

# DEVELOPMENTS IN VALUE FRAMEWORKS TO INFORM THE ALLOCATION OF HEALTHCARE RESOURCES

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**Background:** In recent years, there has been a surge in the development of frameworks to assess the value of different types of health technologies to inform healthcare resource allocation. The reasons for, and the potential of, these value frameworks were discussed during the 2017 Health Technology Assessment International (HTAi) Policy Forum Meeting.

**Methods:** This study reflects the discussion, drawing on presentations from invited experts and Policy Forum members, as well as a background paper.

**Results:** The reasons given for a proliferation of value frameworks included: rising healthcare costs; more complex health technology; perceived disconnect between price and value in some cases; changes in societal values; the need for inclusion of additional considerations, such as ethical issues; and greater empowerment of clinicians and patients in defining and using value frameworks. Many Policy Forum participants recommended learning from existing frameworks. Furthermore, there was a desire to agree on the core components of value frameworks, defining the additional value elements as necessary and considering how they might be measured and used in practice. Furthermore, adherence to the principles of transparency, predictability, broad stakeholder involvement, and accountability were widely supported, along with being forward looking, explicit, and consistent across decisions.

**Conclusions:** Value frameworks continue to evolve with significant implications for global incentives for innovation and access to health technologies. There is a role for the HTA community to address some of the key areas discussed during the meeting, such as defining the core components for assessing the value of a health technology.

**Keywords:** Value framework, Health technology assessment, Decision making

Successful development of and access to disruptive innovations in health care (i.e., health technologies with potential for radical changes in treatment patterns), like those to cure hepatitis C, have become a reality (1). Furthermore, the research and development (R&D) pipelines are likely to contain more complex disruptive health technologies (e.g., molecular diagnostics, personalized medicines). Decision makers around the globe are increasingly feeling challenged by the needs of the (aging) population and in financing the increasing number of (high-cost) health technologies for everyone in their healthcare system and society at sustainable costs. This has led to increased attention on how resource allocation decisions are made and can best be made, including discussions around universal healthcare coverage (2).

To inform such processes, definitions of what is considered a valuable health technology are needed. This conceptualiza-

tion is frequently based on the development of what have come to be called “value frameworks,” where several criteria are proposed to be taken into account when assessing value. The criteria considered by decision makers traditionally include (a) the level of clinical benefit and for some (b) a measure of the incremental cost-effectiveness. Recent considerations have also included indirect, unintended or “hidden” outcomes (e.g., potential benefits and harms for other stakeholders), as well as ethical, legal, and social issues (3). Value is then assessed by a judgment on the relative importance of the criteria that may differ between contexts or countries.

Reasons for a proliferation of value frameworks include: changes to the healthcare system (e.g., in the United States), rising healthcare costs; more complex health technology; the perceived disconnect between price and value in some cases; changes in societal values; the need for inclusion of additional considerations, such as ethical issues; greater empowerment of clinicians and patients in defining the overall value framework, and the processes associated with its use.

Previously in 2013, the HTAi Policy Forum, consisting of HTA leaders from public and private sector organizations (4), discussed the concept of value in the context of HTA (5). Various elements were discussed that reflect value, and several quantitative and qualitative approaches to determining value

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used by different countries were considered. Furthermore, in 2016, the HTAi Policy Forum discussed the concept of value in relation to affordability and access of health technologies (6). The recent proliferation in value frameworks, targeting different health technologies and different stakeholders to inform healthcare resource allocation asks for further reflection from the HTA community (7). Therefore, the topic of value frameworks to inform decision making was selected as the topic for 2017 by the Policy Forum Committee following the 2016 Policy Forum meeting in San Francisco, United States.

## METHODS

From January 29 to 31, 2017, representatives from twenty-nine for-profit and not-for profit organizations met in Barcelona, Spain, to reflect on and discuss this topic. In addition to Policy Forum and HTAi Board members, experts representing different perspectives (economics, ethical/philosophical, political, as well as the patient perspective) attended the meeting (see Supplementary Table 1). For more information on the Policy Forum as well as published material on previous meetings and discussions, we refer to the website of HTAi (4).

To inform the meeting, a background paper was developed; this was based on desk research and input from the HTAi Policy Forum Committee, Policy Forum members, and the wider HTAi community (7). The presentations made during the meeting, both from invited experts as well as those from Policy Forum members on specific themes, provided input for group discussions. The specific themes in relation to the content of value frameworks included: differences (if any) between existing and emerging frameworks for assessing value, criteria used in value frameworks and the challenges for different stakeholders. With regard to the use of value frameworks in decision making, the key topics were: linkage to health needs; early access schemes; adherence to certain principles such as transparency, and accountability; and legitimacy of decisions. Plenary discussions shared insights from across the groups. At the end of meeting, the participants were asked to formulate key messages to take home and to stimulate further debate.

Since 2007, discussions of the Policy Forum meetings have been summarized in this journal. This study provides a summary of the discussions among participants during the 2017 Policy Forum meeting. The meeting was conducted under the Chatham House Rule (8). This study presents the authors' view and is not a consensus statement from those at the meeting or their organizations, and should, therefore, not be taken to represent the views of any of the individuals attending or of the organizations they work for.

## RESULTS

Value frameworks in the United States have proliferated since 2014 and are mainly intended to inform patient–clinician conversations. Examples include the framework of the American

Society of Clinical Oncology (ASCO), National Comprehensive Cancer Network (NCCN), and Memorial Sloan Kettering Cancer Center (MSKCC) (9). Another United States example concerns the framework of the Institute for Clinical Effectiveness and Review (ICER) to determine value-based prices. In Europe, the HTA Core Model® has been proposed as the value framework to be used by HTA organizations when assessing technologies. The model consists of nine domains: health problem and current use of the technology, description and technical characteristics of technology, safety, clinical effectiveness, cost and economic evaluation, ethical analysis, organizational aspects, patients and social aspects, and legal aspects ([www.corehta.info](http://www.corehta.info)).

The purpose of this framework is “to enable production of high quality HTA information in a structured format to support the production of local (national or regional) HTAs and reuse of existing information” (10). However, applying this framework has shown to result in diverging recommendations regarding the same health technology (e.g., ipilimumab for treatment of melanoma patients) across countries (7). It appears that the approach taken is linked to (a) the underlying culture and values of a country; (b) the specific institutional context; and (c) the organization, governance, and financing of the healthcare system (11). This is also reflected in the development of new value frameworks targeting middle-income countries (7).

Finally, we see developments in HTA methodology for measuring value (Advance-HTA, INTEGRATE-HTA, MedTechHTA, and AdHopHTA, projects funded by the Research Framework Program of the European Commission) (12). Their principles and criteria have been described in more detail elsewhere (7). Some of the newer value frameworks aim to address the limitations presented by older frameworks, that is, to properly consider the value of innovative and complex health technologies as well as to focus on patient-centeredness. Therefore, the discussion of the 2017 Policy Forum meeting centered on the reasons for, as well as the content of, current and emerging value frameworks and their use in decision making.

In the discussion of the concept of value, it was immediately clear that several definitions of value are used in practice. During the meeting, two broad alternative approaches to a definition were presented: (a) an economics-based concept of market value: “what someone is (actually) willing to pay or forgo to obtain something (opportunity cost)”; and (b) an approach that focused on ethical concepts: “something which, if realized, has the potential of making the world better (or worse), *ceteris paribus*”. The question is, however: what definition of value is appropriate for the decisions to be made? For example, should value be limited to health benefits in relation to incremental costs? What does value mean when considering rare/ultra-rare diseases; do decision makers reflect public preferences when paying higher prices for orphan drugs that are not cost-effective (13)?

**Table 1.** Prioritization Criteria: Values

Values	Norway	Sweden
Perceived <b>severity</b> of condition	<b>Future loss of QALYs:</b> < 4 QALYs: Low priority (WTP < 33 000 USD) 5–20 QALYs: Medium priority (WTP < 67 000USD) > 20 QALYs: High priority (WTP < 100 000 USD).	Severity and need per se. Future health loss is not considered.
<b>Rarity</b> of the condition	< 50 patients in Norway AND < 1/100 000 patients worldwide.	Even higher WTP for rare and severe conditions.
Size of <b>benefit</b>	No clear cut-off-judgement from case to case.	Size of benefit increases WTP.
<b>Confidence</b> in data	No clear cut-off-judgement from case to case.	Higher WTP for better documentation.

QALYs, quality-adjusted life-years; WTP, willingness to pay.

Furthermore, there are claims that traditional frameworks and metrics applied to medical devices and diagnostics may overlook or undervalue important elements of value provided by these types of health technologies (14). This finding was reflected during the meeting, and there was a discussion among the participants as to whether there is a need for value frameworks for different types of health technologies (e.g., diagnostics, (orphan) drugs, medical devices, and complex technologies).

During the meeting, it became clear that the way in which value is being assessed is determined by a judgment on the relative importance of a range of criteria that may differ between political and cultural contexts. As a case study comparison, the use of values and prioritization in Sweden and Norway was presented during the meeting. In Sweden, for example, an ethical framework is used which includes four central value considerations expressed as the three basic ethical principles underlying the Swedish health system. For the past 20 years, this framework has been used and further refined to ensure evidence was added as a value aspect alongside severity, effectiveness and cost-effectiveness. For example, in Norway, similar criteria are used, but these are operationalized and valued differently by stakeholders, such as patients, carers, regulators, or decision makers (Tables 1 and 2).

Many of the value judgments are, therefore, implicit or tacit. Acknowledging and explicitly addressing value judgments may, therefore, improve the accountability of HTA and related decision-making processes (15).

#### Existing and Emerging Value Frameworks

From the discussions, it became apparent that it is still not clear why, or if, there is a need for these emerging new value frameworks when there are value frameworks in place which are used for several health technologies, such as the HTA Core Model®. However, value frameworks, such as the HTA Core Model® are evolving and considering or taking into account new methodological approaches, such as the MedtecHTA guidance for the

evaluation of clinical effectiveness of medical devices (16) and the INTEGRATE-HTA guidance regarding complex technologies (17).

Furthermore, it was noted by some participants that affordability on new health technologies is becoming a more urgent issue and greater attention and research is needed on how best to define and measure it, and to decide whether or not it should be included in value frameworks. An example is the value framework from ICER in the United States, which aims to include affordability in the assessment and reimbursement decisions (18). Specifically, there is an increased focus on value and affordability in oncology, for example, as expressed in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) with NCCN Evidence Blocks.

Another issue that was mentioned to be defined is the relationship between affordability and the patient benefit. Concerns were raised as well, as the proliferation of frameworks can “muddy the waters” among the many stakeholder groups when there is no clear direction and contextualization of value. Furthermore, it was noted that it could make sense to consider overarching frameworks to respond to the societal needs. Although political and cultural contexts determine the content of value frameworks, it was recommended to learn from existing frameworks and not start from scratch.

#### Value Frameworks: Context and Content

HTA developed because of the problems identified with effectiveness and cost-effectiveness of health technologies, the inequity in access to health technologies and partly because of the needs of health policy and practice for such information. This has led HTA to focus traditionally on several domains and aspects inside each domain to inform the value assessment of health technology. Nevertheless, in the development of value frameworks to assess value of health technology, we see several “additional” aspects being used when assessing value of health technologies, including: budget impact (controversial by some stakeholders); patient (and family) affordability; care

**Table 2.** Examples New Health Technologies

Disease	Conclusion HTA	Norway probable decision on reimbursement	Sweden probable decision on reimbursement
Metastatic prostate cancer	Severe condition but low future health loss. High ICER	No	Yes
Psoriatic arthritis	Very high health loss Very high ICER	Yes	No
Morbus Gaucher	Very rare disease Very high ICER	Yes (Provided incidence <1/100 000 worldwide and < 50 in total in Norway)	Yes, even for high ICER
Cerebral stroke	Medium health loss High ICER	No	Yes

ICER, incremental cost-effectiveness ratio.

delivery economics, total cost of care delivery; economic benefits for country, for example, increased economic development (employment); increased R&D; societal benefits, public health benefits (e.g., healthier lifestyles, healthier populations); employer impacts and systemic changes; innovativeness; reduction in uncertainty; real option value; value of hope; value of insurance; and scientific spill overs (7).

Discussion groups at the Policy Forum meeting differed on the importance and how to consider these additional criteria. The participants agreed that the HTA community, involving all relevant stakeholders, should agree on the core components (i.e., criteria) of value frameworks (e.g., the HTA Core Model®) and work toward understanding of the additional necessary value elements and how they are used in practice (i.e., principles). In this respect, a checklist of domains/aspects to be considered could be of value (19).

An issue that has been extensively discussed during the Policy Forum meeting is to what extent patient benefit is appropriately captured in value frameworks. Outcomes of relevance to the patient such as size of effect, prolonging of life and “hope” are often not considered, while they all influence the final assessment. It is important to understand what is important to the patient, and it was broadly agreed that more attention should be given to the patient voice in value framework development and application. For example, the ICER value assessment framework was developed and recently updated with input from several stakeholders, including patients and the public. This led to the recognition that in addition to clinical outcomes, patients consider other benefits or disadvantages (e.g., ability to return to work, family, and care giver burden) as important in assessing the value of health technologies (20).

It was, however, noted that conflicts may arise between the societal perception of the general population and individual values. Therefore, some description of value at macro-level may help. The description of how principles are used when there

is a conflict between societal/individual perceptions of value should also be considered. For example, individual choice for a particular costly, but effective health technology is difficult to reconcile with a health policy that is focused on addressing inequality in health care (21). Finally, it was emphasized that it should be made very clear that a framework for assessing value of a health technology (technical assessment) is different from a decision framework.

#### Value Frameworks and Decision Making

During the meeting, it was emphasized that decision makers should be held accountable to the populations they serve. It was, therefore, agreed that the HTA decision-making processes need to become more systematic, explicit, timely, and transparent, as well as to promote consistency across decisions. Explicitness and transparency in developing and applying value frameworks, along with taking a long-term, forward looking perspective on technology development were also mentioned to increase predictability.

Some participants felt that putting the use and development of HTA in the perspective of the development of a country's health system needs does not make things necessarily more straightforward in terms of HTA development. However, it is clear that a value framework should serve a country's specific health needs and capacity to set priorities for the most effective policies at a particular time. As such, a more institutionally sensitive approach toward the development of HTA will not necessarily evolve on its own. It was agreed that this would require more awareness of the context in which HTA is to be applied by all stakeholders.

It was felt important that those who use HTA information must show commitment to use the evidence and create policy frameworks that incentivize appropriate behavior and practice (22). Decision makers, including appraisal committees, should

ideally organize their processes in terms of stakeholder deliberation and evidence-informed decision making. For example, it should be clear which stakeholders are involved, the extent to which they are involved, which evidence is collected on the basis of which criteria, and how recommendations and/or decisions are made. It was discussed whether common principles to guide decision making could be approved and whether this could be a template that all countries could use. In the end, the consensus view was that the process as such should not be interpreted as a blueprint but rather be seen as an aspirational goal: countries are advised to take incremental steps, depending on their level of economic and HTA development. It was agreed that the process needs to be legitimate in its given jurisdiction and/or context (23).

Overall, healthcare systems around the globe seem to be evolving toward more accountability for outcomes using deliberative and transparent processes and greater interest among relevant stakeholders in more equitable allocation decisions reflecting the societal values, including disease priorities. In the long run, this should definitely benefit the citizens in these societies. In 2012, the WHO emphasized that initiatives to engage with patients and citizens can “manage expectations, offsetting some of the pressures to provide potentially inappropriate technologies, and balancing responsiveness with efficiency” (24). However, during the Policy Forum meeting, it was mentioned that payers/decision makers are often not involved in these processes and that they use the outcomes of value frameworks differently.

#### Value Frameworks and Innovation

During the meeting, the issue of accelerating the adoption and use of disruptive health technologies with high potential for patients with unmet need, including orphan diseases, was also explicitly addressed. Furthermore, examples of how well available value frameworks can be used for early access schemes were discussed, including the new accelerated appraisal process for drugs under the (new) Cancer Drugs Fund (CDF) in England (United Kingdom). The new approach has been developed by the National Health Service, National Institute for Health and Clinical Excellence (NICE), Public Health England, and the Department of Health and was informed by public consultation and engagement with patient groups and industry. The CDF is linked to NICE (accelerated) appraisal. It aims to give faster access to all new cancer treatments because additional data on the effectiveness of all promising new drugs is collected (for a maximum of 2 years) as soon as they are licensed in the United Kingdom (i.e., coverage with evidence development) (7).

Another example included coverage with evidence development regarding TAVI (Transcatheter Aortic Valve Implantation) in France. Medical devices in France are assessed by the National Authority for Health (Haute Autorité de Santé, HAS)

before decisions are made with regard to pricing and product launch. HAS assesses the clinical effectiveness and added clinical value, they recommend indications and conditions for their prescription, implementation, and usage, as well as define their role within the therapeutic strategy. For some medical devices, they also conduct economic evaluation. In the case of TAVI, HAS adopted early assessment for coverage with evidence development, this has supported TAVI innovation and allowed early access and additional evidence generation.

It was concluded that there are no new value frameworks that specifically aim to address early access of potential valuable health technologies. The participants broadly agreed that existing frameworks for rapid review to highlight promising innovation can be used (e.g., the one used by HAS as described above). It was also mentioned that currently the information infrastructure for continuous/adaptive assessment with regard to real world data/evidence is not in place. Therefore, it was felt important to invest in such an infrastructure to allow for standardization of terminology, continuous registration in electronic health records, and linkage among systems.

The majority of the current value frameworks are targeting health technologies that are already on the market. It is also important to note that values are embedded in the whole chain where HTA engages in processes such as horizon scanning, scientific advice, treatment pathways, and clinical practice. It was suggested that the role of horizon scanning should become more proactive, as is reflected in currently emerging initiatives in several countries (25).

Horizon scanning is important and of great interest to the HTA community, and it was discussed how HTA may need to evolve and adapt to support the deliberations of decision makers regarding strategies for coverage/pricing and technology adoption into the healthcare systems. Furthermore, it could be explored how HTA agencies can liaise more with industry to make them better understand the needs and constraints of the healthcare system in promoting development, innovation, and adoption of health technologies that bring benefits in the long run. This creates a potential to develop a shared agenda, outlining the demands and challenges for HTA and industry both in terms of capabilities and capacities.

#### Concluding Remarks

In the table below, we summarize some of the key messages that came out of the meeting (Table 3). All key messages provided by the participants are listed in Supplementary Table 2.

The discussion at the meeting clearly indicated that further definition of a value framework is needed. Value frameworks are not only about value for money but include other societal values; that is, societal values, such as equity and accounting for reasonableness, among others, in addition to efficiency, are used as the underlying principles of a value framework to guide decision making. Some find the latter an unavoidable

**Table 3.** Some Key Messages

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Create clarity between what constitutes value of health technology versus values of the decision-making process
Define the core components of a value framework for assessing the value of a health technology, using the HTA Core Model as a starting point
Use both quantitative and qualitative methodologies to appropriately address different diseases and/or health technologies
Value frameworks should adhere to the principles of transparency, predictability, broad stakeholder involvement, and accountability, along with being forward looking, explicit, and consistent across decisions
Decision makers have a responsibility to clearly state the rationale and detail behind the application of value frameworks to make a decision

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element for HTA adaptability to respond proactively to the societal needs. Furthermore, it was mentioned that there is a need for HTAi to define the core components of a value framework for assessing the value of a health technology, and that the HTA Core Model® could serve as a good starting point for that.

It should be noted that value frameworks are currently not capturing all aspects of value, for example, all values that are important to patients. Additional components of value and how they can be presented and incorporated should be made more explicit. Also, it may be necessary to adapt methodologies for assessing evidence to address different disease states and types of technologies. Some meeting participants thought this should include quantitative methods whenever possible, and qualitative methods where appropriate.

There was broad consensus among the participants regarding a few key principles that each value framework should adhere to. These include transparency and predictability, broad stakeholder involvement, as well as explicit and consistent processes, which are not too rigid or formulaic. Furthermore, value frameworks and their implementation by means of HTA systems must be flexible and sufficiently adaptable to address health technologies that are revolutionary versus available current processes, that is, forward looking. Furthermore, it was clearly noted that decision makers have a responsibility to clearly state the rationale and detail behind the application of value frameworks when making resource allocation decisions. Even though a value framework is in place that adheres to all the key principles, it was mentioned that it does not negate or replace the need for a conversation/negotiation on how health technologies can be made available while addressing issues such as affordability. In light of this, it is important to recognize that the value frameworks used in HTA can have significant implications for global incentives for innovation and access to technologies. Therefore, we see a role for HTAi and its community to continue this discussion and mapping a way forward, for example, with regard to defining the core components for assessing the value of a health technology.

#### SUPPLEMENTARY MATERIAL

Supplementary Table 1:

<https://doi.org/10.1017/S0266462317000502>

Supplementary Table 2:

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#### CONFLICTS OF INTEREST

Wija Oortwijn is employed by Ecorys, which received funding from HTAi for the work reported in this study. Dr. Sampietro-Colom reports personal fees from HTAi, during the conduct of the study. Fay Habens is employed by the Wessex Institute, University of Southampton, which receives funding from HTAi to provide secretariat support to the HTAi Global Policy Forum.

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