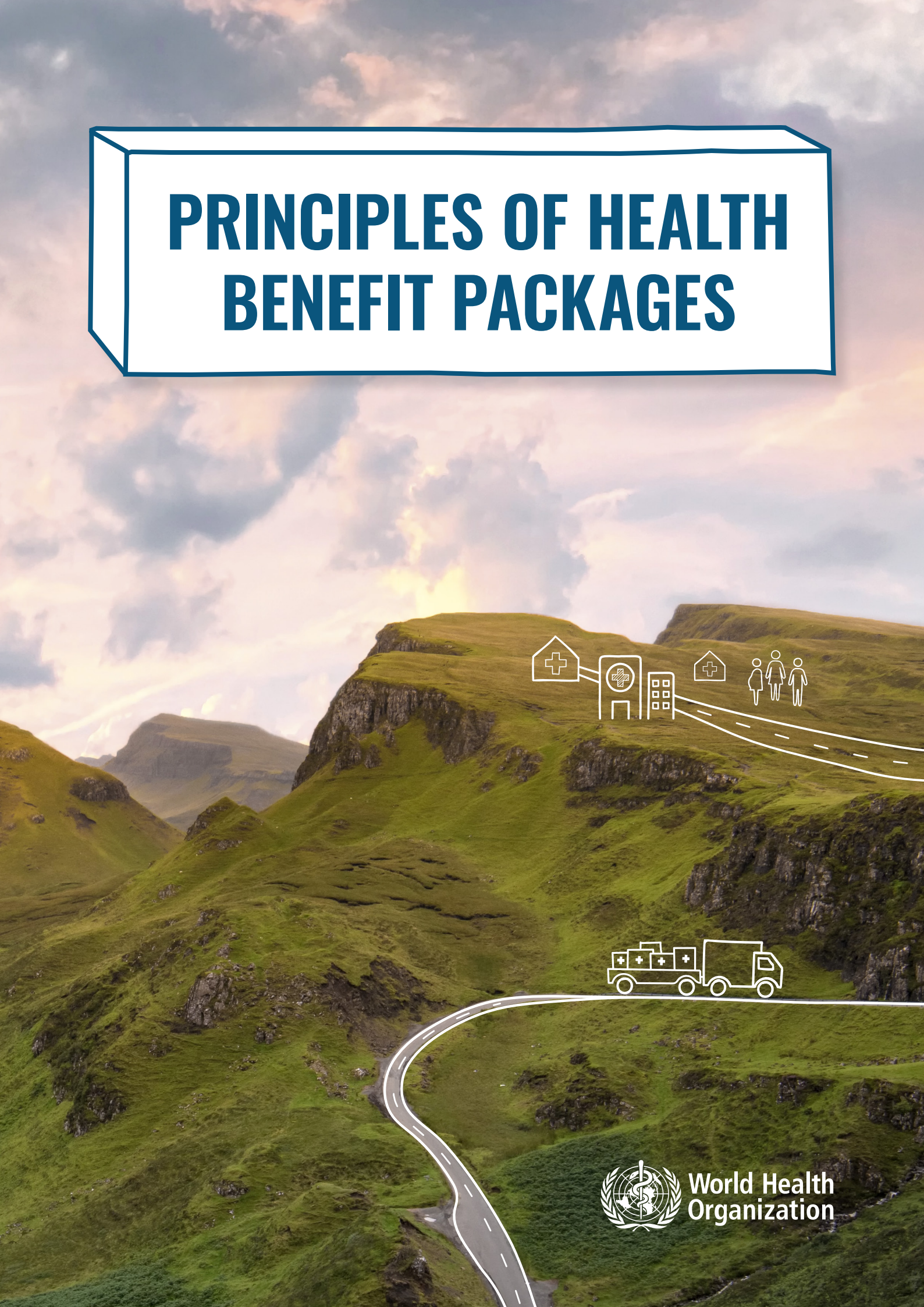
PRINCIPLES OF HEALTH BENEFIT PACKAGES



World Health Organization

Principles of health benefit packages

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Introduction

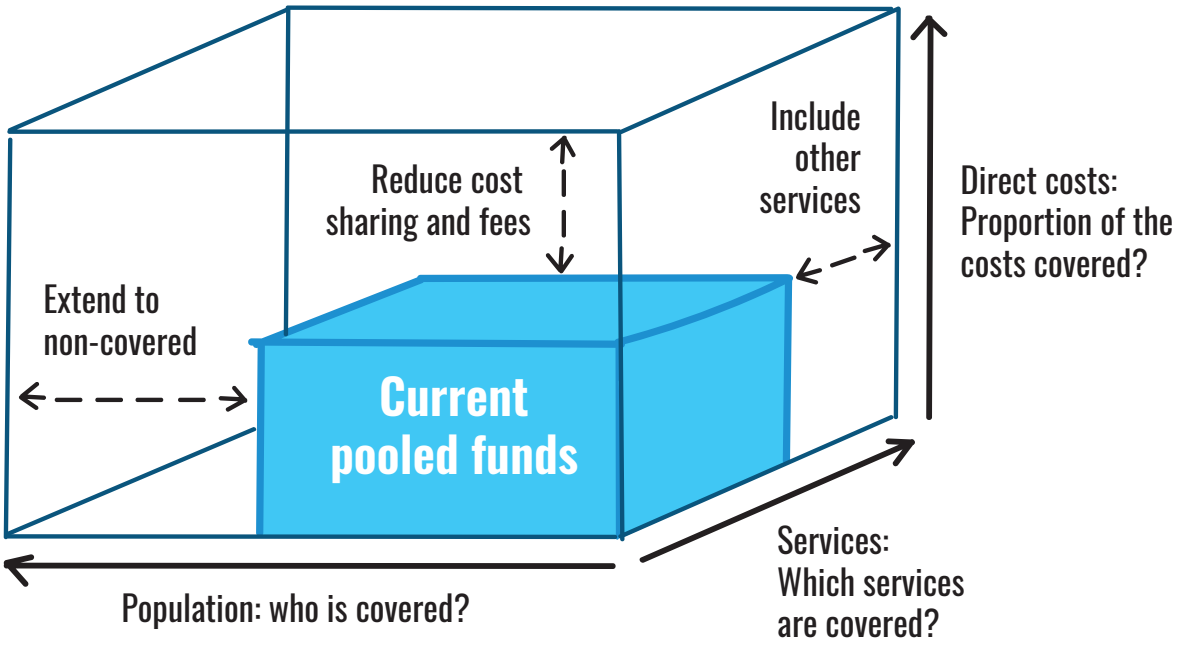
All UN Member States have signed up to the Sustainable Development Goals (SDGs) including target 3.8: "achieve universal health coverage (UHC), including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all." The World Health Organization supports Universal Health Coverage through is Global Programme of Work, empowering countries to expand the reach of UHC. Part of this process is to support the identification of context specific health benefit packages.

The path to UHC will vary from country to country, and there is no 'one-size-fits-all' approach. Local context, history, the existing health system, values and available resources will shape how countries finance and scale up services in their progressive realization of UHC. UHC reform entails securing robust financing for essential services that are available to everyone who needs them, without financial hardship. Since available resources are scarce, priorities must be set, and many countries have found it useful to define high priority services, or packages of essential health care services, that will define the core of what should be made available to all citizens from public funds. In this way, UHC will promote better health for all, with equity, with quality and without financial hardship.

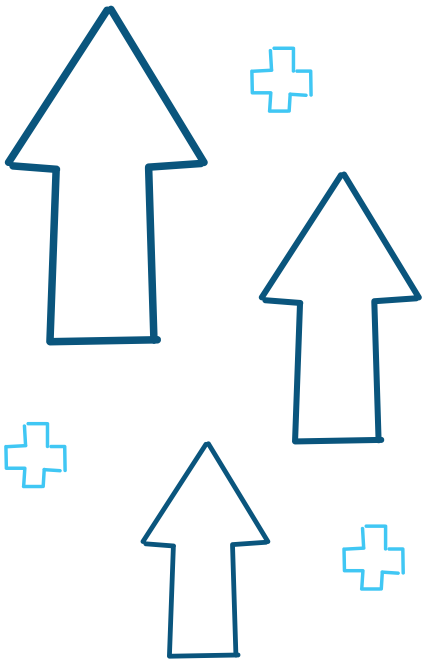
Why defining essential health care services is key

WHO's consultative group on equity and universal health coverage noted that to achieve UHC, countries must advance in at least three dimensions, as previously identified in the 2010 World Health Report (see Fig).2,3

Figure 1: The "UHC Cube" representing the three dimensions of improvement required for Progressive Realization of UHC



Define and scale up essential health services, include more people until there is universal access.



Countries must define and scale up essential health services, include more people until there is universal access, and reduce or eliminate out-of-pocket payments for all essential services. Without defining which services are essential and where and by whom they should be provided to have a health impact, it is hard to scale up all possible services with sustainable funding. No country in the world is able to provide everything to everyone from public funds. Choices must be made on the path to UHC.

Within every health system, current service provision contains a health benefit package, which may be explicit in some cases, or implied in others. By creating an explicit health benefit package, countries can begin to establish guarantees for service access. Citizens should be aware of what they are entitled to receive, and what responsibilities they have for accessing services. In order to select the health benefit package, difficult decisions must be made about what the country can afford to deliver through public funds. This involves a series of trade-offs, whereby different, often opposing, priorities and criteria are balanced against each other in order to develop an explicit package. For example, a country may need to choose whether to spend its limited resources on scaling up HIV screening and testing or second-line HIV treatment. If the country considers maximisation of population health as its main criterion, it may prioritise the former service (other things equal). In contrast, if the country considers it more important to take care of the worst-off segments of its population (here: severely ill HIV patients), it may prioritise the latter service.

Most countries have historically defined high priority services through national planning documents, five-year strategic plans and annual budgets. National priorities have often been sound and reasonable, although sometimes ad hoc and sometimes with lack of clarity. Today, many countries are now in the fortunate position that there is more evidence available than ever before for better priority setting. Whilst not yet the case for every country, in many cases as investments in strong data systems intensify, ministries of health and finance increasingly have access to databases, reports, national and international research that can help them make better decisions informed by evidence on the burden of disease in their country, which programs and services are most effective, and at what cost.

By changing from ad hoc or implicit priority setting and rationing of services, to systematic, evidence-based and transparent priority setting, countries can substantially improve health outcomes, improve access to important high-quality services and achieve national and global SDG targets. Countries can move towards a health system where there is universal access to services that improve health the most, for those with greatest needs. Countries that have made systematic priority setting a key component of their health system include New Zealand, Australia, Thailand, the Philippines, The Netherlands, Sweden, Norway, England, Ethiopia, Chile and Mexico (see table 1).

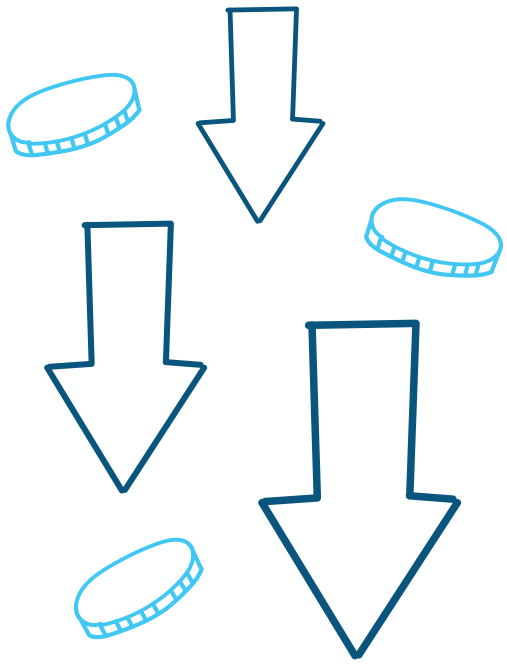
Table 1: Examples of systematic priority setting processes in countries (note list non-exhaustive)

Australia	Pharmaceutical Benefits Advisory Committee	https://pbac.pbs.gov.au/
France	Haute Autorité de Santé	https://www.has-sante.fr/
New Zealand	PHARMAC	https://www.pharmac.govt.nz/
Norway	Norwegian Institute of Public Health	https://www.fhi.no/en/
Sweden	Swedish Council on Technology Assessment in Health Care	https://www.sbu.se/en/
Thailand	Health intervention and Technology Assessment Programme (HiTAP)	http://www.hitap.net/en/
The Netherlands	The National Health Care Institute (Zorginstituut Nederland)	https://www.zorginstituutnederland.nl/
The Philippines	Sentro ng Pagsusuring Teknolohiyang Pangkalusugan (STEP)	https://www.doh.gov.ph/node/16220
Tunisia	National Authority for Assessment and Accreditation in Health Care	http://www.ineas.tn/fr
Mexico	Centro Nacional de Excelencia Tecnológica en Salud	https://www.gob.mx/salud/cenetec

Developing a health benefit package is not a one-off action – it is a dynamic process, with the package changing over time as countries develop. As fiscal space grows, epidemiological profiles change and more information about interventions becomes available, a process to revise decisions should be in place.

This note explains guiding principles for the process of selecting essential health care services. This can serve as useful input to the planning process. A more practical, step-by step guidance is under development and will be available later. Additional resources can be found in the reference list. [4-10]

Reduce or eliminate out-of-pocket payments for all essential services!



The 8 principles

Countries that have proactively adopted systematic priority setting have typically followed all or most of the following eight principles:

1. Essential benefit package design should be impartial, aiming for universality
2. Essential benefit package design should be democratic and inclusive with public involvement, also from disadvantaged populations
3. Essential benefit package design should be based on national values and clearly defined criteria
4. Essential benefit package design should be data driven and evidence-based, including revisions in light of new evidence
5. Essential benefit package design should respect the difference between data, dialogue, and decision
6. Essential benefit package design should be linked to robust financing mechanisms
7. Essential benefit package design should include effective service delivery mechanisms that can promote quality care
8. Essential benefit package design should be open and transparent in all steps of the process and decisions including trade-offs should be clearly communicated

In what follows, these key principles are described and discussed.

1. Essential benefit package design should be impartial, aiming for universality

Universality in this principle refers to all citizens or residents of a country having access to the same level of service provision, regardless of their ability to pay.

Priority setting in the context of essential health benefit package design for UHC will decide 'what is in and what is out', and even more importantly, 'who gets access to what services'. This process will create an explicit rationing system, where not everyone will have access to everything that will benefit them.

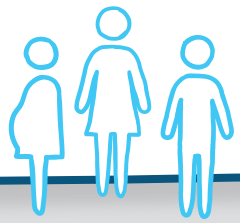
Countries should follow processes of progressive universalism and progressive realisation in order to achieve universal health coverage. In the context of this paper, progressive universalism refers to the process of ensuring all people within a country have access to the same package of services regardless of their ability to pay, thus moving along the coverage axis of the cube described in figure 1. Progressive realisation refers to increasing the scope of the service package over time as financial space increases, thus moving along the services axis of the cube.

In the scale-up phase, certain health services may not initially be selected into the essential package, as they are unaffordable. Citizens in need of such services may have to pay more or not get access to them. It is therefore crucial that the process of decision-making is evidence-based, unbiased, impartial and fair, and that it be seen as fair by all affected parties.

A useful starting point for countries in moving towards UHC can be the financing of common goods for health, defined as population-based functions or interventions that require collective financing, either from the government or donor sources. Common goods for health include such interventions as health taxes, regulations, and policies many of which do not rely on a well-functioning health system and as they have impact across the whole population are considered equitable by definition.

It is therefore crucial that the process of decision-making is evidence-based, unbiased, impartial and fair, and that it be seen as fair by all affected parties.

2. Essential benefit package design should be democratic and inclusive with public involvement, including from disadvantaged populations



Avoiding conflict of interest and sheltering the process from undue influence is a key factor in gaining public trust and ensuring legitimacy in the process. Transparency in all steps of the process can, to a certain extent, secure impartiality, fairness and legitimacy.

Legitimacy and trust can also be enhanced by making sure that the process of defining the essential package is democratic and inclusive. A sound principle is that all affected parties, all stakeholders and their interests, should be represented in the process and able to make their voices heard on conditions of rough background equality. This can be facilitated by user-representation in all steps of the process, and measures to ensure views expressed are meaningfully considered as opposed to symbolic.

It is especially important to include marginalized and historically discriminated groups, and groups that may require specific health services, including women and persons with disabilities. Many countries have experienced good results by involving civil society and patient representatives in the benefit package selection process. All stakeholders can be consulted about the final decisions on 'what's in and what's out' through a formal hearing process, by access to an appeals process or other structured participatory process.

When the conditions are appropriate, this enables relevant data and evidence to be evaluated from multiple perspectives. Throughout this process, the careful management of potential conflicts of interest is crucial to ensure trade-offs made adhere to the processes developed by the country.

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3. Essential benefit package design should be based on national values and clearly defined criteria, including explicit reference to trade-offs

Every country or jurisdiction will decide on national policy goals, and criteria for defining their own essential health services. A legitimate, fair decision-making process will begin with a transparent and inclusive identification of the criteria in the local setting, with all appropriate stakeholders included in the criteria selection process. Policy goals and core values in many settings include health promotion and health improvement, equitable access to services and fair distribution of health outcomes, quality, fair financing and financial risk protection. Non-discrimination and solidarity are other core values.

Social values play an important role in the selection of benefits. Social and political acceptability is also important, but must respect norms against legal or de facto discrimination against any given population or stakeholder group.

One overarching goal of essential benefit packages is to maximise the health status of the population within the available budget. Many other criteria may also be important, and they need to be weighed against the health maximization criterion. Every decision made about which interventions to fund is an implicit decision also about what is not funded or what will be excluded from the benefit package.

The list of criteria for the selection of essential services will often include some or all of the criteria shown in table 2 on the next page.

Every decision made about which interventions to fund is an implicit decision also about what is not funded or what will be excluded from the benefit package.

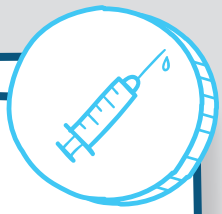
Table 2: Possible criteria for essential health benefit package decision making

Burden of disease	The health loss from diseases, injuries and risk factors at the population level; it is usually expressed in a measure that combines morbidity, mortality and disability
Balance of benefits and harms	The balance of health benefits and harms reflects the health impact of an intervention on individuals or populations
Cost-effectiveness of interventions	The value-for-money of the intervention (usually expressed as a ratio of the costs of the intervention to its benefits).
Equity and priority to the worse off	A qualitative or quantitative measure of the ability of the intervention to address existing inequalities in the health system
Financial risk protection	The extent to which individuals, households or communities can afford the cost of the intervention and are protected from catastrophic health expenditure and health-related financial risk
Budget impact and sustainability	A measure of the resources needed to implement the intervention. For budget impact this is the overall financial implications of implementing the intervention for the available national health budget
Feasibility	The extent to which the intervention can be delivered through the existing health system taking into account available human resources, infrastructure and other resources and whether it is socio-culturally acceptable to the public
Social and economic impact	The societal consequences resulting from the intervention, for instance in terms of stigma, societal cohesion; as well as the broader economic consequences, such as national development and poverty reduction goals.
Political acceptability	A measure of the acceptability to the decision makers

Trade-offs between conflicting goals and values may be necessary, and the selection of different criteria can lead to different decisions. Explicit priority-setting makes these trade-offs transparent and enables all stakeholders to understand the justification for such decisions.

All countries must ensure through their benefit package selection process that available resources are used in the most efficient manner, by ensuring that the greatest possible health benefits are achieved within the budget constraint. Where alternative criteria are prioritized, clear communication of the health loss resulting from the trade-off must occur. Every decision within a finite (whether growing, stable or diminishing in absolute or relative terms) budgetary allocation carries an opportunity cost; i.e. allocating funds to one intervention means that other services which may well have produced more health, protected the most vulnerable from impoverishment or improved access for the least advantaged, will not be provided.

The epidemiological characteristics of the society and the cultural and social aspects are changing over time and that means that not only new technological solutions and new innovative frameworks of organisation should be considered for inclusion in health benefit packages, but also new pathologies, new cultural paradigms and evolving epidemiological profiles.



4. Essential benefit package design should be data driven and evidence-based, including revisions in light of new evidence and changing epidemiological profiles

To select essential health services, decision makers need information about each of the selected criteria (see table 2), and to define a standard measurement and reporting process. This measurement may be qualitative or quantitative and can evolve over time as data and capacity increases but should be consistent across all interventions considered for inclusion.

Reporting of the data or qualitative assessment corresponding to each criterion should clearly acknowledge and depict the uncertainty within the estimate and the applicability of the estimate to the local setting. This is particularly relevant for economic evaluations, where data from other settings is often borrowed and applied, with limited adaptation to local service delivery models.

Modelled quantitative values should wherever possible include locally collected data and acknowledge system constraints which will reduce service quality, including actual quality of care in the local setting and at different levels of care. In addition, the costs and distributional impacts of interventions can be critical to the reliability of the data informing the decision-making process and can only be drawn from local data sources.

This information is not always available for all causes and programs but should as far as possible be collected and analysed in a consistent way, based upon scientific evidence, free from ideological and rent-seeking interests.

As new evidence comes to light, and the epidemiological profile of populations change, revisions to the benefits package are unavoidable. Each country should identify a regular schedule for revisions, based upon the current disease burden and future expected innovations and budgetary increases that may lead to either additions to the benefit package, or the decision to disinvest from intervention that are no longer meeting the needs of the population.

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5. Essential benefit package design should respect the difference between data, dialogue and decision

the three D's

In the context of essential benefit package design, WHO has described the process in terms of the three D's: data, dialogue and decision.[11] For the purpose of essential benefit package design, it is important to recognize that data and dialogue processes (assessment and appraisal in HTA language) follow academic transparent methods (often led by experts) that can help accountable decision-makers conclude whether a program or an intervention should be included in the essential package or not (often led by Ministry of Health, or the Minister themselves as the person designated by law to balance the health sector budget).

The data phase is considered a critical scientific phase, where conflicts of interest must be avoided, and rigorous scientific methods followed. In the dialogue phase all appropriate stakeholders are represented in a transparent deliberative process, using the data from the first phase as a basis for discussion, but without the ability to influence the quantification or qualitative assessment of each criterion.

This final decision is political in the sense that those who are assigned responsibility to approve the essential package are held accountable by political mechanisms, and in the end by all citizens. They must balance a variety of considerations that may go beyond expert evaluation. It is therefore important that essential benefit package design respect the difference between data, dialogue and decision processes.

According to standard terminology in the health technology assessment literature, the process of evaluating a new technology (broadly defined) is divided into three steps: assessment, appraisal and recommendation (ref). Although these steps are standard terminology in HTA literature, responsibility for each of the steps varies across countries. For example, in Tunisia, the HTA body INEAS is responsible only for the assessment of data, whereas in Thailand, HITAP is responsible for assessment and for convening the stakeholder committees to appraise the evidence. Assessment is defined as "A scientific process used to describe and analyse the properties of a health technology—its safety, efficacy, feasibility and indications for use, cost and cost-effectiveness, as well as social, economic and ethical consequences." In the appraisal phase a panel of evaluators representing the stakeholders identified as appropriate by the country scrutinize, discuss and interpret the evidence and other information collected in the assessment phase in a deliberative manner. The aim is to evaluate the robustness of data, often done by using criteria and checklists for appraising the quality of evidence. Based on the appraisal, a recommendation for approval for reimbursement, yes or no, or yes if certain criteria are met, can be developed.

Most important in the separation of the three common steps is a Governance arrangement which does not allow for the undue influence of vested interests and creates an institutional space for data analysis and a separated space for the deliberative dialogue process. This can be challenging to achieve in countries where governance and institutional arrangements within the health sector need strengthening to support UHC progress. Reflecting on the legal framework within which decisions are being made can help countries identify the most appropriate institutional arrangements to support decision making.

It is therefore important that essential benefit package design respect the difference between data, dialogue and decision processes.

6. Essential benefit package design should be linked to robust financing strategies

A key element of UHC reform is to reduce or eliminate out-of-pocket payments for all essential services. Additional public funds must therefore be made available through resource mobilization using compulsory pre-payment mechanisms (tax and/or mandatory health insurance) and effective pooling of funds to maximize income and risk cross-subsidies across socio-economic groups.[12] This is necessary to ensure that everyone is able to benefit from essential services on the basis of need and not ability-to-pay. Accurate projections of future fiscal space for health are needed in order to ensure countries can plan their journey to progressive universalism.

Every new intervention selected for the benefit package will imply a required budget increase, or a disinvestment from an alternative intervention. To ensure that adequate resources are mobilized, the magnitude of resources (financial, human, medical supplies, etc.) required for these services must be estimated accurately. If this does not occur, a situation in which implicit, ad-hoc rationing occurs may be inadvertently encouraged. As part of UHC, out-of-pocket payments for essential services should be reduced or eliminated. This implies that during scale-up, services with low or no priority may still be provided, but with higher co-payment or through private payment mechanisms

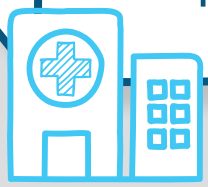
Financial resources must be translated into the delivery of quality services through active or strategic purchasing, including:

- Establishing agreements with providers which make the range, quantity and quality of service delivery expectations explicit
- Using provider payment mechanisms that incentivize the efficient provision of quality services
- Improving the efficiency of the commodity procurement process
- Promoting equitable access to these services, such as through offering higher payment rates in areas that are under-served.

A robust reimbursement mechanism, as one of the strategic purchasing strategies, should be designed to improve quality, performance and efficiency of essential services.

This final decision is political in the sense that those who are assigned responsibility to approve the essential package are held accountable by political mechanisms, and in the end by all citizens.

7. Essential benefit package design should include an effective service delivery mechanism that can promote quality care



Health services, no matter how efficacious in clinical trials, will not deliver themselves. Effectiveness of any technology judged to be a valid component of the benefit package will rely on level of quality with which it is delivered. Quality of even well-known routine services is low in many countries; this will be a challenge for new and more complex services.

Quality of health delivery depends upon effective regulation that does not: (1) leave "gray zones" where it is unclear to some or all actors what is included and what is not (e.g. the prosthetic as well as the surgery); or compliance gaps in program implementation, especially in decentralized or fragmented health systems

At the same time as the essential health benefit package is defined, health system strengthening in order to deliver those intervention needs to occur. Health systems that have achieved good health outcomes and financial protection from introduction of UHC (e.g., Mexico, Thailand) have simultaneously reformed financing and service delivery quality.

Opportunities to invest in health system quality that can be linked to introduction of UHC include: strengthening governance and learning health systems, reorganizing service delivery to maximize outcomes and efficiency, modernizing pre-service education, and involving users in providing system feedback and informing service design.

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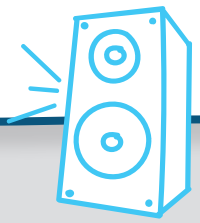
8. Essential benefit package design should be replicable, open and transparent in all steps of the process, and decisions should be clearly communicated



Good decisions are open to scrutiny, debate and criticism. By open we mean that all deliberations and reasoning are publicised in an accessible format, and that all stakeholders including historically discriminated populations can provide input into the final decision. Process is equally as important as the outcome – following the agreed decision-making rules and procedures and reporting on these is essential for transparency and legitimacy.

The decisions agreed to should be communicated openly to all citizens, including rights and entitlements to interventions included in the benefits packages, responsibilities associated with service access, and co-payments and referral pathways. Trade-offs ought to be made explicit and communicated both to the decision maker and to the public. Not all potentially beneficial services and technologies can be provided for everyone.

Decisions should also be communicated effectively to service providers, along with information on how new services will be resourced and whether this requires any disinvestment in existing services.

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Where to start?

The WHO UHC Compendium of recommended interventions can be a useful starting point for countries that have decided to define essential packages as part of their strategy to achieve universal health coverage, but lack local data or an existing process through which to assess interventions. The WHO UHC Compendium brings together all WHO guidance on possible interventions to include in UHC packages – from impact size, to resource needs, to value for money. Whilst adaptation of many of the data fields to the local context will better inform priority setting processes, the WHO UHC Compendium provides a one-stop-shop for all of WHO's information relating to intervention selection. It combines existing recommendations from WHO Guidelines, other WHO recommended interventions, the Essential Medicines and Priority Medical Device lists, along with information on the service delivery level and the resources needed to deliver interventions in terms of human resources and health system capacities. Countries who already have clearly defined and established essential services may evaluate new health services or technologies through the HTA mechanism.

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