USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

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Brief: Key Steps for Defining Pharmaceutical Benefits Packages

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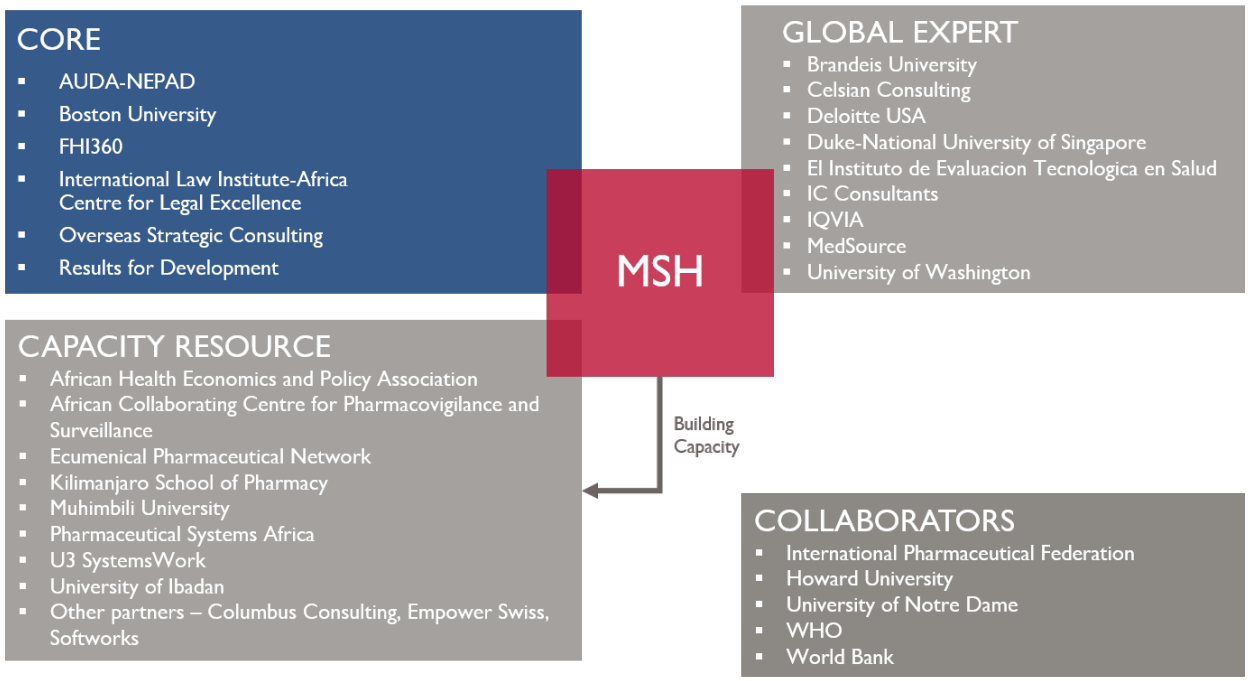
About the USAID MTaPS Program

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to higher-performing health systems. MTaPS focuses on improving access to essential medical products and related services and on the appropriate use of medicines to ensure better health outcomes for all populations. The program brings expertise honed over decades of seminal pharmaceutical systems experience across more than 40 countries. The MTaPS approach builds sustainable gains in countries by including all actors in health care—government, civil society, the private sector, and academia. The program is implemented by a consortium of global and local partners and led by Management Sciences for Health (MSH), a global health nonprofit.

The MTaPS Consortium



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PROJECT SUMMARY

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	Capacity Resource Partners	African Health Economics and Policy Association, Ecumenical Pharmaceutical Network, U3 SystemsWork, University of Ibadan, University of Ghana's World Health Organizations (WHO) Pharmacovigilance Collaborating Center, Kilimanjaro School of Pharmacy, Muhimbili University, Pharmaceutical Systems Africa
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INTRODUCTION

Formulating a health benefits package (HBP) is an integral step for countries as they work toward achieving universal health coverage (UHC) (1). An HBP is a set of health services and medical products that a particular set of beneficiaries is entitled to receive with specified financial protection, funded by the government or another coverage arrangement (1–3). In addition to enhancing financial protection for households, a well-defined HBP can ensure that a country's resources are spent on cost-effective, highly valued services and medical products; help expand coverage to otherwise underserved populations; and provide explicit entitlements for all beneficiaries.

As one of the building blocks of health systems strengthening, medicines (more precisely, "medical products, vaccines and technologies") are a key component in UHC (4). Ensuring that citizens have access to the medicines they need without worry of impoverishment is critical to universal coverage. Every country will face challenges in making best use of the funding available; it often is not possible to cover all pharmaceuticals needed by a population given current resource constraints. Low-income countries in particular are constrained in what they can afford to cover for beneficiaries. The magnitude of pooled funding allocated for health benefits will determine the comprehensiveness of a pharmaceutical benefits package, defined as the set of pharmaceutical products to be covered and made available to eligible beneficiaries. As a result, decision makers must carefully prioritize the contents of a pharmaceutical benefits package to maximize value for money (1). Further, given that these decisions determine how public funding will be spent, the prioritization process should be transparent, systematic, and evidence-based (5).

Medical products and other health technologies warrant special attention within the HBP discussion due to their large portion within the health budget and high rates of out-of-pocket expenditure on medicines. A 2018 study on financial protection in Southeast Asia identified spending on medicines as the main driver of out-of-pocket expenditure in seven of the eight countries involved, comprising more than 70% of out-of-pocket expenditure in six of the eight (6).

The Asia region has an increasing number of middle-income countries. A recent cross-country analysis from the World Health Organization (WHO) notes that reliance on out-of-pocket spending to finance the health system often increases as countries' gross domestic product per capita increases unless their leadership intentionally designs and establishes comprehensive, publicly financed coverage arrangements (7). This pattern makes the financial protection offered by a well-defined HBP with a pharmaceutical benefit component especially important in Asia's rapidly growing countries. Countries moving through the epidemiologic transition may see their burden of disease shift away from communicable diseases toward more chronic diseases, requiring more expensive treatments over a longer period of time. Decreasing foreign assistance can add urgency to the need for domestic sources to finance a greater portion of the country's health needs. In low-income countries where there are even fewer resources, the need to maximize value for spending on health is even more pressing (8).

The process of articulating the services and pharmaceuticals to which beneficiaries are entitled should be done in an evidence-based, transparent manner (9). A number of resources exist to inform the design of HBPs (1,10). A few also offer considerations for countries to design a pharmaceutical benefits package, either as a subset of the broader HBP or as a standalone package (11, 12).

PURPOSE

The purpose of this brief is to summarize guidance for countries on establishing a pharmaceutical benefits package as part of their health benefits policy; the intended audience includes policymakers and planners from Ministries of Health, Finance, or Social Affairs – both at the technical level of research,

budgeting, and planning as well as the executive level where policies are formulated and decisions are made. While healthcare providers, pharmacists, private insurance companies and other stakeholders should have a voice in the definition of the pharmaceutical benefits package, they are not necessarily the target audience of this brief.

This brief was funded by the US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program and is intended to build on another MTaPS report—"Pharmaceutical Benefits and Benefits Packages in Asia: A Cross-Country Mapping of Coverage Arrangements"— which reviewed Asian countries' benefits packages and essential medicines lists (EMLs) and how pharmaceutical benefits are defined (3). That report analyzed 24 different coverage schemes in 14 Asian countries, which define pharmaceutical benefits to varying degrees within the broader package of services. The analysis categorized the coverage schemes into four groups based on how pharmaceutical benefits are specified, ranging from using an EML or national formulary to guide pharmaceutical decisionmaking, to explicitly defining pharmaceutical benefits (3). This brief discusses explicit versus implicit definitions of pharmaceutical benefits and may be particularly useful for countries or coverage schemes seeking to more explicitly define pharmaceutical benefits.

In the following sections, we first define the phrase "pharmaceutical benefits package" in more detail. We then describe a framework for developing such a package and outline its key steps with illustrative examples from countries within the Asia region.

THE ROLE OF PHARMACEUTICAL BENEFITS PACKAGES

Pharmaceutical benefits packages (PBPs) are an important part of health policy. A pharmaceutical benefits package can be defined as an explicit list of medicines and related commodities selected for the treatment of a list of diseases or health conditions for a defined group of eligible beneficiaries. These medicines and commodities, which become an entitlement for covered patients, may be prescribed and dispensed, and will be largely or entirely paid for by pooled health system funds (11). If pharmaceutical benefits are not defined explicitly, they may be rationed implicitly (for instance, on a "first come first served" basis), not prescribed in order to control a facility's costs, or not reimbursed in order to control an insurer's costs, thus limiting the patient's access to care and potentially their financial protection from out-of-pocket costs.

By defining benefits packages that guarantee that beneficiaries are entitled to specified benefits with financial protection and explicitly connecting those entitlements to sources of financing, policy makers can ensure access to care while protecting people from catastrophic health expenditures.

Multiple criteria should be considered by the group tasked with defining pharmaceutical benefits; using cost-effectiveness as one of the main prioritization criteria for the covered health benefits will help countries maximize value-for-money with their limited resources. Defining benefits explicitly may help a purchaser manage costs. Other critical considerations should include the safety as well as religious and social acceptability of a given product.

As outlined in the report on pharmaceutical benefits and benefits packages in Asia, some Asian countries have HBPs that explicitly articulate covered pharmaceuticals, while others rely on an EML or national formulary as the list of what is eligible for prescribing and reimbursement (3). Explicitly defined pharmaceutical benefit packages serve the following important roles/functions in a health system: (1)

- Guide public financing towards cost-effective, high-priority proven medicines, such as those included on an EML.

- Connect the covered benefits to specific source(s) of financing, typically from pooled sources (this brief focuses on publicly financed coverage arrangements). This can in turn improve the predictability of expected financial outlays and inform planning decisions around resource allocation and procurement.

- Clarify who is entitled to the benefits, ensuring financial protection for covered populations. This differs from a national EML, which identifies only the country's priority medicines.

- Clarify that there is an entitlement to the benefits for covered beneficiaries. Beneficiaries rely on the benefits package to understand what pharmaceutical benefits they are (and are not) entitled to. The benefits package also helps health care providers identify the priority pharmaceuticals that need to be available for prescribing and dispensing.

The broader health benefits package, which articulates the country's priority health conditions and services to address those conditions, should be the starting point for prioritization. Pharmaceuticals and other components of the package should be based on and derived from the larger set of services and interventions included in the HBP. Ultimately the pharmaceutical and health benefits packages should be considered cohesively rather than separately or as a standalone package.

A FRAMEWORK FOR DEFINING PHARMACEUTICAL BENEFITS PACKAGES

Defining a pharmaceutical package to support a country's efforts to achieve UHC entails answering a core set of questions: who is covered; what diseases, health conditions, and services are covered; what pharmaceuticals should be covered to address those health conditions; how much they will cost; what resource envelope is available from pooled sources; and how much (if at all) beneficiaries are required to contribute (5). For a pharmaceutical benefits package to be sustainable, these considerations will need to be balanced, and these priorities will inform which pharmaceuticals should be covered. Each country or coverage scheme will approach the process differently based on existing health benefits policy in the country and where it is in the journey to UHC, since most health service coverage schemes already cover some set of pharmaceuticals.

For the purpose of this brief, we are assuming that the question of "who is covered" has already been addressed by health policy makers. The characteristics of the beneficiary population—age, gender, socioeconomic status, and geography—determine their health care needs and the diseases and conditions for which they are most likely to seek treatment (13). For example, if the population in question includes a large number of women of reproductive age, a greater volume of maternal and newborn care will be needed. If the scheme targets poorer populations, there will be implications for how much (if at all) beneficiaries can contribute as copayments for pharmaceuticals.

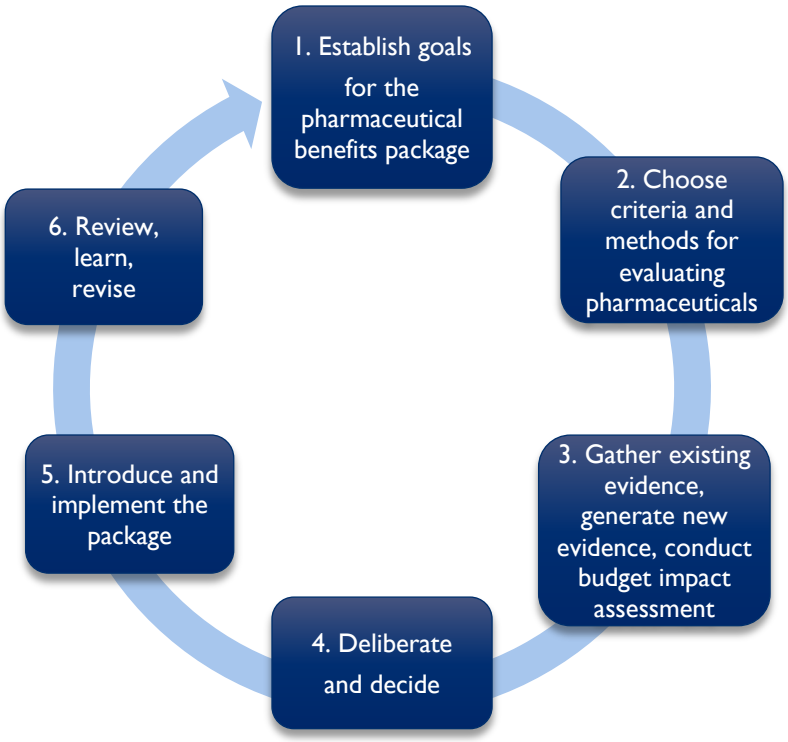
Defining the country's priority health conditions and services to be covered should also take place prior to defining the PBP. Ideally, the process of defining a PBP should not start with individual molecules of pharmaceuticals to be included, but rather derive from the priority services and interventions for that context. Information on the approximate levels of funds available for pharmaceutical purchasing -- from past years' budgets or expenditures – should ideally be available as well. While the available budget should not be the basis on which a PBP is built, resource availability will influence decision-making process.

A framework can be useful to organize the process of defining a pharmaceutical benefits package. The framework developed by Glassman et al. (2016) is particularly relevant here because it provides step-by-step guidance for defining HBPs and linking them to UHC. As a vital part of any HBP, and often a major

cost driver, pharmaceutical benefits should be derived from the services/interventions prioritized, and then defined explicitly to confer maximum financial protection to members eligible for the benefits (5).

Figure 1 offers an adapted framework building on Glassman et al. for defining a pharmaceutical benefits package. The steps are shown as a cycle rather than a linear process to reflect that pharmaceutical benefits should be regularly reviewed and revised to suit changing needs.

Figure 1: Defining a pharmaceutical benefits package



In the rest of this brief, we apply this framework to the specifics of designing pharmaceutical benefits packages.

Who should be involved? Throughout the process described below, it is essential to involve stakeholders both inside and outside of government. Much like the process of defining a HBP, representation of varied backgrounds and interests throughout the process of defining a pharmaceutical benefits package is critical to its success (11). While the group responsible for defining (or refining) a HBP should be representative of a broad group of interests and expertise, defining a PBP requires special attention to pharmaceutical knowledge and expertise. Although the exact stakeholders to be involved will depend on the context and structure of the pharmaceutical system in the country, the WHO's early EML formulation guidance recommends an expert committee comprised of clinicians, pharmacists, pharmacologists, and other health workers set the national EML (14). Other stakeholders relevant to pharmaceutical benefits package design may include: policy makers from the Ministries of Health and Finance; patient advocacy groups; civil society representatives; and potentially representatives from the private sector (e.g., private providers, provider associations). Experts with knowledge of the pharmaceutical manufacturing sector in the country (if applicable) and pricing, procurement, and regulation within the country should also be consulted. In some cases, ethicists and legal experts may also be consulted.

Not all stakeholders will need to participate in all of the same steps or to the same degree, and roles and responsibilities for the process should be communicated clearly in advance of the benefits package design process and adhered to throughout (1). See country example 1 below for an example of multistakeholder engagement throughout the Thai process.

KEY STEPS IN DESIGNING A PHARMACEUTICAL BENEFITS PACKAGE

1. ESTABLISH CLEAR GOALS FOR THE PHARMACEUTICAL BENEFITS PACKAGE

The first step will lay the foundation for the rest of the process; decision makers should articulate what goal(s) they hope will be achieved through the process of establishing and implementing a pharmaceutical benefits package. As noted above, this should all be framed within the broader health benefits policy conversation so that the PBP is well integrated within the HBP; at the highest level the goals will align: to advance the country toward UHC. The overarching goals of any pharmaceutical benefits package should be to improve access to and financial protection around pharmaceuticals and achieve greater efficiency in resource allocation. More granular, specific goals may be to promote safe and rational use of certain medicines or ensure quality of a type of medicines included (11).

A country's first effort to define a pharmaceutical benefits package may have different goals from its subsequent routine revisions, which may aim to fine-tune or update the benefits. For example, in a country with poor child health outcomes, policymakers may consult epidemiological data to identify the main causes of child mortality, and then select and prioritize interventions and pharmaceuticals to help reduce child mortality. Once there is a pharmaceutical benefits package to revise, the goal may be to either replace pharmaceuticals that are no longer cost-effective or determine whether expansion into new technologies is financially feasible and introduce new technologies, or some combination of the two. If there is an alternative drug, this may also be considered during such a revision (5). Clear goals for the pharmaceutical benefits package will determine the direction for the remainder of the steps.

Decision makers should also articulate general principles for including or excluding specific pharmaceuticals from the package to help direct future analyses. Considerations for pharmaceuticals may include safety and efficacy, availability from local manufacturers, and potential availability of generics (see country example 2 below for an illustrative list of considerations from Indonesia's National Formulary).

COUNTRY EXAMPLE 1: HTA AND STAKEHOLDER INVOLVEMENT IN THAILAND

Thailand's Health Technology Assessment (HTA) process is noteworthy in the Asian region. Housed within the International Health Policy Program, the Health Intervention and Technology Assessment Program (HITAP) is a semi-autonomous body in the Ministry of Health charged with providing evidence on health services and pharmaceuticals to decision makers (15). HITAP conducts reviews of the services included in Thailand's Universal Coverage Scheme, which now covers 75% of the Thai population, as well as the pharmaceuticals on its National List of Essential Medicines that are eligible for reimbursement under all three of Thailand's health coverage schemes (16).

Topic selection and stakeholder voice: Several multistakeholder groups contribute to the Thai HTA process, including the subcommittee for the development of the Benefits Package and Service Delivery (SCBP), Health Economic Working Group (HEWG), Health Systems Research Institutes, and topic nomination committee (16). The **HEWG** includes health economists, academics, representatives from the health insurance sector, and the Ministry of Health—particularly those involved in HTA

processes and establishment of an EML (17). The **working group on topic selection** determines which items should be considered for inclusion in (or exclusion from) the benefits package; it comprises three to four individuals representing policymakers, health professionals, academia, patient associations, civil groups, the health care industry, lay citizens, and the committees under the SCBP (16).

These stakeholders follow established process guidelines for deliberation, which delineate how and when stakeholders can offer input for studies on medicines to be included in the EML. The HEWG also considers economic evidence from private companies before presenting their results to the Sub-committee, which makes the final decision about which medicines to include in the EML.

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2. CHOOSE CRITERIA AND METHODS FOR EVALUATING AND COMPARING PHARMACEUTICALS

Step 2 builds on the general principles articulated in step 1 to identify specific criteria for evidence that will be generated or considered in including or excluding a pharmaceutical. Key characteristics of an appraisal method—a method of generating and evaluating evidence—are that it should be robust and justifiable, reflective of social values, easy to understand, and relatively inexpensive to implement (1). According to the WHO, health technology assessment (HTA) is a multi-disciplinary process to systematically evaluate the properties, effects, issues, and/or impacts of a health intervention or technology (18). A number of institutions have been established around the world whose sole purpose is to conduct HTA to evaluate a particular service or pharmaceutical in a given context (including HITAP in Thailand).

WHO's Southeast Asia Regional Office has acknowledged the value of HTA and encouraged member states to use HTA to inform decision making and support collaborative learning across countries in the region (19). HTA provides a multidisciplinary consideration of benefits and consequences of a health technology, such as a medical product or pharmaceutical. HTA is a broad term encompassing several methods decision makers can use to evaluate pharmaceuticals under consideration and inform decisions (see note above on Thailand for examples). In the MTaPS publication, "A Roadmap for Systematic Priority Setting and Health Technology Assessment," the authors found that while many of these international HTA networks have a wealth of resources including past HTA reports, policymakers relying on those resources must account for the context in which the pharmaceutical would be introduced (20).

A range of HTA appraisal methods can inform decisions to include or exclude a pharmaceutical benefit. Each of these methods has unique advantages and limitations; there is no "one size fits all" solution to determining whether a pharmaceutical should be included. Which appraisal method is used will depend on the country context. Below we outline selected methods within HTA that may be useful for determining a benefits package and offer examples of how each has been used to inform decision making.

Cost-effectiveness analysis (CEA) provides an estimate of a pharmaceutical's return on investment in terms of how much health outcomes may improve. Cost-effectiveness is typically reported as an incremental cost-effectiveness ratio (ICER), or the additional costs incurred per the incremental benefits gained (such as the cost per disability-adjusted life year [DALY] averted) (21).

As a concrete example, in a Thai study of cost-effectiveness of two HIV/AIDS treatments, researchers compared the use of Nevirapine (NVP)-based and Efavirenz (EFZ)-based regimens for patients with varying CD4 counts in various age ranges (22). In some cases, the use of NVP has led to complications that could cause serious adverse effects on the patient's quality of life and also require long-term medical

care, with its associated costs. Selected results of this cost-effectiveness study are shown in table 1; ICERs are reported in Thai Baht per DALY averted. For a 20-year-old, beginning with an EFZ-based regimen costs 1.2 million Baht per DALY averted more than a NVP-based regimen. For all other ages, the negative ICER suggests that starting with an EFZ-based regimen is less expensive and more effective at reducing DALYs than an NVP-based regimen (22).

Table 1: ICER of starting with EFZ-based regimens compared with NVP-based regimens, by age group (for CD4 count of 200)

A. Age (years)	B. Lifetime cost of EFZ-based regimens (1,000s)	C. Lifetime cost of NVP-based regimens (1,000s)	D. DALY averted, EFZ-based regimen	E. DALY averted, NVP-based regimen	F. Baht per DALY averted (1,000s) = (B-C)/(D-E)
20	1,954	1,744	6.25	6.08	1,200
30	1,758	1,969	5.98	5.82	-1,342
40	1,532	2,027	5.59	5.45	-3,677
50	1,277	1,892	5.02	4.90	-4,900
60	982	1,560	4.23	4.14	-5,912

CEA results such as the ones above could be used with budget information (step 3) to determine whether a particular medical product should be included in a benefits package or whether there is a more cost-effective alternative.

Cost-benefit analysis (CBA) estimates the costs and monetary value of benefits from a particular intervention or drug and then determines the difference between costs and benefits, which can indicate whether a pharmaceutical product's benefits outweigh its costs (or vice versa) (1).

In a CBA of diagnosis and treatment of leptospirosis, researchers considered five approaches, including no diagnosis or treatment, empirical treatment with antibiotics, and treatment with antibiotics following one of three diagnostic tests (23). Table 2 shows the results of this CBA.

Table 2: Benefit-cost ratios for the different strategies

Strategy	Direct costs (USD)	Productivity loss (USD)	Benefit-cost ratio
No –antibiotic- treatment	13.26	28.4	(Baseline)
Empirical treatment	2.70	11.8	−1.57*
Latex test	15.41	22.6	2.68
Lateral flow test	17.30	25.5	0.71
MCAT	17.23	25.4	0.75

*The negative value is a result of the empirical treatment strategy being both less expensive and more effective than the *no –antibiotic-* treatment baseline
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Source: Suputtamongkol Y et al., 2010

Both costs and benefits are compared to the baseline strategy (no antibiotics), and benefits are estimated in decreased loss of productive days (i.e., how many days of productivity would be gained with a particular strategy). The final column shows each strategy's benefit-cost ratio (BCR): the ratio of the change in benefits to the change in costs. A BCR of more than 1 indicates that benefits outweigh costs (or the added benefit of a particular strategy outweighs the added costs). In table 2, the empirical treatment led to decreased costs and increased benefits (less productivity lost). The latex test strategy led to increased benefits but at an increased cost; the other two strategies were the least cost-beneficial.

For more details and considerations of CEA, CBA, and other appraisal methods, readers can refer to Chapter 4 in the MTaPS HTA Roadmap (20).

3. Gather existing evidence, generate new evidence where needed, and conduct budget impact assessment

Following the selection of appraisal methods, this step involves determining how decisions will be made regarding inclusion or exclusion of pharmaceutical benefits and gathering or generating evidence to inform those decisions. This step should also include implementation of the appraisal(s) identified in step 2 (i.e., CBA, CEA). Policymakers should gather evidence—specific study results or existing benefits packages—from relevant neighboring countries or contexts that are similar in terms of burden of disease, and priorities for pharmaceutical coverage (as outlined in step 1). This evidence can be useful in terms of benchmarking and comparing, however decisionmakers will need to account for the demographic differences in covered populations and ensure the pharmaceutical benefits package fits within the available financial resources.

After the evidence has been reviewed and any new appraisals have been completed, **budget impact analysis** (BIA) should be carried out to determine the financial impact of including the prioritized pharmaceutical products in the benefits package—that is, what it will cost to include a particular pharmaceutical in the benefits package (24). BIA for pharmaceutical benefits packages involves building cost scenarios for adding coverage for a given pharmaceutical product to estimate how its inclusion would affect the overall budget, based on expected utilization and demographic patterns. These would vary based on the characteristics of the population covered by the pharmaceutical package and costs of alternative pharmaceuticals (25). BIA may also be used to analyze the result of excluding a pharmaceutical or changes in treatment or prescribing protocols or service levels.

An additional analysis that can provide valuable evidence for policy and decision makers is a **costing** of the pharmaceutical benefits package, which can serve different purposes depending on assumptions underpinning the exercise (1). A variety of tools have been used to cost health benefits packages; MTaPS conducted a review of these tools to determine which would be most suitable for costing pharmaceutical benefits packages. Based on criteria such as flexibility to adapt to different treatment guidelines, ability to cost specific disease packages and project costs into the future, acceptance by experts, and potential use in-country to cost health benefits packages, the OneHealth Tool was identified as the best option. MTaPS further developed guidance on how to use the OneHealth Tool to cost pharmaceutical benefits packages. [1]

[1] A review of existing costing tools, including recommendations for a tool to cost pharmaceutical benefits packages and instructions for how to use the tool, can be found in separate MTaPS reports: Costing Pharmaceutical Benefits in Asian Countries, parts 1 and 2.

Applications may include a full costing of the comprehensive benefits package to understand the cost of providing the full package to beneficiaries or a more focused look at the costs of including an individual component to inform revisions to a package. While some costing models allow for projections of future demographic and utilization changes, a single costing exercise cannot perfectly predict how the roll-out of a new pharmaceutical benefits package (or modifications to an existing package) might affect the demand for services or pharmaceuticals. Therefore, packages should be reviewed and routine costing updates should be conducted periodically (1,26). Funding available for a pharmaceutical benefits package is widely recognized as the major limiting factor for achieving effective, sustainable population coverage. Without a clear picture of available funding, a pharmaceutical benefits package will not be affordable over time. Possible funding sources could include allocations from the government's budget, premiums paid by beneficiaries of the scheme (if any), copayments made at point of care (balancing concerns of equity and ability to pay), and donor contributions. An estimate of fiscal space available for pharmaceutical benefits should be accessible based on prior years' allocations to the pharmaceutical budget and will be a good starting point for comparison. The available envelope is important to consider in this step, but even more in step 4, as that is where decisions on inclusion or exclusion are ultimately made.

4. Deliberate and decide on pharmaceuticals to be covered

In this step, the working group or committee should weigh options based on the appraisals conducted and results of the BIA. Following the deliberations, recommendations for pharmaceuticals to be included in the benefits package should go to final decision makers for their consideration (if different from the group weighing evidence and making recommendations, although decision-makers may also be a subset of the group). Decision makers should weigh these recommendations against the available resources and results of the BIA to ensure the proposed package is affordable. If additional resources are needed, policy makers may choose to pursue options to generate additional resources (including cost-sharing with patients) or they might remove pharmaceuticals from the package (i.e., pursue a different scenario from the BIA with a different mix of pharmaceuticals) (1, 27).

Country example 2: Indonesia's Formulary

Indonesia's national formulary (*Formularium Nasional* or FORNAS) lists all the drugs providers can prescribe to patients free of charge. Criteria for selection of drugs into FORNAS include (28):

- Scientifically validated efficacy and safety
- Benefit-risk ratio most beneficial to patients
- Approved by Food and Drug Supervisory Agency
- High benefit-cost ratio
- Combination therapies are acceptable provided the combination is at least as effective and safe as its component parts and is more beneficial for patients

According to Indonesian policy, FORNAS is to be revised comprehensively every two years with more regular reviews allowed between. Proposed revisions to the FORNAS may be collected online or submitted by representatives from government and private hospitals, professional medical and dental associations, district and provincial health offices, or the program management unit in the Ministry of Health. The National Commission for the Compilation of FORNAS is tasked with these revisions and

includes a team of independent scientific review experts, who must document that they have no conflicts of interest. The expert commission conducts a public plenary meeting where they jointly review available scientific evidence on proposed additional drugs, develop a list of recommended additions, and present these to the Minister of Health for final approval. The specifics of how additional drugs will be paid for are not considered part of the mandate of the Commission – deliberations are meant to focus entirely on scientific evidence of benefits and safety (28).

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5. Introduce and implement pharmaceutical benefits package reforms

This step entails the processes necessary for the benefits package to become a reality, bearing in mind the goals laid out earlier in the process (5). The body responsible for implementing and managing the package will have a number of key responsibilities, including communicating changes to providers, beneficiaries, and other stakeholders; overseeing quality assurance; and processing, vetting, and paying provider claims (11).

Once a pharmaceutical benefits package is set, there will be implications for resource allocation. If, for example, the coverage scheme handles procurement of pharmaceutical products, resources will need to be allocated to cover the associated costs of procurement and distribution. Arrangements to reimburse providers for pharmaceuticals prescribed to patients covered under the scheme will need to be made (2).

6. Revisit and revise

Finally, policy makers should establish a plan for how revisions to the pharmaceutical benefits package will be made and at what intervals. How frequently a pharmaceutical benefits package is revised will depend on the country context and coverage goals (step 1), but the process should be publicly known and adhered to, particularly if external nominations for pharmaceuticals are accepted for consideration. Policymakers may opt to conduct revisions of the pharmaceutical benefits package at the same intervals as the HBP. Though few countries have established routine revisions, Indonesia's National Formulary is revisited every two years (5, 28), as is the WHO's Model Lists of Essential Medicines (14).

Regular revisions can help account for changes to any of the key steps above, including changes to goals or beneficiaries of the package or to the funding or evidence available to inform its design. The addition of new technologies or treatment protocols should also be considered at any revision. In the Philippines, PhilHealth has expanded its benefits over the years and even introduced a new package in 2012 to cover expensive treatments for chronic conditions (see country example 3 below). Decision makers may revisit prior analyses, consider new evidence, or conduct new evaluations to feed into step 4. Revisions can also account for results of post-approval surveillance, changes in evidence of appropriateness, or new protocols for a pharmaceutical, as well as removal of obsolete or less cost-efficient alternatives. As routine updates take place, they should be communicated to beneficiaries and stakeholders.

Countries may also perform ad hoc revisions to address specific, often unforeseen needs. In India, for example, the COVID-19 pandemic put significant stress on health care facilities and lower-income individuals in need of testing and treatment. As the country faced a rising number of COVID-19 cases, in April 2020 the National Health Authority (NHA) in India revised the health benefits package under the Pradhan Mantri Jan Arogya Yojana (PM-JAY) health assurance scheme to offer free testing and treatment through private facilities (29). Importantly, the NHA maintained room for flexibility under the unprecedented circumstances, allowing for revision of rates of pre-existing COVID-19 treatment packages and customization of these packages by individual states (30). When the NHA found limited

use of the package, the NHA directed state health agencies to link empaneled hospitals to private labs for testing (30).

COUNTRY EXAMPLE 3: PHILHEALTH AND Z BENEFITS

As countries experience shifts in demographics and burden of disease, they may face decisions about covering more expensive treatments for chronic conditions. The Government of the Philippines, along with the Philippine Health Insurance Corporation, or PhilHealth, have taken several notable steps over the years to improve financial risk protection for Filipinos (31).

Introduced in 2011, the "Z Benefits" package is an entitlement for all members of PhilHealth that covers treatment (including cost of drugs and lab tests) for some of the most expensive diagnoses, such as end-stage renal disease, heart disease, several cancers, and certain disabilities in children, among other conditions. The Z Benefits, along with PhilHealth's inpatient and outpatient benefits, are listed on the PhilHealth website, along with accredited facilities for each category of service (32). The package was expanded in 2015 to cover two additional types of cancer (33).

All citizens of the Philippines are automatically enrolled in PhilHealth, as outlined in the UHC Bill of 2019, and while this combined with the Z Benefits marks a strong commitment to UHC, covering the full population comes with a cost. The Government has introduced various sin taxes (on alcohol, tobacco, and sugar-sweetened beverages), the revenues from which have helped increase the allocation of resources to health (33).

CONCLUSION

Determining the package of pharmaceutical products to which a certain population is entitled is an important component of health benefits policy, especially as countries work toward UHC. This brief has built on the MTaPS mapping report on coverage arrangements in the Asia Region and outlined key steps in the process of articulating or revising such a pharmaceutical benefits package. It has suggested that a variety of stakeholders—representing Ministries of Health and Finance, experts from the pharmaceutical sector such as pharmacists or drug procurement directorates, along with ethicists and legal experts—should be involved and consulted throughout the process to identify the interventions and assess the interventions costs.

Defining pharmaceutical benefits should not be a one-time exercise, rather it should be grounded in other health benefits policy, aligned with the service benefits package, and revisited regularly, with clear goals and based on evidence. The definition process can be an important policy tool for ensuring the efficiency of limited public resources and maximizing the value of health attained per dollar spent. While pharmaceutical benefits packages alone cannot guarantee that all beneficiaries will be able to access quality care and affordable medicines, they represent an important piece of health benefits policy with the goal of ensuring efficiency, financial protection, and universal coverage.

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