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Research Article

Defining a Health Benefits Package: What Are the Necessary Processes?

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CONTENTS

Abstract—There is immense interest worldwide in the notion of universal health coverage (UHC). A major policy focus in moving toward UHC has been on the key policy question: what services should be made available and under what conditions? In this article we are concerned with how a feasible set of UHC services can be explicitly defined to create what is commonly known as a "health benefits package" (HBP), a set of services that can be feasibly financed and provided under the actual circumstances in which a given country finds itself. We explain why an explicit statement of the HBP is important and then describe a framework that includes ten core elements that are indispensable if a coherent and sustainable process for setting the HBP is to be established.

Keywords: evidence, health benefits package, health economics, health policy, health systems, health systems financing, health systems management, priority setting, universal health coverage

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INTRODUCTION

Universal Health Coverage

There is immense interest worldwide in the notion of universal health coverage (UHC), culminating in the publication of the World Health Report 2010[1] and given further momentum by the 2014 adoption of the United Nations General Assembly Resolution on UHC. UHC is defined by the World Health Organization 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 assure the delivery of certain health services or products free of charge, or at a subsidized fee, to the entire population.

The interest in moving toward UHC is easy to understand. Done well, UHC improves access to health services for many people who would otherwise be unable to use those services and can improve the use of services designed to prevent future ill health.[3] UHC can reduce the incidence of

serious impoverishment caused by health shocks. In addition, by making access to health services unrelated to ability to pay, UHC 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] A fairly comprehensive form of UHC has been in place in most high-income countries for several decades, and an increasing number of low- and middle-income countries are seeking to make a transition toward UHC.

A central requirement of any system of UHC is that the services made available to the population are consistent with the funds available. This article argues that the creation of an explicit health benefits package is an essential element in creating a sustainable system of UHC. The purpose of the article is then to describe the functions needed to fulfill that requirement, in what we term a *framework* for setting the package. In the remainder of this section, we set out the salient features of the health system needed to implement UHC and explain why an explicit package is necessary. We then describe the framework, which includes ten core elements, and conclude with some brief observations on implementation.

While the need and rationale for a health benefits package has been made in general terms elsewhere, this article adds value to the literature by linking the need for a health benefits package to the UHC mandate and discussion, and by focusing on the practical steps and country experience needed to make a health benefits package an effective policy tool for delivering better health and health care.

The UHC Funding Pool

UHC requires the establishment or expansion 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 principle of UHC, it is essential that a citizen's financial contributions are mandatory and that they are unrelated to the medical circumstances or risks of the individual.[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] A defining feature of UHC is therefore 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 the needed medical services. High-income countries have by and large been able to claim that the funds they have available 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 rationing health services.[8] Such debates are in many ways similar to those in low-income settings of prioritizing only a limited number of treatments for public funding. Though the nature of the binding constraints facing low-income settings is much more dramatic (low-income countries spent 35 USD [average exchange rate] per capita on health on average versus 4,692 USD in high income countries in 2013[9]), 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 low- and middle-income countries. 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 can frustrate the objectives of UHC if poorly designed.[10] Likewise, restriction of UHC or charging differential 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 health care subsidies has been largely unsuccessful.[11] There have been some arguments that UHC might be limited to certain disadvantaged groups, such as poor households,[12] and several of these targeted schemes have found success in enhancing

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 compromise the principle of UHC.

Therefore, in practice, a major policy focus in moving toward UHC has been on this key policy question: What services should be made available and under what conditions?

The Health Benefits Package

The set of 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 disconnect between the aspirational health plans and actually available financial and other resources is the single most common failing of existing benefits plans in low-income countries.[13,14] 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 actually received by patients, which may be severely restricted by factors such as budget, infrastructure, human resources, geographical, cultural, and other constraints. In this article we are concerned with how a feasible set of UHC services can be explicitly defined, to create what is commonly known as a "health benefits package" (HBP), a set of services that can be feasibly financed and provided under the actual circumstances a given country finds itself.[15]

An important characteristic of the HBP as defined is that it is made explicit, so that citizens can be made aware of what services are (and—equally importantly—are not) available and so that payers may assess resource requirements year to year. 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.

Explicit specification of the HBP undoubtedly creates practical and political difficulties. For example:

- Countries may lack the analytic and administrative capacity to set a HBP with any assurance.
- The data necessary to set the HBP may be absent or subject to serious distortions and bias.
- There may be service delivery constraints that preclude changing the current pattern of services.
- There may be legal statutes that 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 Ministry of Finance perspective, the creation of explicit entitlements to treatment may create uncertain budgetary implications that could be resolved if arbitrary restrictions on access were imposed.

The importance of such considerations should not be underestimated. However, an explicit statement of benefits gives rise to numerous benefits; for example:

- 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 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 though 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 a number of potential benefits for the health system as a whole.

The absence of a clear statement of the contents of the HBP has many inefficient and unethical consequences. For example, funding (say) local district hospitals with a fixed budget—but without an explicit statement of the HBP—has been a widely used resource allocation method in the past.[16] It secures strict expenditure control without the need for a statement of services to be delivered. However, this approach leaves the choice of who should secure access to services to the local hospitals and may result in arbitrary decisions as to who secures that access, with obviously adverse consequences for inefficiency (poor use of funds) and inequity. Furthermore, it runs the risk that—either explicitly or implicitly—local providers may seek out informal payments from patients to secure access, further exacerbating inequities.

Though it is difficult to state unconditionally, progress toward UHC seems to be better managed with explicit

specification of the HBP.[3] This article documents the processes that will be needed to pursue such an objective. Setting an HBP involves hard political choices, balancing the claims of various patient groupings, localities, and suppliers of technologies and services.[6] 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 effectiveness 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 low- and middle-income countries (LMICs) face especially severe challenges in implementing systems of UHC. The profound limits to resources available in LMICs intensify the pressures on priority-setting processes. High-income countries have been largely able to develop the HBP in their health systems over time, being able to provide a generous package of benefits by incrementally adding new technologies as they emerge and funding them through regular increases in the health budget as their economies grew gradually alongside. In contrast, LMICs are confronted by a huge array of technologies and services that they cannot possibly fund with existing (or planned) funding levels. This gives rise to immediate and 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 setting the HBP. The level of funds available 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 to be provided. In the same vein, LMICs may come under pressure to adopt recommendations by international agencies, even if those recommendations would not otherwise be a priority or even cost-effective for their setting.[13,14] Such recommendations therefore 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 that might have been averted if the entire budget were allocated jointly with an eye toward maximizing health system objectives.

Choosing the Health Benefits Package

It is important to recognize that the HBP specification can take many forms and vary greatly in the level of detail and specificity. At one extreme it could contain a detailed list of specific treatments and the criteria under which patients become entitled to that treatment; for example, clinical indications or age. At another extreme, the HBP could merely include a general specification, such as any treatment normally occurring in a primary care setting. Both of these extremes give rise to risks: in the first case of unmanageable complexity and in the second case of vagueness and scope for provision of unnecessary or inappropriate services. In practice, the HBP is usually likely to take an intermediate form; a 2014 analysis found a varying degree of explicitness and detail in seven Latin American countries, for example.[18]

We believe that—as far as is feasible—the contents of an HBP should be selected according to consistent and transparent criteria that are aligned with a health system's objectives. It is perfectly feasible to create an HBP without consistency or transparency. However, such an approach will always be vulnerable to criticisms that it unduly favors particular patient groups, service providers, or health technology industries. Setting explicit criteria makes it possible to explain the reasons for adoption or rejection of specific products and services and can allow health systems to set up agencies with explicit terms of reference for assessing technologies and services. These are important approaches for alleviating some of the political difficulties that can arise when setting an HBP and help ensure a sustainable transition toward UHC.

Furthermore, setting transparent criteria for assessing treatments and services allows a proper debate to take place about the objectives of the health system, how priorities are to be set, and how performance should be assessed. In short, it is part of good governance of the health system. The speed of progress toward UHC will largely be constrained by the taxes citizens are prepared to make available to fund the health services in the HBP. 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.[12]

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. The important requirement 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 services on 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 promise major improvements in welfare for citizens in the future, but they also will place major responsibilities on governments and their agencies to ensure that the funds available are spent wisely. This will require reconciling competing claims from numerous interest groups and is therefore 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 the HBP has widespread support and has real impact. We describe those functions in the next section.

Further, the HBP does not exist in isolation. If it is to be more than a *de jure* wish list of services, HBP must inform health system functions such as payment, provision, performance measurement, and accountability. If these conditions are not fulfilled, the HBP will be little more than a tokenistic process that will have little impact on *de facto* services that citizens can use.

An intrinsic characteristic of the transition toward UHC should be that it is sustainable, meaning that:

- the process of setting the HBP is practical and secures broad support from providers, politicians, citizens and other stakeholders.
- the HBP offered can be afforded from available resources.
- the HBP has a real impact on services received.
- similar (or improved) coverage can be offered over future periods, given reasonable projections of future needs, technologies, and resources.
- citizens continue to support the principle of UHC and are prepared to contribute taxes and other funds to pay for it.

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

First, an HBP includes 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 like medicines, for example, the design and adjustment of an HBP may (though does not always) require 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, a 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 analysis, but for the purposes of moving toward UHC it is the full complement of services and products that needs to be considered. This portfolio approach is crucial because it will reflect the full set of services 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.

Second, 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 more effective HBP seen in countries like Chile, Colombia,[18] Liberia pre-Ebola,[19] and Thailand.[20] In contrast, in countries such as Ghana,[21,22] Uganda,[23] and Peru,[18] the HBP was not linked to resource availability and budgeting, resulting in fiscal imbalances and likely implicit rationing.

Third, 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, known as Plan AUGE (or Acceso Universal de Garantías Explícitas), 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, nonprioritized services are still offered but subject to implicit rationing via waiting lists, service availability, and other implicit mechanisms. An HBP might also be complemented by a negative list—meaning a list of interventions, services, and products that will not be publicly funded under any circumstances. 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, for example.

Finally, 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, and most health systems continue to lack these kinds of processes.[18] Perhaps the best example of why this is important comes from health systems that did not have such processes in place; in Mexico, for example, efforts to set up sound process were subverted by politicians raiding the "catastrophic benefits fund" to build a new cancer institute.[24]

THE TEN CORE ELEMENTS OF SETTING AN HBP

In this section we briefly present ten elements that are indispensable if a coherent and sustainable process for setting the HBP is to be established, in line with the requirements outlined in the previous section. It is important to underline that there is no single correct way of organizing these functions, the precise nature and locus of which may vary substantially, depending on policy choices and the nature of the health system. What is important is that structures to undertake the function are in place, that they operate efficiently and effectively, and that the various functions are aligned according to the common purpose of setting an HBP that secures the maximum value for society.

The functions are illustrated diagrammatically in **Figure 1**. There is no suggestion that in practice their operation will be so neatly sequential. Rather, the ordering is intended to underline the interdependence of the various functions. In practice, many functions will occur simultaneously, and there will be cycling back to preceding functions before later functions are undertaken. Moreover, the purpose of illustrating the process as a cycle is to highlight the fact that setting the HBP must be a continuous process, with a requirement for constant review and refinement as new evidence, new technologies, and even new preferences emerge. The reason for describing the inevitably messy process of setting the HBP as a small number of discrete functions is to aid discussion and help policy makers examine the effectiveness of the arrangements in their own health system.

Our 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 multistep and dynamic process that goes 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. We offer brief comments on each element.

1. Setting goals and criteria: A first step in the design of HBP 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 policy makers and politicians to clearly state the intended impact or use of the HBP. In Argentina,

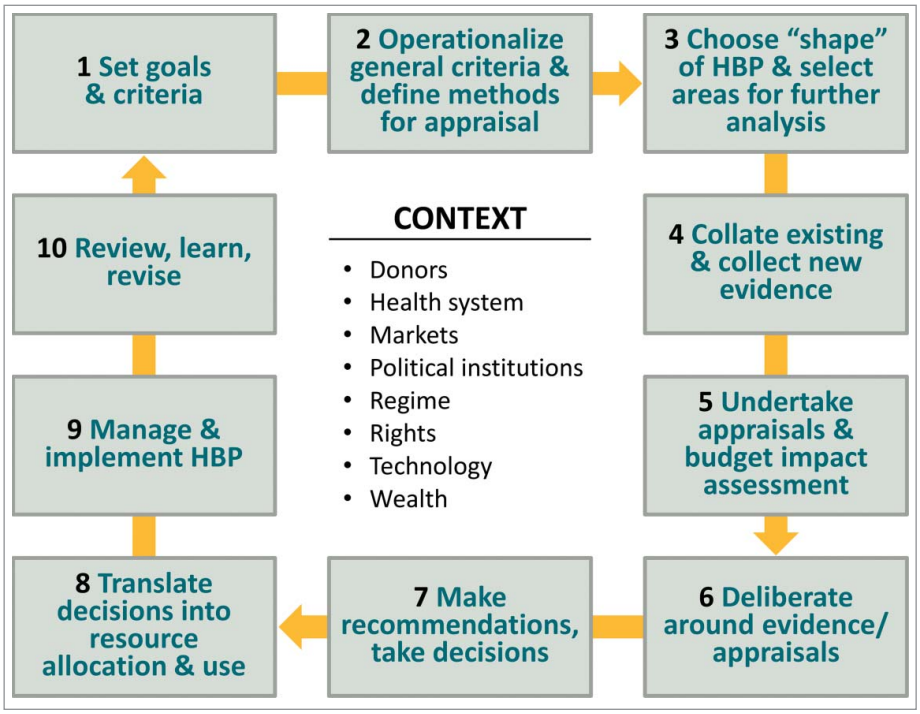

FIGURE 1. Ten Core Elements of Setting a Health Benefits Package

for example, the goal was to protect uninsured mothers and their infants from preventable morbidity and mortality.[18] In Vietnam, for example, 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.[25] In other countries, the HBP is mainly used to define allowable reimbursement for medicines (Uruguay) or to regulate insurers (United States, Colombia). Explicit goal setting is a *sine qua non* condition to assure coherence in all subsequent steps and it is the basis for the implementation of accountability mechanisms that check whether the HBP responds both on paper and in practice to what it was originally 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, policy makers 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 update of the HBP in the Dominican Republic, general criteria of geographic and socioeconomic equity, severity, number of people affected, and other criteria were agreed on as the basis on which to select disease control priorities and services for inclusion, whereas nonprioritized diseases and related interventions would be rationed implicitly.

2. Operationalizing general criteria and defining methods for appraisal: After setting clear goals and criteria but before diving into any specific disease or service category, a next task—likely for technical staff and analysts rather than policy makers themselves—is to operationalize general into specific criteria that can be utilized in pre-agreed and 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 cost-effectiveness analyses may be selected as the appraisal method and general equity criteria can be operationalized into CEA presenting disaggregated analyses by groups. In Thailand, for example, the Health Intervention and Technology Assessment Program has issued a methods manual that is used as the routine reference for CEA conducted[26] and 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 (see Giedion et al.[18]). Whatever method is selected, methods should meet four key principles: they should be technically robust and justifiable; be reflective of social values; be easy to understand; and have a relatively low cost of implementation.[27] Not every disease–service pair will be analyzed using such methods, but the idea is to clearly set out defensible methods choices *ex ante* that will provide structure for the appraisal process where it is deemed to be feasible and necessary via a kind of triage, described next.
3. Choosing the "shape" of the HBP and selecting areas for further analysis: Given the whole inventory of possible health services constituting the universe of potential candidates for inclusion, policy makers 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 HBP (budgeting, payment, accountability, or otherwise). Further, policy makers 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 an HBP is being developed *de novo* (from a zero-based scenario) or whether the HBP includes all services currently being provided and the priority-setting problem is only incremental (i.e., deciding on the use of newly available resources 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 or excluded from the HBP. For example, a country like Vietnam, with a per capita gross domestic product of 5,000 USD per year, might immediately exclude medicines not considered cost-effective by health technology assessment agencies in much wealthier countries like the UK, Germany, and France. 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, perhaps not—with uncertain budget

impact, not currently provided systematically, and worthy of further analysis.[a] Similarly, for countries setting an HBP within certain disease goals, attention can be focused 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 potentially be used to set an AIDS-specific HBP.[28] Other approaches include polling or consulting policy makers 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 (Y Teerawattananon and N Trivasivat, personal communication, July 2015).

4. Collating existing and collecting 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-analyses, and literature reviews grading evidence quality are well-documented and tested strategies for the collation, collection, and analysis of existing and new evidence as input to the appraisal itself that will follow methods decisions (step 2; see GRADE Working Group[29]). Alternatively, some countries have called for periodic wholesale HBP revisions, as in the Dominican Republic example provided earlier. Here, the collation and collection of evidence is essentially a scan of guidelines and medicine lists in other countries (even those with very different resource constraints) and a first-round decision to include wealthiest-country-in-the-world gold-standard cost-effective guidelines for priority diseases and leave any additional evidence gathering and analysis for a later time. Nonprioritized interventions would continue to be provided according to implicit rationing.
5. Undertaking appraisals and budget impact assessment: Cost-effectiveness analysis has become a widely accepted approach toward appraising technologies, as embodied in numerous health technology assessment agencies worldwide. However, CEA is by no means universally accepted or feasible. Implemented from scratch, CEA can require infeasible analytic demands, and transferability of findings from other health systems can be questionable. Methods such as meta-analysis can be used to synthesize results from elsewhere, and regional collaboration may be a means of reducing the analytic burden on single countries. A frequent criticism of CEA is its failure to address objectives other than health maximization, and a variety of 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 (see Mitton and Donaldson[30]). 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.[b] The lack of a robust budget impact analysis of the proposed change can later lead to a lack of coherence between what is being promised in the benefits package and the resources that are allocated to implement it and frequently compromises sustainability of the HBP.
6. Deliberation 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 making a recommendation for inclusion or exclusion (step 7). Though deliberation is more commonly applied as part of health technology assessment in Organization for Economic Cooperation and Development countries, most notably the UK's National Institute for Health and Care Excellence's committees and citizens councils, there are good reasons to consider including a process of deliberation around the entire portfolio of HBP services and its subsequent adjustment as well. The information and methods available to make decisions on what to include or exclude from the benefits package involve substantial uncertainty related to limited local information sources, variable strength of the evidence base, restricted empirical information on what works and what does not work, and the strengths and limitations of having and combining objective criteria. For example, LMIC more often than not lack solid information on the effectiveness and costs of treatment in their own context.[31] Further, beyond incorporating specific criteria into the selected methods and appraisal approach, there are other values or considerations that might be brought to bear in the selection of services. Under

many circumstances, stakeholders can agree on a deliberation process considered fair while acknowledging the uncertainties and constraints that surround the evidence.

7. Making recommendations, taking decisions: In many settings, deliberation ends with a recommendation to policy makers on the individual services or portfolio of services that are to be included in the HBP either during its initial design or later adjustment process but fails to connect the recommendation with decision making. In an ideal process, there is an obligation to consider the appraisal and its recommendations in decision making on whether services are included or excluded for public subsidy. Such an obligation has been established in regulation in some countries (Thailand, Mexico), whereas in others, recommendations are not binding for budget decision makers (UK, Colombia). The key issue is to lay out clearly how appraisals/recommendations will relate to decision-making bodies and individuals, whether payers or providers, and there may be a need to first build confidence in the evidence/appraisal before setting up an explicit connection between recommendations and decision making. Further, attention should be given to communicating recommendations and decisions to policy makers at different levels of government, providers, and the public.
8. Translating decisions into resource allocation and use: Decisions emanating from appraisals, budget impact analysis, and recommendations can be translated into resource allocation in binding or nonbinding ways, but some kind of direct influence on resource allocation—via budgets, fiscal transfers, payment, reimbursements, or product procurement—is a necessary element of an effective HBP. Some health payers are legally required to consider recommendations in resource allocation. For example, as established in regulation, Mexico's Seguro Popular package CAUSES (Catálogo Universal de Servicios de Salud) is the basis for budgeting the payment transferred by the federal government to state governments for the provision of CAUSES services.[c] Similarly, in Colombia and Uruguay, the inclusion of a medication in the published regulations on HBP is a prerequisite for its reimbursement or payment by insurers. However, in the absence of legislation or regulation, there may be other inducements for budget decision makers 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 of non-HBP medicines. There are also non-financial strategies to induce adoption of included services, such as clinical guidelines with peer review and medical audits. Beyond these hard-wired 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 next step).
9. Managing and implementing HBP: Once resources are allocated, there is an ongoing process of HBP services implementation via payers and providers doing care delivery. But in the context of the HBP framing, we use management and implementation of the HBP to denote the tasks that the HBP manager must carry out to continuously update and monitor HBP payment and services using prescription and utilization data, communicate with stakeholder groups on included and excluded services, resolve disputes, manage exclusions, inform price negotiations with manufacturers (see Yothasamut et al.[32] and Pichon-Riviere et al.[33]), prepare financial forecasts and plan needed adjustments, and so on. In essence, implementing the HBP means assuring that it is delivered in practice, in line with the goals that were initially set out, and both financially and institutionally sustainable. In short: implementation is about assuring the coherence of the HBP 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 the Mexican benefits package for its conditional-cash-transfer program and the availability of the infrastructure and inputs required to deliver it found that very few health posts actually had capacity to provide the covered services.[18] 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 Ministry of Health.[34]
10. Reviewing, learning, revising: Based on the management and implementation experience, the release of new technologies in the market, and the emergence of new evidence on existing services, the HBP process should be considered continuous and comprised of learning, adjusting, and starting over. Note that often

countries do not have any systematic processes in place to update their benefits packages and a periodic updating process of benefits packages rarely occurs.[18] Chile is an outlier in this context because its normative framework mandates an update of its HBP every two years.[18] A process for monitoring implementation—for example, in the form of measuring effective coverage of services and treatments included in the HBP—would ideally be considered but is not currently in place in any country. The constraints to implementing desirable technologies should be assessed and—where necessary—appropriate changes to the health system recommended.

CONCLUDING COMMENTS

This article has presented briefly the complex set of interconnected elements that should ideally be put in place to create a sustainable HBP. We have argued that the HBP is the cornerstone of a modern health system that is seeking to make the transition toward universal health coverage. The exposition has highlighted the necessary functions that should be aligned with each other 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 cost-effectiveness analysis will often form a crucial element of the evidence base for the creation of the HBP. However, explicit consideration of the ten 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 decision making, social value assessment, stakeholder engagement, and implementation, which involve quite 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, we would argue that—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. One good example is Chile's AUGE guarantees—which describe a set of highly cost-effective services that will be provided at a given and budgeted standard of quality and timeliness and that can be tracked and providers sanctioned for failure to provide under agreed conditions.[35]

A persistent theme in the discussion has been the need to ensure alignment of all the various functions needed to create and implement an HBP. For example, budgeting processes, clinical guidelines, and provider inspection regimes should all be aligned with the HBP. How such alignment is to be secured will depend on the nature of the health system. A governmentally 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 adherence to the principles and contents of the HBP by all parties.

The creation of the HBP determines what services should be subsidized by public sources of finance. Although the costs of those services should be fully considered, the creation of a publicly funded HBP makes no assumption about whether they should be provided by public, not-for-profit, or private providers. The key issue is that the services should be provided efficiently, in line with intentions, therefore requiring a properly functioning procurement function.

Note also that services excluded from the HBP might still be provided and used within the health system or at minimum there should be a policy 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 the services in the HBP 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 the strategy employed to cope with those technologies that have been excluded from coverage, it is an area that requires specific attention and planning ex ante.

We have sought to emphasize that the creation of a sustainable HBP requires constant review and revision, as new evidence emerges, new technologies are developed, and national circumstances evolve. It should 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, we again underline the need to tailor the HBP process to local conditions and local systems. Though we believe that the ten 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 (say) The Netherlands. However, there will be a need for all systems to ensure that the functions described above are undertaken satisfactorily, often in the context of the existing set of institutions found in the country. Failure to do so will make it hard to set a coherent HBP and may compromise the transition toward UHC.

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NOTES

[a] For example, in Mexico, cost-effective screening looks different than cost-effective screening in the UK because of the early onset of diabetes and relatively high prevalence of prediabetes in Mexico versus UK. See Castro-Ríos et al.[36]

[b] For example, these guidelines for budget impact analysis of health technologies in Ireland. See Health Information and Quality Authority.[37]

[c] However, the accountability on the use of the capitation payments by state government—that is, how well does state spending track to the established HBP priorities—is not well developed and not known in the public domain.

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