

# **HTA in Hospitals**

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### Introduction

The use of HTA as a part of the decision-making process at national, regional, and international levels has evolved considerably over the past 40 years. However, a large number of good-value innovative Health Technologies (HTs) never reach clinical practice while, in many instances, others with no significant added value actually do. This situation can create an ineffective and inefficient resource allocation having impact on the health of the populations and equitable access to healthcare in public healthcare systems facing financial pressures.

A way to overcome this problem is by approaching HTA at hospital level, notably because hospitals are the main entry level for innovative HTs. The adoption of the HTA logic to support managerial as well as clinical decision making at hospital level has been labelled “hospital based health technology assessment” (HB-HTA). HB-HTA can be considered as one possible approach to enhance the use of HTA for managerial decision making in hospitals and other healthcare organizations (HCOs) and to improve the use of evidence, complemented with local information, to inform clinical practice in the “real world”.

Traditionally, HCOs are mainly considered as HTA users. More precisely, hospitals, as well as other HCOs, are seen as places where clinicians and other healthcare professionals use – or should use – HTA to support their decision making processes. Recently, HCOs’ role as HTA producers is becoming increasingly crucial. In fact, ad hoc units are being established with the special purpose to produce customized HTA reports (mini-HTAs) and enhance decision making processes, by applying HTA principles and methods.

Moreover we have assisted to an evolution of the landscape in HTA where national and regional HTA bodies are networking with hospitals to produce and use HTA at different levels.

Thanks to the recent EU funded research project AdHoPHTA (Adopting HTA in European Hospitals) we have a full range of evidence regarding the applications of HTA at hospital level. The project has also produced pragmatic tools that can be ready-to-use such as the mini-HTA template and the AdHopHTA Database. The vast majority of results of the AdhopHTA project have been summarized in a “Handbook”.<sup>1</sup> This contains the results of the literature analysis, various surveys, and the analysis of multiple case studies (Sampietro-Colom et al., 2015). More recently Sampietro-Colom and Martin (2017) have collected 30 case studies of application of HTA in hospitals worldwide.

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<sup>1</sup> The AdhopHTA project has also produced pragmatic outputs: Guiding principles for good practices in HB-HTA and related toolkit; the AdHopHTA Mini-HTA Template; the mini-HTA quality checklist; A database of HB-HTA reports (AdHopHTA Database).

Thanks to this work we have now diffused knowledge about potential applications of HTA at hospital level and a set of tools publicly available that are fostering the diffusion of HTA at hospital level. This chapter is dedicated to clarifying what we should intend for HB-HTA, which are the motivations for the diffusion of HTA in hospitals and how it has been applied worldwide. The chapter is also providing basic information about procedures and tools of HB-HTA and its role within the whole HTA ecosystem.

### **Definition of hospital based HTA**

HB-HTA consists of the implementation of principles, methods and tools of health technology assessment at hospital level. The contextualization of HTA to a specific hospital brings into the assessment process the consideration of its unique characteristics, such as the choice of an available comparator and the specific organizational structure of the hospital. Hospital based HTA can be performed by a team of professionals working at the hospital, or by an external team of professionals that is generating structured evidence to support decision making at hospital level.

### **Definition**

Hospital-based Health Technology Assessment (HB-HTA) means performing HTA activities tailored to the hospital context to inform managerial decisions on different types of health technologies. It includes the processes and methods used to produce HTA reports in and for hospitals.

Definition developed by the partners of the AdHopHTA project (AdHopHTA Handbook; Sampietro-Colom et al, 2015)

### **HB-HTA: a tool for healthcare management**

Different motivations can explain the diffusion of the adoption of HTA methods and tools at hospital level. Taking an “HTA” perspective, HB-HTA can be seen as a solution to support the implementation of national-level HTAs’ recommendation in clinical practice (Cicchetti et al. 2008). The problem of “diffusion” of HTAs and their impact is one of the major issues, still to be solved by HTA agencies (Jacob & McGregor, 1997). An HTA report tailored for the specificity of the organizational context could help the implementation of a recommendation (McGregor and Brophy, 2005). On the other hand, HB-HTA can be considered as a solution for healthcare managers facing the major challenge to decide effectively about the adoption of medical technologies in a challenging context. The role of HTs is crucial for success (or failure) of any healthcare organization.

Hospitals are more and more acting under budget constraints and economic pressures as a result of the tendency present in many healthcare systems to foster micro-economic efficiency to reach financial equilibrium at system level. Actually, a sustainable and successful healthcare organization should be based on a perfect combination of profound professional competencies and valuable health technologies.

Health technologies, in fact, are crucial for clinical effectiveness. On the other hand, new technologies usually increase the costs of care creating pressures for financial sustainability. In addition, the adoption of new health technologies often needs relevant capital investments. Nevertheless, it is not possible to imagine any organizational development and evolution without investing money in new technologies. Managerial decisions regarding investments in new technologies, even when are “evidence based”, can be perceived “discretionary” and have the potential for producing organizational conflicts among professionals. As a result, decisions about medical technologies are usually considered very critical.

As a consequence, hospitals need contextualized assistance on how to make sound investment decisions on innovations, that should be tailored to their specific contexts (e.g. organization of care), focused on the HTs of their strategic interest (financial growth, focusing healthcare services, etc.) and adjusted to their timing (faster answers). Hospital managers are looking for advanced managerial tools, based on economic-rational approaches but also acceptable in medical contexts.

HB-HTA, in general, provides a positive framework that seems to face the need for “rationality” asked by managers about hospital’s technologies related decisions. Thanks to HTA, such critical decisions can be based on criteria that reflect values and visions of all stakeholders inside the system: safety, efficacy, cost-effectiveness are important dimensions for patients, clinicians and managers. HB-HTA also gives the opportunity to healthcare managers to take into consideration the interaction between technology and the organizational texture (e.g. need for new workforce, modification of work processes, infrastructural changes, knowledge creation, etc.). HTA principles, methods and tools seem to fit with the needs of “rational” decision making at this level and it makes HB-HTA an effective tool for management.

### Forms of hospital based HTA

Examples on the use of HTA at hospital level have been reported since the 1980s when CEDIT had been established within the Assistance Publique Hôpitaux de Paris. We have learnt that HB-HTA can be performed with varying organizational complexity. It can be a unit with permanent full-time HTA professionals or a network of clinicians dedicated part-time, but planned and assigned regularly to assessment duties.

There is no “one-size fits all” model to look at when setting up an HB-HTA unit. The way an HB-HTA unit is framed, organized and run depends on the characteristics of both the context and values of the hospital, and is influenced by the culture of the professionals working in the specific healthcare system.

In the past, only a few surveys have tried to capture these experiences in different geographical contexts. The first worldwide survey was carried out by the HB-HTA Interest Sub Group of HTAi in 2008 (Cicchetti et al, 2008). This survey, identified four types of HTA activities carried out in hospitals based on their focus of action and organizational complexity, classified as follows: ambassador model (clinicians recognized as ‘opinion leaders’ play the role of ambassadors of the HTA “message” inside the hospital), mini-HTA (clinicians carry out the assessment process filling a check-list), internal committee (a group of clinicians who perform reviews of evidence to provide a recommendation on a HT), and HTA unit (formal organizational structure based on specialized HTA personnel in hospital). This survey was useful to depict the variety of organizational solutions and ways of application of HTA around the world. Nevertheless, the survey was not able to fully capture the characteristics of the processes, the quality of the products or the impact of each units’ activity.

The most recent results regarding HB-HTA organizational models come from AdhopHTA (Sampietro-Colom et al. 2015). On the base of the analysis of 7 in-depth case studies it was possible to create a taxonomy of models of HB-HTA functions based on two different relevant variables: the level of interaction with nation-regional level HTA bodies and the level of organizational structuration and maturity of the function<sup>1</sup>:

- Independent group; these units operate within the hospital as an “independent group” that provides support for management decisions in a fairly informal way;

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<sup>1</sup> List of Case Studies. Hospital Clinic de Barcelona (HCB/FCRB); Ankara Numune Training and Research Hospital (ANH); University Hospital of Lausanne (CHUV); Hospital District of Helsinki and Uusimaa (HUS); Odense University Hospital (OUH); Policlinicouniversitario “A. Gemelli”, Università Cattolica del Sacro Cuore (UCSC); Auckland City Hospital (ACH), Auckland District Health Board, New Zealand.

- Integrated-essential HB-HTA unit; these are units of small size, with a limited number of staff members, but which are able to involve many other actors and “allies” in their activities;
- Stand-alone HB-HTA units; units with usually highly formalized and specialized procedures, acting internally within hospitals and not strongly influenced by the national or regional HTA organizations (currently the most frequent model in Europe).
- Integrated-specialized HB-HTA units; the functions of the HB-HTA unit are influenced by formal collaboration with the national or regional HTA agency. In general, the involvement of HB-HTA units in the technology adoption process is considered advisable and the HTA-based recommendations are closely followed by hospital decision-makers.

These four groups should be considered as ideal-types, recognizing that none of them is able to capture the real complexity of units belonging to one of the four options. Nevertheless, the model communicates, at least, the richness of available solutions to run an HTA program/initiative within a hospital. The model can also describe a sort of organizational life cycle for HB-HTA programs/initiatives. During start-up, units are typically informal and less connected with the external environment (Independent groups). People work part-time, on a voluntary basis without strong formal endorsement from management and with informal procedures. The presence or absence of national/regional HTA bodies acting as hub of an HTA network, influences the evolution of the unit toward an integrated or a stand-alone solution. Evolution towards a more mature HB-HTA program/initiative is characterized by increasing levels of formalization and structuration in the processes and the progressive alignment between strategies and goals pursued by the HTA program/initiative and hospital-level strategies. In this evolution, the HB-HTA program/initiative gains internal and external legitimation until it is fully recognized as a key actor for the hospital's development strategies and is also considered as a partner at the national-regional level.

Table 1-1 reports a summary of 30 case studies presented by the Sampietro-Colom and Martin in 2017 grouped using the model introduced before.

**Table 1-1. Thirty hospital based HTA units world wide**

Acronym	Name of the hospital	Country	Name of the unit	Establishment (Year)	Model
AP-HP	Paris University Hospital	France	CEDIT	1982	Stand alone
Hospital Garrahan	Pediatric Hospital Garrahan	Argentina	HTA Committee	2001	Stand alone
UCSC	Policlinico Gemelli	Italy	HTA and Innovation Unit	2001	Stand alone
CHUM	Centre Hospitalier de l'Université de Montréal	Canada	HTA Unit	2005	Stand alone
CHU	CHU de Québec - Université Laval	Canada	HB-HTA Unit	2006	Stand alone
EPCs	University of Pennsylvania	USA	Penn Medicine Center for Evidence-Based Practice (CEP)	2006	Stand alone
Sick Kids	The Hospital for Sick Children - Peter Gilgan Centre for Research and Learning	Canada	Technology Assessment at Sick Kids (TASK)	2007	Stand alone
HCB	Hospital Clinic Barcelona	Spain	HB-HTA Unit	2009	Stand alone
Numune Hospital (ANH)	Ankara Numune Training and Research Hospital	Turkey	ANHTA	2012	Stand alone
Hospital El Cruce	Hospital El Cruce	Argentina	Assessment Committee -(MDs, equipment, procedures) Pharmacy and Therapeutics Committee (Drugs)	2010 (Assessment Committee) 2008 (Pharmacy and Therapeutic Committee)	Stand alone
KP	Kaiser Permanente	USA	Interregional New Technologies Committee (INTC)	1980	Stand alone
China (HB Unit Overview)	Overview Very few HTA units	China	General description of HB-HTA Unit	NA	Stand alone
Helsinki Univ Hospital	Helsinki University Hospital	Finland	HTA Group coordinated	2001	Integrated specialized
OHU	Odense University Hospital	Denmark	HTA Unit	2002	Integrated specialized
CHUS	Centre hospitalier universitaire de Sherbrooke	Canada	Health Technology Assessment (HTA) Unit	2004	Integrated specialized
Sahlgrenska	Sahlgrenska University Hospital	Sweden	HTA-Centrum	2007	Integrated specialized
Eastern Health Alliance	Changi General Hospital	Singapore	Health Services Research (HSR) department	2014	Integrated specialized
SSCN	Surgery Strategic Clinical Network of Alberta Health Services (AHS)	Canada	Evidence Decision Support Program (EDSP)	1997	Integrated specialized
Lausanne (CHUV)	University Hospital Lausanne	Switzerland	HTA Unit	2002	Integrated essential
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital	South Africa	Charlotte Maxeke Research Consortium (CMERC) Unit	NA	Integrated essential
VR&VM	Virgen del Rocío/Virgen de la Macarena Hospitals	Spain	Joint Commission for HTA	2002	Integrated essential
Radboud Hop	Radboud University Medical Center	The Netherlands	HTA-Unit	1993	Independent group
McGill University Health Centre (MUHC)	Lachine General Hospital (LGH) Montral Children's Hospital (MCH), Montral General Hospital (MGH), Montral Chest Institute (MCI), Montral Neurological Hospital (MNH) Royal Victoria Hospital (RVH)	Canada	Technology Assessment Unit (TAU)	2001	Independent group
Mon Health	Monash Health	Australia	New Technology and Clinical Practice Committee	2002	Independent group
Auckland DHB	Auckland City Hospital	New Zealand	HB-HTA Committee - Northern Region Clinical Practice Committee (NRCPC)	2005	Independent group
NATS-INC	Instituto Nacional de Cardiologia	Brazil	HTA unit	2009	Independent group
Conceição Hospital Group	Conceição Hospital Group	Brazil	HTA unit	NA	Independent group
HSJD	Hospital Sant Joan de Déu	Spain	HTA Committee	NA	Independent group
Geneva Univ Hospital (HUG)	Geneva University Hospital	Switzerland	Commission for new technologies plus Specific Committees for drugs and devices	not available	Independent group
Vaudois (EHNv)	North Vaudois Hospital	Switzerland	Drug committee for drugs, Biomedical Engineering for equipment and devices	NA	Independent group

Source: (Cicchetti et al., 2017)



**Hospital Based HTA: mission, structure, products and processes**

Table 1-2 is structured to summarize major characteristics of HB-HTA units/functions based on observed trends in many case studies around the world. The use of HTA in and for hospitals is intended to (1) support managerial decision making or (2) just to assess the potential impact of the introduction of a medical technology in the clinical practice. In the first case the HTA process produces direct impact on managerial decisions and is often integrated within procurement procedures of medical technologies. Alternatively, the assessment can only produce a recommendation for clinical practice and, in general, is not mandatory.

In both cases HTA is playing a strategic role for hospital management and for this reason is typically performed by units or individuals reporting hierarchically or in staff to a top management team (CEO, CMO). Alternatively, this activity is depending hierarchically or functionally by quality directorates or research and innovation departments.

HB-HTA is typically a multidisciplinary process that involves clinicians, pharmacists, clinical engineers and health economists. The variety of competencies often includes nurses, sociologists and bioethicists. The number and the variety of professionals involved in HB-HTA depends on different factors such as the dimension of the hospital, its institutional orientation (teaching or non-teaching), and the phase of development of the HTA unit (start-up phase, mature).

The evidence generated by 34 case studies within the AdHopHTA project as well 30 case studies collected by Sampietro-Colom and Martin (2017), provide a full picture of the variety of procedures and products produced by hospital HTA bodies.

**Table 1-2. Characteristics of hospital based HTA units/functions**

Characteristics of HB-HTA	Micro-trends in organization and performance of HB-HTA units
Mission (how it is defined by the HB-HTA unit)	Managerial support for decision-making (in this case, the hospital management body is committed to taking the results of the assessment into account in its decision-making process) Assessing health technologies (in this case, there is no formal commitment to integrate the assessment results in the final decision-making process)



Characteristics of HB-HTA	Micro-trends in organization and performance of HB-HTA units
Position in the organizational structure of the hospital	CMO (Chief Medical Officer) (most) CEO Quality and Research Directorate Research and Innovation Directorate
Funding source (public)	External (e.g., competitive grants, contract with other organizations) – <i>most cases</i> Internal (from hospital budget) (in most cases there is little funding support from the hospital budget)
Role of HB-HTA in the decision-making	Advisory – <i>most cases</i> Mandatory
Role after the assessment	None – <i>most cases</i> Procurement (acquisition) phase – <i>few cases</i> Implementation of recommendation – <i>few cases</i>
Background of professionals in the unit	Clinicians, health economists, public health – <i>most cases</i> The same as a) plus nurses, bioengineers, and other allied health professionals
Careers opportunities	Formal (specific plans for development)– <i>none</i> Informal (e.g., ad-hoc conferences, courses, etc.) – <i>most cases</i>
Staff dedication in the HB-HTA unit	Part time – <i>most cases</i> Full time
Dissemination of the activities performed by HB-HTA unit	Internal (clinical rounds, word of mouth, information sends to clinical departments, broadcast email, presentation at the hospital board meeting) External (media, national journals, newsletters, websites, courses, events and conferences)
Prioritization of health technologies for assessment	Based on specific criteria – <i>few cases</i> First-in-first assessed – <i>most cases</i>
Types of health technologies assessed (in order of frequency)	Medical devices Medical equipment Diagnostic tests Procedures (clinical and organizational) and drugs

Characteristics of HB-HTA	Micro-trends in organization and performance of HB-HTA units
Performance of the assessment	By professionals in the HB-HTA unit involving closely clinicians and hospital managers Shared between clinicians (e.g., literature review) and the HB-HTA unit (e.g., economic analysis + supervision of work by clinicians) By clinicians supported and supervised by the HTA unit
Scope	PICO (patient, intervention, comparator, outcome) – <i>all cases</i> Type Comparator: gold standard and technology available at hospital
Recommendations included	Yes – <i>most cases</i> No, just results (e.g., clinical or economic) of the assessment are presented.
Role of HB-HTA in the decision-making	Advisory – <i>always</i> Mandatory – <i>never</i>
Impact of the recommendations on the final decision	High – <i>most cases</i> Low
Assurance of transparency during the assessment	Internal reviews – <i>often</i> Step-by-step, explicit (e.g., published or shown to clinician) External review – <i>less frequent</i>
System/approaches to assure independence of assessment	Informal – <i>most</i> Systematic
Dissemination of the HB-HTA product/assessment	Internal (e.g., Intranet-database: complete assessment, abstracts or summaries of the assessment) – <i>most cases</i> External (e.g., database open to other hospitals) – <i>few cases</i>
Measurement of impact of HB-HTA unit	None – <i>most cases</i> Non-systematic – <i>few cases</i> Systematic – <i>never</i>

Source: Sampietro-Colom L., et al 2015. The AdHopHTA handbook: a handbook of hospital-based Health Technology Assessment (HB-HTA): Page 63-64.

Different organizational procedures should be designed in order to produce specific outputs. Two main outputs of the work carried out by HB-HTA functions can be outlined:

- Mini-HTA Reports, designed to support managerial and clinical decision-making regarding the adoption of a specific technology in a hospital;
- Broad technical analysis to support multi-year investment plans mainly related to large biomedical equipment.

The evidence shows how it is crucial to ensure that HTA reports are “fit-for-purpose” and meet the needs and expectations of end-users. In the case of HB-HTA, these users are hospital decision-makers. Hospital decision-makers require information on the clinical effectiveness, budget impact, safety, organizational and strategic aspects of the technologies they consider for adoption (Kidholm et al., 2016). This information can be provided at different levels of comprehensiveness. Even more important is the correct timing in relation to the subsequent decision. Moreover, ensuring the quality of information is crucial; AdhophTA has produced a quality checklist for HB-HTA reports and this was applied to assess HTA documents produced by hospitals participating to the consortium. Among the main observations of the analysis are the following:

- There is no one type of HB-HTA report. The reports range from almost full HTA reports to simpler checklists of questions without a deep level of detail;
- The overall quality of the reports evaluated is moderate, leaving room for improvement;
- The higher the quality score of an HB-HTA report, the greater the volume and amount of staff-effort required to produce it.

What is relevant to point out is that the domains of the assessment for HB-HTA products are significantly overlapping with those of traditional HTA with some differences but their relative relevance is different. In fact, doing a mini-HTA “in” or “for” a hospital, is not just re-doing an HTA in a specific context.

Figure 1-1 is providing explanation of this issue. If we consider the 9 domains of the typical EUNetHTA Core model it is clear that some of them are more relevant when the assessment is performed in a hospital. Moreover in the specific hospital context organizational and strategic issues became relevant. In fact, the assessment should take into consideration which is the specific mission of the hospital in the wider healthcare system and its strategic orientation in this scenario. A research hospital, for instance, that is willing to provide excellent care in its context will be keener to adopt innovative medical technologies than a community hospital.

All these considerations were relevant in order to identify the AdHopHTA mini-HTA Template that provides a model to collect the information needed to carry out the assessment of a new technology in a hospital setting. The template is structured as a list of questions (32) grouped in 5 sections to be answered for a comprehensive collection of information to support managerial decision-making regarding the adoption of a specific technology.<sup>1</sup>

**Figure 1-1. HTA and HB-HTA domains**

Domain	HTA Core model	HB-HTA Core model
	EUnetHTA	AdHopHTA
D1: Health problem and current use	✓ relevant	✓✓✓ most important
D2: Description and technical characteristics	✓ relevant	✓ relevant
D3: Clinical effectiveness	✓ relevant	✓✓✓ most important
D4: Safety aspects	✓ relevant	✓✓✓ most important
D5: Costs and economic evaluation		✓ relevant
D5.1 Societal point of view	✓ relevant	✓✓✓ most important
D5.2 Hospital point of view		
D6: Ethical aspects	✓ relevant	✓ relevant
D7: Organizational aspects	✓ relevant	✓✓✓ most important
D8: Social aspects	✓ relevant	✓ relevant
D9: Legal aspects	✓ relevant	✓ relevant
D10: Political and strategic aspects		✓ relevant
D10.1 Political aspects		
D10.2 Strategic aspects		✓✓✓ most important

Source: Sampietro-Colom et al. 2015 (AdHopHTA Handbook).

<sup>1</sup> Structure of the AdHopHTA Mini-HTA Template. Question 1: Summary; Question 2-7: Basic information; Question 8-13: General methodological aspects & reporting; Question 14-27: Results within domains; Question 28-32: Discussion, conclusion and recommendations (Source: [www.adhophta.eu](http://www.adhophta.eu)).

Another relevant output of the AdhopHTA project was the Guiding principles for good practices in HB-HTA that is completed by a toolkit. The Guiding Principles have been defined to guarantee good practices for those hospitals that want to start to carry out or use HTA as well as for those that want to improve their current work on HB-HTA (Sampietro-Colom et al., 2016). The 15 guiding principles for good practices in HB-HTA are grouped into 4 dimensions: the assessment process; the frame of the unit (in particular its leadership, strategy and partnerships); the resources needed by the unit; and the impact of the unit's work.

### **Assessing Hospital Based HTA**

There exists a wide literature regarding the application of HTA logic at the hospital level. The HTAi's Worldwide survey (Cicchetti et al, 2008), case studies in AdhopHTA (Sampietro-Colom et al., 2015) and those collected in the book edited by Laura Sampietro – Colom and Janet Martin in 2017 (Sampietro-Colom and Martin, 2017) has created a significant evidence useful to identify key success factors and potential barriers for the development of HB-HTA functions (Cicchetti et al., 2017).

### **Key success factors**

- Competence and training: The presence of well-trained and motivated people in HTA and easy access to scientific journals and other informational resources, are key factors for a successful experience in HB-HTA.
- Transparency and rigour: Transparency and rigour of the assessment process is considered as one of the major success factors for a HTA hospital based unit.
- Legislative framework: Legitimation of HB HTA unit by law, where it is present (e.g. Quebec), is considered a facilitator.
- Multi-disciplinary Team: Diversity in the cultural and professional background of units' personnel is considered a key success factor for many hospitals around the world.
- Top Management commitment: A clear and formal endorsement from top management team is key to ensure genuine collaboration from clinical departments and other hospitals' units. These conditions are considered fundamental to increase the acceptability of recommendations produced by HB-HTA programs/initiatives.
- Clinicians' (users) involvement: Many of the units highlighted the importance of active end-user involvement (clinicians, nurses) in the assessment process. Continuous education programs that incorporate an evidence - based medicine approach for clinical decision-making, is key to promote the diffusion of a positive cultural attitude towards HTA.

- Research-Management collaboration: University collaboration, especially in the case of academic medical centres, raises the opportunity to have access to specific and broad competencies that may be lacking within the available HB-HTA unit staff and resources. This can ensure greater robustness, and increase acceptability of recommendations.
- Clear role of the HB-HTA unit and explicit methodology: Clarity of the role played by the HTA initiative/program within the hospital organizational processes (e.g. in procurement process) and the existence of a formalised methodology for the assessment is important in order to reduce internal conflicts and improve impact of recommendations.
- Timeliness: Having timely HB-HTA reports is highly appreciated by many hospital clinical staff, managers and clinicians.
- Patient involvement: Only in two cases, direct and systematic involvement of patients and consumer representatives in the HTA process was reported, and in both cases it was considered as a key factor for success.
- Stakeholder and industry interaction: In a few cases, engagement with industry and other business stakeholders was reported as a way to gain extra financing for clinical activities and to find competencies that are not usually available in the hospital.

### **What has not worked**

- Cultural barriers: One of the most common problems reported by HB-HTA units is the presence of cultural barriers. For some hospitals, especially in countries where the HTA is not well established at a national level, lack of a widespread HTA culture across the country, is considered an important barrier. The lack of physician and managerial awareness and training in HTA are suggested as contributors to this cultural barrier.
- Political interests: In those countries where political power has most influence on hospital decision making, the use and the impact of HTA is more difficult.
- Informational barriers: Lack of available global and contextual information for performing specific assessment of hospital technologies remains an important barrier. This is specially the case for relevant cost data and real world data, which are essential for performing a useful contextualized HB-HTA.
- Systematic stakeholder inputs: Input from patients and other stakeholders beyond the usual hospital-based multidisciplinary decision-makers is rare and many hospitals and HB-HTA units indicated a willingness to invest in developing broader stakeholder engagement in the future.

- Limited focus on HTs assessed: Hospitals seem to be mainly devoted to assessing new technologies in their adoption phase; whereas reassessment of pre-existing technologies already in use in the hospital setting are less commonly assessed. Some of the latter may represent better opportunities for assessment due to their lack of effectiveness and inefficiencies relative to better alternatives; therefore, pre-existing technologies should be routinely considered for disinvestment. In particular, efforts provided by clinicians in contributing to the detection of technologies and clinical procedures to be withdrawn, remains insufficient in many HB-HTA programs/initiatives to date. A more structured and proactive disinvestment process may produce financial savings for hospitals and other areas of the healthcare system.
- Lack of resources: Lack of resources to maintain the required HB-HTA activities is reported as a problem in half of the cases. This lack seems to affect productivity more than the quality of the assessments, specifically reducing the potential impact of the HTA program/initiative due to lack of resourced capacity to produce information within the most window of opportunity for decision-makers.
- Inter-organizational coordination: The need for more effective coordination among multiple HTA programs and initiatives in the same country or region is reported in some cases. This coordination is expected to contribute to economies of scale and better use of limited resources for HTA.
- Monitoring: Since the primary focus of most HTA programs/initiatives is on the adoption phase of newer technologies, a lack of attention and processes is reported for monitoring the real impact of the technologies after their introduction. There also remains a general lack of efforts to understand the impact of the assessments on overall indicators of hospital performance (productivity, effectiveness, outcomes, efficiency).
- Internal use variability: The use of HTA in the same hospital may differ from department to department, and the resources available to assess all technologies varies considerably; therefore, hospital decision-making is not uniformly based on HB-HTA recommendations. This may cause concern for inequities and differences in thresholds of rigor for decision-making across departments.

This long list of positive and negative issue provides a sort of guideline that can help in the phase of establishing new units.



### Hospitals in the HTA Ecosystem

The application of HTA principles and tools at hospital level is evolving and is more and more diffused worldwide. The value beyond the application of HTA to support decision making regarding health technology in hospitals and other healthcare organizations has been recognized thanks to a wider and wider range of evidence that has been produced during the last 20 years. It is now clear that HB-HTA is a different application of traditional HTA logics that can contribute to manage the introduction of new technologies within healthcare systems.

**Table 1-3. Most frequently seen differences between standard HTA carried out at national or regional level and at hospitals.**

Characteristics	National or regional agency	Hospital
The Assessment process		
Type of technologies assessed	<b>Drugs</b> <b>Medical equipment</b> <b>Medical devices</b> <b>Diagnostic tests</b>	<b>Drugs*</b> <b>Medical equipment</b> <b>Medical devices</b> <b>Diagnostic tests</b> <b>Organizational technologies</b>
Scope of HTA	The comparator is the "gold standard" or the technology most used in the country	The comparator is normally the technology that is being used in the hospital (current standard practice)
Most frequently required information (criteria)	<b>Description of HT and technical characteristics</b> <b>Health problem and current use of the HT</b> <b>Clinical effectiveness</b> <b>Safety aspects</b> <b>Ethical, organizational, social and legal aspects</b> <b>Cost and economic evaluation (societal and hospital point of view)</b>	<b>Health problem and current use of the HT</b> <b>Clinical effectiveness</b> <b>Safety aspects</b> <b>Organizational aspects</b> <b>Political and strategic aspects</b> <b>Cost and economic evaluation (hospital point of view)</b>
Perspective of the health economic assessment section	<b>Cost-effectiveness with a societal perspective and using average costs</b>	<b>Differential cost analysis process, budget impact analysis, cost-effectiveness using hospital perspective or payer of hospital services (<u>i.e.</u> actual costs for hospital)</b>

Characteristics	National or regional agency	Hospital
Primary target audience of the assessment	<b>Policy-makers, healthcare payers</b>	<b>Hospital and clinical managers</b>
Type of decision which HTA assessment is going to support	<b>Payment, coverage, reimbursement</b>	<b>Acquisition/investment, strategic alliances, collaborative public-private research, disinvestment</b>
Relevant stakeholders involved	<b>Healthcare payers, representatives of clinicians, patients</b>	<b>Clinician asking for the HT, manager, nurses<sup>\$</sup>, bioengineers<sup>\$</sup>, planners<sup>\$</sup></b>
Follow-up process	<b>Hardly ever</b>	<b>Seldom</b>
HTA report	<b>Full HTA review, more frequently rapid reviews</b>	<b>Hospital HTA (e.g., using mini-HTA, rapid review, full HTA review)</b>
Timescale of assessment	<b>12-24 months</b>	<b>1-6 months (average = 3)</b>
Performance of the assessment	<b>Most frequently: Scientists at national or regional HTA agency University scientists commissioned for the purpose</b>	<b>Most frequently: Scientists at HB-HTA unit Clinicians trained in HTA assisted by scientists at HB-HTA unit Scientists at national or regional HTA agency working for the hospital Clinicians trained in HTA assisted by university scientists</b>
Initiators of the assessment	<b>Policy makers, healthcare payers</b>	<b>Clinicians</b>
<b>Leadership &amp; Strategy &amp; Partnerships</b>		
Leaders	<b>Civil servants or contracted by the national or regional agency with different levels of experience and training</b>	<b>Fully or partly dedicated professionals contracted by the hospital, mostly trained in HTA and with long experience</b>

Characteristics	National or regional agency	Hospital
Leadership & Strategy & Partnerships		
Mission, vision and values	<b>Providing high-quality evidence to inform decision-making by national health services</b>	<b>Managerial support to decision-making, assessing health technologies for clinical practice</b>
Priority setting of HTs to evaluate	<b>Established by policy makers or healthcare payers at national (ministry of health) or regional level</b>	<b>Established by clinical leaders and hospital managers</b>
Partnerships and networks	<b>Formal partners of established networks from national or regional HTA agencies and international organizations</b>	<b>Informal contacts between hospitals at local, regional, national and/or international level</b>
Resources		
Financing	<b>Mainly by government (national or regional)</b>	<b>Mainly by external sources (e.g., competitive grants, contracts with other organizations) Rarely by internal sources (from the hospital's budget)</b>
Profiles and skills (more frequent)	<b>Medical doctors Epidemiologists Economists, statisticians Social workers, ethicists</b>	<b>Medical doctors Epidemiologists, public health specialists Economists</b>

Characteristics	National or regional agency	Hospital
<b>Results &amp; Impact</b>		
Capacity of local adaptation	<b>Limited (high degree of adaptation to local needs required)</b>	<b>Frequently total</b>
Impact measurement (benefits / outcomes to end-users)	<b>Usually end-point outcomes (health &amp; social impact); requires significant funds Costly and difficult to prove direct cause-effect relationship</b>	<b>Usually intermediate outcomes (e.g., satisfaction with the HB-HTA unit and its assessments, net present savings or avoided loss from adopting/not adopting HTs). Impact measurement for specific, recommended HTs Costly and difficult to prove direct cause-effect relationship</b>
Customers' results	<b>Level of use and adoption of the recommendations</b>	<b>Level of use and adoption by hospital managers and clinicians (usefulness in decision-making, satisfaction with HB-HTA function)</b>
Impact on society	<b>Difficult to assess</b>	<b>Difficult to assess</b>

Source: Sampietro-Colom L., et al 2015. The AdHopHTA handbook: a handbook of hospital-based Health Technology Assessment (HB-HTA): Pages 24-25.

\*In EU countries there are pharmacy committees in hospitals responsible for analysing drugs to be introduced into the hospital; hospitals usually focus on other technologies, although this may vary from country to country.

\$ If needed by the type of HT being assessed.

HB-HTA can provide an enormous contribution to deliver valuable medicine in healthcare systems worldwide, increasing the appropriateness in resource use and making (public and private) systems sustainable. At the moment HB-HTA seems able to produce “local value”: this has been confirmed within the AdHopHTA project as well as in a recent comparative analysis of 30 HTA hospital functions around the world (Cicchetti et al, 2017).

In order to translate the “local value” in a greater global impact, HB-HTA functions should be interacting and integrating along the HTA “supply chain”, contributing to international, national, regional and provincial HTA efforts, offering unique knowledge about the impact of healthcare technologies on “local contexts”. The role of HB-HTA functions, in this manner, could evolve assuming two different “missions”: on one hand hospital HTA functions could continue to operate as they mainly did up to now, integrating globally produced reviews of clinical research and HTAs with local evidence, experiences and resources and data to provide intelligent support to managerial and clinical decisions. On the other hand, they should be asked to share locally produced evidence with international, national and regional HTA bodies (and networks such as EuNetHTA) and regulatory bodies (such as EMA or CADTH) supporting adaptive / progressive drug licensing models that are under experiment worldwide or complementing the task that National/Regional HTA agencies are performing around medical devices.

In this fashion HB-HTA functions could assume a clear positioning and role within the global “HTA eco-system”, needed to fully manage the life cycle of health technologies. This should be done by extracting the maximum value from the tremendous economic effort that countries worldwide are providing to face the future challenges of healthcare systems.

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