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The new definition of health technology assessment: A milestone in international collaboration

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Background. An international joint task group co-led by the International Network of Agencies for Health Technology Assessment (INAHTA) and Health Technology Assessment International (HTAi) has developed a new and internationally accepted definition of HTA.

Methods. The task group, consisting of representatives of leading HTA networks, societies and global organizations, developed guiding principles for the process and followed an established consultation plan with the broader HTA community to develop the definition. **Results.** The consensus achieved by the international joint task group brings the collective weight of the participating petworks, accidition and organizations behind the page definition.

weight of the participating networks, societies, and organizations behind the new definition. **Conclusion.** The new definition of HTA is an historic achievement and it is offered to the current and emerging HTA world as a cornerstone reference for today and into the future.

Much has been written about the history of health technology assessment (HTA), including compilation on the development of HTA around the globe (1;2). The field of HTA was developed in a very systematic way beginning in the U.S. Office of Technology Assessment which published its first report on HTA in 1976 (3). As the field evolved, there were numerous efforts to evaluate, improve, and harmonize the science, methods, and practice of HTA. Most notably, frameworks for the improved conduct and processes of HTA were developed (4-6), and the European Union Network for HTA (EUnetHTA) introduced its HTA Core Model® (7). Indeed, most HTA agencies created to support public policy have published guidelines and procedural manuals describing HTA methods and processes. There have also been several initiatives to enhance components of HTA including, for example, information retrieval (8), identification and selection of health technologies in need of assessment (9;10), health economics (11-13), patient and public engagement (14;15), ethics (16;17), deliberative processes (18;19), knowledge translation (20), and assessing the impact of HTA (21). The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) HTA Council Working Group report on good practices in HTA (22) provides a comprehensive summary of good practices for different components of HTA.

However, despite efforts to evolve the science and practice of HTA, there has not been a global consensus on the definition of HTA. Over the years, several definitions of HTA have been used. According to Banta, who was among the first to use HTA back in the 1970s, early studies on technology assessment defined HTA as a form of policy research that examines short- and long-term consequences of the application of a technology. The goal was said to be to provide policy makers with information on policy alternatives (23). In the 1990s, Goodman defined healthcare technology assessment as the systematic evaluation of the properties, effects, or impact of medical technology, the purpose of which was to inform technology-related policy making in health care (24). In the early 2000s, Draborg et al. conducted an international comparison of the definition and the practical application of HTA. They concluded that the definition of HTA as a multidisciplinary field of policy analysis that studies the medical, social, ethical, and economic consequences of healthcare interventions does not hold in practice as HTAs are frequently more narrowly defined (25).

More recently, HTA practitioners most often quoted the version of the definition posted in the HTA Glossary (http://www.htaglossary.net), which is a joint initiative of INAHTA and HTAi along with other partner organizations. The definition in the HTA Glossary has now been replaced by the internationally accepted new version (Box 1) but, for reference, the original was as follows: the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health

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Box 1. The new definition of HTA

The definition of HTA is provided below, with important clarifying information provided in four accompanying notes.

HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.

Note 1: A health technology is an intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system (definition from the HTA Glossary; http://htaglossary.net/health+technology).

Note 2: The process is formal, systematic, and transparent, and uses state-of-the-art methods to consider the best available evidence.

Note 3: The dimensions of value for a health technology may be assessed by examining the intended and unintended consequences of using a health technology compared to existing alternatives. These dimensions often include clinical effectiveness, safety, costs and economic implications, ethical, social, cultural and legal issues, organizational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population. The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context.

Note 4: HTA can be applied at different points in the lifecycle of a health technology, that is, pre-market, during market approval, post-market, through to the disinvestment of a health technology.

technologies. Note: HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods. In addition, ISPOR, the World Health Organization (WHO), and the regional HTA networks in Europe (EUnetHTA), Asia (HTAsiaLink), and the Americas (RedETSA) also have used their own versions of the definition of HTA.

The central concepts of HTA are consistent across the definitions used; however, these definitions tend to be technical in nature, with words or phrases that are not easily translatable to other languages from English, and they are not very memorable or aspirational. There was also a need to create a single definition developed and agreed by the broader HTA community through an open consultation process.

With this in mind, a joint international task group, co-led by INAHTA and HTAi, set out to create an internationally accepted new definition of HTA.

Establishing the Task Group and Methodology

In order to ascertain the feasibility of developing a new and internationally accepted definition of HTA, the Board Chair of INAHTA and the President of HTAi at the time (2018) decided to create a feasibility task group to gage interest in embarking on such an initiative. To achieve consensus, it was important to involve key regional and international networks and organizations in the feasibility task group, which was co-Chaired by a representative from INAHTA (Brian O'Rourke) and HTAi (Wija Oortwijn). Invitations to join the feasibility task group were extended to EUnetHTA, HTAsiaLink, and RedETSA, and all

Table 1. Guiding principles for the update of the definition

The joint task group developed a set of principles to guide the update of the definition, which state that the definition should be:

- Simple, use minimal jargon or language not easily understood by non-native English speakers.
- · Short, memorable.
- Descriptive of what HTA is, including the interdisciplinary nature of HTA. It should not be limited to only health economics, for example.
- · Easily translatable to other languages.
- · Acceptable to stakeholder groups associated with HTA.
- Future looking or open to the future, so the definition remains relevant for many years (i.e., health technology management, health technology optimization, health technology reassessment, lifecycle HTA, and so on).
- Congruent with International Organization for Standardization (ISO) standards.

accepted to participate. The task group met once by teleconference in January 2018 to assess the feasibility to improve the definition of HTA and, if so, to propose a plan to update the definition. There was consensus from all participants that it was feasible to create a new definition and that there would be value to the HTA community in the broad international collaboration itself, which had never before been undertaken in the HTA space. Hence, an HTA definition international joint task group was convened with Brian O'Rourke (representing INAHTA) and Wija Oortwijn (representing HTAi) appointed as co-Chairs and with representatives of EUnetHTA, HTAsiaLink, RedETSA, and the HTA Glossary Committee participating. To ensure expansive involvement in the collaboration, additional invitations were extended and ISPOR became a member and the WHO acted as an observer to the group.

The first order of business for the international HTA definition joint task group was to develop a set of guiding principles. These are listed in Table 1.

The task group met on several occasions from May 2018 until September 2019, completing several rounds of consultation and review that were jointly agreed.

Toward a New and Internationally Accepted Definition of HTA

Version 1 of the new definition was developed by the task group and forwarded to the leadership/approval authorities of the participating organizations for early input. The task group discussed and integrated their feedback. Version 2 was then circulated for open consultation with the broader HTA community electronically through the membership and contact lists of task group member's organizations. The 172 responses received to the open consultation were sorted into four groupings:

- Suggestions to consider adding wording about HTA's contribution to achieving health outcomes, as the definition currently focuses on HTA as a process to inform health policy and decision making.
- (2) Recommendations to simplify the definition by removing jargon and minimizing the number of catch words. As set out in

- the guiding principles, the definition should be simple, short, and memorable (Table 1).
- (3) Comments related to the structure of the definition. For example, reducing the number of sentences in the definition; following principles of lexicography and developing it more like a dictionary definition; moving portions of the definition to the notes; using more prescriptive rather than descriptive phrasing; and, creating a more normative and technical description of HTA rather than describing the process of HTA.
- (4) Comments on the concept of value and the use of the word *value* in the definition. There were many divergent opinions on this aspect, which is not surprising as this concept is context-related and largely conditioned by the perspective taken in the assessment (26).

There were also several suggestions to modify the definition of *health technology*; however, the task group decided to use the current definition of health technology that is in the HTA Glossary, and this is referenced in the new definition (Box 1). Suggested edits to the definition of health technology to align it more with concepts that are often used in low- and middle-income settings (i.e., interventions) were passed to the HTA Glossary committee for consideration.

The task group incorporated the feedback from the open consultation and created version 3 of the definition, which was subsequently sent back to the leadership/approval authorities of the participating organizations to obtain their approval. There was consensus from most Boards to approve version 3 of the definition but there were some additional suggestions to improve the definition. As a result, version 4 of the definition was developed and this version (presented in Box 1) has been approved by all participating networks and organizations, and by leadership from the EuroScan International Network.

Discussion

When developing the new definition, several key issues were considered by the task group.

In the first sentence of the new definition (Box 1), the word assess is replaced by the word determine: "A multidisciplinary process that uses explicit methods to determine the value...." This was changed to avoid the duplication of concepts when the definition is translated into other languages (e.g., assess the value becomes evaluar el valor in Spanish). This change also avoids the use of the same word in the definition (assess) as in the term being defined (assessment).

In order to adhere to the principle of keeping it simple and short, the definition does not specify the different levels of decision making where HTA can play a role. However, a phrase in the second sentence, "The purpose is to inform decision making...," is meant to reflect different decision contexts in low-, middle-, and high-income countries, such as: formulary coverage or reimbursement decisions (including disinvestment); clinical practice guideline development; defining emergency kits, disaster planning, (basic) benefit packages, and essential medicine lists; medical device and equipment procurement planning; negotiating prices for health technologies, and other decision contexts at the national, regional, or local levels, including hospitals (27;28).

Similarly, the phrase, "...to promote an equitable, efficient, and high-quality health system" is not further spelled out. Health systems of democratic societies often share these values and principles, but it is noted that health systems can apply

these principles differently. Therefore, these concepts must be defined in the context of the health system under consideration, including how they are applied by the HTA agencies involved and how they are interpreted by decision makers. As a starting point, the HTA Glossary provides good definitions of *equity*, *efficiency*, and *quality* in this context.

A new Note 2 was created to capture some of the words that were removed from the definition following the open consultation with the broader HTA community. Additionally, in Note 2, *all available evidence* was changed to *the best available evidence*. This is more consistent with a recent position document published by EUnetHTA (29). The note is also in line with the recent article on scientific development of HTA of Van der Wilt et al. on behalf of the HTAi Scientific Development and Capacity Building Committee (30).

A few commenters noted that the definition may exclude those activities and institutions that span the appraisal/decision/selection space, but task group members felt this was already sufficiently addressed. Note 4 clearly specifies that HTA can be applied at different points in the lifecycle of a health technology, that is, premarket, during market approval, post-market, through to the disinvestment of a health technology. Also, HTA is a process that can include several interrelated components: governance and structure of the process, scoping, assessment, appraisal and implementation, and monitoring, as described in more detail in the ISPOR HTA Council Working Group report on good practices in HTA (22).

Conclusion

The collaboration among the leading HTA networks, societies, and global organizations: HTAi, INAHTA, EUnetHTA, RedETSA, HTAsiaLink, ISPOR, the HTA Glossary Committee, and the WHO was a milestone undertaking reflecting the maturity of the international HTA community to come together for a common purpose. The consensus achieved by the international joint task group brings the weight of these participating networks, societies, and organizations behind the new definition. The robust, consultative process followed further strengthens the credibility of the process and the resulting output. The internationally accepted new definition of HTA is an historic achievement and it is offered to the current and emerging HTA world as a cornerstone reference for today and into the future.

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