UNIVERSAL HEALTH COVERAGE
AND THE ROLE OF EVIDENCE-BASED APPROACHES IN BENEFIT BASKET DECISIONS

By: Juliane Winkelmann, Dimitra Panteli, Miriam Blümel and Reinhard Busse

Summary: The extension of universal health coverage along its three dimensions – population coverage, benefit coverage and financial protection – has dominated health policy agendas in recent years. However, decisions on the benefits covered by publicly financed schemes have only recently received increased attention, being supported by evidence-based approaches such as health technology assessment (HTA) to ensure quality and “value for money” of care. Yet, new developments in the area of high-cost specialty medicines have highlighted the limitations of HTA in guiding the optimal allocation of finite resources, posing a challenge to “universality” of coverage and requiring increased efforts towards aligned HTA in Europe.

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Introduction

All health care systems are confronted with the question of which treatments and pharmaceuticals to pay for publicly as resources for health are limited, thus competing with other sectors within the public budget. Despite health needs and desires, it is not possible for a health system to afford to pay for all available health care benefits for everyone, even under universal coverage aspirations. Therefore, trade-offs arise in coverage decisions when priorities have to be set between different benefits and cost-sharing levels as well as the population groups covered. As a consequence, most countries opt for two-tiered models of health coverage, encompassing a mandatory public and a voluntary private component.

The rationale behind covering certain benefits while excluding others varies between jurisdictions, reflecting both societal norms and system characteristics. Public benefit “baskets” or packages are usually defined more broadly at the legislative level with a stipulation of the areas of care to be covered. They are then regulated more concretely, centrally or regionally and usually within each area of care, resulting in more or less explicit benefit baskets. Especially in the realm of coverage decisions for health
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In recent years, benefit baskets in many European countries have been expanded by costly innovations in medicines and devices leading to rising health expenditures. In a context of already constrained health budgets, formal structures to support evidence-based decision-making in a multitude of countries have been established to identify (non-) cost-effective services. At the same time, the fundamental values of universal health coverage (UHC) and solidarity have come under threat; this became evident particularly during the economic crisis when countries had to decide between restricting the number of people covered (most visibly in Greece), the services included the benefit basket (see Box 1) and the extent of the cost to be borne privately for services in the benefit basket.

Achieving UHC along the ‘coverage cube’

In the last 20 years, UHC has substantially gained importance with governments demonstrating their commitment to achieving health care for all. Today it is one of the most prominent global health policies, most notably retained in the Sustainable Development Goals (SDGs) in 2015. The UHC concept encompasses three dimensions: coverage for everyone (breadth), type and number of needed health services covered (depth) and the proportion of total health service costs that are publicly funded and not subject to cost sharing (height), also referred to as financial risk protection, and is best reflected in the UHC cube (see Figure 1). The UHC cube was first conceived in mid-2000 and was further developed for the framework behind the European Observatory’s Health Systems in Transition reports. It was most prominently used in the World Health Reports 2008 and 2010 and has since become known as the coverage cube. Today, it is used worldwide to illustrate UHC and supports related analyses.

Defining the health benefit basket is still challenging

Despite the importance of the range of benefits covered, the focus in the discussion on UHC to date has been dominated by the two dimensions of population coverage and financial protection. While both dimensions offer little scope for policy variation if the fundamental values of universality and solidarity are not to be contradicted, the range of services covered by publicly financed schemes constitutes a playing field in health policy for decision-making.

Indeed, there is a lot of variation in the level of explicitness and the approaches countries use to define their priorities and benefit packages. They range from very detailed (positive) lists of all goods and services available through statutory coverage to a vaguely formulated and implicit benefit package with reference to broad categories of services (e.g. primary care, pharmaceuticals). For example, UK legislation defines very broad categories of health care services, considering services necessary within ‘reasonable limits’, while leaving providers with the possibility to establish positive lists. At the same time, an institution tasked with identifying necessary, appropriate and cost-effective care, the National Institute for Health and Care Excellence (NICE) provides very clear guidance on whether a new medicine should be made available to NHS patients who meet particular criteria. Health benefit baskets can also be defined negatively by excluding certain benefits. For example, Italy and Spain use positive and negative lists and have a structured and detailed minimum benefit baskets that can be further adapted by regional health authorities. Israel is probably the only country in the world with one detailed list of all benefits across all sectors covered under the National Health Insurance Act; the list is updated once a year.

Over the last two decades, there has been a general trend to make positive lists more explicit, both in tax-funded countries (where benefits were previously left to the discretion of providers) as well as those with Social Health Insurance (where lists used to be merely fee schedules), and to expand the range of services in the benefit baskets. However, the opposite can also be observed, in particular during the economic crisis when services were removed from the benefits package (see Box 1).
The importance of HTA for coverage decisions has grown

Tools supporting evidence-based decision-making are increasingly incorporated in formal decision-making structures, as mentioned above, especially in the realm of coverage decisions for health technologies (i.e. pharmaceuticals, medical devices, procedures or interventions). The concept of technology assessment as a policy-informing tool to guide decision-making for coverage in health care was first introduced in the United States in 1975. The evaluation model of the Office of Technology Assessment (OTA) included elements of safety, effectiveness and cost, as well as socioeconomic and ethical implications of adopting (new) technologies in health care. It was subsequently adapted by national health technology assessment programmes in a number of European countries.

The exact scope and configuration of HTA are country-specific and heterogeneous. However, HTA is generally applied following marketing authorisation. After selection of the technologies to evaluate (most commonly following an application for inclusion in the benefit basket by the manufacturer or a request by relevant decision-makers), scientific evidence is collected and evaluated (evidence assessment) and subsequently appraised in context (evidence appraisal).

These formal assessment mechanisms are most frequently in place for pharmaceuticals. In Europe, pharmaceuticals have historically represented one of the largest expenditure items in health care spending with costs predominantly being covered by statutory funds. To bring a new medicine to market, demonstration of safety and clinical “efficacy” are usually sufficient. These are demonstrated within randomised controlled trials, with selected patients (e.g. excluding multimorbid ones) and using placebo as control. It is the role of the subsequent HTA to determine whether – at least in principle – the therapeutic benefit is meaningful to patients compared to alternatives in real world conditions – and therefore whether, to what extent and/or at what price new medicines will be covered publicly. To ensure that they are subsequently used appropriately is mainly the domain of clinical guidelines.

Expensive innovations have big implications for coverage decisions

New developments in the output portfolio of the pharmaceutical industry have highlighted the limitations of traditional HTA-based systems in guiding the optimal allocation of finite resources. The market entry of breakthrough therapies with large target populations and steep price tags (such as the pharmaceuticals against Hepatitis C in 2014) served as a wake-up call for policymakers, who were suddenly confronted with unmanageable budget impacts and a lack of suitable management levers. The number of new high-cost specialty medicines and so-called “niche-busters” (aimed at very narrowly defined patient sub-populations) has increased substantially over the last two decades. At the same time, evidence suggests that a substantial majority of these new pharmaceuticals do not provide substantial patient benefit gains compared to existing alternatives. However, they do require evaluation and investment of HTA-related resources.

New medicines based on novel mechanisms, such as gene and cell therapies, have started entering the market with extremely high price tags (e.g. Novartis’ immunocellular therapy against leukaemia was priced at $475 000 per infusion for the US market). Viewed against a backdrop of a per capita pharmaceutical expenditure of USS PPP 553 (OECD country average in 2015), it becomes clear that health systems will be unable to bear such costs in a routine manner as part of the benefit package. A new discussion on the effect of these medicines on the “universality” of coverage in European health systems is warranted. Indeed, the Dutch Presidency of the European Council in 2016 placed the spotlight on the imbalances in the current system of development, pricing and reimbursement of medicines and raised questions about its sustainability for Europe and Europeans.

Looking forward

Decision-makers are increasingly confronted with difficult coverage decisions due to budget constraints and new and costly health technologies. Over the last two decades numerous techniques have been applied to guide the decision-making process and to direct the optimal allocation of finite resources. The desire to maximise the value for money of health services and to ensure the long-term sustainability of access to technologies, have been met by increased use of evidence-based approaches. In this context, the application of HTA has received increased attention in health policy in most European countries and will continue to play an important role, thus requiring enhanced collaboration and knowledge exchange. Indeed, the European Commission has been promoting related research and collaborative activities for more than 15 years, culminating in the establishment of an HTA network in Directive 2011/24/EU. The scientific and technical cooperation of the network has been the responsibility of the EUnet HTA Joint Actions.
A further promising step towards aligned and centralised HTA in the EU was made on 31 January 2018 when the European Commission issued a proposal for regulation building on the experience of EU Member States in the area of HTA and related collaboration and mandating joint assessments of clinical elements (effectiveness and safety) of new medicines and certain new medical devices. Although the proposal has been criticised for various reasons (e.g. manufacturers are not mandated to provide full trial data but are afforded the possibility to comment on assessment drafts and specify which information is not to be made publicly available), more collaboration in the evaluation of new medicines is a welcome concept on the path to ensuring that new technologies with true patient benefit are identified early and evaluated for inclusion in the benefit basket at affordable costs.

References

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