Health Professionals' Involvement in HTA

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HTAi™

The participation of health professionals and citizens in the assessment of health technologies facilitates the evaluation process and contributes to improving the quality of evaluation reports and the acceptance and implementation of their conclusions.

Participation is relevant in all phases of the process: guidance on the development of the protocol, help in the critical appraisal of the clinical evidence and interpretation of the clinical relevance of the results.

There have been several efforts to ensure the involvement of patients in HTA (see specific chapter in this Handbook) and even the society HTAi holds a patients and citizens interest group since the very beginning (https://htai.org/interest-groups/pcig/). Notwithstanding, although clinicians or health professionals' involvement in HTA processes is seen as crucial, critical or at least, relevant, no such groups are established, in which discussions around their roles, processes in which they should participate and how and defined functions.

What do we mean by health professional?
A health professional or healthcare professional is a provider of health care that embraces the overall management of a patient, a group of patients or a group of citizens and in concrete, activities such as prevention, diagnosis, treatment, follow up, promotion and advice based on certified training and personal expertise and experience. The field includes those who work as a nurse, physician (such as primary or community care physician), internist, radiologists, psychiatrist, radiologist, surgeon etc.), physician assistant, registered dietitian, veterinarian, veterinary technician, optometrist, pharmacist, pharmacy technician, medical assistant, physical therapist, occupational therapist, dentist, midwife, psychologist, or who perform services in allied health professions. Experts in public health and community health are also considered as health professionals.

Why health professionals are so important in HTA processes?
As part of the group of stakeholders that should be considered when starting a HTA report or exercise, health professionals are not more important than others in HTA processes, however their participation should not be circumvented or replaced in certain phases. In fact, health professionals maintain health in humans through the application of the principles and procedures of evidence-based medicine (EBM) and caring. In accordance to HTA definition (O'Rourke et al, 2020), HTA uses the principles and procedures of EBM, in order to help decision-makers reaching to the best decision possible in the context of application.

Furthermore, health professionals give advice on or apply preventive and curative measures and promote health with the ultimate goal of meeting the health needs and expectations of individuals and/or populations, and as such, improving individuals and population's health outcomes.

Types of health professionals and their role
It has been stated that health professionals belong to a wide range of specialties and as such their role could differ along the HTA process. In fact, there is a need to differentiate between those that are going to contribute in the scoping process and those that are advising on certain parts of the methodological roadmap of building up a HTA report. In accordance with the EUnetHTA Handbook of Building Capacities in HTA, 2008, not all the HTA agencies have all the capacities installed to complete a HTA report as required, there are certain skills that are fundamental in the HTA process, meanwhile there are others that are commonly hired or requested when needed, such as biostatistics, bioethics, legal or social skills or more recently environmental advice on the impact of technologies. Same can apply to biomedical engineers, experts in regulatory aspects or social or mass media experts. These experts are fundamental in many occasions in contributing to the development of HTA exercise. The inclusion of professionals that bring expertise in certain areas of the process and especially in methods and analysis is more common in small HTA teams or units, meanwhile big organizations of more than 30-40 professionals, they have all those capacities among their workforce. Although some of those could be considered as health professionals, from now on we will refer as such to those that contribute to the scoping process and along the elaboration of the HTA report and its discussion, due to their expertise in the specific questions that are related to the characteristics of the patients, the pathology or condition, the care pathway and possible alternatives and the outcomes of interest to be measured in accordance to their expertise.

Scoping is the exercise by which HTA doers define the research questions within the HTA process. This stage should address five major components: a) target population, b) technology or intervention, c) comparator/s and d) outcomes of interest, and e) perspective (Tanvejsilp and Ngorsuraches, 2014).

HTA doers are not specialists in all the fields of healthcare and apart from reading the literature and the evidence, it is crucial to have the perspective of those that are linked to the patients, their characteristics and the way systems could manage or are managing them, and which are the desired outcomes to be changed from the different perspectives that can be adopted.

The identification of the values and the diversity of approaches to determining the value and the possible inconsistencies requires a dialogue among the different stakeholders including the HTA team. The role of the HTA team is identifying the divergences and discuss them with the stakeholders, among those, health professionals, in order to resolve the controversies, or at least to characterize the reasons or the argues behind those differences.

Approaching the health professionals
The HTA Team should establish a clear strategy to approach stakeholders and specifically health professionals. This strategy should include: a) what HTA is; b) what HTA is for; c) which the methods that are used are; d) how the project will be structure and e) their role in the HTA analysis. In this sense, it is important clarifying which the role of them could be.

In certain occasions, the HTA teams include health professionals at the end of the process as peer-reviewers or discussants of the results and conclusions of the analysis. This should not be considered a good practice, but it is sometimes needed when fast approaches to evidence gathering and analysis is needed due to constraint timeframe to provide evidence to decision-makers. Thus, the HTA teams should plan ahead which the necessities of stakeholders' engagement are, when they are going to occur and how conflicts will be resolved in order to deliver the final product/report on time.

Figure 1. Validate-HTA concept of looking for values in the determination of value (used with permission from VALIDATE-HTA consortium
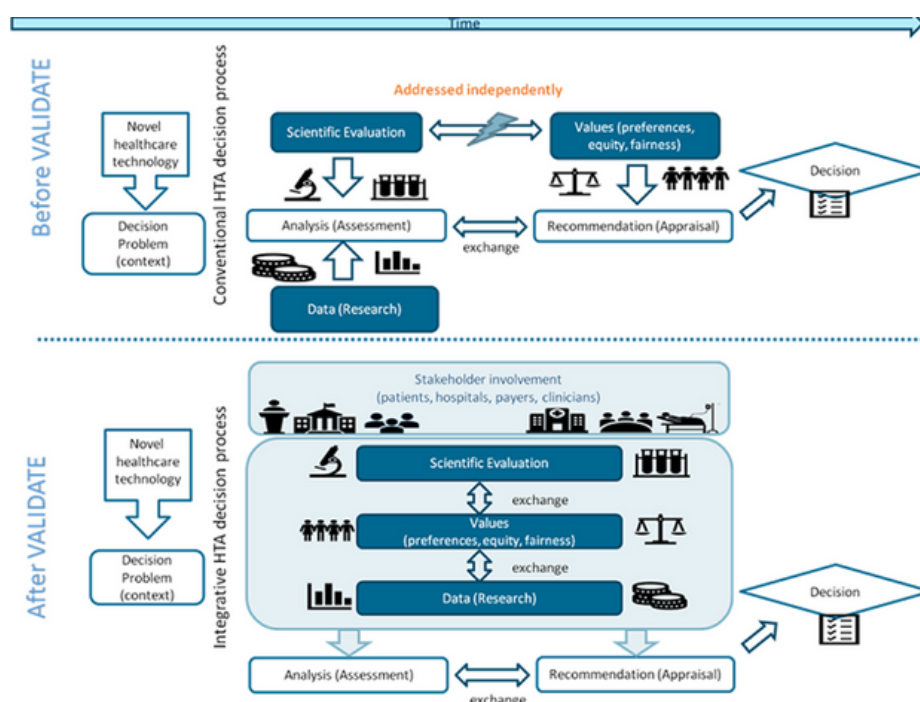
Which health professionals should be included
There is an eternal debate on who should be included and why. Notwithstanding, this applies to any stakeholders' group. In this regard, the level of representation and the characteristics of the health professional is key. There is no way to ascertain that the health professionals that we have chosen are the right ones, same applies to patients and patients' representatives. However, there are some tips that could be useful when choosing the adequate people. First of all, which the objectives that we are prosecuting are. Among those we can mention at least three: a) obtaining health professionals views and their values; b) ascertaining that this group of stakeholders understand what HTA work means and which the strengths and limitations of a HTA exercise are ("proselytism"); c) improving the acceptance of HTA reports and their conclusions and recommendations by groups of stakeholders, in this case, health professionals. There are other objectives that can also be covered with this exercise. It is worth mentioning, a) accuracy in the way the reports are written; b) accountability to other health professionals and; c) reliability by health professionals and thus, improvement in the subsequent processes of dissemination and diffusion of the final HTA reports and their conclusions/recommendations.

The dilemma here is who we should choose. There is a trend to identify key opinion leaders (KOLs) in the area or the theme we are working on. By choosing KOLs, we are ensuring that when finishing the report and disseminating the conclusions, it is more likely that the conclusions and recommendations are followed and accepted by a wide range of professionals. It occurs similarly when clinical practice guidelines are elaborated and finally published (Borbas et al, 2000). If those are supported, endorsed or accepted by KOLs, the impact of their recommendations and their use in real practice is expected to be higher. Nevertheless, the selection of KOLs could pose another issue, that is the management of time and agendas and their capacity to contribute to the discussions needed with the process of elaborating the HTA report. Therefore, it is worth considering including "second-line" health professionals when building the HTA project team. Furthermore, a strategy that can also be applicable or useful in this case would be to be in touch with local/national health professionals' societies and ask them for representatives of the society in the area or theme we are starting. It is also worth considering including health professionals we have already worked with, and the work they have developed is adequate. In this sense, there are agencies that have networks or lists of professionals "trustful professionals" they are involving when elaborating the reports.

The professionals finally involved need to be conscious that the process is demanding, and the timeframe is sometimes tight. So, we need to be very careful when detailing the tasks and phases, deliverables and milestones that meeting deadlines is part of a well-developed HTA project.

A clear strategy and project plan on health professionals' involvement including the phases in which their participation is required and their role in each of the phases could help reducing the pressure on professionals and managing their expectancies. Sometimes it helps also having their acceptance or renounce to participate in the project. For that, a detailed Gantt chart, in which milestones, meetings and deliverables are detailed could be useful.

If finally, KOLs are not considered for HTA project team, we can always engage them at the end of the process, that is peer-review phase. This is also a way to confront the recommendations, inform around the report and improve the level of acceptance of other professionals by convincing them that the course of action has been sound, and the final conclusions are accurate. The final endorsement of KOLs and scientific societies also can be sought for when publishing the final report, within a so-called, public open consultation.

When health professionals should/could be involved
The HTA project, as it has been pointed out in other chapters of this monography, encompasses an iterative process that consist of different phases such as: a) identification; b) filtration; c) prioritization; d) scoping; e) analysis; f) findings discussion; g) conclusions and/or recommendations' elaboration; h) peer-reviewing; i) public consultation; j) dissemination and; k) impact analysis. See Figure 2.

In previous paragraphs, we have mentioned when the role of professionals could be key, but it has not been revealed, in detail, in which phases of the HTA process, health professionals' involvement makes sense, or it is needed/required.

Figure 2. Phases of the HTA process and health professionals' involvement

Identification	Filtration
•Health professionals **	•Health professionals *

Prioritization	Scoping
•Health professionals **	•Health professionals ***

Analysis	Findings' discussion
•Health professionals *	•Health professionals ***

Conclusions and/or recommendations' elaboration	Peer-reviewing
•Health professionals ***	•Health professionals **

Public consultation	Dissemination
•Health professionals **	•Health professionals *

Impact analysis
•Health professionals *

* health professionals' involvement low
** health professionals' involvement medium
*** health professionals' involvement high.

First things first. Managing the conflict of interests

Prior to start any process and when we are considering the involvement of any stakeholders, but specifically health professionals, there is a need to record their possible conflict of interests. Why in this case, it is even more crucial than in any other cases. Health professionals are those that are using, prescribing, diagnosing and managing patients by means of health technologies. On many occasions, they have relation with technology producers such as: grants to attend meetings, funds for research projects or funds for publications, involvement in commercial trials and or companies funded registries among others. This does not discard them from becoming part of the team at the very beginning, but the declared conflicts and their influence on the assessment should be considered by the HTA team and when it is anticipated that a conflict could arise, the health professional involved should not participate in the discussion or should be discarded from the project team. Sometimes, it is difficult to discard certain professionals from processes of analysis of certain topics, because they are the main experts. In those occasions the best way to manage it, it is to transparently declare the conflicts and make them publicly aware. The minimization of any conflicts and their consequences should be attentively considered by the HTA team at any time. Although each organization could have a conflict of interests disclosure form, there are standard ones that could be used such as that of the International Committee of Medical Journal Editors (ICMJE, 2021: https://www.icmje.org/disclosure-of-interest/) or a specific one from EUnetHTA and how to manage declarations of interests (https://www.eunethta.eu/wp-content/uploads/2019/11/EUnetHTA-Procedure-Guidelines-DOI.pdf).

Identification

This phase describes the step by which topics that are potentially suitable for evaluation by the HTA process are identified. Typically, these could be topics that are publicly financed, covered by private insurances or covered by compulsory health insurance or included in publicly or privately funded health benefits' packages. Each healthcare system could have different needs due to their characteristics or the epidemiological paradigm the country or the region may have. The identification phase could differ from country to country and from system to system. Thus, some healthcare systems use horizon scanning that include health professionals among those that identify the items to be evaluated (EuroScan toolkit, 2014. Health professionals are a good source of identification because they know their needs, they are connected with advancements in their field of knowledge, and they can contrast those advancement with their practice and the current value of their practice.

Filtration

Once topics are identified not all of them are suitable for evaluation or they could be covered by the HTA team. Filtration means discard, there are different reasons by which technologies or topics are discarded, among those it can be mentioned that: a) they are not covered by the healthcare benefit; b) they are already being evaluated; c) potentially they do not respond to the needs of the systems; d) the level and quality of the information is not sufficient for the assessment; e) the technology is at an early stage of development and it is unlikely that it will impact the system in a short term. Filtration with explicit criteria is normally done by the HTA team. Notwithstanding, health professionals can potentially provide arguments or information to aid in this process.

Prioritization

Prioritization relates to the process by which the healthcare systems and HTA teams decide on what is going to be assessed first or even, what is not going to be evaluated due to the limited capacity of a HTA team to evaluate all the things that have been identified and filtrated. In big agencies or systems, prioritization defines a process of establishing the importance of a topic in accordance with the characteristics of the healthcare and the patients/citizens' needs. In big agencies with huge capacities none of the topics are discarded and prioritization just defines the order of assessment, which topic will be first, second and so on. Health professionals could play a double role in prioritization, first defining the criterion or set of criteria that will be used to judge and prioritize the technology (Varela-Lema et al, 2014) and then to prioritize as part of stakeholders' groups the topics that have been identified and filtrated.

Scoping

Once the topics to be evaluated have been selected and the HTA team starts to define the HTA project, the first exercise to be done is scoping. Within the scoping process, the questions to be addressed (normally PICO system is used) and the divergences among stakeholders should be identified and if possible, resolved. The involvement of health professionals at this stage is essential. They could even constitute part of the evaluation team as researchers within the project or just limit their role to give opinion at the first stage and then participate in the ulterior discussion. As it has been mentioned before, health professionals know better than any other stakeholders how the technology could be used in real world and all those aspects related to patients' management, specifically organizational aspects at the micro level. This could also aid helping when building up the economic models and the micro-costing analysis (health professionals involved, time devoted, phases, etc.).

The Validate-HTA consortium (Validate-HTA Handbook, 2022) considers this phase critical as it could bring out the intended and unintended consequences of using or discarding the health technology/ies that are going to be evaluated.

Analysis or assessment
The analysis or assessment includes information gathering, critical appraisal of the information/evidence and summary of the final evidence that will be included in the report and it is normally conducted by the HTA team. On some occasions, the process of discarding pieces of evidence could be discussed with stakeholders, principally patients and health professionals, but it is more a mechanistic, transparent and well-defined process that has its own rules (mainly good practices in systematic reviews are followed). The process finish with presenting the evidence gathered in the form of evidence tables and when GRADE methodology is used (https://www.gradeworkinggroup.org/), the HTA team fills the GRADE forms for the posterior discussion of the findings with the stakeholders.

Findings' discussion and conclusions/recommendations elaboration
Once the evidence has been found, analyzed and summarized, the HTA team proceeds to discuss the findings with the stakeholders. This is a process in which health professionals and patients' involvement is essential. It is obviously needed that the stakeholders understand which their role in this process is and which will be the final output and to whom the conclusions/recommendations are directed. When GRADE methodology is used to reach to conclusions and recommendations, this is also a well-defined, standard and structured process.

Peer-review
HTA reports being scientific documents follow a process of peer-review before publication. This is one of the last chances to have specialized feedback from the stakeholders. Most HTA bodies have formal processes for peer-reviewing, and they adhere to publications best-practices. It has been pointed out that perhaps this is a good chance to involve KOLs as they will open the window for disseminating the results if they agree with the method and its conclusions. Health professionals are normally involved in this phase and depending on the topic different professionals are included. The HTA Teams have the right to include or not the comments provided by the peer-reviewers but they need to at least rebate or give argues on the changes that have been proposed.

Public Open consultation
Some HTA bodies provide the chance to comment or give feed-back at different stages of the HTA projects.

Normally that is accessible before development, during development or after publication. The most common one is just before or when the publication is to be published. The open-consultation process is another chance for interaction with stakeholders including health professionals (https://www.nice.org.uk/get-involved/consultations). The difference with involving directly the stakeholders is that the process is not structured, the interaction and roles are not well-defined and that the feed-back though valuable could be diverse depending on the topic and the sole interest of the stakeholders. Open consultations are more adequate for further involvement of patients and citizens than health professionals. In the case of the health professionals interaction with scientific societies and professionals colleges seems to be more efficient.

Dissemination and diffusion
As part of the HTA projects, there is a phase of diffusing or disseminating the results and recommendations. One of the target audiences is health professionals and as such their role is passive, although in some occasions HTA bodies contact with scientific societies to help them distributing the results or including the conclusions among the newsletters, mass media, social media or journals. It is also common that some reports are adapted for publication in scientific journals and dedicated specialized journals are chosen to increase the impact of the results and the diffusion of the recommendations/conclusions.

Impact analysis of the HTA work
This phase is also a duty that is played mainly by the HTA team. Once again, the role of health professionals is minimum, and they are mainly the actors that are selected to analyze if the conclusions/recommendations have been adopted when managing the patients or groups of patients. Variability in practice and its translation on health results could be also analyzed. However, most of the HTA organizations analyze the adoption, inclusion, exclusion or modification of use of the assessed technology without considering the value that those actions could have in the final patient or group of patients. Nevertheless, HTA practices are changing and the analysis of Real World Data and the monitoring of technologies after their introduction in practice is becoming more and more demanded (Serrano et al, 2021). In this case, the role of health professionals is becoming more important as they are the actors that use the technology and participate in the elaboration of the protocol for data gathering and collect the data that is used for ulterior analysis. Health Professionals' role in other processes such as reassessment and disinvestment, considering the life cycle of health technologies needs to be also carefully analyzed, as such, it could be even more crucial than in assessment activities, because they are already using the technology/ies and now the value they are obtaining by means of them.

Concluding Remarks

Health professionals are part of the stakeholders that play an essential role in HTA processes. Their involvement is key in certain phases but especially in the case of topic identification, scoping, prioritization, findings discussion, recommendations elaboration and peer-reviewing, although their role in other phases could be important and as such it is worth mentioning their role in defining the value of the technology once it has been implemented in the system. Main aspects to be considered when selecting health professionals is what we are going to demand from them and which their role and rights will be. In this regard, the planning of the HTA project is critical and the communication to those involved important in conducting a smooth and successful project.

The management of conflict of interests in the different phases of the HTA project and the inclusion, exclusion or consideration of the involvement of health professionals in accordance with what they have declared in the disclosure of interests need to be carefully discussed by the HTA team. The use of KOLs in the different phases needs also to be counterbalanced.

Bibliographic sources and suggested readings

Borbas C, Morris N, McLaughlin B, Asinger R, Gobel F. The role of clinical opinion leaders in guideline implementation and quality improvement. Chest. 2000 Aug;118(2 Suppl):24S-32S. doi: 10.1378/chest.118.2_suppl.24s. PMID: 10939996.

EUnetHTA Work Package 8. EUnetHTA Handbook on Health Technology Assessment Capacity Building. Barcelona (Spain): Catalan Agency for Health Technology Assessment and Research. Catalan Health Service. Department of Health Autonomous Government of Catalonia; 2008.

EUnetHTA JA2 Declaration of Interest and Confidentiality Understating-FINAL -STATEMENT ON TERMS OF PARTICIPATION AND EXTERNAL ACTIVITIES OF EXPERTS (potential conflict of interest and confidentiality undertaking), 20140502 (as endorsed by Plenary Assembly, Madrid, 2014.04.10).

EUnetHTA Standard Operating Procedures (SOP) Manual, EUnetHTA Joint Action2; 2012-15; Developed by the EUnetHTA Secretariat July 2013; Amended and approved April 2014.

EuroScan International Network, A toolkit for the identification and assessment of new and emerging health technologies, 2014, EuroScan International Network: Birmingham. Available from: https://www.euskadi.eus/contenidos/informacion/osteba_formacion_/es_def/adjuntos/EuroScan_Methods_Toolkit_October_2014_FINAL_CC_added.pdf.

International Committee of Medical Journal Editors, 2022. ICMJE, 2021: Conflict of Interest Disclosure form. Available from: https://www.icmje.org/disclosure-of-interest/ .

Oortwijn, W., & Sampietro-Colom, L. (eds.). (2022). The VALIDATE handbook: an approach on the integration of values in doing assessments of health technologies. Version 2.0. DOI: 10.54195/CKHB1659. Available from: https://validatehta.eu/.

O'Rourke B, Oortwijn W, Schuller T; International Joint Task Group. The new definition of health technology assessment: A milestone in international collaboration. Int J Technol Assess Health Care. 2020 Jun;36(3):187-190. doi: 10.1017/S0266462320000215. Epub 2020 May 13. PMID: 32398176.

Serrano-Aguilar P, Gutierrez-Ibarluzea I, Díaz P, Imaz-Iglesia I, González-Enríquez J, Castro JL, Espallargues M, García-Armesto S, Arriola-Bolado P, Rivero-Santana A, Perestelo-Pérez L, González-Pacheco H, Álvarez-Pérez Y, Faraldo-Vallés MJ, Puñal-Riobóo J, Ramallo-Fariña Y, Sánchez-Gómez LM, Asua-Batarrita J, Reviriego-Rodrigo E, Moreno-Rodríguez A, Juárez-Rojo C, Vicente-Saiz M, Orejas-Pérez E, Knabe-Guerra J, Prieto-Yerro I, González Del Yerro-Valdés C. Postlaunch evidence-generation studies for medical devices in Spain: the RedETS approach to integrate real-world evidence into decision making. Int J Technol Assess Health Care. 2021 May 4;37(1):e63. doi: 10.1017/S0266462321000295. PMID: 33942712.

O'Rourke B, Oortwijn W, Schuller T; International Joint Task Group. The new definition of health technology assessment: A milestone in international collaboration. Int J Technol Assess Health Care. 2020 Jun;36(3):187-190. doi: 10.1017/S0266462320000215. Epub 2020 May 13. PMID: 32398176.

Serrano-Aguilar P, Gutierrez-Ibarluzea I, Díaz P, Imaz-Iglesia I, González-Enríquez J, Castro JL, Espallargues M, García-Armesto S, Arriola-Bolado P, Rivero-Santana A, Perestelo-Pérez L, González-Pacheco H, Álvarez-Pérez Y, Faraldo-Vallés MJ, Puñal-Riobóo J, Ramallo-Fariña Y, Sánchez-Gómez LM, Asua-Batarrita J, Reviriego-Rodrigo E, Moreno-Rodríguez A, Juárez-Rojo C, Vicente-Saiz M, Orejas-Pérez E, Knabe-Guerra J, Prieto-Yerro I, González Del Yerro-Valdés C. Postlaunch evidence-generation studies for medical devices in Spain: the RedETS approach to integrate real-world evidence into decision making. Int J Technol Assess Health Care. 2021 May 4;37(1):e63. doi: 10.1017/S0266462321000295. PMID: 33942712.