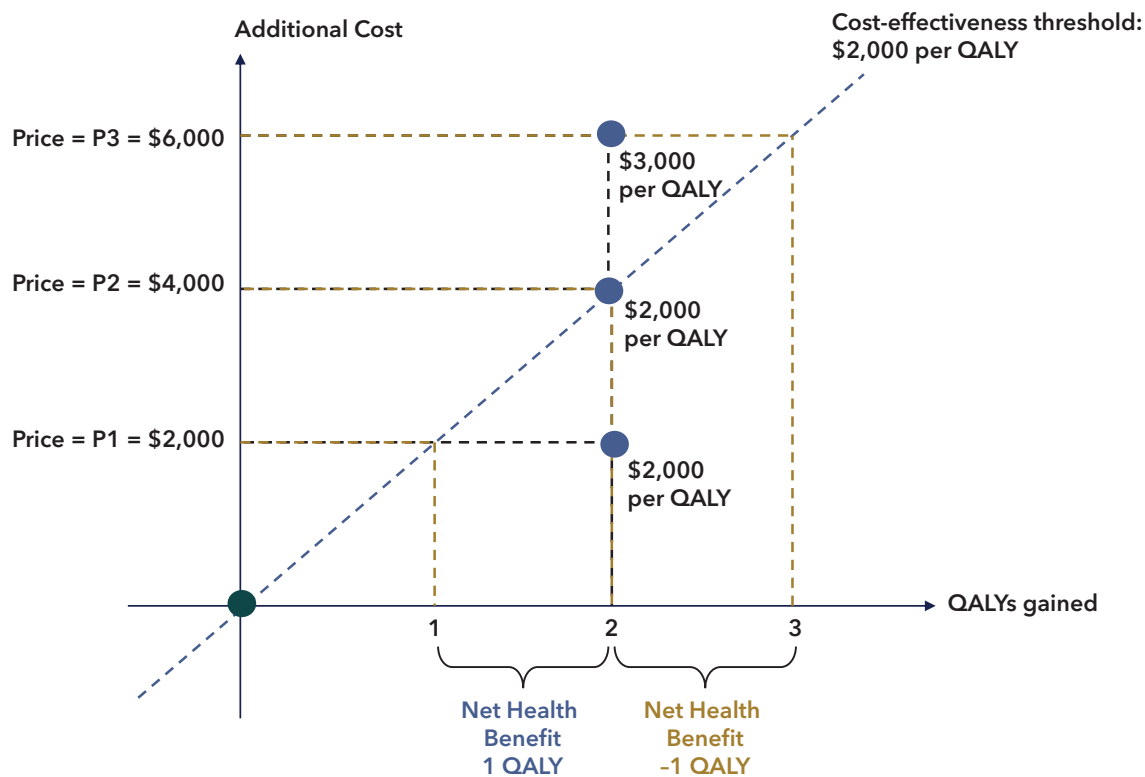
If the NHB is positive, the new option is cost-effective compared to a mutually exclusive alternative.

Figure 2 also shows how NHB changes as the price of the new intervention increases. At P2, the additional cost per patient increases to \$4000, hence the ICER is $\$4000 / 2 = \2000 , which is equal to the cost-effectiveness threshold. This means that the NHB is $\{2 - \frac{\$4,000}{\$2,000} = 0\}$. Therefore, P2 is the maximum price that the health system can afford to pay for the new intervention without incurring losses

in terms of population health; this price has been defined as the *value-based price*.¹³ At a price of P3, the additional cost per patient is \$6000, which means the ICER is \$3000 and, with a threshold of \$2000 per QALY, NHB is negative $\{2 - \frac{\$6,000}{\$2,000} = -1\}$, and the funding of the new option would result in net losses to population health. Figure 2 shows how health systems can think about the maximum prices of proprietary health interventions that can be afforded. This is important in negotiating suitable prices from manufacturers and shows the implications (for net population health) of agreeing to fund interventions at too high an acquisition cost.

An example of a CEA with two options

Numerous CEAs have been conducted in LMICs. One example is a study assessing the cost-effectiveness of cotrimoxazole prophylaxis in HIV-infected children in Zambia.¹⁴ The analysis used a Markov model to estimate future benefits and costs. The model characterized HIV disease progression in terms of CD4 T-cell percentage (CD4%) and took its effectiveness estimates from a randomized trial that had shown a 43 percent reduction in mortality with cotrimoxazole prophylaxis. Costs considered included the cost of the cotrimoxazole and other drug therapies, diagnostic and monitoring tests, inpatient stays and outpatient visits. Health outcomes were expressed both in terms of QALYs and DALYs, where gains in expected survival duration were estimated in the Markov model, and HRQoL weights came from other published sources. Table 2 shows the base-case results from the study. These show that prophylaxis with cotrimoxazole adds costs to the budget but also improves expected outcomes. The authors presented ICERs for both QALYs and DALYs: \$94 and \$53 per additional unit of benefit, respectively.

FIGURE 2. The Concept of the Net Health Benefit (Top-Right Quadrant of the Cost-Effectiveness Plane)

Source: Claxton and others (2008).

TABLE 2. Base-case Results from a CEA of Cotrimoxazole Prophylaxis in HIV-infected Children in Zambia

	No prophylaxis	Cotrimoxazole
Expected costs per patient (2006 US\$)	2,032	2,158
Expected outcomes per patient		
QALYs	2.49	3.83
DALYs	-22.74	-20.39
Incremental cost-effectiveness ratios (2006 US\$)		
QALYs gained		94
DALYs avoided		53

Source: Ryan and others (2008).

CEA with more than two mutually exclusive options

In reality, more than two options often are available for a given patient group. Indeed, in some situations there are many options, as in evaluating alternative diagnostic strategies where there can be numerous ways to use single or multiple tests, particularly when alternative diagnostic strategies have a range of possible therapeutic options. The steps needed to determine the cost-effective option among more than two mutually exclusive alternatives are illustrated using an example of a study looking at the cost-effectiveness of drug resistance testing to assess the need for drug switching from first- to second-line ART in HIV patients in low-income sub-Saharan Africa.¹⁵ The analysis was based on an infectious disease model that simulated the HIV epidemic in Zimbabwe. Table 3 shows the 10 mutually exclusive options from which a single cost-effective option was to be drawn. The additional costs (in million \$US) and DALYs averted were estimated over a 10-year period relative to the standard practice of no monitoring or second-line ART (Option A in the table). The following steps are taken to identify the cost-effective therapy:

1. Establish the full list of mutually exclusive options from which a cost-effective intervention is to be identified.
2. Rank the options in terms of their expected costs or expected outcomes (here, DALYs averted have been used).
3. Remove options that have higher expected costs and lower expected outcomes than at least one other option (these are *dominated*, and cannot be cost-effective). This removes Options C and I from further consideration.
4. ICERs for all options that are not dominated are shown in the fifth column. As shown for two options

in table 3, this involves taking the ratio of additional costs to additional DALYs averted between each option and the next most effective.

5. Identify the options that cannot be cost-effective as they are less effective and have higher ICERs than other options. For example, Option D has an ICER of \$1,958 compared with B but Option F is more effective and has a lower ICER. For any given cost-effectiveness threshold, Option D could not be selected in preference to Option F. Options D, E, and G are removed from further consideration for this reason, and are defined as being subject to *extended dominance*.

6. Ascertain the cost-effective option from those remaining. In this example, there are five: Options A, B, F, H, and J. Calculate ICERs between these options in ascending order of effectiveness. For example, the ICER of Option J is compared to the next-less-effective remaining option (Option H):

$$\frac{\$270,600,000 - \$190,400,000}{178,537 - 140,713} = \$2,120$$

7. As for the two-option case, the cost-effective option depends on the cost-effectiveness threshold. This will be the most effective option with an ICER below the threshold. For any threshold below \$552 per DALY averted, Option A will be cost-effective. For thresholds between \$552 and \$1,414 per DALY averted, Option B will be cost-effective. For thresholds between \$1,415 and \$2,103, Option F will be cost-effective. For any threshold between \$2,104 and \$2,119, Option H will be cost-effective. For any threshold of \$2,120 and above, Option J will be cost-effective.

Figure 3 shows these steps as a graph, which is the top-right quadrant of the cost-effectiveness plane shown

TABLE 3. Results of an Incremental Cost-Effectiveness Analysis of More Than Two Options

Option	Description	DALYs	Costs (millions)	ICER(1)	ICER(2)	NHB (\$500)	NHB (\$1000)	NHB (\$1500)	NHB (\$2500)
A	No second line, no monitoring	0	\$0.00	—	—	—	—	—	—
B	Clinical monitoring with VL confirmation	37,673	\$20.80	\$552.12	\$552.12	-3,927	16,873	23,806	29,353
C	Clinical monitoring with VL confirmation and resistance test	26,983	\$21.30	Dom		-15,617	5,683	12,783	18,463
D	Clinical monitoring alone	45,435	\$36.00	\$1,958.26 (ED)	ED	-26,565	9,435	21,435	31,035
E	CD4 count monitoring with VL confirmation	91,857	\$116.20	1,760.67 (ED)	ED	-140,543	-24,343	14,390	45,377
F	CD4 count monitoring with VL and resistance test	106,212	\$117.80	\$1,415.25 (ED)	\$1,415.25	-129,388	-11,588	27,679	59,092
G	CD4 count monitoring alone	111,424	\$159.40	\$7,981.58	ED	-207,376	-47,976	5,157	47,664
H	VL monitoring with VL confirmation	140,713	\$190.40	\$2,104.29	\$2,104.29	-240,087	-49,687	13,780	64,553
I	VL monitoring with VL and resistance test confirmation	139,589	\$191.10	Dom		-242,611	-51,511	12,189	63,149
J	VL monitoring alone	178,537	\$270.60	\$2,120.35	\$2,120.35	-362,663	-92,063	-1,863	70,297

ICER (1): incremental cost-effectiveness ratio (ICER) including those options subject to extended dominance.

ICER (2): ICER after options subject to extended dominance have been excluded.

NHB: Net health benefit as defined in Section 3.1; the number in the parentheses on the column header indicates the cost-effectiveness threshold used to calculate the NHB.

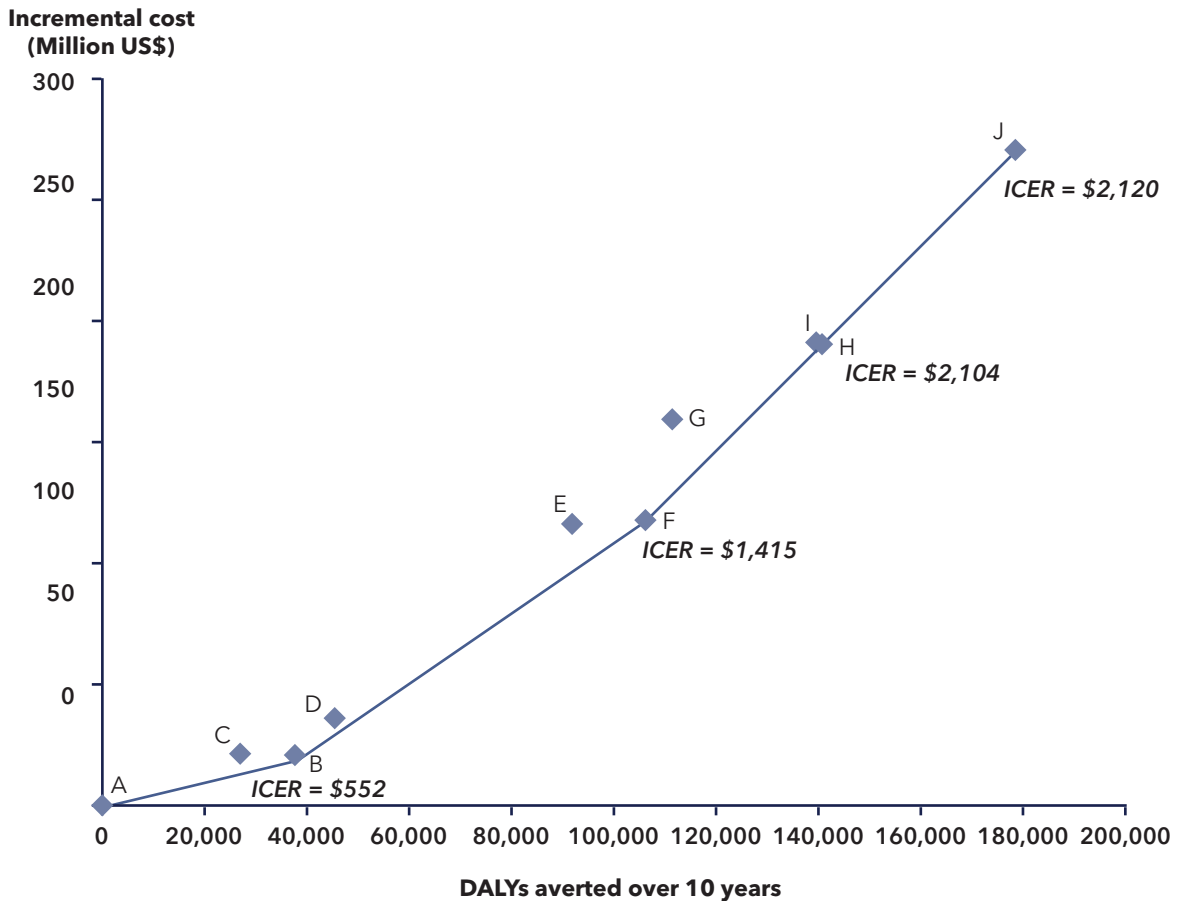
Based on Phillips and others (2014) analysis of drug-resistance testing to assess the need for drug switching from first- to second-line antiretroviral therapy in HIV patients in low-income Sub-Saharan Africa.

in figure 1. The expected costs and DALYs averted for each of the 10 options are plotted on the figure. Lines link those options that are not subject to dominance or extended dominance, and this is known as the *efficiency frontier*. The gradients of the lines linking these nondominated options are the ICERs between them, as shown in the figure.

As for the two-option example, these 10 options

can be compared in terms of expected NHB. This is shown in the last four columns of table 3, where NHB has been calculated for alternative cost-effectiveness thresholds ranging from \$500 to \$2500 per DALY averted. The cost-effective option is always the one with the highest positive expected NHB. This is Option A at a threshold of \$500 per DALY averted, Option B for \$1,000 per DALY averted, Option F for

FIGURE 3. Identifying the Most Cost-Effective Therapy



Note: Top-right quadrant of the cost-effectiveness plane showing 10 options for resistance testing to inform second-line ART for HIV (based on Phillips and others (2014)). The alphabetical labels for the options are shown in table 3.

\$1,500 per DALY averted, and Option J for \$2,500 per DALY averted. The use of NHB (conditional on a given threshold) rather than estimating ICERs is particularly helpful when many alternative options are being compared.

The Cost-Effectiveness Threshold

It should be clear that the cost-effectiveness threshold has a critical role in CEA in that, based on an estimate of the marginal productivity of the health system, it

avoids the need to quantify the costs and benefits of every feasible intervention for every patient (sub-) group and at different scales of implementation. When there are limits on expenditure, from which interventions for a range of patient groups and sub-groups have to be funded, the threshold represents a clear concept: namely, the health other patients forgo when other options are funded instead of ones that would benefit them. This has been described as a “supply-side” cost-effectiveness threshold¹⁶ because it represents what the healthcare system currently delivers, distinct from a “demand side” concept

representing a view of how much society should be willing to pay to improve health (often based on estimates of individuals' willingness to forgo personal consumption to improve their health).¹⁷ An example is the WHO guidance that a cost-effectiveness threshold be defined, for a given country, on the basis of a multiple of that country's gross domestic product per capita (suggested as multiples of between 1 and 3).¹⁸ Demand-side thresholds may provide some information to guide the setting of aggregate budgets for publicly funded healthcare (although this view can be criticized)¹⁹ but such metrics do not inform allocation decisions for constrained financial resources to support interventions across patient groups in light of the funding available.

Supply-side cost-effectiveness thresholds are especially important because they enable countries to assess individual treatments without needing to reappraise the entire contents of the HBP. However, the challenge for analysts is the limited availability of empirical estimates of the value of the threshold reflecting the opportunity costs of funding treatments for countries at different levels of income. This has been the case in high-income countries where, for many years, thresholds have been based on little evidence at all. One of the first examples of empirical estimates based on opportunity costs comes from a study in the United Kingdom regarding the threshold of funding new interventions in the National Health Service (NHS) in England and Wales.²⁰ Using routine NHS data, this study estimated the relationship between changes in expenditure (overall and by clinical area) across local healthcare commissioners and changes in mortality in those clinical areas for which such an outcome can be quantified. An estimate of the threshold was derived on the basis of available evidence and alternative assumptions about how changes in mortality can be expected to relate to life-years and QALYs gained, and about how this can be considered a surrogate for QALYs gained in clinical areas where changes in expenditure have

no quantifiable mortality effects. This can be interpreted as the impact on health associated with marginal changes in overall expenditure, a necessary point of information to secure an empirical estimate of the cost-effectiveness threshold.

For those countries concerned with ensuring that HBPs are consistent with the cost-effective use of resources from available funding, research to estimate relevant cost-effectiveness thresholds is a high priority. A preliminary basis of estimation for individual jurisdictions has been proposed based on the work undertaken in the United Kingdom.²¹ This uses the estimates the NHS threshold²² and adjusts for estimates of how changes in national income affect how individuals are willing to forgo their consumption of goods and services other than healthcare in order to improve their health. Other work has used existing published estimates of the mortality effects of health expenditure across LMICs to estimate the cost per DALY thresholds for 57 low-income and 64 middle-income countries, reflecting the demographic and other characteristics of each LMIC.²³ The results suggest that a threshold that represents health opportunity costs is likely to lie below 1 × per capita.

Decisions about whether to fund new interventions often are made separately, and by different agencies, from decisions about disinvestment—that is, what interventions to remove or to reduce in scale to accommodate the new investments. The estimated cost-effectiveness threshold can help link those two types of decisions: it informs those deciding on the new interventions what their decisions will mean for other patients whose services will not be supported. In the context of HBP decisionmaking, balancing investment and disinvestment could be characterized as “one option in, one option out.” The principle would be the same as outlined more generally above: to identify one or more candidates for disinvestment that would generate sufficient funding to include a new option elsewhere and result in an overall NHB gain. However, such an approach

risks disinvesting in interventions that are more cost-effective than other currently funded options even if they generate less population health gain than the new option.²⁴ Therefore, an estimate of the cost-effectiveness threshold should always be used as a measure of the marginal impact of the health budget on population health to guide both new investments and disinvestments.

Further Analytical Issues in Guiding Decisions

The focus of this chapter is an introduction to CEA to support healthcare resource allocation decisions in general and those relating to HBP in particular. The use of CEA to support actual decisions regarding resource allocation needs to reflect inevitable complexities and evidence in a way that is consistent with the characteristics of decisions. Many jurisdictions have embraced these methods, but challenges remain in making them as useful as possible to decisionmaking. The following sections provide a brief overview of some of those challenges and of how CEA has evolved in response.

Broader objectives and constraints

The earlier sections described CEA using an objective of gains in population health subject to the single constraint of a limited budget. The majority of applied studies also follow this approach. In reality, decisionmaking is set in a context where a number of considerations, in addition to health outcomes, are relevant to decisions. In principle, CEA can incorporate a more complex objective function, using two analytical steps. The first step would be to specify the trade-offs between the relevant objectives. For example, if reductions in health inequality as well as gains in health outcomes were considered relevant objectives, it would be necessary to define how much forgone

health gain would be acceptable to reduce inequalities and vice versa. Such trade-offs might be quantified based on the preferences of the general public or of the ultimate decisionmakers. The second step would be to estimate the cost-effectiveness threshold using this broader array of objectives. A new, more expensive intervention will impose opportunity costs in terms of benefits that patients (probably in other clinical areas) will forgo because they will have to accept less-effective but less-costly options to fund the new intervention. These forgone benefits should be characterized the same as the benefits received from the new intervention; for example, incurring health opportunity costs may accentuate health inequalities.

CEA has been further developed to reflect a wider set of objectives, including severity,²⁵ financial protection,²⁶ and health inequalities.²⁷ (In this book, chapters 5 and 6 consider some of these methods more fully.) These studies are, however, largely conceptual, and as yet there are only a few examples of empirical studies that have been used to support real decisions. Given the limited number of appropriately estimated cost-effectiveness thresholds, it is not surprising that there has been little attempt to incorporate a wider set of objectives into those estimates. Recent empirical work in the United Kingdom on cost-effectiveness thresholds has considered how this work might be broadened to include disease burden and productivity.²⁸

Other methods have been suggested to capture a fuller range of objectives in decisionmaking. Multi-criteria decision analysis (MCDA) is one approach that has gained considerable interest in recent years, principally in high-income countries.²⁹ These methods (covered in more detail in chapter 6) seek to specify a full range of “criteria” that are considered relevant to a resource allocation decision, to define systems for scoring alternative options on each criterion, and to identify weights to indicate the relative importance of each criterion. There is a range of approaches to these analytical steps but, in general,

decisionmakers should play a key role in defining the relevant criteria, scoring systems, and weights used to generate a weighted average score for each options being compared.

There are various examples of these methods being used to guide decisions and there is some variation in how these are specified. For instance, work by EVIDEM in Canada identified a set of attributes that could be seen as part of the potential benefits of interventions, including effectiveness, tolerability, convenience, public health interest, disease severity, and size of patient population.³⁰ These applications, however, do not explicitly reflect constraints to decisions, in particular to the limits on resources, and consequently they generally do not explicitly consider opportunity costs (which should be expressed in terms of all the decision-relevant criteria). As such, they should be considered complements, rather than alternatives, to CEA.

Decisionmaking organizations that use CEA generally do so as part of a deliberative process. They augment the results of the analysis with other information, including any particular considerations about patient groups concerned, such as the rarity of their disease, and the challenges in generating evidence, such as whether the measure of benefit reflects all aspects of value.³¹ Ideally, decisionmakers would make explicit judgments about these wider considerations and how they relate to the CEA's conclusions. One aspect of this would be to show the implications of bringing additional criteria to bear for the CEA estimates of changes in population health. For example, if decisionmakers are considering funding an option that may not be cost-effective in terms of health outcomes but makes treatment available to a patient group that has no other therapeutic options, the implications for overall reduced population health can be shown. Quantifying the opportunity cost in this manner can improve decisions and, if the decisionmakers' evidence, analysis, and deliberations are all transparent, can enhance accountability.

As described earlier, the constraints that decisionmakers need to reflect in their decisions can also extend beyond a limited budget. These may include, for example, human resource constraints, whereby relevant skilled staff are not available in a healthcare system, at least in the short term. As shown, incorporating additional constraints into CEA using formal mathematical modeling is a straightforward approach, at least in principle. Examples of such analyses include those that specify equity as a constraint. There are few examples, however, of the more widely used form of practical CEA reflecting multiple constraints. Developing and using such methods can be considered a research priority.

A method that has relevance to the issue of constraints is "value of implementation" analysis.³² CEA can be seen as effectively estimating the *potential* impact of a specific option on, say, population health. The *realized* impact will partly depend on the extent to which the option is implemented in the system. A number of factors may explain the fact that realized implementation is less than its potential, including a failure of clinical staff to recommend/adopt the option, patient reluctance to use it, or a failure in the healthcare system to deliver the option because of financial or human capital resource problems. These potential factors explaining low levels of implementation of a cost-effective intervention can be considered examples of constraints that were not included in the CEA, either because they were not known or it was not considered feasible to incorporate them formally into the analysis. The gap between the potential and realized impact on population health of an intervention can be termed the value of perfect implementation. It indicates the maximum that the health system can spend to increase implementation in a cost-effective way—that is, it can show how much more cost can be added to the intervention to address the limited implementation and for it to remain cost-effective. This information can guide decisionmakers regarding what they can do to

increase implementation. They may invest in inventions to promote implementation to address supply-side problems, such as funding additional staff to deliver the service or training existing staff; demand-side issues, such as funding travel to get patients into the clinic to have the intervention administered; and health system strengthening more generally. The approach can also include a CEA of particular implementation interventions (alone or in combination). For example, Paul Revill and colleagues used a value of implementation approach to inform the value of strengthening drug supply chains for cotrimoxazole prophylaxis for children with HIV.³³ It offered a means of addressing the challenge of anticipating all the constraints facing health systems at the point of an initial CEA. It also provided a way of linking the economic evaluation of interventions to research into health system structure, financing, and organization, all of which are research areas that have developed largely independently.

Quantifying uncertainty to guide decisions

In guiding decisions, CEA needs to reflect the inevitable uncertainty in estimating the impact of alternative options on population health. This uncertainty can relate to the evidence used as part of the analysis: for example, underlying risks of particular clinical events, the effect of alternative options on this risk, the costs of interventions and of managing the clinical events they are seeking to prevent, the impact of these events on patients' HRQoL, and the longer-term prognostic implications of the events. This evidence is generally drawn from primary studies such as randomized trials and various forms of observational research, and from secondary sources. Evidence is inherently uncertain, however, owing to factors such as sampling uncertainty and the risk of potential bias; together, these can be termed *parameter uncertainty*.³⁴ There is also uncertainty in understanding how the evidence fits together; that

is, *structural uncertainty*, as reflected in assumptions inherent within any analysis such as how long a given treatment remains effective or what happens to a patient's disease when they cease treatment.

A common tool for assessing the implications of uncertainty is sensitivity analysis. This often has taken the form of varying the estimate of a single given parameter to reflect its uncertainty and establishing how the ICER or NHB changes. A thorough uncertainty analysis will, however, consider the combined implications of all forms of uncertainty. Using a method known as probabilistic sensitivity analysis, decisionmakers can be informed about the probability that each mutually exclusive option for a given patient group is cost-effective.³⁵ This can be used to present decision uncertainty: the likelihood that a particular decision—implementing Option B rather than staying with Option A in figure 2, for instance—will be the wrong decision. The implications of any wrong decision can also be presented in terms of wasted resource costs or forgone population health. If a decision is made to fund an intervention that is not actually cost-effective or not to fund one that is, there will be a reduction in net population health compared with decisions made with perfect information. The combination of the probability of a wrong decision and the implication of that decision can be termed the *expected cost of uncertainty*: the cost that the decisionmaker faces as a result of the limitations of existing evidence and understanding. As such, it provides an indication of the maximum value the decisionmaker should place on reducing uncertainty (to improve evidence and understanding) through additional research.³⁶ Methods known as “value of information analysis” extend this to place a value (in terms of financial resources or population health) on particular research studies.³⁷

As well as informing decisionmakers on whether to adopt particular options given existing research, CEA with appropriate uncertainty analysis can guide more nuanced decisions such as adopting an

option only in the context of an active research study, adoption across a patient group but with additional research, or either of these choices with a change in the price that the system pays for a proprietary technology.³⁸ Although this framework for using uncertainty to guide a broader range of decision options has been described, its use in actual decisionmaking is as yet limited. Understanding how the value of an intervention interacts with the value of further research to reduce uncertainty, and reflecting this awareness in decisionmaking, is an untapped source of information for resource allocation decisionmaking.

Conclusion

For many LMICs, the HBP forms a central component of an overall health sector strategic plan. A health sector strategic plan is typically designed for implementation over the medium term, often around five years, and guides the activities of the public healthcare authority (usually the ministry of health) and its closest partners, including bilateral and multilateral donors and nonprofit providers of healthcare. The HBP specifies the interventions that are prioritized for funding. Malawi is one such country that has had a HBP—the Essential Healthcare Package (EHP)—since 2004, and its experience is detailed in box 2.

One of the challenges in using CEA to support decisions in LMICs, as in the case of Malawi, is the limited number of analysts available in many countries to implement this type of work. An international priority is to address this through training and education. Efforts have been made to develop methods to provide generalizable estimates of cost-effectiveness.³⁹ The Disease Control Priorities Project has sought to generate estimates of “good buys” in LMICs for many interventions and disease areas.⁴⁰ However, a key issue is how to support individual countries in taking this type of evidence

and interpreting and adapting it in each setting, and using it as part of a decisionmaking process. It is important to see CEA as a framework for structuring and informing decisions, working closely with relevant decision- and policymakers, rather than solely as a technical exercise that dictates decisions. A recently developed International Reference Case for economic evaluation emphasizes the importance of adhering to CEA principles to support decisions, even when time and analytical resource is short.⁴¹

This chapter has focused on the key elements of CEA methods, but has also considered recent further developments that may enhance the decisionmaking support value of CEA. These developments include empirical research to quantify the cost-effectiveness threshold as an expression of opportunity costs, approaches to augment population health with other objectives as part of CEA, value of implementation analysis, and uncertainty analysis. Other CEA developments may help decisionmakers use CEA to guide decisions about the content of HBPs. These include methods to synthesize complex networks of evidence from many different sources,⁴² the development of decision analytic modeling as a CEA vehicle linking all available information to the decision specifics,⁴³ and improved methods to measure and value HRQoL in a way that is suitable for CEA.⁴⁴

There are particular considerations in using CEA to populate HBPs. Standard CEA methods were developed mainly to support decisions when a defined set of funded interventions already exists, often regarding whether to further invest or disinvest at the margin and, if so, with what opportunity costs. Such decisions could include marginal investments in additional interventions for patient groups not currently covered on the list, or potentially more effective options for patient groups for whom other interventions are currently on the list. This is a similar context to the one in which CEA is used to support decisions about new medical technologies (generally branded pharmaceuticals) in high-income countries.

BOX 2. HBP Design in the Real World: The Essential Healthcare Package in Malawi

The initial motivation of the 2004 Essential Healthcare Package (EHP) in Malawi was to identify interventions for funding that were the most cost-effective and were targeted toward the diseases with greatest overall burden, and then to provide those selected interventions to the whole population free at the point of delivery, without user fees. Malawi's Ministry of Health and its development partners agreed to provide the EHP through a collaborative Sector Wide Approach, which also included combining some of their funding into a common "pooled" account.

The EHP was updated and expanded to include additional interventions in 2011. Cameron Bowie and Takondwa Mwase find that 33 of the 55 EHP interventions fell below an internationally recommended cost-effectiveness threshold of \$150 per DALY-averted (that is, would be deemed "cost-effective," if this were the appropriate cost-effectiveness threshold).^a However, a number of included interventions had ICERs above this level and other excluded interventions had ICERs lower than \$150. Overall it appeared that burden of disease was at least as important a factor in determining choice of interventions for the EHP as cost-effectiveness.

The Malawi experience brought forward a number of challenges in developing a HBP. First, the time available to develop it was limited—it needed to be ready in time for the HSSP, even though more time would have been valuable to determine the optimal plan. Second, the evidence base on the cost-effectiveness of interventions was severely limited—one source of ICER estimates was used^b and no estimates were derived specifically for Malawi. Third, the EHP criteria were not clearly established and the validity of some factors (such as burden of disease) to inform resource allocation was unclear. Fourth, there was no explicit plan for how the EHP would evolve as the evidence base on cost-effectiveness and important inputs (for example, prices) changed.

A further question that has emerged since 2004 as the EHP has been updated is what its role should be in generating revenues for the health sector as opposed to only informing resource allocation. Since 2001 the EHP has expanded and increased in cost from \$17.53 per person per year (pp/py) to \$44 pp/py in 2011—far exceeding any growth in available resources, which changed from <\$5 to \$14.5 pp/py for "all" functions of the health system, including management and health systems strengthening in addition to the direct funding of interventions.^c One reason provided for a large benefits package is its possible role in generating resources. However, trying to implement a HBP that is not fully funded must surely incur large opportunity costs when this leads to the highest value interventions not being implemented. The Ministry of Health in Malawi is currently revising its EHP yet again and is grappling with how to optimally allocate its severely limited resources while also increasing its resources to achieve population health gain.

a. Bowie and Mwase (2011).

b. Jamison and others (2006).

c. Phoya and others (2014).

The methods are also amenable to guiding decisions about which existing interventions are no longer cost-effective and are suitable for disinvestment to make financial room for new activities.

CEA can also be used to guide HBP drafting and development decisions when no existing options are

funded. The mathematical modeling approach to CEA outlined earlier in the chapter is highly suitable for supporting these types of decisions, as it simultaneously identifies the bundle of mutually exclusive options across a range of patient groups, consistent with maximizing a given objective subject to a set

of specified constraints. As discussed earlier, the challenge with the formal use of these methods is the data needed on the costs and benefits of the full range of candidate options for the packages. The simple implementation of CEA, by contrast, would involve estimating a cost-effectiveness threshold and funding the most effective option for each relevant patient group with an ICER below that threshold. The problem here is that these decisions are no longer marginal, as they are likely to involve a commitment of a large proportion of the budget. As decisions are made on what to include in the HBP, the estimate of the threshold will change. Unless the endogenous nature of the threshold is reflected in decisions, there is no means of ensuring that the budget constraint will be respected.

These challenges suggest that something of a hybrid approach to the use of CEA is necessary. This would not generate simple lists, but would contribute to a deliberative process of decisionmaking. An estimate of the current cost-effectiveness threshold reflecting the existing HBP would be a starting point for assessing whether particular interventions are feasible candidates for entering a new package. This cannot be done in a deterministic way, but interventions with ICERs markedly above the existing threshold could be considered a low priority for inclusion. Analysis would then focus on modeling different scenarios regarding which interventions will generate the greatest health gain (in terms of DALYs averted, for instance) with the defined budget. The focus here would be on the absolute costs and health outcomes of the interventions rather than ICERs. A range of scenarios would be necessary that might start with some simple assumptions—for example, that there are no constraints in getting interventions to relevant patient groups or in patient utilization, and that health gain is the only relevant objective of interest. Then changes could be made to those scenarios to reflect the complexities of the system and other policy objectives. For example, scenarios could be

modeled that look at the health gain forgone because of different supply- or demand-side constraints, such as if a given set of interventions only reaches 50 percent of a relevant patient group. The models may give some insights into the value of policy initiatives to relax the constraints, or to strengthen the system. Scenarios could also be run to consider additional policy objectives, such as financial protection, in which the scenario would evaluate what health might be lost if interventions that produce modest gains in health but offer significant financial protection are included in the package. These sorts of analyses do not provide definitive answers for decisionmakers, but rather help inform their judgments about the expected benefits and opportunity costs associated with different HBP configurations. An early example applying these methods was recently developed to inform decisions for the Malawian HBP.⁴⁵

It is possible to identify some priorities for further development in CEA methods for their use specifically in informing decisions about HBPs in LMICs. First, whether formal CEA is used or not, any decisions regarding the allocation of limited resources to alternative healthcare interventions and programs needs to estimate opportunity costs—the benefits forgone by funding one option rather than alternatives. With the practical CEA outlined in this chapter, this measure of opportunity cost is represented by the cost-effectiveness threshold: the maximum acceptable ICER. Few countries have empirical estimates of this threshold; further empirical work is underway, but a major research program is needed for this area. A second research priority relates to health system constraints in LMICs other than those related to financial resources, particularly in terms of developing methods to reflect these additional constraints more formally in CEA. Assuming that these constraints can be identified and appropriately quantified, they can be readily incorporated into mathematical modeling and then perhaps into the more widely used form of CEA, perhaps building

on the methods of value of implementation analysis outlined earlier. A third research priority involves the broad area of evidence—the estimates of clinical, resource use, and epidemiological quantities that drive CEA. There is not enough appropriate evidence for CEA in all jurisdictions, but this lack is particularly acute and likely to continue in LMICs. Therefore, improved methods are needed to make the most efficient use of existing evidence and to generalize evidence from the settings in which it was generated to inform decisions made elsewhere.

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CHAPTER 5

Benefits beyond Health

Evaluating Financial Risk Protection and Equity through Extended Cost-Effectiveness Analysis

Stéphane Verguet

Dean T. Jamison

At a glance: Extended cost-effectiveness analysis helps quantify equity and the non-health impacts of health policy, like financial risk protection.

Multiple criteria are involved in decisionmaking and prioritization of health policies.¹ The trade-offs between efficiency and equity are among these criteria, and have long been emphasized in the field of HIV/AIDS treatment and prevention, for example.² Notably, several mathematical frameworks, including mathematical programming, have proposed to incorporate equity considerations into resource allocation in the public sector.³

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Protection from financial risks associated with healthcare expenses is emerging as a critical component of national health strategies in many low- and middle-income countries (LMICs). The World Health Organization's (WHO) 1999 and 2000 *World Health Reports* included provision of financial risk protection (FRP) as one criterion of good performance for health systems.⁴ The reduction of these financial risks is one objective of health policy instruments such as universal public finance (UPF): full public finance for healthcare services irrespective of whether services are provided privately or publicly. Indeed, out-of-pocket medical payments can lead to impoverishment in many countries, with households choosing from among many coping strategies such as borrowing from friends and relatives or selling assets in order to

manage health-related expenses.⁵ Absent other financing mechanisms, household medical expenditures can often be “catastrophic”⁶—defined as exceeding a certain fraction of total household expenditures.

Health policies such as UPF of health interventions entail consequences in multiple domains. Fundamentally, uptake of interventions and hence UPF provides increased health benefits, including disease cases prevented and deaths averted. Yet UPF also can generate distributional benefits such as enhancing equity (in the sense of equalizing health among individuals in a given population) and non-health benefits, such as preventing medical impoverishment or providing FRP.

Traditionally, economic evaluations of health interventions, known as cost-effectiveness analysis (CEA), have focused on health improvement and have estimated an intervention cost per health gain, in dollar per death averted or dollar per disability-adjusted life-year (DALY) averted.⁷ That said, arguments have been developed for some time that CEA in health should start to explicitly consider the multiple dimensions of outcome. The CEA chapter of the *Oxford Textbook of Public Health*, for example, argues that FRP should be included in the outcome side and utilization of scarce health system capacity should be listed on the cost side.⁸ The goal of this chapter is to detail the methods of extended cost-effectiveness analysis (ECEA),⁹ which extends traditional economic evaluation with distributional aspects (such as health and financial aspects) and with an evaluation of the FRP consequences of policy. ECEA thus serves broader objectives than CEA in providing guidance in the design of health policies in general and health benefits packages (HBPs) in particular.

The basic concepts and methods of ECEA were first laid out in an analysis of policies for expanding tuberculosis treatment in India, and ECEA has since been applied in more than 20 contexts. The genesis of ECEA was to improve the policy relevance of the third edition of *Disease Control Priorities in Developing*

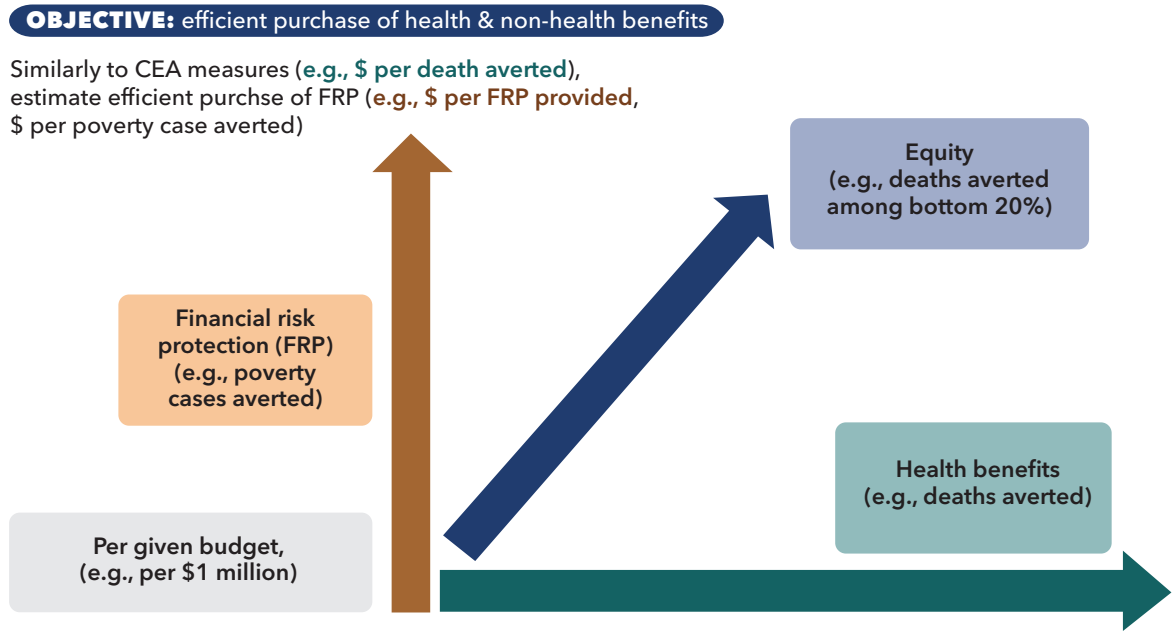
Countries, and multiple ECEAs were undertaken in support of this goal.¹⁰ In this respect, ECEA presents similarities with the existing frameworks of cost-benefit analysis and cost-consequence analysis tabulating disaggregated results,¹¹ with analytical frameworks incorporating equity and FRP concerns into economic evaluations.¹² It enables the design of HBPs that quantify health, distributional, and non-health benefits for a given expenditure on specific health policies, based on the quantitative inclusion of how much distributional and non-health benefits are being bought, as well as how much health benefits are being bought with a given investment on a policy. In this respect, ECEA can give answers to some of the policy questions raised by the 2010 and 2013 WHO *World Health Reports*¹³ on how to select and sequence the health services to be included in HBPs in LMICs.

Approach

Consider the implementation of a given health policy in a given population, such as public finance for a package of vaccines, taxation on tobacco products, or legislation to enforce mandatory wear of helmets. The population can be subdivided into subgroups: per socioeconomic status according to five income quintiles, per region according to geographical locations (such as by state, region, or county), or per gender.

The policy presents a given coverage and given effectiveness on preventing disease burden in the population, as well as a net cost. What the ECEA methodology examines is a health policy assessment in quantifying not only the health benefits but also selected non-health benefits in the population, and their distributions, for a given increment in public (or private) expenditure (see figure 1, which graphically depicts the main objective of ECEA).

FIGURE 1. The Main Objective of ECEA

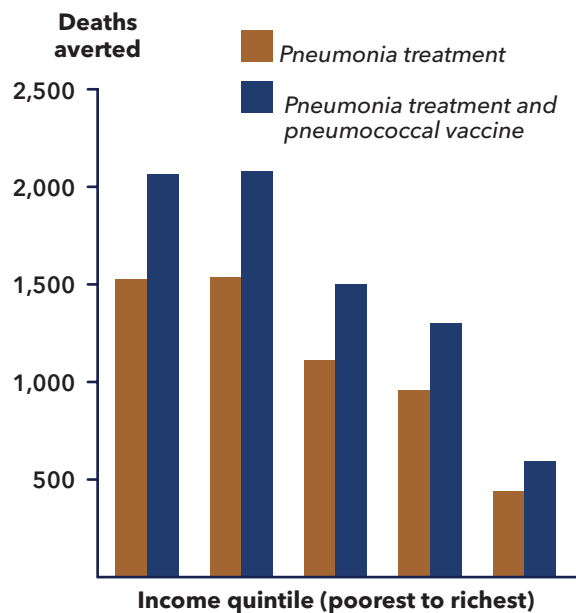


Source: Verguet and Jamison (2017).

Health benefits

With the introduction of the policy, health benefits are procured, quantified (for example) by the sum of the burden of disease averted in each population subgroup, potentially with a specific effectiveness of the policy assumed to be constant per population subgroup. In this respect, the ECEA estimates the distributional health consequences, and in particular benefits (such as mortality, morbidity averted, disability-adjusted life-years [DALYs] averted, quality-adjusted life-years [QALYs] gained), per population strata, whether per socioeconomic group or geographical setting (see figure 2, which displays per income quintile the under-five deaths averted with UPF of pneumonia treatment and/or vaccination in Ethiopia).

FIGURE 2. Under-five Deaths Averted with UPF of Pneumonia Treatment and/or Vaccination in Ethiopia



Source: Verguet, Pecenka, and others (2016).

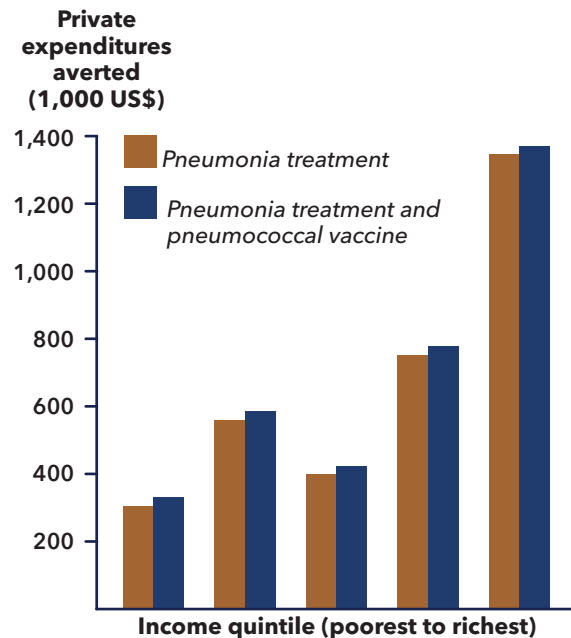
Non-health benefits

With the policy, non-health benefits (such as FRP or number of school days gained) are procured. For example, if one considers FRP, given a preexisting burden of illness-related impoverishment—including medical expenses, direct nonmedical costs such as transportation costs, and wages lost—the related non-health benefits could be expressed, for example, by the sum of the burden of illness-related impoverishment averted in each population subgroup. Illness-related impoverishment can be driven by direct medical costs at the point of care or transportation costs to seek care in a health facility, as well as the income lost and productivity losses among individuals and their families incurred by the onset of illness. Data on the out-of-pocket medical costs incurred by LMIC patients are scarce, and there is even less information on transportation costs borne by patients and families and extremely little information on the income and productivity losses incurred, even though some conditions like chronic diseases can have a substantial negative effect on productivity and income.

So far, ECEA has essentially focused on one type of non-health benefits: private expenditures averted and FRP. In addition, ECEA has mostly accounted for out-of-pocket costs due to medical care and transportation, and has put little emphasis on indirect costs such as income and productivity losses. ECEA does not intend to have a narrow view of FRP, but simply is limited in its application by both the availability of data and the observation that health system policies affect health outcomes and health-expenditure-related financial outcomes. ECEA thus encompasses the usual range of health policy objectives while acknowledging that other dimensions of social policy (such as sick leave) may also be significant.

Specifically, the ECEA approach will disaggregate what is usually called the “societal” perspective in traditional economic evaluations¹⁴ to examine the

FIGURE 3. Private Expenditures Averted with UPF of Pneumonia Treatment and/or Vaccination in Ethiopia



Source: Verguet, Pecenka, and others (2016).

perspective of households in estimating the amount of private expenditures incurred by households (including direct medical and nonmedical costs as well as indirect costs) that could be averted by a specific policy (see figure 3, which displays per income quintile private expenditures averted with UPF of pneumonia treatment and/or vaccination in Ethiopia).

Subsequently, once the amount of out-of-pocket private expenditures borne by households that may be “crowded out” is estimated, ECEA will attempt to “scale” this amount of out-of-pocket household expenditures by households’ disposable income in order to estimate FRP. A household with a \$100,000 annual income and \$10 in out-of-pocket expenditures remains much less severely impacted than a household with a \$100 annual income but the same amount of expenditures.

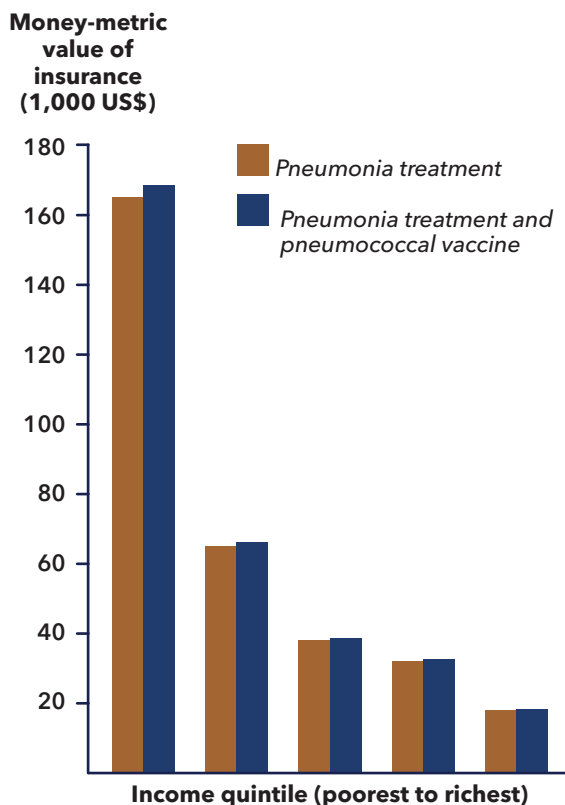
To estimate FRP, several metrics can be used,¹⁵ including the following:

- Number of catastrophic health expenditures averted, estimating the number of households no longer crossing a “catastrophic” threshold (such as 10, 20, or 40 percent of income or capacity to pay) due to out-of-pocket expenditures;
- Number of poverty cases averted, estimating the number of households no longer crossing a national “poverty line” (for instance, in 2010 about 30 percent of the Ethiopian population was estimated to be below the poverty line)¹⁶ due to out-of-pocket expenditures;
- Number of forced asset sales or forced borrowing averted; and
- A money-metric value of insurance provided, quantifying the willingness to pay or risk premium associated with the policy (see figure 4, which displays per income quintile the insurance value provided with UPF of pneumonia treatment and/or vaccination in Ethiopia).

Equity benefits

With the policy, equity benefits, as estimated here in terms of health distribution, can be procured. For example, if the policy provides more health benefits for poorer segments of the population than for richer segments of the population, the policy could be deemed “equity enhancing” (see figure 2). There are many ways to numerically quantify the equity benefits: one simple metric is the ratio between the health benefits procured by the policy among the poorest group and the total sum of the health benefits in all groups.

FIGURE 4. FRP with UPF of Pneumonia Treatment and/or Vaccination in Ethiopia

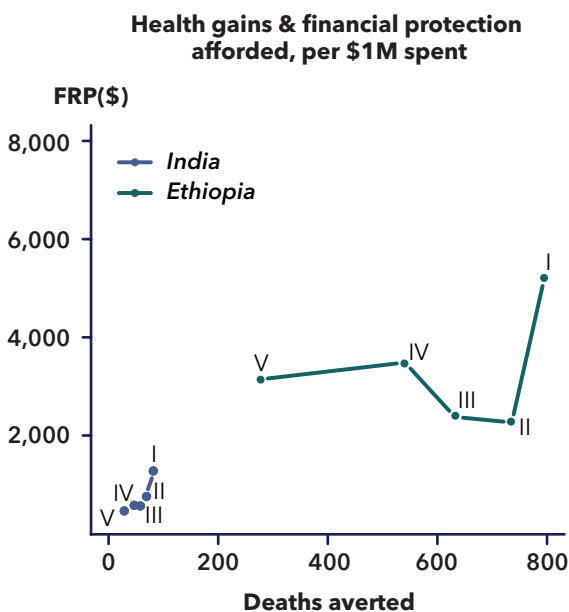


Source: Verguet, Pecenkova, and others (2016).

“Efficient purchase” of health and non-health benefits

Consider the net cost of the policy is C , hence for that net cost the policy purchases “efficiently” health benefits B_H , but also non-health benefits B_{NH} (e.g., B_{FRP}) and distributional benefits (B_{Eq}). This then presents, as in CEA, a usual incremental cost-effectiveness ratio (ICER) such as $ICER = C/B_H$, but can also define an ICER for the non-health benefits (for FRP, with $ICER_{FRP} = C/B_{FRP}$); and the distributional benefits (for equity, with $ICER_{Eq} = C/B_{Eq}$). In this respect, ECEA can help quantify the efficient purchase of both equity and FRP, in addition to the efficient purchase of aggregated health gains. To illustrate, figure 5 displays the number of child deaths averted and FRP provided (measured by money-metric value

FIGURE 5. Deaths Averted and FRP with UPF for Rotavirus Vaccination per \$1M India and Ethiopia



I = poorest, II = poorer, III = middle, IV = richer, V = richest. Source: Based on estimates from Verguet and others (2013).

of insurance) among income groups per \$1 million spent on publicly financed rotavirus vaccines in India (with a vaccine price of \$2.50 per dose) and Ethiopia (with a vaccine price of \$0.20 per dose).

Applications

ECEA was initially developed under the auspices of the Disease Control Priorities Network (DCPN) grant funded by the Bill & Melinda Gates Foundation and the *Disease Control Priorities*, 3rd edition (DCP3). The DCPN/DCP3 agenda enabled the construction of a broad range of health policy assessments for policies and settings (table 1). The policies in question included public finance, excise tax, legislation,

regulation, conditional cash transfers, task-sharing, education, and improved access to credit.

ECEAs are context-specific and depend substantially on the epidemiology of the setting, including endemicity and distribution of specific diseases; the local health system infrastructure, including the presence and distribution of health facilities; the wealth of the location; and the financial arrangements, including the presence of social health insurance or community-based insurance. As with CEAs, patterns are likely to emerge as the number of completed ECEAs increases.

Dashboard Utilization Example

The following example (table 2) illustrates ECEA in considering UPF for tuberculosis (TB) treatment in a population composed of five income quintiles totaling 1 million people (with 200,000 people per each income quintile), drawing on the first completed ECEA.¹⁷ It assumes an average incidence of TB of $p_0 = 100$ per 100,000 per year, with incidences of respectively 200, 150, 100, 50, and 0 per 100,000 in the five population subgroups. TB treatment is assumed to be effective at 90 percent and current coverage is assumed to be 40 percent uniformly across each income quintile. It also assumes a coverage increase of 10 percent equal across all five subgroups through UPF. The case fatality ratio from TB is assumed at 25 percent. In addition, before the policy is introduced, individuals who are TB-infected purchase TB treatment (40 percent of them) at $c = \$100$ out of pocket; after UPF of TB treatment, they spend no money out of pocket. Finally, it assumes a population income distribution following a gamma distribution based on a mean income of \$1,600 and a shape of 3.5, as produced by an algorithm given by Salem and Mount,¹⁷ which yields the following median income within the five population subgroups: $\{648; 1068; 1450; 1916; 2747\}$.

TABLE 1. ECEA Completed as of May 2017 for the *Disease Control Priorities*, 3rd ed.

Health policy/Intervention	Setting	Source
Universal public finance; improved access to credit/ Tuberculosis treatment	India	Verguet, Laxminarayan, and Jamison (2015)
Universal public finance/Rotavirus vaccine	Ethiopia/India/ Malaysia	Verguet, Murphy, and others (2013); Loganathan and others (2016)
Universal public finance/Immunization	India	Megiddo and others (2014)
Universal public finance/Diarrhea treatment	Ethiopia	Pecenka and others (2015)
Universal public finance/Pneumococcal vaccine and pneumonia treatment	Ethiopia	Johansson and others (2015)
Universal public finance/HPV vaccine	China	Levin and others (2015)
Clean piped water and improved sanitation/ Water and sanitation	India	Nandi, Megiddo, and others (2016)
Universal public finance/Home-based neonatal care package	India (rural)	Ashok, Nandi, and Laxminarayan (2016); Nandi, Colson, and others (2016)
Universal public finance/Mental health package	Ethiopia/India	Chisholm and others (2016); Johansson and others (2017); Megiddo and others (2016); Raykar and others (2016)
Universal public finance/Bundle of interventions	Ethiopia	Verguet, Olson, and others (2015)
Excise tax/Tobacco	China/Lebanon/ Armenia	Verguet, Gauvreau, and others (2015); Salti, Brouwer, and Verguet (2016); Postolovska and others (2017)
Legislation/Salt content in foods	South Africa	Watkins and others (2016)
Regulation/Motorcycle helmets	Vietnam	Olson and others (2016)
Conditional cash transfer/Measles vaccine	Ethiopia	Driessen and others (2015)
Task-sharing/Surgical delivery	Ethiopia	Shrime and others (2016)
Education/Postponing age at parity among young adolescent women	West Africa/ South Asia	Verguet and others (2016)
Commodity subsidy/Use of liquefied petroleum gas and other clean energy sources in household	India	Pillarisetti, Jamison, and Smith (2017)

Source: Verguet and Jamison (2017)

Per 1 million population, the total number of deaths averted would be about 23 per year. The health benefits would be concentrated among the bottom income quintile (40%) as TB is more incident among this subgroup. The total number of

private expenditures averted by UPF would be about \$40,000. The bottom income quintile would benefit from about 40% of the private expenditures averted. The total (incremental) treatment costs incurred by UPF would be about \$50,000 (\$40,000 + \$10,000).

TABLE 2. ECEA Results for UPF of Tuberculosis (TB) Treatment to 40 + 10 Percent Coverage (per 1 million population)

Outcome	Total	Income Quintile I	Income Quintile II	Income Quintile III	Income Quintile IV	Income Quintile V
TB deaths averted	23	9	7	5	2	0
Private expenditures averted	40,000	16,000	12,000	8,000	4,000	0
Poverty cases averted	160	160	0	0	0	0

The total FRP afforded by UPF, estimated here as the number of poverty cases averted (number of individuals no longer falling under a poverty line of say \$600 of income) would be about 160, all of which would be among the bottom quintile. Lastly, the equity benefits of UPF would be (for example) 9 divided by 23 divided by 50,000 = approximately 8 per 1 million (table 2).

Examining the efficient purchase of health and non-health benefits, $ICER = \$2,222$ per death averted, and $ICER_{FRP} = \$313$ per poverty case averted. Scaling per \$1 million spent, this example shows 450 deaths averted, 180 of which are among the bottom income quintile, and 3,200 poverty cases averted, all of which among the bottom income quintile. The policy option of improving access to credit—to facilitate borrowing for treatment—was also examined. While under reasonable assumptions the health outcomes were almost as good as for UPF, the financial outcomes calculated for the poor were (not surprisingly) far worse.¹⁸

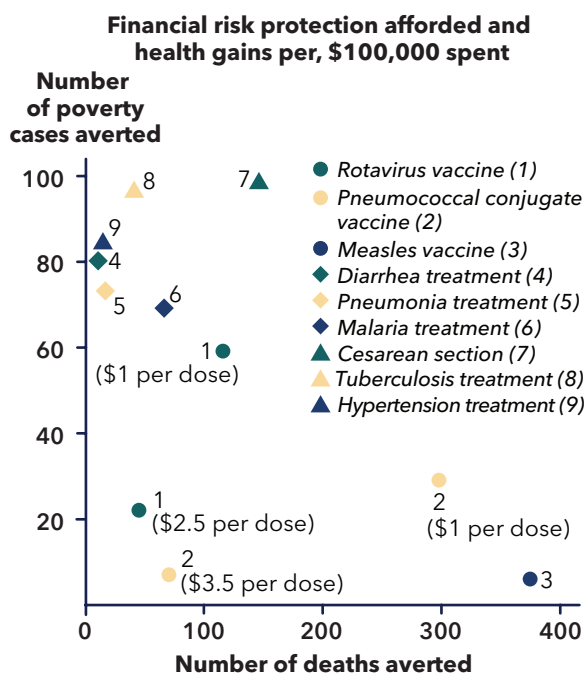
Discussion

The above examples present detailed methods for the broader economic evaluation of health policies, known as extended cost-effectiveness analysis or ECEA. ECEAs build on CEAs in assessing consequences in not only the health domain but also in the distributional (equity) and non-health domains

(starting with FRP). These two domains encompass major objectives for health systems.

ECEA stresses the potential poverty reduction benefits of health policies. Specifically, ECEA explicitly quantifies the FRP benefits—which could be translated into poverty alleviation benefits—of policies. In this respect, it fulfills two major objectives.

FIGURE 6. Poverty Cases Averted versus Deaths Averted for Nine UPF Interventions in Ethiopia



Source: Verguet and others (2015).

First, it provides a quantitative tool that enables intersectoral comparison of health policies with other sectors, such as education and transport, of particular relevance for ministries of finance in LMICs. Second, it provides valuable information to policymakers for assembling a basic HBP, taking into account how much health along with how much equity and FRP they can buy per dollar investments in specific interventions (see figures 5 and 6).

The ECEA approach enables multiple criteria to be included in the decisionmaking process: health gains, FRP, and distributional considerations. Depending on the preferences of policymakers and users, decisionmakers can directly select and optimize the choice of the interventions to be included in the HBP, depending on the “scores” or returns on investment of each intervention on the three criteria of health, FRP, and equity. As a case in point, figure 6 displays, for each of nine interventions provided through UPF in Ethiopia, the deaths averted (x-axis) and poverty cases averted (y-axis) by incremental public expenditure of \$100,000 on each intervention. From these two-dimensional findings, one would first certainly discard the “dominated” interventions (those situated within the bottom-left quadrant), which are the interventions that would score low on both health and FRP benefits. Traditionally, investments in health for the HBP have focused on the right side of the figure: the selection of the cost-effective interventions yielding a low cost per DALY averted or a low cost per death averted, such as the measles vaccine shown in figure 6. What ECEA adds to the selection process is the consideration of the interventions and policies that are cost-effective in terms of FRP (shown in the upper side of figure 6), including Caesarean section, TB treatment, and hypertension treatment.

Conclusion

Although ECEA is not prescriptive with regard to what should be included in the HBP, this type of analysis enables policymakers to take both the health and FRP domains, as well as returns on investment, into account when finalizing the package. For instance, based on the findings displayed in figure 6, hypertension treatment might be retained in the HBP based on its FRP dimension score even though it likely would be excluded on the basis of its health benefits dimension score. Similarly, universal public financing of a 10 percent increase in TB treatment and a 10 percent increase in malaria treatment seemed to provide similar numbers of deaths averted per dollar expenditure. However, TB treatment seemed to provide substantially more FRP than malaria treatment, and thus would likely be the better investment if one had to decide on only one of the two interventions for inclusion in the HBP.

ECEA allows policymakers to take health, distributional, and non-health outcomes into account when making decisions and thus to more effectively target scarce healthcare resources toward specific policy objectives. The ECEA approach also provides policymakers with information on how they might sequence over time the development of HBPs as the health and financial needs of populations evolve and resource envelopes change, which is especially relevant in the context of economic development, the epidemiological transition, and moving toward UHC.

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CHAPTER 6

Comparing Apples and Oranges

Strategies to Weigh Health against Other Social Values

Alec Morton

Jeremy A. Lauer

At a glance: What are some strategies to balance health against other social goals? Consider cost-effectiveness analysis, multicriteria decision analysis, or cost-benefit analysis.

The management of health services presents a unique difficulty: although some services are highly effective, in that they can deliver significant value to some patients, at least some of the time,

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identifying which services deliver such value is a difficult and costly undertaking. Since patients in general are unable to assess, on a treatment-by-treatment basis, which services (if any) they may benefit from, health services in rich countries generally are funded through government or heavily regulated private insurance schemes. These schemes, which have a risk-pooling function, are able to employ expertise to make informed decisions about what to reimburse.

As low- and middle-income countries (LMICs) expand the share of population that is covered in such insurance schemes (in the broadest sense), the range of services covered, and the extent to which costs are met, they have to make difficult decisions about what and how much to fund. At the same time, as medical science advances, many rich countries have found that they are unable to afford all conceivably

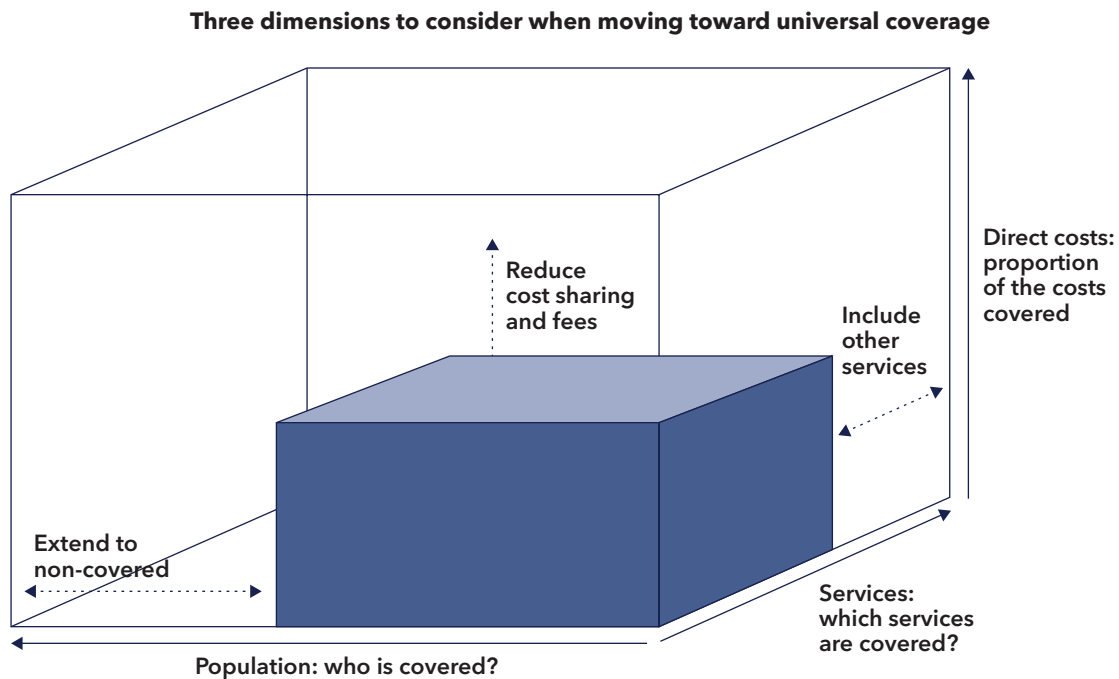
beneficial medical technologies within the budget envelope determined by the public financing settlement. These pressures on rich countries have been exacerbated by the financial crisis and seem set to intensify further as their populations age. Thus, the questions of how to decide what to cover, whom to cover, and how much to charge is becoming increasingly pertinent in both richer and poorer countries—as illustrated in the famous cube of universal health coverage (UHC) (figure 1).¹

This chapter takes the view that defining the HBP should be driven by *explicit* social values. Social values affect the selection of goals and objectives, as well as the weight attributed to them. One approach to making choices is through “implicit rationing” where the decision about what to provide is delegated to a resource-constrained local provider, which then discourages excess demand through, for example,

requiring long waits for treatments or imposing local clinical thresholds for treatment. However, this approach is likely to result in arbitrary, inconsistent, and unfair decisionmaking. Using explicit goals and values to guide the construction of the HBP promotes transparency in decisionmaking, accountability of decisionmakers to the demands of good governance, ownership of the outcome by stakeholders who can participate, and demonstrable fairness to beneficiaries. (See chapter 1 for a more detailed discussion of these issues.)

Clearly, an important goal of a HBP is the maximization of population health. Lists of other goals (objectives, criteria, and the like) often include items such as affordability, financial protection, fairness, economic productivity (especially labor productivity), and exogenous goals such as the goals of aid donors. Other important concerns

FIGURE 1. Cube of Universal Health Coverage



Source: Reprinted from World Health Report 2010: *Health Systems Financing: The Path to Universal Coverage*, p. 12, Geneva: World Health Organization. Copyright (2010). Reproduced with permission.

include accessibility, feasibility of implementation, and strength of evidence. The UHC cube provides a useful way to summarize and capture all of these goals and concerns.

Affordability is a key idea in the cube because it conceptualizes the construction of the HBP as an exercise in allocating a fixed quantum of pooled funds. *Financial protection* is represented along one axis as the proportion of costs which are to be covered. *Fairness* and *economic productivity* are captured by the “who should be covered” axis (should it be those who are most ill and poor, or disadvantaged in some other way? Or should it be those whose health is most valuable to society, because of the labor they contribute, whether formally in the labor market or informally as parents and carers?). Exogenous goals such as the *goals of aid donors* may be expressed with reference to the services provided (many donors have a mandate for a single or small number of diseases) and/ or the populations served (donors may have a particular focus on groups or issues such as children or excluded populations). *Accessibility*, *feasibility of implementation*, and *strength of evidence* all relate to instrumental concerns about whether the services provided do in fact contribute to the overall goal of a HBP, namely population health itself.

The social value that has engendered perhaps the most discussion and controversy is the criterion of fairness or equity (see also chapter 13).² However, there is not yet any consensus on whether fairness should be taken into account in formal analysis, and if so, how to do so.³ Some authors have recommended the presentation of distributional information about baseline levels of health and computation of equity indices so that the equity implications of particular investment choices can be made.⁴ Others have proposed forms of sensitivity analysis that enable decisionmakers to get a feel for what sorts of decisions might be compatible with a plausible range of values, operationalized as differing weights for different sub-populations.⁵ Different people have wildly different

and conflicting judgments about what constitutes a fair allocation—for example, should more economically productive people receive more access to healthcare on the grounds that they contribute more to society; or should poorer people have priority on the grounds they have suffered other injustices? Perhaps even more than other considerations, the central importance of fairness is a reminder that decisions about the contents of a HBP cannot be determined by algorithm, but must be developed by or through close consultation with politically legitimated decisionmakers in a deliberative process.

Whatever one’s objectives, the critical informational problem—knowing what is the best technology for some particular medical problem and whether that medical technology works well enough to justify spending money on it—remains hard to solve. Moreover, funders face the additional complexity of having to decide not just what to fund for an individual but how to balance funding across the entire insured population, and what system of financing or copayment works best for the population concerned. Over the past several years, various methods have been developed and proposed to help policymakers that are struggling with such tough decisions.

This chapter presents three principles to guide a review of available methods. The premise of this chapter is that methods for supporting decisions about what is to be included in a HBP should be reflective of the range of social values that feature in health policy discourse alongside the improvement of population health. However, methods should also be:

- **Technically robust and justifiable.** Agreed standards for good practice should exist, and it should be possible to justify the analysis to relevant professional and lay communities both nationally and internationally.
- **Easy to understand.** It should be possible for nonexperts (patients, journalists, politicians) to

engage with analyses and understand the rationales for decisions. Even if models are complicated, it should be possible to communicate key qualitative insights clearly.

- **Have low cost of implementation.** All methods require some cost and some specialized staff to implement properly. However, methods should not impose excessively burdensome demands in terms of analytic staff.

This chapter critically reviews some of the methods that have been advocated and used to support investment decisions about medical services and technologies with respect to an explicit HBP. It begins with an overview of the standard cost-effectiveness paradigm and discusses multicriteria decision analysis (MCDA), extended cost-effectiveness analysis (ECEA), and cost-benefit analysis (CBA). The methods are illustrated with country case studies from Mexico, Thailand, Chile, and India. The chapter concludes with a critical review of the methods presented against the principles introduced above.

Cost-Effectiveness Analysis

In chapter 4, Mark Sculpher and colleagues summarize the principles underlying the usual practice of cost-effectiveness analysis (CEA) in health systems.⁶ CEA was developed and synthesized in the 1970s and 1980s and is the current dominant paradigm of health economic assessment in rich countries. Generalized CEA (GCEA) was synthesized by the World Health Organization (WHO) following the Global Burden of Disease studies and was designed for use in LMICs. In their usual application, both these approaches take the view that in deciding what healthcare programs to fund, the critical elements to consider are the costs of supplying the intervention (*c*), and the health benefits which are delivered (*b*).

These two measures are often synthesized in terms of a cost-effectiveness ratio, *c/b*. ECEA and CBA can be viewed as extensions of this basic paradigm in which analysts seek to capture a broader range of benefit consequences. (See box 1 for a CEA case study involving healthcare reform in Mexico.)

BOX 1. Use of CEA to Support the Mexican Health Care Reform Agenda

In 2003, under Minister of Health Julio Frenk, Mexico introduced a set of health reforms called the System of Social Protection in Health (SSPH, or Sistema de Protección Social en Salud).^a The SSPH included the provision of a defined set of population-based interventions as well as a defined set of personal healthcare services for uninsured persons. Explicit consideration of evidence on the effects, costs, and cost-effectiveness of interventions was an integral consideration in determining the sets of services to offer.^b

Although the reforms increased coverage substantially (according to official estimates, 88 percent of the previously uninsured population was covered by 2010), costs also rose, and the ministry of health continued to rely on evidence of cost-effectiveness in determining the modification of benefit packages:

After the reform, evidence on cost-effectiveness continues to inform decisionmaking regarding amendments to the packages of services covered by SSPH; state-level policies regarding coverage of interventions beyond the defined minimum packages; and broader debates over the advantages and disadvantages of explicit packaging based in part on economic evidence—for example, among social security institutions in Mexico that do not currently base coverage decisions on explicit packages of interventions.^c

a. Frenk and others (2006).

b. González-Pier and others (2006), and Salomon and others (2012).

c. Salomon and others (2012).

QALYs or DALYs?

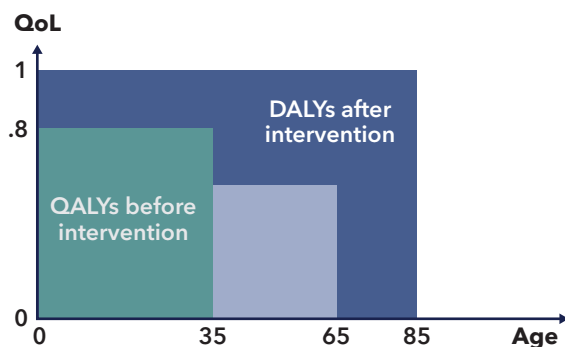
In the application of CEA to high-income settings, the dominant measure of health outcomes used has been the QALY (quality-adjusted life-year).⁷ In contrast, the dominant outcome instrument used in lower-income settings, and in particular using GCEA, has been the DALY (disability-adjusted life-year). Both concepts represent attempts to integrate survival and wellbeing in a single measure of health. These concepts differ, however, in the sense that QALYs are a measure of health gain, whereas DALYS are a measure of health loss. Specifically, the DALY seeks to indicate the extent to which the individual’s lifetime health falls short of a full life in perfect health up to some reference age, sometimes defined as the average age attained in the country with longest life expectancy.

This difference is illustrated in figure 2. To understand this figure, consider a man who lives to age 35 with some troublesome health condition, which means that his quality of life is rated as 0.8 on a scale where 0 is dead and 1 is full health. The man then receives a life-saving intervention that extends his life (in some further degraded health state) until age 65, whereupon he dies. Before the intervention, this man would have a lifetime health stock of $35 \times 0.8 = 28$ QALYs (the area of the light-shaded region in figure 2). To calculate his DALYs, the evaluation requires a reference age, which for the purposes of

illustration here is given as 85. The example man’s DALYs are $85 - 35 \times 0.8 = 57$ (the area of the top right-hand dark blue region plus the area of the middle light blue region in figure 2). Extending this man’s life provides a gain in QALYs, or an equivalent reduction in DALYs, equal to the area of the middle light blue region in the figure.

Although QALYs and DALYs are conceptually similar (while differing in sign), they differ significantly in terms of the way the quality-of-life weights for particular health states are derived. Typically, the weights used in the QALY are based on a generalized descriptive instrument such as the EQ-5D (Euro-Qol Five Dimensions Questionnaire),⁸ which seeks to capture the main dimensions of health-related wellbeing; in the case of EQ-5D, these are mobility, self-care, ability to carry out usual activities, pain/discomfort, and anxiety/depression. In other words, to calculate QALY gains, changes in disease status have to be mapped into this generalized descriptive scheme. DALYs, by contrast, classically use diagnostic categories from the WHO International Classification of Diseases (ICD) for weighting. A further complication in using the DALY is deciding on the reference age—Mara Airoidi and Alec Morton, for instance, point out that if (as recommended in the original WHO guidance) reference lifetables are used, this can lead to counterintuitive results.⁹ In current thinking about GCEA, the term “DALY” is now downplayed, other than in the original burden of disease context where a loss measure is the natural one to use. GCEA now uses a gain measure called “healthy life-years,” which differs from QALYs only with respect to the weights used for health states.

FIGURE 2. Difference between QALY and DALYs



Overview of the CEA approach

Chapter 4 gives an extended discussion of the main elements of the usual applications of CEA. This subsection will discuss two specific approaches to using CEA: league tables and expansion paths. To keep

the examples manageable, the discussion focuses on technologies and services for chronic obstructive pulmonary disease (COPD), although there is no reason for analysts to restrict their analysis to a single disease, with data drawn from the 2012 *IMPRESS Guide to the Relative Value of COPD Interventions*.¹⁰ Indeed, the methods presented here are explicitly designed to aid in prioritization across disease programs and clinical areas.

A critical first step in undertaking a CEA is to specify the base case for coverage. Costs and benefits are incremental to this base case. One interpretation of this base case is that it is “current care”: that is to say, coverage that is assumed to be provided if no changes are made on the basis of the analysis. In practice this is often the assumption made by countries when first developing a HBP. However, one might take alternative views of the base case: for example, one might define a “zero-based” base case in which no care is provided (this is what is typically recommended in GCEA). This view may be particularly useful if one wishes to establish whether current care represents the most efficient mix of services, and can offer an indication of the opportunity cost of failing to choose the HBP on the basis of CEA principles.

The motivating problem for the league table approach is whether a candidate investment provides a sufficient improvement in health gain relative to the increase in cost, compared to some specified baseline such as current care, to justify funding. Within this problem frame, a natural way to report results

is as so-called cost-effectiveness league tables. As an example of a league table, consider table 1, showing interventions for COPD.¹¹ The intended base case in this case is current care in a locality with the characteristics of a typical London borough.

An important assumption behind the QALY league table is that the different interventions which are being considered are independent. In the case of the interventions of table 1, interventions 1 and 4 are targeted at different population subgroups from interventions 2 and 3, and so 1 and 4 cannot interact with 2 and 3. Moreover, interventions 1 and 4 are unlikely to interact with each other, as uptake for exercise and smoking cessation will be relatively small as a percentage of the target population and so the people who obtain the benefits from smoking cessation will be mostly different people than those who obtain the benefits from exercise. It is a reasonable first-cut assumption to suppose that interventions 2 and 3 are independent (smoking cessation is concerned with slowing disease progression and provision of oxygen is concerned with symptom relief), but one could envisage interactions between these two interventions—for instance, oxygen may give less benefit to nonsmokers as their symptoms will be milder—and so there may be scope for additional modeling. This could, for example, take the form of considering smoking cessation and oxygen provision together as a distinct, independent “combination” intervention.

From a normative point of view, it can be shown that subject to the assumptions about independence,

TABLE 1. QALY League Table for COPD Investments

Intervention	Incremental £ / QALY
1. Exercise—Mild to moderate COPD	1,486
2. Oxygen—Severe COPD	10,333
3. Smoking cessation—Severe COPD	10,400
4. Smoking cessation—Mild to moderate COPD	24,375

the optimal solution to the problem of allocating money between these different treatments has the following form: invest in all treatments with cost-effectiveness ratios below a certain level and none of the treatments with cost-effectiveness ratios above that level.¹² For example, if the cost-effectiveness threshold to be applied in the COPD example of table 1 is £20,000 per QALY, one would invest in the exercise and oxygen interventions, and smoking cessation for people with severe but not mild to moderate COPD.

This raises the question of where the threshold should lie. The most natural meaning of the threshold in economic theory is as the shadow price of the budget. In the context of UHC, this would be the cost to the health budget of the marginal health benefit at optimality. As discussed in chapter 4, evidence on the likely value of this threshold in countries at different income levels is scarce. Analysis by Beth Woods and colleagues seeks to estimate country-level thresholds by extrapolating analysis from the United Kingdom to other countries.¹³

One way to enrich the analysis is to assess not just the costs and benefits of treatment but also the scale of treatment. This leads into the expansion path approach.¹⁴ This approach avoids the necessity of identifying a cost-effectiveness threshold but requires instead an explicit budget envelope for expenditure. To do such an analysis requires additional information, since while information on individual costs and benefits can be derived from clinical studies, multiplying the estimates of costs and benefits up to identify the total budget impact requires a further assessment of the population’s capacity to benefit (which in turn requires knowledge of the current coverage of the intervention considered and the prevalence of the condition that the intervention is intended to treat). This may be relatively simple. For example, if one is substituting drug-eluting stents for bare-metal stents, this is unlikely to significantly change existing demand for angioplasties. However, collecting information may also be difficult and

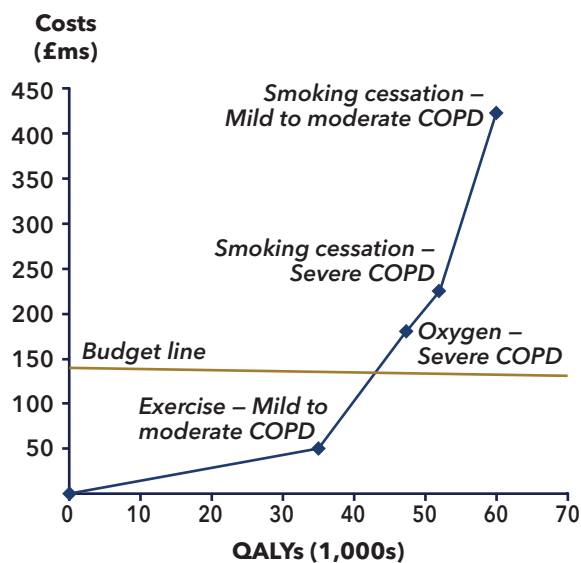
costly; if one is rolling out a new program for treating bilharzia in a remote region, for instance, the prevalence of the condition in the target population may be substantially unknown.

If one is able to find such information, a convenient way to display costs and benefits is the expansion path, which is recommended as part of GCEA (see figure 3). This figure shows the cumulative costs (on the vertical) and population health gains (on the horizontal) of the four different investment opportunities for COPD of table 1, in cost-effectiveness order where lower points in the graph relate to more cost-effective projects.

A useful feature of this display is that if the monetary budget is known, it is possible to draw the budget line directly on the graph and implement everything falling underneath the budget line. Thus, in figure 3, if the budget line is drawn at £140 million, the recommended portfolio of investments would be to invest fully in the *exercise program for mild to moderate COPD* and use the remainder of the funds for providing oxygen for patients with severe COPD.

Both of the analysis tools discussed in this section—the cost-effectiveness league table and

FIGURE 3. Expansion Path for Four COPD Investments



expansion path—make strong assumptions about the absence of any cost or benefit interactions between projects. Thus, there is no modeling of cost savings that arise from implementing two programs that are able to share staff and infrastructure (for instance, the same sexual health clinics that provide HIV testing and treatment may also test for and treat syphilis, chlamydia, and gonorrhea), or which interact in terms of benefits (such as pharmaceutical and psychotherapeutic interventions for depression). Should such interaction effects be quantified, there is no reason why they should not be included in analysis. Some tools, such as WHO-CHOICE, incorporate ways to handle exactly this issue.¹⁵ In general, modeling may necessitate the use of optimization modeling tools¹⁶ (see chapter 10), but nowadays such tools are not hard to use or obtain (for example, a simple optimization solver is included in Microsoft Excel) and it is possible to generate similar user-friendly displays to that of figure 3 to communicate the results.

Multicriteria Decision Analysis

Multicriteria decision analysis (MCDA) is an alternative to CEA in which there has been increasing interest recently.¹⁷ The approach, which is a general framework for decision support rather than one specific to the health sector, is based on the observation that alternative investment opportunities can typically be characterized as good or bad on multiple dimensions and therefore any decision recommendation should be based on the aggregation of the performance of options across these different dimensions. (See box 2 for the details of a MCDA case study involving the selection of essential drugs in Thailand.)

Overview of the MCDA approach

Advocates describe MCDA as an accessible and transparent approach to decision support, which is

BOX 2. A Multiplicative MCDA Model for the Selection of Essential Drugs in Thailand

P. Chongtrakul and colleagues document the use of ISafe, a multiplicative MCDA model, for the prioritization of drugs for Thailand's essential medicines list.^a The ISafe acronym refers to the model's information, efficacy, and safety criteria, as well as a criterion "af" relating to the ease and frequency of administration. There are systematic procedures for assessing the scores on each criterion. Reflecting the logic of the multiplicative model, the scales on which each criterion are assessed are restricted to an interval $[x,1]$ where x is some fraction: the lower x , the greater the potential impact of a score on that criterion. The ISafe scores are divided by an estimate of cost to produce an overall cost-effectiveness index. According to Worasuda Yongthong and colleagues, ISafe is used primarily to structure the deliberations of the National Expert Panels that report into a subcommittee of the National Drug System Development Committee; the subcommittee may request additional information, such as local cost-effectiveness studies, before making a decision.^b

a. Chongtrakul and others (2005).

b. Yongthong et al (2012)

based on the principle that a rational choice is one which compares a number of relevant alternatives in a common way. To get a sense of the overall MCDA approach, consider the following example, which is meant to establish what to include in a HBP for people with COPD.¹⁸ Table 2 presents the different options for investment.

Many MCDA models use an additive value model. In this approach these different levels of performance are typically scored on a 0–100 scale, with 0 as the least attractive option and 100 as the most attractive option. (A treatment for a severe illness

TABLE 2. Investment Options for COPD Spending

	Effectiveness	Number of people who can benefit	Equity	Severity of illness
Drug treatment for severe patients	*	200	Inequity neutral	Severe
Oxygen for severe patients	*	180	Inequity neutral	Severe
Drug treatment for mild-moderate patients	**	300	Inequity neutral	Mild-moderate
Offering smoking cessation for mild-moderate patients	**	120	Inequity neutral	Mild-moderate
Encouraging exercise for mild-moderate patients	***	300	Inequity neutral	Mild-moderate
Offering smoking cessation in the community	**	2,000	Inequity averse (community services can be geographically targeted on worst off populations)	Mild and undiagnosed

may receive a score of 100 for severity, for instance, if it is deemed more attractive than a treatment for a mild and undiagnosed illness.) These scores are aggregated through the use of a weighted sum, as in table 3. For example, the option *encouraging exercise for mild-moderate patients* has the highest overall score, calculated as $58.4 = 100 \times 0.3 + 17.6 \times 0.25 + 0 \times 0.15 + 80 \times 0.3$.

A serious limitation of this approach is that it ignores interactions between criteria. In the COPD example above, *number of people who benefit* is a pivotal criterion: if an option does not benefit anyone, then whether it is targeted at more or less severe illness should not matter, as it is not worth doing regardless.

In this light, these additive value models often ignore the key notion that even though there may be social values other than population health, health is not one criterion among equals in the context of

healthcare prioritization. As a criterion, health is critical in the sense that if a healthcare intervention does not improve health—perhaps because it is not effective (for instance, homeopathy for cancer) or is for a disease with zero prevalence (for instance, vaccination for smallpox in 2015)—one should not make the investment. An alternative approach, which recognizes this idea, is to use a multiplicative model.¹⁹ In this approach, one would convert the effectiveness star ratings of table 1 into numbers that would reflect how much more individual health benefit they contribute relative to no treatment. For example, converting a “*” into a 1 and “***” into a 3 implies that the health benefits of a *** option like *encouraging exercise for mild-moderate patients* are three times greater than those of * option such as *oxygen for severe patients* for the person who benefits, relative to doing nothing. For *number of people who benefit*, the raw scores are acceptable, and for *equity* and *severity of illness* there

TABLE 3. Scored and Weighted Investment Options for COPD Spending—Additive Model

	Effectiveness	Number of people who can benefit	Equity	Severity of illness	Overall score
<i>Criterion weights</i>	0.3	0.25	0.15	0.3	
Drug treatment for severe patients	0	4.3	0	100	31.1
Oxygen for severe patients	0	3.2	0	100	30.8
Drug treatment for mild-moderate patients	60	9.6	0	80	44.4
Offering smoking cessation for mild-moderate patients	60	0.0	0	80	42
Encouraging exercise for mild-moderate patients	100	17.6	0	80	58.4
Offering smoking cessation in the community	60	100.0	100	0	58

TABLE 4. Scored Options for COPD Spending—Multiplicative Model

	Effectiveness	Number of people who can benefit	Equity	Severity of illness	Overall score
Drug treatment for severe patients	1	200	1	1.3	260
Oxygen for severe patients	1	180	1	1.3	234
Drug treatment for mild-moderate patients	2	300	1	1.1	660
Offering smoking cessation for mild-moderate patients	2	120	1	1.1	264
Encouraging exercise for mild-moderate patients	3	300	1	1.1	990
Offering smoking cessation in the community	2	2,000	1.25	1	5,000

are adjustment indices that set scores greater than 1 for criterion levels to prioritize and scores equal to 1 otherwise. These scores are presented in table 4 and aggregated through multiplication, with *offering smoking cessation in the community* achieving the

highest score of $5000 = 2 \times 2,000 \times 1.25 \times 1$. It should be emphasized that the procedures for arriving at scores depends on the nature of the combination rule, which is to be used for calculating the overall value (discussed in more detail below).

Notably, cost has not been taken into account in either the additive or the multiplicative models, but it could be accounted for in various ways. One way is to take the overall value score v and divide by the cost of implementing the option c to get an overall index of value for money v/c . Another is to calculate a net value concept by determining an exchange rate for the overall value score with money w and then calculating $wv - c$. Still another approach is not to consider money directly but to explicitly generate all possible combinations of options that are feasible with respect to some budget constraint. A final way would be to use cost-effectiveness as a screening criterion, in which the MCDA considers only options that meet some predetermined cost-effectiveness threshold (for example, three times gross domestic product per capita). Any of these different ways to approach this calculation may be appropriate depending on the circumstances.

Establishing scores and weights in MCDA

It is critical to determine how these scores and weights are to be arrived at. This can be broken down into three subissues:

- **Who is to be involved** in assessing model parameters such as scores and weights?
- What **questions** should people be asked in order to elicit model parameters such as scores and weights?
- How can these assessments be made in the most **reliable** way possible?

It has been argued that there are three grounds for deciding who is to be involved in a MCDA (or any other decision support) process: *expertise*, *experience*, and *legitimacy*.²⁰ In the COPD example, the people who possess expertise on the disease and its treatment will be primary and secondary care physicians,

allied health professionals, public health experts, and health economists or accountants. Patients and their caregivers may be involved based on their relevant experience, and members of the public may be considered as having a legitimate role as the payers of the taxes or insurance premiums that fund the system. In democratic systems, elected representatives are the ultimate legitimated authorities, yet these representatives often take the view that they cannot be expected to make considered decisions individually on each and every technology, preferring to set broad direction. A purist view would be that the experts and patients should generate the data table (table 2) and then stand back to let public representatives express their scores and weights, reflecting their valuations. In practice, this separation may be hard to maintain, as expressing a meaningful score or weight seems impossible without some relatively detailed clinical understanding (for instance, what is the quality of life and prognosis for someone with “severe” COPD?). Hence, pragmatically, it is often the case that such scores and weights arise from a dialogue between expert, experienced, and legitimized participants.

The literature has numerous suggestions as to what questions should people be asked to elicit scores and weights. In the “value theory” paradigm, for example, respondents are encouraged to reflect on value differences: for example in the additive model, to establish a weight for *severity of illness* versus *equity*, respondents should first be asked a question along the following lines:

“Considering an investment that is targeted at people with mild and undiagnosed COPD and is inequity neutral, WOULD YOU PREFER
 (1) to replace it with otherwise identical but inequity averse investment
 OR
 (2) to replace with an otherwise identical intervention targeted at severe patients?”

If the answer is (2), for instance, this suggests that the *severity* criterion should have higher weight than the *equity* one.

The next question value theory suggests is the following:

“Considering

- An investment *a*, which is targeted at people with severe COPD and which is inequity neutral, or
- And an investment *b*, which is targeted at people with mild and undiagnosed COPD and which is inequity averse,

Supposing these investments to be otherwise indistinguishable, relative to the base case, HOW MUCH MORE do you like investment *a* than investment *b*?”

A question of this form (known as a “swing weighting” question) can be interpreted as the ratio between the respective weight parameters: if the answer is “I like *b* half as much as I like *a*,” then the weight on *equity* should be half the weight on *severity*.

Often, the structure of the model itself will suggest elicitation questions. In the multiplicative model for the COPD example, for example, one could ask the following question:

“Consider the two variants of *offering smoking cessation in the community* shown in table 5. How big would *x* have to be to make you indifferent between (1) and (2)—that is, to compensate for the failure of variant (1) to address health inequalities?”

If the answer to this question is $x = 2,500$, then it must be the case that the score for inequity aversion is $1.25 = 2,500 / 2,000$. (This follows from the principle that if a respondent likes two options equally, they must get an equal overall score.)

Another approach to assessing a value function is to use a Discrete Choice Experiment (DCE) approach.²¹ In the DCE setup, a set of options is presented to subjects who are asked to express direct preference judgments between pairs of alternatives directly, without explicit scoring and weighting. Some form of logistic regression can then be used to extract the implicit criteria weights from these overall holistic judgments. Such an approach may have the advantage that it is more “natural” for respondents than being forced to assess options criterion by criterion; however, the discipline of having to examine each option is the key added value of MCDA. An additional attractive feature of using DCE in this setting is that the mode of questioning makes no specific assumptions about the form of the underlying value model (additive or multiplicative). Therefore, it should be possible to fit different model forms to the

TABLE 5. Trade-off Question to Establish an Equity Score Using Two Smoking Cessation Options

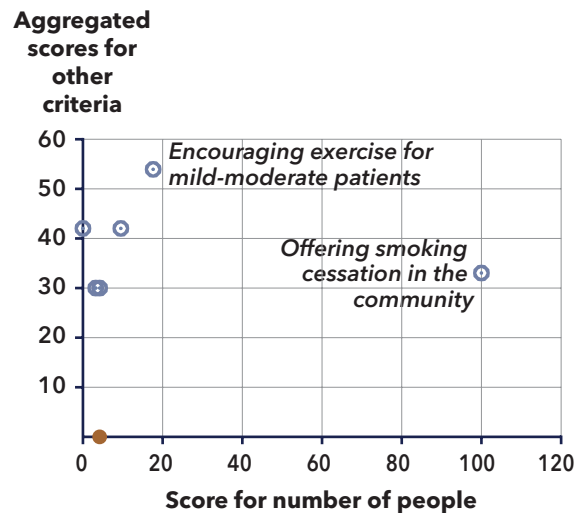
	Effectiveness	Number of people who can benefit	Equity	Severity of illness
Offering smoking cessation in the community (1)	**	x	Inequity neutral	Mild and undiagnosed
Offering smoking cessation in the community (2)	**	2,000	Inequity averse	Mild and undiagnosed

gathered stakeholder preference data in order to see whether recommendations are impacted by technical assumptions about the nature of the underlying preference model. It would also be possible to use tools that make modest structural assumptions about the underlying model and produce more nuanced recommendations of the form “*a* seems better than *b* and *c*, but with the information given, we cannot say whether *b* is better than *c* or *vice versa*”.²²

It is sometimes argued that MCDA is an unreliable method because it relies heavily on subjective judgment. This argument misses the point: leading MCDA practitioners advocate that analysis *should* focus on the subjective values that drive choice²³ instead of concealing taken-for-granted value judgments under a veil of spurious scientific objectivity. A key preoccupation in the technical MCDA literature is how to make reliable subjective score and weight judgments, ensuring that they represent well-thought-through positions.²⁴ The most critical guarantor of this outcome is ensuring that MCDA is used within a properly designed and facilitated process, with opportunities for all stakeholders to provide high-quality reflection and arguments.

The most important tool for facilitating such interactions is sensitivity analysis, which can help participants come to an understanding of model behavior and the meaning of the model parameters. Figure 4 shows an example of a sensitivity analysis display for the additive model. The figure shows the aggregate weighted scores of all the criteria except those for *number of people*, plotted against *number of people*. What this display communicates is that *offering smoking cessation in the community* is a genuinely mass intervention that may be able to offer health gains to a large section of the population; whereas *encouraging exercise for mild to moderate patients* has high scores on the other criteria because it is highly effective and targets people who are actually ill (thus getting a good score for disease severity). All of the other options perform worse on both number

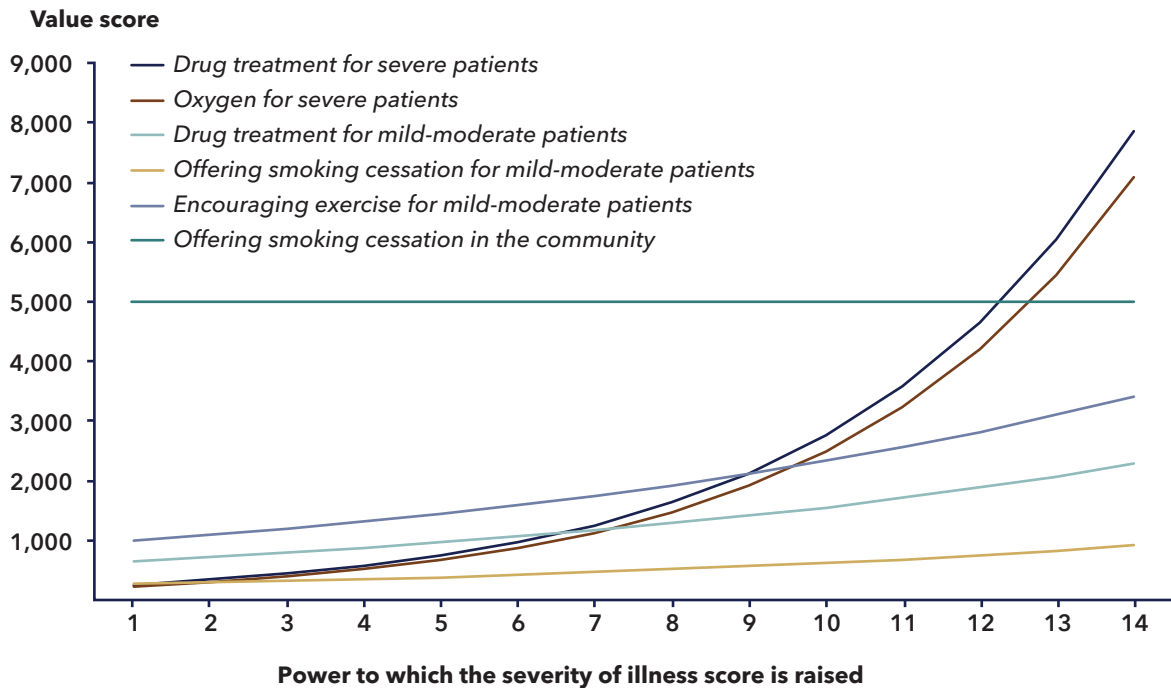
FIGURE 4. Sensitivity Analysis Display (Additive Model): Scores for Number of People vs. Other Criteria



of people and the aggregated scores of the other criteria. Thus if money is not a consideration (for example, because all options are very cheap and one anticipates being able to raise premiums to cover any additional expense) and one wishes to promote one option, this model suggests choosing either *offering smoking cessation in the community* or *encouraging exercise for mild to moderate patients*. A variant of this display is to plot not the individual options, but the combination of options that are feasible within the budget constraint.

Figure 5 shows an example of sensitivity analysis for the multiplicative model. Here, to get a feel for the impact of varying the importance of severity, this analysis raises the severity of illness index to increasingly greater powers. Here, *offering smoking cessation in the community* (which got the highest overall values for the numbers of table 4) continues to be attractive even when the severity-of-illness score is raised to a power of 10 or more. It is only when the severity-of-illness index is raised to 13 or more that treatments for severe patients start to score higher. What one can take from this display is that, in the context of this

FIGURE 5. Sensitivity Analysis Display (Multiplicative Model):
Effects of Varying the Power to which the Severity-of-Illness Score Is Raised



model, the relative attractiveness of *offering smoking cessation in the community* is robust to large changes in how much one cares about severity of illness.

Summary assessment of the MCDA approach

MCDA is not a technique specific to healthcare. The diverse literature on MCDA has contributions from a range of mathematical, social science, and administrative perspectives.²⁵ This is both a strength and a weakness in the context of supporting decisions about inclusion in HBPs: MCDA has nothing to say about healthcare specifically; hence, it may be more accessible to nonexpert stakeholders who are familiar with using similar forms of analysis in their day-to-day lives. However, MCDA is dependent on other existing forms of analysis—for example, many MCDAs in healthcare use some sort of “cost-effectiveness”

criterion that presumably relies on data produced by third-party published economic analyses—and brings little additional depth. Moreover, as stressed above, many MCDAs, in using an additive model, do not seem to recognize the primacy of population health in setting HBPs: while other social values are relevant, they moderate population health and cannot substitute for complete ineffectiveness.

In chapter 4, Sculpher and others have additionally argued that an important shortcoming of such methods is that there is “generally no explicit consideration of opportunity costs.” However, if one knows that one has a surplus of £*x* that will completely fund *a*, *b*, or *c*; appraises these options using a technique such as MCDA; and, as a result, chooses to do *a*, then one is being explicit about the opportunity cost of doing *a* in the sense that the opportunity cost is that one does not do *b* or *c*. The difference between MCDA and the CEA league table approach is that the

latter seeks to consider, via the threshold, unspecified marginal options that will be displaced. The reason for taking this line is clear—one cannot explicitly include in one’s league table and appraise all possible things that the health service does. This simply is not a practical option. But the threshold-based concept does pose a conceptual difficulty for concretely-minded people, in the sense that in the face of a challenge regarding the opportunity costs of marginal options, a proponent of CEA would not be able to produce an example of a marginal intervention that will be displaced and lay it on the table. (See box 3

for the details of a multicriteria and CEA case study involving decisions of what interventions to include in Chile’s HBP.)

Other Economic Evaluation Methods: Extended Cost- Effectiveness Analysis

Very recently, some authors²⁶ have observed that standard CEA does not have very much to say about the financial protection benefits associated with provision of healthcare through the public system, or with its differential impact on various social groups. Yet financial protection is an important aspect of health service provision as stressed by the WHO in the 2000 *World Health Report*,²⁷ and corresponds to one of the axes of the UHC cube shown in figure 1. One reason for this neglect is that in many rich-country jurisdictions where CEA is used to guide investment, coverage is already universal and copayments are small or nonexistent. This is not the case in LMICs that are starting on the path to UHC, where an expanding publicly funded healthcare system encroaches on an existing private system of provision.

Stéphane Verguet and colleagues propose an alternative form of CEA, extended cost-effectiveness analysis (ECEA), in which the financial protection benefit of public provision is explicitly modeled (see also chapter 5).²⁸ For those who would not be able to afford a given intervention, the effect of public provision is to give them access to healthcare that would not otherwise be available and thus increase their health. For those who would otherwise purchase healthcare, public provision may improve their well-being in three ways. First, it may result in better care if the care is being provided by a well-run public system that is not distorted by the incentives to overtreat that inevitably are present in unregulated private systems. Second, there will be a financial benefit in the cost savings from not having to purchase healthcare

BOX 3. Chile’s Multicriteria and Cost- Effectiveness Approaches to HBP Inclusion

Chile operates a plan called Explicit Guarantees and Universal Access (AUGE). According to Vargas and Poblete, the intention behind AUGE was to focus the public system on a relatively defined set of interventions so that a uniform level of quality and coverage could be achieved.^a Rather than prioritizing interventions, AUGE prioritized conditions, using nine objectives reflecting existing system competencies; financial and epidemiological burden; and various cost, inequality, and fairness considerations, although it did not use a formal multicriteria approach. Cost-effectiveness was also used within this prioritization process (although cost-effectiveness makes conceptual sense only at the treatment level, rather than at the intervention level). Veronica Vargas and Sergio Poblete note that some health problems were excluded from coverage because “despite having high burden of disease, there were not cost-effective (such as glaucoma) or effective (Alzheimer’s disease, cirrhosis of the liver and lung cancer) interventions available.”^b

a. Vargas and Poblete (2008).

b. *Ibid.*, p. 788.

(although the richer classes are likely to shoulder the lion's share of the tax burden, so in a comprehensive sense they may be worse off as a result of the implementation of UHC). Third, the publicly funded system will provide risk pooling, distributing financial responsibility for the system across well and sick alike—a major benefit in countries without functioning health insurance markets that can be captured in monetary terms. The ECEA approach stresses the modeling of these different consequences explicitly for different socioeconomic groups. ECEA does not currently recommend a way to aggregate these diverse benefits, and does not provide a ranking of options or a decision rule as CEA does. Rather, it provides information that a decisionmaker may wish to take into account informally. Consequently, it is hard to compare the recommendations of ECEA with those of standard CEA, but presumably the qualitative effect of factoring in such considerations would be to give extra priority to diseases of the poor and to diseases that are costly to treat. It would be possible to use MCDA techniques and ideas to explore how these diverse benefits can be integrated; indeed, this seems a natural methodological development in this area. (See box 4 for the details of an ECEA case study on vaccination options in India.)

Other Economic Evaluation Methods: Cost-Benefit Analysis

An alternative approach to economic assessment is economic cost-benefit analysis (CBA).²⁹ CBA is a general method for supporting decisionmaking based on welfare economics principles, and can be applied in health, among many other domains. The principle behind CBA is that all welfare consequences flowing from an intervention should be captured and valued in common terms (such as money) and then investments should be undertaken if their overall net benefit is positive. In particular CBA also

BOX 4. ECEA Support for the Rotavirus Vaccine in the Indian Universal Immunisation Programme

Itamar Megiddo and colleagues describe an ECEA application to inform whether and how to extend coverage of the Indian Universal Immunisation Programme and introduce a rotavirus vaccine into the vaccination schedule.^a Their analysis uses a stochastic agent-based simulation, IndiaSim. The authors simulate three policy scenarios and track the costs to government and avoided out-of-pocket costs and deaths, as well as calculating a monetized value of the insurance benefit. Their analysis suggests that expanding the modeled actions likely will be affordable and will have a material impact on both under-five mortality and financial hardship.

This study was presented to the National Technical Advisory Group on Immunization of India (NATGI) and was one of a number of studies published in a supplement of the journal *Vaccine* (which provided part of the technical case). Following the NATGI recommendation, the government of India decided to include the rotavirus vaccine into the immunization program in 2014.^b

a. Megiddo and others (2014).

b. GAVI (2014).

provides a framework to capture in a systematic way the impacts of investment in health on economic productivity through improved workforce participation.

Performing full and rigorous CBA is a time-consuming and intensive exercise. Some of the implications of CBA may also be ethically disconcerting; for example, the health of someone who is employed may be considered to be more valuable than the health of someone who is past retirement age, because the employee's health enables them to return to work and

generate further economic surplus. However, the primary use of CBA in the health sector is typically not in helping the allocation of monies from an insurance fund but in making the case to donors or the finance ministry that some substantial project (for instance, malaria eradication) will result in economic benefits that will justify an exceptional investment of central funding, outside the usual financial allocation for the health system. The virtue of CBA is that, in principle, it provides a consistent framework within which to assess all such competing projects.

Discussion

Table 6 presents a summary comparison of the various methods discussed in this chapter. All of the methods covered here are “competitive” in the sense that they would be appropriate choices for a healthcare funder looking to define a HBP. There is no “one best way,” and funders should experiment with different methods with a view to understanding their strengths and weaknesses. Overall, the following points should be noted:

- CEA type methods are well established. Such methods do not explicitly capture social values (other than, of course, health), but generally they are intended be used in a deliberative context and such values may be evoked as part of this broader discussion. As chapter 4 makes clear, CEA can play a useful role in clarifying trade-offs, in the sense that the quantity of population health forgone in order to secure some other putative benefits can be assessed. Guidelines for good practice and institutional support for undertaking CEA-type approaches exist. CEA methods can be applied in a relatively participative and basic fashion or in a more technically intensive way, depending on what best suits the institutional context and what level of precision and reliability is expected. Using such methods may be particularly appropriate in settings where being able to demonstrate compliance with internationally established good-practice norms is important and where there is readiness and enthusiasm to draw on the growing body of high-quality analysis based on CEA principles.
- The key strength of MCDA is that it explicitly takes into account multiple social values. It may be an attractive method where demonstrably taking such values into account is important and where stakeholders are prepared to engage relatively deeply in supplying scores and weights which represent considered opinion about critical trade-offs. In the absence of a strong body of good-practice guidance in healthcare, generic guidance³⁰ or guidance from other domains³¹ may be useful. ISPOR has recently published the results of its MCDA taskforce,³² which hopefully will stimulate further high-quality guidance in the healthcare domain.
- The strength of ECEA is that it allows the modeling of the financial consequences and the differential impact on various population groups, alongside the population health consequences. Thus, this method may be particularly attractive where out-of-pocket payments are a particular concern. However, as more is being modeled in ECEA (in the sense that standard CEA disregards the financial consequences), this method adds complexity and makes additional data demands on top of “standard” CEA approaches, and it may make most sense to apply where there is already established CEA capacity and experience.
- CBA stands on a different philosophical foundation from other forms of CEA in that the healthcare system is not viewed as solely producing population health but rather as contributing to a

TABLE 6. Comparison of different methods

	Cost-effectiveness analysis (CEA)	Multicriteria decision analysis (MCDA)	Extended cost-effectiveness analysis (ECEA)	Cost-benefit analysis (CBA)
Reflective of social values	Methods assume that population health gain is the overriding objective.	In principle, method can take into account any possible social values, but care should be taken in structuring the criteria.	Method reflects a key concern in LMICs where avoidance of catastrophic financial payments is important alongside population health gain.	Methods involve modeling all-welfare relevant consequences. Opponents argue that CBA embeds unacceptable value tradeoffs.
Technically robust and justifiable	Method is very well established within the healthcare sector. Guidelines for good practice exist although methodological controversies remain.	Method is well established outside the healthcare sector and popular within the healthcare sector. Several general (i.e., nonhealthcare specific) good practice guidelines exist, but there is not yet a strong body of healthcare-specific guidelines.	Method is new and established guidelines on good practice do not yet exist.	Method is well-established outside the healthcare sector and popular within the healthcare sector. Several general (i.e., nonhealthcare specific) good practice guidelines exist, but there is not yet a strong body of healthcare-specific guidelines.
Easy to understand	Methods can be implemented at various levels of sophistication: more complicated models will be harder for lay people to engage with.	Ease of understanding is one of the principle selling points for these methods. However, appropriately structuring criteria and choosing aggregation rules is subtler than is often appreciated.	Same comments apply as in the case of CEA but with the proviso that some of the additional financial modelling (in particular the concept of insurance value) adds an additional layer of complexity.	Models can be very technical and expression of costs and benefits in monetary terms is often a stumbling block for lay engagement.
Have low cost of implementation	Can be done at varying levels of intensity, from “quick and dirty” to more expensive and robust analyses. Expansion path analysis at the population level involves bringing together clinical and epidemiological data, which can be time-consuming.	Does not require specialized modelling resources, but requires relatively intensive engagement from stakeholders to supply scores and weights.	Same comments apply as in the case of CEA, but with the additional proviso that modelling of financial and payment aspects is required.	Same comments apply as in the case of CEA and ECEA but requires a more extensive modelling of welfare consequences.

range of economic goods, of which health might be one. CBA may have a role in countries where this philosophical view has particular resonance, or where it is necessary for “health” to make its

case to other public sectors. CBA is a more complex method and requires specialized analytic resources: however, there are many general texts on how to apply CBA. One might argue that CBA

is no worse than other forms of analysis in terms of embedding controversial value assumptions, but experience shows that, from a public relations point of view, it is vulnerable to attack on the grounds that it “reduces everything to money,” even though it actually attempts to express non-monetary benefits in monetary terms.

The form that analysis takes will be shaped by the question being asked: for example, whether it makes most sense to use local or national data, whether one seeks to model one technology in detail or multiple technologies at a relatively high level of resolution, or whether it is necessary to attend to the costs and benefits of technologies that might be displaced if a new technology is added to the reimburseable set. However, there is no simple one-to-one mapping between the assessment techniques shown in this chapter and the problem statements outlined above.

This chapter has sought to give an overview of the different technical methods available to incorporate social values additional to health in analysis informing selection of the HBP. This discussion has attempted to be nonprescriptive, but deploying any of the methods described here involves many subtle modeling choices. However, there is now a wealth of experience internationally on how to conduct analysis that can support decisions about health services and technology funding in a transparent, defensible way. Indeed, beyond the questions of tools and methods, albeit important, there are the overriding concerns of values and goals. Priority-setting for a HBP can be performed with any one of several tools and methods: the important point is that goals (objectives) are clearly defined and methods for arriving at the contents of a benefit package are acceptable in the eyes of key stakeholders and society at large.

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CHAPTER 7

Square Pegs, Round Holes

Addressing Health Sector Interventions with Non-Health Benefits

Rachel Silverman

At a glance: Some health services also boost dignity, empowerment, or economic returns. When, and how, should the health benefits package consider these non-health benefits?

Intuitively, interventions delivered by the health sector are expected to improve the health of users—and in most cases, better health, as measured through quality-adjusted life years (QALYs) gained or disability-adjusted life years (DALYs) averted, is indeed their main outcome of interest. However, some subset of interventions delivered through the health sector—that is, provided in health facilities; using drugs, medical devices, or surgical techniques; and/or delivered by health sector professionals (doctors, nurses, dentists, technicians, or community health workers)—will *not* have health improvement as their sole or even primary objective.¹ (The inverse is also true—non-health interventions like taxation, housing policy, or traffic enforcement may have positive or negative implications for health). Instead, their main benefit could be non-health-related quality of

life, dignity, economic growth, empowerment, or some combination thereof.² The interventions may be health-improving to some degree, or have other benefits that can be captured by the empirical methods discussed in this section, but standard methods may not fully account for their non-health value. As a result, these categories of interventions merit special consideration from policymakers when designing the health benefits package (HBP)—though not necessarily inclusion in the package.

This chapter first lays out general criteria for policymakers in identifying those interventions that require consideration of non-health benefits. It then highlights three common interventions that fall in this category: contraception, palliative care, and reconstructive/aesthetic surgery or services. All of these services are, by necessity, usually delivered

through the health sector, as they involve drugs, devices, or surgical techniques that can only be safely administered by trained medical professionals. (In addition, these services carry at least some risk of adverse health effects during their administration, including side effects, overdose, or surgical complications.) Each of these services challenges standard methodological frameworks for HBP design, and different approaches should be considered when evaluating their potential inclusion in a HBP.

The goal of this chapter is not to offer prescriptive solutions, but merely to flag areas that deserve special consideration, with due regard to their cross-sectoral implications and local social preferences. Ultimately, there is no “right” answer to address these interventions, and the appropriate approach will be context-specific. Nonetheless, interventions such as these may not be adequately considered if they are not looked at independently; policymakers would be wise to ensure that they receive due attention.

General Criteria

Almost all health services have *some* non-health benefit, but not all health services can receive special consideration from this perspective. Accordingly, policymakers must follow some general principles to identify the subset of interventions that merit consideration vis-à-vis their non-health benefits. The following general principles offer some guidance; ultimately, however, each country will need to select criteria appropriate to the local context.

- **Is the service cost-effective with regard to a non-health goal?** Some health sector services have an important impact in advancing explicit non-health goals. For example, deworming, in some contexts, is thought to improve cognition and encourage school attendance. If deworming

is found to be a cost-effective strategy for improving educational outcomes within the local context—that is, compared to other educational interventions currently offered—it might be considered for inclusion in the HBP on that basis. In some cases, however, it might be appropriate for the relevant beneficiary sector (for instance, the ministry of education) to cover the marginal cost of providing the treatment.

- **Is the service (or motivation for the service) explicitly recognized as part of the HBP goal?** In many countries, the goal of the HBP is explicitly codified in law or policy, and that goal should guide policymakers in determining which non-health benefits to consider. For example, a HBP policy might explicitly identify access to palliative care as a component of the benefits plan, or it may stress that the plan should provide “dignity” or “comfort” to those accessing health services.
- **Is increasing access to the service explicitly recognized as a non-health national policy goal?** For some interventions, such as contraception, countries may already have an explicit policy goal to increase access and/or uptake, in part due to consideration of associated non-health benefits. Ideally, the HBP should be harmonized with all relevant national strategies and goals, pursuant to budget constraints.
- **Do citizens value the non-health benefits more highly than health foregone?** Citizen preference surveys and focus groups can offer valuable guidance in determining which non-health benefits to consider. By offering respondents a series of trade-offs—for example, 9 years lived with clear skin versus 10 years lived with severe scarring—policymakers can better understand how citizens value non-health benefits relative to health benefits.

Example 1: Contraception

Contraception services include short-term, long-acting, and permanent methods that allow women to prevent unwanted pregnancies and control the timing of their births. With the possible exception of some less-effective prophylactic methods (such as condoms), contraceptive services are almost always financed and delivered through the health sector. Effective provision of contraceptive services requires a supply of contraceptive commodities—including pills, intrauterine devices, implants, and injectables—plus dedicated staff time for counseling, insertion, administration, and/or surgery (for permanent methods).

With respect to contraception, a HBP must address two fundamental questions. First, will contraception be covered at all? Second, if yes: which methods will be made available? These questions are complicated by the unique cost-benefit characteristics of contraceptive services. Access to contraception *will* usually be health-improving by standard DALY or QALY measures, and in some contexts may be cost-effective by these measures alone. Every pregnancy carries some risk to the mother's health, by reducing the overall number of pregnancies, fewer women will experience pregnancy complications or maternal death (holding the rate of maternal complications or death constant). There is also evidence that higher-parity, closely spaced, or unwanted pregnancies are riskier than other pregnancies for both mother and baby, in part because the mothers may be relatively young or old, because they may seek unsafe abortions, and because the women who are otherwise most vulnerable to maternal complications are least likely to have access to contraception.³

Nonetheless, standard cost-effectiveness measures are problematic when considering inclusion of contraceptive services generally, or individual methods specifically, as part of a HBP. Health is just one of

several rationales for the provision of these services, and often it is not the most impactful or compelling reason. Other rationales for increasing contraceptive access include women's economic and social empowerment (control over fertility facilitates investment in human capital and labor force participation);⁴ demographic and macroeconomic considerations (accelerating the "demographic dividend" and preventing unsustainable population growth, though the importance of the latter issue is contested); and the fundamental right of women and families, reaffirmed at the 1994 Cairo Conference on Population and Development, to make autonomous and informed choices about their own fertility.⁵ When contraceptive cost-effectiveness is measured in cost per DALY, or even using more sophisticated tools like an extended cost-effectiveness analysis or multicriteria decision analysis, the results will likely understate the full social value of providing these services and may seemingly justify their exclusion in highly resource-constrained contexts. For example, the Disease Control Priorities 3 (DCP3) rankings suggest that modern contraception costs approximately \$150 to \$350 (precise figures not available) per DALY averted, though only two evaluations were identified that considered cost-effectiveness of contraception in terms of DALYs.⁶ This assessment would rank contraception as "highly cost-effective" in almost all countries using the thresholds defined by the World Health Organization (WHO), but could exceed empirically derived thresholds in many low- and middle-income countries (LMICs) such as Ethiopia, India, Malawi, and Nepal⁷—each of which has committed to increase access to or adoption of voluntary family planning as an explicit national goal.⁸

Even if this cost-effectiveness ratio merits inclusion, a second problem relates to the range of methods that would be offered. Pregnancy carries risk, but it is not a disease; women are not necessarily looking to optimize their "protection" from pregnancy with

their choice of method. Instead, different women will prefer different forms of contraception depending on their individual needs and circumstances. Some women will want only short-term protection, allowing for healthy birth spacing; others, who have completed their desired childbearing, may want permanent sterilization. Some women may want to conceal their contraceptive use from their partners or families, leading them to prefer nondetectable methods like injectables. Others will experience adverse side effects from the first method they try. Accordingly, access to a balanced mix of contraceptive methods is required for countries to increase contraceptive prevalence—a common goal—while respecting women’s dignity and choice. (The WHO essential medicines list concurs, including 13 different contraceptive methods across six classes).⁹ In contrast, simple cost-effectiveness measures treat all methods as equal given equal protection from pregnancy; strict logical fidelity would lead the package to include only those methods that offer the greatest “protective” power with regard to price. At worst, strict adherence to cost-effectiveness standards could lead the HBP to include only long-term (and sometimes irreversible) methods like sterilization, which may offer the most health “gain” over a lifetime relative to price.

A final consideration concerns budget impact and the social value or cost of an averted pregnancy. To the extent that contraception prevents births—and, consequently, the health system expenses of pregnancy, childbirth, and child care, plus costs to other sectors like education—contraception may be cost-saving in the long run, or at least budget-neutral. Actuarial studies from the United States show that inclusion of contraceptive services in private insurance plans does not impact premiums;¹⁰ public expenditure on family planning (Medicaid) has been found to be cost-saving, yielding four dollars in savings for each dollar spent.¹¹ Research suggests that contraception, or more effective contraceptive

methods, is likely to be cost-saving in most settings, ranging from the United Kingdom¹² to Latin America¹³ and sub-Saharan Africa.¹⁴ However, because these “savings” are incurred by averting births, they can be ethically fraught and should be treated with caution. It is of course appropriate for a government to provide access to contraception for those women who want it, but there is a risk that overzealous policies or poorly crafted incentives to encourage contraceptive use or sterilization may infringe on women’s rights and autonomous choice, as has historically occurred in India and elsewhere. Regardless, conducting cost-effectiveness analyses for contraception will require a judgment call about the moral and/or functional benefits and costs of an averted pregnancy. For example, the United Kingdom’s National Institute for Health and Care Excellence (NICE) conducts its analysis under the “[assumption] that before conception, the value of a future baby to society is neither positive nor negative. From this, it is clear that preventing conception cannot be measured in QALY terms, because future QALYs do not exist before conception. Thus the cost effectiveness of preventing a conception has been measured in terms of cost per pregnancy averted.”¹⁵

How, then, does a country make fair decisions on inclusion of contraceptive services—and the range of services to be provided—within its benefits plan? Treatment of contraception in LMIC HBPs has not been well documented. One recent study from a sample of 20 countries in sub-Saharan African and Asia suggests that most fledgling national health insurance schemes have excluded contraception from the reimbursable benefits package—though a few offer weakly defined contraception benefits (without specifying contraceptive methods) through capitation packages or other input-based financing streams.¹⁶ Another practical issue is that LMIC family planning efforts are often organized as vertical programs, relying heavily on donor funds, nongovernmental organization (NGO) implementers, and/or

in-kind commodity donations; in low-income countries specifically, country governments provide just 2 percent of all funding for commodities, while about three-quarters of funding comes from international donors and NGOs.¹⁷ Given this dynamic, some countries have excluded family planning from the HBP with the justification that those services are available through other mechanisms, as initially occurred under Ghana's National Health Insurance Scheme.¹⁸ In Chile, all family planning methods but sterilization are available free of charge—but women must enter a waiting list to receive an intrauterine device.¹⁹

One common approach for resource-constrained governments—adopted as a core indicator for the international Family Planning 2020 (FP2020) initiative²⁰—is to ensure availability of at least three different method classes at primary care facilities. A higher standard, encouraged in some circles²¹ and also tracked by FP2020,²² is the availability of at least five method classes at secondary or tertiary care levels. Ultimately, each country will need to determine what is affordable and sensible within the local context; in making inclusion decisions, policymakers should consider not just health optimization but also the minimum standards for a rights-based package of care. Ideally, this package should include at least one barrier method, one concealable short-term method, and one long-acting reversible method.

Example 2: Palliative Care

There is no single accepted definition for “palliative care,” but the term typically focuses on “effective pain relief and a team approach to care throughout the course of the illness” with the “primary goal of . . . improving the quality of life of patients and those around them; it is not the prolongation of life or the hastening of death.”²³ The need for palliative care is most commonly associated with cardiovascular disease (38.5 percent of global need, according to the

WHO); cancer (34 percent); and chronic respiratory disease (10.3 percent), but it is also applicable for a wide range of other conditions.²⁴ Access to palliative care is included within the WHO definition of universal health coverage,²⁵ the WHO's essential medicines list includes both opioid and non-opioids for pain relief,²⁶ and the United Nations Committee on Economic, Social and Cultural Rights recognizes palliative care as a human right.²⁷

In wealthy countries, palliative care may allow patients to live their last days in the comfort of their own homes, averting expensive hospital stays and creating net cost savings for the health systems. In LMICs, however, curative or hospital-based end-of-life treatment may not be offered or available; in such cases, palliative care would represent an additional cost for the health system.²⁸ The question then becomes whether that additional cost represents “value for money”—and standard cost-effectiveness metrics may not offer appropriate guidance for whether (and to what extent) palliative care should be included within the health benefits package. Palliative care reduces pain and improves health-related quality of life, and will thus be “health-improving” as measured by QALYs. However, palliative care is typically offered to patients at the end of life and does not aim to extend longevity; as a result, the period over which quality of life will be improved will, by definition, be short, and the measured health improvement (QALYs) will be small. As a result, palliative care will generally rank as an effective intervention, but depending on the cost of provision it may not be universally cost-effective in the most resource-constrained settings.

Yet there are other reasons to consider including palliative care in the HBP. Palliative care can greatly ease the suffering of patients and families alike, and in at least some contexts patients may prioritize improving quality of life over extending life when facing terminal illness.²⁹ (Benefits measured in QALYs consider only benefits to the patient, not

to caregivers, family, and the broader community). And in highly resource-constrained settings, where curative care for cancers or other advanced-stage illness may necessarily be excluded from publicly subsidized benefits, palliative care may be seen as an ethical imperative (see chapter 13).

In practice, palliative care may be listed on a LMIC benefits packages, but effective access is highly constrained outside of the wealthiest countries, and expanding effective coverage will require systematic regulatory and organizational change even if palliative care is notionally included. As of 2006, an estimated 72 percent of the global population lived in countries with “virtually no consumption” of opioids for pain relief; just 7 percent lived in countries with “adequate consumption,” overwhelmingly in high-income countries.³⁰ In a study of 19 countries in Latin America, all included palliative care on the list of services provided at the primary care level but varied widely in the availability of specialized palliative care in practice.³¹ The reasons for constrained access in large part stem from international and national regulations that restrict prescription of opioids in an attempt to prevent illicit use,³² and which require accurate annual demand forecasting prior to importation.³³ Thus increasing access to palliative care is an issue that extends well beyond HBPs, and also requires regulatory reform and capacity-building. In addition, citizen preferences for palliative versus curative care vary by setting, so citizen preference surveys can be a useful tool to inform prioritization within the HBP.

Example 3: Reconstructive Surgery and Aesthetic Services

A number of services delivered through the health sector have aesthetic improvement as a significant or primary benefit. These can include elective plastic surgery—widely recognized as inappropriate

for inclusion in publicly subsidized health benefits plans—but also reconstructive surgery following trauma or medically necessary surgery; some dermatology; orthodonture and dentures; or surgery to repair congenital anomalies. Such medical services might be health-improving to the extent that they address functional impairments, but their primary value will rest in improvements to quality of life that may not be captured by standard methods for measuring disability, such as dignity, self-esteem, and stigmatization. For example, the EuroQol Five Dimensions Questionnaire (EQ-5D)—a common instrument used to develop QALY weights—measures mobility, self-care, ability to perform usual activities, pain/discomfort, anxiety/depression, and self-described health on a scale from 1 to 100.³⁴ These measures would not clearly capture the quality-of-life impact of a cleft palate, severe scarring, or missing teeth, and thus may risk underprioritizing these services. Yet because benefits from such services are not easily measured or quantified—and because the constituents demanding access to them are likely to come from relatively advantaged segments of the population, with strong stakes in their provision—there is a risk that they may be included in the plan without sufficient consideration of the opportunity cost, increasing inequities.

Many HBPs do include services from within these classes. For example, the United Kingdom’s National Health Service (NHS) offers breast reconstruction to all women undergoing mastectomy for breast cancer,³⁵ and the Ghanaian National Health Insurance Scheme (NHIS) covers “reconstructive surgery, such as is performed on burns patients.”³⁶ Of course, availability of these services will necessarily vary with resource level and the opportunity cost of displaced spending. A consensus statement from the Breast Health Global Summit, for example, suggests that reconstructive surgery be offered only in “enhanced” resource settings.³⁷ Likewise, the Lancet Commission on Global Surgery suggests that cleft

palate, lip, and clubfoot repair would be appropriate for a basic HBP under universal health coverage, but does not list any other reparative surgeries for aesthetic considerations.³⁸

As with palliative care, citizen preference surveys and focus groups can be helpful to policymakers in considering whether to include reconstructive or aesthetic services, and may yield surprising results. In Chile, for example, the AUGE package originally intended to exclude dentures from the guaranteed list, but changed course after social preference studies revealed the high social and psychological burden of poor or missing teeth, which disproportionately affected poorer women.³⁹

Conclusion

This chapter has laid out a general framework for considering non-health benefits of health sector services, focused on three categories of health sector services whose cost-benefit structures present a challenge for standard methods of economic evaluation: contraception, palliative care, and aesthetic or reconstructive services. These services may require special consideration from policymakers during HBP design, with due attention to their cross-sectoral effects, externalities, and citizen preferences. In practice, HBPs in LMICs vary substantially in their treatment of these interventions. Contraception typically is excluded from reimbursable lists but may be covered in capitation packages, palliative care is likely to be notionally included but highly constrained in practice, and many HBP packages cover at least some subset of aesthetic or reconstructive services.

The general dilemma laid out in this chapter—that some health sector services may have important or primarily non-health benefits—applies to a far broader range of categories than those explicitly considered here. Other potential areas include menstrual hygiene, adult diapers for incontinence, infertility,

sexual dysfunction, weight loss surgery, and sensory impairment. The extent to which an LMIC HBP can or should address these areas will necessarily depend on the cost of the service, the health and non-health benefits, resource availability/opportunity cost, and citizen preferences. There is no single right answer, but policymakers can consult the general criteria laid out in the chapter to flag those areas requiring additional attention. More generally, transparent and participatory decisionmaking processes can help ensure that decisions on these services are acceptable to the population and appropriate to local context.

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Endnotes

1. This chapter draws a distinction between the health *system*—defined by the World Health Organization (WHO) as "all the activities whose primary purpose is to promote, restore or maintain health" (see WHO [2000])—and the health *sector*, defined in this chapter as all services provided in health facilities (such as clinics or hospitals) and/or by health professionals (such as doctors or nurses).
2. In this chapter, health-related quality of life is defined as those dimensions of quality of life captured by the EuroQol Five Dimensions Questionnaire (EQ-5D): mobility, self-care, ability to perform usual activities, pain/discomfort, and anxiety/depression. Non-health quality of life is defined as all other dimensions of quality of life as described in the World Health Organization Quality of Life (WHOQOL) including (but not limited to) emotional and social support; feelings of enjoyment and meaning in life; quality of social and sexual relationships; acceptance of bodily appearance; and perceptions of safety and financial security. See Seattle Quality of Life Group (2014).
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CHAPTER 8

At What Price?

Costing the Health Benefits Package

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Annette Özaltın

At a glance: Costing the health benefits package can help to estimate total resource needs, inform inclusion decisions at the margin, and negotiate payment rates with providers.

Throughout this volume, contributors emphasize that a key principle underlying the selection of the health benefits package (HBP) should be to select services according to the “value” they offer, in terms of satisfying social objectives, given the costs of providing the services. Financial resources are limited, and governments committed to making progress toward universal health coverage (UHC) face an ongoing challenge to balance available funds with the cost of making the services in the HBP accessible with financial protection. Strategic HBP purchasing by health purchasers, such as health ministries, social insurance funds, or private insurance funds, is critical to getting the most value for limited health funds by driving more efficient delivery and utilization of health services to make the HBP more affordable.

The “cost” of a HBP is the total amount of financial resources required to ensure the delivery of the services included in it.¹ The cost of making the portfolio of services in the HBP accessible is driven by a complex set of interactions between the underlying costs to providers to obtain and combine inputs to deliver the services (service costs) and other factors that affect the expenditure required for purchasers to buy the package from providers of care (total expenditure on the HBP), including payment rates to service providers—a policy decision and typically not exactly equivalent to service costs—and utilization rates for the services in the HBP.

The relationship between service costs and total expenditure on the HBP is an important factor in sustainable progress toward UHC. To ensure

financial sustainability of the health system, the total HBP expenditure by purchasers cannot regularly exceed available resources.² However, if the benefits plan is out of alignment with available resources and the supply of services is inadequate or payment rates paid by health purchasers are chronically below the costs to providers, quality of care will likely suffer and out-of-pocket payments may increase to close gaps, both of which erode access to services and financial protection.

The expenditure required to make the HBP accessible does not exist in a vacuum, however, and it is affected by ongoing, real-world factors.³ The cost of delivering services is not a single point to be calculated—rather, it is a function of decisions made by providers on how to deliver care, along with the prices of inputs and the level of realized demand (service use). Policy choices also affect the expenditure required to purchase the HBP, particularly supply and demand incentives.⁴ For example, a UHC system that emphasizes primary healthcare and creates incentives on the supply and demand sides to manage conditions at the primary healthcare level, such as Thailand, may be able to afford more generous HBPs than systems that do not effectively leverage those policies to manage costs and direct resources and utilization to the most cost-effective parts of the health system.⁵ In particular, how and how much to pay providers for services is a set of policy decisions that both directly and indirectly affect the cost of the HBP.

Estimating the approximate resource requirements for implementing or expanding a defined HBP is an important part of fiscally sustainable progress toward UHC. Information on the cost of delivering health services is an essential part of the evidence base needed to make decisions to establish and expand a HBP, strategically purchase the covered services, and inform policies to drive efficient service delivery and utilization of cost-effective services. The cost of delivering the health services included in the HBP, including outpatient visits, diagnostic tests,

inpatient bed-days, and entire courses of treatment, is foundational information for three sets of HBP policy decisions:

- Costing to estimate total expenditure required to make the HBP align with available resources (or, how generous a package can be borne by the country's financial capacity)
- Costing of individual outputs/services to make decisions about inclusion of services in HBPs at the margin (or, what are the cost implications of adding individual services or medicines)
- Costing of individual outputs/services or sets of services to set/negotiate provider payment systems and rates (or, how much will providers be paid for services included in the HBP).

For each of these uses of costing for HBP policy, the fundamental building block is the unit cost—the average cost of a unit of service in the HBP, or the marginal cost of delivering an additional unit of service given current volume. Unit costs are typically defined at the level of the specific service output (cost per outpatient visit), persons receiving a service (cost per person treated), or by a combination of persons and time (cost per person-month of treatment).⁶ This cost evidence can be generated from existing administrative and other data or new prospective data collection. Where cost data are unavailable, many countries use proxies, such as fees paid by purchasers or charges by providers for individual services, but these are imperfect measures and may not correlate well with costs because of market distortions or other contextual factors.⁷

The following section provides an overview of the main costing methods to generate unit costs used for HBP policy, followed by a section on the application of costing to different policy aspects. The final sections discuss costing resources, priorities for further research, and conclusions.

Generating Unit Costs of Health Services: Costing Methods

The unit cost of a health service is the economic value of the resources (inputs) used to produce and deliver the service.⁸ The *cost* of a health service is different from the *price*, which is the market value of the service or the rate paid to providers of the service by government or other purchasers. Costing involves measuring and valuing the resources, or cost items, consumed by a provider organization, department/specialty, service, or patient over the period covered by the costing exercise. These resources are the inputs (direct and indirect) that the provider uses to deliver health services to patients and operate the facility.

Identifying the Scope and Methods of a Costing Exercise

A costing exercise starts with a well-defined purpose, as well as a definition of the perspective, provider types, cost objects, and cost items. The perspective is the point of view from which costs are estimated, or which entity is paying the costs. The perspective can be that of the purchaser, provider, patient, or society. The purchaser perspective estimates the cost of *covering* a service or set of services for beneficiaries, and the provider perspective seeks to estimate the cost of *delivering* the service.⁹ The two perspectives may differ, particularly if the purchaser does not pay for all cost items through its payment systems. The provider perspective gives a more complete picture of total costs, and therefore is used most often in costing exercises that are intended to inform health financing policy decisions. Health services costing also can be performed from a patient or societal perspective. A patient perspective is concerned with patient out-of-pocket spending on healthcare services. If it is a priority to expand coverage to reduce out-of-pocket spending, it may be useful to understand costs from the patient perspective.¹⁰ A

societal perspective includes all costs regardless of who pays them.

The costing exercise also should identify the categories of providers that will be included in the exercise, which should include all types of providers that may be engaged to deliver services in the HBP in terms of ownership status, facility type, level of service, and size.

The cost object refers to the level at which cost data can be collected: provider organization, department/specialty, service, disease/condition, or patient.

Regardless of the costing method, a health services costing exercise involves three main steps:

- 1. Identify** the resources used by the cost object—provider, department/specialty, service, or patient (for instance, cost items such as personnel)—and determine which to include.
- 2. Measure** the amount (volume) of resources used by the provider, department/specialty, service, or patient (for instance, number of full-time equivalents for personnel).
- 3. Assign** a monetary value to the resources used by the provider, department/specialty, service, or patient (for instance, salary paid per month per full-time equivalent).

The cost items refer to which types of costs will be included in the costing exercise. Cost items are typically divided into recurrent cost items and capital cost items (table 1). Most countries include both capital and recurrent costs in their costing exercises, even if the former are treated differently than the latter in health system budgets and purchasing arrangements.¹¹

The accounting and economics fields offer many methodologies for measuring and valuing resources to calculate unit costs of health services. They primarily include micro-costing versus gross costing, bottom-up versus top-down costing, normative costing,

TABLE 1. Categories of Cost Items

Sample Categories of Cost Items	
Recurrent Costs	
<i>Personnel</i>	The cost of all wages paid to permanent, contract, and temporary personnel. May also include local proxy wages for donated, volunteer, or free labor.
<i>Drugs/Medical Supplies</i>	The cost of all drugs and medical consumables used in direct and ancillary (paraclinical) patient care.
<i>Utilities</i>	The cost of utilities consumed by the facility.
<i>Other Recurrent Costs</i>	The cost of all other recurrent inputs that cannot be classified as personnel, drugs/medical supplies, or utility costs.
Capital Costs	
<i>Building</i>	Total building depreciation costs.
<i>Medical Equipment</i>	Total medical asset depreciation costs
<i>Nonmedical Equipment</i>	Total nonmedical asset depreciation costs.

Source: Adapted from Özaltın and Cashin (2014)

and so on. Different methodological approaches may be appropriate for economic evaluation and/or priority-setting, financial planning and resource requirements estimation, budgeting, and efficiency analyses.¹² No single methodology is ideal for every country context or cost analysis perspective, but certain approaches are better suited to different uses of the costing information.¹³

Cost accounting methods, as the name implies, use accounting principles to identify and measure all costs incurred in carrying out an activity, primarily for financial planning and reporting purposes. Economists, by contrast, view cost as the value to society of resources utilized to produce a healthcare good or service if they had been put to their next highest-valued use (opportunity costs or economic costs).¹⁴ For example, the economic cost of providing cancer therapy may be considered in terms of the number of lives saved by that therapy against the number that could have been saved by using those resources for childhood immunization instead. Measuring the opportunity costs of all resources involved in

producing health services is not a feasible exercise, and cost accounting is typically considered a reasonable alternative.¹⁵ Costing that uses cost accounting methods but also assigns value to resources used without expenditures (such as donated equipment and volunteer labor) come closer to estimating economic costs. Economic costing methods also often focus on statistical analysis of marginal costs to understand the change in cost as a result of a change in activity.¹⁶

Cost accounting methods

In cost accounting methods, the first distinction is between micro-costing and gross costing. Micro-costing includes activity-based accounting of all inputs consumed for an output/service, whereas gross costing accounts for aggregate costs and divides the total by the volume of services/outputs.¹⁷ In micro-costing, all relevant cost components are defined at the most detailed level, whereas in gross costing, cost components are defined at a highly aggregated level (for instance, inpatient days only).¹⁸ Micro-costing

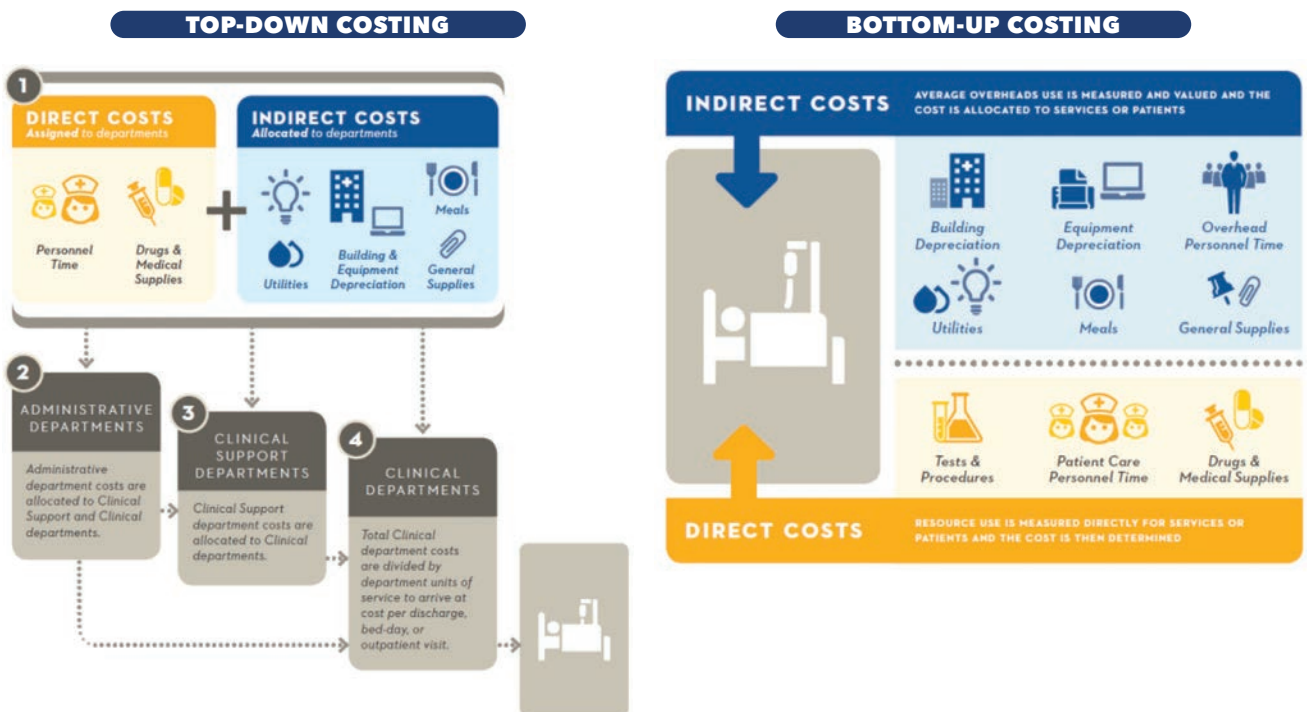
provides a way to identify costs per individual patient and to gain insight into patient subgroups that might have a greater share in the total costs.

The second distinction in methods is between bottom-up and top-down approaches, which relate to how resources are allocated to the units being costed. The key difference is that the bottom-up approach relies on detailed measurement of input quantities at the service or patient level while the top-down approach relies on average costing. Bottom-up costing documents the specific resources used to deliver a narrowly defined service or to treat a type of patient. The top-down approach, by contrast, first documents total facility or program costs or expenditures; it then allocates the total down to departments and divides by the service/patient quantity to arrive at the unit cost (figure 1). Typically, gross costing is performed top-down and micro-costing uses both bottom-up

measurement of the inputs used and top-down allocation of some input costs, such as indirect costs.

The main advantages of the top-down costing approach are that it is more complete and it uses readily available data sources. Top-down costing is easier to implement and requires less time and fewer financial resources for data collection. Total costs are distributed among all health services in a facility, so any costing errors in one part of the facility will be counterbalanced by errors in other parts. The main disadvantage of the top-down approach is that the cost estimates may be viewed as less accurate because they are averages constructed from aggregate data.¹⁹ Also, variations in accounting practices and interpretation of data across institutions can make aggregation and comparison of cost data problematic. Whereas the criteria used to allocate total costs are based on resource use, the choice of allocation bases

FIGURE 1. Top-Down vs. Bottom-Up Costing



Source: Özaltn and Cashin (2014).

may be somewhat subjective, thereby compromising accuracy. Further, to derive average costs, the quantity of resources used to provide services or treat patients within a department is assumed to be equal across all patients. Because actual differences in the distribution of resources are not distinguished, the costs of particular components of a stay or outpatient visit are not detectable.²⁰

The bottom-up approach may yield more accurate results for specific services/patients because it uses direct and detailed cost measurement. In practice, however, costing at a more detailed and disaggregated level can introduce inaccuracy due to the complex nature of capturing all inputs and the risk of double-counting inputs across services.

Analysts sometimes use both approaches in the same costing exercise—one as the primary approach, and the other to obtain supplemental information. A costing team might use the bottom-up approach within a top-down exercise to target the measurement and valuation of the following items:

- Priority services, treatment episodes, activities, or cost items
- Services that differ significantly in their resource use, such as intensive care unit services, laboratory tests, and surgical procedures
- Services for which a precise and accurate cost measurement is important
- Services that involve heavy personnel time or overheads related to using a technology
- Services that involve extensive sharing of personnel, buildings, or equipment between technologies or services
- Cost items that are expected to have the highest impact on total cost
- Data that are missing or not routinely captured.

Applying Costing Analysis to Health Benefits Policy

As mentioned above, there are three reasons for analyzing the costs of a HBP: to evaluate how generous a package the country can offer based on its existing and projected financial capacity, to consider what cost implications might be involved in adding individual services or medicines, and to determine much will providers be paid for their services. The following section will examine these applications in greater detail.

Costing the entire HBP

Several countries make efforts to cost the entire HBP at the time it is being established, or periodically to inform adjustments in the package or to funding levels. These costing efforts typically combine point estimates of the unit costs of each of the services in the HBP, derived from various costing methods, with projections of utilization to estimate the total annual cost of making the services in the HBP accessible. Some estimates of the total expenditure required to make the HBP accessible are based on provider payment rates and projections of service utilization. The total expenditure requirements for HBPs are sometimes updated with frequent new costing studies (as in the case of Chile), applying across-the-board inflation rates (Thailand), or some other periodic validation (Mexico and the Philippines). Table 2 provides examples of country experience costing entire HBPs using different methods.

In both Chile and the Philippines, the cost of delivering the HBP is estimated through micro-costing of services, which is also used to negotiate provider payment rates. The payment rates for services in the HBP are combined with predicted volume of service demand to estimate the total expenditure required by the purchaser to make the HBP accessible. In the Philippines, the costing of

TABLE 2. Examples of Country Experience Costing HBP

Country	HBP Costing Exercise Description and Methods	Use of Cost Information in HBP Policy
Chile	<p>Successive cost studies on the Explicit Health Guarantees (GES) plan commissioned by the Ministry of Health to estimate the cost of the GES for the public purchasing agency (FONASA) and private insurers (ISAPREs). Micro-costing of GES services informs the FONASA payment rates, and the payment rates in turn are used to estimate the cost to the insurers of making GES available.</p>	<p>To negotiate the FONASA budget, determine and adjust premiums paid to insurers, and adjust provider payment rates.</p>
Mexico	<p>Beneficiaries covered by Seguro Popular, introduced in 2003 for those not covered by social security scheme (~45 percent of the population), are entitled to the services of two explicit HBPs: the Universal List of Health Services (CAUSES) and the List of High-Cost Interventions (CIAC), financed by the Catastrophic Health Expenditure Fund (FPGC). Micro-costing was carried out using normatives for inputs required for each service and applying the average cost of basic functions (out-patient consultation, inpatient day, etc.).</p> <p>Ongoing annual financial and actuarial valuation of CAUSES and the FPGC is required by law.</p>	<p>Micro-costing was used as an input into a top-down costing exercise, which allocated a fixed budget ceiling across services in the HBP to allocate funding based on relative costs but keeping total expenditure within Seguro Popular's budget ceiling.</p>
Philippines	<p>The Philippine Health Insurance Corporation (PhilHealth) undertook a costing exercise for a new primary care HBP known as Tsekap (Tamang Serbisyo para sa Kalusugan ng Pamilyang Pilipino). The cost of each individual service was estimated using a bottom-up approach. These unit costs were summed up and adjusted according to prevalence and utilization rates to estimate the cost for the entire population.</p>	<p>The process of costing was carried out through several iterations, along with HBP adjustments to fit the available resources and inform provider payment rates.</p>
Thailand	<p>Thailand's Universal Coverage (UC) Scheme was introduced in 2001 to extend coverage to those not included in a formal-sector scheme (more than 75 percent of the population). The HBP is defined as a comprehensive set of outpatient and inpatient services, with new higher cost services added incrementally. The cost of the package initially estimated using bottom-up costing and projected utilization rates. Cost estimates are updated each year based on inflation.</p>	<p>Service cost and utilization estimates are translated into a per capita amount, which is used to inform budget allocations for the UC Scheme, although per capita budget allocations are typically lower than cost estimates. Provider payment rates for inpatient, outpatient, and other services (such as disease management) are informed by cost estimates but are capped to remain within the budget.</p>

the primary care benefits package (Tsekap) was carried out iteratively with discussions about provider payment rates for the services in the package and cross-checking with available resources to ensure alignment between projected total expenditure on the package and available resources.²¹ Nonetheless, this method has tended to underestimate the actual cost to the purchasers of making the HBP available, owing in part to utilization decisions of beneficiaries or other market forces that were not accounted for in the costing exercises.²² In Chile, for example, the cost to the public purchaser (FONASA) and private insurers (ISAPREs) of purchasing the Explicit Health Guarantees (Garantías Explícitas en Salud; GES) is based on payment rates negotiated with GES-preferred providers, but in practice 20 percent of FONASA beneficiaries and 80 percent of ISAPREs beneficiaries choose to receive GES services from other providers using the “free choice” option. These providers typically are paid at higher rates than those negotiated with GES-preferred providers.²³

In Mexico and Thailand, micro-costing of services in the HBP is balanced with a top-down exercise based on resource availability for the HBP; this helps ensure that total expenditure remains within the budget.²⁴ In Thailand, for example, service cost and utilization estimates are translated into a per capita amount, which is used to inform budget allocations for the Universal Coverage (UC) Scheme. In turn, while provider payment rates for inpatient, outpatient, and other services (such as disease management) are informed by cost estimates, final total payments to providers are capped to remain within the budget.

Costing for decisions about individual services in HBPs

For decisions about inclusion of individual services or medicines in HBPs, analysts often apply costing to individual services under consideration to use

in cost-effectiveness analyses (CEAs, also known as economic evaluation) and budget impact analysis (see chapter 4). A CEA provides a standard, well-accepted methodological approach for judging whether a health service provides value for money relative to other services. The CEA generates a calculated ratio of some measure of the cost of a service against a measure of the benefits. An average cost-effectiveness ratio is the total cost of a program, intervention, or service divided by a measure of its effectiveness compared to “doing nothing” (the base-case alternative). An incremental cost-effectiveness ratio is the incremental cost of a program, intervention, or service divided by the incremental effectiveness compared to the next most effective program, intervention, or service. Progress has been made in recent years to develop standards for measuring the denominator of the cost-effectiveness ratio—measure of health effects or benefits—such as the number of disability-adjusted life-years (DALYs) averted or quality-adjusted life-years (QALYs) gained.²⁵ Costing methods for CEAs, by contrast, have been slow to be standardized, making it more challenging to interpret and compare CEA results.²⁶ This is particularly true as CEAs have expanded to more complex health services and interventions from the more traditional focus on pharmaceutical therapies (where costing is more straightforward). Even studies of the cost-effectiveness of the same intervention can employ a wide range of costing methods and approaches. For example, a review of 79 cost-effectiveness studies on the introduction of rotavirus and pneumococcal vaccines found that fewer than half of the studies systematically measured costs beyond vaccine procurement.²⁷ Variations in service costing stem from highly variable country resources, infrastructure, and accounting methods.

One area of inconsistency in costing for CEA is the perspective of the analysis. Costing for CEA can take a purchaser, provider, or a societal perspective.²⁸ Most CEA costing aims to take a societal

perspective—including all resources used to deliver and access the service, including direct out-of-pocket payments by patients and nonmonetized resources such as volunteer labor and donations—but in practice most take the purchaser perspective.²⁹ Another area of inconsistency in costing for CEA is whether marginal costs of adding interventions to a HBP are analyzed (in which case only variable costs are included), or whether average costs are analyzed (in which case both fixed and variable costs are included). The importance of fixed costs in CEA is highly dependent on whether the infrastructure is in place to deliver the service or needs to be added. Incremental costs to the purchasers of adding a service to the HBP can vary widely depending on the existence of the delivery platform. For example, the cost of setting up a new home-based approach to HIV status testing and treatment will vary based on what kind of infrastructure is already available for that type of service delivery. If infrastructure for home-based health services already exists, the incremental costs of adding HIV testing and treatment may be relatively modest, as the existing services will share some portion of the fixed costs. If no infrastructure is in place, however, the new services will have to bear the entire cost.

Recent efforts aim to provide a set of principles to encourage standardization in methods and reporting for economic evaluations of health policy options and interventions, and some countries are adopting standard approaches.³⁰ Thailand, for example, has a well-established infrastructure for carrying out health technology assessment, including CEA, to inform health benefits policy.³¹ The Health Intervention and Technology Assessment Program (HITAP) was established in 2007 to build capacity for health technology assessment in Thailand and contribute evidence for decisionmaking on HBP expansion in the UC Scheme. One of HITAP's contributions has been to develop and institutionalize a standardized costing method for CEA as part of health technology assessment.³² It will go beyond previous efforts by

providing systematic economic evaluation of policy choices affecting the access, uptake, and quality of interventions and delivery platforms for low-and middle-income countries.

Costing to establish provider payment rates for HBP services

The way health purchasers pay healthcare provider institutions to deliver covered services is a critical element of strategic health purchasing. Strategic health purchasing is one lever to balance the expenditure required to make the HBP accessible and the resources available. The payment methods purchasers use to pay providers and the rates they pay all create incentives that affect service delivery and utilization patterns. Cost information is important both for the design of provider payment systems (for example, case weights used in diagnosis-related group payment systems) and the calculation of payment rates (including fees, diagnosis-related group base rates, or capitation rates). Cost evidence should inform calculations of payment rates, but final payment rates are almost always modified based on other factors such as policy considerations, resource constraints, and negotiations.³³ To set realistic payment rates and create the right incentives, policymakers need to understand current cost structures. Provider costs are not the only factor in provider rate-setting, but understanding the cost to providers of delivering various services can help ensure that they are paid adequately for priority services and are motivated to deliver them. The most important cost information factors in provider payment policy include:

- Estimated average unit costs of services in the HBP across providers
- Relative costs to get incentives right
- Insights into cost drivers and where efficiency gains might be possible.

The relationship between provider payment rates and provider costs is a key part of the incentive environment that purchasers create. The objective in setting provider payment rates is not simply to cover individual provider costs but to deliberately create incentives to ensure access to HBP services while also encouraging efficient service delivery.³⁴ Providers need to be paid adequately to efficiently deliver high-quality services, with stable payment rates that allow for planning and inform investment decisions. If payment rates are chronically below costs, providers may excessively reduce their costs by skimping on care and reducing quality, or they may demand extra payments from patients to close the gaps. If they have the choice, providers who perceive payment rates to be too far below their costs will exit the market. In Vietnam, for example, cost analysis among 76 commune health stations from two provinces revealed that current payment rates covered only about 19 percent of their total costs for primary care visits for services in the HBP.³⁵ The large gap between provider costs and payment rates for services in the HBP is one possible reason why out-of-pocket payments remain high even while population coverage has expanded in Vietnam.³⁶ The costing results provided valuable information for policymakers as they revised the provider payment methods to better reflect the costs of services and give greater priority to primary care.³⁷

In some countries health purchasers strategically set payment rates to manage the total expenditure in the system. For example, payment rates for services in the HBP derived directly from the pool of available resources can create a budget-neutral payment system.³⁸ When a new national health insurance system was introduced in Kyrgyzstan in the mid-1990s, the payroll tax revenue for health insurance was highly unpredictable; the national health insurance fund was unwilling to commit to unsustainable payment rates and introduced a budget-neutral payment system. The purchasing agency calculated the base rate for the new case-based hospital payment

system directly from the portion of the total projected budget set aside for hospital services divided by the historical volume of cases. It also reserved the right to adjust the base rate downward during the year if actual revenue was less than projected or if the volume of cases increased beyond historical levels. But because the insurance funds added new money to the system, no provider received less revenue overall.³⁹

In Thailand's UC Scheme, the purchaser (National Health Security Office) aims to strike a balance between setting realistic payment rates that cover provider costs and using payment policy to ensure financial sustainability of the system. Costing information is used to inform annual budget requests for the UC Scheme, but provider payment rates are set based on the budget pool and caps at the level of the health services contracting unit enforce budget neutrality.⁴⁰ Consequently, although the aim is to maintain realistic absolute payment rates, the main concern is aligning relative prices to relative treatment costs, which is important for maintaining the incentive for providers to take on more complex (and therefore more costly) cases. If the global budget allocated to the purchaser is inadequate, however, the HBP may be unsustainable over time as providers skimp on quality, limit access to services, or withdraw from the market completely because their costs consistently exceed their revenues.

Challenges with Costing for Health Benefits Policy

Estimating the cost of making the HBP accessible provides useful benchmarks for aligning available funding with the cost of delivering the HBP. To align expenditures with available resources, the cost of the HBP should be projected using information on service cost as well as actuarially informed estimates of current and future utilization. Generating valid cost estimates of health benefits plans, however, presents

a number of challenges. Calculations can be time-consuming, and reliable high-quality data are often lacking. Furthermore, building up the cost of a HBP by summing the cost and utilization of individual services is likely to double-count some resources and thus possibly overestimate total costs. Conversely, utilization estimates may fail to take into account the beneficiaries' different utilization choices and underestimate the cost to the purchaser of the HBP, as in the case of Chile's GES plan.

Health services costing exercises may overestimate costs by failing to account for economies of scope and scale, which can be substantial. Economies of scope arise where it is less costly for a provider to produce two or more services together because of "shared costs," than for two providers to produce each service separately.⁴¹ For example, health workers may deliver multiple services in one visit, so the cost of each service is lower when they are delivered together. Cost estimates of each individual service may double-count the health worker's time and overestimate the unit cost.⁴² Economies of scale generally are found where fixed costs of production are high in relation to variable costs, so that long-run average costs fall as the scale of production increases. This may be true for health services that rely on expensive equipment such as scanners, but can also be true when labor costs are fixed because of civil service laws governing health worker employment, for example.⁴³

Another challenge is that HBP costing exercises are often undertaken as static analyses producing point estimates of costs, and although these point estimates can provide useful benchmarks for resource requirements, the actual implementation of HBPs is a dynamic process. For example, access to some services will affect the demand for others in a way that may be difficult to predict.⁴⁴ Also, the financial data from health facilities used to generate unit costs may not reflect the actual market forces that will come into play when the package is implemented.⁴⁵ These analyses rely on many assumptions

about the dynamic response of key variables, such as the extent to which utilization will increase when financial protection is provided for services in the HBP and the likely effect on unit costs.⁴⁶ Because of economies of scale, marginal costs may initially decrease as demand for services increases, but marginal costs may then increase as coverage expands to hard-to-reach populations and places.⁴⁷ Sensitivity analysis for different assumptions about the insurance effect on utilization and the subsequent effect on unit costs as coverage expands can help capture the dynamic nature of purchasing HBPs and make expenditure projections more realistic.

Finally, HBP costing exercises are based on the status quo—the existing cost structures for service delivery, which may include inefficiencies. The cost of delivering services may include inefficiencies because of decisions of providers on input use, outdated technology, rigidities in public finance and procurement systems, or other factors.⁴⁸ Utilization patterns are also affected not only by health needs but also by the cost to users of accessing services, user preferences and constraints, and other contextual factors that may be difficult to predict but are also influenced by policy.⁴⁹ Most costing, actuarial, and expenditure projection models do not take into consideration policy levers, such as purchasing and provider payment strategies, that may generate efficiency gains and reduce the overall cost of the HBP over time.⁵⁰

Existing Resources and Priorities for Research

There are many resources available on costing theory, methods, and application.⁵¹ Some specific resources related to costing for health benefits policy include the Joint Learning Network for Universal Health Coverage Manual on Costing of Health Services for Provider Payment (box 1), the multi-donor One-Health costing tool (box 2), and the International

BOX 1. Joint Learning Network Manual on Costing of Health Services for Provider Payment

The Joint Learning Network for Universal Health Coverage (JLN) convened a Collaborative on Costing of Health Services for Provider Payment (“Costing Collaborative”) to share experience and solve common challenges related to costing for provider payment in JLN countries. The Costing Manual developed by the Costing Collaborative members bridges costing theory with practical, step-by-step guidance to address multiple challenges related to costing health services in low- and middle-income countries. Although the manual is designed specifically to support costing to design health provider payment systems and set payment rates, it provides general methodological guidance and specific tools and templates for data collection and analysis based on country experience.

Source: www.jointlearningnetwork.org/resources/costing-of-health-services-for-provider-payment-a-practical-manual.

BOX 2. OneHealth Tool

In response to requests from countries to harmonize the content, format, and outputs of existing costing tools, an Inter-Agency Working Group on Costing—composed of UNICEF, World Bank, the World Health Organization, the United Nations Population Fund, the United Nations Development Programme, and UNAIDS—has been working on the harmonization of costing and impact assessment tools used for health sector planning. The resulting OneHealth Model is a software tool designed to strengthen health system analysis, costing, and financing scenarios at the country level and to assess public health investment needs in low- and middle-income countries. OneHealth presents detailed components of existing disease-specific costing tools in a uniform format and links them together.

Source: www.who.int/choice/onehealthtool/en/

Decision Support Initiative reference case for economic evaluation (box 3).

In spite of the wealth of resources, key gaps remain in better standardizing and applying costing analysis to health benefits policy. A particular area where more research is needed is in support of modeling, simulation, and scenario analysis to capture the dynamic nature of costing for HBP policy. More options are needed to incorporate behavioral decisions and other contextual factors into costing, actuarial analysis, and expenditure projections for HBP design, implementation, and expansion over time. Costing studies can reveal information on the underlying cost structure of service delivery and enable the modeling of different scenarios using various assumptions about

prices, the impact of incentives, changes in service delivery configuration, and levels of service use (such as the specific features of a system driven by primary care). More powerful modeling and simulation tools are needed to predict the impacts of policies, especially those aimed at improving efficiency and changing the cost structure.

In addition, as economic evaluation becomes more sophisticated, the costing methods must also keep pace. For example, in the United Kingdom CEA is being extended to efforts to develop complete care pathways and even for evaluating the cost-effectiveness of the Quality and Outcomes Framework pay-for-performance policy.⁵² The Disease Control Priorities Network (DCPN) periodically publishes the most up-to-date evidence on health intervention efficacy and program effectiveness for the leading causes of global disease burden.

BOX 3. iDSI Reference Case for Economic Evaluation

The Bill & Melinda Gates Foundation requested that the United Kingdom's NICE International convene a team to develop a set of methods for calculating the value of health technologies to help the foundation make recommendations to countries about which medicines to make available. This set of methods, called a Reference Case, takes a principle-based approach: instead of providing explicit details about every aspect of how researchers should calculate the value of a treatment or health service, it outlines principles that researchers should follow when deciding how to make their calculations. For example, the Reference Case does not specify exactly which costs should be included in or left out of calculations, but requires researchers to identify all relevant direct costs, using local experience and knowledge of where a treatment might be used in the health service. The Reference Case is designed to be useful to local, national, and international decisionmakers and is applicable to different types of health technology, including individual medicines and diagnostics, public health initiatives and programs, and different types of health service delivery.

Source: www.idshealth.org/knowledge_base/the-reference-case-for-economic-evaluation/

The third edition of the DCPN's *Disease Control Priorities* (DCP3) introduces new extended CEA methods for assessing the equity and financial protection considerations of policies that may extend coverage of proven effective interventions to prevent and treat infectious and chronic diseases, including conditions related to environmental health, trauma, and mental disorder.⁵³ These new dimensions to CEA also add new methodological challenges for costing

policies and interventions and valuing benefits that are relevant for HBP policy, including how to cost program administration and assign a value to financial protection.⁵⁴

Finally, it remains unclear how influential cost evidence actually is in making decisions about HBP policy, especially in low- and middle-income countries. More research is needed to better understand the role that cost evidence plays in the HBP policy process, what the demand is for different types of cost analysis, and how to generate better information that is used routinely in HBP design and implementation.

Conclusion

Cost information is crucial for several aspects of health benefit policy—estimating the total expenditure required to make a HBP accessible to align with available resources, analyzing the incremental cost of individual services to make decisions about inclusion in HBPs at the margin, and costing individual health services or sets of services to set or negotiate provider payment systems and rates. Costing the entire HBP is important when establishing benchmarks for resource requirements to ensure that commitments align with resources available, and when building scenarios for different population and provider responses to increase coverage and financial protection. HBP costing is also important for informing a dialogue to use policy levers, such as strategic purchasing, to make benefits affordable.

Even though well-accepted costing methodologies are available, these methods continue to be applied inconsistently in many areas related to HBP policy. Furthermore, a number of specific challenges can affect costing for health benefits policy, including time-consuming calculations and a lack of reliable high-quality data. Other policy choices, particularly supply and demand incentives, also affect the expenditure required to purchase the HBP.

Despite these challenges, estimating the approximate resource requirements for implementing or expanding a defined HBP is an important part of fiscally sustainable progress toward UHC. Information on the cost of delivering health services is an essential part of the evidence base needed to make decisions to establish and expand a HBP, strategically purchase the covered services, and inform policies to drive efficient service delivery and utilization of cost-effective services. Many health reforms are aimed at changing the health system's cost structure by reconfiguring service delivery, as this is an important factor in being able to sustainably finance the HBP, particularly as it grows.

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CHAPTER 9

Beyond Cost-Effectiveness

Health Systems Constraints to Delivery of a Health Benefits Package

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At a glance: Can your health system deliver its health benefits package? Consider money—but also infrastructure, implementation, costs, politics, and governance.

Cost-effectiveness analysis (CEA) of health services has been extensively applied to evaluate interventions, and is a key input in developing evidence-based clinical guidelines and care quality standards. These guidelines and standards offer systematic guidance on how healthcare professionals should care for individuals with specific conditions.

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The principle underlying conventional CEA is that it seeks to identify the set of health interventions that maximizes some social objective (usually improvements in aggregate health) subject to a single publicly funded budget constraint. Although many methodological challenges remain unresolved, great strides have been made in resolving key issues.¹ CEA is becoming an important mechanism for strategic priority-setting in health systems, and many countries have established agencies to advise on health system cost-effectiveness issues. International organizations are increasingly appealing to CEA as a basis for advising countries on priority-setting, in particular to determine benefit packages for universal health coverage in resource-constrained settings.²

However, it often remains the case that the recommendations arising from CEA are not fully implemented, even when decisionmakers agree with the underlying principle of CEA—of obtaining maximum value from a limited health service budget. The failure to secure full implementation of CEA recommendations does not necessarily indicate a weakness in the principles underlying the analytic approach or the institutional arrangements employed by the health system. It may be often the case that decisionmakers invoke perfectly legitimate criteria that are not considered in the CEA methodology when coming to priority-setting decisions. Failure to implement in these circumstances may not negate the usefulness of the CEA, which has at the very least demonstrated what is sacrificed (often in the form of lost health improvement) by failing to implement. Nevertheless, the frequent and widespread reports of CEA recommendations being ignored or modified does highlight the importance of understanding the motivations of decisionmakers, and raises the issue of whether CEA ignores important elements of the priority-setting process.

One class of practical factors that may have a major influence on priority-setting is the potentially large set of constraints that inhibit change in the health system, in addition to the global budget constraint. For example, all systems have an existing configuration of institutions such as hospitals that cannot be altered in the short term and a limited pool of skilled human resources. Many changes will also impose short-term costs (such as training) that detract from direct patient care. In addition, governance and information infrastructure may be inadequate to ensure that new services are delivered effectively, and various powerful political forces may inhibit change throughout the health system. The constraints discussed in this chapter are gathered together under six headings: the design of the health system, costs of implementing change, system interdependencies between interventions, uncertainty in estimates of

costs and benefits, weak governance, and political constraints. Not all priority-setting decisions face these constraints. For example, replacing therapeutic drugs may face hardly any barriers, whereas the implementation of complex public health interventions will face multiple constraints.

This narrative review assumes that decisionmakers wish to maximize the societal value secured from their health services budget and are considering the use of CEA to guide that process. It then explores the role that constraints play in influencing priority-setting decisions, and assesses whether and how they can be accommodated within the CEA methodology. The review is inspired by various group discussions conducted as part of the International Decision Support Initiative (iDSI). Its objective is to develop a typology of constraints that may act as barriers to implementation of cost-effectiveness recommendations. Where possible and applicable, it sets out ways in which these constraints can be accommodated within CEA models.

The Constraints

The cost-effectiveness model generally used for the evaluation of health technologies—and healthcare and public health interventions more widely—has become a central tool for public sector policymakers in many healthcare systems.³ It was developed to help decisionmakers with fixed public resources to compare different interventions for the same health problem and programs in different disease areas. For a particular level of healthcare resources, the goal is to choose from among all possible combinations of programs the set that maximizes total health benefits produced.⁴ The traditional CEA methods presume the existence of only one salient constraint: the public finance budget constraint. Yet all the evidence suggests that many other constraints impinge on decisionmakers, at least in the short run. These

limitations to traditional CEA gives rise to difficulties in interpreting CEA findings for implementation by local decisionmakers. Practical policymaking generally encounters six broad categories of constraints, although there are additional ones that are not discussed here.⁵ They may explain why strategic decisionmakers depart from national or international guidance.

Design of the health system

System design constraints preclude certain flexibilities, and relate to the institutions of the health system (purchasers and providers), the financing mechanism(s), regulatory arrangements, and the role of external agencies such as donors. Important practical system constraints are the short-run availability of capital or labor. For example, a highly cost-effective new intervention may require substantial additional staffing, but if the existing workforce is already working at full capacity and existing interventions cannot be abandoned, implementation may be infeasible. With respect to financing mechanism constraints, CEA implicitly assumes that providers are paid solely by a single national funder that specifies which interventions are funded. In practice, however, private payments such as user charges make it difficult to ensure that designated services are always provided to the intended recipients.⁶ Constraints imposed by donors can often take the form of “vertical” organization of services for specific programs such as HIV/AIDS.⁷ This requirement may optimize delivery for the chosen program, but it can create serious rigidities in how resources are deployed and prevent systems from realizing the economies of scope⁸ available by integrating services “horizontally” for a wide range of conditions.

Provider reimbursement through capitation payments or global budgets can be another important financial constraint, because it may provide weak incentives for providers to deliver a recommended

intervention as intended. Augmenting conventional provider payment methods with various forms of pay-for-performance may address this constraint, and there is some evidence that pay-for-performance is leading to improved discipline in strategic purchasing of health services, including adherence to HBPs.⁹ Regulatory constraints can arise from the way relations between the different institutions of a health system—such as hospitals, primary care organizations, local governments, and insurers—are organized through legal arrangements and professional regulations.¹⁰ This implies that the autonomy of the institutions is usually limited by regulatory statutes that may preclude adoption of certain innovations. For example, efforts to move certain interventions out of a hospital setting may be frustrated by the organizational boundaries and funding mechanisms in place.

Many health system constraints can be eased in the medium to long term. However, in the short term, decisions usually are subject to prevailing constraints. CEA recommendations can in principle allow for the type of health system in place. For example, system design constraints can be addressed technically by more careful analysis of supply- and demand-side responses to the introduction of an intervention, and (where necessary) by extending the optimization model to include multiple resource constraints.¹¹ In addition to yielding evidence that is more immediately relevant to priority-setters than crude CEA, such analysis offers a great deal of valuable additional information, for example on the effect of short-run constraints in reducing the potential longer-run achievements of the health system. It can therefore help point to the most urgent priorities for health system redesign.

Costs of implementing change

In its purest form, the rational cost-effectiveness model assumes that change is instantaneous. This

often does not reflect realities of implementation. Any significant change to the health system is likely to require irreversible investment, for example in the form of capital (new clinics), personnel (training or redeployment), information resources (data capture), implementation (new guidelines), or administrative complexity. Such irreversible investments are transition costs. They can often act as a major decisionmaking barrier to implementing programs with long-term benefits; even if the priority-setting process is functioning properly, it may take considerable managerial effort to ensure that the technology is implemented.¹² Therefore, an important consideration for any priority-setting endeavor is the transition costs of implementing a new intervention.

A more gradual reform may reduce transition costs substantially. It may be not only infeasible but also inefficient for a government to reappraise continually the entire health system. Rather, a more realistic aspiration is that a government should progressively remove ineffective programs and replace them with more effective actions. An incremental “threshold” formulation of CEA may be closer to political reality than a comprehensive “zero-based” formulation. The zero-based approach requires a ranking of the cost-effectiveness of *all* potential interventions, with only the most cost-effective being selected for inclusion in the publicly funded HBP, as attempted in the famous Oregon experiment.¹³ The zero-based approach is likely to be especially important when fundamental reform of a system is needed, such as the introduction of universal coverage. As well as defining the package, CEA can be used to inform health system reforms necessary to maximize returns from expenditure.

The incremental model implies that governments may set priorities for action based on criteria that are not considered in conventional cost-effectiveness models. These might include:

- The magnitude of the program, where the greatest potential gains may be secured by first

reconsidering programs that consume a large part of healthcare expenditure;

- The existence of large differences between competing technologies in terms of outcomes, externalities, or equity considerations; or
- The practical considerations, such as prioritizing programs according to feasibility of changing delivery patterns and the size of transition costs.

A number of approaches have been developed to deal with the constraints imposed by transition costs, of which program budgeting and marginal analysis (PBMA) is among the most prominent. PBMA can be interpreted as an attempt to systemize the incremental budgeting approach. A practical focus on the evaluation of relatively modest and manageable changes, as opposed to adherence to historical patterns, is the key contribution made by the PBMA approach.¹⁴ The PBMA approach can be interpreted as a complement to CEA, as cost-effectiveness often remains an important criterion for prioritizing.¹⁵ The cost-effectiveness and strategic planning project of the World Health Organization (WHO-CHOICE) has addressed the inclusion of implementation costs by proposing to assess mutually exclusive scenarios across various disease areas, including noncommunicable diseases, HIV/AIDS, malaria, and tuberculosis in various low- and middle-income settings.¹⁶

In summary, it is important that a recommended intervention should be implemented as intended, and substantial transition costs often can be an important requirement to ensure its success. Such costs should in principle be incorporated into the CEA and written off over the expected lifetime of the program. Costs could be disaggregated as far as possible to highlight major implementation cost components that may arise. However, in practice short-term transition costs can act as an important decisionmaking barrier to implementing programs with long-term benefits. Certain aspects of system design, such as the use

of separate public sector budgets or donor funds to cover the resulting costs, can mitigate the rigidities caused by transition costs. However, it may also be necessary to adapt CEA methodology to accommodate transition costs, either by explicitly including such costs in the optimization model or by embedding CEA in a broader decisionmaking process.

System interdependencies between interventions

Most interventions rely on the existence of certain aspects of health system infrastructure without which delivery would be infeasible. This infrastructure might include physical capital, the workforce, various supply chains, and information technology. With a few exceptions, such resources are shared with many other interventions, often yielding the manifest economies of scope that can be observed in all health systems. From an accounting perspective, the costs of providing these resources should be shared across the interventions that use them. Changes to the mix of services using the infrastructure may alter the costs and effectiveness of all interventions that rely on it. (For instance, existing infrastructure may sometimes *reduce* costs, at least in the short run, relative to those assumed in the CEA, thus potentially making the service under scrutiny more cost-effective than indicated.) And the absence of certain types of infrastructure may preclude or at least seriously increase the costs of adopting a new technology. Thus, decisions cannot be made only on comparisons of average costs of individual services but must consider bundles of the services being provided, the implications of shifting resources and redefining packages, and the corresponding losses or gains due to changes in scale and scope of the packages. For example, a new intervention to be delivered by community-based nurses may only be highly cost-effective if a network of such nurses is already in place, but not if major new investments in such a network were required. Furthermore,

the adoption (or absence) of certain interventions may have implications for other programs of care. The most obvious example of this is the joint supply of a bundle of early-childhood interventions.

System interdependencies illustrate the limitation of examining interventions in isolation. Any significant reform of the health system design may affect not only the long-run average costs of the intervention under immediate scrutiny, but also of many other interventions. System reform may require the comparison of two entirely different configurations of service delivery, with profound implications for different patient groups and system costs. It is possible that such zero-based reforms can never be fully adopted as a basis for decisionmaking, but they can still be used to indicate where the scope for improved performance lies and determine policy on more incremental changes to the system. The presence of systemwide effects, and the complexities they introduce, may explain why the greatest impact of CEA has been in the realm of pharmaceutical treatments. New drugs can often be adopted without major changes to the configuration and mix of human and physical resources. Proper modeling of system interdependencies is feasible in principle within a CEA framework,¹⁷ but may be challenging in practice (see David Wilson and Marelize Gorgens' discussion in chapter 10). The interactions between interventions must be modeled explicitly, perhaps by modeling an intervention under two mutually exclusive scenarios, with and without its complement. At the very least, where feasible, there may be a CEA argument for presenting a range of cost-effectiveness ratios for interventions where both costs and benefits are dependent on the prevailing system configuration.

Uncertainty in estimates of costs and benefits

Uncertainty is inherent to all priority-setting. It can take numerous forms, including uncertainty in

model parameters (costs and benefits of interventions, especially in the longer term),¹⁸ uncertainty about the nature and performance of competing interventions (either now or in the future),¹⁹ uncertainty about patient behavioral responses (such as uptake and compliance), and uncertainty about provider responses. CEA has long recognized the importance of uncertainty, and there has been lively academic debate about how to incorporate uncertainty into analytic models.²⁰ The role of uncertainty in constraining decisions is that, other things equal, greater levels of uncertainty inhibit decisionmakers from implementing change. This may be due to natural risk aversion, especially when political or managerial futures are at stake. However, uncertainty also puts at risk any irreversible investment costs associated with change.

Uncertainty can therefore act as a powerful barrier to any change. In some circumstances the conservatism it causes may be warranted, as a delayed decision may avoid unnecessary investments and keep future options open. However, a vague appeal to uncertainty may inhibit timely adoption of cost-effective programs. The key requirement then is to inform decisionmakers about the true level and nature of uncertainty, so that they can make balanced judgments. CEA can act as a powerful device for assessing and communicating uncertainty. A range of analytic methods have been developed to address and communicate parameter uncertainty, and these should be adopted wherever feasible. Accounting for parameter uncertainty by probabilistic sensitivity analysis, and the presentation of its results via cost-effectiveness acceptability curves, is well established and required for submission of CEAs to the United Kingdom's National Institute for Health and Care Excellence (NICE).²¹

However, there is also a broader issue of "structural" uncertainty, which reflects potential limitations in modeling, such as the inclusion/exclusion of relevant comparators or relevant events, the

statistical models to estimate specific parameters, and clinical uncertainty or lack of clinical evidence.²² This structural uncertainty is the main source of concern in priority-setting, because its magnitude is difficult to quantify and risk-averse decisionmakers naturally will be reluctant to act when there are concerns about the relevance and quality of the analytic evidence base. Sensitivity analysis is of course then an important instrument for assessing the robustness of estimates to alternative model specifications. Novel approaches such as model averaging are becoming more widely used to address problems related to model uncertainty, such as for uncertainty related to the choice of explanatory variables in a statistical model.²³

The most obvious way to reduce any form of uncertainty is to commission relevant research, seek out high-quality data, undertake relevant meta-analyses, improve the quality of modeling, and carry out "value of information" analyses to identify priorities for generating new evidence.²⁴ This will help incorporate uncertainty into the evidence base in a systematic manner. Of course, these endeavors are both costly and time-consuming, and will in themselves create new delays. Robustness analysis can be used as a practical means of handling uncertainty in decisionmaking.²⁵ It assesses the flexibility achieved or denied by particular acts or commitments, provided they can or must be staged sequentially. In the same vein, Stephen Palmer and Peter Smith have applied option pricing theory to economic evaluation, with the aim of assessing the value of deferring decisions pending the arrival of better information²⁶. Despite these methodological advances, uncertainty will always remain intrinsic to strategic priority-setting. As long as decisionmakers are kept informed about the true level and nature of uncertainty, they will have a base from which to make balanced judgments. Failure to convey uncertainty properly may give rise to "uncertainty about the level of uncertainty" underlying a decision, and therefore inhibit

warranted change. For decisionmakers with little technical expertise, innovative ways of communicating uncertainty may be needed.

Weak governance

Whatever type of health system is under consideration, most health policy tools assume the existence and effectiveness of certain instruments of good governance. In choosing to include a treatment in the HBP based on the results of a CEA, policymakers are presuming that it will be delivered in line with the CEA's modeling assumptions. The governance requirements to underpin any priority-setting task are likely to include:

- Clear mechanisms for articulating health system goals, promulgating guidelines, and financing the required activity, possibly extending to contractual arrangements;
- Effective data collection mechanisms designed to audit delivery of care and adherence to quality standards; and
- Functioning accountability mechanisms that enable providers and other relevant parties to be held to account for the performance they have secured.²⁷

The level of detail at which priorities can be set may be determined by the administrative capacity of the health system. At one extreme, the benefits package might be explicitly defined in terms of detailed interventions and eligibility criteria. International bodies such as the WHO and the Global Fund to Fight AIDS, Tuberculosis, and Malaria could help in this task by providing generic resources that may be suitable for assessing the cost-effectiveness of specific interventions. At the other extreme, priorities might be set in broad terms, such as emphasizing a larger role for primary care relative to secondary and

tertiary care. Of course, the risk of adopting a broad definition of priorities is that the prioritized sector may provide some services that are not cost-effective.

In many health systems, limited audit and performance reporting capacity inhibits the ability to set and monitor detailed priorities.²⁸ The most poorly developed aspects of governance are the mechanisms to hold to account providers and other relevant agents for the levels of performance they have achieved, via mechanisms that include consumer markets, administrative procurement arrangements, democratic elections, or professional regulation. The prime purposes of an accountability mechanism are to allow stakeholders to check on adherence to standards and give them a means of offering rewards or sanctions depending on results.

An absence of good governance in any of these three key areas—priority-setting, performance measurement, or accountability mechanisms—seriously undermines the capacity for change and may make certain services infeasible or ineffective. It is difficult to offer generic guidance on how to confront or sidestep the constraints caused by weak governance. CEA may consider these realities by constraining the number of decisions that can be made in a given time period. In all health systems, there is likely to be a trade-off between the health gains secured by detailed priority-setting and the governance costs of specifying and monitoring adherence to the package. Whatever approach is taken, CEA can play an important accountability role by demonstrating the costs to the health system of continued shortcomings in governance capacity, and indicating where the priorities for improvement may lie.

Political constraints

The process of priority-setting takes place in a profoundly political context, in which numerous influential political interest groups seek to participate.²⁹ Katharina Hauck and Peter Smith present several

models of political economy that describe how decisionmakers react to political realities and how these reactions may influence priority-setting decisions.³⁰ Such models try to explain why the political decisionmaking process fails to generate apparently welfare-improving policy changes. With Maria Goddard, Hauck and Smith also argue that there may be substantial benefits to seeking to understand priority-setting processes using models based on political concepts.³¹ Five classes of political forces exert particular influence on decisionmakers: the median voter model, interest groups, bureaucratic decisionmaking, decentralization, and equity.

The *median voter model*³² asserts that political decisionmakers will seek to develop policies that attract the median voter in an effort to maximize political support. The implication of this insight for priority-setting is that the size and contents of a public HBP may be skewed toward the preferences of key voting groups. Gaining taxpayer support for health policies has high importance for policymakers, particularly in many low-income countries with high levels of informal employment where tax contributions are concentrated among a relatively small, urban elite. Models of competing *interest groups* assume that powerful interest groups may seek to skew decisions in their own favor at the expense of less-organized stakeholders.³³ Within healthcare, small groups with a clearly defined common objective—for example, health services providers, the pharmaceutical industry, or patients with a specific disease—have low costs in organizing themselves, securing cohesion, and effectively lobbying decisionmakers to their advantage. Compared with the broader population, whose interests may be more diffuse and who experience higher costs of organizing, these small groups may have a disproportionate voice in health policy decisionmaking.

The institutional theories of James Buchanan and Gordon Tullock³⁴ and William Niskanen³⁵ focus on *bureaucratic decisionmaking*, specifically the interests

of bureaucrats in maximizing their influence and the effect of their behavior on the level and nature of government output. The essence of this approach is the belief that such bureaucrats receive power and remuneration in proportion to the size of their enterprise, with the implication that bloated and inefficient public services emerge if there is a lack of effective control over government growth. Many healthcare systems make extensive use of *decentralization*, and these subsidiary levels of government add further complexities that affect variations in health spending and HBPs,³⁶ although the direction and magnitude of effects is likely to depend on specific institutional arrangements for such policies. Decentralization may be associated with improved performance resulting from increased horizontal competition between different levels of governments, although empirical evidence is mixed and the outcomes depend on institutional structures. In some respects, the promotion of *equity* in health and healthcare can be viewed as a political constraint. Equity concepts can readily be incorporated into conventional CEA, for example by placing greater weight on health gains for disadvantaged population groups. However, the nature of equity criteria adopted in health policy is likely to vary between health systems, and so it will be difficult to develop universal equity-weighted measures of cost-effectiveness.³⁷

Public involvement in decisionmaking has been advocated as one approach to ameliorate potentially unwarranted impacts of political constraints. However, a scoping review found it difficult to assess the extent to which public involvement is more or less vulnerable to capture by interest groups because formal evaluations of public engagement efforts are rare.³⁸ Priority-setting is ultimately a political undertaking. To some extent, the health technology assessment agencies now being put in place across the world are an indication that politicians feel it is helpful and expedient to devolve some aspects of that process to agencies with politically legislated terms of reference.

At its best, this approach can lead to better informed rankings of interventions, made on a consistent basis, aligned with social preferences. However, the technical recommendations of those agencies must almost always be viewed from a broader perspective than that of narrowly defined CEA. In some cases that broader scrutiny may be undertaken within the agency (as in NICE); in others it must be left to those who are ultimately accountable for choosing priorities. In either case, a key consideration will be the political context within which the decision is being made.

Discussion and Conclusion

This chapter has assumed that a decisionmaker accepts the general principles underlying CEA. It

then considered six types of constraint under which such decisionmakers must operate when considering the implementation of CEA recommendations. Table 1 presents an overview of the abovementioned constraints and potential approaches to addressing them, whether by incorporating them into CEA directly, or by informing decisionmakers that adjustments to institutional arrangements that may be required. The classes of constraint frequently are linked and none can be considered in isolation. For example, many of the constraints caused by uncertainty arise because of the irreversible costs of implementing a change. Health system design constraints may arise in part because of weaknesses in governance. The difficulty of assessing interactions within the health system may reflect limited analytic and decisionmaking capacity. This may change in future, as efforts are

TABLE 1. How to Incorporate Constraints into Economic Evaluations

Constraint	Solution
Design of the Health System	<ul style="list-style-type: none"> ▪ Inform on required institutional adjustments ▪ Analyze supply- and demand-side responses ▪ Incorporate multiple resource constraints into the mathematical modeling
Implementation Costs	<ul style="list-style-type: none"> ▪ Incorporate transition costs into the mathematical modeling ▪ Disaggregate costs to highlight major cost components
System Interdependencies between Interventions	<ul style="list-style-type: none"> ▪ Model interactions between interventions by incorporating economies of scope ▪ Model intervention under alternative scenarios (with and without complementary intervention) ▪ Present range of cost-effectiveness ratios dependent on prevailing system configuration
Uncertainty in Estimates of Costs and Benefits	<ul style="list-style-type: none"> ▪ Conduct probabilistic sensitivity analysis ▪ Present extent of uncertainty via cost-effectiveness acceptability curves ▪ Address structural uncertainty with sensitivity analyses ▪ Commission additional research ▪ Evaluate robustness of decisions under alternative future scenarios
Weak Governance	<ul style="list-style-type: none"> ▪ Inform on required institutional adjustments ▪ Constrain the number of decisions that can be made in a given time period
Political Constraints	<ul style="list-style-type: none"> ▪ Inform on required institutional adjustments ▪ Devolve priority-setting to agencies with politically determined terms of reference ▪ Involve the public in decisionmaking

made to increase analytical capacity and international collaborations among modelers.

Where feasible, the chapter has outlined possible ways of addressing these strategic constraints. A fundamental choice is often whether to accept and accommodate the constraint, or to seek to relax the constraint itself. It is important to recognize that some constraints may be in place for good regulatory reasons (such as a concern with equity), and that relaxation of other constraints may in any case not be feasible in the short run. For some of the constraints, in particular the ones related to costs of change, the implicit assumption is that a new intervention is compared against current standard of care. The discussion may need to be slightly more nuanced if two or more new interventions are compared.

Many of the constraints described can in principle be modeled by augmenting the simple CEA mathematical programming model to include additional considerations. For example, additional resource constraints, say in the form of workforce numbers, can be added; interdependencies between interventions can be modeled by incorporating constraints that reflect economies of scope and considering portfolios of interventions using integer programming; nonlinearities, such as variable returns to scale, can be reflected in the model; limited decisionmaking capacity can be modeled by constraining the number of decisions that can be made in a given time period; the model can be formulated as an incremental priority-setting model, which assesses potential change from the current situation; and uncertainty can be incorporated by adding variability to parameters and (for example) reformulating as a stochastic mathematical program.

Although such innovations offer more realistic modeling of the decision setting, they also introduce serious drawbacks. First, they increase considerably the analytic complexity and information demands, and in many circumstances it would be infeasible to identify parameters for the augmented model.

Second, the model would have to be tailored to each individual setting, leading to a vast increase in the need for analytic capacity. And third, the simple transferability and clarity of the conventional CEA would be lost. In short, further tailored refinements of the mathematical decision model will be helpful in individual settings, but they are less likely to be appropriate when seeking to offer generic advice to a wide range of countries. Some classes of constraint related to governance and politics cannot be managed analytically. Rather than trying to model the constraints, the role of CEA under such circumstances is to indicate the opportunity costs of not being able to adopt certain optimal courses of action. Thus, although it can be argued that the world is rarely as simple as that represented in the theory of CEA, such an analysis can nevertheless yield powerful benefits by identifying the key bottlenecks to reform and indicating the priority areas for action. It may also help overseas aid organizations identify where their funds are best directed.

To conclude, a discussion of constraints can draw out a number of principles for disseminating CEA. For example, cost could be explained and disaggregated in more detail, so that decisionmakers can see more clearly the assumptions underlying the analysis and identify the major sources of costs. In this way, they can make adjustments if they feel that the original setting or costs were inappropriate to their situation. The CEA could be accompanied by a narrative that sets out the significant interactions of the intervention under scrutiny with other interventions in the health system, and the circumstances in which they may be important. The strength of CEA recommendations could be varied depending on the robustness of the cost-effectiveness evidence. However, this must be accompanied by clear guidance on what is considered robust evidence. Uncertainty could be treated more systematically. Great strides have been made in modeling certain types of uncertainty, but further improvements could be made in helping decisionmakers understand the implications for their

system. Subgroup analysis could be encouraged in order to help decisionmakers understand the implications for equity objectives and the implications of heterogeneity in costs and benefits of an intervention across the population.

Progress has been made in some of these areas, and the main thrust of future work should be to consolidate and formalize existing methods. Other areas may need preliminary ground-clearing work before significant progress can be made. The complications introduced by system constraints in no way undermine the central role that can be played by CEA in the process of strategic priority-setting in health services. Rather, the existence of such constraints underlines the importance of ensuring that the CEA's underlying modeling process accounts for the constraints as far as is feasible. Where it is not feasible, results should be presented so that decisionmakers can properly understand the simplifying assumptions that have been made. Failure to implement the CEA recommendations should offer an important indication of the opportunity costs (measured in terms of lost health) arising from system constraints and other considerations that may have affected the decision. Where necessary, by quantifying the opportunity cost of failing to implement, the CEA can then act as a powerful driver for health system reform designed to address particularly serious constraints to improvement. CEA methods can therefore help decisionmakers tailor recommendations to local circumstances, understand the most important constraints inhibiting adoption or abandonment of technologies, and assess whether and how to address those constraints.

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- arrangements that may affect the relation between the agency producing the CEAs and the decisionmakers. There are further important demand-side responses to the introduction of an intervention. Individuals’ uptake and acceptance of an intervention are important behavioral responses that may greatly affect the feasibility of an intervention. They may explain why strategic decisionmakers depart from national or international guidance.
6. Smith (2013).
 7. Atun, Bennett, and Duran (2008).
 8. Economies of scope are a proportionate saving gained by producing two or more distinct goods, when the cost of doing so is less than that of producing each separately.
 9. Cashin and others (2014).
 10. Oliveira-Cruz, Hanson, and Mills (2003).
 11. Stinnett and Paltiel (1996); and Adang (2008).
 12. Fenwick, Claxton, and Sculpher (2004).
 13. Dixon and Welch (1991).
 14. Mitton and Donaldson (2001).
 15. Airoidi and others (2014).
 16. WHO (2017).
 17. O’Brien and Sculpher (2000).
 18. Meltzer (1997).
 19. Fenwick, O’Brien, and Briggs (2004).
 20. Griffin and Claxton (2011); and Revill, Woods, and Sculpher (2016).
 21. Claxton, Sculpher, and Drummond (2002); and Spiegelhalter and Best (2003).
 22. Bojke and others (2009).
 23. Jackson, Thompson, and Sharples (2009).
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 26. Palmer and Smith (2000).
 27. Smith and others (2012).
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 29. Glassman and Chalkidou (2012).
 30. Hauck and Smith (2015).
 31. Goddard, Hauck, and Smith (2006).
 32. Ahmed and Greene (2000).
 33. Olson (1971).
 34. Buchanan and Tullock (1965).
 35. Niskanen (2007).
 36. Tuohy and Glied (2011).
 37. Asaria and others (2015).
 38. Mitton and others (2009).

Endnotes

1. Drummond and others (2005).
2. WHO (2014).
3. ISPOR (2017).
4. Conversely, CEAs can be formulated as seeking to minimize the costs needed to achieve a certain level of health benefit. The two formulations are mathematically equivalent See Drummond and others (2005).
5. Additional constraints are for example the capacity of countries to produce high-quality CEAs, or governance

CHAPTER 10

See the Bigger Picture

Resource Optimization Tools to Inform HBP Design

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At a glance: Address the limits of cost-effectiveness analysis by using constrained resource optimization tools, considering all quantifiable factors in a system together rather than interventions or technologies in isolation.

Working within a limited budget means that not all health services will be available for everybody. A challenge faced by decisionmakers is how to use limited funds optimally across the large set of health technologies, healthcare programs, and patient groups, targeted to the right people, in the right locations, in the right time, and in the right ways to achieve the greatest population health gains while also addressing equity.

These decisions may range from those with nationwide effect—whether a country should add a specific drug to its essential medicines list, where to open new primary healthcare clinics, or how to react to a new public health threat—to those with effects

at a more individual client level, such as whether to prescribe a specific diagnostic test or preventative measure or whether to seek healthcare in the first place. Prioritization is usually considered with respect to the most impactful and lowest-cost services. However, prioritization within budgets also implies that some services are likely overfunded for the epidemiological and budgetary context. Reducing access or defunding services is a difficult choice to make, but also is an important consideration in regularly reviewing and setting priorities. Underuse (failing to use effective and affordable interventions when there is need for them) and overuse (providing treatments that may do more harm than good,

Governments in low- and middle-income countries are legitimizing the implementation of universal health coverage (UHC), following a United Nations General Assembly Resolution on UHC in 2014 and its reinforcement in the sustainable development goals set in 2015. UHC will differ in each country depending on country contexts and needs, as well as demand and supply in healthcare. Therefore, fundamental issues such as objectives, users and cost-effectiveness of UHC have been raised by policy-makers and stakeholders. While priority-setting is done on a daily basis by health authorities—implicitly or explicitly—it has not been made clear how priority-setting for UHC should be conducted.¹

wasting resources, or deflecting investments for health systems) is common for countries across all income levels, institutions, and even individual persons.²

The key question for health systems, therefore, is less about whether to set priorities and more about how to make priority-setting processes explicit and transparent for the greatest value for health. Because the pressure and momentum to prioritize is greater than ever, decisions should not be made without the knowledge that can be provided by rational calculations in transparent quantitative algorithms. Moreover, when defining *packages* of services and technologies, interventions should not be considered in isolation, but the mix of interventions should be considered together.

This chapter explores the practical use of analytical tools and mathematical models to improve priority-setting for such packages of services in universal health coverage (UHC) and in the determination of explicit health benefits packages (HBPs). It presents examples from the field of HIV where, in the most recent decade, mathematical modeling has been extensively deployed (with some proven success) to improve priority setting, resource allocations, and allocative efficiency. By describing the approaches used, showing how they have been successful, and drawing some conclusions about the practical lessons learned in “doing” priority-setting for public health responses to HIV, the chapter will

provide suggestions about how these methods may be applied to UHC priority-setting as well.

What Should Be Prioritized?

In understanding what should be prioritized, it is essential to understand what is meant by UHC, and thus what is meant by priority-setting in UHC. The World Health Organization (WHO) defines UHC as “all people receiving the quality health services they need, without being exposed to financial hardship.”³ Amanda Glassman and colleagues have a more narrow definition: “In practice, UHC aims to assure the delivery of certain health services or products free of charge, or at a subsidized fee, to the entire population.”⁴ Practically, the scope and depth of services or products that can be made available intrinsically depend on the existing and potential service infrastructure, the amount of resources available, the costs to provide services, political economy considerations, and the burden of disease (and anticipated changes to this burden in future) in the population at large and in specific subpopulations.

UHC’s goals are aspirational: WHO and the World Bank have set the UHC targets of 80 percent coverage of essential services with 100 percent financial protection coverage.⁵ The UHC goal in the Sustainable Development Goals has three equally important arms: health (quality essential

health service coverage extended to the whole population), financial protection (prevention of financial catastrophe or impoverishment due to out-of-pocket spending on health), and equity (closing the health gaps caused by economic status, place of residence, gender, or other factors). In thinking about which of these aspects could be prioritized, it is generally accepted that the focus should be on prioritizing a set of essential health services, setting targets for service coverage levels in specific populations in specific places, and delivering those services in ways that maximize access and minimize costs.

How Should Priority-Setting Be Done?

The need for explicit evidence-informed priority setting and decisions was recently reinforced in the 2016 “Bangkok Statement.”⁶ This statement emphasizes scientific evidence as an indispensable starting point for explicit rationing that informs the inherent trade-offs in cost-effectiveness, equity, and financial risk protection. Policymakers should then make the final priority choices by placing evidence in the political context of interest groups and in the ethical context of universal and culturally specific values. Ideally, these characteristics also can be formalized as clearly specified objectives to refine and reapply scientific approaches toward attaining these objectives. The aim of such a transparent process is to make the trade-offs, criteria, and values used in making decisions explicit, and to make those who made the decisions known and accountable.⁷

Formal methodologies, some of which are covered in earlier chapters, are available to provide a quantitative basis for resource allocation prioritization. These methodologies include CEA and its extensions. The best trade-offs can be made when the selection of health services using CEA is combined with epidemiological models and costing modules,

burden of disease analysis (including the impact of different packages on disease burden among different social strata and geographical areas), and fiscal space and budget impact analysis. These methodologies can be useful in various decision steps of a well-managed priority-setting process (see chapter 3).

Prioritization using CEA and extensions

When considering only health gains and noninteracting interventions, CEA (described in chapter 9) is a widely accepted analytical method used in choosing interventions that offer good value for money. The “value” of a health outcome is expressed by a single measure encompassing mortality and morbidity aspects, either quality-adjusted life-years (QALYs) or disability-adjusted life-years (DALYs), discussed in detail in chapters 9 through 11. Since these measures capture both lifespan and quality of life, either can measure the outcome of a wide range of health interventions and their individual impact on such health outcomes, but generally not a package of interventions and its impact on one health outcome. Incremental cost-effectiveness ratios (ICERs) are defined as the difference in costs (based on unit cost of intervention) divided by the difference in outcomes (usually expressed in DALYs or QALYs). Interventions are ranked in a league table according to their cost-effectiveness ratios. Health outcomes are assumed to be maximized if the selection begins with the most cost-effective intervention at full coverage and then moves down the list to successively less cost-effective interventions, until the budget is exhausted. Some countries, such as Australia, Canada, Sweden, and the United Kingdom, use formal CEAs based on ICERs in guiding productively efficient resource allocations, at least for pharmaceuticals and some well-defined medical consultations, diagnostics, procedures, and other benefits.

CEA principles can be applied to estimate cost-effectiveness not just in terms of health outcomes,

but also the degree of financial protection or equity in a healthcare package, as described in chapter 10 in an extended cost-effectiveness analysis (ECEA). The goals of ECEA are to find a balance between the interventions that are cost-effective in averting illness and death and interventions that afford financial risk protection—that is, avert poverty caused by large out-of-pocket healthcare expenses—or decrease the health gap between the poorest and the richest strata of society. This means finding a balance between funding more expensive vs. cheaper life- and health-saving interventions under UHC (for example adult tuberculosis treatment vs. child vaccination), and is a demand on UHC to meet the need of poor populations. Methods maximizing health and financial risk protection or health equity often yield conflicting results; the first category attempts to maximize the number of deaths or DALYs averted, while the second assesses interventions based on the number of poverty cases averted or the decrease in equity gap. The right balance usually requires a decision that weights each outcome depending on a country's HBP goals.

Limitations of CEA and extensions

CEAs and their extensions are usually based only on efficacy-level evidence focusing on the benefit to the individual who accesses a health service for the duration specified. CEA and its extensions do not usually take the following aspects into account:

1. The interrelationship between causes of burden of disease and associated health interventions. It considers interventions as independent, neglecting their interactions.
2. The nonlinear relationship between health service coverage and health outcomes.
3. The nonlinear relationship between cost and coverage of interventions, by not calculating

the marginal costs of scaling up or scaling down a service.

4. The dynamic nature of burden of disease due to wider primary prevention, epidemiological, or population-wide impacts of the health services being implemented (for instance, the impact of vaccination or treatment on transmission of infection).
5. The changing nature of financing for interventions, such as starting costs and diminishing returns, or the fact that health services cannot instantly be either scaled up or scaled down.
6. The fact that priority-setting may change at different funding levels or provide different scenarios for a health system stakeholder.
7. The pragmatic reality that health services may be funded by different sources and that even a HBP could be partially financed through development assistance for health. Different funding sources might have different funding restrictions and requirements. A newly established HBP is not starting from nothing; services and funding already exist, and both the development of and priority-setting within that context needs to take existing services into account, to not contribute to further fragmentation.

The fifth, sixth, and seventh points are examples of health system constraints discussed in more detail in chapter 15.

Advancing CEA to more practical policy tools: Selection of health services using CEA combined with epidemiological models and costing modules

Traditional CEAs can be extended by incorporating an epidemiological framework which account for interacting and dynamic effects, and programmatic cost functions. This can be achieved through use of

mathematical models calibrated to the burden of disease in all subpopulations and links to relationships between marginal costs and programmatic coverage attained in target subpopulations. It can be extended by defining and using relationships between programmatic coverage in targeted subpopulations and the relevant outcomes related to reducing the disease burden. These additional components advance analyses to closer linkages with programmatic realities. Once established, these analytical frameworks, including epidemiological models and programmatic relationships, are well suited to comparing the projected effects of alternative budget allocation to specific programs, populations, and areas, and to an intervention's impact on a population. Such models can better capture changes in burden of disease, or different cost-effectiveness ratios at different programmatic coverage levels or in the context of different mixes of other interventions in operation. Cost functions of any shape, to reflect the deliverability of services as they are applied, can be defined in the model as appropriate and as data will allow. These frameworks can be used to estimate the “best” (or “good”) health financing allocations across interventions—or to decide what goes into a HBP, for example, as suggested through the scenario analysis or mathematical optimization processes described in chapter 3.

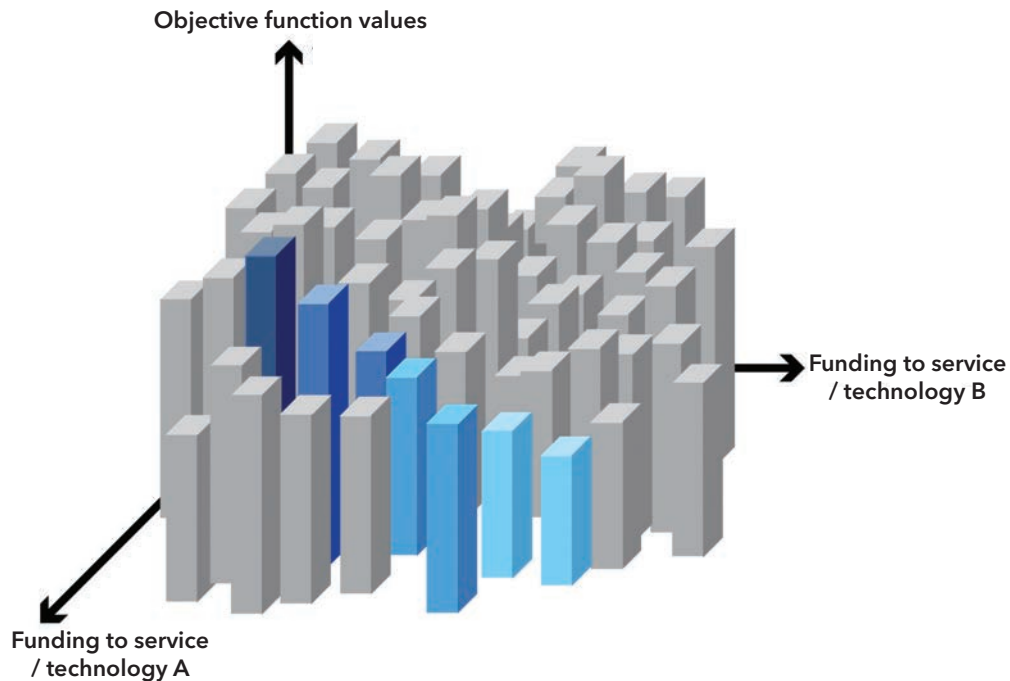
1. Scenario analyses. These analyses explore the changes in cost and impact on health (deaths and number of specific disease cases prevented, or general measures like QALYs or DALYs) and possibly other outcomes (impoverishment cases, equity gap) over a chosen time period, when scaling up or introducing a package of interventions at different cost-effectiveness ratios that comply with different constraints in the health system. (See chapter 15 for a discussion of constraints.) In this type of analysis, after considering a number of scenarios those with most suitable outcomes that fall within the country's

anticipated health budget are chosen for further deliberation. The limitation of this method is that it would take significant computer power and an unworkable amount of time to manually set and calculate the impact of each allocation, and would thus require either (1) a limited set of scenarios chosen for analyses (hence the name of the method) or (2) a selection of the best options from prespecified scenarios without knowing whether a better option existed outside the scope of the selected scenarios.

An example of a scenario analysis model is the Spectrum suite by Avenir Health,⁸ which contains epidemiological models and program impact modules, such as for HIV financing (Goals) and for reproductive, maternal, neonatal, and child health (LiST). These models include the effects of changing coverage of a large number of interventions in each module. The suite includes the OneHealth Tool,⁹ a strategic planning and budgeting tool that incorporates costing of all health system components including interventions, human resources, facilities, equipment and transportation, medicines and supply chains, information systems, monitoring and evaluation, governance, finance, and administration.

2. Mathematical optimization. In this method, the most cost-effective mix of interventions and their optimal combination of coverage levels to achieve a predefined set of health-related goals are determined using a formal mathematical optimization algorithm, conceptually shown in figure 1. In comparison with scenario analysis, mathematical optimization chooses and re-chooses funding allocations based on a set of decision rules, calculates the impact using the epidemiological and costing modules, determines if the selected allocation is a global best solution against the objective, and (if not) repeats the process until the mathematical best solution is found. In this situation, the solution would be the theoretically best health benefits package for this setting given its epidemiological context, infrastructure, costs, objectives,

FIGURE 1. Schematic of an Optimization Algorithm in Two Dimensions of Health Services



and constraints. Rather than sample all possible scenarios, optimization algorithms efficiently find a path toward the mathematical best solution against the objective function.

The goal, called the “objective function” in this context, can be a combination of gains in health, financial protection, and equity, as described above, and even additional chosen social values represented by a suitable measure. (For a discussion of social values in a HBP, see chapter 11.) Some social values like quality of life are already included in the optimization when using DALYs or QALYs as a measure of health outcomes. Other types of social/ethical values can be formally introduced as constraints—for example, “rule of rescue” can involve never defunding emergency care for life-threatening health conditions, even when there is only a small chance of saving a life. Other political, ethical, logistic, and budgetary constraints can be specified within the

optimization algorithm to enable all relevant criteria to be included in an objective assessment.

An objective function can either be one goal (for example, preventing new conditions), or a combination of goals (averting new conditions from arising and averting deaths). In this case, the objective function needs to use weights to determine the relative importance of the various goals. Establishing appropriate time horizons and discounting rates are important to setting appropriate objective functions to reflect the priorities of decisionmakers and the societies they represent. Building a formal objective function with weights assigned to different types of outcomes is usually an interactive process that relies upon stakeholder engagement. Health priority targets (national health strategic plans) or global Sustainable Development Goals targets can help establish the combination of factors and weights in an objective function. The optimization algorithm

then explores the space of possible interventions at different coverage levels (figure 1) within the budget and other constraints, and finds the combination that produces the greatest gains in the objective function.

The Optima Consortium for Decision Science's (OCDS) Optima suite of models¹⁰—the development of which was supported by the World Bank, the U.S. Centers for Disease Control and Prevention, the Global Fund, the Australian National Health and Medical Research Council, the University of New South Wales, the Macfarlane Burnet Institute, and other partners—is a prominent example of an optimization approach that has been used to extend CEAs to resource allocation, against set objectives, constraints, program and population interactions, and cost functions. It has been used mainly for cross-program-population targeting of resources within specific disease areas, including HIV, tuberculosis, malaria, nutrition efforts, and hepatitis C. A module for maternal and child health is currently under development.

Examples of Mathematical Optimization of Funding Allocations to HIV Treatment Program

To illustrate mathematical optimization for priority-setting in a practical context, the following section presents case examples of HIV service provision in Sudan, South Africa, and Indonesia.

Mathematical optimization to improve priority-setting: The case of HIV in Sudan

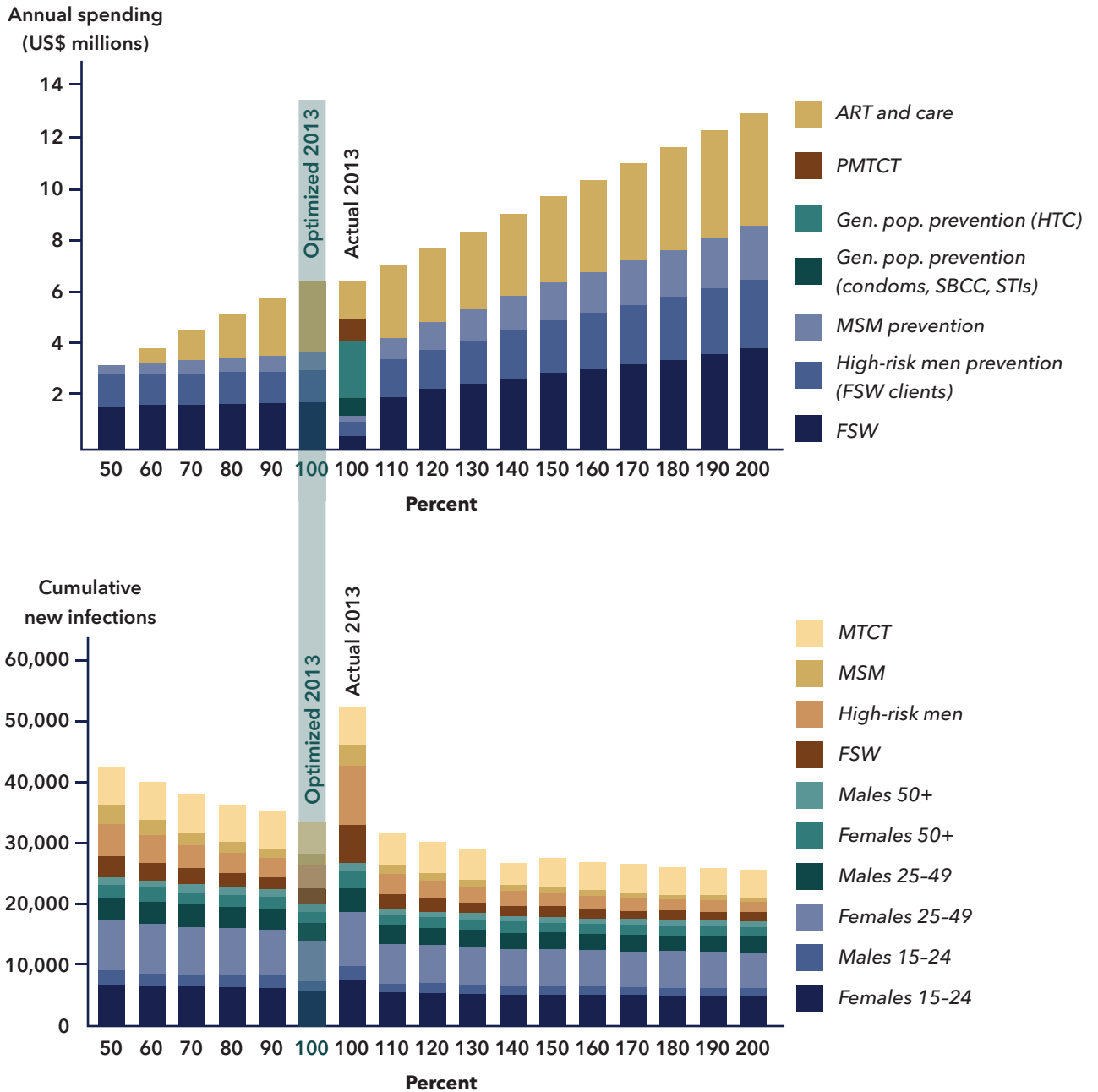
Around 40 countries have used the Optima approach to priority-setting of interventions, many of which have benefited from better targeting of health resourcing. In Sudan, the Optima HIV model was used to prioritize proportions of funding allocations to specific HIV prevention and care services as part

of an HIV allocative efficiency study.¹¹ The Optima analysis was conducted with the government of Sudan and its partners for establishing the objective function, designated constraints, cost functions, and resource envelope. As shown in figure 2, the Optima epidemic model and optimization function showed that by reallocating funds toward antiretroviral therapy (ART) and HIV prevention programs for key populations, 37 percent of new HIV infections could be averted with the same amount of funding compared to how that funding was being spent.¹²

The Sudanese government then applied the findings in its national HIV strategic planning process and Global Fund concept note, and increased allocations to ART from 12 percent to 18 percent and HIV prevention for key populations from 7 percent to 29 percent of all HIV funding (based on the financial gap analysis including budgeted national, Global Fund, and other resources) while deprioritizing HIV prevention targeted at the general population including HIV counseling and testing, condom distribution, and behavior change communications (figure 3).

The study further concluded that these allocations combined with additional technical efficiency gains would allow for increasing ART coverage from 6 percent in 2013 to 34 percent in 2017, and more than double program coverage for key populations.¹³ The reallocations in the 2015–17 HIV budget for the national response were projected to avert an additional 3,200 new infections and 1,100 deaths in these three years compared to initially planned allocations. Longer-term time horizons beyond the strategy period were also considered, and the analyses found that by 2030 the improved allocations were projected to avert an additional 33 percent of new infections, 22 percent of deaths, and 20 percent of DALYs. The reallocations were achieved through a rigorous HIV allocative efficiency analysis and evidence-informed policy process, conducted by a multidisciplinary team of national and international partners working

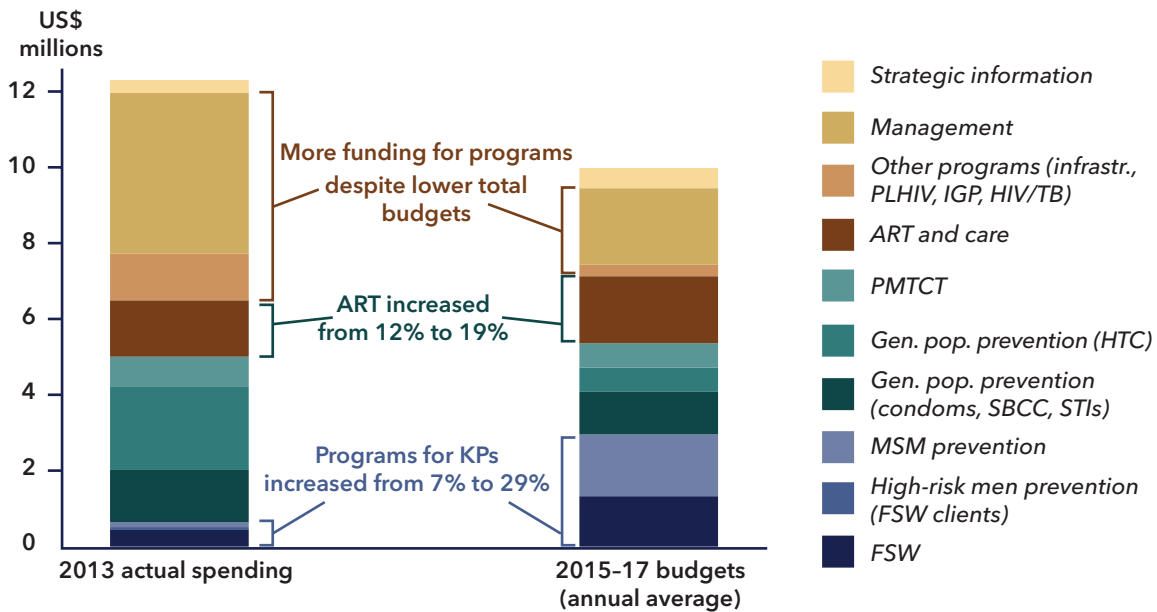
FIGURE 2. Optimized Allocations to Minimize HIV Incidence by 2020 at Different Funding Levels, Sudan



Notes: FSW = female sex workers
 HTC = HIV testing and counseling
 MSM = men who have sex with men
 PMTCT = prevention of mother-to-child transmission
 SBCC = social and behavior change and communication
 STI = sexually transmitted infections

Source: World Bank (2015).

FIGURE 3. Reallocation of HIV Resources in the 2015–17 HIV Response Budget, Sudan



Notes: ART = antiretroviral therapy
 FSW = female sex workers
 HIV/TB = HIV/tuberculosis
 HTC = HIV testing and counseling
 IGP = Innovation Grant Program
 KPs = key populations

MSM = men who have sex with men
 PLHIV = people living with HIV
 PMTCT = prevention of mother-to-child transmission
 SBCC = social and behavior change and communication
 STI = sexually transmitted infections

Source: World Bank (2015).

to make Sudan’s HIV response more manageable and sustainable.¹⁴

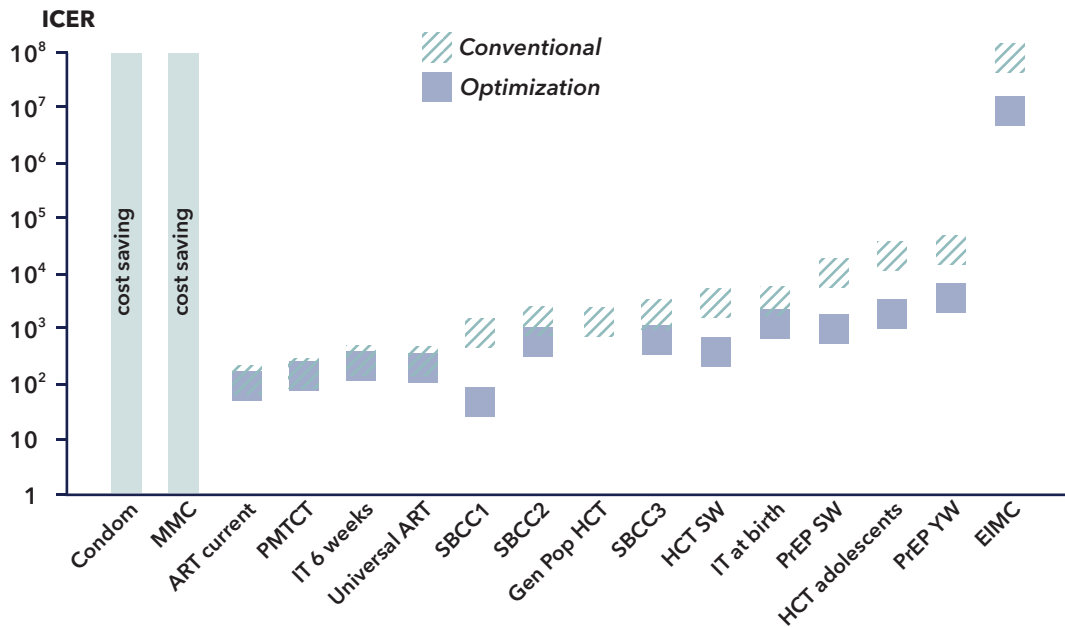
**CEA and mathematical optimization:
 Modeling HIV program funding
 allocations in South Africa**

South Africa has an extensive HIV program with many interventions at high levels of coverage. In conventional CEA (using league tables) these interventions are assumed to have no interactions. In a recent study the authors questioned the validity of

this assumption at close to full coverage of the most cost-effective interventions. They showed that, when the most cost-effective interventions of condom distribution, male medical circumcision, and ART were sequentially scaled up to high but feasible coverage levels, ICERs of the remaining interventions increased by up to 400 times and their order in the league table changed (figure 4).¹⁵ This finding demonstrates that interactions between interventions are important, especially when there are other interventions which achieve similar outcomes, leading to strongly diminishing returns. For example, if

FIGURE 4. (a) Rank and (b) Comparison of ICERs (cost per DALY averted)

Rank	Conventional league table	Rank	Optimization routine
	Condom availability		Condom availability
	Male medical circumcision		Male medical circumcision
	SBCC 1 (HCT in adolescents, reduction in MSP)		ART (current guidelines)
	ART (current guidelines)		PMTCT
	PMTCT		Infant testing at 6 weeks
	Universal ART		Universal ART
	Infant testing at 6 weeks		SBCC 1 (HCT in adolescents, reduction in MSP)
	HCT for sex workers		SBCC 2 (condoms)
	SBCC 2 (condoms)		General population HCT
	SBCC 3 (condoms, HCT, MMC)		SBCC 3 (condoms, HCT, MMC)
	PrEP for sex workers		HCT for sex workers
	General population HCT		Infant testing at birth
	Infant testing at birth		PrEP for sex workers
	HCT for adolescents		HCT for adolescents
	PrEP for young women		PrEP for young women
	Early infant male circumcision		Early infant male circumcision



ART = antiretroviral therapy
 EIMC = early infant male circumcision
 HIV/TB = HIV/tuberculosis
 HCT = HIV counseling and testing
 IGP = Innovation Grant Program
 IT = infant testing

KPs = key populations
 MMC = male medical circumcision
 PMTCT = prevention of mother-to-child transmission
 PrEP = pre-exposure prophylaxis
 SBCC = social and behavior change and communication

Source: Chiu and others (2017).

nearly all sexual acts are protected by condoms, medical male circumcision will be less effective. Mathematical optimization, by contrast, gives much more realistic cost-effectiveness ratios that account for the interacting effects of programs and dynamic influences on burden of disease for different programmatic coverage levels.

Resource optimization analysis and actuarial sciences to incorporate HIV services into an existing HBP: The case of Indonesia

In Indonesia, three interrelated analyses were performed: (1) an HIV allocative efficiency study to determine the size and nature of the risk pool for HIV prevention and care services; (2) actuarial estimations to estimate the incremental increases that would be needed in the social health insurance premiums (and subsidies) in order to add different HIV service packages to the country's current UHC scheme; and (3) a health financing system assessment to understand the broader context of health financing in Indonesia. (The last of these analyses is available on the World Bank's Open Knowledge Repository website (okr.worldbank.org), but because of space considerations it has not been described in detail below.)

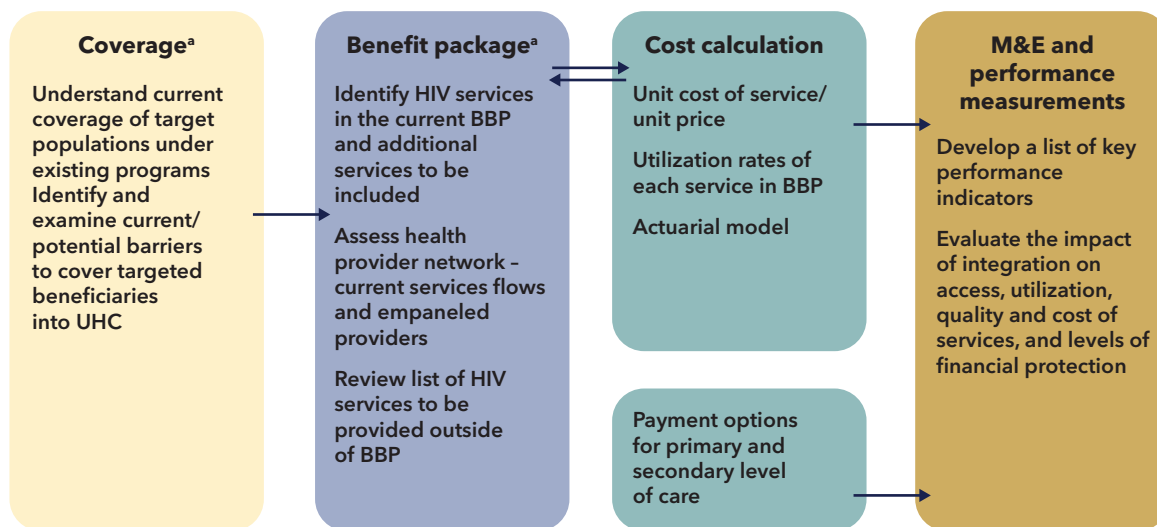
HIV allocative efficiency study. The mathematical optimization study was undertaken to assess the allocative efficiency of current HIV spending. It concluded that to be more efficient, Indonesia needed to:

- Increase program coverage and impact for key populations at high risk of HIV infection in non-Papua and expand ART coverage through optimized allocation of domestic and external funds.
- Strengthen domestic sources of HIV financing to reduce the dependency on international sources for the financing of essential HIV prevention services. Encourage district- and provincial-level financial contributions, and aim to fully integrate HIV services into the national social health insurance program, Jaminan Kesehatan Nasional (JKN).
- Develop a clear strategy for sustainability and undertake transition planning as part of the effort to ensure an HIV response that can be maintained that includes not only financial, but also institutional, administrative, legal, and service-delivery-related considerations.

These recommendations then fed into the JKN premium actuarial estimates.

Actuarial estimates for adding HIV services to JKN benefits package. Integration of existing vertical programs, such as HIV services, into a national health insurance program requires careful consideration of the services to be included in the basic HBP, the implications of access to care for target populations, and the expected cost. Like many other low- and middle-income countries (LMICs), Indonesia is currently facing challenges in ensuring sustainability of its HIV programs because external funding for them is decreasing. External donor financing remains significant, and makes up almost 60 percent of total spending for HIV programs. As the country is implementing its national social health insurance program, JKN, to achieve UHC, integrating HIV services into JKN is considered one of the strategies to ensure HIV program sustainability. JKN is one of the largest single-payer social health insurance programs in the world; by 2019, everyone in Indonesia is expected to have coverage under JKN. In 2015, nearly 160 million individuals, or more than 60 percent of Indonesia's population, were covered by JKN. Figure 5 illustrates the link between the allocative efficiency analysis and the actuarial calculations for JKN premium increase estimates.

FIGURE 5. Relationship between the HIV Allocative Efficiency Study Outputs and the JKN Premium Increase Calculations



a. Allocative efficiency results used in these steps.

Source: World Bank (2016).

The cost to include HIV services into the JKN benefits package was projected for the next five years using 2014 cost as the baseline. The calculations showed that, using the 2014 per member per month cost as the baseline, additional HIV comprehensive services added a monthly premium/subsidy cost of Indonesia rupiah (IDR) 532 per member, or IDR 6,384 (equivalent to US\$0.50) per member per year.¹⁶

Conclusions

Priority-setting in UHC is difficult because it involves making complex decisions with limited evidence. Explicit and transparent priority-setting with possibilities of scrutiny and challenge requires decision-makers to provide a clear formulation of objectives and a statement of assumptions, and thus increases their accountability. As scientific evidence of effectiveness of different health interventions grows, it is becoming increasingly possible to effectively allocate

funds based on scientific knowledge and methods. Timothy Evans and Toomas Palu note that the availability of better and more evidence will propel UHC priority-setting: “The rapidly growing science related to rational choice and relative cost-effectiveness will help inform better decision making.”¹⁷

A growing number of analytical tools integrate epidemiological modeling with costing modules and cost-effectiveness in dynamic ways. The advantage of such tools is that they account for interactions between interventions and changes in outcomes, population profiles, and disease burden over time in projecting the effects of changes in funding allocations and health budget scale-ups. Resource optimization models address some of the weaknesses of the more established analytic approaches, such as CEA. These models go one step further than CEA, which treats all interventions as independent, because a well-executed model can define optimal *portfolios* of services for the HBP. This is one of the defining characteristics of resource optimization modeling for

improved allocative efficiency. The examples shared in this chapter have shown that mathematical optimization is possible and feasible as a tool for priority-setting and estimating targets: it can inform which programs should be supported to certain coverage levels over certain time periods, focusing on how many of which populations will yield the best set of health outcomes.

Resource optimization modeling tools add value to the priority-setting process in several ways, including the following:

- Models can link epidemiology to costs and impacts in a dynamic way, in which changes in one influences changes in the other and in which several iterations can be run until an ideal (most optimal) package of services is found. Part of the dynamic nature of models is the ability to change resource allocations, or service packages, over time and for different populations, recognizing the temporal changes in populations and health services.
- Because of the epidemiological aspect built into these tools, it is possible to estimate the benefit of one (or multiple) programs on one (or multiple) health outcomes not just in the population who receive the intervention, but in the population-at-large. (One such example of these epidemiological knock-on effects would be if male circumcision led to fewer new HIV infections not only in circumcised men but also in their sexual partners.) Simple CEA cannot usually incorporate these social network effects into its analysis, and yet as Tyler VanderWeele has recently argued, such effects are important to his concept of outcome-wide epidemiology.¹⁸
- Costs can be modeled in a nonlinear way, allowing for subsidies paid to those who cannot pay for programs directly. This is a major benefit, given the need to often subsidize a HBP for populations in developing countries. Nonlinear cost functions can also account for program initialization, early adopters, scale-up phases, and phases of targeting harder-to-reach populations.
- Mathematical optimization can be conducted in the context of defined real-world constraints to take program scale-up and scale-down specificities into account. This makes it directly applicable to, and able to influence, HBP design. Any constraints can be formalized and included in analyses. The major benefit of this explicit specification is the transparent process and objective nature of the outcomes.
- Beyond bringing about increases in funding for specific health services, mathematical optimization has yielded real-life reductions in funding allocations for some poor value services, which are notoriously hard to achieve.
- Mathematical optimization, with its focus on the data needed to inform the algorithms behind the objective function, has been shown to result in complementary efforts to address data gaps. This reliance on data (parameters) as inputs into the analytical process is both an advantage and challenge. Data can help provide more information for predictions and link epidemiology with costs and outcomes, and can be used for assumptions and to test their sensitivity to results. However, more data may be required than for typical CEA analyses and gaps in data can hamper modeling efforts. However, experience in working on HIV modeling has shown that model development and availability can highlight to stakeholders where data gaps exist. In HIV modeling, improvements have been seen in costing data; the inclusion of data points about the coverage

of health services in household surveys; and improved efforts to disaggregate indicators by sex, place of residence, and wealth quintile.

- Results of mathematical optimization can be used in actuarial calculations to estimate the incremental changes in budget requirements, including in insurance premium increases, to accommodate new services added to a HBP.
- Beyond calculating the effect of adding specific services to a HBP, mathematical optimization results can be expressed in terms of the effects (costs and benefits) of a portfolio of health services and related health policies on the national budget and governments' medium-term, multi-year expenditure frameworks in the context of economic growth projections and the country's debt sustainability, giving finance and health ministries a common language for dialogue about changes in health financing and the effectiveness of that financing. Modeling thus can be a basis for dialogue between these ministries. Dynamic modeling can inform finance ministries of longer-term fiscal impacts, beyond the immediate health-driven decisions, and can assure governments that health money is being spent wisely. International development aid for health applications (most notably, the Global Fund, GAVI, and PEPFAR [President's Emergency Plan for AIDS Relief]) also increasingly require that countries specify and quantify the value for money of their health spending plans.
- Modeling—if done through appropriate consultative processes—can be transparent, which allows policymakers to interact with the analytical process and test different options and scenarios. Although many assumptions made in such tools remain open to challenge, given the

limited evidence base and the inherent simplifications in any estimation analyses, the virtue of this approach is that it allows assumptions to be made transparent and the sensitivity of end-line results to be tested against them. Alternatives (scenarios) can therefore be readily tested and different options considered.

- Mathematical optimization has helped to change allocations of actual funding to more effective programs, even in politically challenging situations. In achieving these changes, mathematical optimization appears to have been more persuasive to stakeholders than other previous approaches.

Resource optimization tools remain at an early stage of development, and there remain many opportunities for heightened impact if analysts can address a range of challenges.

- *Currently, none of the available tools mathematically optimize across health services to address all causes of disease burden, though more sophisticated tools are available for within-program optimization (such as within HIV or nutrition programs).* None of the currently available tools contains the full range of Sustainable Development Goals' health services addressing all of the goals' health targets, with noncommunicable diseases the least represented (perhaps because of the lack of reliable data in LMICs). Although it is possible to investigate the impact of interventions on morbidity and mortality from different diseases separately, with current tools it is not possible to optimize benefits packages for a range of conditions simultaneously, including comorbidities, or to take advantage of program overlap. Additional methods and new tool development in these areas are needed.

- *None of the currently available models accommodate user-defined weighting of health, financial protection, and equity maximization.* Most models can implicitly incorporate a range of fiscal and political constraints in different scenarios, but none can currently perform a formal optimization of allocation of funds with a user-defined objective function—that is, a user-defined weighting of health, financial protection and equity maximization. New model development in this area is needed. The Health Foundation's STAR is the only tool that to some extent evaluates the impact of a health program on financial protection and equity.¹⁹ STAR, however, is more of a process of stakeholder engagement that considers financial and equity consequences of decisions. Additional methods and new tool development are needed here as well.
- *Costing data used in current analytical tools inconsistently include upstream costs.* Upstream costs such as supply chain, health system management and administration, training and capacity-building, transaction costs in reallocating funds, planning, and coordination are inconsistently (if at all) included in unit costs. Consequently, one cannot take a funding allocation from a model and apply it directly to a health system budget, especially not if activity-based costing is the basis for costing and budgeting. One reason for the inconsistency in including these costs is that they are not well documented; another is that the evidence of the impact of these activities on health services is largely lacking.²⁰
- *Costing data used in analytical tools typically assume linear relationships between costs and coverage.* Most analytical tools estimate the cost of introduction and scale-up of interventions based on unit costs. The biggest limitation of this approach is that it typically assumes a linear relationship between cost and coverage (unit

cost \times quantity = total cost). Cost functions with nonlinear marginal costs are necessary to accommodate startup costs, economies of scope and scale, and changes in the marginal costs of service delivery over time.

- *Efforts to convert recommendations on specific funding allocations to specific health services into actual spending priorities within a health systems context are not straightforward or evident, and need to be unpacked.* Modeling can be used to prioritize health interventions by indicating which health interventions should be supported and to what level. Using these allocations for actual funds (annual budgets) within the existing health system funding setup, however, is not straightforward for two reasons. First, health sector funding typically is not allocated by individual health service, but by one or more of the six WHO-defined health system components.²¹ Second, priority-setting happens at different levels and for different purposes, from whether a client decides to access a service to how they access it, and from the decisions that providers make about which services to provide to the decisions that ministries of health make about which services to prioritize and how to allocate sector funds. Further work is needed to examine the various complicated aspects of how and whether priority-setting by healthcare users (clients), healthcare providers, and the institutions that govern and regulate healthcare systems influence the development of different health system components and funding allocations, compared to allocating discrete amounts for specific health services. One option might be to use results from analytical optimization tools to decide which services are affordable within available budget envelopes and optimal funding for drugs or human resources for health, or other health system components that are easily

TABLE 1. Allocation Challenges with Optimization Models

		Components of the health system that they could influence with priority setting					
		Leader-ship and governance	Health infor-mation systems	Health financing	Essential medical products and tech-nologies	Health service delivery	Human resources for health
Health system stakeholder	Typical priority-setting questions and decisions	Health services: HIV testing, nutrition services, maternal and child health services, noncommunicable disease services, and others. Priorities of and funding for these services					
Client level (healthcare consumer)	<ul style="list-style-type: none"> Do I need this service? Do I want to go to get this service? What other services do I need? Will this service be useful to me? What can I do to improve my health and prevent illness? Can I afford to access this health service? Can I afford the medications that I need? Will I take the medication that is needed? 				Drug and technology access and use	Health service demand, access, and use	
Health service providers	<ul style="list-style-type: none"> What kind of health service does the client need? Am I allowed to provide this health service? How will the provision of the service be financed? Do I have the technologies I need to provide the service? Do I want to provide that service? What data about the client do I need to capture? Are these data important? Am I paid enough? Do I want to perform this service? 	Data capture and use	Afford-ability and access		Drug and technology demand, use, and application	Health service pro- vision and quality	Human resources for health motivation and dis- crimination
Health system regulators and “governors”	<ul style="list-style-type: none"> What information systems do we need? How many, of which kind of technology, should be sent to which places? What kind of health services should be provided at which places? How will this be financed? What human resources for health are needed? How should the health workforce be educated? What health information system and architecture is needed? 	System leadership, account- ability and governance	Data system design Data use for improved decision- making	Health financing architecture Volume of funding available Funding allocations to specific programs	Develop- ment of essential medicines list Decisions on the application and avail- ability of new health tech- nologies	Health service architec- ture—who can provide which ser- vice where	Cadres of health workers Placement of health workers Health worker education Health worker motivation

Source: Authors

“allocable” as discrete funding priorities (and thereby as line items in a budget). Table 1 shows this disconnect and the associated allocation challenges.

- *Analytical tools cannot yet address some (unrealistic) stakeholder expectations that results are directly fed into an annual budget: “translation” of analytical results into program priorities and detailed annual budgeting is still needed.* The results of analytical outputs (how much to spend on which health service) are useful, but cannot directly be used for budgeting purposes. Typically, the outputs of a model will indicate on which health service to spend more money and on which ones to spend less money. These results can be used to prioritize funding allocations (and inclusion in a HBP). But the absolute funding level for individual health services, as suggested by the analyses, cannot necessarily be fed into an annual activity-based budget.
- *As health services become more integrated, it will become more challenging to use analytical tools to explicitly prioritize funding to individual health services.* If a person visits a health provider and receives, for example, HIV drugs, condoms, and nutritional supplements, then this person has received three different health services, in one visit. Calculating the cost of those services individually (which is needed for funding allocations to these health services to be optimized in an individual way) involves parsing out the human resource costs, drug costs, commodity costs, and other input costs separately and determining the unit cost (or cost function) of delivering such services. As people demand and receive more integrated care, instead of visiting different providers for different services, it becomes more challenging to model the optimized allocation for individual services in the HBP.
- *Analytical tools do not currently take the constraints imposed by diverse funding sources into account.* In LMIC settings, health financing costs typically come from multiple sources. Development assistance for health sometimes comes with constraints on how it can be spent. Given that this assistance often is not in the same currency as the country itself and comes with constraints, decisions about which parts of the health system are supported by development assistance dollars may not be best made along the lines of specific services but rather in terms of health system components. Such decisions might even need to include macroeconomic considerations: for example, if a developing country’s HIV drugs are purchased in a U.S.-dollar-traded market because of the nature of only a few global suppliers, for example, then it makes sense for development assistance for health to focus on those specific types of purchases within the healthcare system.
- *All quantitative approaches in priority-setting for UHC and HBP are supply-side efforts and are not yet people-centered in the sense that user choice is not yet explicitly defined or quantified in models:* Current analytical methods consider clients as health system “users” and the health system itself as the “provider” of healthcare. Analytical methods for UHC priority-setting support this construct in that the outcomes of such efforts are typically expressed in terms of supply-side funding allocations or impacts. Thus, although priority-setting needs to occur at all three levels of the health system (health system users, health system providers, and health system regulators/governors—see table 1), current analytical efforts focus only on the health system regulator level of priority-setting. The efforts of health providers in terms of prioritizing clients and of health system clients in managing and

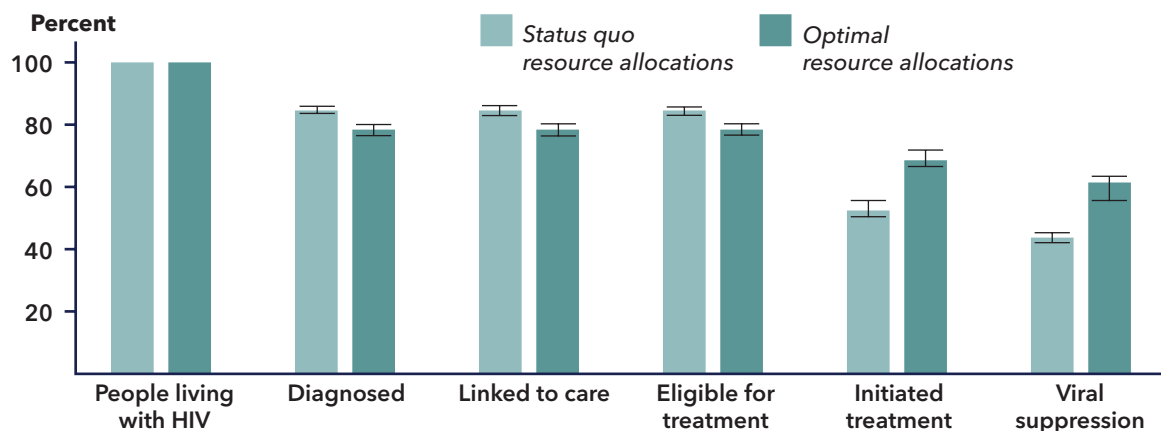
improving their own health—such as clients deciding to improve their nutritional habits or wearing step-tracking devices to improve their own health—is not yet considered or explicitly modeled and therefore cannot yet be prioritized.

- *Most current analytical models focus on prioritizing health services, such as what should be included in a HBP; few are designed to help countries make decisions about prioritizing the modalities of delivering those health services.* For example, in a country with a large HIV disease burden, prioritizing HIV testing and treatment could be an anticipated outcome of a priority-setting process. If it was known that fewer than 50 percent of persons living with HIV have been diagnosed, one might conclude that HIV testing is important. But decisions on how that HIV testing is performed—through home-based testing, provider-initiated testing, self-testing, or voluntary counseling and testing—typically are not yet made based on evidence, models, or prioritization, even though these decisions are as critical as the first-tier optimization (prioritizing HIV testing). Because different modalities of health service delivery have quantifiable different costs associated with them and quantifiable different yields (proportion of persons tested who are newly diagnosed), analytical models can help support this “second-tier” layer of priority-setting.
- *Modeling tools are not yet extensively used to help prioritize which interventions should be provided to minimize “leaks” in an implementation cascade.* We can expand the concept of the second tier of priority-setting to the entire implementation process—the progression from the number of persons with the specific disease burden to the percentage diagnosed, to the percentage who have initiated treatment, to the percentage who have completed or are adhering to treatment. In

a country like South Africa with a high HIV disease burden, significant priority has been given to HIV. Yet there are significant leaks in the HIV treatment cascade in South Africa (see the gray bars in figure 6).²² An assessment in South Africa identified 31 interventions that could address these leakages, and used an optimization model to prioritize these 31 interventions in terms of relative funding allocations, within a given funding envelope. Figure 6 (purple bars) shows how the optimization of these 31 interventions, by reallocating the same overall resources to better target the most impactful services, significantly reduces leaks in the HIV treatment cascade in South Africa. Minimizing leakage was possible through prioritizing the most cost-efficient interventions, particularly fast-track treatment initiation counseling, at the expense of the classic treatment initiation counseling model. Adherence support for those receiving ART should be prioritized with a focus on text messaging services and enhanced adherence counseling implemented by lay counselors, and decentralized delivery and adherence club services for treatment dispensing should be prioritized for eligible people living with HIV.

Beyond analytical tools, countries must focus on addressing health implementation and absorption capacity challenges. As Kalipso Chalkidou and colleagues have observed, “implementation without priority setting is as bad as priority setting without implementation.”²³ But, getting to full-scale quality implementation will require more than modeling results. A recent WHO report reviewed by the *Lancet* revealed that for every US\$100 available for government spending in Africa, on average US\$16 is allocated to health, only US\$10 is in effect spent, and less than US\$4 goes to the right health services.²⁴ Although each country should define its own essential package of public health and clinical services on

FIGURE 6. Current Estimated HIV Care and Treatment Cascade in South Africa and Estimated Optimized Potential Cascade



Source: Stuart and others (forthcoming). Optimizing resources across service delivery models to improve the HIV care and treatment cascade in South Africa. (submitted for publication).

the basis of cost-effectiveness, epidemiological conditions, political preferences, and country income,²⁵ in the interests of equity the largest funding priority should be at the primary care level rather than at higher levels of care (which usually are used by more wealthy individuals). Unfortunately, currently in Africa the largest portion of health budgets is often allocated to much more expensive specialist care, increasing the equity gap.²⁶ Financial, institutional, political, governance, and practical service delivery (quality and delivery modality) challenges need to be overcome, in addition to the structural barriers to health and the legal and policy environment.²⁷ Other levers of change include the downstream incentives around engaging, and what happens, in a clinical encounter.²⁸ Moving from status quo prioritization undoubtedly causes conflict, especially since it could require reducing access to some services. However, the potential opportunities for greater overall population and individual health and wellbeing is within reach through better prioritization decisions using rational calculations of all evidence, objectives, and constraints examined together.

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Endnotes

1. Chalkidou and others (2016), for the 2016 Prince Mahidol Awards Conference.
2. On underuse, see Glasziou and others (2017); on overuse, see Brownlee and others (2017); for a general overview, see Kleinert and Horton (2017).
3. WHO (2015, p. 1). Other definitions of UHC have suggested that this should encompass the entire gamut of health services—promotive, preventive,

curative, rehabilitative, and palliative—and that such services need to be of sufficient quality to be effective.

4. Glassman and others (2016, p. 39).
5. WHO (2015).
6. PMAC (2016).
7. Chalkidou and others (2016).
8. Avenir Health (2015).
9. Avenir Health (2012).
10. World Bank (2015b).
11. Fraser and others (2014).
12. Fraser and others (2014), and World Bank (2015a).
13. World Bank (2015a).
14. Ibid.
15. Chiu and others (2017).
16. HIV comprehensive services include HIV counseling and testing, lab tests and treatment for sexually

transmitted infections, diagnostic tests for pre-ART, ART, side effect treatments, and prevention of mother-to-child transmission. See World Bank (2016).

17. Evans and Palu (2016, p. 21).
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CHAPTER 11

Reliable Sources?

Generating, Selecting, and Applying Evidence to Inform the Health Benefits Package

Neil Hawkins
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At a glance: Is a health benefit cost-effective? Consult the evidence—but critically evaluate its applicability, internal and external validity, and precision.

Decisionmakers need to determine, based on currently available evidence, which interventions should be included in a health benefits package (HBP). They may also need to decide whether additional research should be required or funded. Quantitative economic evaluations can aid these decisions. The challenge is to conduct useful evaluations given typical limitations in both the available data and resources available for analysis. It is important to make the best use of the available data and to not impose unrealistic evidence standards that effectively deny decisionmakers access to useful evidence.

Unfortunately, most published evidence evaluation tools tend to focus on the evaluation of the internal validity of individual studies and do not consider

their potential contribution within the context of a specified decision analysis. Given that there will often be a limited number of directly relevant studies conducted in low- and middle-income countries (LMICs), it is important that researchers do not simply discard individual items of evidence because of concerns about internal validity.

This chapter examines the principles underlying the selection and synthesis of evidence within cost-effectiveness analyses (CEAs) intended to inform the development of HBPs in LMICs. A number of health technology assessment guidelines recommend that all *relevant* evidence should be included in CEAs.¹ For example, the “Gates Reference Case” developed as part of the Bill & Melinda Gates Foundation–funded

Methods for Economic Evaluation Project states, as a principle, that economic evaluations “should consider all available evidence relevant to the decision problem.”² It also recommends that a systematic and transparent approach is taken to obtaining and using such evidence. Taking this recommendation as a starting point, this chapter will explore the concept of relevant evidence, its selection, and its use, and focus on the use of evidence within CEAs as a fundamental component of the process of developing a HBP.

The body of this chapter is divided into four sections. The first section describes how evidence is used in CEAs, and provides context for the remaining sections. The second section describes three core concepts (bias, precision, and the relevance of evidence) that underpin the appropriate use of evidence. The third section discusses how best to identify and select evidence for inclusion in CEAs. The final section discusses the role of sensitivity analyses.

Synthesis of Evidence within Cost-effectiveness Analyses

CEAs synthesize evidence in order to provide estimates of the mean incremental costs and effects associated with alternative treatment options. These estimates are used to estimate incremental cost-effectiveness ratios (ICERs).³ ICERs reflect the opportunity cost associated with the decision to include a particular option in a HBP and so help decisionmakers to design packages that maximize productive efficiency.⁴

It also is often necessary to provide information about the total cost of funding a treatment or its “budget impact.”⁵ Doing so allows decisionmakers to assess whether a treatment is “affordable” and what effect it might have on the budget remaining for other treatments.⁶ It also provides an indication of whether funding a treatment is likely to change the acceptable threshold. If a treatment with a high budget impact

is funded, this will effectively reduce the acceptable threshold for remaining treatments.⁷ Estimates of budget impact help decisionmakers assess the opportunity cost of funding a technology. Finally, in addition to considering mean incremental costs and effects, it is necessary to provide information regarding the uncertainty in these estimates. Estimates of uncertainty are important because decisionmakers may not be risk neutral⁸ and/or may need to understand the value of conducting future research and reducing uncertainty.⁹

The estimates of incremental costs, incremental effects, and budget impact are typically derived from the synthesis of evidence within a trial-based analysis or decision-analytic model.¹⁰ In trial-based analyses, the estimates of incremental costs and effects are based on the relationships between treatment choice and final endpoints *directly* observed within clinical trials. Typically, a trial-based analysis will be based on a single trial, although examples of meta-analysis of cost-effectiveness estimates do exist.¹¹

In model-based analyses, the estimates of incremental costs and effects are based on *indirect* relationships mediated by one or more intermediate endpoints. The “model” combines the predicted effects of treatment choice on the intermediate endpoints and the estimated relationships between these intermediate endpoints and the final decision endpoints of costs and effects. The relationships between treatment choice and the intermediate endpoints are typically estimated based on the relationships observed within clinical trials, from either individual trials or meta-analyses including multiple trials. The relationships between the intermediate endpoints, and between the intermediate endpoints and the mean costs and effects, may be estimated from a variety of sources including data from clinical trials, observational studies, and even clinical opinion.¹²

In a sense, the cost-effectiveness model synthesizes the available evidence in order to recreate an ideal randomized controlled trial. Such a trial would

include patients who are representative of the target clinical population, compare all treatment strategies of interest, include assessments of the final decision endpoints, and provide unbiased estimates from the randomized comparison. The cost-effectiveness model attempts to re-create this ideal trial by synthesizing available evidence. The synthesis facilitates a series of extrapolations: from surrogate to final endpoints, beyond the time horizons of the available studies, beyond the available trial comparisons. The synthesis can attempt to correct for known biases and increase precision by borrowing strength through the meta-analysis of multiple trials.

The evidence synthesized in the cost-effectiveness model may come from a variety of sources, including experimental trials, observational studies, and elicited expert opinion. It may provide information regarding the epidemiology of the condition and treatment, the effectiveness of the reference treatment, the relative effectiveness of other comparator treatments, the value of treatment outcomes, and estimates of resource use and unit costs. The evidence helps to refine the decision problem, select an appropriate structure for the predictive model, and to derive its parameter estimates. Individual items of evidence may be used to estimate treatment-specific parameters describing relative treatment effects, non-treatment-specific parameters describing the relationships between modeled variables, parameters describing quality of life or utilities related to health status, and parameters describing cost and resource use.

Core Concepts for the Selection of Evidence

Overall, the aim of a CEA is to improve the state of knowledge regarding the appropriate selection of treatments. Knowledge can be defined as justified true belief.¹³ In the case of CEAs, this justification comes from our belief in the accuracy of the estimates

derived from our cost-effectiveness model, which in turn depends on both the validity of the model structure and the accuracy of the parameter estimates incorporated in the model.

The accuracy of the parameter estimates can be described in terms of bias and precision. Precision is the expected variation between the estimated values from the current sample and the value that would be obtained from an infinitely large sample. The precision of an estimate can be increased by increasing the sample sizes of the underlying studies. Bias is the difference between the estimated and true values of a parameter that would remain if the sample was infinitely large (and there was no sampling error). If a study is unbiased, the estimate will converge on the true value of a parameter as the sample size increases. However, if the study is biased, the estimate will converge on a biased value. We can estimate the precision of a parameter estimate based on observed data, assumptions regarding the statistical properties of the sample, and the size of the sample. Estimates of bias generally will be based on prior beliefs.

Beliefs regarding the potential magnitude of bias in estimates derived from a study are reflected in statements regarding the study's validity or quality. Valid studies are regarded as providing *relatively* unbiased estimates. Study validity can be subdivided into internal validity—did the study answer the question(s) it was designed to?—and external validity—does the study answer the question(s) we are interested in? External validity can be further subdivided into population validity—is the study population generalizable to the real world population?—and ecological validity—are the study materials, methods, and setting generalizable to the real world setting?

These concepts of internal and external validity can be linked to the concepts of efficacy (the extent to which an intervention does more good than harm when provided under ideal circumstances) and effectiveness (the extent to which an intervention does

more good than harm when provided under usual circumstances). Studies with high internal validity but poor external validity provide estimates of efficacy. Studies with both high internal and external validity provide estimates of effectiveness. Studies with low internal validity arguably provide little useful information.

These concepts of bias and precision are useful in determining whether an item of evidence is relevant. Borrowing from a legal definition, evidence is relevant if it makes a fact more or less probable than it would be without the evidence; and if the fact is of consequence.¹⁴ In the context of a CEA, this translates to evidence being relevant if it might change a parameter estimate, the definition of the decision problem, or the selection of model structure; and if the ensuing change might alter the final decision.

Practical Issues in Selecting and Synthesizing Evidence

It is relatively easy to determine whether an item of evidence might potentially influence a parameter estimate. However, it is difficult to determine, *a priori*, whether the inclusion or exclusion of a particular item of evidence will alter the final decision. Therefore, decisionmakers typically are concerned about the potential for omission of items of evidence, either inadvertently or intentionally, that might alter the final decision.

Ideally, all evidence that could possibly be used to inform the model would be identified, and a final selection made from this set. Decisionmakers may therefore require that systematic reviews are conducted to identify relevant evidence. The scope of these reviews will be determined based on *a priori* judgments regarding which forms of relevant evidence are likely to be available and adequate to inform decisionmaking and the resources available for information retrieval and synthesis.

Identification of evidence

The scope of a search is defined in terms of methods used for the search itself and the characteristics of the items of evidence or studies that it is intended to identify. In terms of methods, the searches may be formal systematic reviews¹⁵ intended to identify all studies that match the defined criteria in a reproducible fashion, or may use techniques such as pearl growing¹⁶ and snowballing to improve efficiency. The target studies themselves may be defined in terms of design, location, population, intervention, comparators, and outcomes. The target study designs will depend on the particular question that the evidence is intended to address, and the likely availability of, and anticipated biases associated with, different study types.

For example, a search for evidence intended to inform estimates of relative treatment effect might include studies conducted in any location, but be restricted to randomized controlled trials reported in English. A search for evidence intended to inform estimates of costs might include any study design, but might be restricted to studies conducted locally. In contrast, local observational studies might be used to provide estimates of response to a reference treatment and epidemiological parameters. When searching for “local” studies, it is important to include studies published in the relevant languages.

The searches themselves might be iterative, with the scope being broadened if the previous iterations have not identified sufficient studies or if there are concerns about study biases. For example, a search for studies intended to inform estimates of relative treatment effect might initially be restricted to randomized controlled trials but subsequently be broadened to include observational studies.

Selection of evidence

Having identified a candidate set of evidence, the next step is to determine which items of evidence

should be included in the analysis. However, the objectives of maximizing precision and minimizing bias may conflict. In general, studies are selected that minimize bias in the final estimates, for example by limiting research considerations to local studies or to randomized trials. Yet doing so may reduce the number of studies available to use, thereby reducing precision. In some circumstances, particularly when the likely direction of bias is known, a precise but biased estimate may be preferred over an imprecise but unbiased estimate. For example, when estimating cost-effectiveness for infectious diseases, a biased but more precise static estimate may be preferred over the less biased dynamic estimate when the intervention is cost-effective according to the static analysis and any effects on transmission are believed to improve cost-effectiveness.¹⁷

To aid the selection of evidence, a number of tools have been developed to assess study “quality” or risk of bias. Most of these tools focus on internal study validity; the EVAT (External Validity Assessment Tool) is one exception, as it focuses on external validity. The focus on internal validity is understandable as it is relatively straightforward to define objective assessment criteria related to study design and conduct. In contrast, external validity is context dependent and judgment is required to evaluate the potential impact differences between study and clinical populations. However, when selecting evidence it is important to consider both internal validity and external validity and precision. Researchers should consider:

1. The geography the evidence relates to
2. Internal validity
3. External validity
4. Likelihood that all relevant evidence has been identified
5. Feasibility of collecting further evidence
6. Related decision uncertainty

Synthesis of evidence

In some cases, multiple items of evidence may be related to individual or related parameters. In these cases, it may be helpful to perform some form of meta-analysis to synthesize these items. Meta-analysis is the process of synthesizing the results from related studies in order to obtain an overall estimate of effect. It can increase the “power” of analyses, avoid the arbitrary selection of individual studies, and clarify the effects of the heterogeneity between studies.¹⁸

Traditionally, meta-analyses have synthesized the results from a set of trials that all directly compare the same two treatments. This is commonly referred to as pairwise meta-analysis. However, this may lead to the exclusion of trials that could provide indirect estimates of the treatment effect. This, in turn, may preclude the estimation of a treatment effect of interest or the exclusion of relevant information. In addition, where there are more than two treatments of interest, it can be hard to interpret the results of pairwise meta-analysis. If a series of separate pairwise comparisons are undertaken, it may be difficult to estimate relative treatment effects and associated uncertainty for all comparisons of interest and the results of individual pairwise comparisons may be contradictory.

Network meta-analysis is an extension of pairwise meta-analysis that provides estimates of the relative efficacy of two or more treatments that are derived from a statistical analysis of data—typically a set of randomized clinical trials that form a connected network of comparisons. A network is described as *connected* when all treatments are connected either directly or indirectly by randomized clinical trial comparisons to all other treatments. A network meta-analysis is conducted by obtaining estimates of average treatment effects for all observed comparisons included in the network that both conform to a consistency constraint ($\delta_{AB} = \delta_{AC} - \delta_{BC}$) where δ_{AC} and δ_{BC} are the estimates of the effects of treatment A and

B compared to the common comparator treatment C) for any given set of comparisons and best fit the results of the observed trial comparisons.¹⁹

Consideration of uncertainty

It is tempting to assess the validity and usefulness of a CEA based on an assessment of the quality of the individual items of evidence used to derive parameter estimates for the analysis. If all of the items of evidence are of high quality and judged to be unbiased, then the parameter estimates used in the model will be unbiased, and as a result the estimates of cost-effectiveness should be unbiased and decisions based on those estimates reliable.

However, the logical fallacy of “denying the antecedent” is a real concern; if one or more of the items of evidence is of “low” quality and the estimates derived from them possibly biased, it is not axiomatic that the final decision is unreliable. For example, it is possible that the decision simply is not sensitive to the uncertainty in particular parameters. At an extreme, reliable decisions may be possible even in the absence of any empirical data regarding certain parameters if the decision does not change when those parameters are varied across their credible range. It therefore is useful to work backwards, using methods of sensitivity analysis, to evaluate the contribution of the uncertainty in individual parameters to the overall decision uncertainty. Sensitivity analyses typically comprise a number of steps:

1. Based on the available sensitivity analyses, determine whether there is uncertainty in the decision given the uncertainty in the parameter estimates. The uncertainty of the decision can be evaluated using either deterministic or probabilistic sensitivity analysis.²⁰
2. Determine whether the uncertainty is material. It is possible to be highly uncertain about a decision

even if the consequences (in terms of opportunity cost) of making the wrong decision may be inconsequential. For example, one may be highly uncertain about whether to take acetaminophen/paracetamol or aspirin for a headache. However, the potential cost of an incorrect decision, in terms of wasted resource or missed opportunities to improve health outcomes, are limited. The potential losses associated with decision uncertainty can be evaluated by using deterministic sensitivity analysis to assess the impact on incremental costs and effects on the cost-effectiveness plane.²¹ Alternatively, estimates of expected value of perfect information can be derived from a probabilistic sensitivity analysis.²²

3. Identify which parameters contribute the most to decision uncertainty. Deterministic sensitivity analysis can be used to assess the impact of varying individual parameter estimates on incremental costs and effects. Alternatively, a probabilistic sensitivity analysis can be used to derive estimates of expected value of partial perfect information: an estimate of the value of obtaining perfect information on individual parameters.²³

If decisionmakers are not able to make decisions contingent on the collection of further evidence, they will need to substitute their best judgments for key parameters and make a recommendation based on current evidence. They may be able to use the results of existing deterministic sensitivity analyses to do this, or they may need to conduct or request another analysis. By contrast, if decisionmakers are able to make contingent decisions, they need to decide whether it is feasible to collect further evidence that would reduce uncertainty. If it is feasible, they need to decide whether to make their recommendations contingent on the collection of this evidence.²⁴ If it is not feasible, they will need to substitute their best judgments regarding key parameters.

Figure 1 presents a flowchart illustrating the sensitivity analysis process.

Discussion

A careful consideration of the available evidence based on the concepts of bias, precision, and the relevance of evidence is essential for all evaluations. Such consideration is particularly important in the context of evaluations set in LMICs given the likely limitations in both the available data (particularly in the local setting) and the resources available for research and analysis. This may involve potential trade-offs in precision and potential bias when selecting relevant evidence. For example, there may be a choice between basing an analysis on a very limited set of local data with good external validity but limited precision and internal validity, or on more extensive “global” data that is more precise but may have less external validity.

It is important that decisions regarding evidence selection are considered in the context of their potential impact on the final analysis, rather than naively applying simple heuristics such as hierarchies of evidence. Sensitivity analyses provide information on the impact of uncertainty in estimates derived from individual items of evidence on the final decision. The results of sensitivity analysis can inform decisions around the selection of evidence, the potential need to search for further evidence, and the interrelated decisions of whether to include a treatment in the HBP based on current evidence and whether to require or commission further research.

Conclusion

Decisions should be made from the best use of the available data, without imposing unrealistic evidence standards. This is a particular issue in evaluations set

in LMICs where the availability of local “high-quality” data may be limited. The following process might be useful in assessing the evidence available for a CEA;

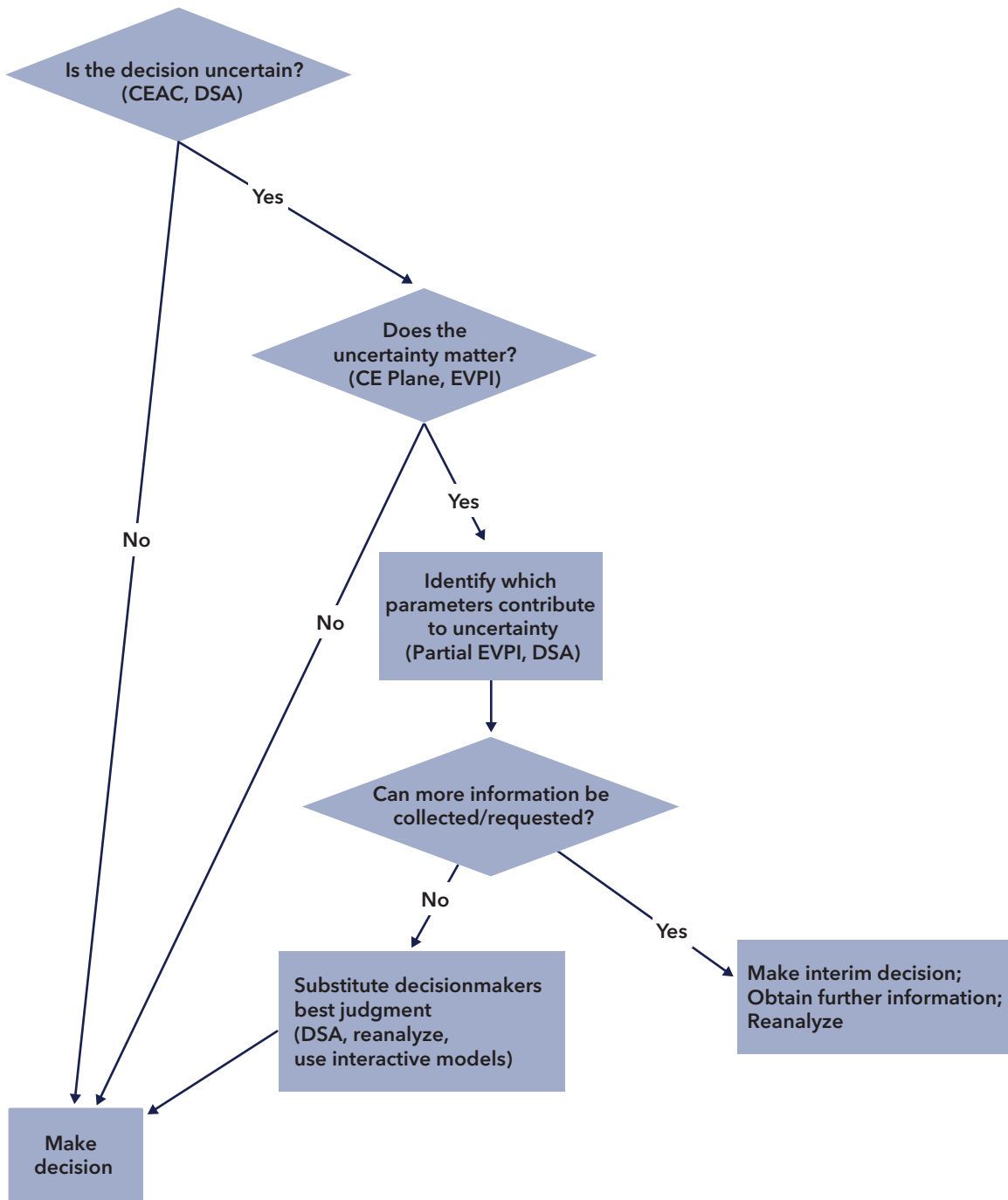
1. Group the items of evidence in an analysis according to the type of parameters that they inform, for example:
 - Relative treatment effect
 - Relationships between modeled variables
 - Utilities
 - Costs/Resource use
2. For each individual item of evidence consider:
 - The geography the evidence relates to
 - Internal validity
 - External validity
 - Likelihood that all relevant evidence has been identified
 - Feasibility of collecting further evidence
 - Decision uncertainty resulting from parameter estimates derived from the evidence item

This analysis then can be used to judge the reliability of the individual evidence items and the reliability of the analysis as a whole. Box 1 shows this scheme applied to a published CEA regarding a medical intervention to treat cardiovascular disease in Tanzania.

The analysis suggests that the interventions assessed are potentially cost-effective. However, the treatment effects and absolute probability of events are estimated from data collected in Europe and North America. It is uncertain whether these estimates are directly applicable to a Tanzanian population. Therefore, there is considerable uncertainty in the estimates of incremental costs and effects. The feasibility and costs of collecting further evidence regarding treatment effects and absolute probability need to be considered when interpreting the results of this study.

This chapter has described the concepts that underlie decisions regarding the identification and selection of evidence. These decisions often require trade-offs in choosing evidence that maximizes

FIGURE 1. Suggested Process for Sensitivity Analysis



Abbreviations:
 CE Plane = Cost-Effectiveness Plane
 CEAC = Cost-Effectiveness Acceptability Curve
 DSA = Deterministic Sensitivity Analysis
 EVPI = Expected Value of Perfect Information

BOX 1. Case Study: Cost-Effectiveness Analysis of Medical Interventions to Prevent Cardiovascular Disease in Tanzania

The case study is based on a CEA of medical interventions to prevent cardiovascular disease in Tanzania.^a The aim of the analysis was the assessment of the potential cost-effectiveness of a number of interventions for the primary prevention of cardiovascular disease in Tanzania. It included the following interventions: acetylsalicylic acid, a diuretic drug (Hydrochlorothiazide), a beta-blocker (Atenolol), a calcium channel blocker (Nifedepine), and a statin (Lovastatin). A Markov model was developed to estimate clinical outcomes and costs under the different treatment scenarios. The following model parameters were estimated:

- 1. Relative treatment effects.** The relative treatment effects were estimated from a meta-analysis of North American and European randomized controlled trials. These studies have high internal validity but the external validity in a Tanzanian setting is uncertain. It is unclear whether all relevant evidence has been identified; this should be checked. It is unclear whether further local studies of sufficient size are feasible.
- 2. Relationships between modeled variables.** The Framingham equations were used to predict absolute probability of cardiac events and the variation of these rates with age. The Framingham equations predicting risks were estimated based on a U.S. study. The estimates of diabetes prevalence came from a Tanzanian study and estimates for other baseline characteristics from the Framingham study. Overall, the estimates have good internal validity but the external validity in this setting is uncertain. It is likely that all relevant evidence has been identified. It is unlikely that further local studies of sufficient size and quality are feasible.
- 3. Utilities.** Standard weights of disability-adjusted life-years (DALYs) were used. These estimates have good internal and external validity. It is likely that all relevant evidence has been identified. It is unlikely that further local studies of sufficient size and quality are feasible.
- 4. Resource use.** International drug prices were adjusted according to a domestic margin. Health facility costs came from a Tanzanian study. The drug price estimates should be subject to sensitivity analysis. These estimates have good internal and external validity. It is likely that all relevant evidence has been identified. Further local studies of sufficient size and quality may be feasible.

a. Robberstad, Hemed, and Norheim (2007).

precision and minimizes bias given the resources available for research and assessment. These trade-offs will often be particularly sharply defined when assessing the use of technologies in LMICs due to evidence and resource limitations. It is important to make decisions regarding the selection of evidence in a pragmatic fashion, selecting the most relevant

evidence that will support the current decision making problem, rather than simply applying simple generic heuristics of evidence selection. As John Tukey put it: “Far better an approximate answer to the right question, which is often vague, than an exact answer to the wrong question, which can always be made precise.”²⁵

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POLICYMAKER COMMENTARY

Confronting Tight Fiscal, Human Resource, and Evidence Constraints, Malawi Revises Its Benefits Package

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At a glance: In resource- and data-constrained Malawi, policymakers marry technical methods with human judgment to craft a realistic but fair health benefits package.

All Malawians have experienced the death or undue suffering of loved ones from ill health, knowing that their conditions could have been prevented or treated with medications widely available in other, wealthier parts of the world. By some measures Malawi is the poorest country on earth, with 2013 annual per capita income of US\$226¹ and total healthcare spending of only \$38 per person annually.² Preventable ill health is one of the most obvious manifestations of underlying poverty. However, in determining health policy and allocating resources, program managers and budget holders need to ensure

that their actions do more good than harm—and a central aspect of this goal is addressing the perennial economic problem of ensuring that the benefits of healthcare spending exceed opportunity costs. Any resources spent on one activity are subsequently unavailable for other priorities, and so the challenge facing Malawi is to do the best with its very limited available resources.

Health benefits packages (HBP) offer the promise of supporting efficient resource allocation in ways that are scientifically sound, transparent, and yet open to ongoing scrutiny and revision. This book, the

first of its kind, demonstrates to national policymakers how effective policy environments can be built around institutions that reflect social values. Further, it offers a coherent theory and accompanying set of methods, essentially based on cost-effectiveness analysis, for how HBPs may be designed in ways that are likely to achieve agreed social objectives. HBPs have had central roles in the design of health systems in the past and this is likely to, and should, continue into the future. However, the experience of Malawi's HBP shows that even though HBPs can support efficient resource allocation, there are also risks associated with their development and implementation that may lead to a failure to live up to the promise.

This chapter outlines the history of the HBP in Malawi and highlights three of these development and implementation risks: (1) confusing the health system goals of resource allocation and revenue generation; (2) focusing exclusively on direct investments in healthcare at the expense of enhancing the conditions for successful delivery and receipt of interventions (including health systems strengthening); and (3) overly relying on a direct interpretation of technical analyses when sound judgment is also necessary, especially when data quality is poor. By highlighting how HBP design and use can go wrong, it is hoped that in the future the promise of HBPs will more likely be realized by carefully considering their use in real and often complex healthcare systems.

History of the Health Benefits Package in Malawi: Confusing the Goals of Resource Allocation and Revenue Generation

Malawi has had a health benefits package, known as the Essential Health Package (EHP), since 2004.³ The initial EHP (2004–10) was introduced as a core component of a new health Sector Wide Approach (SWAp), in which government and development

partners explicitly agreed to work toward common identified priorities. This included the pooling of much of their funds into a common, single account. The package was particularly aimed at reducing child and maternal mortality and combating infectious diseases such as HIV. The EHP's limited scope had some advantages; it focused efforts on activities deemed to be priorities and, perhaps for the first time, encouraged stakeholders to think carefully about competing calls on resources.

The EHP was updated in 2011 for the next health sector strategic plan (2011–16) with a notable feature being the expansion of health benefits to a larger number of disease areas and interventions.⁴ The update was based upon two criteria: burden of disease and intervention cost-effectiveness, with burden of disease representing an initial criterion to prioritize interventions before a more careful assessment of their cost-effectiveness.⁵ The expansion was motivated by the recognition that the initial EHP had not included interventions in many important disease areas (such as mental health) and a sense that the country could do more to meet the desperate health needs of the population. However, the final package was too large and could not be adequately funded from available resources. The gap between the expectations of the population and the realities of provision grew larger.

The unsettling truths are that the EHP has not been fully funded since its introduction and that the growth in costs has outstripped any increases in resources. The initial 2004 package was estimated to cost US\$17.53 per person per year.⁶ This cost far exceeded the less than \$5 per capita per year of government resources available for all health system functions, including not only the direct delivery of healthcare but also management and stewardship, surveillance, and health systems strengthening.⁷ The cost of the EHP then escalated to \$44.4 per person per year, compared to only \$14.5 per person per year of available resources in 2011.⁸ Moreover, it has

been shown that around 20 percent of district-level expenditures have been on interventions that are not included in the EHP.⁹ The predictable result is that large coverage gaps for even the most basic and low-cost interventions remain. Although some services are available in parts of the country, particularly in major cities and other urban locations, in large swathes of Malawi, particularly in poor rural areas, not many interventions (except perhaps some HIV services) are delivered at all.

The experiences of Malawi's EHP have shown that packages can encourage stakeholders to think critically about competing claims on resources. However, much discipline is required to ensure that the scope of a package remains feasible and can be implemented at scale. There were pressures in Malawi to pitch ambitious EHPs in the hope that gaps in perceived need would lead to revenue generation by encouraging international donors and Malawi's Ministry of Finance, Economic Planning and Development to commit additional resources to the sector. However, finances still remained inadequate, which meant that some of the most cost-effective interventions were underprovided and existing healthcare inequalities were exacerbated. The analyses underpinning HBPs may show what could be achieved if additional funding were to be made available, but if stakeholders confuse efficient resource allocation with the need for revenue generation, the consequences can be severe and devastating.

The 2016 EHP revision was based on work by the University of York¹⁰ and will be used in the next health sector strategic plan (2017–22). It has been motivated by recognition that the existing EHP is dated and unaffordable, and that some of the methods used to develop it (such as use of the burden of disease criterion) may not necessarily lead to efficient resource allocation. The revision comes at a challenging time for the Malawian health sector, partly as a result of the “Cashgate”¹¹ government financial management crisis, as well as changes in donor priorities.

Ministry of Health and international development partners no longer pool their resources in the health SWAp. The sources of healthcare funding have therefore become more fragmented and coordination is now weaker.

The methods developed in the revision are intended to be compatible with Malawi's more uncertain and challenging healthcare environment. At their core is a desire to better reflect resource constraints (especially financial, but also nonfinancial) and reveal the opportunity costs when resources are committed to particular interventions or when the health system is designed in ways that limit health attainment. The 2011 EHP used an arbitrary cut-off to determine cost-effectiveness: interventions offering health gains of less than \$150 per disability-adjusted life-year (DALY) averted were deemed “cost-effective,” although some interventions offering health gains at less than this amount were excluded and others at far higher than this amount were included.¹² For the 2016 revision, an empirically derived value of \$60 per DALY averted was used based on the mean from two papers that provided initial estimates of health opportunity costs for low- and middle-income countries.¹³ Although all estimates are highly uncertain, the revised package is now more feasible within the available level of resources, and is likely to consume around 50 percent to 70 percent of the annual health budget. It is hoped that future resource allocation decisions will be based on a truer reflection of the level of resources available.

HBP Interventions, Incomplete Implementation, and Health Systems Strengthening

Another benefit of attempting to reflect opportunity costs more accurately is that doing so can help stakeholders compare the value of directly funding healthcare interventions to the value of other calls on the

budget, in particular the pressure to enhance conditions for successfully delivering healthcare (including investments in health systems strengthening).

Ensuring that health interventions are successfully delivered and received is of particular concern. Health systems strengthening is sometimes an ambiguous term, but in a broad sense it can include actions to address supply and demand constraints, beyond the direct funding required for an intervention, that limit an intervention's delivery, receipt, and/or use, and thus impede health improvement. These diverse constraints include donor-imposed funding silos (in which, for instance, committed funds may be spent only on HIV services); limits in key healthcare inputs, such as a lack of trained healthcare personnel; restrictions imposed by preexisting healthcare infrastructures, such as the balance of community, primary, and secondary care; insufficient demand (caused, for example, by incomplete patient knowledge of the benefits offered by an intervention); and political and regulatory issues.¹⁴ Constraints may act on single interventions or across a number simultaneously.

Typically, HBP design has been concerned only with the choice of healthcare interventions. As a result, governments and healthcare providers may have missed opportunities to improve population health, such as by altering delivery models or other elements of the healthcare system based on an assessment of how healthcare delivery routes can affect health improvement. When a HBP's design problems make the package likely to more than exhaust all available resources—as has been the case in Malawi—any implementation and health systems interventions that could improve health are also likely to be inappropriately designed and/or seriously underfunded.

The 2016 EHP revision made a particular effort to develop an approach that could help stakeholders determine which implementation and health system interventions are likely to offer greatest improvements in population health from within

available resources. Under this idea, the EHP offers a framework within which such interventions can be designed and evaluated using economic criteria. To do so, the EHP must move beyond reporting cost-effectiveness simply as the ratio of costs to outcomes (such as cost per DALY averted) and toward a better understanding of the magnitude of net health effects (health gains less opportunity costs) resulting from interventions across the whole population. Estimates of the costs and effects (DALYs averted) of interventions are used together with national estimates of attainable health service coverage given existing constraints and the estimates of opportunity costs. This information can then inform which interventions are likely to be cost-effective in the Malawian context at existing attainable delivery levels; how to prioritize these interventions; and what, if any, value can be gained through implementation and systems strengthening to address additional supply and demand constraints, whether these affect the whole system or only particular interventions.

When the policy choices or spending commitments of a government, donors, or other stakeholders impose constraints on healthcare implementation and health systems in general, HBPs can also be used to improve system accountability. For instance, if donors commit funding to particular interventions or healthcare inputs (such as new diagnostic machinery or new clinics) that are not shown to be of highest priority in the EHP framework—especially if the donors have made the provision of this funding conditional on matching government funding—the health consequences of such actions can be exposed and challenged.

The Limits of Analysis and the Need for Judgment: Problems of Poor Data Quality

Perhaps the major difficulties in developing the past and upcoming EHPs have been overcoming the

critical lack of jurisdiction-specific data on the costs and effects of interventions that could be considered for implementation. Despite billions of dollars spent on healthcare in low-income countries, the literature on intervention cost-effectiveness remains worryingly sparse. HBP design has to make the best use of often relatively poor information with a high level of uncertainty remaining over almost all estimates.

The 2011 EHP relied exclusively upon the 2006 *Disease Control Priorities in Developing Countries* compendium,¹⁵ but many of the source studies on cost-effectiveness came from an array of different health systems. For the 2016 revision, past estimates were deemed to be outdated and no longer reliable. Instead, the Tufts Global Health Cost-Effectiveness Registry¹⁶ was used as the main source, but this approach ran into a number of problems when stakeholders translated the study results to inform prioritization in Malawi. Specifically, estimates differed in terms of the modeling methods applied; the discount rates (if any) used; the ranges of costs and benefits reported (such as whether these were annual or lifetime); the jurisdiction to which the estimate applied (for instance, some estimates given were for the World Health Organization's WHO-CHOICE regions, as opposed to actual data from Malawi itself); and the currency in which results were given. HBP developers had to make judgment calls as to whether to accept estimates that were not Malawi-specific as generalizable to Malawi, or to reject these estimates and thus exclude evidence on the cost-effectiveness of a particular intervention from the analysis. Where multiple estimates from low- and middle-income countries were available, those that were deemed most generalizable to Malawi were used and appropriate adjustments had to be made so the result could inform the Malawi EHP.

As the power and speed of computing continues to increase, the bounds of modeling and technical methods to directly determine HBPs start to appear unlimited. If an objective function (typically “health

improvement”) can be set and information on the effects and constraints of delivering a full range of interventions—perhaps differentiated by patient subgroup, geographical location, or delivery combination—can be obtained (or assumed), some HBP designers may feel that all that is required is to solve a simple constrained optimization problem. In theory, this may be the case, but the actual experience of designing the 2016 EHP for Malawi shows that a gulf remains between the technically possible and the reality facing HBP designers in national programs.

Given the uncertainties over the reliability of all estimates and their applicability to the Malawian context, it obviously is necessary to deliberate over evidence and make careful judgments when designing a HBP. In this way, HBP design becomes the art of the possible, not the science of the optimal. The required judgments include both *scientific judgments* on the use of evidence and numerous *value judgments*. (Examples of the latter include whether “health” really is the sole objective or whether, and the extent to which, other non-health consequences such as financial protection, effects in other sectors, or distributional concerns also should be considered when determining the final package.) The role of an appropriate process in making such judgments is crucial.

A particular danger is that use of technical methods (modeling to seek *optimal* resource allocation) risks coming into conflict with human appraisal of evidence on cost-effectiveness and on other values. The experience in Malawi indicates that HBP design is clearly political—it is enabled by the institutions that determine its role, and it may be subject to adverse political influence—but it works best when analysts who can remain independent are willing to engage in dialogue with those who have the mandate to make decisions. The advantages are two-way: analysts can inform, support, and expose the values and preferences of decisionmakers, and decisionmakers can highlight important concerns that may not have been well reflected in methods and should

be considered more carefully. It is this reality—that objective methods and suitable processes for making real decisions need to come together if HBP are to bring health gains to populations—that this book captures so well.

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POLICYMAKER COMMENTARY

More than a List

Reforming a Country's Health Benefits Package— A Rigorous Approach to Tackling Costly Overutilization

Yot Teerawattananon

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Benjarin Santatiwongchai

Thanaporn Bussabawalai

Kittiphong Thiboonboon

Saudamini Dabak

At a glance: By specifying appropriate, evidence-based indications—not just a list of medicines—this country trims millions in wasted healthcare spending

Prioritizing the health services guaranteed by the government is one challenge in implementing universal health coverage (UHC). Some countries with established UHC systems such as Australia, England and Wales, and Thailand have made significant investments in priority-setting institutions such as, respectively, the Pharmaceutical Benefits Advisory Committee (PBAC), the National Institute for Health and Care Excellence (NICE) and the Health Intervention and Technology Assessment Program (HITAP).¹ However, there is insufficient literature

on the process by which countries with limited resources and technical capacity assess a large number of interventions to develop a health benefits package (HBP). This chapter offers a novel approach that could be instructive in resource-constrained settings: rather than taking an incremental approach in conducting health technology assessment (HTA) for each technology separately, this approach provides robust evidence by using systematic reviews, incorporating clinical expert judgment, and analyzing secondary data.

Approach

This chapter sets out a real-world example of a lower-middle-income country that is committed to UHC and currently provides a generous HBP that includes more than 25,000 interventions. The government was keen to reform the HBP in order to rationalize its investment in UHC. To that end, it asked HITAP, as part of the International Decision Support Initiative (iDSI), to collaborate on a pilot study. The study was completed in four months by a small research team that gathered robust, locally relevant evidence for 14 medicines. Given the sensitivities around the results of the study, which the country's decisionmakers have taken on board, the authors cannot identify the country or the staff involved. This chapter describes the methods used in the study and its potential policy impact.

Scope of Work

As this was a pilot study, a list of priority medicines was identified for assessment based on their budget burden to the country's UHC program. In the preliminary analysis of claims data, it emerged that the top 20 medicines accounted for more than one-third of the UHC program budget for medicines (39%). This reflects a high concentration of budget spending on very few items. Fourteen medicines were selected for the study: albumin, amino acid, cilastatin/meropenem, ciprofloxacin, erlotinib, esomeprazol, factor VIII, imatinib, meropenem, oxaliplatin, paclitaxel, rituximab, sorafenib, and zoledronic acid.

Decisionmakers and stakeholders agreed that the HBP revisions should look at not only the clinical evidence on safety, efficacy, and effectiveness, but also economic dimensions, such as cost-effectiveness. In addition, the study incorporated tacit knowledge of local clinical experts to ensure local relevance and policy acceptance.

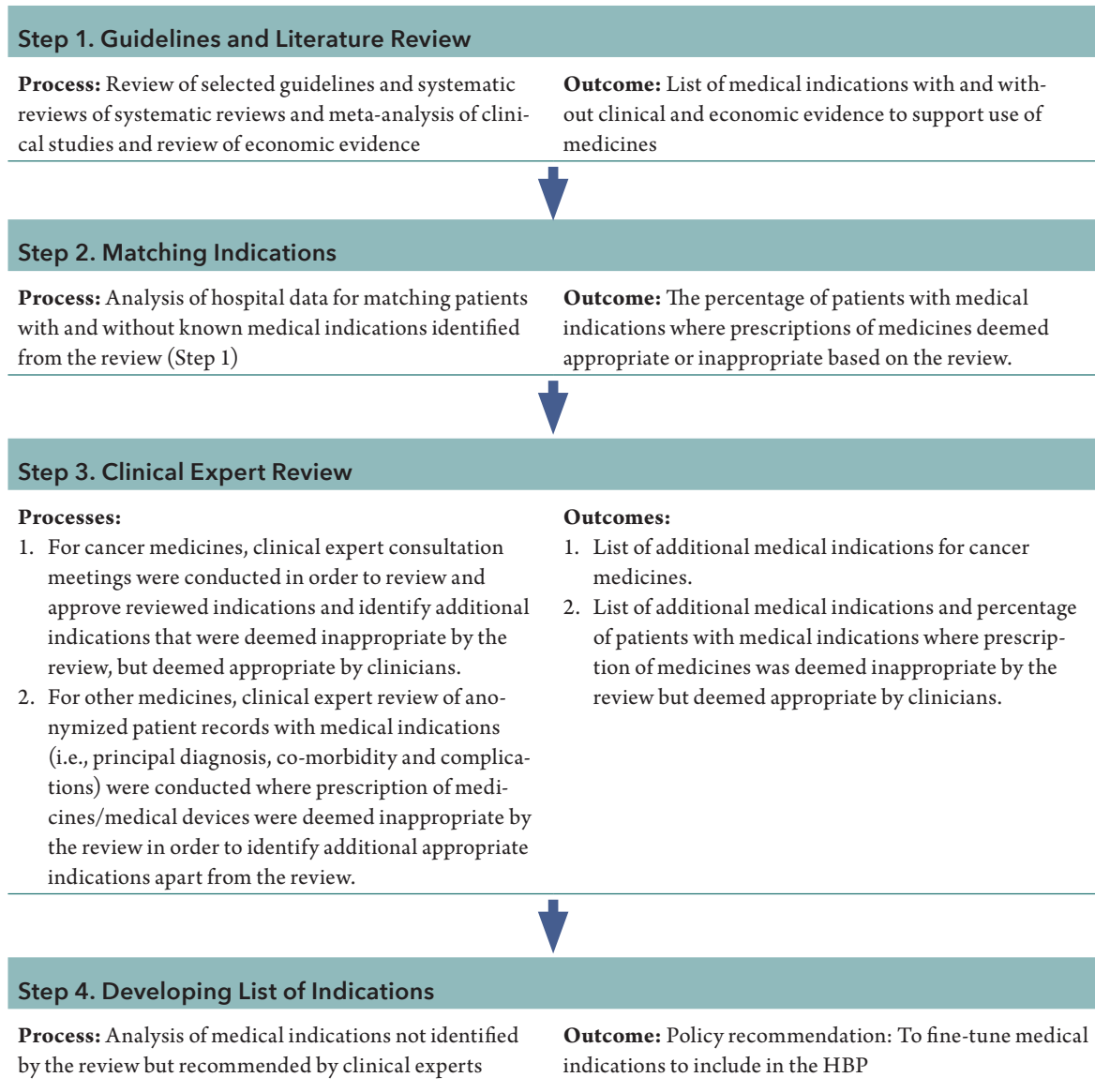
Process of developing the list of appropriate indications for selected medicines

The study's four steps are illustrated in figure 1. In step 1, selected guidelines and literature from databases were reviewed to determine the list of indications and to find supporting evidence for appropriate use of the selected medicines. The list of medical indications was developed based on how they were assessed and presented in each study or guideline. It is therefore possible that a particular medical indication was assessed in general terms (for instance, chronic myeloid leukemia) as well as for a subgroup of patients (for instance, accelerated phase of chronic myeloid leukemia). The following guidelines were consulted: 19th World Health Organization (WHO) Model List of Essential Medicines, Thailand's National List of Essential Medicines (NLEM), local guidelines issued by the national body, and other guidelines developed by international professional associations.

Systematic reviews and meta-analyses of clinical studies, along with economic evaluations, were selected for review in accordance with a protocol developed for this purpose. A systematic review of studies that were themselves systematic reviews of clinical studies was preferred over a systematic review of individual clinical studies for two reasons. First, given the time and resource constraints, it was considered a feasible approach that provided robust results. Second, this second-order review of clinical evidence offered more reliable information on the appropriate use of the technologies, as systematic reviews and meta-analyses take into account a larger sample size compared to individual studies and account for variations in practice across settings.² MEDLINE and Cochrane Database were used to conduct the systematic review.

Because conducting economic evaluations for each medicine and its associated medical indication can be time- and resource-consuming, this study

FIGURE 1. Review Process



focused on reviewing economic evaluation evidence available in the Center for Review and Dissemination, a database that includes all economic evaluation studies published in MEDLINE from 1994 to March 2015. Unlike clinical evidence that is generalizable across healthcare settings, economic evidence relies heavily on context-specific factors such as healthcare costs, availability of the intervention

options, and health preferences.³ Thus a hierarchy of economic evidence was developed with the first priority given to studies conducted in the country, followed by studies conducted in the same region, other low- and middle-income countries, and studies conducted anywhere in the world, in that order. If a study for a medicine and its associated indication with a higher place in the hierarchy was identified,

other studies were ignored. For studies conducted outside the country, all monetary units reported were adjusted to local currency using purchasing power parity based on International Monetary Fund (IMF) data. If the study was conducted before 2015, the consumer price index (CPI) was used to adjust for inflation, also using IMF data. Consequently, all incremental cost-effectiveness ratios are reported in 2015 prices. The ceiling threshold of 1 gross domestic product per capita per quality-adjusted life-years (QALY) gained or disability-adjusted life-years (DALY) averted was used to determine whether the medicine for its associated indication was good value for money.

Given the complexity of the evidence reviewed, the presentation of results was simplified to be

accessible to people without a background in health or economics, using a traffic light system (figure 2). The medicines with indications that are assigned a dark green color should be given the highest priority because they have been demonstrated to be safe, efficacious/effective, and good value for money. Light green medicines and indications are given second priority since, although there is evidence supporting their safety and clinical efficacy/effectiveness, no economic evidence has been identified to support their use. The medicines and corresponding indications with a yellow color are similar to those with a light green color but with evidence suggesting that they are not good value for money. The orange-colored medicines and indications should not be included in the HBP because no evidence of their clinical

FIGURE 2. Traffic Light System Presenting the Results of the Review

Safety	Clinical efficacy/ effectiveness	Cost effectiveness	Color
✓	✓	✓	Dark Green
✓	✓	Unknown	Light Green
✓	Unknown, X	X	Yellow
✓			Orange
X			Red
✓ = there is a supportive evidence X = there is no supportive evidence unknown = no data			

benefits was found, and red-colored medicines and indications may cause harm.

In step 2, hospital data were analyzed. The data included patient-level information on a range of variables such as inpatient and outpatient visits in 2014 and the WHO ICD-10 codes on principal diagnosis, co-morbidity, complications, and treatment, among others. The analysis aimed to match indications of patients who were prescribed any of the selected medicines with known medical indications identified in step 1. First, the number of patients for the known medical indications for each medicine were recorded and ranked. The top ten indications where prescriptions were deemed appropriate by the review was determined. Then, indications that were deemed inappropriate based on the literature review were listed for use in step 3.

In step 3, two approaches were used to incorporate the inputs of clinical experts on medical indications identified during the review and obtain additional medical indications that had been deemed inappropriate during the review process, but might be deemed appropriate by the clinicians. This process allowed for applying local clinical judgment and social values to identify appropriate medical indications to be used under the UHC program. For cancer medicines, expert meetings were arranged to verify the list of medical indications identified from step 1 and to examine the profiles of patients with medical indications where prescriptions had been deemed inappropriate based on the review in step 2. Experts were then asked to endorse the list of medical indications for each medicine, including those medical indications that had been deemed inappropriate by the review but appropriate by the clinicians. The meetings allowed the experts to deliberate and draw conclusions on additional medical indications.

For other medicines, anonymized records of patients who were prescribed the medicines for indications that were deemed inappropriate from step 2 were extracted from the hospital database described

above and shared with clinical experts. The anonymized patient records were distributed among clinical experts based on their area of expertise. Each clinical expert was asked to identify for each of the patient records, using a standard template, whether the prescription was justified for the given indication. This step identified the proportion of patients with medical indications where prescription of medicines was deemed inappropriate based on the review but appropriate by clinicians. This step resulted in the list of indications and justification for their appropriate use.

In step 4, the data for medical indications not identified in the literature review but recommended by clinical experts for each medicine were analyzed. The key outcome of this analysis was a list of medical indications for given medicines that should be reimbursed under the UHC program based on the evidence in the literature review and local expert opinion.

Estimation of potential economic impact of recommendations

When data were available, three variables were used to estimate the impact on the UHC program budget of including the recommended indications for each medicine: total annual expenditure under the UHC program for each medicine, unit cost of each medicine, and proportion of patients for a given indication for each medicine derived from the hospital database. First, the total UHC program expenditure per medicine was divided by the unit cost per medicine to determine the total number of patients for each medicine in the country. Then, the total numbers of patients for each medicine were distributed across the associated indications based on the proportion of patients for each indication obtained from the hospital data. This distribution yielded the number of patients and budget spent for each indication for a given medicine. The patient and budget numbers were used to estimate the potential economic

impact of adopting the recommendations from the previous section.

Stakeholder consultations

Throughout the process, several stakeholder meetings were held to ensure transparency and participation of groups. At the first consultation meeting, participants agreed on the guideline and literature review protocol and solicited criteria for selection of medicines to be reviewed in the first phase. The second consultation meeting presented preliminary results from steps 1 and 2. At this meeting participants had the opportunity to comment on and verify the findings, and to fine-tune policy recommendations.

Findings

This section describes the results from the four steps of developing medical indications for selected medicines and the estimates of the potential economic impact of implementing the policy recommendations. Tables 1 through 6 show the list of medical indications by medicine identified from the review of guidelines and systematic reviews. The results are presented using the traffic light system. Table 1 focuses on cancer medicines. There are systematic reviews and meta-analyses for all 7 cancer medicines in the review; a total of 47 medical indications were assessed. While each cancer medicine has been assessed for more than one indication, none of these medicines fall in the dark green category for all the indications for which evidence of their use was assessed. This suggests that cancer medicines should be prescribed carefully. Zoledronic is the only reviewed cancer medicine that falls in the dark green category for at least one indication, whereas imatinib is not marked as dark or light green for any indication.

Table 2 summarizes the review of indications for three antibiotics, including meropenem, which

is regarded as a medicine reserved for treating serious illnesses caused by antimicrobial-resistant bacteria. In total, 27 medical indications were assessed for these antibiotics; although the medicines were assessed for several indications, none were found suitable for all the indications for which they were assessed. For example, ciprofloxacin was assessed for 22 indications, whereas cilastatin/imipenem and meropenem were assessed for only 5 and 7 indications, respectively, suggesting that ciprofloxacin is a popular antibiotic. However, for 15 indications, there was no evidence supporting clinical benefit in the guidelines. Only meropenem was coded as dark green for one indication (severe pneumonia).⁴

Table 3 presents results for albumin. It was assessed for 11 medical indications but was found to be safe and clinically effective in only 2 of these, and there was no evidence on value for money (light green). Albumin was not recommended by any of the guidelines referred to in this review.

Table 4 shows the list of indications associated with amino acid through the literature review and guidelines. Although it was assessed for 26 indications, there is no evidence available on the clinical benefit of using this medicine (orange) and none of the indications were included in the guidelines.

Table 5 presents results for esomeprazole, which was assessed for six indications. There is variation in the evidence available for the different indications: it was coded as dark green for maintenance therapy of gastroesophageal reflux disease (GERD), light green for erosive esophagitis and *Helicobacter pylori* infection, yellow for GERD as well as the initial therapy for GERD patients with certain conditions, and red for cardiovascular patients currently receiving antiplatelet therapy. For the red case, a systematic review and meta-analysis found that concomitant use of esomeprazole and antiplatelet medicines was associated with greater risk of adverse cardiovascular events.⁵

In Table 6, only hemophilia A was identified as a medical indication for Factor VIII. The review showed

TABLE 1. Cancer and Immunosuppressing Medicines

Indications	Erlotinib	Imatinib	Oxaliplatin	Paclitaxel	Rituximab	Sorafenib	Zoledronic
Cancers							
Bronchus and lung cancer							c
▪ Non-small cell lung cancer	b						
• Advanced stage				a, d			
Chronic myeloid leukemia							
▪ Chronic phase		* a,c					
▪ Accelerated phase							
▪ Blast crisis							
Chronic graft-versus-host disease							
Colorectal cancer							
▪ Stage II			a				
▪ Stage III			a, d				
▪ Advanced/metastatic stage (First-line treatment)			a				
▪ Advanced/metastatic stage (Second-line treatment)			a				
Esophageal cancer							
Gastrointestinal stromal tumor		a					
Multiple myeloma and plasma cell neoplasm							
Oral and oropharyngeal cancer							
Pancreatic cancer							
Pulmonary arterial hypertension							
Thyroid carcinoma							
▪ Metastatic stage							
Thyroid-associated ophthalmopathy							
Breast cancer							
▪ Early stage				a			
▪ Metastatic stage				a, d			
• HER2 positive				a			
B-cell non-Hodgkin lymphomas							
▪ Diffuse large B-cell lymphoma					a, c		
▪ Follicular lymphoma					a, c		
▪ Double hit lymphoma							
Leukemia							
▪ Chronic lymphocytic leukemia					a, c		
Acute rejection in kidney transplantation							
Nephrotic syndrome							
Advance or metastatic renal cancer							

(continued)

TABLE 1. Cancer and Immunosuppressing Medicines (continued)

Indications	Erlotinib	Imatinib	Oxaliplatin	Paclitaxel	Rituximab	Sorafenib	Zoledronic
Chronic immune thrombocytopenia							
Myasthenia gravis							
Systemic lupus erythematosus							
Relapsing-remitting multiple sclerosis							
Hemophilia A/B							
Hepatocellular carcinoma							
▪ Advanced stage							
▪ Before liver transplantation							
▪ Recurrence							
Bone and Joint							
Osteoporosis without pathological fracture							c
Bone problem due to bone metastatic cancer							
▪ Breast cancer							c
▪ Renal cancer							c
▪ Prostate cancer							c
Hypercalcemia of malignancy							
Rheumatoid arthritis							
Others							
Preventing risk of cardiovascular events							

*depends on dosage.

a = 19th WHO Model List of Essential Medicines

b = International guidelines

c = Local guidelines

d = Thai NLEM

TABLE 2. Antibiotics

Indications	Cilastatin, Imipenem	Ciprofloxacin*	Meropenem†
Diseases of the digestive system			
Crohn's disease			
▪ With perianal fistulas			
Acute pouchitis			
Diseases of the respiratory system			
Pneumonia			
▪ Hospital-acquired pneumonia (Nosocomial pneumonia/ Ventilator-associated pneumonia)		c	c
▪ Severe pneumonia			c
Acute exacerbations of chronic bronchitis			
Stable non-cystic fibrosis bronchiectasis		c	c
Acute bacterial sinusitis			
Osteomyelitis		c	
Diseases of the genitourinary system			
Urinary tract infection		c	
▪ Complicated urinary tract infection			
▪ Uncomplicated urinary tract infections			
Acute cystitis			
Chronic bacterial prostatitis			
Infectious and parasitic diseases			
Hospital based infection	a, c		
Severe infections			
Typhoid and paratyphoid fever			
Intra-abdominal infections			
Dysentery			
Uncomplicated gonorrhoea		c	
Cholera		c	
Pseudomonas infection		c	
Meningococcal infections (meningitis)			a (children ≥ 3 months)
Brucellosis			
Skin and soft tissue infections			
Bacterial infection			
Diseases of the blood and blood-forming organs			
Febrile neutropenia	c		
Venous leg ulcers			

*Ciprofloxacin is listed in "a" without a specific indication. Ciprofloxacin is listed in "d" for indications used based on the opinion of clinical experts in infectious diseases.

†Meropenem is listed in "c" for another 12 indications including bronchiectasis, community-acquired/hospital-acquired/ventilator-associated pneumonia, empyema, sepsis, biliary infection, pyogenic liver abscess, infectious acute pancreatitis, bacterial peritonitis, and immunodeficiency. It is listed in "d" for indications used based on the opinion of clinical experts in infectious diseases.

a = 19th WHO Model List of Essential Medicines

b = International guidelines

c = Local guidelines

d = Thai NLEM

TABLE 3. Albumin

Indications	Summary of evidence
Paracentesis in cirrhotic patients	
■ Cirrhotic patients without any infection	
■ Cirrhotic patients with any infection	
Spontaneous bacterial peritonitis	
Intradialytic hypotension in hemodialysis patients	
Acute respiratory distress syndrome	
Low serum albumin in preterm newborn infants	
Severe sepsis and septic shock	
Critically ill	
Acutely ill hospitalized patients	
Postoperative blood loss in cardio-pulmonary bypass surgery	
Severe ovarian hyperstimulation syndrome	

a = 19th WHO Model List of Essential Medicines

b = International guidelines

c = Local guidelines

d = Thai NLEM

TABLE 4. Amino Acid

Indications	Summary of evidence
Stroke	
Nontraumatic intracerebral hemorrhage	
Upper gastrointestinal bleeding in patients with acute/chronic liver disease	
End-stage liver disease	
Cirrhosis or porto-systemic encephalopathy	
Before and after liver transplantation	
Hepatic encephalopathy	
Upper gastrointestinal bleeding in people with acute or chronic liver disease	
Young infants with severe gastrointestinal disease	
Crohn's disease	
Chronic kidney disease	
Acute kidney injury	
Chronic obstructive pulmonary disease	
Building muscle mass in elderly people	
Older people recovering from hip fracture	
Children with cancers undergoing chemotherapy	
Preterm infants	
Neonatal jaundice	
Inborn errors of metabolism	
Neonatal growth	
Lipid tolerance and ketogenesis; gain weight for neonates	
Prevention of necrotizing enterocolitis	
Head injury	
Critically ill	
Prevention and treatment of pressure ulcers	
Patient receiving bone marrow transplant	

a = 19th WHO Model List of Essential Medicines

b = International guidelines

c = Local guidelines

d = Thai NLEM

TABLE 5. Esomeprazole

Indications	Summary of evidence
Cardiovascular patients currently receiving antiplatelet therapy	
Erosive esophagitis	
Gastroesophageal reflux disease (GERD)	
Initial therapy for GERD patients with continued reflux symptoms and failed the PASS test.	
Maintenance therapy	
Helicobacter pylori infection	

a = 19th WHO Model List of Essential Medicines
 b = International guidelines
 c = Local guidelines
 d = Thai NLEM

that the use of Factor VIII for treating hemophilia A with high-titer inhibitors was effective and good value for money, whereas the use for prophylaxis was clinically beneficial but not good value for money.

Figure 3 shows the proportion of patients who were prescribed medicines for various indications in

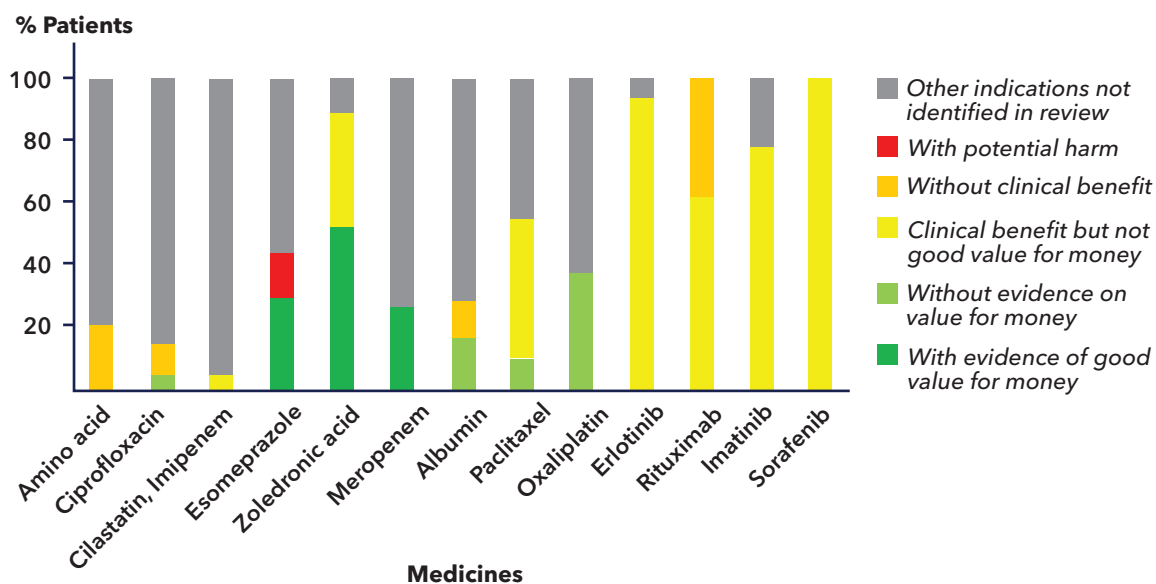
TABLE 6. Factor VIII*

Indications	Summary of evidence
Hemophilia A	c, d
■ Hemophilia A with high-titer inhibitors (ITI therapy compared to rVIIa)	
■ Hemophilia A prophylaxis versus treatment on-demand	

*Factor VIII is listed in “a” without a specified indication.
 a = 19th WHO Model List of Essential Medicines
 b = International guidelines
 c = Local guidelines
 d = Thai NLEM

terms of traffic lights for each medicine. Only a small proportion of patients are diagnosed with medical indications that are in dark green (8 percent across three medicines) and light green (2 percent across four medicines) category. Meanwhile, a majority of prescriptions for each medicine are largely outside the identified indications, with 74 percent of patients being prescribed medicines for other indications that were not identified from the reviews (represented in

FIGURE 3. Matching Hospital Data with Review Findings



the gray category). Only two medicines, rituximab and sorafenib, were not prescribed outside reviewed medical indications, whereas in the case of cilastatin more than 90 percent of the patients were prescribed the medicine for indications outside the reviewed indications. No medicine was prescribed for indications that are only dark or light green. Notably, esomeprazole is administered to about 14 percent of patients for an unsafe (red) indication.

Figure 4 shows the result of the clinical expert review of medical records of patients whose prescriptions had been deemed inappropriate according to the review, including medical indications not identified from the review (gray category in figure 3). The clinical experts confirmed, after reviewing principal diagnosis, co-morbidity, and complications, that a significant number of patients overutilize the reviewed medicines. Overall, even though experts found that 29 percent of prescriptions outside of the identified indications from the review were justifiable, they confirmed that a majority of these prescriptions (58%) were unjustifiable. For 13 percent of medical records, clinical experts were not able to determine whether the prescriptions were justifiable or unjustifiable.

Figure 5 displays the potential saving from using medicines for appropriate indications (except for Factor VIII, for which no data was available). An appropriate indication is defined as one that was coded as either dark green and light green during the literature review process, plus the additional indications found to be justifiable by expert review. The blue-coded proportion shows the amount of expenditure for each medicine that is being currently spent on appropriate medical indications. The yellow-coded proportion shows the amount of expenditure, for each medicine, on indications with evidence showing clinical benefits but not good value for money in the country. The brown-coded portions show expenditure, for each medicine, on medical indications that have been deemed inappropriate through the literature review and are considered unjustifiable by clinical expert judgment. If the government specifies appropriate medical indications for each medicine, the UHC manager would be able to save US\$231 million annually or 78 percent of its annual budget on these medicines. However, if decisionmakers decide to support prescribing these medicines for indications that have proven clinical benefits but not good value for money in the country—in other words, to

FIGURE 4. Results of Expert Review

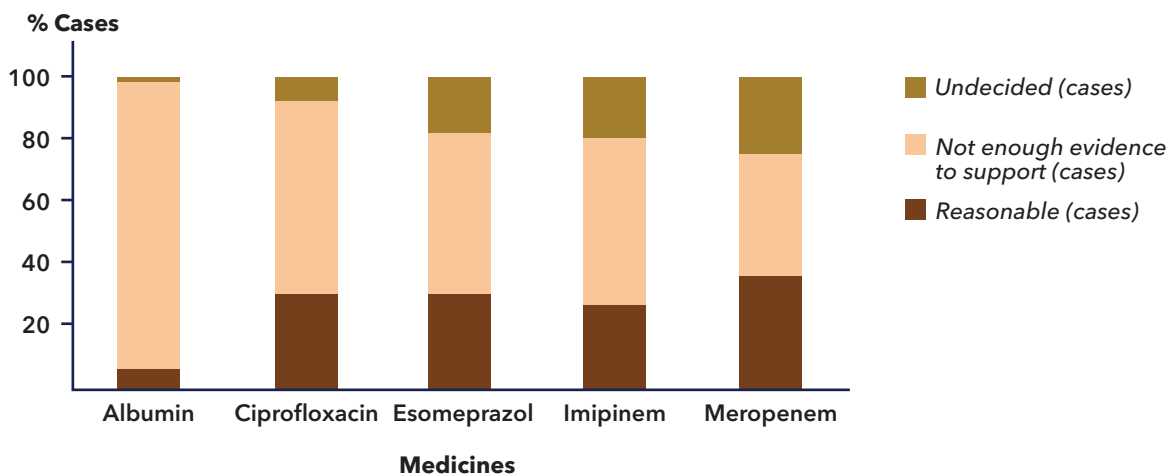
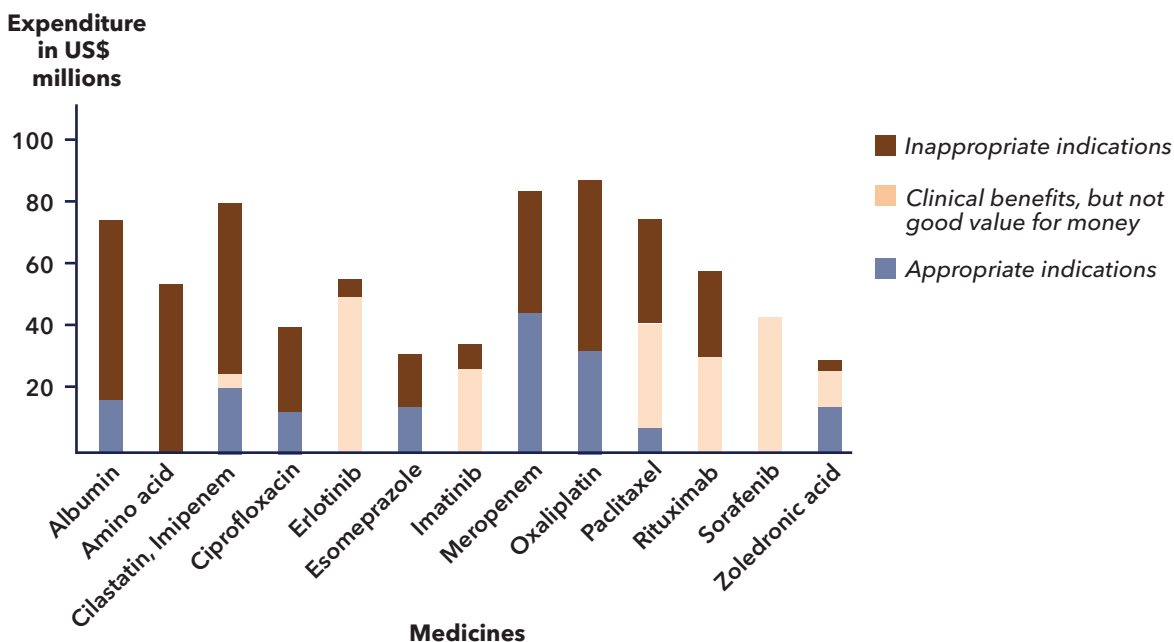


FIGURE 5. Proportion of Spending on Appropriate vs. Inappropriate Indications

include the yellow-coded medicines as well—the potential saving would decrease to US\$152 million or 51 percent of its annual medicine budget.

Discussion

The review found that only 22 percent of current expenditures for these medicines were for appropriate indications; the remainder were for inappropriate indications. The proportion of appropriate indications varied substantially across these medicines. The results suggest that the generous reimbursement policy—namely, not specifying appropriate indications for these medicines—has had a significant negative effect on the UHC budget. By removing inappropriate indications, ones with no evidence of clinical benefit and indications with poor value for money, the UHC manager can free up a significant portion of the budget for further investment.

This study draws five key lessons. First, a well-defined HBP can ensure that UHC resources are invested in priority services. Second, paying providers based on a fee schedule can lead to overutilization of health services, especially when the HBP does not specify indications for each intervention. Third, identifying and addressing interventions that account for a large proportion of UHC resources can lead to significant gains for the health system. Fourth, it is feasible to systematically conduct a document review, analyze service utilization, and incorporate expert input to develop a list of medical indications for reimbursement in resource-constrained settings. Finally, and most important, it is critical to specify medical indications for each intervention that is to be reimbursed in the HBP. These findings have already informed policy change in the study's subject country, ensured rational use of technologies, and helped secure sustainable financing to expand UHC across the country.

The development of a HBP, of course, is a continuous process and should not be viewed as a one-off exercise. In this country, the ongoing work includes expanding the list of interventions to be reviewed as well as updating reviews of the interventions, given that evidence is constantly being generated and indications considered inappropriate today may be deemed appropriate in the future (and vice versa). Health systems in countries committed to UHC should institutionalize priority-setting mechanisms to develop the HBP, and should invest in infrastructure development to serve priority-setting activities. One key component of a priority-setting mechanism is a comprehensive health information system, especially one that includes hospital data, which should be available from all hospitals with an acceptable level of accuracy. This type of data can serve several purposes, such as supporting provider payment systems, monitoring and evaluating appropriate access to priority services, and supplementing other types of research. As the data scale is massive, the data should be digitalized to ensure their timely and effective use.

This study has some limitations. First, it covered only interventions reimbursed by the UHC manager. It focused on the interventions with the highest budget impact and offered policy recommendations to contain their costs. Although this approach appears to have had a significant impact on mitigating wasteful investments, it neglects interventions for which reimbursement claims have been rejected. Given that UHC aims for financial protection and equitable access for essential healthcare, these rejected claims (for which the burden of payment falls solely on households) also should be addressed when developing a HBP. Unfortunately, the study country's UHC agency, like other UHC managers, has maintained records only for claims that have been paid and has neglected claims that were rejected. This is a lost opportunity for useful information for future fine-tuning of a HBP. The study authors therefore

recommend that records of rejected claims be maintained in a usable format.

Second, the review of appropriate indications of selected interventions focused only on a systematic review of literature and domestic and international clinical guidelines rather than individual randomized-controlled trials. The use of systematic review was justified by the fact that it offers more reliable and established information, and better precision. The approved indications identified through systematic reviews are likely to be acceptable by healthcare professionals, not only in the study country but also globally. Although the literature review might have missed emerging indications not yet included in any systematic reviews, the expert reviews compensated for this weakness.

Finally, the economic evaluations used in this study were mainly adopted from studies in other settings. The use of purchasing power parity to transfer economic evaluation results is not a standard approach, but was developed for this study. The analysis relies on the key assumption that resource use for given interventions are the same in the setting of the study and in the country. This may not be the case if the medicines and medical devices are offered by different types of health facilities (comparing, for instance, secondary and tertiary care levels). Nevertheless, this adaptation was the best possible approach given the limitations that the study faced, and the study authors recommend that stakeholders conduct local economic evaluation studies for particular interventions that are important to decisionmakers.

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Endnotes

1. Glassman and Chalkidou (2012).
2. Evans and others (2011).
3. Walker and others (2010).
4. Edwards, Campbell, and Plumb (2006); and Edwards, Wordsworth, and Clarke (2012).
5. Sherwood and others (2015).

POLICYMAKER COMMENTARY

Starting with the Essential Medicines List

How New Zealand's PHARMAC Prioritizes and Purchases Pharmaceutical Benefits

Thomas Wilkinson

At a glance: PHARMAC—an independent agency charged with managing pharmaceutical benefits in New Zealand—links cost-effectiveness and budget impact analysis with commercial strategies to achieve substantial savings to the health system and optimize access to treatments.

Although the shape of a health benefits package (HBP) will be unique to a country's needs, the way that pharmaceutical benefits are managed as part of the package will be critical for sustainability and maintaining universal access. Many countries have some form of Essential Medicines List or schedule of medicines that are fully or partially funded for particular indications or groups of people, and globally there are some excellent examples of accountable and effective approaches to managing access. New Zealand is one such example.

PHARMAC's Origins

A country of just 4.6 million people in the southwest Pacific, New Zealand has maintained an independent

health technology assessment unit called the Pharmaceutical Management Agency (PHARMAC) to manage pharmaceutical benefits since 1993, and its example is instructive to high- and low-income countries around the world.

The origins of PHARMAC date back to the 1980s, when medicine prices were increasing at a faster rate than most other government spending, threatening to crowd out other healthcare funding. To address this risk, PHARMAC was created and has the singular legislative objective “to secure for eligible people in need of pharmaceuticals the best health outcomes that are reasonably achievable and from within the amount of funding provided.”¹

The structure of New Zealand's healthcare system devolves significant administrative and pur-

chasing functions to 20 local District Health Boards around the country. PHARMAC operates by assuming responsibility for a portion of each District Health Board's annual budget (typically 7–8 percent), and using these pooled funds, determines what medicines should be funded.

PHARMAC's independence is important. It reports to the Minister of Health but as an Independent Crown Agent it is not within the health ministry and has its own board of directors and chief executive officer. This structure has allowed PHARMAC to operate with autonomy and to minimize political or other stakeholder influence.

Controlling Expenditure

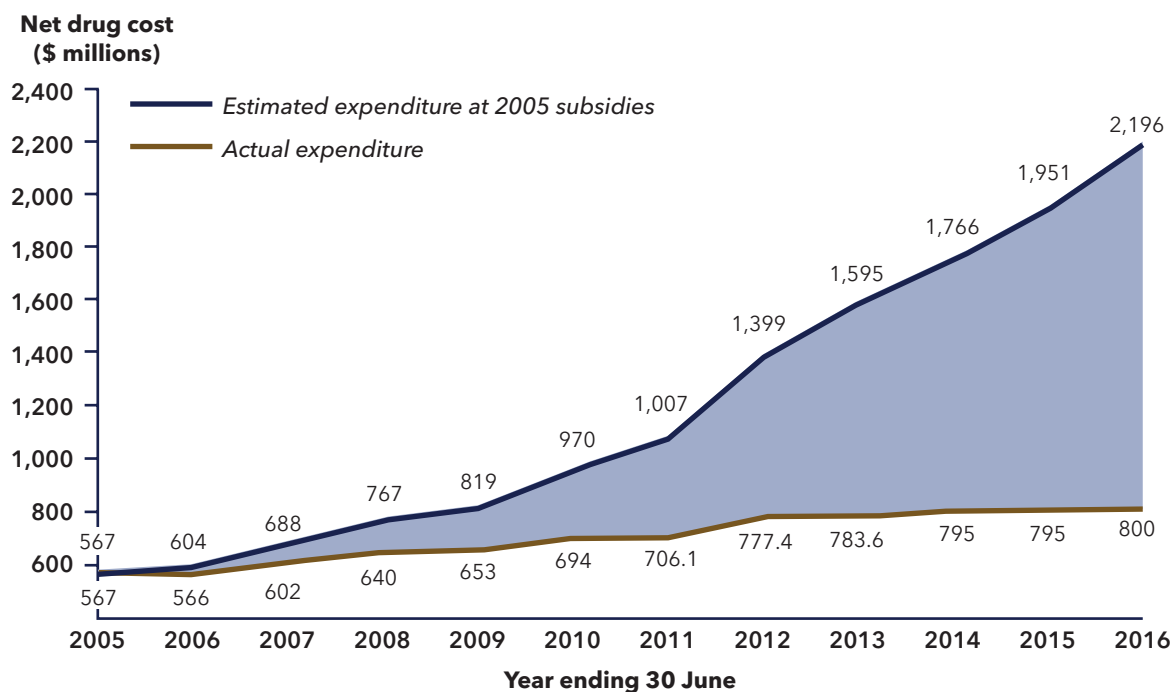
PHARMAC has seen remarkable success in controlling expenditure on pharmaceuticals, while maintaining a comprehensive schedule of pharmaceutical benefits.²

As shown in figure 1, it achieved savings of US\$2.8 billion in the first 20 years of its existence, maintaining an annual average increase in pharmaceutical expenditure at 3.5 percent while prescription volumes increased at approximately 6 percent annually.³

End-to-End Health Technology Assessment

PHARMAC is an “end-to end” health technology assessment agency. It manages the identification of new topics and opportunities for health improvement and savings, conducts analytical assessment, manages the decision, and drives implementation through commercial procurement strategies and schedule production. The Pharmaceutical Schedule is a comprehensive list of medicines and rules that stipulate funded medicines, specific brands, indications and formulations, and the conditions under which

FIGURE 1. Actual Impact of PHARMAC on New Zealand's Predicted Drug Expenditure, 2005–16



Source: PHARMAC (2016, p. 29). Reproduced with permission.

a medicine is funded. The schedule ensures that the decisions made by PHARMAC become an enforceable and universally applied list of health benefits.

In a similar way to other health technology assessment agencies globally, PHARMAC uses cost-effectiveness analysis (CEA) to determine the efficiency of medicines to inform its decisions. Given its limited human resources, PHARMAC has introduced a stepwise approach to the analytical complexity of CEA. If a decision about adding a medicine to the Pharmaceutical Schedule is relatively straightforward with limited clinical uncertainty and financial risk, PHARMAC will do a rapid assessment, taking one to two weeks. As uncertainty about relative clinical benefit or potential budget impact increases, PHARMAC will conduct more comprehensive and detailed analysis, taking up to six months.

PHARMAC has achieved substantive savings through commercial procurement strategies, commonly referred to as strategic purchasing. By adopting different strategies for generic and proprietary medicines, one of the agency's central aims is to introduce competition to markets that previously were not competitive. PHARMAC regularly runs a simple multiproduct tender for the majority of generic medicines and frequently enters into value-based pricing negotiations and risk-sharing arrangements.

Making Decisions

PHARMAC is a decisionmaking body. It regularly makes decisions that have far-reaching effects on the health and wellbeing of New Zealanders, and it often attracts intense public pressure and media interest. PHARMAC's legislative remit means that it needs to consider not just the benefits and risks of a medicine under consideration but the wider implications of its decisions—spending money on one medicine means less money available for other medicines and healthcare.

PHARMAC uses a “Factors for Consideration” framework to aid its decisionmaking process (see

figure 2).⁴ The framework is a form of multicriteria decision analysis, and contains four dimensions: need, health benefits, costs and savings, and suitability. Each dimension is then divided into sections for the individual, the community and family (*whānau*), and the collective New Zealand population and health system. The framework helps PHARMAC to make transparent, accountable, and consistent decisions, but it also to explain to the wider public how and why it is making decisions.

The Pharmaceutical Benefits Package

Determining the shape of a HBP will involve considering how eligible pharmaceuticals are decided and communicated. New Zealand's approach involves a dedicated, independent agency with a singular remit to achieve value for money from the available budget. Its Pharmaceutical Schedule is an example of an explicit positive list, and has enabled PHARMAC to link cost-effectiveness and budget impact analysis with commercial strategies to achieve substantial savings to the health system and optimize access to treatments. Although PHARMAC does make recommendations in some instances on technologies such as devices and diagnostics, PHARMAC does not produce standard treatment guidelines or directly determine access to specific services. New Zealand does not have exhaustive lists or schedules that explicitly define all the health benefits available to the population, as eligibility for health benefits is determined through a dynamic arrangement of local and national policies.

It is unlikely that an isolated approach to a pharmaceutical benefits package development will be appropriate for all countries attempting to move toward universal health coverage. However, as a first step, strengthening decisionmaking processes and methods for pharmaceutical benefits will provide highly visible and measurable progress toward a more comprehensive approach.

FIGURE 2. PHARMAC's Factors for Consideration



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PART III

TOUGH CHOICES

Considering Ethics, Rights, and Political Economy in Defining Benefits

Introduction

Amanda Glassman

Political, ethical, and rights issues are intrinsic to all aspects of the design and adjustment of health benefits packages (HBPs), and their adequate analysis and management is central to a policy's eventual effectiveness for universal health coverage. People who decide how to spend health budgets hold the lives and livelihoods of many other people in their hands, and they must literally make life-or-death choices on what services are provided and how they are delivered, at what quantity, to whom, at what time, and at whose expense. These choices operate in each country's political reality and have inevitable ethical and moral implications. Yet difficult choices in the context of limited financial resources will always raise questions about whether the interests of some population or disease groups are being treated unfairly. Politics, or competing interests or demands,

also explains why it is sometimes very difficult to make coverage decisions based on health maximization criteria alone.¹

In many ways, political, ethical, and rights issues can be addressed and managed by setting up and practicing good governance and process as part of HBP policy, as laid out in the chapters of part 1. For example, governance setups that ensure due process, public engagement, and transparency in coverage decisions can also better inform patients on the rationale behind choices, defend decisionmaking processes in a court of law, and manage competing interest groups more transparently. As described in the chapters in part 2, the methods adopted to weigh evidence on costs and benefits can also address some political, legal, and ethical issues as well. For example, cost-effectiveness models will use sensitivity analyses

to show how different assumptions, evidence, or data will affect outcomes, helping decisionmakers to adequately consider the quality of evidence or the fairness of the distribution of outcomes. Ages of different kinds of patients might be weighted differently within an analysis to correct for past inequities or to favor children (if that is a societal preference), or to give preference to medicines that reduce the severity of disease and suffering.

However, political, ethical, and rights issues deserve priority on their own terms and from their own disciplinary vantage points, independent of governance and methods considerations. There are no universal answers to the tough issues that will come up, so the purpose of the third part of this book is to provide framing to understand the dilemmas that are likely to emerge, examples of how low- and middle-income countries and other countries have dealt with similar challenges, and directions for further research and practice. It presents a sampler of what is politically, ethically, and legally at stake when making the difficult trade-offs to decide what's in and what's out of a HBP.

In chapter 12, Jesse B. Bump and Angela Y. Chang discuss a political economy framework for analyzing HBP decisions. They review relevant political economy theories and several case studies to develop a framework to help analysts and policymakers better understand, predict, and manage the political and economic forces that shape HBPs. The process of negotiating, adopting, and implementing HBPs is an intensely political activity because of its profound impact on entitlements and responsibilities. Healthcare is particularly vulnerable to small groups that have a clearly defined common objective and lower organizational costs that allow them to effectively lobby decisionmakers to their advantage, at the expense of the larger population whose interests may be more diffuse and who may have higher costs of organizing. Patient associations, for example, have successfully lobbied governments to fund drugs

publicly, even if there is doubt about their cost-effectiveness, or their clinical efficacy—for example, in 2006, patient pressure contributed to the United Kingdom National Health Service's decision to fund the breast cancer drug Herceptin.²

Even the more technical aspects of HBPs have political dimensions because of their consequences. For instance, there are political implications in choosing the interventions included in the package because not all groups need or want the same things. Interventions for noncommunicable diseases, for instance, tend to be consumed more by urban elites because nonurban citizens do not have as many risk factors linked to wealth, such as high-fat diets, tobacco use, sedentary lifestyles, or even the requisite longevity. The choice of intervention also carries many economic implications. For manufacturers, distributors, and retailers, inclusion in a benefits package guarantees a market—often a large and lucrative one—for their products. For providers, HBPs influence the services they will perform, the populations whom they will serve, and the rates they will be paid, all of which impact professional autonomy, working conditions, and pay.

Bump and Chang illustrate the application of different political economy frames to two real-life cases: a specific technology (adoption of the pneumococcal conjugate vaccine in Costa Rica) and a comprehensive benefits package design (the national HBP as part of the National Health Insurance Scheme in Ghana). Both cases illustrate the myriad stakeholders and political and economic interests at play and suggest how better prospective analysis of the political economy context could potentially result in better HBP policy and implementation.

In chapter 13, Carleigh Krubiner and Ruth Faden examine some of the same issues through the lens of ethical analysis, starting with a framework to understand the ethical issues at work in HBP design and implementation, and providing concrete guidance to policymakers on how to systematically incorporate

ethical analysis across various stages of developing and delivering on a HBP. Most important, the authors describe the ethical implications of setting goals and objectives for the HBP as a whole, and how doing so can directly translate into choices that have knock-on ethical implications to consider and address. Krubiner and Faden lay out some familiar ethical considerations (such as process, efficiency, and evidence) that are discussed from different perspectives in earlier sections of this book, but add issues of avoiding harm to individual patients, providing respect and dignity for patients, and ensuring respect for clinician judgment, and then describe how all of these issues pertain to HBP. Again, the emphasis is not on “a right choice” but rather on ways to proactively consider, justify, and cope with the ethical consequences of different decisions.

In chapter 14, Rebecca Dittrich and colleagues consider how governments and decisionmakers address the question of whether the inclusion or exclusion of a certain benefit aligns with the right to health of each individual and the larger population as a whole. Rights-based legal arguments have been used to compel the provision of therapies, particularly in Central and South American countries where the right to health is enshrined in constitutional law, based on United Nations recommendations related to Article 12 of the 1966 International Covenant on Economic, Social and Cultural Rights, among other international laws. As Dittrich and colleagues note, the ability to access a country’s judicial system is invaluable to securing citizens’ health rights. The opportunity for legal remedy holds governments, health ministries, policymakers, and other decisionmakers accountable for maintaining a population’s guaranteed right. Even when decisions to include or exclude certain benefits have been made deliberately and judiciously, they will not always be made correctly, and the judiciary is empowered to right those wrongs.

Yet sometimes courts will overturn explicit benefit exclusions without regard for trade-offs, evidence,

or due process, with perverse effects for HBP policy and its goals. The authors look at some of the major court cases of the past decade, and make practical suggestions to reduce the vulnerability of explicit benefits plans to litigation, while still recognizing the importance of the legal system as an essential recourse for all stakeholders in the health system.

Finally, in his policymaker commentary, Antonio Infante recalls how Chilean policymakers managed the politics of priority-setting during a broader reform of the health sector. Observing from afar, Chilean leaders had watched the Clinton administration flounder during its failed 1994 attempt at health reform in the United States, and were determined to avoid the same mistakes during their own domestic effort in the early 2000s. Seeking broad public buy-in, Chilean leaders convened focus groups, consulted key stakeholders, and exposed the proposal to scrutiny through congressional debates and mass media. Further, the structure of the proposal itself was designed to mollify political opposition while also achieving health improvement and equity goals. The Universal Access with Explicit Guarantees (AUGE) benefits package offered something extra to rich and poor alike: a government guarantee of quality, timeliness, and financial protection for a set of prioritized conditions. Meanwhile, nonprioritized services would still be available and publicly subsidized (though not subject to timeliness or quality guarantees), so Chileans did not perceive themselves as “losing” preexisting entitlements. Broad public support enabled policymakers to manage industry objections and forge ahead with the reform. A decade later, the scheme has helped ensure more equitable treatment for chronic conditions and reduce the share of out-of-pocket expenditure. Yet even today, Chilean policymakers confront constant pressure to expand the scope of guarantees, risking strain on the budget and system capacity, and illustrating how political minefields can be navigated—but never fully defused.

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CHAPTER 12

Priority-Setting as Politics

A Political Economy Framework for Analyzing Health Benefit Package Decisions

Jesse B. Bump
Angela Y. Chang

At a glance: What gets covered, and who decides? Political economy theories—veto points, interest groups, and more—help explain common dynamics.

Designing health benefits packages (HBPs) is far from simple because it raises politically difficult and economically significant issues, such as what services will be provided, to whom, under what circumstances, and at what cost. HBP decisions are increasingly important and complex as more countries embrace the goal of universal health coverage (UHC), more low-income countries reach middle-income status, more populations age, and more interventions are developed. These dynamics underpin increased attention to building and strengthening health systems, as opposed to programs focused on narrow problems. Many of the most contentious elements of building a health system are encapsulated in the process of designing and updating HBPs.

In the context of low- and middle-income countries (LMICs), international actors have proposed various priority-setting methods and metrics, including economic evaluation, burden of disease, social acceptability, and financial affordability, to help facilitate the process of deciding which interventions should be included in HBPs. Most analyses of priority-setting and most assistance in this area have focused on technical issues, such as calculating disease burdens and training staff to apply cost-effectiveness models. Far less attention has been paid to the political economy of HBP design—the processes, interests, institutions, and politics that characterize decisions on budgets, coverage of services and interventions, and costs for users. Yet knowledge

of the political economy of priority-setting can help to structure more effective resource allocation institutions, processes, and decisions by recognizing and managing rather than ignoring competing political and economic interests.

Many observers will recognize the results of political economy conflicts in policies that do not make sense from a technical perspective. For instance, in one of the cases examined in this chapter, Costa Rica adopted a pneumococcal vaccine even though the main national technical agency recommended against it and the primary supporting evidence was written by a graduate student funded by the vaccine's manufacturer. The national insurance schemes of both Ghana and Mexico have struggled to maintain financial viability, but both include coverage for very high-cost services for elite populations. The United Kingdom has one of the most robust institutional mechanisms for assuring the cost-effectiveness of interventions offered by its National Health Service, but it also has the Cancer Drugs Fund, which was designed by politicians specifically to circumvent the cost-effectiveness requirement.¹ Whether these examples represent a legitimate expression of democratic choice or a subversion of good governance for the inequitable benefit of a few is secondary to the reality that political economy forces are highly influential in government decisions in health.

Understanding and managing these political economy forces is one of the largest challenges for policymakers trying to shepherd technically informed plans through the gauntlet of reality. Political economy is a useful lens for analyzing the processes that underlie priority-setting in health because it is fundamentally concerned with conflicts of interest,² which are central to policymaking in health for three reasons. First, demand for health services is unlimited but resources are finite, meaning that setting priorities is inescapably an exercise in rationing that determines what interventions and services will be available to whom,

along with related questions of quality, timing, and price. In part, conflicts of interest reflect differences of opinion about the optimal distribution of resources. Second, as Kenneth Arrow and others have observed, health is characterized by market failures, meaning that health policymaking is unavoidably redistributive.³ Conflicts arise over different views of who should subsidize whom and to what extent. Third, government decisions are typically binding on many parties, which creates contests between different interest groups with different preferences, whether between payers and providers; between parties in power and minority groups; or between groups with different needs, wants, or perspectives.

This chapter focuses on the political economy of decisionmaking about HBPs, an important area of priority-setting in health. The process of negotiating, adopting, and implementing HBPs is an intensely political activity because of its profound impact on entitlements and responsibilities. Even the more technical aspects of HBPs have political and economic dimensions because of their consequences. For instance, choosing the interventions included in the package carries political implications because not all groups need or want the same things. Interventions for noncommunicable diseases tend to be consumed by urban elites because other citizens do not have the same wealth-related exposures, such as high-fat diets, tobacco use, sedentary lifestyles, or even the requisite longevity. The choice of intervention also carries many economic implications. For manufacturers, distributors, and retailers, inclusion in a HBP guarantees a market for their products—often a large and lucrative one. For providers, HBPs influence the services they will perform, the populations whom they will serve, and the rates they will be paid, all of which impact the sensitive issues of professional autonomy, working conditions, and pay.

The technical approaches favored by many analysts in global health are not well suited to

understanding or managing these complex issues of political economy. Typical tools in epidemiology and econometrics are essential to defining technically optimal strategies because they help identify where diseases are, what burden they cause, and who is affected, among many other factors required for intervention. However, they do not fully address the underlying political economy issues that are central to the distribution of health-related risks and resources.

This chapter presents an illustrative and diagnostic framework to help analysts and policymakers better understand and predict the political and economic forces that shape HBPs, which can be a useful tool for developing management strategies. Two brief case studies illustrate what types of actors engage the HBP process, with what interests, and at what stage of the policy process, in order to highlight the advantages of a political economy lens. For readers interested in the methods and theories used to develop the framework, a later section discusses these issues in detail. It concludes with suggestions for how policymakers can better understand the political economy of HBP design, and provides questions to inform their thinking at each stage in the policy process.

The Political Economy of HBPs: A Diagnostic and Illustrative Framework

The following illustrative and diagnostic framework draws on the theories and methods described later in the chapter to briefly explain the steps of the policy cycle, how they apply when HBPs are discussed, what contests of interest tend to arise in each one, and what questions could be used to guide a political economy analysis during each stage. Table 1 presents the results, a series of general questions that readers can use to guide their own inquiries.

Case Example 1. Some Political Economy Aspects of Costa Rica's Adoption of Pneumococcal Vaccine

Costa Rica's technical agencies considered the pneumococcal vaccine (PCV) and recommended against its inclusion in the national program. However, PCV was adopted anyway. Political economy theories help to identify the interest groups, the points in the political process that could be used to influence the outcome, and the strategies that were used. Information for this discussion was gathered from the ProVac evaluation report⁴ and expert interviews.

Case Description

Costa Rica has a well-developed national health system structured around a semi-autonomous agency, the Costa Rican Department of Social Security (Caja Costarricense de Seguro Social; CCSS), that both funds and provides health services to the entire population. The country's Ministry of Health plays a regulatory and oversight role. Historically, the addition of new vaccines to the Expanded Program on Immunization followed a two-stage process: first, the National Commission on Vaccination and Epidemiology (Comisión Nacional de Vacunación y Epidemiología; CNVE), an autonomous agency attached to the Ministry of Health, develops a recommendation for adoption. The CNVE is composed of two ministry officials, three CCSS staff, one pediatric association member, and one staff member from the National Children's Hospital. Recommendations are then submitted to the ministry, which determines whether the vaccine should be added to the national immunization schedule. In parallel, CCSS, as both a payer and provider, has its own process to determine whether it would fund and provide the vaccine, regardless of the health ministry's decision.

In 2007 the Ministry of Health reportedly became interested in the national introduction of PCV.

TABLE 1. The Political Economy of HBPs: A Diagnostic and Illustrative Framework

	Agenda-setting	Formulation and Adoption	Implementation	Evaluation
	The process in which the need for a HBP receives greater attention, for instance for cost or equity reasons	Legislatures and other decisionmaking bodies consider how to address the problem, such as via a HBP	Putting the policy into effect, such as by specifying and enforcing a HBP	Assessment of impact, such as evaluating the consequences of a HBP
Typical Contests of Interest	Advocates for different diseases or conditions and their interventions compete to advance in the political process. Includes attempts to define and quantify problems and solutions, frame debate, and assert the primacy of one issue over others. Also contested are narrow versus universal approaches, and contests of authority, as between government and medical professional associations.	Debate includes the definition of the issue, its framing, the groups affected, the assignment of responsibility, the solution, the goals of the policy, and its expected mechanisms.	Implementation contests include who or what groups will have responsibility for carrying out the policy, the timing of activities, where action will be taken, and the source and amount of funding. Challenges to the legality of the policy and/or its implementation plan are common.	Advocates and opponents contest the evaluation of policies by arguing over what counts as evidence, what constitutes a reasonable counterfactual, what mechanisms were engaged by the policy, and other issues related to what has happened under the policy and what can be expected under it in the future.
Stage-specific Questions for HBP Analysis	<ul style="list-style-type: none"> ■ What are the baseline expectations of different actors (policy-makers, general population, etc.)? ■ Are there potential risks of retrenchment and unintended consequences that may arise with the introduction of HBP? How can we mitigate these risks? ■ Who were the leading advocates and supporters? Why were they pushing for it, and how? 	<ul style="list-style-type: none"> ■ Who are the existing international agencies/donors involved in national health policy? ■ Has similar policy process/incidence taken place in neighboring countries or countries with similar historical backgrounds? ■ Who are the median voters, and what health service demands do they have? ■ Can politicians' strategies be characterized as credit claiming or blame avoiding? 	<ul style="list-style-type: none"> ■ What is the role of bureaucracy in current health service delivery (regulatory, administrative, payment to providers)? ■ How will the role of bureaucracy change with the introduction of the HBP, if at all? ■ How does the current payment system incentivize the providers? 	<ul style="list-style-type: none"> ■ How can we design a strong evaluation system to mitigate opportunities for manipulation by external actors?
Questions Relevant across Policy Stages	<ul style="list-style-type: none"> ■ Where are the key institutional constraints and veto points at each stage, and who are the veto powers that hold those positions? ■ Are veto points (or the institution itself) more powerful than individual actors? Are the institutions stable enough to counterbalance the power of individual actors? ■ How can we design the process with appropriate number and type of veto points to ensure fairness and transparency? ■ What are the strategies of interest groups in interacting with key veto players? ■ What have been the strategies and actions taken by interest groups in the past? 			

CNVE unanimously voted to recommend adding the vaccine to the list, and yet the health ministry announced that the vaccine would be included. However, there were criticisms that the decision had been influenced externally—some claimed that Merck, the vaccine manufacturer, may have attempted to influence the decisions of the health minister and another CNVE member by funding their participation in an international academic event where PCV was discussed.⁵ Following the criticism of the listing decision by the local media, the minister requested a cost-effectiveness study to substantiate the decision. The study did not list its authors, but it was written by a local master's degree candidate with funding from Merck. The director of the program in which the student was enrolled indicated that “the study was done to support the Minister's cause.”⁶ But even with the publication of this study, CCSS still did not purchase PCV. Thus, to introduce PCV without financial support from CCSS, the minister obtained a donation from Merck to implement several PCV campaigns.

Both of the minister's actions—publishing the study and receiving donations—were opposed by the CCSS, the media, and other government agencies. In 2008 the immunization program within CCSS conducted a second cost-effectiveness study which found that the vaccine was cost-effective. Yet the pharmacoeconomics unit within the CCSS rejected this study because there were uncertainties in the model. Later that same year, the pharmacoeconomics unit itself conducted a third cost-effectiveness study which found that PCV was too expensive given its benefit. Based on this finding, the CCSS decided not to offer PCV to its beneficiaries. However, in 2008 the decision faced an *amparo judicial*—a judicial protection mechanism for individuals who believe their rights are being violated—which demanded that CCSS provide PCV to all children. The court ordered CCSS to meet the demand starting in 2009, even though CCSS at that time was facing a financial shortfall and supplying PCV was expected to

consume 5.8 percent of its total budget.⁷ Nevertheless, CCSS followed the court order and PCV was introduced in 2009.

In 2010 the comptroller general of Costa Rica investigated the process by which PCV had been introduced to the country's HBP and formally recommended that further cost-effectiveness studies be required to support the investment. The report noted “the current studies used by CNVE are all funded by the manufacturer of the vaccine, which makes evident the need for health authorities to join forces and guarantee independent and objective studies.”⁸ The minister of health subsequently resigned in 2011.

Political Economy Analysis

This case study of PCV introduction in Costa Rica looks at the spaces of contestation and the strategies of influential actors. In the policy cycle, this case takes place in both the *formulation* stage, in which decisionmaking bodies design and enact policies, and the *implementation* stage, in which the policy is carried out.

Veto points and veto actors. According to the veto point theory, this case involves four spaces of contestation. First the CNVE considered whether to recommend the vaccine to the Ministry of Health. Second, the Ministry of Health decided whether to add PCV to the national immunization schedule. Third, as both the payer and the provider, the CCSS made its own decision independent of the ministry's recommendation. Fourth, the judiciary issued a court order regarding the funding and provision of PCV. Costa Rica has no explicit constitutional right to health, but in recent years the Supreme Court has become deeply involved in many healthcare decisions.⁹ In the case of PCV, the court compelled CCSS to fund and provide PCV, and CCSS had no further recourse.

Interest groups and strategies. A political economy lens helps identify the actors and explain where they intervened and how they influenced the process. The groups most interested in the incorporation of

the vaccine into the national scheme were the manufacturer and the families of children who stood to receive the vaccine. Even though technical evidence suggested mixed results and did not support the adoption of the vaccine, the manufacturer was able to win the support of the minister and then promoted a study to justify her position. Although this tactic was not well received and ultimately failed, the manufacturer still prevailed by circumventing the technical process entirely with a favorable judgment from the judiciary. Some evidence suggests that the manufacturer may have also supported patient groups to bring their case to court.

The characteristics of a health product also can influence politicians' behavior. Vaccines are politically powerful for three reasons. First, vaccines comprise a large proportion of the health budget in Costa Rica, and some have speculated that this leaves more room for budget manipulation and corruption. Second, vaccines are distributed to nearly all citizens, leading to greater recognition for the politicians that introduce them. One stakeholder observed that politicians gain more credit by pushing for nationwide adoption of a vaccine instead of, for instance, approving a hospital renovation project (which would remain important only to users of that hospital). Third, in recent years vaccines have received much financial and political support from powerful international actors such as the World Health Organization (WHO), the Bill & Melinda Gates Foundation, and the GAVI Alliance. Powerful external actors may pressure and offer incentives to countries to adopt vaccines through a range of actions, including dissemination of information and offering strong economic incentives. Support from large technical international organizations, such as WHO and the Pan-American Health Organization, is politically powerful because voters trust these agencies and are receptive to their advice. Local politicians seek to cooperate because endorsements burnish their credentials and enhance future career prospects.¹⁰

Case Example 2. Ghana and the Design of the National Health Benefits Package

Ghana's adoption of a comprehensive HBP has been cited widely as an example for other LMICs hoping to deliver more services to their citizens. Its National Health Insurance Scheme (NHIS) was established with a defined HBP covering 95 percent of the disease burden, with services such as outpatient and inpatient care, oral health, maternity care, and emergency care. Because of the NHIS's prominence in global health, this case study briefly describes how this ambitious policy was passed and analyzes the political economy factors that shaped the process. (To focus narrowly on the HBP process, many important and related contextual factors—such as payment reforms using a value-added tax, a carve-out of social security funds, the decentralization process, and immediate legacies in the mutual health organizations—are not discussed here.)¹¹

Case Description

In late 2000, Ghana's major opposition party, the New Patriotic Party (NPP), won the national elections with the promise of replacing out-of-pocket payments at health facilities with a social health insurance scheme. Shortly after the election, the minister of health formed a task team to design the HBP. According to Yogesh Rajkotia, the team first analyzed the national health service utilization data and found that 80 percent of all services provided were low-cost outpatient services that could be provided at the level of health posts. Another 15 percent were services delivered in secondary and tertiary care centers that "cause the most financial distress to society"; and the remaining 5 percent included both expensive services (such as heart and brain surgery) and services that are not of public health concern (such as cosmetic surgery).¹²

In deciding which services to cover under the HBP, a former member of the design committee

stated that one of the key principles in designing the HBP was to prioritize benefits for the poor population; thus, there was strong agreement on covering essential services that the poor may not be able to afford (namely, the 15 percent described above). The team also quickly reached consensus that the most expensive 5 percent of services should not be covered. However, there was no clear consensus on whether the remaining 80 percent should be covered. Some technical members argued that only inpatient services that result in catastrophic expenditures should be covered first, and the rest should be introduced incrementally once the actuarial cost of NHIS was better understood. However, since the HBP (and the abolition of user fees) was considered a political commitment made by the ruling party, other members argued that it would be politically unacceptable to refuse to cover the aforementioned 80 percent. However, even before the team presented its recommendation to the Ministry of Health, it was publicly announced that the HBP would cover 95 percent of the disease burden in Ghana.

Political Economy Analysis

The above brief historical narrative makes this process seem deceptively simple, but how did it actually happen and what were some of the forces that shaped it? In the policy cycle, this case takes place in the *formulation* stage, in which decisionmaking bodies design and enact policies. Contestation at this policy stage often narrows to the definition of the issue, its framing, the groups affected, the assignment of responsibility, the solution, the goals of the policy, and its expected mechanisms.

Institutional and contextual factors. The main contextual factors in this case were the national elections that occurred in 2000 and 2004, during which health was advanced to the top of the national agenda because the general dissatisfaction with the health system and intense dislike of the cash-and-carry policy under which citizens paid user fees at the point

of service. In the 2000 election, NPP secured power for the first time in Ghana's history by capitalizing on this discontent with pledges to abolish the cash-and-carry user fee policy. To keep this promise and gain support for the 2004 elections, the policy had to be formulated and passed through the parliament very quickly.¹³ The National Health Insurance Act was passed in 2003, a year before the second election.

The following stakeholders were key veto points and veto players in the process:

- **The minister of health.** In January 2001 the minister of health was appointed by the elected NPP president. He established a task team of technical experts to develop the policy, though he later disagreed with the task team's recommendations on political and ideological grounds. The minister then replaced the task team chair with a trusted former associate and asked the team to redevelop its recommendations. In 2001 the cabinet was reshuffled, and the newly appointed minister brought in consultants with strong political ties to the NPP and appointed a trusted political ally of the NPP as the chair of the design process. Despite technical concerns with the HBP design, the HBP was approved by the minister and sent to the parliament. This suggests that the minister had strong veto power in determining who chairs and joins the task team, as well as filtering policy recommendations that were sent to the parliament.
- **The parliament.** The parliament was tasked with passing the policy. However, the likelihood of a veto depended on which party held the majority. Before the passage of the bill, the opposition parties contested the policy, arguing that there was insufficient evidence to support its claims and that it lacked accountability mechanisms. Even though the opposition walked out during the voting process, they were unable to prevent

the passage of the bill because they held only a minority of seats.

- **The president and the ruling party (NPP).**

The leaders of the ruling NPP held strong veto power because they controlled ministerial appointments and could dictate which bills were passed in the parliament. Furthermore, they were crucial in determining the composition of the task team. One senior NPP official stated that in the early phase of the policy development, the party was suspicious of the task team's party loyalty and thus disregarded its policy recommendations.¹⁴

A long history of citizen engagement in health discussions and particular anger over the cash-and-carry policy elevated the political viability of reform and diminished the importance of technical feasibility considerations. As Rajkotia states, the objectives of the NPP leadership were to establish and scale up a national system, to claim electoral credit by casting the policy as an NPP initiative, and to pass the policy through the parliament before the next election.¹⁵ The NPP was far less concerned about the technical designs. Given this background, it is not surprising that the technical details of the policy were articulated vaguely, which has led to some of the challenges that remain today. This vagueness is also reflected in the fact that the politically connected consultants, who had helped the NPP government develop campaigns during the election, were among the most influential actors in the process.

Actors and strategies. The strategies put forward by the politically connected consultants, such as covering 95 percent of all disease burden in the HBP despite the lack of technical evidence, can be explained by their strong ties to the ruling party and private businesses. The consultants first gained the support of the NPP leaders by developing successful tactics during the 2000 presidential election.

They were appointed to the policy task teams by the minister of health, and proposed policies that satisfied the NPP's political considerations, even though they often lacked technical expertise. For example, in defining the minimum benefits package, technical experts suggested that more analysis was needed to carefully assess the population and financial data for NHIS to be sustainable. The consultants dismissed these suggestions by labeling the experts as "a member of the political opposition whose motivation was to sabotage government policy . . . and labeling the suggestions as part of attempts to slow down a process that needed to be completed as fast as possible."¹⁶ The consultants were so powerful that "sometimes technical working groups would find that decisions on the issues they had been charged to work on had, in effect, already been taken." The relationship between the NPP and the consultants can also be considered as a patron-client relationship: a relationship of exchanges in benefits between the patron (who has power) and the client (who receives the benefits of the patron's power in return for loyalty). The consultants had helped the NPP reach rural populations during its election campaigns, and in return the NPP placed these individuals in influential positions that could lead to personal gains. Furthermore, the consultants were thought to have private business interests.¹⁷

Political parties. Ghana's political parties also played a notable role in the HBP policy struggle. During the 2000 election, both major parties were campaigning on proposals to abolish user fees, but the NPP had an advantage because it was not in power and had never presided over the current unpopular policy. The winning party had to ensure that their alternative policy—any policy perceived as different from the old policy—would be established and implemented before the next election. These political imperatives took precedence over the technical challenges of doing so. Ultimately, the NPP pursued a politically ambitious agenda: it would end

all copays, cover 95 percent of the disease burden, and charge a very low one-time premium of about \$8. This premium reflected an amount that had proven politically viable in Ghana, but it is unlikely that even the proponents expected it to adequately fund the insurance scheme. But the NPP was also pragmatic, and continued to use existing public and private delivery mechanisms, retaining the basic structures of previous community insurance schemes by simply incorporating them into the national plan and taking advantage of the fact that Ghana's delivery capacity was so modest at the beginning of reforms that it could not immediately absorb vast sums of money. Using bold claims and quick progress, the NPP gained the electoral support to remain in power long enough to effect meaningful change.

Methods and Frameworks

Political economy is challenging to analyze because it concerns sensitive relationships between money and power, and reflects influences that are hard to specify precisely and in many cases are not publicly disclosed. These problems are well-known features of the policymaking environment, but a review of the literature provided no adequate framework for characterizing them or applying them to HBPs. To construct a suitable novel framework, theories of political economy had to be reviewed in order to capture a wide range of forces, circumstances, and actors that could be relevant to HBPs. Syllabi on health policy and political economy from leading graduate programs in health systems and political science—the Harvard TH Chan School of Public Health, the Johns Hopkins Bloomberg School of Public Health, the London School of Hygiene and Tropical Medicine, Princeton University's Department of Politics, and New York University's Department of Politics—were reviewed to identify relevant theories. These syllabi would reflect the expert judgment of scholars

working in this or related areas, and might provide theories to explain how best to analyze HBP design.

To help policymakers understand some of the political economy ideas and theories that apply to HBPs, table 2 presents a brief summary of each theory, a description of how it applies to HBP, and the categories of analysis used to understand the cases. The discussion that follows is organized according to the four stages of the policy cycle:

1. Agenda-setting, or the processes by which some issues gain enough momentum to warrant the attention of policymakers.
2. Formulation, in which the policy is designed (combined here with adoption for simplicity).
3. Implementation, in which the policy is put into practice.
4. Evaluation, in which the policy is reviewed, its impact is assessed, and it is adjusted based on feedback and new data.

In reality, these steps do not always occur in order and some or all of them may overlap, but nonetheless they are used here clarify the different areas of contestation that shape policies and actions.

The first stage of the policy cycle is agenda-setting, in which the need for a HBP receives greater attention. Agenda-setting is crucial in public policymaking processes, as it determines whether a problem will be considered as an issue for government decisions. Actors such as clinicians, pharmaceutical companies, and patient advocates compete for attention and resources as they attempt to advance or protect their interests in the political process. For example, one of the key reasons why the Clinton administration's health reform to introduce universal health insurance failed in the United States in the mid-1990s was due to strong opposition from the medical associations at this stage.¹⁸ Theories such as historical

TABLE 2. Political Economy Theories and Their Application to HBP Analysis

PE theory	Important Elements	Major categories of analysis	Questions for HBP Analysis
Veto points (and players)	<ul style="list-style-type: none"> Veto points are steps in the political process where decisions are made to advance or block a policy. Veto points define the spaces where interest groups can attempt to influence policy outcomes, such as hearings, review processes, or other formal steps. Veto players are groups or individuals empowered by institutional position with the authority to advance or block policy. 	<ul style="list-style-type: none"> Structure of the political process 	<ul style="list-style-type: none"> Are veto points (institutions) more powerful than individual actors? Are the institutions stable enough to counterbalance the power of individual actors? Where are the key institutional constraints and veto points on developing new policies and passing into law related to a HBP, and who are the veto powers that hold those positions? What are the strategies of interest groups in interacting with key veto players?
Historical institutionalism	<ul style="list-style-type: none"> Actions of individuals are significantly affected by institutions, and therefore pose questions in understanding how institutions affect individual behaviors. The concept of path dependency emphasizes the causal relevance of preceding stages in a temporal sequence. 	<ul style="list-style-type: none"> Historical and current political-economic context 	<ul style="list-style-type: none"> What relevant context is there to describe the baseline expectation of different actors (policymakers, general population)? Are there potential risks of retrenchment and unintended consequences that may arise with the introduction of HBP? How to mitigate these risks?
Agenda setting	<ul style="list-style-type: none"> Coupling of the three “streams”—problem, policy, and political—leads to a window of opportunity in which there is greater chance of proposals landing on the political agenda. 	<ul style="list-style-type: none"> Conceptualization of the problem The policy and its framing Political context 	<ul style="list-style-type: none"> Does the HBP resonate with a recognized problem? Are there “invisible actors” developing alternative solutions and proposals? How politically prominent is the issue? Are the key ingredients in the three streams in place?
Interest groups	<ul style="list-style-type: none"> Interest groups exercise their influence over the policy process to maximize benefits. Power differences between actors exist when some groups are better positioned than others to participate and influence priority-setting processes. 	<ul style="list-style-type: none"> Interest groups 	<ul style="list-style-type: none"> What have been the strategies and actions taken by interest groups in the past?
1) Bureaucracy	<ul style="list-style-type: none"> Behaviors and decisions taken by bureaucrats can be explained by the incentives and information they perceive. Instead of performing acts to enhance public interest, bureaucrats will pursue their own interests and form actions based on personal incentives. 	<ul style="list-style-type: none"> Incentives of bureaucrats 	<ul style="list-style-type: none"> What is the role of bureaucracy in current health service delivery (regulatory, administrative, payment to providers)? How will the role of bureaucracy change with the introduction of HBP, if at all?
2) External players—diffusion theory	<ul style="list-style-type: none"> External players may exert their influence through one of the four models: external pressure, normative imitation, rational learning, and cognitive heuristics. 	<ul style="list-style-type: none"> Regional context 	<ul style="list-style-type: none"> What existing international agencies/donors are involved in national health policy? Has similar policy process/incidence taken place in neighboring countries or countries with similar historical backgrounds?
3) Legislatures and politicians	<ul style="list-style-type: none"> Politicians make careful calculations and engage in benefit-cost analysis for every political action they make. Politicians will design policies that will appeal the most to median voters. A relationship of exchanges in benefits exists between the patron and the client. Credit claiming and blame avoidance—policy-makers act to make constituents believe that they were personally involved in achieving desired outcomes or to avoid being blamed for negative policy outcomes when they are in conflict with constituents’ interests. 	<ul style="list-style-type: none"> Politicians’ incentives and decisions 	<ul style="list-style-type: none"> Who are the median voters, and what health service demands do they have? Will politicians endorse inclusion of health services that affect the demographics that belong to the median voters, such as the middle class, urban voters, or the adult population? Can politicians’ strategies be characterized as credit-claiming or blame-avoiding?

institutionalism, the streams model, and diffusion theories offer insights into how the institutional and contextual factors at this stage may evolve. Historical institutionalism, for example, offers key insights that are helpful for analyzing the political economy of designing HBPs. The theory states that actions of individuals are significantly affected by institutions—such as the formal or informal procedures and conventions of the political environment—and therefore explores how institutions affect individual behaviors. First, instead of starting from a blank slate, governments often have to design policies around existing institutions.¹⁹ Second, sequencing is critical. Different sequences may produce different outcomes, and in the case of HBP it is likely that earlier events will generate certain dynamics between stakeholders and thereby impact later events and decisions. Furthermore, one could hypothesize that certain critical events may reduce the power of potential opponents, such as when the HIV/AIDS epidemic in the late 1990s provoked strong protests by civil society against pharmaceutical companies, which weakened the industry's ability to contest that and other issues. Third, in relation to the second point, once a certain policy decision is implemented, networks of beneficiaries and stakeholders emerge and will resist future proposals that may reduce their benefits. The process of retrenchment is unpopular and politically very difficult since it requires the government to reduce the privileges of well-organized groups. Therefore, before introducing a new program, in addition to the technical considerations listed above, one should consider the potential risks of retrenchment and the unintended future consequences.

The second stage of the policy cycle is formulation and adoption, which is the step for legislatures and other decisionmaking bodies to design and enact policies after they have gained a place on the political agenda. Compared to the first stage, the focus of the contention narrows to specific issues, such as the definition of the issue, its framing, the groups

affected, the assignment of responsibility, the solution, the goals of the policy, and its expected mechanisms. The theory of veto points and veto players is helpful in this policy stage. Veto points are defined as “strategic opportunities stemming from the logic of political decision processes,” in which interest groups may seek to block legislations.²⁰ Or, as stated by Ashley Fox and Michael Reich, the demands of different interest groups “are mediated through political institutions that structure the kind of legislative change possible in a given system.”²¹ Veto players are the actors who occupy the veto points and whose agreements are required for a policy decision.²² Some hypothesize that policy stability increases with the number of veto players, the difference in their political positions, and their internal cohesion: consequently, the greater the number of veto players, the higher the likelihood that the status quo will prevail. Yet others state that with the increase in the number of veto points, interest groups will have higher likelihood of gaining access and control over the policy process.²³ In the case of HBP, the number of veto players appears to have increased the complexity of reaching an agreement on HBP, but this complexity is not necessarily linked to the quality of decisions produced by the process. Furthermore, different sets of veto players engage in different stages of the policy process, and their level of engagement and power should vary by stage. Also, the veto points (or the institution itself) are prone to interest captures if they are not stable and advanced enough. This consideration is especially relevant in LMICs, where individual actors often appear to be more powerful than institutions that are too weak to counterbalance individual influences. In the case of the adoption of PCV in Costa Rica, four veto points were identified for their potential weakness to external influence in the face of instability.

The third stage of the policy cycle, implementation, involves determining who or what groups will be responsible for carrying out the policy, how

the activities will be timed, where actions will be taken, and what funding sources and amounts will be required. At the implementation stage, challenges to the legality of the policy and/or its implementation plan are common. A classic case is the approval of the breast cancer drug Herceptin for the United Kingdom's National Health Service. Even though many pointed to key gaps in the evidence for the drug's effectiveness and cost-effectiveness, it was approved by the National Institute for Clinical and Health Excellence (NICE) for treating early-stage breast cancer. Some accused the drug manufacturer of persuading and supporting patients to go to the media to get the drug, and several patients "threatened to shame their local health authorities, either by selling their homes, or by taking their trusts to court."²⁴ Although NICE has denied any external influence on its decision to expedite the approval of the drug, the potential influence of various stakeholders cannot be ignored. Furthermore, in countries with judicial protection of the right to health, such as Colombia and Brazil, the contestation at the implementation stage becomes more complicated as the constitutional courts become involved.

Another key factor at the implementation stage is the role of bureaucracy. It encompasses public sector actors within administrative institutions who are closely involved in the daily operations of policy implementation. Taking a rational choice approach, James Buchanan and Gordon Tullock state that the behaviors and decisions made by bureaucrats can be explained by the incentives and information they perceive.²⁵ Instead of performing acts to enhance public interest, bureaucrats are likely to pursue their own interests (as other people do) and form actions based on personal incentives. One prominent global health scholar described bureaucracy as one of the biggest barriers in all of the many national-level health reforms with which he had been involved.²⁶ Furthermore, HBP designers often focus more on the design of the policy and fail

to account for the implementation plans, leading to bureaucratic overload.

The final stage of the policy cycle, evaluation, involves assessing the impact of the policy and adjusting its formulation or implementation based on feedback and new data. Advocates and opponents contest the evaluation of policies by arguing over what counts as evidence, what constitutes a reasonable counterfactual, what mechanisms the policy engaged, and other issues related to what has happened because of the policy and what can be expected under it in the future.

This exercise in exploring political economy ideas for analyzing HBP decisions helps suggest how different actors will behave at different stages of the policy cycle. Compared to existing stakeholder analysis tools, this chapter's framework offers a wider view of the complete policy cycle rather than a static cross-sectional picture. It takes into account the institutional and contextual factors that shape policy outcomes, and can help explain or predict actors' behaviors and strategies at different points of the policy cycle.

Conclusion

HBP design is fundamentally a challenge of political economy because it affects the distributions of entitlements and responsibilities. Different groups contest this process throughout the policy cycle. Ideas and theories from political economy can illuminate these dynamics both in general, as in the abovementioned illustrative framework, and in specific cases described in the two case studies. The crucial importance of political-economic forces in the HBP processes and the ways in which these forces take shape present a number of questions that policymakers should consider in order to better detect the likely points of contestation and better predict some of the issues that will arise.

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CHAPTER 13

A Matter of Morality

Embedding Ethics and Equity in the Health Benefits Policy

Carleigh Krubiner
Ruth Faden

At a glance: Coverage decisions have significant consequences for people's health and well-being - and can be a matter of life or death. Benefits policy design decisions require careful ethical consideration of how they will impact the range of people they are meant to help.

Health benefits packages (HBPs) have become an increasingly popular approach to setting priorities and allocating resources for health, in both low- and high-income settings.¹ A HBP lays out an explicit set of services, activities, and goods that will be covered in the package, and specifies which populations and what proportion of the costs will be covered. The move toward universal health coverage (UHC) has sparked renewed interest in HBPs as a tool to expand access to essential health services through effective, efficient, and equitable investments.²

When designing a HBP, policymakers encounter a number of challenging decisions. Which services, activities, and goods should be included? Who should be covered? What kinds of cost-sharing arrangements should be in place for beneficiaries? These and many

other choices have ethical implications. Difficult choices in the context of limited financial resources always raise questions about whether the interests of some population or disease groups are being treated unfairly. The design of a HBP can engage other moral values as well, like respect for cultural traditions or patients' rights. Ethics also matters to the processes by which HBP decisions are made, including the role of public engagement and transparency. Ethical analysis examines policy options, processes, and outcomes through a different lens. In ethical analysis, these options, processes, and outcomes are evaluated against a range of morally relevant principles, norms, and values, referred to here as applicable moral considerations. Like economic analysis, ethical analysis can provide policymakers with insights, tools, and

arguments that can help them make better decisions for the HBP.

In recent years, there have been increasing attempts to incorporate considerations of equity in efforts to achieve UHC, including a report from a World Health Organization (WHO) Consultative Group on Equity and Universal Health Coverage called *Making Fair Choices on the Path to Universal Health Coverage*.³ Additionally, there is a growing literature on practical ethics in conducting health technology assessments (HTAs) surrounding the adoption of new health interventions.⁴ These resources provide valuable frameworks and heuristics surrounding a key aspect of any HBP—defining the services and populations covered.

This chapter expands on this work to provide an ethics framework for addressing broader considerations for HBP design and implementation. The framework recognizes that ethics analysis must be sensitive to the context, including the specific policy and population health aims of the HBP. It provides concrete guidance to policymakers on how to systematically incorporate ethical analysis across various stages in developing and delivering the HBP. It discusses why ethics and equity are critical, and provides an overview of specific ethical considerations for a HBP as well as a guide for applying these considerations to relevant design and implementation decisions across the lifecycle of the HBP.

Why Ethics and Equity Matter in Policymaking for HBPs

Ethics are inextricably embedded in all health policymaking. Ethical judgments and explicit and implicit values shape the assumptions that policymakers use and the decisions they make, and they have a significant impact on the wellbeing of those affected by them.⁵ Creating a HBP is no exception. Policymakers have to navigate across a range of commitments to deliver essential services, protect populations from

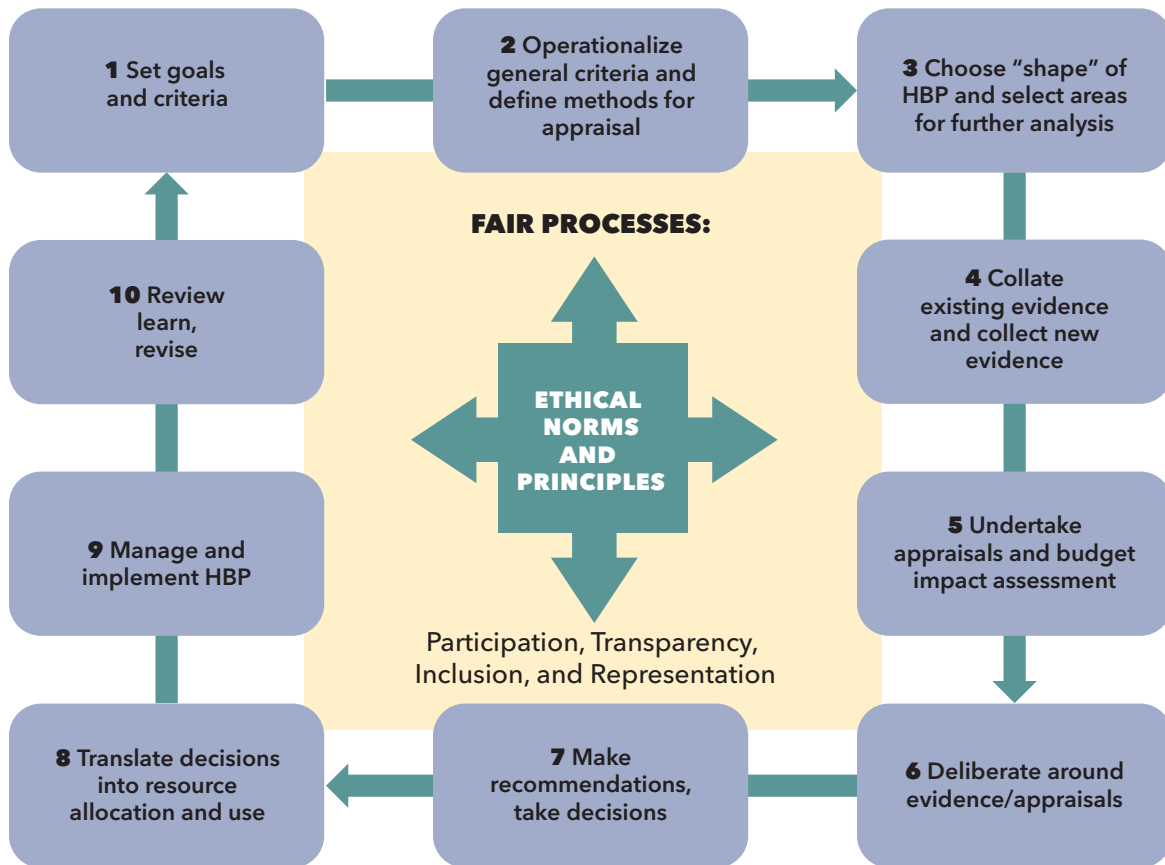
the costs of ill health, and address health inequities. With limited resources to support these commitments, hard choices must be made in prioritizing which goods and services will be included and for whom. Ethical considerations arise across the entire HBP policy cycle, from the specification of goals to the designation of benefits and ultimately to the ongoing implementation and adjustment of the package (figure 1). Paying careful attention to ethical considerations can be especially important in the politically difficult context of designing and adjusting HBPs. Analysis of ethics considerations at each stage can provide guidance to HBP policymakers navigating the moral contours of decisionmaking for HBP:

“One important role for ethics in policy . . . is the identification of the ends sought in policies, examination of the values embodied in these ends and the assessment of the extent to which these ends are in keeping with social values.”⁶

One particularly important function of ethical analysis in designing HBPs is to clarify and critically examine its aims or goals. A firm conception of the HBP goals provides the foundation for all other decisions when structuring the package.⁷ For instance, some countries use HBPs to meet basic health needs for the entire population, offering services that are seen as essential benefits to which all citizens are entitled by virtue of their human right to health. In other cases, HBPs are used to meet the health needs of specific populations, such as pregnant women, children, the elderly, or the poor. Financial protection is a common objective, with packages seeking to shield beneficiaries from the economic burden of high-cost health interventions.

HBPs have also been introduced to achieve operational advantages, serving as a management tool to improve health service planning, financing, and delivery, and to promote greater efficiency in health

FIGURE 1. Ethics and the Core Elements of an HBP



Source: Adapted from Glassman and others (2016).

spending. For instance, the vision for the National Health Insurance scheme in South Africa, as laid out in the country's 2015 White Paper, aims to address multiple structural and factors surrounding fragmentation of the health system, financing mechanisms, and misallocation of human resources for health, while putting forth explicit aims to address the massive health inequities across racial and socio-economic groups reinforced by the current system.⁸ With myriad motivations for adopting a HBP and setting its objectives, a clear conception of the goals and their relative priority at the onset of the design is essential.

Many HBPs embrace commitments to equity, either implicitly by using the package as a means to achieve UHC or explicitly by naming equity as a central objective (table 1). However, equity is not a one-size-fits-all term. Table 2 provides examples of some of the different types of equity commitments frequently underlying HBPs, as well as explanation of two distributional terms often used by economists.

In some instances, a commitment to equity means providing equal access for all to a predetermined set of services. HBPs seeking to offer an identical package of essential health benefits to the entire population—such as PIAS (Plan Integral de

TABLE 1. Plan Types, Equity Aims, and Samples of Relevant Considerations

Single HBP with explicit guarantees for the entire population	HBP targeting specific groups to address disparities	HBP providing coverage for segments not otherwise covered
<p>Primary Commitment: Equitable access for all to at least a minimum basic set of services</p> <ol style="list-style-type: none"> 1. Does the set of covered services/interventions distribute benefits across the population fairly? <ul style="list-style-type: none"> ■ Whose health needs are not met by the plan? What justifications exist for those health needs that are excluded? ■ Does the composition of benefits covered exacerbate or narrow existing disparities? 2. Are the services covered in the plan meaningfully accessible to all beneficiaries? <ul style="list-style-type: none"> ■ What additional investments in the health system might be necessary to promote equitable access across the population? 3. Is the quality of the services available relatively consistent, so that those utilizing these interventions have equal opportunities to achieve health gains? 4. Do the financing arrangements unduly burden or restrict access for certain members of the population? <ul style="list-style-type: none"> ■ What kinds of adjustments to the cost-sharing arrangements (sliding scales, waivers, exemptions) can be made to mitigate the negative impacts on the most vulnerable? 	<p>Primary Commitment: Improve health outcomes and access for those with the greatest need</p> <ol style="list-style-type: none"> 1. Which populations are highly disadvantaged and ought to be covered by the plan? <ul style="list-style-type: none"> ■ Which services best meet the needs of these disadvantaged populations? ■ How well does the plan do in closing gaps in health outcomes between these groups and the rest of the population? ■ How well are the needs of subgroups within the target population being met? 2. Are there any features of the plan that could exacerbate disparities or compound disadvantages for these vulnerable populations? <ul style="list-style-type: none"> ■ Do the payment mechanisms and cost-sharing arrangements limit financial barriers to accessing services? ■ Are the services delivered in a way so that services are geographically, socially, and culturally accessible to target populations? 	<p>Primary Commitment: Address existing gaps in coverage on the path to UHC—Tiered/Mixed System</p> <ol style="list-style-type: none"> 1. How does the service package and coverage under this plan compare to what is available to those covered under other existing options? <ul style="list-style-type: none"> ■ Are fewer interventions and/or conditions covered? 2. How do cost-sharing arrangements compare under this scheme to other existing coverage schemes? <ul style="list-style-type: none"> ■ Is there disproportionate economic burden, risk of impoverishment, or adverse impacts on health seeking due to associated out-of-pocket expenditures under this scheme as compared to others? 3. Are there barriers to enrollment and/or utilization under this scheme that could undermine closing of coverage gaps?

Atención en Salud; Comprehensive Healthcare Plan) in Uruguay—embody this type of commitment to equity (see table 3). But equity can also require distributing goods unequally according to need and circumstance, prioritizing services and groups within the population to address existing disparities.⁹ These equity aims would support the development of a

HBP that targets segments of the population who are in some way disadvantaged—organizing coverage to meet the needs of those who have poorer health outcomes or less access to care.

Note that these two types of commitments are not mutually exclusive. A HBP could have a bundle of services to which all people are entitled, and also

TABLE 2. Commitments Related to Equity

Commitments	Explanations
Equity in Financial Protection and Cost-Sharing	Ensuring that the burdens of out-of-pocket payments and plan contributions are fairly distributed across the population, so that no one experiences an undue financial burden in accessing services
Equity in Access to Care	Ensuring that all beneficiaries experience both coverage and availability of health services
Equity in Quality of Healthcare	Ensuring that all beneficiaries have access to high-quality services and respectful treatment regardless of personal circumstances (geography, socioeconomic status, gender, ethnicity, age, etc.)
Equity in Outcomes	Ensuring comparable improvements in health status (morbidity, mortality, burden and severity of disease) among different groups within the population

TABLE 3. Equity as a Central Motivation for Adopting an HBP—Select Examples

Year of Adoption	Country HBP Name	Central Motivation
1993	Colombia POS	Establishment of an insurance framework with separation of duties and resource mobilization <i>to improve equity and ensure a minimum level of coverage for all</i>
2003	Mexico CAUSES and FPGC	<i>Mobilization of resources for greater equity</i> ; quality assurance tool designed to ensure that the necessary services were provided according to standard protocols; and empowerment of the insured population, making individuals aware of their rights
2004	Ghana NHIS	Ensure <i>access to basic healthcare services to all residents. Ensure equity in healthcare coverage, access by the poor to healthcare services, protection of the poor and vulnerable against financial risk.</i>
2005	Nigeria NHIS	To ensure that <i>every Nigerian has access to good healthcare services</i> ; protect families from financial hardship; ensure <i>equitable distribution of healthcare costs</i> among different income groups; limit the rise in the cost of healthcare services; maintain high-quality standards; ensure efficiency in healthcare services; improve and harness private sector participation in the provision of healthcare services; <i>ensure equitable distribution of health facilities</i>
2006	Uruguay PAIS	<i>Equity in access</i> to explicit and enforceable benefits
2009	Peru PEAS	<i>Equity</i> ; the desire to provide a <i>minimum level of coverage for all citizens</i> as part of a universal insurance plan
2015 (<i>White Paper outlining objectives of the scheme</i>)	South Africa NHI	<i>Ensure a fair and just health system for all and that those with the greatest health needs will be provided with timely access to health services</i> ; [reflecting] <i>values of justice, fairness, and social solidarity</i> . By 2030 there should have been a significant <i>shift in equity, efficiency, effectiveness, and quality of healthcare provision</i> ; <i>ensure that all South Africans have access to comprehensive quality healthcare services</i> ; <i>The risks posed by the social determinants of health and adverse ecological factors should also have been reduced significantly</i>

Source: Adapted from Giedion, Bitrán, and Tristao (2014).

have a specific set of additional services available only to those recognized under additional equity considerations. Equity commitments will also inform the sequencing of who receives services first and how the package is adapted over time on the path to UHC.

That it is possible to have very different equity objectives, and also more than one, highlights the importance of being explicit about the specific equity aims embodied in the HBP. Making a firm commitment to particular equity objectives will greatly inform which services, populations, and portions of costs will be covered. Given the central role that equity plays in motivating many HBPs, policymakers should carefully weigh how design and allocation decisions will impact various equity considerations. The following sections will provide concrete guidance and examples of how different kinds of HBP goals, including equity objectives, can inform HBP design decisions. Ethics provides a framework to set forth these package goals, justify why these matter morally and what principles or values motivate these goals, and use these to ensure HBP choices cohere with the intended objectives.

Another important function of ethical analysis in designing HBPs is to make sure that ethical considerations other than equity are not overlooked. These include considerations of dignity in health-care provision, respect for patient autonomy, and how care delivery can impact and interact with the broader experience of disadvantage. Even with the best of intentions, HBP decisionmaking can set back the interests of some people in ways that are morally problematic. For example, a careful ethical analysis can help identify when prioritizing one approach for care could inadvertently stigmatize groups or be delivered in a way that interferes with culturally valued practices.

At minimum, careful consideration of ethics will safeguard the HBP from unintentionally introducing egregious harms or contributing to the exacerbation of existing inequities. At best, ethical analysis will

support development of a defensible package that not only takes account of political realities but also of ethical norms. Building careful assessment of ethical considerations into the policymaking process for the HBP will support the development of a package that is both morally sound and justifiable to the public. Policymakers can demonstrate how ethical considerations informed their decisions and the processes they used to reach them, providing explicit moral rationales for selected courses of action and conferring legitimacy to the policy choices ultimately pursued.

Ethical Considerations for HBPs

Structuring a HBP requires attention to a number of ethical considerations that range in relevance from the organization of the health system¹⁰ to delivery of population health services, and all the way down to care provision for individual patients. This section lays out the array of morally relevant considerations that come into play in the design and ongoing adjustment of HBPs, with a description of what is entailed under each, including specific questions, concerns, and examples to illustrate these considerations. These considerations will then be mapped to relevant stages in the HBP policy cycle.

These considerations are not meant to produce specific answers to questions about which services should be included in or excluded from any given package. Rather, this list provides guidance on aspects that decisionmakers should take into account across the various stages of designing, implementing, and adjusting the HBP. These considerations can illuminate what is ethically at stake when making difficult trade-offs, and can help explain and justify why specific decisions were taken. They are not ranked in any particular order, and the relative importance of these considerations may vary by setting. These considerations are meant for policymakers to weigh on balance and apply to the specific context in which they are working. Table 4 presents the summarized

TABLE 4. Ethical Considerations for Health Benefits Packages

Ethical Consideration	Description
Equity	Doing what is just and fair, often with regard to how to fairly distribute goods, resources, opportunities, costs, and burdens across a population.
Fair Processes and Procedures	Committing to fair processes, as expressed through inclusion of relevant stakeholders in participatory processes, transparency about the decisions being made and the rationales for adopting them, accountability mechanisms to ensure the plan delivers on its promises, and opportunities for stakeholders to participate in and influence revisions to the plan in light of the changing needs of the population and emergence of new evidence and technologies.
Efficiency	Using limited resources efficiently to advance population health and to avoid inefficient allocations that could threaten the sustainability of the plan and lead to unrealized health benefits that often disproportionately affect the disadvantaged. Efficiency entails assessing the value-for-money of various services in the plan, prioritizing low-cost and high-value services, with limited to no investment in high-cost, low-value services.
Producing Benefits and Avoiding Harms to Individual Patients	Assessing and taking account of how decisions to include or exclude certain interventions will lead to corresponding health gains or losses for individuals in need of those services. This includes those who have highly individualized needs or respond differently than most to common treatments, such as those with rare conditions. Priority-setting decisions should be sensitive to the magnitude and nature of associated benefits and risks to individuals, minimizing harmful outcomes where possible and considering what provisions can be made to provide care to those with more specialized needs.
Respect and Dignity for Patients	Recognizing individuals as dignified human beings deserving of equal moral concern. This includes respecting the autonomous choices of individuals, eliminating forms of disrespectful treatment and discrimination based on ethnicity, race, religion, gender, or other group membership, reducing forms of stigma, and preserving human dignity. The HBP should be sensitive to these elements of respect for patients, in the composition of benefits covered, the process for determining the package, and the delivery of services in the implementation of the plan
Respect for Clinician Judgment	Recognizing the value of providers in promoting the best interests of individual patients, as well as the critical importance of provider buy-in for the successful implementation of the HBP, it is important to consider how different design aspects of the HBP may constrain clinicians' ability to exercise their best judgment in delivering care.
Using and Generating Evidence	Using the best available evidence to inform programmatic decisions for the HBP, including assessment of how different options fare with regard to the above ethics considerations. This also includes building upon the existing knowledge base, using the introduction or amendment of an HBP as an opportunity to generate evidence for improving the quality, efficiency, and responsiveness of care.

list of ethics considerations comprising the framework. It indicates the moral considerations that have featured prominently in recent global discussions on guiding principles for health priority-setting, then presents additional moral considerations that have received less attention in recent global discourse.

Equity

As noted above, equity is a central commitment for many HBPs.¹¹ Equity is the focus of a recent WHO report on Fair Choices on the Path to UHC (see box 1) and a number of new methods for economic evaluation aimed at incorporating health equity to better address fairness and distributive justice in priority-setting.¹²

Broadly speaking, equity encompasses a cluster of related moral principles and considerations surrounding what is just or fair, with particular attention in the health policy context to what constitutes a just distribution—how to fairly distribute goods,

resources, opportunities, costs, and burdens across the population. Since HBPs designate specific health services and goods that will be available to their beneficiaries, including what services will be available to different disease groups as well as the cost-sharing arrangements often used to help fund the scheme, a variety of equity considerations arise when developing them. Furthermore, since health is central to wellbeing and critically affects one's prospects to live a decent life, HBPs engage broader issues of social justice.¹³

HBPs can reinforce existing systematic disadvantage by institutionalizing inequitable distributions. For instance, consider a HBP that consistently covers health services for conditions that tend to afflict those comparatively better off while excluding diseases more common to the poor. Similarly, it is well known that cost-sharing arrangements used to finance HBPs can have regressive effects, which is why many countries limit copayments to select services, cap total annual out-of-pocket payments

BOX 1. WHO Making Fair Choices on the Path to Universal Health Coverage: A Summary

This report, developed by the WHO's Consultative Group on Equity and Universal Health Coverage, presents a three-part strategy to help countries make choices for fair progressive realization of UHC:

- 1.** Categorizing health services into high-, medium-, and low-priority classes. Determining the level of priority involves consideration of cost-effectiveness, with adjustments based on priority to the worse-off and financial risk protection.
- 2.** Expanding coverage for high-priority services for everyone. This includes eliminating out-of-pocket payments for those unable to pay while increasing mandatory, progressive prepayment with pooling of funds.
- 3.** Ensuring that disadvantaged groups, such as low-income households and rural populations, are not left behind.

The report also includes five "unacceptable trade-offs," such as covering low-priority services before all have access to high-priority services, expanding coverage to well-off groups before adequately covering worse-off groups, and including only those able to pay or using other regressive financing schemes.

for beneficiaries, or waive copayments completely for certain segments of the population. Additionally, failures to adequately address the supply-side constraints and deficiencies in health infrastructure can reinforce and deepen disparities in access to quality care as the HBP is rolled out.

Alternatively, the HBP can be an instrument to interrupt patterns of disadvantage associated with ill health and poverty by providing equitable opportunities to realize health gains and prevent financial hardship associated with poor health. For instance, an examination of Turkey's Health Transformation Program showed that in the 10 years following the introduction of the program, there were notable improvements in health coverage and utilization as well as substantial reductions in catastrophic health expenditures, particularly among the most disadvantaged.¹⁴ These successes were in part attributed to targeted efforts to better reach women and children as well as address the needs of the poor through the Green Card scheme.

One of the first equity considerations HBP policymakers must engage in is determining the HBP's specific equity aims. There are many different types of HBPs seeking to achieve different ends (see table 1). A clear orientation to the package's equity objectives will inform the corresponding equity considerations (tables 2 and 3). For instance, a HBP could be designed to provide access to a package of basic services for everyone, appropriate to each person's state and stage of life, as a central equity commitment.¹⁵ With this kind of universal package, a first task would then be to determine which health benefits to cover, and in particular how to ensure that the package meets as many and diverse health needs as resources permit. The breadth of what can be included will largely depend on the available financing, ranging from very limited bundles of services to more comprehensive packages. From an equity perspective, universal packages should begin with interventions that are most central to the health and wellbeing of

beneficiaries across all members of society—taking into account that the basic needs of beneficiaries will vary by age, gender, and other relevant characteristics such as pregnancy status. These benefits often include basic preventive, curative and emergency health services, early childhood health interventions, and maternal care.

Inevitably, there will be disagreements about what counts as a basic or essential service, and more patient groups will claim that their health needs are basic than resources can accommodate. In HBPs where the specific equity objective is to provide a core package of basic services to everyone, there is no ethical requirement to include a service that is so expensive that it cannot be provided to everyone who would need it, either absolutely or without gutting or severely compromising the rest of package. Where the trade-off is not so stark, adjudicating ethically between the claims of competing patient groups will require careful attention to other dimensions of equity as well as other moral considerations, noted below.

An equity commitment to a universal package of basic services generally entails that no intervention be included in the HBP that cannot be provided to everyone for whom the intervention is medically indicated. Because instances can arise in which an intervention that is or should be included in the basic package is in short supply—for example, when a new vaccine is adopted or there are disruptions in the production of an essential medicine—the HBP should stipulate the processes and criteria that will be employed to fairly allocate the scarce intervention.

Equity requires HBP architects to pay close attention to how the package affects those who are disadvantaged or vulnerable. Does the package perpetuate or exacerbate existing health inequities across the population? Are certain key benefits for the most disadvantaged excluded while costly interventions for more privileged members of society included? A package covering a wide range of expensive services

for conditions most commonly affecting affluent, urban communities while excluding services for conditions typically affecting the rural, poor, and marginalized would be highly inequitable.

Attention to how the HBP can contribute to health disparities is a continuous obligation—one that must be revisited as the package evolves and expands over time—given that population health needs are dynamic and that the addition of new technologies can shift the distribution in favor of those who are already experiencing better health and overall wellbeing. For instance, Colombia's Mandatory Health Plan (Plan Obligatorio de Salud; POS) made notable improvements in providing UHC, particularly among the poorest segments of the population. Yet, after two decades of implementation, increasing investment in new and expensive interventions threatened both the sustainability and the equitable distribution of program benefits, with less than 1 percent of payments for new drugs covering people in the poorest quintile of society while 70 percent of these payments covered drugs for the top two richest quintiles.¹⁶ Monitoring how benefits are distributed and making adjustments to address distortions are critical components for promoting an equitable HBP.

Beyond a commitment to equity in the designation of HBP services, it is vital to ensure that the entire population actually derives benefit from these services. If the covered services are not of decent quality or are not reasonably accessible, then the equity commitment is hollow and the objective unfulfilled. For a HBP to deliver on the promise of equitable access, policymakers have to examine the distribution of health facilities and health workers, the supply chain for drugs and goods, and other systems-level factors that could support or hinder equitable access to services.¹⁷ A commitment to quality standards across the health system also has implications for the equitable distribution of benefits associated with the HBP. Investments to bring facilities and providers up to certain quality standards may be necessary to

ensure that patients will actually utilize the covered services and benefit from equitable realization of associated health impacts.

Cost-sharing arrangements can also impede access to services, differentially impacting those with fewer resources as well as those with chronic conditions that require frequent financial outlays.¹⁸ The relationship between out-of-pocket expenditures and decreased utilization, particularly among the poor, has been widely documented in many developing countries.¹⁹ For this reason, many HBPs offer certain services free of charge, set ceilings for individual payments, and adjust required financial contributions based on beneficiaries' ability to pay, often exempting the poor from cost-sharing arrangements altogether. Other aspects of financing the HBP should also be examined for potential negative impacts on equity objectives, such as regressive forms of tax-financing or how provider payment mechanisms could create perverse incentives to treat only certain kinds of patients.²⁰ All of these options help level the playing field to ensure equitable distribution of the costs and benefits of the package.

Thus far, this chapter has focused on equity considerations for HBPs that seek to provide universal coverage for a set of services and goods. However, other HBPs may embody vertical equity goals as their primary objective, seeking to improve health access and outcomes for the most disadvantaged. Recognizing that some populations suffer disproportionately from the effects of ill health and are otherwise far worse off than others in society, these narrow HBPs seek to address specific sources of disadvantage that can be mitigated by access to health services. In some instances, recognizing the vicious cycle of poor health and poverty, HBPs can serve as safety nets for the poor, who are at greater risk for a number of health conditions, face greater barriers to access, and are most vulnerable to the economic shocks associated with ill health. Many countries have focused their path to UHC by providing benefits packages to

those below a certain poverty threshold—adopting what some have called a “bottom-up approach” to expanding coverage.

“No ethical principle can eliminate the fact that individual interests must sometimes yield to collective needs. Public accountability, however, ensures that such trade-offs will be made openly, with an explicit acknowledgment that individuals’ fundamental well-being and values are at stake and that reasons, grounded in ethics, will be provided to those affected by the decisions.”²¹

Other narrow HBPs target populations in other ways by focusing, for example, on children, who are not only less able to seek out and provide for their own health needs, but who are also at risk for lifelong disadvantage and poor health outcomes if their basic health needs are not addressed at critical stages in development. The Basic Health Package (Paquete Básico de Servicios de Salud; PBS) in Honduras is a prime example of a targeted HBP, serving the poorest among rural populations with an emphasis on maternal and child healthcare services. Benefit

packages can also focus on certain disease categories, providing packages of services based on the condition of interest. For instance, Mexico not only has a list of basic services covered under the Seguro Popular HBP, but also maintains a Catastrophic Health Expenditure Fund (Fondo para la Protección contra Gastos Catastróficos) that includes coverage for specific conditions such as childhood cancers and HIV. In the United States, individuals with a permanent disability or end-stage renal disease become eligible to enroll in Medicaid, the national- and state-funded program that provides health coverage to low-income households.

Because these HBPs aim to serve narrowly defined populations, the included benefits should be determined by a careful analysis of what these populations most need in order to experience as much health and relief of suffering as is possible. Especially in the case of children, it is important to focus not only on present and immediate clinical needs but also on services that can improve prospects for wellbeing later in life, such as health services that improve cognitive development and otherwise reduce health-related barriers to learning, such as vision tests and eyeglasses. Many of the aforementioned considerations

BOX 2. Considerations Regarding Efficiency

- Given the specific commitments of the HBP to promote health and improve equity, what is the most relevant explication of “value” for determining “value for money”?
- Do the economic evaluation methods employ appropriate measures of value (so explicated) when determining value for money, and if not, what additional approaches can be adopted to include broader understandings of value?
- Does the plan generally favor interventions that are high value for money?
- Are there high-value, cost-efficient interventions that are not included? If so, what is the justification for why these services are not covered?
- Are there any proposed interventions in the plan that are low value for money? Is there an adequate moral justification for including them?
- What is the quality of the data being used for economic analysis? How reliable are the estimates produced?
- Does the current bundle of services favor a financially sustainable HBP?

surrounding equity in accessibility, quality, included services, and attention to differential impacts across subgroups of the beneficiary population also pertain to more narrowly focused HBPs. With explicit equity commitments to address particular disparities, the HBP should ensure that its structure and benefits cohere with the aims of the program to address these disadvantages.

Fair processes and procedures

In addition to equity considerations, another facet of justice pertains to the extent to which the processes used to develop and adjust the HBP are fair. Given that no HBP will be able to cover all services that people might need or desire, and that reasonable people will disagree about which trade-offs ought to be made, a commitment to fair processes to make coverage decisions will improve the likelihood that the resulting package is ethically acceptable.²² Commitments to fair process are expressed by including relevant stakeholders in participatory processes, being transparent about the decisions being made and the rationales for adopting them, establishing accountability mechanisms to ensure that the package delivers on its promises, and providing opportunities for stakeholders to participate in and influence revisions to the package in light of the changing needs of the population and emergence of new evidence and technologies.²³

Health systems experts and ethicists alike recognize the moral importance of transparency and stakeholder engagement.²⁴ A commitment to transparency—clearly communicating the goals, processes, and rationales underpinning HBP decisionmaking—not only conveys respect for the public, but is instrumental in building and maintaining public trust in both the package and the health system. Policymakers will not be able to satisfy everyone with the package they develop, but they can appeal to their constituents by providing reasonable

justifications, through open communication and dialogue, for why certain decisions were made. Furthermore, transparency lays the groundwork for accountability mechanisms.

Beyond open communication and transparency, it is critical to engage the public and relevant stakeholders in the design and adjustment of HBPs. There are many approaches for engaging stakeholders in participatory processes, including research activities to solicit public views, public forums, citizen panels, ongoing deliberative meetings to work toward consensus among representative actors, and direct involvement in priority-setting institutions.²⁵ The information gathered through engagement activities is an important piece of evidence that should be used to inform the priority-setting process (among other forms of evidence discussed in greater detail below). The appropriate methods for public engagement will vary by context. Regardless of the approach, key considerations for public engagement include:

- Ensuring that participants have adequate information to meaningfully contribute
- Having authentic and balanced representation of key stakeholder groups, which includes safeguarding against disproportionate influence of powerful interest groups and ensuring the representation of the interests of marginalized and disenfranchised populations
- Making an effort to elicit social values, not merely individual interests
- Conducting engagement activities at relevant stages in the processes, allowing adequate time for input to inform decisionmaking.

If done properly, participation can lead to development of a HBP that reflects public values for priority-setting, is responsive to the needs of the beneficiaries, and is perceived as fair and legitimate.

BOX 3. A Brief Checklist for Setting Equity and Ethics Goals for the HBP**1. Which of the following equity goals should be adopted for your plan?**

- Ensuring that all people have access to some basic package of healthcare services
- Narrowing disparities in access, health outcomes, economic burdens of health spending, and other dimensions of wellbeing between different population groups
- Providing coverage for disadvantaged groups

2. Which of the follow efficiency goals should be adopted for your plan?

- Including affordable high-value services (good value for money interventions)
- Excluding low-value services
- Efficiently allocating nonmonetary resources, such as human resources for health
- Efficient purchasing of medical goods and commodities

3. Which goals should be included for producing individual benefits and avoiding/minimizing harms?

- Including provisions for special circumstances (rare diseases, super-responders)
- Including palliative services where curative treatments are unavailable
- Reducing medical errors, adverse events, and low-quality services

4. Which goals should be included for respecting patients?

- Respecting patient choice
- Preserving respect and dignity through coverage decisions and care provision
- Responsiveness to religious and cultural beliefs
- Responsiveness to patient values and preferences

5. Which goals should be included for respecting clinician judgment?

- Allowing clinician choice in care of patients
- Preserving models of shared decisionmaking between clinicians and patients

6. Which goals should be included related to evidence-informed decisionmaking and generating new evidence?

- Basing coverage and systems design decisions on evidence wherever possible
- Systematic and continuous collection of new evidence in healthcare delivery

Fair Process Considerations for Setting and Communicating Plan Goals

- How do you plan to set the broad goals and specific objectives for the HBP?
- Who will be involved and how?
- How transparent are these processes?
- Have you thought about ways you could engage the public and key stakeholders in setting goals for the HBP?
- Are the selected HBP goals clearly communicated to the public?

When developing approaches for disseminating information and soliciting input, policymakers should aim to be inclusive, presenting information and gathering feedback through formats and channels that are accessible to the relevant stakeholder groups. Additionally, when developing participatory approaches, they should explore mechanisms that limit the disproportionate influence of powerful interest groups on the process. (Additional considerations related to participation, transparency, fair processes, and governance are covered in-depth in chapter 1.)

Advancing population health by using resources efficiently

Promoting population health is always a major ethics goal for HBPs, and it is often the *primary* health goal for the package. Societies have a general moral obligation to promote popular welfare and wellbeing, with health as a core constitutive dimension of wellbeing and one that is instrumental to securing other aspects of wellbeing. Obligations to advance population health include moral considerations related to efficiency. When structuring the HBP, policymakers have a general moral obligation to use limited resources efficiently. Inefficient allocations carry morally salient opportunity costs, forgoing health improvements that could have been realized with alternative investments.²⁶ Furthermore, without an efficient use of resources, HBPs are highly unlikely to meet their objectives to provide universal and equitable coverage of services.

Discussions of ethics and health priority-setting tend to focus on how commitments to equity and efficiency conflict. Although there may be instances in which conflicts between equity and efficiency arise, any plausible account of equity in health must include a commitment to efficiency as well. Inefficient allocations are often significant impediments to progress toward equitable HBPs and UHC. The

opportunity costs of inefficient allocations take a significant toll on national goals to improve population health. Moreover, these costs often do not fall fairly on all groups in the population. Inefficient allocations can divert resources away from services that could improve the health and health security of politically less powerful or less vocal groups. It is also true that many interventions addressing the needs of the most disadvantaged are cost-effective—and these should be given high priority for inclusion in the benefits package.

An interesting example of how efficient spending can promote more equitable access to care emerged in response to the 2013 WHO HIV Treatment Guidelines, which recommended the use of viral load monitoring (VLM) of patients on antiretroviral therapy (ART) in lieu of the previous standard of CD4 testing.²⁷ A group at the Centre for Health Economics at the University of York assessed the real-world implications of a low-income country adopting this recommendation, noting that there was weak evidence that VLM would improve patient outcomes, and that testing viral loads was significantly more expensive than CD4 testing (\$45 as compared to \$9), even if both met WHO cost-effectiveness thresholds.²⁸ They demonstrated that the same funds that could be allocated for the uptake of VLM could instead be used to expand HIV testing and ART coverage with CD4 testing, producing three times the population health benefit (in quality-adjusted life-years [QALYs]) and improve progress toward universal ART access by 15 percent.

Efficient spending will also ensure a more sustainable HBP. Failure to account for the relative costs and benefits of covered interventions can set a package on a collision course to fiscal collapse. It can also compromise public support and political will for tax-based schemes that rely on these contributions to finance the package. Ghana is currently undertaking massive reforms to its National Health Insurance Scheme, in large part to address the growing budget deficit that threatens the financial viability of

BOX 4. Considerations When Setting Ethics and Equity Goals

Which of the following *equity* goals are most relevant to the HBP?

–Ensuring that all people have access to some basic package of healthcare services

If so, how are you structuring the package to meet this goal? What are your objectives?

- Provision of a universal package covering the entire population (ranging from basic to comprehensive packages)
- Provision of a package for those not currently covered under existing schemes—with attention to how the HBP compares to the coverage received under other schemes

Under this package, who is included under *all people*?

- Citizens, legal residents, anyone in the country in need of healthcare

–Ensuring that all people have equal access to the same set of healthcare services

If so, how are you structuring the package to meet this goal?

- Introduce a package covering the entire population equally for a range of approved services

–Narrowing disparities between population groups, including inequities in health status, the burdens of health spending, and clustered forms of disadvantage related to health that affect multiple dimensions of wellbeing

If so, which of the following inequities does your HBP plan to target? What specific targets will you have for each objective?

- Disparities in health *outcomes*
- Disparities in access to health services
- Disparities in *life opportunities* resulting from poor health
- Disparities in the *economic burden* of illness and medical care (effects on poor households, those with chronic conditions)
- Populations whose needs have been overlooked in past programs and allocations

How can your HBP best target these inequities and narrow the identified disparities?

- Target the HBP to select populations with inequitable outcomes and/or access
- Cover services for conditions that disproportionately affect target populations and/or further disadvantage those who suffer these conditions (can include effects related to both health and financial hardship)
- Design cost-sharing arrangements to shield beneficiaries from financial hardship associated with out-of-pocket spending—consider the amount and frequency of out-of-pocket payments, possibilities to set contributions based on ability to pay, and exempting payment for certain populations and/or services

What specific targets will the package have to measure progress on selected equity objectives?

Should you include any of the following goals related to using resources *efficiently* to advance population health?

–Inclusion of affordable, high-value services

What services and interventions have significant impact on health and wellbeing with relatively small budget impact? What objectives will you adopt for this goal?

- Invest in benefits that have high-value impacts that broadly improve population health (preventive services, vaccine coverage, generic antibiotics for common illnesses, containing the spread of epidemics, services with large positive externalities)

- Within disease categories, cover interventions that represent the best value for money (lower-cost options of medications that have similar efficacy)
- Include low-cost interventions with high impacts among priority groups (oral rehydration salts and treatment of diarrheal disease in children under-five)

–Exclusion of most, if not all, expensive, low-value services

What services and interventions have limited impact on health and wellbeing with high budget impact? What specific objectives will you adopt to support this goal?

- Exclude costly drugs with insufficient evidence of health benefits or evidence of only modest health gains (expensive cancer drugs that have limited evidence of improved survival, such as Avastin/bevacizumab)^a
- Eliminate high-cost diagnostics or screening services for which lower-cost, effective alternatives exist

If you want to include a low-value service, what kinds of moral considerations might justify their inclusion in the package? What moral criteria should be used to evaluate whether a low-value service should be included?

- Rule of rescue^b and role-specific obligations of physicians to provide emergency/trauma services for those with urgent need, even where probability of survival may be low
- “Last-hope” drugs for terminal illnesses where all other treatments have been exhausted
- High-cost treatments for rare, incurable diseases—*orphan drugs*, particularly for patient populations whose needs historically have been overlooked

–Efficient allocation of human resources for health

What objectives can help the package best utilize the mix of providers to deliver quality care that best meets the needs of those covered?

- Task-shifting and sharing that uses mid-level providers to deliver care for which a physician is not required, as appropriate to services and provider training
- Appropriate referral mechanisms for specialist visits
- Inputs to enhance workforce productivity, improve provider-patient ratios, and improve skill mix to meet patient needs^c

–Efficient purchasing of medical goods and commodities

What types of strategies might be employed to drive down costs and increase purchasing power for goods covered by the package?

- Reference pricing, price regulations, profit ceilings, pooled procurement, etc.

Should you include any of the following goals for producing individual benefits and avoiding/minimizing harms?

–Include coverage of services that meet the special needs of certain types of patients to promote their individual benefit or reduce their exposure to harm

Are there services that should be provided for those who are different from the general population?

- Access to medications for those who are super-responders to particular drugs
- Provide alternative therapies to those likely to be under-responders to the standard treatment

–Provide coverage of populations with certain rare diseases and conditions

When considering coverage, are there certain populations who suffer from rare conditions and require certain kinds of access to care and/or financial protection from expenses related to their illness? What objectives might you include to meet the needs of these individuals?

BOX 4. Considerations When Setting Ethics and Equity Goals (*continued*)

- Include special provisions in the package for the diagnosis and management of these conditions
- Provide additional services to especially vulnerable populations (e.g., children) who suffer from rare diseases
- Provide coverage for rare diseases that tend to affect disadvantaged populations (e.g., sickle cell disease)

–Provide coverage of services that minimize suffering or reduce adverse impacts on wellbeing

Are there services that deserve special priority because they reduce or minimize harms?

- Include drugs that may be more expensive but have fewer side effects (e.g., less likely to negatively impact cognition or sexual function)
- Include palliative care when curative treatments are unavailable

–Include services that help reduce medical errors and adverse events

Should certain services or products be covered, or certain systems interventions adopted, because they will reduce the likelihood of harms associated with care or specific procedures?

- Favor including medical products with fewer associated adverse events (e.g., catheters that reduce instances of bloodstream-related infection)
- Invest in technologies and services that reduce errors (e.g., diagnostic tools, health information systems)

Should your package include any of the following goals related to *respecting patients*?**–Respect for patient choice**

In what contexts are patient choices most meaningful to promote and preserve?

- Access to care choices relevant to patients' personal values
- Choice in care providers
- Choice among medications or procedures that differentially impact important aspects of one's life (e.g., medications comparable in effectiveness, but with differing side effects impairing other aspects of functioning, like cognitive abilities with pain management; two comparable procedures for a condition with different associated recovery times)

–Respectful provision of care/services and preservation of dignity

What benefits ought to be considered for inclusion in order to preserve patient respect and dignity? How might services be provided in the most respectful ways?

- Hygiene products (e.g., adult diapers, menstrual care products)
- Long-term care for the elderly and end-of-life care
- Home testing kits for sensitive conditions
- Delivery of care in appropriate languages, formats, and settings

–Coverage and delivery of services responsive to religious and/or cultural beliefs

Are the services offered through the HBP culturally sensitive to the beliefs, values, and norms of various ethnic, religious, and cultural minorities? How might religious and cultural beliefs influence the kinds of services and benefits that would be acceptable to patients and the ways in which they are provided?

- Handling of biospecimens in accordance with belief systems
- Inclusion of traditional healers or incorporation of traditional practices into the care delivery
- Attention to dietary restrictions in hospitals and inpatient facilities
- Gender-sensitive practices in care settings

–Tailoring package benefits to be responsive to patient preferences and values

Are there specific services that better match the expressed interests of the patients?

- Consideration of patient-centered outcomes in coverage decisions
- Access to assistive technologies (e.g., wheelchairs, prosthetics), related services, and investments in the physical environment for those with disabilities
- Medications that have fewer side effects relevant to other valued dimensions of wellbeing (psychological affect, sexual function, cognition, etc.)

Should your package goals include any of the following objectives to respect clinician judgment?**–Allow for clinician choice in caring for patients**

How might package restrictions on services negatively care providers' ability to exercise their discretion in delivering appropriate care? How stringent are these limitations? Are the restrictions reasonable and justifiable?

- Which aspects of clinician judgment are most important to preserve?
- Aspects of care that require highly individualized approaches based on patient characteristics
- Care decisions for which there is limited systematic evidence and for which the clinician is best situated to make decisions in the best interest of the patient

In what areas of practice are constraints on clinician judgment justified?

- Strong evidence and clinician consensus on best practice (existing clinical guidelines)
- Aspects of care that are unlikely to have any meaningful difference for patients' wellbeing

–Allow for models of shared decisionmaking among providers and patients

Is the package unnecessarily restrictive in ways that interfere with patients' ability to actively engage in care decisions with their physicians? Are there specific ways in which the package might negatively impact the provider-patient relationship by limited care decisions?

- Preserving greater choice for patients and physicians with regard to services that engage important self-determination interests

Are there certain processes that could preserve patient choice and clinician judgment, as circumstances warrant?

- Special appeals for coverage of certain services, procedures, or medications

Should your package goals include any objectives related to evidence-informed decisionmaking and generating new evidence?**–Base coverage and systems design decisions on evidence wherever possible**

Are there promising new therapies that do not yet have a strong evidence base that should be included in the package to learn more about how well they work in practice?

- Pragmatic clinical trials

–Commit to the systematic and continuous collection of evidence in healthcare delivery

Are there opportunities to use the package to learn more about the relative advantages and disadvantages of different services and bundles of services?

- Investment in health information systems and electronic medical records to support population studies
- Ensure that evidence is generated to provide pertinent information for each of the core ethics considerations

- a. Gilbert and others (2014).
- b. Rulli and Millum (2016).
- c. Chisholm and Evans (2010).

program—a result of inefficient spending that failed to provide corresponding value for money.²⁹ In recent years, the massive deficit and delayed payments to providers led many provider networks to withdraw services under the package and revert to a cash-and-carry system, in which patients must pay at the point of service. This provider response placed enormous financial pressure on the poor and severe limitations on access to healthcare, and eroded public confidence in the national package.³⁰

The Cancer Drugs Fund (CDF) in the United Kingdom provides another cautionary tale of how inattention to efficiency and sustainability can undermine public health objectives. The program was introduced in 2010 to increase access to cancer drugs that had not been adopted for routine use in the National Health Service (NHS)—and in doing so, it bypassed standard appraisals of cost-effectiveness. Over the next five years, the CDF budget ballooned from £200 million to over £340 million in 2015–16, each year exceeding its allotted budget, often to cover cancer drugs that offered limited clinical benefit.³¹ Economists have criticized the excessive funds poured into the CDF as an irresponsible waste of NHS resources that could have much better served the broader patient population, with others calling it a political maneuver that was “unethical,” unfairly privileging patients with cancer over those afflicted with other life-threatening illness so that they could gain access to treatments that would not meet standard National Institute for Health and Care Excellence (NICE) criteria for NHS coverage.³² Furthermore, the CDF compromised the NHS’s ability to negotiate prices with pharmaceutical companies. In light of these follies and the unsustainable price tag, the CDF was restructured to become a managed access fund that NHS England would run in collaboration with NICE.³³

From an ethics perspective, economic methods for assessing value for money provide information that can help determine the mix of interventions

and services that a HBP can afford to support, what impacts might be achieved through those investments, and highlight trade-offs associated with covering less cost-effective options. There are ongoing debates about the appropriate methodological approaches to economic analysis, including questions regarding appropriate thresholds, the use of various weights, and limitations of QALYs and DALYs (disability-adjusted life-years) as summary measures.³⁴ A review of the ethical implications of the various methodological approaches to economic evaluation is beyond the focus of this chapter, but there is growing interest in approaches that endorse an expanded view of value for money. These include accounting for a broader set of morally important gains associated with different health interventions. For instance, methods like extended cost-effectiveness analysis incorporate the benefits of financial protection alongside health gains, and various forms of multicriteria decision analysis build in quantitative or qualitative assessments of broader benefits associated with an intervention.³⁵ Other novel approaches are under development to better link economic evaluation with broader assessment of how a health intervention can affect the experience of disadvantage across multiple dimensions of well-being, such as impacts on the experience of stigma, shame, and strain on interpersonal relationships.³⁶

Whether approached quantitatively or qualitatively, a broader conception of what is valuable (going beyond QALY-per-dollar calculations) can shift the overall determination of whether an intervention is good value for money. For instance, providing feminine hygiene products or end-of-life care could produce significant value for money under an expanded definition. Lack of appropriate menstrual hygiene management methods and products can result in shame, embarrassment, and absence from school and increased drop-out rates. Thus, covering feminine hygiene products for girls can reduce shame while addressing a major barrier to continued

schooling for adolescent girls, which in turn can contribute to broad-ranging benefits in long-term health and wellbeing.³⁷ Similarly, accounting for QALYs alone would be unlikely to suggest end-of-life care as a “good buy.” However, other gains such as preserving dignity and alleviating suffering at the end of life are worth considering, and might yield a different determination. This broader conception of value illustrates that these interventions often can be good value for money, even if they do not offer as many QALYs per dollar as some other services.

Against the backdrop of this broadened understanding of value, and thus of broader types of returns on investment, it is evident that low-cost, high-value services should be prioritized and high-cost, low value services should receive limited investment, with some challenging decisions to be made at the margins. Other ethical considerations, as detailed in this chapter, can help inform which high-cost, high-value services should be included at various HBP design and adjustment stages. Most if not all services that are cost-effective in the traditional sense will still be good value for money under the broadened definitions. Other services, such as those that are high cost but produce little value (QALYs or otherwise), will never seem like “good buys,” and investment in them carries significant opportunity costs where much greater value could have been generated.

Admittedly, traditional, extended, and augmented economic analyses have limitations, such as limited availability of local data and technical capacity to do the analyses in a given setting. These limitations and the open questions about which methods to adopt notwithstanding, economic evaluations remain a useful tool, among others, to help decision-makers make ethically appropriate investments in services to improve population health. These methods are essential to avoiding the ethically unacceptable outcome of diverting resources to interventions that produce few benefits related to population health or other ethical goals at the expense of services that

provide significant value. They also help remind policymakers that a specific moral justification is always necessary for services that fall above cost-effectiveness thresholds. Although investment decisions for the HBP should generally reflect a commitment to allocate resources efficiently, other moral considerations may provide compelling reasons to include interventions that are less cost-efficient.³⁸ Box 2 presents a checklist of efficiency-related points to be considered during the HBP design process.

Producing benefits and avoiding harms to individual patients

While efficiency considerations focus on producing aggregate net benefits for the population, HBP designers also have specific moral obligations to consider how the package can produce benefits and avoid harms to individual patients. Choices to include or exclude certain interventions will lead to corresponding health gains or losses for those who need the services in question. Although the HBP is generally concerned with providing services that meet the broad needs of the beneficiary population, some subset of people have highly individualized needs or respond differently than most to common treatments. Attention to population-level health may mask the specific needs of some patients, such as those suffering from rare conditions or who have unusual responses to common conditions, who may be overlooked when determining what belongs in the HBP. Although rare diseases affect far fewer people than other conditions, the health consequences for those afflicted are no less real. Even though it is not possible for a HBP to secure all potential benefits or prevent all harms, the priority-setting process should be sensitive to the magnitude and nature of associated benefits and risks to individuals, minimizing harmful outcomes where possible.

Package designers ought to consider what provisions can be made to address the concerns of those

with more specialized needs. For instance, for a given therapy, there may be a small subset of patients who are exceptional responders to a drug that, while not particularly effective among the general population, produces significant health gains for these patients given their genetic makeup and specific biology.³⁹ Where resources permit, policymakers should consider including services to cover medications for super-responders, provide alternative medications for those who are unlikely to respond well to standard courses of treatment, and cover therapies for rare diseases. Some countries have developed supplementary plans to address rare conditions. For instance, in 2007 Mexico introduced the 21st Century Health Insurance program, which provides access to 131 additional interventions for rare diseases affecting children under five. Since 2012 Peru has offered coverage for orphan diseases and end-stage renal disease under its Comprehensive Health Insurance scheme (Seguro Integral de Salud; SIS). When it is not possible to directly provide these kinds of benefits, package designers should consider if there are alternative beneficial provisions. For example, even when the HBP is unable to cover dialysis for patients with chronic kidney disease, offering palliative care would minimize the suffering of these patients.

Since HBPs will not be able to cover all services that people would reasonably want or benefit from, they should consider which ones will produce the most meaningful and impactful benefits for those affected. This does not categorically exclude therapies for conditions for which there is little opportunity to produce significant health improvement (as measured by life-years gained), since there are other meaningful benefits such as ease of suffering and management of symptoms. In fact, for many health interventions, some of the most important benefits affect other dimensions of wellbeing. For instance, the value of surgery to correct obstetric fistula extends far beyond health improvement.

Fistula repair is the first step to restoring the dignity of affected women and enabling them to re-engage with their communities to lead a social and productive life. As noted in the discussion of efficiency above, HBP designers should assess the ways in which candidate health interventions can provide benefits across the broader dimensions of wellbeing, especially when (as is the case with fistula repair or myopia correction) health interventions are critical if not indispensable to improving wellbeing in areas other than health.

Policymakers must also carefully assess the potential harms associated with their coverage decisions. This includes attention to the harms of not covering interventions for particular conditions. Because the harmful consequences of not covering interventions for severe conditions are generally more serious for the patients affected, many endorse including disease severity as a relevant criterion for priority-setting, often in combination with treatment effectiveness.⁴⁰ Including such a criterion does not necessarily mean that interventions that may benefit the seriously ill must always be prioritized over other interventions, but it does mean that there must be good ethical justification for failing to do so.

Another set of harms to consider are those directly associated with the services covered. Different interventions carry differential risks, and decisions to cover a particular therapy may produce harms for some. Even if two drugs are comparably effective, one may have greater toxicity, side effects, and adverse events. All else being equal, a HBP should prioritize interventions with lower risk profiles. However, given the complexity and variability of individual biological factors, there may still be some individuals who will have predictable adverse reactions to medicines that most patients tolerate well. Where possible, the package should make allowances for those who are contraindicated for the standard therapy. Additionally, adjustments to

BOX 5. Considerations for Collecting, Collating, and Assessing Evidence to Support Coverage Decisions

What evidence exists to inform how well various coverage decisions will satisfy the ethics and equity objectives selected for the HBP? What evidence needs to be generated to determine how well the intervention coheres with the adopted goals?

This includes epidemiological data on health conditions and the characteristics of populations affected, effectiveness and comparative effectiveness data on potential interventions, cost data and economic analyses, and information on societal values and stakeholder interests.

Does the evidence provide data that are disaggregated to allow assessment of how inclusion of services will affect different subgroups of the beneficiary population?

Based on the available data, whose needs seem to be met by the intervention, and whose interests are not well met? In addition to population-level benefits, what might be the associated individual harms or benefits?

- When considering a drug or class of medicines for inclusion, is the drug more effective in a particular subgroup of the population (e.g., gender or racial differences in the effectiveness of the drug)? Does serving the needs of this subgroup cohere with the package's equity objectives or does it exacerbate disparities?
- Is there any evidence to support that services under consideration will be more beneficial to priority groups or more responsive to their needs and values?
- Is there evidence that some people might be "super-responders" or "exceptional responders," realizing significant health gains from a therapy that is not effective for most?
- Is there any indication that some segments of the population will not respond to or clinically benefit from the covered treatment options?
- Is there evidence that including this drug or intervention, in lieu of an alternative, will produce harms for certain types of individuals?
What is the evidence that the intervention will be good value for money?

Have you or others done relevant economic analysis? Does it suggest the intervention is cost-effective?

- How reliable are the estimates produced?
- What values are embedded in the selected methodology used in the economic evaluation?

Does the intervention produce other important gains and contributions to wellbeing not captured in the economic analysis?

- What additional improvements in wellbeing can be generated by including the intervention, and are they sufficient justification for including the service (e.g., end-of-life care to relieve suffering and preserve dignity in death)?

the HBP, such as changes in the list of covered medications, can produce harms if those who are well managed on a given treatment regimen are forced to switch therapies. Having policies that allow people to stay on their existing successful regimens could mitigate this potential harm. As the field of personalized medicine advances, evidence can be applied to coverage decisions to help achieve the best balance of benefit to harm for individual patients.

Still other medical harms to patients can arise from poor quality of services, medical errors, and broader problems with the health system infrastructure, many of which are preventable and thus ethically unacceptable. HBPs need to include processes and practices to monitor for and reduce such harms on a regular basis. Supply-side aspects of the health system should be assessed before and while the package is implemented to ensure that the benefits covered do not introduce unjustified harms to those seeking services. Moreover, the assessment of harms is not limited to medical outcomes. When developing and adjusting HBPs, policymakers should consider the ways in which the design could negatively impact the non-health interests of package beneficiaries: for example, are the services delivered in a way that could produce social stigma or expose patients to threats of physical violence?

The HBP decisionmaking process should account for the benefits and harms associated with coverage decisions with respect to how individual patients' interests will be affected. Insight about benefits and harms can be elicited from clinicians and patients through various engagement activities, allowing them to provide perspective from their lived experience to inform which benefits and harms matter most to those affected. Even though not all harms to individuals can be avoided, policymakers have an obligation to consider what harms various HBP design decisions might introduce, who is most likely to be negatively affected, how serious the associated harms are, and in what ways they can minimize

negative effects associated with the overall HBP and its delivery.

Respect and dignity for patients

Respect is central to wellbeing and a core ethical consideration in any health policy. Respect for persons entails recognizing individuals as dignified human beings deserving of equal moral concern. This includes respecting the autonomous choices of individuals, eliminating forms of disrespectful treatment and discrimination based on group membership (including ethnicity/race, religion, and gender), reducing forms of stigma, and preserving human dignity. The HBP should be sensitive to these elements of respect for patients in the composition of benefits covered, the process for determining the package, and the resulting delivery of services.

Respect is particularly important in public health policies that aim to serve disadvantaged groups. Especially when a primary function of the HBP is to address health inequities and expand coverage to disadvantaged populations, the package must be structured so as to respectfully meet the needs of these groups. This requires careful attention to cultural norms, practices, and values, particularly potential barriers to access. If the package limits covered services to interventions that are not culturally acceptable to disenfranchised populations, it is not adequately meeting their needs. These considerations extend beyond the planning phases into the administration of the package.

Any HBP seeking to successfully promote equitable access to care must address forms of disrespect that perpetuate systematic disadvantage and insult the dignity of marginalized populations. For example, despite important public health gains in Central America, deep inequities in health outcomes persist for many indigenous communities, including high rates of maternal and child mortality.⁴¹ The Salud Mesoamérica 2015 Initiative, introduced in 2010

BOX 6. Considerations for Deliberation and Decisionmaking**Are the processes employed to deliberate and make decisions for the package fair and transparent?**

- Are the processes and criteria used to make decisions for the package clearly communicated to the public in accessible and understandable ways?
- Who is involved in the decisionmaking processes and in what ways?
- Are the interests of relevant parties, including minorities and vulnerable populations, represented in the processes and procedures?
- What approaches are being used to include relevant interests and perspectives? Are they captured in a fair and balanced way?
- Are precautions in place to prevent deliberative and participatory processes from being captured by powerful interest groups?

Based on the ethics and equity objectives adopted for the package, have any services or populations been overlooked in the deliberative engagement processes? Who and what should be guaranteed coverage under the package, regardless of what emerges from the engagement processes?

- Interventions that dramatically improve wellbeing for the most disadvantaged, vulnerable, and marginalized populations
- Benefits that carry special significance with regard to respect and dignity
- High-value affordable services, especially for priority issues and populations

Are the results of the decisionmaking processes consistent with the ethics and equity objectives set forth for the package?

- Do the included services address package objectives that have been given the highest priority?
- Do the services under consideration serve populations that are already advantaged, favoring nonpriority populations? Does coverage of these services exacerbate inequities across the population?
- Are any low-value, high-cost services included in the current list of services? Why are these services included? What, if any, is the legitimate basis for their inclusion?
- Are any high-value, low-cost services not included in the current list of services? Why are these services excluded? What, if any, is the legitimate basis for their exclusion?
- Do the included services provide options that are culturally sensitive and/or allow patients meaningful choice in the care they receive?
- Do limitations on included services negatively impact clinician judgment in meaningful ways?

to address disparities in the region between the general population and poorest and most marginalized, encouraged adapting health services to cater to indigenous populations.⁴² In a baseline assessment for this initiative, poor rates of patient satisfaction were attributed to the lack of available interpreters or culturally sensitive materials and practices in health facilities.⁴³

Related considerations include reducing potential sources of stigma, and ensuring privacy in the delivery of care and confidentiality in the management of personal health information. Attention to stigma entails two sets of considerations: 1) including interventions that address existing sources of stigma (such as covering adult diapers for incontinence) and 2) minimizing the potential that covered, but improperly implemented, interventions can introduce new forms of social stigma (such as voluntary testing for HIV). Fear of social stigma and inadequate privacy protections can be significant barriers to accessing services. Some interventions can offer additional protections against these potential harms. For instance, innovations in home-based testing for conditions like HIV may offer alternative service delivery approaches that provide greater privacy protections to patients.⁴⁴ These threats to the social bases of respect not only should inform the HBP's design and delivery strategy, but also should be captured through relevant monitoring and evaluation indicators.

Lastly, HBP coverage decisions will affect the degree to which patients have meaningful choice about the care they receive. In many settings, a high premium is placed on respecting patient autonomy by having them take an active role in decisionmaking for their care. In other settings, less weight is placed on the value of individual autonomy.⁴⁵ Regardless, some care decisions may likely engage values of central importance to patients.⁴⁶ For example, many patients will want a say when treatment decisions entail a trade-off between likely life expectancy and

significant disability or when a severe medical condition can be treated either conservatively or surgically. The HBP does not have to allow for patients to have unlimited choices in care options, but policymakers should recognize that certain care decisions will affect important self-determination interests, and the package should make allowances so that it does not undermine patients' ability to have a say over choices that matter greatly to them.⁴⁷

Respect for clinician judgment

The importance of respecting clinician judgment—that is, allowing providers to determine the course of care that best suits their individual patients' needs—is widely recognized.⁴⁸ Although the policymakers developing HBPs have obligations to both individuals and the population as a whole, clinicians' obligations center around promoting the wellbeing of their individual patients. Given their training, professional experience, and personalized knowledge of patients' characteristics, preferences, and beliefs, these providers are well positioned to make care decisions that will best serve their patient's interests in terms of both clinical outcomes and respect for patient autonomy. Recognizing the value of providers in promoting the best interests of individual patients, as well as their critical role in the broader health system, respect for clinician judgment is key when considering how the HBP will affect clinicians' continued ability to exercise their best judgment in delivering care.

That said, not all limitations placed on clinician judgment are equally restricting or need to be avoided. For instance, standard screening algorithms for diseases like tuberculosis or HIV pose little to no threat to physician judgment or patient wellbeing, but at the same time these screenings require more expensive diagnostics for confirmatory tests. Similarly, the use of essential medicines lists can limit choice among brands for a particular class of drug, but this minor

constraint on physician prescribing practice is often justified by the gains achieved through more efficient drug procurement and wider availability.

Deferring to clinician judgment in the name of promoting patient wellbeing assumes that providers are making decisions based on the best available medical evidence. Unfortunately, this may not always be the case, given the range of biases that can influence physician practice and the well-documented lag in translating new research findings into practice.⁴⁹ Therefore, if the HBP uses the most rigorous and up-to-date evidence to inform coverage decisions, and allows for exceptions for outlier patients, then limitations on the exercise of clinician judgment in order to promote better clinical outcomes for patients is generally justified.

However, the ethical importance of respecting clinician judgment in the formulation of the HBP extends beyond the instrumental value of clinical judgment in promoting patient wellbeing and autonomy. A HBP that overly restricts professional medical practice can have perverse effects that undermine the integrity of the health system and the goals of the package. If physicians do not feel adequately respected or free to practice on their own terms through the public system, they may challenge the package and its legitimacy, or seek private sector opportunities that offer greater liberty in how they care for their patients. For instance, POS in Colombia has faced increasing scrutiny and resistance from the medical community on the grounds that the explicit benefits package undermines their professional autonomy. Continued resistance from medical practitioners has contributed to the move away from explicit priority-setting toward more implicit rationing approaches. This example highlights the importance of fostering buy-in from provider stakeholders so as not to alienate the health workforce, which could directly undercut the aims of the HBP.

Policymakers must carefully weigh the trade-offs associated with respecting clinician judgment and

other moral obligations, and should engage clinical practitioners in decisionmaking processes. Medical professionals who participate actively in the HBP can identify which areas of practice matter most to clinicians and their patients, allowing greater room for clinician judgment where it is most valued. Involving clinicians also recognizes the vital role they play in realizing the aims of the HBP, and in the system more broadly, and respects their accumulated knowledge and experience in caring for patients.

Evidence-informed action and contribution to new health systems knowledge

There is an increasing push for evidence to drive policymaking and priority-setting for health. The emergence of new forms of health policy and health services research—including comparative-effectiveness and standard practice research, as well as more flexible research designs (such as pragmatic clinical trials) and new funding streams—are continuing to fuel the push to continuously assess the effectiveness of medicines and technologies in everyday practice.⁵⁰ Evidence-informed decisionmaking for the HBP enables the package to satisfy a number of ethical obligations. Epidemiological evidence provides information on how disease burden is distributed across the population, informing how the package can target those disproportionately affected by preventable and treatable health conditions. Relevant data from clinical trials, practice guidelines, and comparative effectiveness research provides insight into the expected risks and benefits of various interventions. Economic analyses will support the development of more efficient HBPs. Data from engagement activities with relevant stakeholders offers insight into public values and priorities. Having a strong empirical evidence base is essential for doing a robust ethical analysis of the program. Different types of evidence will be needed at different stages in the iterative design and adjustment process. All these data should inform how policymakers

BOX 7. Considerations for Implementation, Monitoring and Evaluation, and Adjustment**IMPLEMENTATION**

What *supply-side and health infrastructure* investments need to be made to ensure that the HBP design delivers on its promises and realizes its ethics and equity goals and objectives?

- Appropriate distribution of facilities and health workers; provision of complementary services as needed (e.g., transportation vouchers, mobile health services)
- Investment in quality improvement and oversight to ensure standards of care and reduce medical errors
- Supply-chain enhancements to support access to needed drugs, services, and goods
- Training of HBP personnel and care providers for quality assurance, communication about package, privacy and confidentiality, and cultural sensitivity

How can *enrollment procedures* be adopted to ensure equitable access to coverage under the package, as consistent with the equity objectives set forth by the package?

- Are package materials provided in appropriate language to ensure that eligible populations can enroll in the package?
- Are procedures simple and are resources available to assist enrollees?

How can efficiencies be realized in the delivery of the HBP?

- Drug procurement strategies for cheaper purchasing
- Appropriate provider mix to deliver different kinds of care
- Health information systems and information and communications technologies to better manage patient data, process reimbursements, refer for care, order supplies, process prescriptions.

MONITORING AND EVALUATION

At this point, the package's ethics and equity goals should have corresponding, measurable objectives. For each of these specific ethics and equity objectives, are the relevant indicators being regularly captured in order to track performance on ethics objectives and thus progress towards ethics goals? Are these data being analyzed at appropriate intervals? Have appropriate package officials been designated with the responsibility of assessing the findings of these periodic, ethics-specific analyses?

Special attention should be paid to—

- Coverage of key populations and their utilization of services
- Impacts on relevant outcomes for health and wellbeing
- Impacts on financial protection (e.g., changes in out-of-pocket payments)
- Patient satisfaction with the package and covered services
- Provider satisfaction
- Public opinion of the package
- Budgetary impacts
- Tracking harms and benefits

Are appropriate types of data being collected to assess performance along core ethical objectives?

- Disaggregated data to assess impacts on specific population segments and subgroups
- Mix of qualitative and quantitative data sources
- Inclusion of patient-centered outcomes

Are relevant indicators being captured in a timely manner to make adjustments, improvements and address any adverse ethics consequences? This includes capture of unintended and morally problematic effects outside the scope of the state objectives.

Are there mechanisms to:

- Rapidly identify any morally relevant harms produced and introduce strategies to reduce or avoid them
- Respond to the changing health needs of the beneficiary population
- Respond to temporal shifts in social, cultural, and religious norms
- Identify instances in which the disadvantaged have been made worse off by the HBP

Where the package failed to deliver on its ethics targets, why did the HBP fall short? What can be done in the future to avoid pitfalls?

ADJUSTMENT

When making adjustments, how can fair processes be used to introduce changes to the package?

- Is there transparency about changes and why they are being made?
- Have relevant stakeholders been included in certain types of adjustment decisions?
- Are clear and stable procedures in place to make adjustments to the HBP, as needed?

What types of adjustments may need to be made to better realize the stated ethics goals and objectives set forth?

- Where the package is failing to meet its stated objectives, what changes can be made to improve performance and better realize the package goals?

Over time, what types of adjustments may need to be made to the ethics goals, objectives, and targets themselves?

- When progress has been realized on ethics objectives, what adjustments to objectives can be made or new objectives adopted to further advance the HBP ethics goals?
- As new priorities emerge, as informed by the epidemiological data, public consultations, and the broader health sector agenda, what adjustments in ethics goals and objectives may need to be made?

Are there ways in which proposed changes can introduce individual harms? How can these be avoided?

- When adjusting HBPs to change covered interventions, are there ways to mitigate adverse consequences of switching patients well managed on current therapies? (For instance, allowing those on certain drugs to continue with their regimen and apply changes only to treatment-naïve patients)

assess the ethical implications for each design aspect and which decision is ultimately made to craft and adjust the package:

“... securing just health care requires a constantly updated body of evidence about the effectiveness and value of health care interventions.”⁵¹

When considering the benefits associated with interventions, decisionmakers should examine the evidence on clinical effectiveness. Is there strong evidence that the medicine, service, or therapy will actually lead to patient health improvements? How large are the associated benefits for health and other dimensions relevant to individual wellbeing? How reliable and credible is the evidence? How does the associated benefit of a particular intervention compare to that of other interventions for the same condition? Some interventions will have a long history of use and a large, reliable evidence base; others may have a similarly long history of use but no reliable evidence about effectiveness; and still other, more novel approaches may show promise but carry greater uncertainty. As is often the case, policymakers will have to make tough decisions with imperfect information. However, this uncertainty further emphasizes the strong role that the HBP can have in contributing new knowledge to the evidence base available for HBP planning by systematically collecting information during the routine delivery of care.

Clearly, evidence has a place in informing HBP design. However, the obligations for evidence flow two ways: the introduction of the HBP creates an opportunity to generate significant knowledge to improve the quality, efficiency, and responsiveness of care delivered. This notion embraces the idea of a learning healthcare system, which the U.S. Institute of Medicine (now the National Academy of Medicine) has defined as a system “in which knowledge generation is so embedded into the core of the practice of

medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care.”⁵² As they implement a HBP, nations can systematically collect data on the risks and benefits of drugs and procedures, coverage and utilization gaps, quality metrics, the health of special populations, and healthcare costs, all of which can be used to improve the design of the HBP and the broader organization of the health system. Moreover, this commitment to generating new knowledge will help create and maintain a just health system. Knowing which interventions work best for which patients will enable more efficient allocation of resources and will allow the HBP to expand its coverage. The systematic collection of data will not only allow for possible expansion of coverage (by uncovering opportunities to improve care and recover efficiencies) but also allows the HBP’s equity objectives to be monitored regularly. When developing the benefits package, policymakers should take into account both how existing data can help to design and secure the full range of the package’s objectives and how the HBP can contribute to the evolving evidence base for medicine and healthcare delivery more generally.

Mapping Considerations across the HBP Policy Cycle

Different ethical considerations come into play and vary in importance throughout HBP design, implementation, and adjustment. To help policymakers address these moral considerations, this section lays out a working framework for which moral considerations HBP designers should take into account at different points in the policy cycle. Given the iterative nature of the design process, some considerations will arise at multiple stages as options are debated and deliberated and as those involved in decision-making seek to balance multiple, potentially conflicting considerations.

Box 3 presents a checklist of important ethical considerations for the early planning stages, gathering and assessing the evidence, package development, implementation, and monitoring and evaluation. The early planning stages focus on ethical considerations relevant to setting goals for the entire HBP, and identify specific objectives and targets. The section on evidence narrows the focus to highlight the kinds of information needed to evaluate ethically relevant aspects when making coverage decisions for a specific service or class of interventions. The following section then considers the actual deliberation and decisionmaking process for discrete coverage decisions. The final section on implementation, monitoring and evaluation, and adjustment highlights ethical considerations relevant to specific coverage decisions as well as for assessing broader HBP performance across its ethics and equity objectives.

Early planning stages: Setting goals for ethics and equity

In the early planning stages of a HBP it is important to establish clear equity and ethics goals with specific objectives, targets, and indicators. Clarity about broad ethics goals and specific objectives will inform the prioritization of included services and help set up accountability mechanisms to track how well the HBP performs on its stated ethics objectives. Although the motivations for introducing a benefits package may vary, in most cases multiple and overlapping goals will align. However, tensions may arise between different types of goals, and HBP decisions may require trade-offs related to equity, ethics, and other package goals. This includes potential trade-offs between multiple commitments related to equity, as well as other ethical commitments. Therefore, it is important to reflect on an array of possible ethics and equity goals for the package, keeping track of those that are not ultimately included and why.

This section provides a range of equity and ethics goals that could be included in HBP design and implementation. The following questions, considerations, and examples are meant to help policymakers think through possible ethical objectives, weigh which ones matter most for their specific package, and develop justifications for why certain ethics objectives will be pursued while others will not. This includes attention to the evidence and reasoning supporting the resulting positions on particular ethics or equity goals. Although this list provides some questions and examples, it is not exhaustive of either all morally relevant considerations for package goals or the specific design options that can be used to achieve concrete objectives.

When assessing the relative importance of alternative ethics and equity objectives and selecting among them, it is also important to recognize that not all objectives need be pursued with the same time horizon. Differentiating between near-term and long-term ethics goals and the specific objectives for the package can have significant impacts on package design and implementation. Box 3 above presented a brief checklist for setting equity and ethics goals, with some common types of examples. Box 4, which follows below, presents a more in-depth list of potential objectives, considerations, and examples for how these goals can be realized.

For each of the ethics objectives adopted, clear and measurable objectives should be established so that progress can be tracked. For example, if the package adopts an equity goal to narrow existing disparities in health outcomes, specific targets should be identified on what kinds health outcomes will be targeted (such as maternal and child mortality), which disparities will be addressed (such as difference between rural and urban populations or across wealth quintiles), and the anticipated improvement over a defined time period. If the package is committed to ensuring financial protection among the poorest, specific targets should be set to reduce

out-of-pocket expenditures by a certain percentage over a fixed period. For other HBP objectives, targets can identify milestones and process measures for how those objectives will be realized—for instance, culturally sensitive services may be rolled out in a subset of facilities within the first five years, or electronic health records may be introduced in all district health facilities with a certain number of years.

Commitments to different ethics objectives may come into conflict in some cases. In identifying and specifying ethics objectives for the HBP, it can help to determine whether any ethics objectives clearly rank higher than others at the given time and in what circumstances obligations to one ethics objective should supersede another. The relative priority of these commitments must be responsive to the specific setting, populations, and resources available.

Collecting, collating, and assessing evidence to support coverage decisions

Once the ethics goals for the HBP have been established and defined with corresponding objectives targets, the evidence will inform how well coverage of a particular service or intervention supports the realization of the stated package goals. To determine how well an intervention fits with the package's ethics goals and objectives, it will be necessary to collect information to assess the intervention as it relates to the adopted objectives. For instance, a package that commits to covering specific disadvantaged groups, such as women and children, will need to see evidence about how a particular intervention affects these priority groups. Similarly, if the package commits to respecting patients and their dignity, evidence will need to be generated to determine what kinds of services will constitute respectful treatment among covered populations as articulated by the package's specified respect and dignity objectives.

Furthermore, the evidence can highlight ways in which covering certain services could be morally

problematic. For instance, evidence should be collected or generated to determine when covering an intervention would exacerbate circumstances for those who are already disadvantaged or create undue harms for certain types of patients. Box 5 provides various considerations for the types of data that are needed to assess the ethical dimensions of the HBP and specific questions for how to examine the evidence with attention to ethics.

The ethics goals and objectives are one set of standards against which services being considered for inclusion in the package should be evaluated. In some, if not many instances, the evidence needed to assess how a service might impact ethics goals and objectives will also be useful in assessing their impact on other package goals. At the same time, however, it cannot be assumed that the kind of evidence that would otherwise be examined will necessarily be sufficient to assess the impact on ethics goal and objectives; to do so, assessments for ethics-specific evidence must be built specifically into planning.

Deliberation and decisionmaking for coverage decisions

Once there are clearly delineated ethics goals and objectives for the HBP, as well as robust evidence to assess how well specific interventions may deliver on and cohere with various ethics objectives, decisions need to be made regarding which services will be included and excluded from it. At this stage of deliberation and decisionmaking, the ethics lens emphasizes two aspects: (1) fair and legitimate procedures and (2) adherence to the substantive ethical commitments adopted by the package. Once the ethics goals are established, any coverage decision that goes counter to those goals and objectives would require a moral justification. Chapter 1 provides extensive good governance guidance on decisionmaking processes and approaches, and a few additional considerations are provided in box 6 below. Although the

information here is not exhaustive, it provides core illustrative examples of how to integrate relevant ethics considerations in decisionmaking processes depending on the objectives adopted.

Implementation, monitoring and evaluation, and adjustment

The true determination of how ethical and equitable a HBP is ultimately relies on how the package is implemented and how well it performs in realizing its stated ethics goals and objectives. Having set goals and objectives for the package, in consultation with various stakeholders, and having made evidence-informed decisions about the inclusion of various services in relation to these ethics objectives, the work continues through the delivery, monitoring and evaluation, and adjustment of the package. The points in box 7 lay out specific considerations that will be relevant to the ethics of how the package is delivered, monitored, evaluated, and adjusted.

Conclusion

Designing and delivering a HBP is a complex endeavor, one that requires ongoing monitoring and adjustment. At the same time, a HBP can be an effective policy instrument to realize important health gains for the populations, organizing the health system and public financial resources in support of key policy objectives—including the progressive

realization of UHC. As key decisions are taken surrounding the primary goals of the HBP, the services and populations it will cover, the ways in which it will be financed and delivered, and the procedures through which it can be changed over time, policymakers will have to navigate a range of trade-offs with morally relevant considerations and consequences.

This chapter has laid out a set of ethical considerations that matter when evaluating different options for how the HBP will be structured and delivered. Since there are many ethically justifiable paths for HBP design and implementation at each decision point, and these decisions must account for deeply complex and diverse social, political, and epidemiological contexts, this set of considerations is not meant to be prescriptive. Rather, it provides a structure for policymakers to engage with a fuller range of ethically important considerations to inform decisionmaking and justify the selected approaches for the HBP.

At minimum, these ethical considerations provide a framework for a “moral sensitivity analysis” to be used with other methods and approaches for priority-setting. With fuller integration, applying these considerations at critical junctures in HBP design, delivery, and adjustment can help ensure that the package coheres with its core commitments; that patients and the population are protected against unintentional harms that the package could introduce; and that public resources are being responsibly stewarded in the service of effective, efficient, and equitable investments in health and wellbeing.

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Endnotes

1. Giedion, Bitrán, and Tristao (2014); Glassman and others (2012); and Cotlear and others (2015).
2. Brearley, Marten, and O'Connell (2013).
3. Norheim and others (2014); and WHO (2014).
4. Hofmann (2005); Saarni and others (2008); and Burls and others (2011).
5. Churchill (2002); and Kenny and Giacomini (2005).
6. Churchill (2002).
7. Glassman and others (2016).
8. Department of Health, South Africa (2015).
9. Note that many economists refer to these notions as horizontal and vertical equity. Horizontal equity is the like treatment of like individuals, such as equal access to medications for those with the same health condition, and vertical equity involves different allocations with respect to different need.
10. Krubiner and Hyder (2014).
11. Even HBPs that aim to cover "everyone" may require further specification about who is included. For instance, will the HBP cover all citizens? All persons living within the country? In many countries, migrants and undocumented residents may be among the most disadvantaged and suffer the worst health outcomes, yet they may not be eligible for care through the HBP.
12. Cookson and others (2016).
13. Powers and Faden (2006).
14. Atun and others (2013).
15. The commitment to provide equal access/universal coverage under a HBP does not satisfy all equity considerations. Even when a nation universally guarantees access to a set of services, the composition of the package of benefits offered could be inequitable.
16. Gavia (2014).
17. Guerrero, Arreola-Ornelas, and Knaul (2010).
18. Peters and others (2008).
19. Gilson (1997); Burnham and others (2004); and Nabyonga and others (2005).
20. Mills and others (2012); and Lagarde, Powell-Jackson, and Blaauw (2010).
21. Childress and others (2002).
22. Daniels and Sabin (1997).
23. Daniels (2001).
24. Childress and others (2002); Baum and others (2007); Saarni and others (2008); Sibbald and others (2009); Sabik and Lie (2008); and Clark and Weale (2012).
25. Abelson and others (2013).
26. Jamison and others (2006).
27. WHO (2013).

28. Revill and others (2014).
29. Saleh (2013); and Reich and others (2016).
30. Owusu-Sekyere and others (2014).
31. Keogh and Baumann (2016).
32. McKie (2015).
33. Littlejohns and others (2012).
34. Nord, Daniels, and Kamlet (2009); Powers and Faden (2006); and Brock (2003).
35. Dukhanin and others (forthcoming).
36. Ibid.
37. Sommer and others (2015).
38. Baltussen and others (2006).
39. Cain (2014).
40. Kapiriri and Norheim (2004); Shah (2009); and Nord (1993).
41. Mokdad and others (2015).
42. Pablos-Mendez and others (2013).
43. Mokdad and others (2015).
44. Fylkesnes and others (2013); and Sabapathy and others (2012).
45. Gilbar and Miola (2015); and Padela and others (2015).
46. Faden and others (2013).
47. Littlejohns and others (2012).
48. Emanuel and Pearson (2012).
49. Sah and Fugh-Berman (2013); and Morris, Wooding, and Grant (2011).
50. Fielding and Briss (2006); and Brownson and others (2010).
51. Fadel and others (2013).
52. Olsen, Aisner, McGinnis (2007); and Faden, Beauchamp, and Kass (2011).

CHAPTER 14

The Right to Health and the Health Benefits Package

Accounting for a Legal Right to Health When Designing a HBP

Rebecca Dittrich
 Leonardo Cubillos
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 Ryan Li

At a Glance: International and national law enshrines the right to health. Considering the impact of right-to-health litigation, how can priority-setting and the health benefits package account for the right to health and balance individual and collective health rights?

When designing health benefits packages (HBPs), decisionmakers must consider how to make packages fair, ethical, efficient, and affordable—and those decisions sometimes include difficult trade-offs. Important to the design of a well-balanced HBP is whether the inclusion or exclusion of a certain benefit aligns with the right to health of each

individual and the larger population as a whole. In some instances, where individuals contend that their inability to access a certain benefit is against their right to health, they have relied on the court system in an effort to gain access to that benefit.¹

On a most basic level, right-to-health litigation arises when an individual does not have access to a specific treatment, pharmaceutical, or medical device—here, as part of universal health coverage. Desiring government provision of that inaccessible health benefit, she turns to the court system to file a claim asserting that by denying to cover a specific health benefit, the government is restricting

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her guaranteed right to health.² This judicialization of the right to health occurs across Latin America, where citizens file *tutela* or *amparo* actions (protection writs) with frequency, but it is by no means unique to Latin America alone.³ Importantly, the right-to-health claims to which this chapter refer rarely involve the government preventing access to a certain treatment or medication purchased privately, but rather the failure of the government to actively fund and make the treatment available. As such, the question here is not about whether an individual should be able to access treatment independently and privately (a different question entirely), but whether the public expenditure should fund the treatment. When the courts grant access to a specific benefit, that decision may apply only to the individual asking for access, depending on the structure of the legal system and the type of legal claim brought, not to the numerous other people who could ostensibly benefit from the same treatment.⁴

Right-to-health claims typically arise in two contexts. In the first scenario, a benefit has been explicitly included in the HBP but an individual is unable to access that benefit due to some inefficiency or systems failure. In those instances, the judiciary can play a critical role. It can reinforce what is already mandated and ensure that all individuals can access the benefits they are legally entitled to obtain.⁵ This is, of course, assuming that the benefit is rightfully included in the HBP. In the second scenario, the health benefit has not been included, or has been intentionally excluded, from the HBP as part of an explicit decisionmaking process; an individual then challenges that intentional choice as being against her right to health.⁶ In these latter instances, if the decision to exclude a benefit has been made imprudently or incorrectly, the judicial system plays a critical role granting citizens access to that benefit. Courts have played a marked role drawing attention to injustices and shaping public policy where the large-scale denial of some critical treatment has threatened the health

of populations—such as the denial of antiretroviral drugs for HIV/AIDS.⁷ If and when the decision has been made properly, however, the interference of the courts could jeopardize the stability of HBPs. Funds may be diverted from more essential treatments to lower-priority care.⁸

The ability to access a country's judicial system is invaluable to securing the right to health of citizens. The opportunity for legal remedy holds governments, health ministries, policymakers, and other decision-makers accountable to maintaining a population's guaranteed right. Even when decisions about including or excluding certain benefits have been made deliberately and judiciously, they will not always have been made correctly, and the judiciary is empowered to right those wrongs. Yet in instances where explicit benefit exclusions are overturned without regard for how and why those decisions have been made, conflicts between the contents of HBPs and the right to health beget the question of how packages can be best designed to anticipate litigation and to “protect” and “fulfill” a population's right to health as a whole.⁹ Finding a way to balance the role of the courts with the necessity of healthcare priority-setting will require explicit consideration of, and attention to, the right to health.¹⁰

Outlining the Right to Health

The right to health is embodied in international and national law, multilateral treaties and issue-based human rights treaties protecting everything from race to gender to age.¹¹ All United Nations member states universally recognize the right to health, with regard to the Universal Declaration of Human Rights.¹² That right is enshrined in Article 12 of the International Covenant on Economic, Social and Cultural Rights; it is further elucidated in General Comment 14 to the International Covenant on Economic, Social and Cultural Rights, and emphasized

in the World Health Organization (WHO) Constitution (table 1).¹³

Nearly every country has joined at least one international treaty acknowledging the right to health,¹⁴ and many countries have further embedded the right to health into their national constitutions. 36 percent of United Nations member states' constitutions guarantee the right to health, and another 13 percent aspire to protect it; in some instances, national constitutions acknowledge the right to public health or the right to medical care services (table 2).¹⁵ Beyond national constitutions, states have also incorporated the right to health in domestic statutes, backing the right with the force of domestic law.

That the right to health, specifically, is not incorporated in a country's national constitution or domestic law does not necessarily preclude a citizen's ability to bring a legal claim. Individuals may challenge that the denial of some desired benefit is against their aforementioned international right to health, or that it contradicts some other nationally guaranteed right such as the right to life or dignity.¹⁶ Thus, the right to health may be protected through

the ratification of international treaties, the national constitution, or domestic statutes, or a combination of the three. As a result, as cases are brought in mass quantities to challenge the denial of a certain health benefit,¹⁷ countries with domestic law that both does and does not specifically guarantee a right to health are confronted with how to respond.

A citizen's ability to bring a right-to-health claim requires the pathways and mechanisms to do so. Right-to-health litigation should be managed in a way that recognizes the challenges of allocating scarce resources when designing a HBP, while ensuring that the most fair, effective, and equitable treatments, in alignment with social values, have actually been prioritized. Doing so does not include preventing or thwarting the right of citizens to bring legal actions. Citizens should have the ability to challenge the government's decisionmaking—a pathway for legally challenging the contents of the HBP is key. The questions instead are the following: How can these claims be best managed to ensure that right-to-health litigation preserves the rights of the entire population, including the protection of marginalized populations,

TABLE 1. The Right to Health Embodied in International Law

<i>Universal Declaration of Human Rights</i> Article 25	“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including . . . medical care and necessary social services” ^a
<i>The International Covenant on Economic, Social and Cultural Rights</i> Article 12	“Recognize[s] the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” ^b
<i>The International Covenant on Economic, Social and Cultural Rights</i> General Comment 14	Explains the three right-to-health obligations of states: to respect, to protect, and to fulfill ^c
<i>World Health Organization</i> Constitution Preamble	“The enjoyment of the highest attainable standard of health [is] one of the fundamental rights of every human being” ^d

a. United Nations (1948).

b. Office of the High Commissioner for Human Rights (1966).

c. United Nations Economic and Social Council (2000).

d. WHO (2006).

TABLE 2. The Right to Health in National Constitutions

Brazil ^a	Article 196	“Health is the right of all and the duty of the National Government and shall be guaranteed by social and economic policies aimed at reducing the risk of illness and other maladies and by universal and equal access to all activities and services for its promotion, protection, and recovery”
Colombia ^b	Article 49	“Public health and environmental protection are public services for which the State is responsible. All individuals are guaranteed access to services that promote, protect, and restore health. . . . It is the responsibility of the State to organize, direct, and regulate the delivery of health services”
Latvia ^c	Article 111	“The State shall protect human health and guarantee a basic level of medical assistance for everyone.”
Kenya ^d	Article 43	“Every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care”
South Africa ^e	Section 27	“Everyone has the right to have access to health care services, including reproductive health care The state must take reasonable legislative and other measures, within available resources, to achieve the progressive realisation of each of these rights”

a. Constitution of Brazil (1988).

b. Constitution of Colombia (1991).

c. Constitution of Latvia (1992).

d. Constitution of Kenya (2010).

e. Constitution of South Africa (1996).

and not only those taking their health rights to court? And, how can strong priority-setting protect against the rights-based vulnerability of the HBP?

When Right-to-Health Claims Challenge the Stability of HBPs

A key feature of any HBP is the public budget within which the package must be constrained. Therefore, judicial decisions that require the government to fund a treatment intentionally excluded will divert public resources from the treatments in the HBP that have been explicitly decided upon. The judicialization of the right to health can overwhelmingly force the government to fund expensive drugs not offered by the public health system, for members of the population with an already-advantageous place in the healthcare system, leaving the most vulnerable

individuals with the greatest need for essential services, behind.¹⁸

The diversion of public funds from HBPs is especially problematic where evidence suggests that courts end up granting disproportionate access to low-priority or experimental drugs, often ones that are not included on WHO’s Essential Medicines List or a country’s own drug formulary.¹⁹ In 2014, Ole Frithjof Norheim and Bruce Wilson selected a pool of 192 right-to-health cases filed with the Costa Rican Supreme Court of Justice (Constitutional Chamber) against the Costa Rican Social Security Fund (Caja Costarricense de Seguro Social). They randomly selected 37 cases for which the judiciary had granted the individual’s desired treatment and examined the severity of the disease without the new medication, the effectiveness of the new medication, the cost-effectiveness of the new medication, and the quality of evidence on the latter three. The

researchers then classified the disease and treatment in each case into one of four priority groups: high priority, medium priority, low priority, or experimental. Of the 37 cases evaluated, Norheim and Wilson concluded that 73 percent of the treatments “could be classified as either low priority or experimental and can be described as providing ‘marginal’ health benefits for very severe conditions at a high cost to the health care system.”²⁰

Further, courts may grant access to treatments for which generic or less-expensive alternatives exist.²¹ For example, of the drugs ultimately mandated for coverage by the Brazilian courts, one study found that nearly 80 percent had therapeutic alternatives otherwise available in the health system.²² Although it is debatable as to whether any of those drugs ultimately should have been included on the standard list of medicines on a policy level, the courts may not have played an appropriate role by mandating the individual provision of treatment not included on the list and otherwise available to citizens through other drug programs. For a sample case, see box 1—but note that since 2001, the Costa Rican Constitutional Chamber of the Supreme Court of Justice has changed its jurisprudence and no longer favors the use of branded medication.

Some courts also defer to the prescribing physician without considering additional important

evidence about the treatment. In a study of 2007 to 2008 Rio de Janeiro, Brazil court decisions, Miriam Ventura and colleagues found that 97 percent of cases were decided only on the medical evidence provided by the prescribing physician. In evaluating these cases, the courts accounted for the clinical value of the provider’s prescription but did not also consider existing regulations or the defense provided by the health system.²³ For a sample case from Uruguay in which the reviewing court relies heavily on the recommendation of the prescribing physician, see box 2.

Setting aside whether sorafenib could have been effective in treating Mr. Edward Hernandez’s cancer (see box 2), the judiciary places an unbalanced amount of weight and emphasis in the opinion of the prescribing physician alone. Such heavy reliance on the testimony of the prescribing physician is particularly problematic where the funding sources for right-to-health litigation can be unclear. Pharmaceutical companies may be indirectly sponsoring physicians, patients, patient groups, or NGOs to utilize the judicial process to gain government funding for their products.²⁴ In Brazil, clinical trials may be used to strategically distribute a new drug by encouraging trial participants to pursue the drug through litigation, with support from physicians, lawyers, judges, and patient associations.²⁵ Right-to-health litigation also can disproportionately reward wealthier

BOX 1. Ms. Vera Salazar Navarro vs. Caja Costarricense de Seguro Social, 01-0090007-CO (2001)

The Costa Rican Social Security Fund (La Caja Costarricense de Seguro Social) substituted the branded drug prescribed to Ms. Navarro to treat her multiple sclerosis with a less expensive generic alternative. Although the Social Security Fund argued that the effects and makeup of the generic alternative were the same, Ms. Navarro argued that the substitution of the exact drug she was prescribed violated her right to health.^a

The Constitutional Chamber of the Supreme Court of Justice held that the Social Security Fund must supply Ms. Navarro with the exact drug she was prescribed, as the substitution of drugs violated her right to health.

a. Hogerzeil, Samson, and Casanovas (2004); and Ms. Vera Salazar Navarro v. Caja Costarricense de Seguro Social (2001).

BOX 2. Edward Hernandez v. Fondo Nacional de Recursos, No. 393/2011 (2011)

The Uruguayan National Monetary Fund (Fondo Nacional de Recursos) appealed the lower court's decision requiring it to cover Sorafenib for Mr. Hernandez's liver cancer until a decision about the drug's inclusion on the Therapeutic Drug Roster (Formulario Terapéutico de Medicamentos) had been made. In its appeal, the fund argued that the drug Sorafenib was not included on the Therapeutic Drug Roster for liver cancer, and therefore the fund only followed procedure by denying coverage of the drug. The drug was only included for renal cancer.

Finding for Mr. Hernandez, the Second Chamber of the Court of Civil Appeals considered the National Monetary Fund to have unlawfully denied Mr. Hernandez coverage for Sorafenib. The court stated:

The [National Monetary Fund's] denial of coverage of the medication prescribed by the treating physician, based on its regulation in force at the time, and on the fact that the drug was only indicated for another type of cancer, has no logical or scientific basis whatsoever, and therefore, in the Court's opinion, the decision was manifestly unlawful, particularly given the fact that the expert testimony indicated that the medication that is the subject of the present action is appropriate for claimant's condition (pp. 5-6).

The court placed particular emphasis on the opinion of the prescribing physician:

Prescriptions and therapies chosen by the physician cannot be dictated by politicians and administrative authorities. . . . If administrative authorities are permitted to tell doctors what to do, this would be putting patients in the hands of political powers (p. 4).

Having cited international legal and national constitutional protections for the right to health, as well as the ratification of international law, the court also highlighted the rights of patients:

The medical profession must be governed by the principle of discretion, which manifests itself in the physician's choice of drug for a patient's treatment, with his or her knowledge of the particularities of the case and the fact that all consumers have the right to a treatment that causes the least problems or dangers to them, in light of all scientific advantages that medicine can put at the patient's disposal (p. 4).

a. Edward Hernandez v. Fondo Nacional de Recursos (2011).

individuals²⁶ and those with more knowledge of their legal rights.²⁷

Yet, other evidence suggests that right-to-health litigation has a net positive societal impact, especially by overwhelmingly allowing the least advantaged individuals to obtain medicines that are on the government drug formulary but inaccessible.²⁸ In Rio Grande do Sul, Brazil, for example, the opportunity to utilize the courts to access medications may

allow the poorest members of society a chance to hold the state accountable for providing strong, quality access to care.²⁹ The research concludes that even the minority of individuals requesting off-formulary drugs are not necessarily more advantaged or represented by private attorneys.³⁰ The varying evidence points even more strongly to the need to consider the right to health at the outset and engage in strong priority-setting when designing a HBP, and to follow

through on the public provision of services following proper priority-setting, in order to protect the right to health while also accounting for the realities of allocating scarce resources.³¹

The Critical Role Played by the Judiciary

While the judicialization of the right to health could hinder the stability of HBPs, the judiciary also plays a critical role upholding the right to health. The judiciary has been quintessential in challenging imprudent decisions to exclude treatments that could be

considered essential, or in criticizing governments that have failed to provide the access to care that the HBP guarantees. In the former instance, for example, courts have brought attention to the necessity of granting individuals access to life-saving HIV/AIDS medication that the government should have funded in the first place, and, as a result, have influenced important policy changes regarding treatment coverage decisions.³² (Box 3 presents one such seminal case involving treatment for mother-to-child HIV transmission in South Africa.)

In the latter instance, the judiciary also plays a fundamental role identifying benefits that have been promised as part of a HBP, but that the government

BOX 3. Minister of Health v. Treatment Action Campaign (No 2) **ZACC 15; 2002 (5) SA 721; 2002 (10) BCLR 1033 (2002)**

In an effort to address mother-to-child HIV transmission, the South African government launched a pilot program to distribute Nevirapine to expectant mothers.^a The drug, which prevents mother-to-child HIV transmission, would be provided at no cost at select research and training sites, but none were within public health facilities. The petitioners maintained on appeal that the restriction of the program to pilot sites violated their right to health, among others. The government asserted four reasons for restricting the program to select research and training pilot sites:

1. Concern about the efficacy of Nevirapine if the comprehensive package of care could not also be provided to a recipient, where the comprehensive package included testing, counseling, monitoring, and providing formula, vitamins, and antibiotics;
2. Concern about resistance to the drug;
3. Concern about unknown safety and hazards; and,
4. Concern about the capacity of the public health sector to provide the comprehensive package of treatment.

In holding that the government violated the Section 27 constitutional rights of those needing but unable to access Nevirapine, the court stated that while it was reasonable for the government to test the efficacy of the program before national expansion, the pilot period must be limited.

Sections 27(1) and (2) of the Constitution require the government to devise and implement within its available resources a comprehensive and coordinated programme to realise progressively the rights of pregnant women and their newborn children to have access to health services to combat mother-to-child transmission of HIV (p. 75).

a. *Minister of Health v. Treatment Action Campaign (No 2)*. (2002).

has failed to provide, as referenced in the prior section. In 1993, Colombia reformed its healthcare system through Law 100. The law recognized health as a human right, mandated that certain essential services be provided at no cost, and ordered a reform of insurance and service provision.³³ The reform had the effect of restructuring the healthcare system to create two tiers of benefits. The first tier, POS (Plan Obligatorio de Salud; Mandatory Health Plan), was a contributory regime; the second, POS-S (Plan Obligatorio de Salud–Subsidiado; Subsidized Mandatory Health Plan), established a subsidized regime offering half the benefits of POS.³⁴ Following the passage of Law 100 and the implementation of the reform, right-to-health litigation in Colombia increased dramatically.³⁵ This increased utilization of the legal system signaled that the law had failed to achieve the increased access to and standards of care it had aimed to achieve. Citizens turned to the judiciary to demand access to the healthcare treatments they were guaranteed as a result of Law 100 but were not being properly provided.³⁶ By 2008, the judicial system could not accommodate the insurmountable number of 142,952 *tutela* actions that had arisen.³⁷

Seeking to address the regulatory failures of Law 100 on a larger scale, the Colombian Constitutional Court joined 22 *tutela* claims in the case T-760 (see box 4).³⁸ Of the 22 cases combined in T-760, 20 were related to well-settled principles that had been repeatedly upheld by the court but that publicly funded health insurers and healthcare providers had failed to maintain because of poor management and regulation.³⁹ Case T-760 analyzed whether the failure to grant individuals the access to care mandated in Law 100 violated their constitutionally guaranteed right to the respect, protection, and fulfillment of their health. While the court reviewed all 22 claims, its decision extended beyond the claims asserted by the 22 plaintiffs to hold the government accountable for broader issues such as progressivity, fairness, and societal empowerment.⁴⁰

Law 100 guaranteed that both POS and POS-S would cover the same basic services, with similar funding, by the year 2000, thus providing similar *de jure* healthcare access to all Colombians irrespective of income.⁴¹ Yet by the time the T-760 case was heard, that goal had not been achieved. The court acknowledged the evident progression of existing and ongoing healthcare reform. It also recognized, however, that by 2008—15 years after Law 100 had been enacted—the legislature had not fulfilled its healthcare reform promises and the government was failing to protect its citizens' right to health as a result.⁴² Consequently, notwithstanding its decision on the 22 *tutela* claims, the court mandated that the government unify the content and financing of the POS and POS-S benefit plans, holding the government accountable to the commitments it made in Law 100.

The T-760 case included helpful language to guide the Colombian government in understanding how the Colombian Constitutional Court interprets the right to health and decides *tutela* claims. (See box 4 for a more extensive description of the explanations provided and the language used by the court.) Yet it also introduces a new function for the courts in upholding the right to health on a level that extends beyond individual claims to treatment or services, and holds the government accountable on a broader policy level.⁴³ The question, then, becomes, what is the proper role for courts to play, for example, in holding governments accountable for failing to progressively allocate resources to health, disregarding legislative commitments to healthcare access, or failing to adequately abide by constitutional or international law mandates? On one hand, court intervention can have a significant impact accelerating the realization of legislatively mandated healthcare interventions. On the other hand, the courts do not always have the capacity to analyze or anticipate how policy-level rulings could unintentionally disrupt healthcare priorities. Striking a delicate balance

BOX 4. T-760/08, Corte Constitucional (2008)

In its *T-760* decision, the Colombian Constitutional Court went beyond finding all 22 *tutelas* in favor of the petitioners by ordering broader remedies for the general regulation failures in the health system; but, the court also acknowledged the limitations on the right to health and access to services. It noted that the right to health is a finite right, and in a variety of instances, the court has failed to find that an individual should be granted the treatment or service for which he or she petitioned.^a These include *tutelas* for cosmetic services and obesity prevention before the disease poses irreversible dangers to life or personal integrity. The court noted:

The benefits plan need not be infinite but can be circumscribed to cover the health needs and priorities determined by the competent authorities in light of the efficient use of scarce resources (3.5.1).

The court emphasized its reliance on the recommendation of the attending physician, when the attending physician suggests that the service is required. (4.4.2). When the opinion of the physician and the Scientific Technical Committee of the Health Promoting Entity contradict, “the decision of a physician to order a drug excluded from the POS, which he deems necessary to safeguard the rights of a patient, must prevail and be respected, unless the Scientific Technical Committee determines otherwise based on (i) opinions of medical specialists in the field in question, and (ii) a full and sufficient knowledge of the specific case under discussion” (4.4.4).

The Colombian Constitutional Court identified the instances in which the failure of a compulsory plan to cover a certain health service would deny an individual’s right to health:

- (i) [T]he lack of medical service violate[s] or threatens the rights to life and personal integrity of those who need it,
- (ii) [T]he service cannot be replaced by another that is included in the obligatory plan,
- (iii) [T]he patient cannot afford to directly pay for the service, nor the amounts that the health care provider is legally authorized to charge, and cannot access the service by another different plan, and
- (iv) [T]he medical service has been ordered by a doctor attached to the entity charged with ensuring the provision of the service to those requesting it. (4.4.3).

a. *T-760/08* (2008).

between a passive and overly active judiciary is key to protecting healthcare priority-setting mechanisms while maintaining the right to health.

Colombia enacted Law 1438 in January 2011 to structurally strengthen its healthcare system. The law mandated universal coverage and sought to unify benefits while gaining financial sustainability. For

strong priority-setting, Law 1438 directed that HBPs use clear and transparent priority-setting methods while engaging stakeholders.⁴⁴ Yet even so, the Colombian courts decide countless *tutelas* each year, raising the question: how can HBPs best be designed to align with the right to health and decrease vulnerability to litigation?

Reducing the Vulnerability of HBPs to Right-to-Health Litigation

HBP vulnerability to right-to-health claims varies greatly. Although some countries have litigated right-to-health cases in droves on the basis of a denied benefit, others have been highly deferential to legislation and health system structure.⁴⁵ Yet, in both instances, and as previously nonlitigious countries begin to hear their first cases challenging the contents of HBPs,⁴⁶ accounting for the judicialization of the right to health when designing HBPs will be critical to maintaining HBP stability and integrity if and when those HBPs are brought to court.

Ensure that decisions are made based on a strong methodology and with an eye on ethics

Not every treatment, medication, service, or device can be covered by a HBP under a universal health coverage scheme; doing so obviously would be financially unreasonable. Clear, transparent, and precise methods for determining what is included and what is not (or, what is explicitly excluded) are most likely to be defensible in court. Governments should utilize these priority-setting methods rigorously and consistently, accumulating adequate documentation for the decisionmaking, thereby setting a record that courts can rely upon without needing to question the legitimacy of a priority-setting decision. And, where possible, those methods and coverage decisions should be defended. Another case from Colombia, *Estrella Mórrigan v. Coomeva EPS* (see box 5), highlights what can happen in the court system when the decision to deny a benefit has not been fully explained and justified. Regarding the case at hand, the medical community commonly considers labiaplasty a nonessential cosmetic genital surgery.⁴⁷ Yet, due to a lack of information regarding the effects of vaginal labia hypertrophy, the court ordered that the decision to deny

coverage of the procedure be reevaluated to assess the impact of the condition on sexual and reproductive health.⁴⁸ Recognizably, where right-to-health cases may be brought in mass quantities, defending health coverage decisions can be financially burdensome and inefficient—and in some cases, infeasible. But, where the judiciary purports that all benefits should be government-provided to comply with the right to health, defending the composition of the HBP requires referencing strong methods for making inclusion determinations. A prescribing physician's support for a particular medication can and should be met with arguments against that medication's inclusion by an equally qualified physician.

HBP inclusion decisions should also consider the ethics of allocating scarce public resources and the equity determinations required when designing a benefits package. (For a more extensive discussion of morality and inclusion, see chapter 13.) According to the United Nations Committee on Economic, Social and Cultural Rights, the progressive realization of the right to health requires that states use their maximum available resources to efficiently and effectively secure the highest attainable level of health for the population.⁴⁹ When the judiciary awards reimbursement of expensive medications to the few, the highest attainable standard of health for everyone may be threatened. This is especially true if the judiciary's decision requires valuable public resources to be diverted from low-cost, high-effectiveness treatments toward high-cost, low-priority care, in the context of adequate priority-setting. Where courts are willing to recognize the nature of fairly and equitably distributing scarce public resources, it must be clear that ethics have been properly considered. In 1997 the Constitutional Court of South Africa recognized that an unqualified right to human life cannot be granted to all persons:

The State has to manage its limited resources in order to address all these claims. There

BOX 5. Estrella Mórrigan v. Coomeva EPS (T-310/10), 2010

In Colombia, a 25-year-old female was prescribed ninfoplasty [or labiaplasty] to treat her vaginal labia hypertrophy. The procedure was denied by the Scientific Technical Committee of her Health Promoting Entity (Coomeva EPS), as it was considered outside the realm of coverage granted by POS, Colombia's publicly funded health insurance plan, with no "functional objective" (p. 1). Ms. Mórrigan argued that denial of the labiaplasty violated her right to health.^a When denying the claim, the municipal court stated that the "procedure was not essential to improve her health condition. Failing to perform it did not put her health or dignified life at risk. . . . It is more aesthetic than functional" (p. 2).

On appeal, the Constitutional Court First Reviewing Chamber considered that sexual and reproductive health are critical components of an individual's right to health. It could not establish whether the attending physician and Scientific Technical Committee had properly investigated whether the labia minora hypertrophy seriously affected Ms. Mórrigan's sexual and reproductive health. It held that the impact of the condition on her sexual and reproductive health would need to be evaluated, and the procedure would need to be provided if the effects were "serious" (p. 7).

The Review Chamber does not discard the fact that the physician who evaluated Estrella Mórrigan considered, in particular, the affection of her illness on her reproductive health on one hand and her sexual health on the other. Nonetheless, because of the general nature of the opinion, this Chamber cannot clearly establish whether the physician considered this matter or not. This absence implies that the Court, following its case law, has to protect the plaintiff's right to health; must request a new evaluation, considering, in particular, her sexual health, and, in the event that the service is necessary, it orders that performance of the service (p. 7).

a. *Estrella Mórrigan v. Coomeva EPS* (2010).

will be times when this requires it to adopt a holistic approach to the larger needs of society rather than to focus on the specific needs of particular individuals within society.⁵⁰

Even where courts are willing to recognize the need to ethically and efficiently allocate scarce resources, they may regard the government as having the responsibility to prove that funding a petitioner's desired treatment would divert funds from some other critical treatment for the masses. Thus, the government's defense—demonstrating that the decision has been made fairly, explicitly, and thoughtfully, with due financial considerations—is key.

Devise strong legislation and policies

A country's legal system determines the role played by its judiciary, as well as the court that will hear the claim,⁵¹ which in turn can influence the judiciary's approach to right-to-health claims.⁵² Civil law systems typically follow a written constitution that outlines specific codes and enshrines basic rights and duties, and judges are tasked with applying that law.⁵³ Courts are not generally required to follow the precedent of previous court decisions on similar matters, though they often do so in practice.⁵⁴ Civil law systems have separate constitutional courts⁵⁵—as seen in Latin America, where *tutela* and *amparo* actions are heard. Unlike civil law systems, in common law systems both legislation and judicial opinions are

binding law. Courts play a role interpreting legislation; and, because of the impact that the courts in common law systems can have on shaping the law, they rely on precedent to follow judicial decisions made in similar, earlier cases.⁵⁶ By way of example, most of Latin America follows a civil law system, while the United States, England, and India follow common law. Other countries, such as South Africa and Kenya, follow a combination of the two systems. Thus, the impact of strong legislation and policies may vary according to how the courts rely on them, but the contents of the policy and its impact on leading to strong, sound HBP development will remain ever-critical.

Reviewing past right-to-health judicial opinions with an eye on how decisions are made and how each country has defined the right to health will be important to properly devising a HBP that aligns with a country's specific circumstances, and implementing strong law and policy. Where the right to health has been reasonably interpreted under national law, with due consideration for fair resource allocation and the priority-setting process, ensuring that the contents of and funding for the HBP appropriately align with that interpretation can both uphold the right to health⁵⁷ and make the HBP less vulnerable to right-to-health litigation. Note, however, that where judicial decisions are not required to rely on those that have come before them, previous judicial decisions on the right to health alone may not necessarily dictate how the courts will define the right in the future.

Although HBPs are often defined as a positive list of rights, services, and treatments, some systems have devised negative exclusionary lists as well. For example, Article 15 of Colombian Law 1751 directs Colombia's Ministry of Health and Social Protection to delineate lists of included and excluded benefits.⁵⁸ Some courts, including in Colombia, have argued that a lack of inclusion is separate and distinct from explicit exclusion, and that explicit exclusionary lists ought to undergo a more rigorous assessment

to ensure preservation of the individual's right to health.⁵⁹ Mandating explicit exclusionary lists, however, may require that *all* available treatments and technologies be given an inclusion or exclusion determination—a difficult task considering the ever-changing landscape of available services and treatments. Further, such explicitness may fail to appreciate the value of discretion in a well-regulated system if a reliable, functional, and rigorous priority-setting process guides the HBP design, implementation, and update.

Include a process for appealing decisions prior to judicial review

When making important decisions about the contents of a HBP, policymakers should also consider a formal process by which those decisions can be challenged. Because important services may well be overlooked, or patients may struggle to access their entitled care, some process must be in place for individuals to assert their rights and challenge the HBP's contents. So, if not directly to the courts first, then where?

Providing an opportunity for appeal prior to judicial review of a HBP exclusion decision may not only divert cases from the courts but also increase court confidence in how inclusion and exclusion decisions have been made. Such administrative appeals procedures will also allow governments to collect primary data concerning where and how the process of designing the health benefits package—or the contents of that package—could be strengthened or corrected. Courts have demonstrated an inclination to defer to a just and fair priority-setting process; for example, the Mexican Supreme Court recently declined to grant reimbursement for the expensive drug Soliris (eculizumab)—used to treat the rare, life-threatening disease paroxysmal nocturnal hemoglobinuria—requiring that the commission in charge of designing the HBP review the pharmaceutical.⁶⁰ An appeals process allows an opportunity for

independent review of an exclusion decision, following the already transparent, explicit, methodical, ethical, and evidence-based processes used to make the initial decision as advocated throughout other chapters. Informed, independent arbiters prior to judicial review have been utilized successfully in other contexts, such as vaccine compensation courts in the United States, where medical staff reviews a petition for compensation, making a recommendation to a court-appointed special master, and the special master's decision can be later appealed in civil court.⁶¹

Some countries—England being one of the most notable examples—allow such an opportunity for independent review and stakeholder involvement in the HBP design. Individuals who believe that the National Institute for Health and Care Excellence (NICE), England and Wales' health technology assessment agency, has made an unfair decision, exceeded its powers, or made an unreasonable recommendation in light of the evidence, may appeal that decision.⁶² Following the decision of the appeals panel, individuals may still seek judicial review of decisions they believe are procedurally unfair, discriminatory, or irrational.⁶³ Colombian Law 1122 of 2007 also designed administrative tribunals with jurisdictional responsibilities in the National Superintendence of Health;⁶⁴ the tribunals currently attend to approximately 1,500 cases per year.⁶⁵ Without question, the structure of an appeals process for challenging the HBP would vary significantly based on a country's judicial system and legal processes. Whether or not challenges could mandatorily be filtered through independent review prior to being brought to court would also be highly country-dependent. But, universally, general inclusion of an independent review process may help reduce a HBP's vulnerability to fast and frequent litigation based on the right to health.

Involve the judiciary in the conversation

Ultimately, judicial input may be necessary in order to design HBPs that best account for the constitutional right to health and to reduce the package's vulnerability to litigation. The right to health plays varying roles depending upon the healthcare system; the extent to which countries rely on and incorporate health rights can depend on their income levels.⁶⁶ And, where a country's judiciary considers government support for every health benefit to be essential to upholding the right to health, no amount of proper methods, ethical considerations, or appeals processes could insulate a HBP from court claims. Understanding the perspective of the judiciary will be key.

The level at which the judiciary is authorized to participate will vary by country. Ideally, finding a role for the judiciary in the HBP decisionmaking process, and ensuring that the judiciary feels comfortable with that process, may encourage it to consider the best interpretation of the right to health that fairly balances provision of treatment to one individual with the right to health of the broader population, as well as the specific needs of marginalized and vulnerable groups. In multiple Latin American countries, including Brazil, Costa Rica, and Uruguay, *SaluDerecho* (the Initiative on Priority Setting, Equity, and Constitutional Mandates) has had success involving the judiciary in a multistakeholder approach to evaluate the judicialization of the right to health. *SaluDerecho* "increased participation, transparency, and accountability among stakeholders, influencing institutional and organizational changes" to understand right to health litigation through the lens of a human rights-based approach.⁶⁷ Involving the judiciary has led judges to seek access to information regarding evidence-based medicine and has strengthened decisionmaking involved in designing a HBP.⁶⁸ Aside from increasing internal country communication, assistance from international health organizations to lead the conversation on how to best balance

individual rights to health with the population-based social right to health may play a critical role.⁶⁹

Conclusion

The judiciary plays a fundamental role upholding the right to health by ensuring that citizens have access to the health services to which they are entitled; it also ensures that the government makes judicious, fair, and accurate decisions about what is included in HBPs. Where the judiciary's decisions require the government to fund low-priority, high-cost services, critical resources can be diverted from the HBP, and the stability of the package as a whole can be threatened. By properly considering the right to health and the judicialization of the right to health when designing HBPs, policymakers can minimize, or at least reduce, a HBP's vulnerability to right-to-health claims.

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POLICYMAKER COMMENTARY

Chile's Guaranteed Package of Health Benefits Navigates Political Challenges

Antonio Infante

At a glance: In Chile, the health system guarantees a package of essential care—but must resist pressure to expand benefits beyond sustainable levels.

At the turn of the century, many Chileans expressed dissatisfaction with the country's two-tiered system. A minority (about 15 percent) of relatively wealthy and healthy Chileans received care through private insurance and providers, known as ISAPREs (Instituciones de Salud Previsional; Health Insurance Institutions), while most others (about 75 percent of the population) enrolled in the public insurance system, known as FONASA (Fondo Nacional de Salud; National Health Fund). (The remainder, about 10 percent of the population, received care through the armed forces or was not covered by insurance.) FONASA offered near-universal and subsidized care, but resource constraints often led to poor quality and long waiting lists. This segmentation of the population by income and risk created deep inequities

in health outcomes. For example, Chilean women with no education were 6.6 times as likely to die from gallbladder cancer and 4.9 times as likely to die from cervical cancer as their compatriots who had attended university.¹

Previous governments had encountered political backlash in their interactions with the health system, triggering doctors' strikes and fierce pushback from the powerful Chilean Medical Association. And Chilean leaders had seen efforts at health reform abroad stall and fail—most notably, the United States effort under the Clinton administration. Chile's then President Ricardo Lagos was fully aware that health reform would be a political minefield. Nonetheless, Lagos believed that health reform was necessary, and he resolved to proceed despite the inevitable political challenges that would result.²

The Politics of Health Reform

A careful, well-designed process was necessary to craft a health reform package that would work for the Chilean people while preempting and neutralizing political opposition that could sink the whole effort. In 2000, Lagos selected close friend and colleague Dr. Hernan Sandoval to lead the reform process through creation of an interagency Health Commission. To inform its design, Sandoval reached out to former Hillary Clinton advisor David Michaels to learn more from their failed attempt. From their interaction, Sandoval realized that a successful reform process would need to include politicians and political constituencies from the start, not just technical experts. And to get broad social buy-in, the reform would need to offer something for all Chileans, not just the worst off.³

Sandoval thus sought technical advice and public feedback in parallel. Early on, the Health Commission conducted focus groups and workshops with national stakeholders, including the Chilean Medical Association, to better understand their priorities and concerns. Later, emergence of broad outlines of the proposed reform prompted debate in Congress and mass media, inviting public participation.⁴

At the center of the reform proposal was the introduction of a health benefits plan called AUGE (Acceso Universal con Garantías Explícitas; Universal Access with Explicit Guarantees), intended to facilitate equitable access across the population for a subset of health conditions. Conditions would be prioritized on this list if they (1) contributed greatly to Chile's burden of disease and (2) had cost-effective solutions. For prioritized conditions, the reform guaranteed not just access to treatment but also timeliness, quality of care, and financial protection, applied equally across the public and private sectors. Prioritized conditions would be selected through a participatory technical process, marrying technical analyses of disease burden, health system capacity,

and cost-effectiveness with consultation from key stakeholders. Nonprioritized conditions would still receive public subsidy, but would remain under the status quo system, in which care was implicitly rationed through waiting lists.

Polling suggested widespread public support for reform,⁵ even as the reform bill and subsequent prioritization process sparked a heated debate within the health sector. Nonetheless, the very concept of "prioritization" proved contentious to key stakeholders. Some advocacy groups recognized that prioritization was a prerequisite to providing more equitable healthcare access to poor and marginalized segments of the population. Others disagreed; critics asserted that prioritization was simply discrimination by another name and would postpone necessary care for patients who had the misfortune of contracting a nonprioritized condition. Instead, they argued, the government should simply increase the resources available to the public sector so all could receive needed treatment. And, as expected, the medical association voiced strong opposition. Doctors (and ISAPREs) feared that better public sector care would cannibalize their private sector clientele and undermine their financial standing; they also objected to the reform's clinical guidelines and protocols as potentially undermining their professional autonomy. Drawing on the public support, President Lagos and Sandoval were able to push through the reform over their objections.

A Decade of Better Health

A decade later, the impact of the AUGE reform process is obvious. Both the public and private systems have achieved near-perfect compliance with the legal mandate, ensuring equitable and timely access to high-quality care for the guaranteed conditions. As a result, many more Chilean families now enjoy access to treatments previously limited

to the wealthiest segment of society. Between 2005 and 2008, for example, treatment coverage for five chronic health conditions covered by AUGE rose dramatically among FONASA's public-sector beneficiaries—from 27 percent to 39 percent for hypertension; 44 percent to 65 percent for type 2 diabetes; 67 percent to 100 percent for type 1 diabetes; 16 percent to 36 percent for child epilepsy; and 20 percent to 30 percent for depression.⁶ The AUGE has also helped protect patients' pocketbooks; between 2005 and 2014, Chile's share of out-of-pocket expenditure (as a percentage of total expenditure on health) dropped from 42 percent to 32 percent.⁷ Even so, Chileans' out-of-pocket expenditure still ranks among the highest in the Organisation for Economic Co-operation and Development (OECD), meriting further government attention.⁸

Perhaps most importantly, the reform appears to have improved Chileans' health. Earlier access to preventative care appears to have helped stem the burden of chronic disease; between 2002 and 2006, Chile saw an 11 percent drop in case fatality from hypertension and a 48 percent drop for type 1 diabetes amid concurrent declines in hospitalization.⁹ Researchers have also documented declines in fatality from common illnesses, likely attributable to higher-quality care; for example, the one-year risk of case fatality following acute myocardial infarction fell by half between the pre- and post-AUGE periods as more patients received recommended pharmacotherapy, both during hospitalization and after discharge.¹⁰

Whither the Nonguaranteed Conditions?

The success of the AUGE reform process required widespread social buy-in, achieved through the careful engagement of all Chilean stakeholders and political leadership from the government. Still,

the government must continue to grapple with the scheme's limitations.

The most politically salient challenge relates to the very structure of the AUGE: a set of prioritized conditions, with nonprioritized conditions still eligible for coverage but without timeliness or quality guarantees. This structure has proven to be a double-edged sword. On the one hand, the fact that no conditions were explicitly excluded from coverage made the plan more politically palatable, helping neutralize common objections related to equity and patients' legal and ethical rights. On the other hand, long wait-times for nonguaranteed conditions create ongoing tensions within the health system and depress overall public satisfaction. Waiting lists also lead to pressure on the government to expand the scope of guarantees for an ever-greater number of conditions, at the risk of exceeding the system's capacity and undermining its fiscal solvency. Fully resolving these tensions may not be feasible, underscoring the importance of fair, transparent, and evidence-based processes in managing competing political pressures during any further revision of the guarantees list.

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ADDITIONAL RESOURCES

The **International Decision Support Initiative (iDSI)** is a global partnership of leading government institutes, universities, and think tanks to provide policymakers with coordinated support in priority-setting for universal health coverage. iDSI provides demand-driven practical support and knowledge products to help both policymakers and funders make better decisions for better health. The innovative partnership brings together the Global Health and Development Group at Imperial College London, the Health Intervention and Technology Assessment Program (HITAP), the Center for Global Development, and Priority Cost Effective Lessons for Systems Strengthening South Africa (PRICELESS SA). The initiative receives funding support from the Bill & Melinda Gates Foundation, the United Kingdom Department for International Development, and the Rockefeller Foundation.

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In March 2017, Thailand's Health Intervention and Technology Assessment Program, along with the International Decision Support Initiative, launched a global platform specializing in helping low- and middle-income countries, academics, researchers, and health technology assessment practitioners worldwide conduct high-quality, policy-relevant health economics research. Explore the solutions and research questions with mind maps, recommendations, and comparisons of the guidelines, and by interfacing with experts in the field!

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GLOSSARY

antiretroviral therapy (ART) The combination of several antiretroviral medicines used to slow the viral progression of HIV. Although as yet there is no cure for HIV, ART can control HIV so that those with the disease may live longer, healthier lives and reduce the risk of transmission. *See also* HIV.

AUGE (Acceso Universal con Garantías Explícitas; Universal Access with Explicit Guarantees) Chile's health benefits package implemented within a social guarantee framework. It describes a set of highly cost-effective services for which access and quality will be guaranteed.

Bill & Melinda Gates Foundation The largest private foundation in the world, founded by Bill and Melinda Gates in 2000. The goals of the foundation are to enhance healthcare and reduce poverty worldwide, and to expand educational opportunities and access to information technology in America.

Cancer Drugs Fund (CDF) A program introduced in the United Kingdom in 2010 to increase access to cancer drugs that had not been adopted for routine use in the National Health Service. However, in doing so, it bypassed standard appraisals of

cost-effectiveness. The CDF was later restructured to become a managed access fund.

cost-benefit analysis A systematic process to calculate and compare costs and benefits, in dollar value, of a program, decision, or policy.

cost-effectiveness analysis A systematic process to calculate and compare costs and benefits, by key outcomes, of a program, decision, or policy.

disability-adjusted life year (DALY) A metric used to quantify disease burden. One DALY can be thought of as one year of "healthy" life lost. DALYs combine the years of life lost due to premature mortality in the population and the years lost due to disability for people living with a disease or its consequences.

Disease Control Priorities Network (DCPN) A seven-year project managed by University of Washington's Department of Global Health and the Institute for Health Metrics and Evaluation. The program is designed to promote and support the use of economic evaluation for priority-setting at both global and national levels. DCPN was funded in 2009 by the Bill & Melinda Gates Foundation.

Essential Healthcare Package (EHP) Malawi's health benefits package, created in 2002 to guide both planning and funding of health service delivery and to ensure that services are oriented toward local burdens of disease and mortality.

extended cost-effectiveness analysis (ECEA) A cost-effectiveness analysis approach that extends traditional economic evaluation with distributional aspects (such as health and financial one). ECEA thus serves broader objectives than cost-effectiveness analysis in providing guidance in the design of health policies in general and health benefits packages in particular.

financial risk protection (FRP) Safeguards to prevent individuals from suffering financial hardship associated with paying for healthcare services. A key component of universal health coverage.

FONASA (Fondo Nacional de Salud; National Health Fund) Chile's public health insurance authority. A significant majority of Chileans are enrolled in this government-funded health system.

GAVI, the Vaccine Alliance A public-private global health partnership that was founded in 2000 with the goal of creating equal access to new and underused vaccines for people living in the world's poorest countries.

Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) An international financing organization founded in 2002 to accelerate the end of AIDS, tuberculosis, and malaria as epidemics.

health benefits package (HBP) The defined list of healthcare services covered by public monies and the financial terms of such coverage (such as cost-sharing). Some countries use HBPs to meet basic

health needs for the entire population; others use HBPs to meet the health needs of specific populations, such as pregnant women, children, the elderly, or the poor.

Health Intervention and Technology Assessment Program (HITAP) A semi-autonomous health technology research unit under Thailand's Ministry of Public Health. HITAP is a core iDSI partner.

health sector strategic plan (HSSP) A strategic plan that leads the activities of a public healthcare authority and its partners, typically designed for implementation over the medium term (five years).

health technology assessment (HTA) The systematic evaluation of properties, effects, and impacts of health technologies.

Health-related Quality of Life (HRQoL) A multidimensional concept that includes domains related to physical, mental, emotional, and social functioning. Instead of simply focusing on direct measures of population health, life expectancy, and causes of death, it focuses on the impact that health status has on one's quality of life.

horizontal public health programs A set of general healthcare services delivered through public finance to target prevention and care for prevailing health conditions.

HIV (human immunodeficiency virus) A virus spread through certain bodily fluids that weakens the immune system by destroying T cells or CD4 cells. HIV can progress to the acquired immune deficiency syndrome (AIDS), the last stage of HIV infection.

Instituto Mexicano del Seguro Social (IMSS) The Mexican Social Security Institute, founded in 1943.

International Decision Support Initiative (iDSI) A multicountry, multidisciplinary partnership of health-care practitioners and researchers, launched in 2012 following the publication of a report by the Center for Global Development on priority-setting institutions for better spending on health. Led by the Institute of Global Health Innovation at Imperial College London, iDSI stands for “better decisions for better health.”

ISAPREs (Instituciones de Salud Previsional; Health Insurance Institutions) Chile’s system of private health insurance and care providers. This system provides care to a minority of the population, mostly those with higher incomes.

Joint Learning Network for Universal Health Coverage (JLN) A country-driven network of practitioners and policymakers from around the world who codevelop knowledge products to help bridge the gap between theory and practice and extend coverage to people across the globe.

low- and middle-income countries (LMIC) For the 2017 fiscal year, low-income economies are defined as those with a gross national income (GNI) per capita of \$1,025 or less in 2015; lower middle-income economies are those with a GNI per capita between \$1,206 and \$4,035; upper middle-income economies are those with a GNI per capita between \$4,036 and \$12,475.

monitoring and evaluation (M&E) *Monitoring* refers to a family of methods for data collection and analysis. It is a systematic effort undertaken during the implementation and operation of a project or a policy that is intended to help improve its design and adoption. *Evaluation* is concerned with the outcome of a project or policy, and is conducted with the aim of fine-tuning design or informing future projects or policies. It examines longer-term results and identifies how

and why activities succeeded or failed. Monitoring is undertaken more frequently than evaluation.

multicriteria decision analysis (MCDA) An alternative to cost-effectiveness analysis, providing a general framework for decision support rather than one specific to the health sector. MCDA is based on the observation that alternative investment opportunities typically have multiple dimensions, and any decision recommendation should be based on the aggregation of the performance of options across these different dimensions.

National Health Insurance Scheme (NHIS) The national health insurance system established by the government of Ghana to provide basic healthcare services. In Ghana, the NHIS covers 95 percent of the disease burden in the country.

National Health Service (NHS) Publicly funded national healthcare system for the United Kingdom. It is the largest and oldest single-payer healthcare system in the world.

National Institute for Health and Care Excellence (NICE) Provides national guidance and advice to the United Kingdom to improve health and social care. Originally created to reduce variation in the availability and quality of NHS treatments and care.

Plan Integral de Atención en Salud (PIAS; Comprehensive Healthcare Plan) Uruguay’s health benefits package, which seeks to offer an identical package of essential health benefits to the entire population.

Plan Nacer A healthcare program and benefits package established in Argentina after a deep economic and political crisis in 2001. The program was composed of a narrow set of health interventions to prevent, treat, and reduce child diseases and mortality.

Plan Obligatorio de Salud (POS; Mandatory Health Plan) The explicit benefits package that Colombia's universal health insurance scheme operated with from 1993 to 2015.

President's Emergency Plan for AIDS Relief (PEPFAR) A U.S. government initiative established in 2003 to help save the lives of those suffering from HIV/AIDS around the world.

program budgeting and marginal analysis (PBMA) An analytical approach developed to deal with the constraints imposed by transition costs. It has a practical focus on evaluating relatively modest and manageable changes, as opposed to adherence to historical patterns. PBMA is a complement to CEA.

quality-adjusted life year (QALY) A metric used to quantify disease burden. One QALY can be thought of as one year of "perfect health."

Seguro Popular Social health insurance in Mexico for low-income citizens. This system has two health benefits package: one for common ambulatory and hospital services and another for infrequent and high-cost services.

Sustainable Development Goals A set of 17 goals that aim to end extreme poverty and hunger, fight inequality and injustice, combat climate change, and more. On September 25, 2015, the leaders of 193 United Nations member states adopted the goals as part of a new global sustainable development agenda. The 17 goals and their targets for 2030 are described at www.un.org/sustainabledevelopment/sustainable-development-goals/.

tuberculosis (TB) An infectious bacterial disease characterized by the growth of nodules in the tissues, especially in the lungs.

tutelas Special constitutional protection writs that citizens in Colombia can file with the judicial system to protect the right to health.

universal health coverage (UHC) According to the World Health Organization, UHC "means that all people and communities can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship."

universal public finance (UPF) Full public finance (for healthcare) irrespective of whether services are provided privately or publicly.

vertical public health programs Programs selectively targeted toward specific health interventions not fully integrated in health systems.

WHO-CHOICE (CHOosing Interventions that are Cost-Effective) An initiative started by the World Health Organization in 1998 to help countries choose their healthcare priorities. The WHO-CHOICE team works with policymakers at the country level, providing information on cost-effectiveness, costs, and strategic planning to help guide decisionmaking.

World Health Organization (WHO) United Nations agency specializing in international public health, founded on April 7, 1948 (now celebrated as World Health Day). Its primary role is to direct and coordinate international health within the United Nations system.