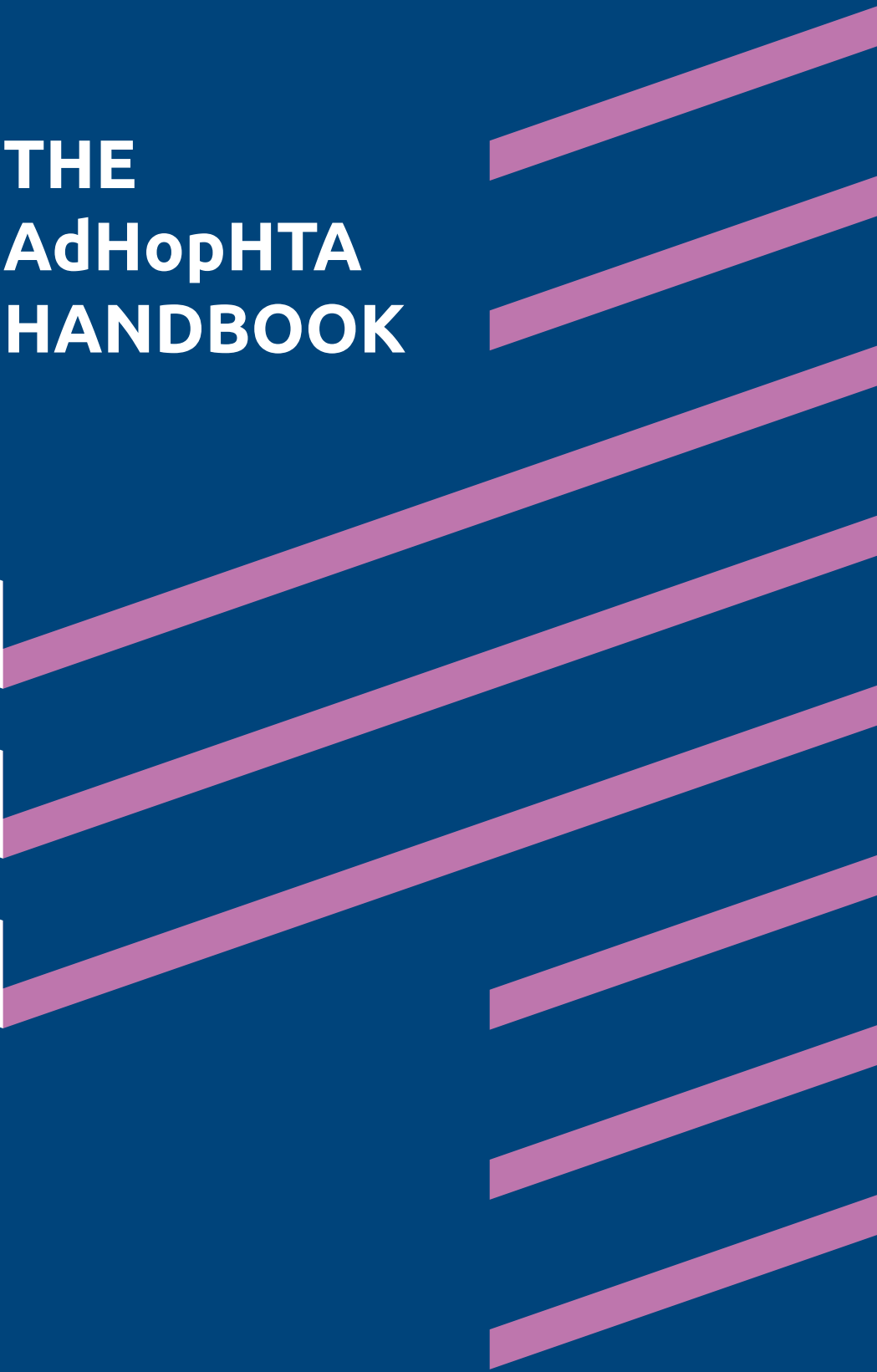# THE
AdHopHTA
HANDBOOK

THE AdHopHTA HANDBOOK

A HANDBOOK OF HOSPITAL-BASED HEALTH TECHNOLOGY ASSESSMENT

Information and knowledge for decision-making on managing technology at hospital level through the use of **hospital-based Health Technology Assessment**

AdHopHTA
Adopting Hospital Based
Health Technology Assessment

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pdf available on
www.adhophta.eu

This handbook is one of the final results of the AdHopHTA (Adopting hospital-based Health Technology Assessment in EU) research project, funded by the European Commission under the 7th Framework Programme (Grant Agreement 305018). Over 385 people from 20 different countries have collaborated in the research that has led to the creation of the handbook of AdHopHTA.

THE CONSORTIUM OF THE ADHOPHTA PROJECT IS FORMED BY THE FOLLOWING ORGANISATIONS:

- Hospital Clínic de Barcelona – Fundació CLINIC per a la Recerca Biomédica (FCRB), Spain – *Coordinator*
- Center for Research in Healthcare Innovation Management (CRHIM), IESE Business School, Spain
- Odense University Hospital (OUH), Denmark
- Centre Hospitalier Universitaire Vaudois (CHUV), Switzerland
- University of Helsinki and Helsinki University Hospital (HUS), Finland
- Tartu University Hospital (TUH), Estonia
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- Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA), Austria
- Ankara Numune Training and Research Hospital (ANH), Turkey
- Norwegian Knowledge Centre for the Health Services (NOKC), Norway

Read more about the AdHopHTA in: www.adhophta.eu

RELEVANT LINKS THAT COMPLEMENT THE CONTENT OF THE HANDBOOK

Scientific publications related to the research conducted in the AdHopHTA project: www.adhophta.eu/publications

The AdHopHTA toolkit for setting up and running an HB-HTA unit is accessible online at: www.adhophta.eu/toolkit

The AdHopHTA database of HB-HTA reports: www.adhophta.eu/database

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FOREWORD

This is the first handbook describing the state-of-the-art and principles for good practices in hospital-based Health Technology Assessment (HB-HTA) in Europe. HB-HTA helps in the management of health technologies in hospitals as it brings together evidence and other relevant and reliable information for hospital managers to guide good investment decisions.

Ever advancing technical developments are fuelling innovative and attractive health technologies, both promising and questionable. Objective, science-based information is of special importance for hospitals as they are the entry point for new technologies. This handbook provides the necessary information and knowledge to guide those who want to embark on or improve their HB-HTA activity. The objective is not only to improve the quality of HB-HTA reports and increase the efficiency and transparency of hospital decision-making processes, but also to work towards the sustainability of healthcare systems.

We very much hope that this handbook and its accompanying toolkit and database will be useful to all the stakeholders involved in HB-HTA as well as in HTA on a larger scale by providing them with a comprehensive view of this very important activity for the efficiency and safety of modern medicine as well as for the health of our population.

The AdHopHTA project consortium
August 2015

EXECUTIVE SUMMARY

SCOPE

Healthcare systems are under pressure facing multiple challenges that condition their present and future sustainability. One on these challenges is the expansion in scientific knowledge and technical developments that are fuelling innovative and attractive health technologies that claim to have the potential to solve many of the current healthcare system challenges as well as provide answers for unmet health needs. While this potential does exist for many innovations, there are others where the claim is questionable. Still, innovation is highly rewarded since it usually contributes to improved health status, life expectancy and quality of life of populations and also drives the economy. All this is taking place in the current context of worldwide economic shrinkage which is forcing healthcare managers to be more accurate in decisions affecting public expenditure. This is of special relevance in hospitals, which are generally the entry point for new technologies. The solution to this complex conundrum calls for the availability of solid processes and tools to guide decisions on innovative and new health technologies (HTs).

This handbook focuses on how to improve decision-making on investments for new health technologies (HTs) in hospitals through the use of hospital-based Health Technology Assessment (HB-HTA). The overarching principle of HB-HTA is to provide hospital decision-makers with relevant, comprehensive, objective, reliable information on the effects and implications of introducing a new HT into the hospital. The information provided by HB-HTA is analysed considering the specific context of the hospital where the HT is to be introduced.

This handbook provides information and knowledge to support the development of an evidence- and knowledge-based decision-making process for management of HTs in hospitals, placing special emphasis on how to set up and develop an HB-HTA unit. It is one of the final results of the AdHopHTA (Adopting hospital-based Health Technology Assessment in the EU) research project, funded by the European Commission under the 7th Framework Programme (Grant Agreement 305018). Over 385 people from 20 different countries have collaborated in the research and this has led to the creation of the handbook and its accompanying toolkit and database.

AIM AND TARGETED READERSHIP

The first aim of the handbook is to reinforce the use and impact of excellent quality HTA results in hospital settings, making available information and knowledge (from research and experience) to facilitate development and running of HB-HTA units. The second aim is to present the role of HB-HTA units in the management of HTs in hospitals and the organisational and performance characteristics of several HB-HTA units in Europe as well as to propose the grounds for setting up an HB-HTA strategy for the EU.

The AdHopHTA handbook is meant for any stakeholders involved in the assessment of new HTs as well as those responsible for making decisions on investing in new HTs, their users and developers of innovations; this includes hospital managers and healthcare sector executives, healthcare professionals, HB-HTA units, health authorities and national or regional HTA agencies, producers of potentially innovative health technologies, international organisations dealing with hospital care, patients and the general public, the worldwide HTA community and the European Commission. Section 1.5 points out the most relevant contents of this according to the interest of these particular target audiences.

MOTIVATION

With this handbook, the partners in the AdHopHTA project aim to respond to the request of the Council of the European Union in its European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) "to improve the sustainability and efficiency of social and healthcare systems" and its recommendation that "Europe's expertise and resources must be mobilised in a coherent manner and synergies between the EU and Member States must be fostered in order to ensure that innovations with a societal benefit get to the market quicker". Moreover, it aims to answer the recommendation from the European Science Foundation on "increasing the use and implementation of high-quality HTA reports and clinical guidelines in hospitals, primary care and all administrative processes, including financing of treatments and technologies". It further aims to contribute to fulfilling the requirements of Directive 2011/24/EU on HTA cooperation in Europe which encourages Member States to provide "objective, reliable, timely, transparent, comparable and transferable information on relative efficacy as well as on the short- and long-term effectiveness of health technologies and to enable an effective exchange of information", and also to highlight the contribution of HTA units in hospitals to the creation of a comprehensive HTA ecosystem in Europe.

CONCEPTUALISING HOSPITAL-BASED HEALTH TECHNOLOGY ASSESSMENT (HB-HTA)

Chapter 1 of this handbook describes what is understood by HB-HTA and why it is important for hospitals. It also shows schematically how it is different from HTA conducted by national or regional agencies and includes a table indicating where in the handbook the different stakeholders can find information relevant for their activities.

Hospital-based Health Technology Assessment (HB-HTA) consists in the implementation of HTA activities "in" or "for" hospitals, which includes processes and methods of organising and carrying out HTA at hospital level with a multidisciplinary, systematic and evidence-based approach. HTA "in" hospitals means that the assessment process is carried out internally by the team of hospital professionals (e.g. clinicians, HB-HTA unit) and always leads to taking managerial decisions on health technologies; whereas HTA "for" hospitals is performed by external bodies on the

basis of different lines of action such as consultations, temporary contracts, freelance activities or projects. However, HTA both "in" and "for" hospitals needs to be tailored to the hospital context and serve for managerial decisions.

The contextualisation of HTA to a specific hospital brings into the assessment process the consideration of its unique characteristics, such as a choice of an available comparator, specific organisational models and patterns within the hospital, a sharper focus on the HTs of interest for the hospital, timely adjustments to the hospital context and collaboration with hospital decision-makers.

Some of the main reasons for promoting HB-HTA in hospitals are that:

- HB-HTA makes it possible to take better-informed decisions supporting effective and safe healthcare.
- HB-HTA facilitates more efficient investment decisions allowing hospitals to save money by reducing unnecessary use or avoiding inappropriate investments.
- HB-HTA is based on scientific knowledge and relevant hospital-specific information. It is objective and targeted to a specific context.
- HB-HTA may lead to improvements in patient safety.

THE CURRENT STATUS OF THE MANAGEMENT OF HEALTH TECHNOLOGIES IN HOSPITALS

Chapter 2 of the handbook describes the process of adoption of new health technologies in European hospitals. This process encompasses a range of actors and is influenced by several factors. It also provides data on informational needs for hospital decision-makers and how existing HB-HTA units are answering this requirement. Organisational models of HB-HTA units are also presented and framed based on existing European experiences. Finally, current experiences in collaborations between HB-HTA units and national and regional agencies are explained.

The role of HB-HTA units in the management of health technologies

The decision-making process for the adoption of new technologies varies from hospital to hospital. Furthermore, the process can differ depending on the type of technology being considered (equipment, medical devices or drugs) and on the existence or not of an HB-HTA unit. **Section 2.1** describes the most frequent decision-making processes followed by European hospitals and presents barriers to and facilitators of the adoption of HTs; **section 2.2** shows the contribution of current HB-HTA units to the decision-making process. Some of the main observations presented are:

- National and regional health authorities of many countries play only a minor role in the decision-making process on the adoption of health technologies in hospitals.
- The main factors influencing the decision-making process of adoption of health technologies are values, external environments, organisational factors, presentation and use of evidence, economic factors and resources needed. These factors may act as facilitators or barriers depending on the hospital setting and context.
- Hospitals with an HB-HTA unit seem to have a better organised and more efficient process of health technology adoption.
- The length of the adoption process is affected by the type of technology; however, the use of HTA in hospitals seems to control risk factors associated with delaying the duration of the adoption process.

Organisational models of HB-HTA units

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, organised and run depends on the characteristics of both the context and values of the hospital, and it is influenced by the culture of the professionals working in the specific healthcare system. **Section 2.3** presents an analysis of current HB-HTA units in Europe showing how they can differ in the level of formalisation, specialisation, integration, centralisation of authority and power and professionalisation.

Based on these factors, 4 organisational models for HB-HTA units have been identified:

1. Independent group — these units operate within the hospital as an "independent group" that provides support for management decisions in a fairly informal way.
2. Integrated-essential HB-HTA unit — these are units of small size, with a limited number of staff members, but who are able to involve many other actors and "allies" in their activities.
3. Stand-alone HB-HTA units — units with usually highly formalised and specialised procedures, acting internally within hospitals and not strongly influenced by the national or regional HTA organisations (currently the most frequent model in Europe).
4. Integrated-specialised 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.

The process of assessment for health technologies in hospitals with HB-HTA units

The main objective of any HTA report is to provide the right information for decision-making. Therefore, 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, organisational and strategic aspects of the technologies they consider for adoption (**section 2.4**). This information can be provided at different levels of comprehensiveness. More important is the correct timing in relation to the subsequent decision. However, ensuring the quality of information is crucial; to this end, the handbook provides a quality checklist for HB-HTA reports (**section 2.5**) and the results of the quality analysis of a sample of HTA reports from AdHopHTA partners' countries. The main observations from the analysis include 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 the deep level of detail.
• The overall quality of the reports evaluated was 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.

Collaborative experiences for HB-HTA with national or regional HTA agencies

Most HB-HTA units are found in healthcare systems where national or regional HTA agencies exist. It is logical to think that both organisations should interact and collaborate to create an HTA ecosystem where fruitful results are obtained from the collaboration. **Section 2.6** aims to describe the extent and patterns of collaboration between HB-HTA units and national or regional HTA agencies in Europe and Quebec. A list of facilitators of and barriers to good collaboration is also provided. Currently, the interactions and collaborations are for the most part informal, although formal organisation is deemed necessary by most. Hospital-based HTA units and national or regional HTA agencies typically share documents and training efforts, as well as provide individual expertise and give political support. Different expectations regarding timeliness and methodological quality of HTA reports have been identified as a barrier that limits the perceived usefulness of sharing the work. Informal interactions are considered important for the creation of mutual understanding and trust.

GUIDING PRINCIPLES FOR GOOD PRACTICES IN HB-HTA

Chapter 3 of the handbook presents the guiding principles for guaranteeing 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. The methodologies used to compile these are presented in **section 2.7**.

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 for the unit; and the impact of the unit's work.

Guiding principles for good practices in HB-HTA units

DIMENSION 1: THE ASSESSMENT PROCESS

1. **HB-HTA report: scope, hospital context and informational needs**
   The HB-HTA report clearly states its goal and scope, reflects the hospital context and takes into account the informational needs of hospital decision-makers.

2. **HB-HTA report: methods, tools and transferability**
   The HB-HTA report is performed systematically using good practice methods and appropriate tools. It should be done in a way that can be adapted by other hospitals (transferability).

3. **HB-HTA process: independent, unbiased and transparent with stakeholder involvement and communication**
   The HB-HTA process involves all relevant stakeholders. It is conducted in an unbiased and transparent manner, ensuring independence and it is properly communicated to hospital stakeholders.

DIMENSION 2: LEADERSHIP, STRATEGY AND PARTNERSHIPS

4. **Mission, vision and values and governance**
   The mission, vision and values of the HB-HTA unit are clearly defined and are coherent with the hospital's overall mission and strategy and allow for clear governance of the HB-HTA unit.

5. Leadership and communication policy/strategy
Clear leadership at the top of the HB-HTA unit acts as a role model when striving for excellence and defining and promoting a good communication policy/strategy.

6. Selection and prioritisation criteria
Criteria for the selection of technologies to be assessed are clearly stated.

7. Process of disinvestment
The process for identifying and evaluating technologies for potential disinvestment is defined and established.

8. Improving through innovation
There is a willingness to improve in the light of experience and a capacity to learn and innovate.

9. Knowledge and resource sharing
There is a clear policy and mechanism for sharing knowledge, information and resources.

10. Collaboration with HTA organisations
The HB-HTA unit collaborates with regional, national and European HTA organisations.

11. Links with allies and partners
Key allies and partners are proactively identified and proper interaction between them, staff at the HB-HTA unit, customers and other relevant stakeholders, is facilitated.

DIMENSION 3: RESOURCES

12. Skilled human resources and career development
Well-defined profiles and skills for human resources, recruitment policies and career development plans are established.

13. Sufficient resources
Financial resources are sufficient to cover operational costs and ensure an appropriate place of work.

DIMENSION 4: IMPACT

14. Measuring short- and medium-term impact
Short- and medium-term impact is measured and maintained.

15. Measuring long-term impact
Long-term impact is measured and maintained.

CREATING A COMPREHENSIVE HTA ECOSYSTEM IN EUROPE

The prominent position of HTA on the EU health agenda is firmly established as a result of the long history of support from Member States and the EU. However, until now, European coordination efforts in HTA have basically involved national and regional organisations without specific consideration of the hospital level. HB-HTA initiatives answer hospital decision needs related to health technologies better and represent a bridge to a more effective transfer of HTA results from national or regional level to the hospital context. A better collaboration with and involvement of HB-HTA units within the European HTA scientific and professional network would result in a more comprehensive approach across the different health system levels.

Chapter 4 aims to give an overview of the history and current state of EU health policies, institutions and initiatives relevant for HTA activities in order to reach a better understanding of the need to incorporate HB-HTA into EU policy. It also provides a set of recommendations for the European Union, including support for the creation of a European Network of HB-HTA, which would foster HTA activities at the hospital level and contribute to the creation of a comprehensive EU HTA ecosystem. The mission, vision, values and objectives of this network are also defined. Other specific recommendations are also directed at Member States and relevant stakeholders.

COMPLEMENTARY MATERIAL

The handbook is supplemented with 3 appendices:

- **Appendix 1** provides a model for collecting the information needed for carrying out the assessment of a new technology in a hospital setting (called AdHopHTA mini-HTA template).
- **Appendix 2** summarises the methodology used to develop this handbook.
- **Appendix 3** summarises the history of the development of HB-HTA in the EU within and alongside HTA at a national or regional level.

ACCOMPANYING TOOLS

Finally, the handbook is accompanied by two related products. One is the **AdHopHTA toolkit** providing practical guidance on setting up and effectively running an HB-HTA unit. The toolkit provides both answers to frequently asked questions and tools for practically developing an HB-HTA unit and carrying out the assessment of new HTs. The other is the **AdHopHTA database**, which includes all the assessments performed by 8 HB-HTA units and is intended to be the seed for an expanded database which will include the work of more HB-HTA units in Europe. The toolkit and the database can be accessed through the AdHopHTA website: www.adhophta.eu

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INTRODUCTION

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INTRODUCTION

1.1 HEALTH TECHNOLOGY ASSESSMENT (HTA)

Health Technology Assessment (HTA) is a research-based, practice-oriented assessment of relevant available knowledge on both the direct and intended consequences of health technologies, and on their indirect and unintended consequences (HTAi 2014), in the short and long term (Health technology assessment 2009). The consequences include clinical benefits and economic and organisational impact, as well as the social, ethical and legal implications associated with the health technology being assessed.

The aim of HTA is to provide responses to the specific questions asked by decision-makers on the likely value of health technologies (HTs). Methodological rigour and inclusiveness are required when collecting and analysing context-specific information for an HTA report.

1.2 HOSPITAL-BASED HTA (HB-HTA)

HTA which is performed in the hospital context for managerial decisions is called hospital-based Health Technology Assessment (HB-HTA). It is usually performed in hospitals, but not always. HB-HTA provides responses to hospital managers' questions relating to implementing new technologies[1] in their hospitals, among others.

Hospitals are generally the entry point for new technologies. The new technologies may replace or add on to existing technologies, which means that decision-makers need to know their value in relation to the current standard practice in their hospital. Furthermore, the information needs to be in place when the implementation decisions are made in the hospital, which means that the assessment timelines are usually strict.

HB-HTA is not only about producing context-specific and methodologically sound reports; it is also a way to organise HTA activity in hospitals aimed at informing managerial decisions, taking into consideration the specific question of organising work in hospitals. HB-HTA needs to comply with the leadership and strategies of the hospital and adapt to the existing resources and established partnerships. HB-HTA is also about measuring the results of the unit and its assessments and the overall impact of its performance on customers[2], hospital and society.

Hospital-based Health Technology Assessment (HB-HTA) consists in the implementation of HTA activities "in" or "for" hospitals, which includes processes and methods of organising and carrying out HTA at hospital level with a multidisciplinary,

[1] In the context of this handbook, by "new technologies" we understand technologies which are not yet established in widespread use (at an early stage of diffusion). Some of them may be true innovations with a completely new way of action and proven potential value (see Glossary for "new" and "innovative" technologies).

[2] Customers of the HB-HTA unit are hospital managers, clinical managers, clinicians and nurses.

systematic and evidence-based approach. HTA "in" hospitals means that the assessment process is carried out internally by the team of hospital professionals (e.g. clinicians, HB-HTA unit) and always leads to taking managerial decisions on health technologies; whereas HTA "for" hospitals is performed by external bodies on the basis of different lines of action such as consultations, temporary contracts, freelance activities or projects. However, HTA both "in" and "for" hospitals needs to be tailored to the hospital context and serve for managerial decisions.

The contextualisation of HTA to a specific hospital brings into the assessment process the consideration of its unique characteristics, such as a choice of an available comparator, specific organisational models and patterns within the hospital, a sharper focus on the HTs of interest for the hospital, timely adjustments to the hospital context and collaboration with hospital decision-makers.

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

Different types of health technologies include medical equipment, medical devices, drugs and clinical procedures as well as organisational and e-health technologies.

HB-HTA can be performed with varying organisational complexity (Cicchetti et al. 2008). 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. The following activities **cannot be considered as pure HB-HTA** in the light of the definition of HB-HTA, but rather represent important interim steps when moving to actual HB-HTA:

- Use of national or regional (or other hospitals') HTA reports without proper adaptation to a hospital's own setting and where clinical leaders act as promoters (the so-called Ambassador Model) (Rehnqvist 2005).

- Production of recommendations on health technologies by a committee of clinicians without basic understanding of HTA methods and/or comprehensive information as required by international HTA standards.

- Completion of a checklist of questions for assessing health technologies in hospitals without using the quality standards required for any HTA process.

- Assessing health technologies solely from a bioengineering or organisations-of-care viewpoint.

For more details about varying organisational models of HB-HTA, units go to section 2.3.

- Using evidence to inform procurement processes.

1.3 REASONS FOR ADOPTING HB-HTA

Current hospitals are under increasing pressure and face multiple challenges such as being in the front line of innovative technologies. Socio-demographic changes due to population ageing increase the demand for healthcare. The advancement of scientific knowledge and technical developments are fuelling innovative health technologies that could overcome many of these challenges. However, while many new technologies may be valuable and truly innovative, there are others whose value and innovation are questionable. Additionally, society's expectations as regards the quality of and access to healthcare services are rising. This translates into a societal demand for more accountability and participation in decisions affecting people's health. All of which means that hospitals need to manage available resources more efficiently.

At the same time, there is global pressure to improve quality of life and life expectancy through the introduction of innovative health technologies. The challenge is how to identify which technologies translate into better health outcomes. HTA, with its evolved processes and methods for producing reliable assessments to guide healthcare decisions, has been proposed as a solution to this challenge (WHO 2014).

HTA was originally established to serve governments, which led to the creation of the first HTA Office in the 1970s (read more about the history of HTA in Appendix 3). Later on, it was noticed that HTA might have even greater relevance and impact for hospitals (McGregor & Brophy 2005). Preliminary evidence shows that HTA activities at hospital level can improve efficiency in hospital budget management and also contribute in a real, positive way to decision-making.

Despite the fact that the HTA reports developed by national or regional HTA agencies are generally easily available, clinicians and hospital managers perceive them as connected only loosely to their daily clinical and management practices (McGregor 2006). The main reasons for this are the mismatch in topic prioritisation (Kidholm et al. 2009), content and timing (Cicchetti et al. 2008, Sampietro-Colom et al. 2012) when compared with hospital requirements. Furthermore, clinicians have expressed scepticism regarding HTA agencies or even mistrust of them (Hailey 2003).

Hospitals also require information on emerging technologies for which there is hardly any (good quality) evidence available to produce a reliable HTA report according to the standards of national or regional HTA agencies. Moreover, hospitals need information on many medical devices where no assessment from an HTA agency has been performed.

Hospitals require budget impact analysis (BIA) rather than cost-effectiveness analysis (CEA), which is the type of economic evaluation usually performed from the national or regional HTA perspective. In addition, organisational aspects are scarcely addressed by HTA reports produced by HTA agencies although they are of particular importance for hospitals (Nielsen et al. 2011). What is more, in order to be able to support decision-making in hospitals, HTA reports should focus on local infrastructure, prevailing treatment options, patient populations, learning curves and competing priorities (Martin 2014).

Furthermore, the spectrum of decisions made in hospitals, based on recommendations from HTA reports, is much wider than in national or regional contexts. Instead of a simple "yes", "no" or "yes, for specific subpopulations", there may be decisions made for:

- a single case on an emergent basis;

- strategic alliances with industry for research and further development;

- referral to national or regional authorities (if the decision is beyond the scope of HB-HTA/entails governmental funding) (Poulin et al. 2012).

One final reason for adopting HB-HTA is the need to examine and make decisions on available health technologies that do not deliver the expected health gains or have even been proven to be harmful (Nielsen et al. 2011). This can be the case when technologies are introduced in hospitals without proper evaluation or when there is no transparent decision-making process in place in the hospital to avoid veiled conflict of interest or marketing pressures.

All this justifies the need to carry out HTA in hospital contexts.

SIX REASONS FOR ADOPTING HB-HTA

1. Stable or tightening hospital budgets combined with an increasing influx of new technologies make prioritisation a necessity. HB-HTA is a tool for prioritisation.

2. HB-HTA provides hospital decision-makers (managers and clinicians) with science-based, multifaceted information and the necessary arguments on which to base the decision on whether or not to invest in a technology.

3. Information derived from HB-HTA is superior to information provided by national or regional HTA agencies because it is:

   a) rapid and timely,

   b) tailored to the hospital's setting, and

   c) tailored to the information requirements of hospital managers.

4. HB-HTA increases the effectiveness of the technologies used in hospital.

5. HB-HTA has been shown to improve efficiency in hospital budget management.

6. HB-HTA may lead to improved patient safety.

FOUR FACTS FROM EXPERIENCE FOR PROMOTING HB-HTA IN HOSPITALS

1. HB-HTA separates the wheat from the chaff in new technologies based on scientific knowledge, and hospital information.

   - *A case example: The HB-HTA reports provide clear recommendations on the benefits and impact of HTs for the hospital. In one hospital, 165 HB-HTA reports were produced in a 7 year period. These activities yield to the following recommendations: 51 reports recommended the introduction of the HT; 20 recommended not to introduce the HT assessed and for 94 HTs it was recommended to introduce it with limitations (e.g. specific subgroup of patients).*

2. HB-HTA allows you to make better informed investment decisions.

   - *A case example: Results from 4 hospitals show that recommendations from HB-HTA reports have been adopted in more than 90% of the cases by hospital decision-makers (for some hospitals the rate reaches 99-100%).*

3. HB-HTA answers the question relevant for an individual hospital's HTs decisions.

   - *A case example: HB-HTA reports answer the specific information needs of hospital management bodies. Experience from one hospital showed that after a 10 year period (and 40 HB-HTA reports produced), 85% of the clinicians involved in a HB-HTA process acknowledge the utility and necessity of HB-HTA. Another hospital showed that, 5 years after the set-up of the unit (and 23 HTs assessed), managers and clinicians were highly satisfied with the information provided by HB-HTA: 100% of them would ask for the support from the HB-HTA unit again and would recommend working with the unit to other hospital colleagues.*

4. HB-HTA underpins better investment decisions that save money to hospital.

   - *From 1 specific assessment (i.e. laboratory use), a saving of US$ 371,000 and a 10% reduction in unnecessary tests were achieved in one year.*

   - *The budgetary impact of the first 16 HB-HTA documents produced by a hospital resulted in estimated annual savings of US$ 3,000,000 (McGregor & Brophy 2005).*

   - *After the assessment of 23 HTs, 12 technologies were accepted and it was estimated that their net present value will yield €4,100,000 in savings for the hospital over the next ten years. Conversely, 11 technologies were not recommended; if these HTs had been introduced in the hospital, they would have generated a loss of €13,600,000 over the next ten years (Sampietro-Colom 2014).*

The most frequently observed features of HB-HTA and traditional HTA performed by national or regional agencies are presented in Table 1. Despite some varying characteristics HB-HTA and HTA performed by national or regional agencies may benefit from increasing degree of interaction and collaboration between each other to overcome weaknesses and enforce strengths.

TABLE 1 (NEXT PAGE)
GENERAL TRENDS THAT CHARACTERISE HTA CARRIED OUT
AT NATIONAL OR REGIONAL LEVEL AND AT HOSPITALS.

CHARACTERISTICS	NATIONAL OR REGIONAL AGENCY	HOSPITAL
THE ASSESSMENT PROCESS		
Type of technologies assessed	• Drugs • Medical equipment • Medical devices • Diagnostic tests • Organisational technologies	• Drugs* • Medical equipment • Medical devices • Diagnostic tests • Organisational technologies
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)	• Description of the health technology and technical characteristics • Health problem and current use of the technology • Clinical effectiveness • Safety aspects • Ethical, organisational, social and legal aspects • Cost and economic evaluation (societal and hospital point of view)	• Health problem and current use of the health technology • Clinical effectiveness • Safety aspects • Organisational aspects • Political and strategic aspects • Cost and economic evaluation (hospital point of view)
Perspective of the health economic assessment section	Cost-effectiveness with a societal or healthcare payer perspective and using average costs	Differential cost analysis process, budget impact analysis, cost-effectiveness using hospital perspective (i.e. actual costs for hospital)
Primary target audience of the assessment	Policy-makers, healthcare payers	Hospital and clinical managers
Type of decision which HTA assessment is going to support	Payment, coverage, reimbursement, regulation	Acquisition/investment, strategic alliances, collaborative public-private research, disinvestment
Relevant stakeholders involved	Healthcare payers, representatives of clinicians, patients	Clinician asking for the assessment of the health technology, manager, nurses[$], bioengineers[$], planners[$]
Follow-up process	Seldom	Seldom
HTA report	Full HTA, sometimes rapid reviews	Hospital HTA (e.g. using mini-HTA, rapid review, full HTA review)
Timescale of the assessment	12-24 months	1-6 months (average = 3)
Performance of the assessment	Most frequently: • Scientists at national or regional HTA agency • University scientists commissioned for the purpose	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
Initiators of the assessment	Mostly policy makers, healthcare payers	Clinicians

CHARACTERISTICS	NATIONAL OR REGIONAL AGENCY	HOSPITAL
LEADERSHIP, STRATEGY & PARTNERSHIPS		
Leaders	Civil servants or contracted by the national or regional agency with different levels of experience and training	Fully or partly dedicated professionals contracted by the hospital, mostly trained in HTA and with long experience
Mission, vision and values	Providing high-quality evidence to inform decision-making by national health services	Managerial support to decision-making, assessing health technologies for clinical practice
Priority setting of health technologies to evaluate	Mostly established by policy makers or healthcare payers at national (ministry of health) or regional level	Established by clinical leaders and hospital managers
Partnerships and networks	Formal partners of established networks from national or regional HTA agencies and international organisations	Informal contacts between hospitals at local, regional, national and/or international level
RESOURCES		
Financing	• Mainly by government (national or regional)	• Mainly by external sources (e.g. competitive grants, contracts with other organisations) • Rarely by internal sources (from the hospital's budget)
Profiles and skills (more frequent)	• Medical doctors • Epidemiologists • Economists, statisticians • Social workers, ethicists	• Medical doctors • Epidemiologists, public health specialists • Economists
IMPACT		
Capacity of adaptation to local needs	Limited (high degree of adaptation to local needs required)	Frequently total
Impact measurement (benefits/outcomes to end-users)	• Usually end-point outcomes (health & social impact); significant funds required • Costly and difficult to prove direct cause-effect relationship	• Usually intermediate outcomes (e.g. satisfaction with the HB-HTA unit and its assessments, net present savings or avoided loss from adopting/not adopting) • Impact measurement for specific, recommended health technologies • Costly and difficult to prove direct cause-effect relationship
Customers' results	Level of use and adoption of the recommendations	Level of use and adoption by hospital managers and clinicians (usefulness in decision-making, satisfaction with HB-HTA unit)
Health of the community	Difficult to assess	Difficult to assess

* 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 a health technology being assessed.

Depending on the national or regional context some information may vary.
SOURCE. Adapted from Sampietro-Colom et al. 2015.

The aim of this handbook is to provide information and knowledge for decision-making on managing technology at hospital level through the implementation and use of HB-HTA. Therefore, the handbook's objectives are:

- to describe the current characteristics of HB-HTA based on findings in several European countries, how they are organised, what their role in the uptake of new health technologies is, what information and tools are used in the assessment of health technologies, and how they interact with national or regional HTA agencies;

- to provide a knowledge base (facts, evidence and experience) in order to support the introduction and use of HTA at hospital level; and

- to provide the principles that guide good HB-HTA practices.

HB-HTA can be used throughout the whole life-cycle of technologies: from research and development, emerging and new technologies, through early adoption to established use and obsolescence by disinvesting in technologies (Figure 1). This handbook is a product tailored to the hospital context focusing on the use of HB-HTA for assessing new technologies at the adoption stage of the curve.

STAGES OF
UPTAKE OF HTs
IN HOSPITALS
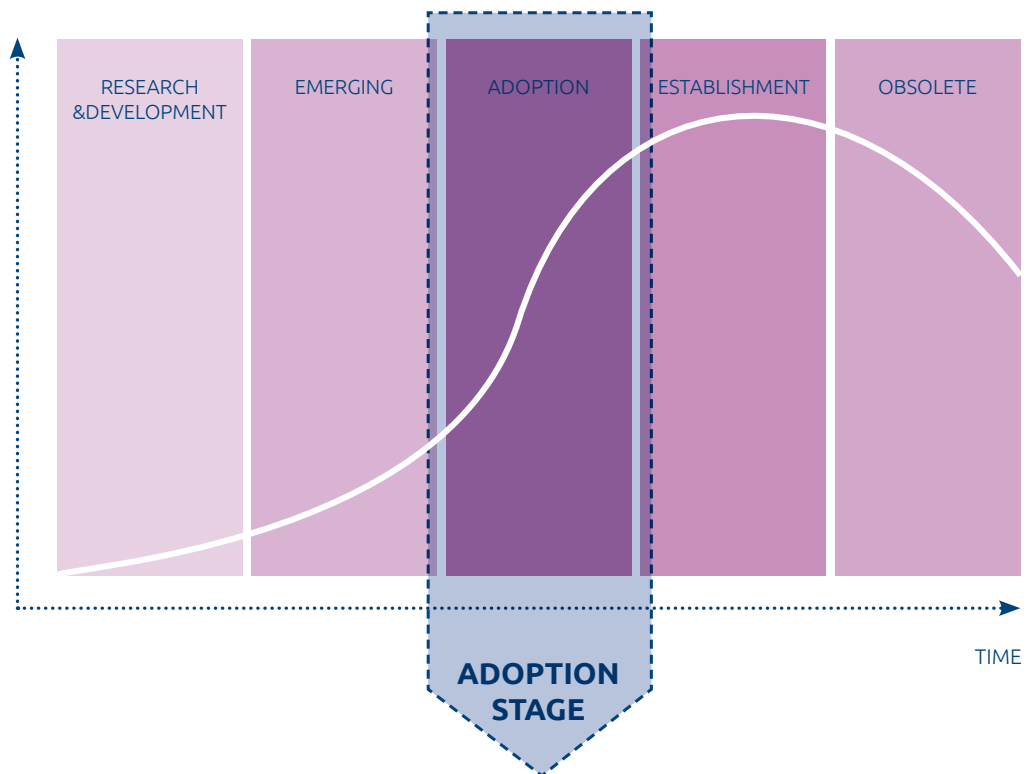
FIGURE 1
FOCUS OF THE
HANDBOOK
WITHIN THE
LIFE CYCLE
OF HEALTH
TECHNOLOGIES

SOURCE
Adapted from Smale
1996.

RESEARCH &DEVELOPMENT · EMERGING · ADOPTION · ESTABLISHMENT · OBSOLETE

TIME

ADOPTION STAGE

ASSESSMENT > DECISION > PROCUREMENT > INTRODUCTION

1.5 TARGET AUDIENCE

The handbook of hospital-based Health Technology Assessment is intended to reach various audiences with different profiles, needs and levels of knowledge who are interested in HB-HTA.

The wide audience of stakeholders, to whom the handbook is addressed, embraces users and doers of HB-HTA as well as those who have an interest in HTA (Table 2).

TABLE 2 (NEXT PAGE)
MOST RELEVANT CONTENTS OF THE
HB-HTA HANDBOOK FOR DIFFERENT
TYPES OF TARGET AUDIENCE.
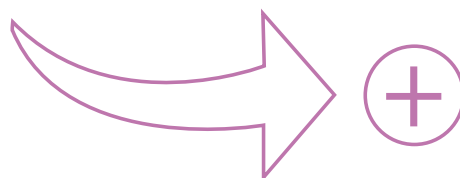
TARGET AUDIENCE	LEARNING OBJECTIVES
Hospital managers especially, but not exclusively, from university hospitals **Healthcare sector executives** (e.g. health insurance companies)	• Support the role of target audience as entry points and gatekeepers for new and potentially innovative health technologies at hospital level • Raise awareness of HB-HTA as a process that can improve decision-making on investment in innovation • Provide directions to set up an excellent HB-HTA unit
Healthcare professionals	• Provide support on decisions concerning the adoption of innovative technologies • Raise awareness of HB-HTA as a process for assuring high-quality medical outcomes in the context of limited resources • Provide directions to set up an excellent HB-HTA unit • Provide information on how to produce a good quality HB-HTA report
HB-HTA units in different settings	• Raise awareness on guiding principles for best practices in HB-HTA • Provide knowledge on a portfolio of HB-HTA management and practices
Health authorities (e.g. policy decision-makers) **and national or regional HTA agencies/units**	• Raise awareness and motivation to assure future support towards fostering the establishment of HB-HTA units in their constituencies • Foster effective collaboration with HB-HTA units to spread the culture and effective use of HTA across hospitals in their nation or region
European Commission	• Implement Directive 2011/24/EU setting up a comprehensive HTA ecosystem across healthcare levels in EU, where HB-HTA is considered • Raise awareness of the need for and usefulness of recommending the design and implementation of an HB-HTA strategy in EU member states
Producers of potentially innovative health technologies (e.g. medical industry)	• Provide information on how hospitals manage the adoption of health technologies, on potential ways of collaboration with HB-HTA units, and on a range of potential collaborations with hospitals on investments in innovative health technologies through HB-HTA • Understand the informational needs of hospital decision-makers as regards their innovative
International organisations dealing with hospital care (e.g. The European Hospital and Healthcare Federation-HOPE; International Federation of Hospitals)	• Understand the need and usefulness of promoting HB-HTA among their members • Raise awareness on organisational models of HB-HTA • Provide directions on setting up an excellent HB-HTA unit
Patients, general public	• Raise awareness of HB-HTA as a process for ensuring patients' benefits and safety when using health technologies at hospital level • Raise awareness of HB-HTA as a process to support rapid access to innovative technologies with proven added value for the hospital
General HTA community at European and global level (HTA networks, such as EUnetHTA or INAHTA, and scientific & professional HTA associations, such as HTAi)	• Understand and promote best practices in HB-HTA around the globe

CONTENT OF INTEREST												
Ch1	Ch2.1	Ch2.2	Ch2.3	Ch2.4	Ch2.5	Ch2.6	Ch2.7	Ch3	Ch4	A1	A2	A3
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2

CURRENT STATUS OF THE MANAGEMENT OF HEALTH TECHNOLOGIES IN HOSPITALS AND THE ROLE OF HB-HTA UNITS THEREIN

2

CURRENT STATUS OF THE MANAGEMENT OF HEALTH TECHNOLOGIES IN HOSPITALS AND THE ROLE OF HB-HTA UNITS THEREIN

This chapter aims to present the current processes and informational needs in the adoption of new health technologies in European hospitals and the role of hospital-based HTA (HB-HTA) in these. The current characteristics of HB-HTA units in European hospitals are described and categorised within specific organisational models. The types of current HB-HTA reports and their quality characteristics compared with described desirable standards are presented. Finally, these observations are utilised together with a healthcare business excellence model to guide the development of good practices for establishing and maintaining HB-HTA units.

All the material presented in this chapter is based on knowledge (facts, evidence and experience) generated under the AdHopHTA research project, by professionals working in hospitals with HTA activities, in national and regional HTA agencies, and a business school. This knowledge derives from 6 literature reviews, 107 face-to-face interviews, 40 Case Studies (38+2), 1 large-scale survey (163 respondents), 1 Focus Group (8 participants) and 1 Delphi process (36 participants) performed by the researchers of AdHopHTA. A detailed description of the multi-method approach used for producing the knowledge base is provided in Appendix 2 of the handbook.

2.1 THE PROCESS OF ADOPTION OF HEALTH TECHNOLOGIES IN HOSPITALS

This section of the handbook describes the most frequent decision-making processes for technology adoption followed by hospitals. Information is derived from a literature review and face-to-face interviews, a large survey and case studies performed in several countries in:
(i) university, research and training hospitals with an HB-HTA unit; (ii) university, research and training hospitals without an HB-HTA unit; (iii) small to middle-sized hospitals without an HB-HTA unit, i.e. community hospitals.

2.1.1 TYPICAL STEPS IN THE ADOPTION PROCESS

The process of adoption of health technologies in hospitals usually consists of the following steps (Figure 1):

- Step 1: preliminary analysis of the clinical needs (e.g. burden of disease, number of patients that require treatment, available treatment options).

- Step 2: evaluation of appropriate setting (level of care) in which the technology is to be used, economic and organisational impact of adopting the technology as well as definition of requisites for tenders.

- Step 3: market analysis and consultation.

- Step 4: choice of procurement procedure[1].

- Step 5: analysis of the offers received and the final decision.

- Step 6: the procurement and logistics associated with the introduction of the technology.

These steps are affected by the types and specific characteristics of the technologies to be adopted; the structural, organisational and procedural characteristics of the hospital; and by the individuals or groups involved in the whole decision-making process (Cicchetti 2013).
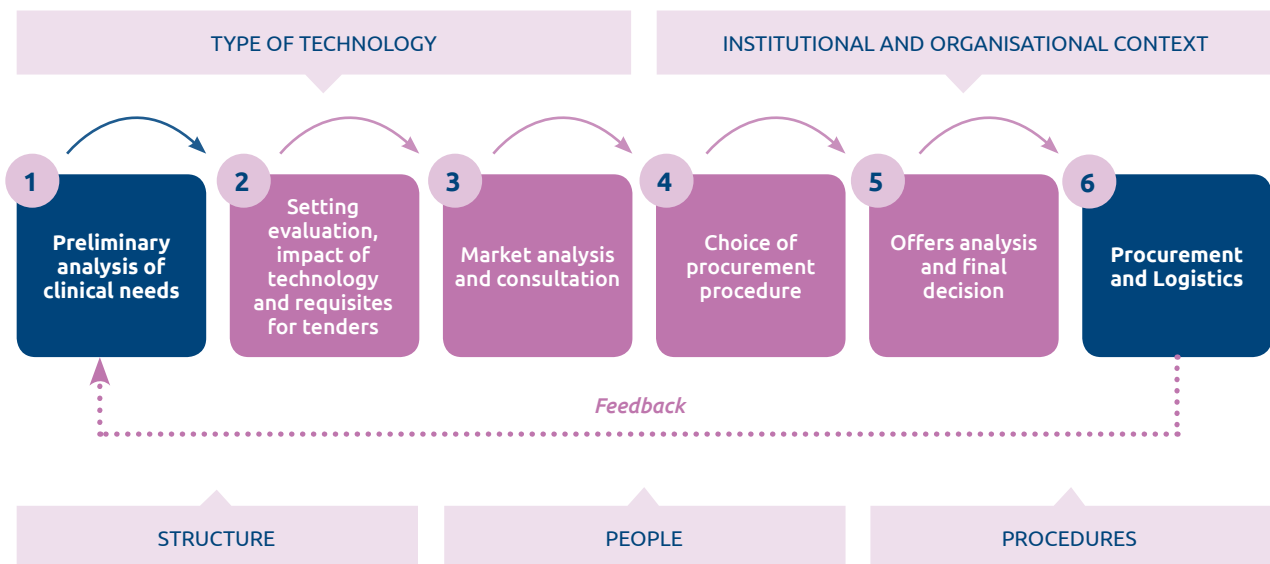
SOURCE
Adapted from Cicchetti 2013.

FIGURE 1

THE PROCESS OF ADOPTION OF HEALTH TECHNOLOGIES IN HOSPITALS (an Italian case).

The steps related to the procurement are gaining special attention among actors involved in the adoption process, particularly in the light of recently issued EU law on public procurement (European Union, 2014). One of its important findings for costly health service contracts (equal or above 750 000 €) is expanding the procurement award criteria beyond solely a price. Now, quality, continuity, accessibility as well as comprehensiveness of services and innovation can be taken into account while undertaking a procurement procedure. Considering these criteria, tendering boils down to a "best value for money" question that can be successfully addressed by the use of HB-HTA. Therefore, HB-HTA use in the technology adoption process is strengthened, even more since it uses local data that is directly applicable to a particular hospital where the technology is about to be implemented.

2.1.2 ACTORS INVOLVED IN THE ADOPTION PROCESS

Initiators of the process

Clinicians, together with chief medical officer (CMO) and heads of the clinical departments are recognised as the main initiators of the health technology adoption process (Figure 2). This was the case in all the hospitals analysed regardless of the country or the type of HB-HTA-activity.

A "bottom up" approach has been identified: clinical experts and local opinion leaders, regardless of their managerial position, participating in medical conferences and meetings, bring in information on the merits of the new technology, which is then communicated to hospital decision-makers.

Involvement of the CEO and/or the heads of clinical departments, as initiators of the process, occurs especially in the case of organisational innovations. Nurses, as well as some other professional groups, such as biologists and clinical engineers act as initiators too, but less frequently. Given that nurses deal with health technologies a lot in their everyday work, their role in the future will probably grow. Finally, procurement and purchase offices and administrative and financial departments can occasionally be the initiators of the process.
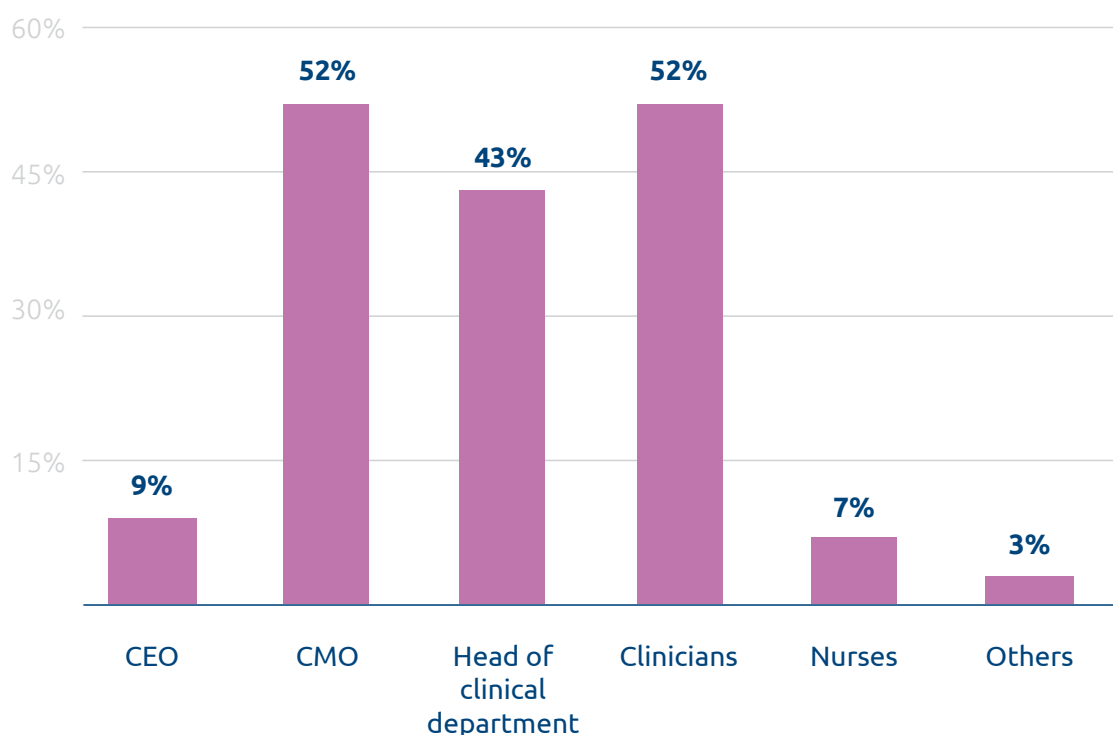
SOURCE
Large scale web-based survey with 163 respondents from 82 hospitals in Spain, Italy, Turkey, Switzerland, Austria, Estonia, Denmark, Finland and Norway (Cicchetti et al. 2014).

FIGURE 2
INITIATORS OF THE DECISION-MAKING PROCESS OF ADOPTION OF HEALTH TECHNOLOGIES.
(Proportions represent absolute frequency i.e. whether a particular actor was or was not the initiator)

Main actors at different phases of the adoption process

Different actors and stakeholders play a major role in different phases of the health technology adoption process (Figure 3). Clinicians and HB-HTA units play a prominent role not only as initiators but throughout the process of health technology adoption, since they generally provide information for all the health technologies.
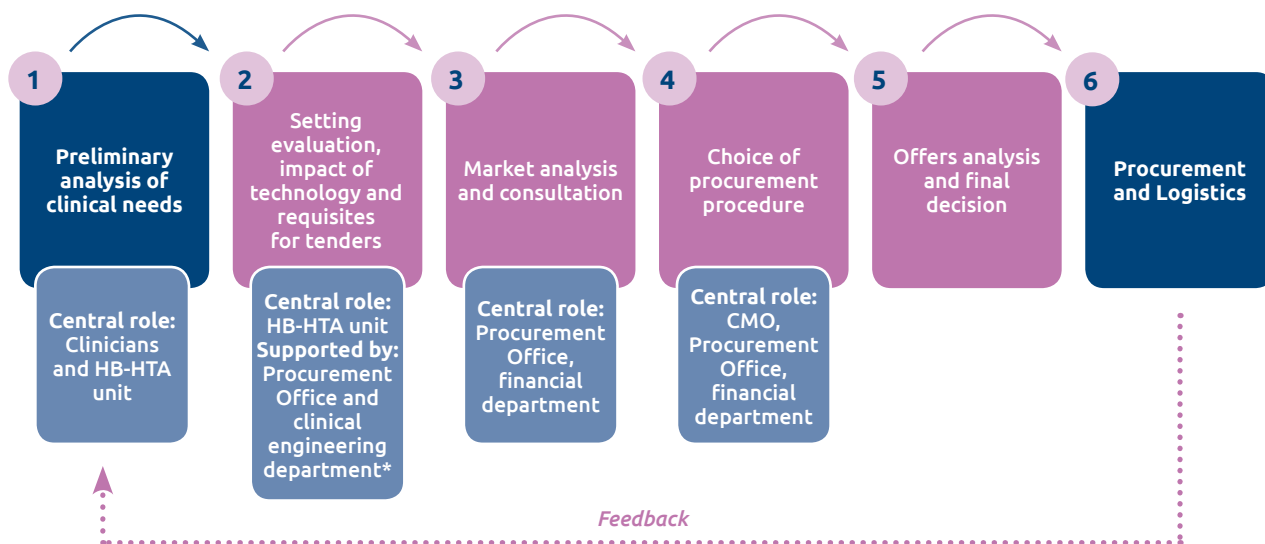
FIGURE 3
AN EXAMPLE OF STAKEHOLDERS' ROLES AT DIFFERENT PHASES OF THE TECHNOLOGY ADOPTION PROCESS (an Italian case).
*Procurement office plays supporting role in setting evaluation and impact of technology, whereas clinical engineering department supports an HB-HTA unit in requisites for tenders.

It is worth mentioning that the involvement of nurses in the process is mainly observed in large hospitals, and in particular, within university or research and training hospitals with an HB-HTA unit. Nurses seldom act as the main actor in the process and their involvement is linked to the process of adoption of, for example, disposable products such as bandages, probes, treatments for ulcers and so on.

Final decision-makers on health technology adoption

In general, top management (the CMO along with the technical committees, such as the hospital purchase committee), and especially the CEO, are usually the ones taking the final decision on the acquisition of health technologies (Figure 4). Heads of clinical departments are less frequently responsible for this. Nevertheless, heads of clinical departments (directorates) or the heads of clinical divisions (units) are recognised as final decision-makers when considering less expensive health technologies.
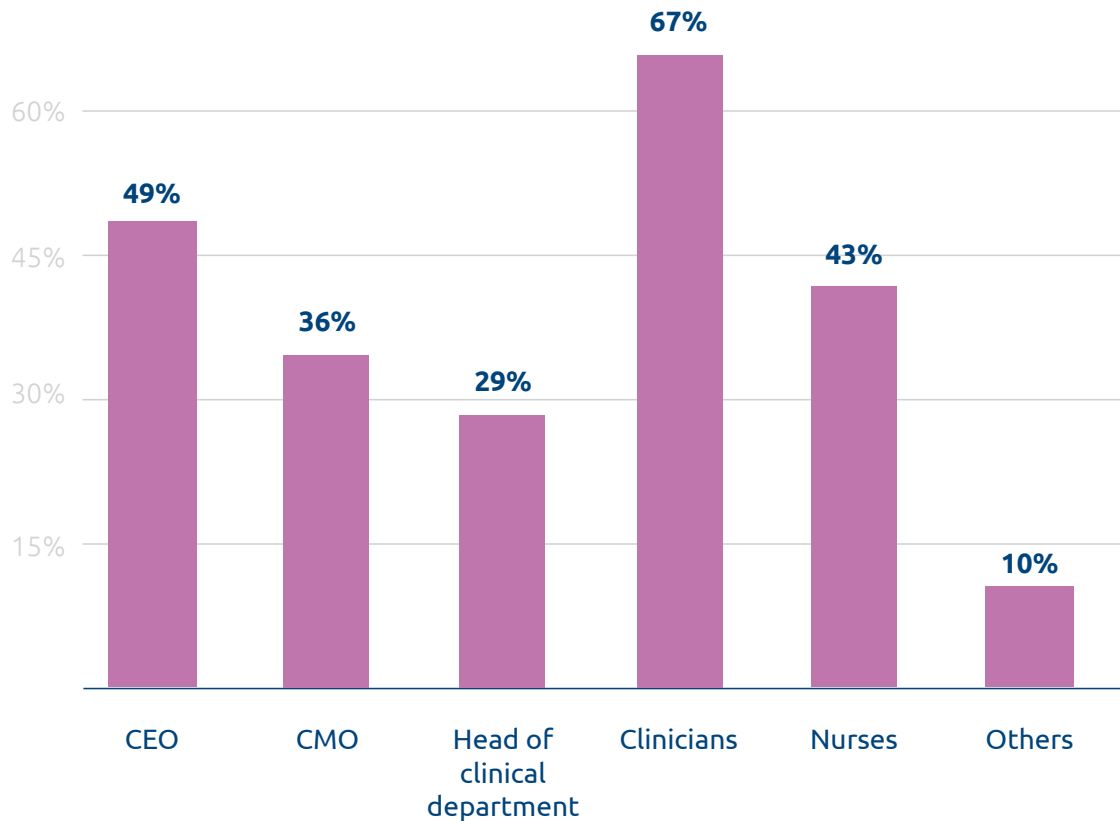
FIGURE 4
FINAL DECISION-MAKERS IN THE ADOPTION OF HEALTH TECHNOLOGIES.
(Proportions represent absolute frequency i.e. whether a particular actor was or was not the final decision-maker)

2.1.3 THE ROLE OF HEALTH AUTHORITIES (NATIONAL AND REGIONAL) IN THE ADOPTION PROCESS

Health authorities at national and regional level rarely influence the planning, procurement and adoption processes of health technologies in hospitals (with or without an HB-HTA unit). Their role is mainly centred on the planning and allocation of resources and of healthcare activities (e.g. definition of budget and planning the number of beds). Seldom are they involved in the procurement of very costly health technologies and large-scale healthcare programmes that require central planning and guidance (e.g. in budgets and calculation of staffing levels).

In other words, hospitals are generally free to choose the kind of health technologies they wish to adopt. There are some exceptions, for example in the case of the adoption of drugs which are regulated by national or regional healthcare authorities. Authorities may also indirectly influence the adoption of health technologies in high-tech or teaching hospitals through negotiation of the type and volume of healthcare activity.

In general, national and regional health authorities seem to have a closer relationship with small and middle-sized hospitals than with larger ones.

2.1.4 BARRIERS TO AND FACILITATORS IN THE ADOPTION PROCESS

There are a variety of decision-making models for the adoption of health technologies in hospitals. They vary according to the context of the specific hospital and the technology under consideration.

A framework of major barriers and facilitators is presented in Table 1. Depending on the specific context and setting; each factor can either facilitate or hinder the adoption of health technologies. For example, information or knowledge can facilitate the adoption of innovation if it provides clear answers to the people in charge, but will be a barrier to decision-making if presented in a way that cannot be understood. Similarly, resources are a facilitator when sufficient, but a barrier when lacking. The factors are organised under five headings: values, external environment, organisational factors, scientific evidence, and economic factors and resources needed.

Definition

Values: Values are those of patients, clinicians and hospital managers.

External environment: the factors, events, rules and norms surrounding the hospital (i.e. regulatory system, payment mechanisms, national or regional regulation).

Organisational factors: the internal characteristics describing a certain organisation (i.e. the hospital capacity, the size, the level of specialisation and all the internal organisational arrangements).

Presentation and use of evidence: availability, clarity and the strength of empirical scientific evidence on a technology.

Economic factors and resources needed: costs of adoption of technology, organisational change required, availability of resources to be allocated.

TABLE 1
MAJOR FACTORS INFLUENCING THE ADOPTION OF HEALTH TECHNOLOGIES.

SOURCE
Literature review carried out in AdHopHTA research project (Cicchetti et al. 2014).

A. VALUES	ACTS AS FACILITATOR WHEN…	ACTS AS BARRIER WHEN…
Clinical need for new technology	There is potential to achieve considerable clinical benefit or to decrease risks	Several alternatives are already in use
Patient expectations	The technology makes it possible to answer unmet needs and launch new health services	The use of the technology is restricted to a limited group of patients or diseases
Prestige of medical and managerial staff	The prestige of the hospital will increase if the technology is adopted	The use of the technology is limited to common diseases, symptoms or situations
Professional ambitions	The technology is in line with the clinical and research ambitions of senior medical staff	The technology is not in line with the clinical practices or research interests

B. EXTERNAL ENVIRONMENT	ACTS AS FACILITATOR WHEN…	ACTS AS BARRIER WHEN…
National or regional regulatory environment	There is no regulatory control on medical equipment and medical devices	National or regional requirements exist to perform HTA prior to adoption
Marketing and sales efforts of pharmaceutical and medical industries	Senior clinicians are encouraged to implement new technologies	Competitors can disseminate biased information and create false perceptions
Payment mechanism (reimbursement) to hospitals by third parties	There is a fee for service payments that can cover costs and generate income	Global budgets and diagnosis-related groups (DRGs) do not allow easy transfer of costs to the healthcare payer
Payment by performance is used and quality of care is demanded by the healthcare payer	Existing research has demonstrated the efficacy and cost-effectiveness of the new technology	Information about the technology available is poor

C. ORGANISATIONAL FACTORS	ACTS AS A FACILITATOR WHEN…	ACTS AS A BARRIER WHEN…
Specialisation and size	The hospital is large and has a wide range of specialties	The hospital is small or medium-sized and has a narrow range of specialities
Competition in the region where the hospital is active	There is much competition for specific patient populations	There is a monopoly situation
Budget flexibility	There are favourable economic planning mechanisms	There is an inability to transfer resources from one budget line to another
Managerial flexibility	Decision-making is autonomous and decentralised	Complex and rigid financial control mechanisms are in place
Resistance to change	Adoption requires only modest training	The technology will interfere with the dominant diagnostic and treatment pathways

D. PRESENTATION AND USE OF EVIDENCE	ACTS AS FACILITATOR WHEN…	ACTS AS A BARRIER WHEN…
Availability of scientific information	Research results have been published and are widely available	There is a lack of skills to identify and appraise relevant research results and scientific information
Clarity of scientific information	Summaries are in plain language and provide clear recommendations	The format of publications is inappropriate and the dissemination of information ineffective
Strength of evidence	Technology has been recognised in international clinical guidelines	Information collected is sparse or contradictory
Attitude towards research activities of hospital managers	There is trust in researchers and good personal contacts	There is mutual distrust and lack of personal contact
Evidence on efficacy and safety	Efficacy and safety are well established as clinical trials have been performed	Formal research has not been carried out or is unavailable
Evidence on costs and cost-effectiveness	Cost-effectiveness is well studied and favourable	No information about cost-effectiveness is available
Local context	The results can be directly adapted to the specific hospital context	The results are based on research done in different or unknown environments

E. ECONOMIC FACTORS AND RESOURCES NEEDED	ACTS AS FACILITATOR WHEN…	ACTS AS A BARRIER WHEN…
Amount of capital investment needed	Adoption costs are low	There is a need for substantial additional financing
Amount of resources needed	Implementation by existing staff in the current premises is possible	New premises have to be constructed and new staff hired
Expected economic results	There is an economic rationing of costs by shortening the list of supplies	There is an increasing variety of supplies needed
Organisational change required	Organisational change is limited to department level	The technology requires considerable organisational change in the whole hospital or in many departments
Revenues for hospital	The technology brings in increased revenues	It is not possible to transfer costs to the healthcare payer

Key observations:

- Clinicians initiate and play a main role in the adoption process of health technologies by assessing clinical needs whereas HB-HTA contributes to the process by the assessment of health technologies.

- The final decision-maker on the adoption of costly health technologies is the hospital's top management (CEO, CMO, board of management). For medium and small health technologies the decision is usually made by the head of the clinical department.

- National and regional health authorities of many countries play only a minor role in the decision-making process of adoption of health technologies in hospitals.

- The main factors influencing the decision-making process of adoption of health technologies are: values, external environments, organisational factors, presentation and use of evidence, economic factors and resources needed. These factors may act as facilitators or barriers depending on the hospital setting and context.

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European Union, 2014. Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC. Official Journal of the European Union, 2014(28.3.2014), pp.65–242.

2.2 THE ROLE OF HB-HTA UNITS IN THE PROCESS OF ADOPTION OF HEALTH TECHNOLOGIES IN HOSPITALS

This section aims to underline the role of HB-HTA units in the process of decision-making on the adoption of health technologies by comparing the process in hospitals with and without HB-HTA units.

In the multi-method approach used to obtain the relevant findings, a large number of the hospitals sampled reported the existence of some type of HTA activity (65% of respondents) – this was mostly within large hospitals. Furthermore, hospital managers were more familiar with HTA than clinical managers were (97.4% as opposed to 76.6 % of respondents, respectively).

For the development of this section, 38 case studies were undertaken in 9 countries covering the following health technologies:

TABLE 1
HEALTH TECHNOLOGIES COVERED BY THE ADHOPHTA.

SOURCE
38 case studies undertaken in Spain, Italy, Turkey, Switzerland, Austria, Estonia, Denmark, Finland and Norway (Cicchetti et al. 2014).

MEDICAL EQUIPMENT INVESTIGATED IN THE CASE STUDIES (N=22):

- Positron Emission Tomography - Computed Tomography (PET-CT) (2 case studies)
- Computed Tomography (CT) (1 case study)
- Spiral Computer Tomography (spiral-CT) (1 case study)
- Robotic Surgical System (7 case studies)
- Light Intraoperative Accelerator (LIAC) (2 case studies)
- Ion-Coupled Plasma Mass Spectrometer (ICP-MS) (1 case study)
- Intraoperative Neurophysiological Monitoring (IONM) (1 case study)
- Neuro-monitoring (1 case study)
- Electrocardiogram (ECG) (1 case study)
- Hybrid Operational Theatre (1 case study)
- Intra-Coronary Optical Coherence Tomography (OCT) (1 case study)
- Intra-Operative Radio-Therapy (IORT) with Linear Accelerator (2 case studies)
- Remote Magnetic Navigation System for ablation of cardiac arrhythmias (1 case study)

MEDICAL DEVICES INVESTIGATED IN CASE STUDIES (N=10):

- Portable Ultrasonography Device* (1 case study)
- Servo Feedback Hypothermia Device (1 case study)
- Trans-catheter Aortic Heart Valve (TAVI) (2 case studies)
- Intra-Aortic Balloon Pump (IABP) (1 case study)
- Kyphoplasty (3 case studies)
- Radioactive seed implants for the treatment of prostate cancer (2 case studies)

DRUGS INVESTIGATED IN CASE STUDIES (N=4):

- Medical treatment of Dupuyten's contracture (3 case studies)
- Vemurafenib (1 case study)

CLINICAL PROCEDURES INVESTIGATED IN THE CASE STUDIES (N=2):

- Extracorporeal Photopheresis (1 case study)
- Atrial fibrillation outpatient clinic (1 case study)

* in the case studies the *Portable Ultrasonography Device* has been considered as a medical device and not as medical equipment (FDA 2014), however it may be classified otherwise.

2.2.1 HOSPITALS WITH AN HB-HTA UNIT MANAGE BETTER THE PROCESS OF ADOPTION OR REJECTION OF HEALTH TECHNOLOGIES

The process of adoption of health technologies differs depending on whether the hospital has an HB-HTA unit or not. The presence of an HB-HTA unit at a hospital tends to foster the formalisation of the process of adoption of health technologies. Consequently, hospitals with an HB-HTA unit usually have a better organised process of adoption of innovations. In this case, the clinician is recognised as the main initiator of the process of adoption.

Hospitals without an HB-HTA unit, in turn, show a lower level of formalisation compared to hospitals with an HB-HTA unit. Moreover, there is a higher variability in the number and type of actors (e.g. clinician, financial department, head of clinical division, etc.) participating in the decision-making.

In hospitals with HB-HTA units, the main actors involved in the adoption process of medical equipment are the clinicians, the HB-HTA unit and the management board, which is also responsible for final decision-making together with the CEO and CMO. The number of different actor groups participating in the decision-making process is slightly greater in hospitals with HB-HTA activities. The main actors involved in the adoption process of medical equipment in hospitals without HB-HTA are the clinicians, the management board, the nurse coordinator and the CMO, with top management, i.e. the CEO, CMO and the management board, playing a major role in the final decisions. The financial department has a more prominent role in the final decisions in hospitals without HB-HTA activities as compared with hospitals with HB-HTA activities.

Facilitators of and barriers to the process

In hospitals with HB-HTA units, availability and clarity of scientific evidence and a positive attitude towards research activities on the part of hospital managers were identified as factors facilitating the adoption of technology.

For hospitals without an HB-HTA unit, values, economic factors and resources needed, and the presentation and use of evidence were identified as main facilitators (see table 2), and organisational factors emerged as the most relevant potential barriers (see table 3).

	HOSPITAL WITH HTA UNIT	HOSPITAL WITH NO HTA UNIT
MEDICAL EQUIPMENT	• No national or regional regulatory control over hospital on medical equipment and devices • Well-defined and formalised adoption process • Limited number of actors involved in the decision-making process • Prestige of the hospital will increase if implemented • Research has demonstrated the efficacy and cost-effectiveness of the technology • Positive internal or external experts' opinion	• Clinical need for the new technology • Positive internal or external experts' opinion • Past experience • Research has demonstrated the efficacy and cost-effectiveness of new technology • Availability of external funding (e.g. donations)
MEDICAL DEVICES	• No national or regional regulatory control over hospital on medical equipment and devices • Availability of an internal HTA report • Past experience • Positive internal/external experts' opinion	• Prestige of the hospital will increase if implemented • Low adoption cost • Limited number of actors involved in the decision-making process • Positive internal or external experts' opinion • Research has demonstrated the efficacy and cost-effectiveness of the technology
DRUGS	• Availability of an internal HTA report • High internal consensus • Positive internal or external experts' opinion • Technology analysed in a randomised controlled trial (RCT)	• Strong national or regional regulatory control over hospital on drugs • Limited number of actors involved in the decision-making process • Availability of comparative analyses • Research has demonstrated the efficacy and cost-effectiveness of the technology
PROCEDURES	• Limited number of actors involved in decision-making process • Availability of an internal HTA report • Research has demonstrated the efficacy and cost-effectiveness of the technology • High internal consensus on the technology to be adopted	• Low adoption cost • Availability of comparative analyses

TABLE 3
BARRIERS
TO HEALTH
TECHNOLOGY
ADOPTION.

SOURCE
38 case studies
undertaken in
Spain, Italy, Turkey,
Switzerland, Austria,
Estonia, Denmark,
Finland and Norway
(Cicchetti et al. 2014).
(see table X for the
complete list of
technologies studied)

	HOSPITAL WITH HTA UNIT	HOSPITAL WITH NO HTA UNIT
MEDICAL EQUIPMENT	• Need for substantial additional financing • The technology requires considerable organisational changes in the whole hospital or in many departments • Difficulties in reaching an agreement with external payers	• Need for substantial additional financing • Adoption requires high investments in training • Lack of internal consensus on the technology
MEDICAL DEVICES	• Lack of internal consensus on the technology	• Adoption requires high investments in training • Existence of a national follow up registry for patients treated with the technology • Difficulties in finding an agreement with external payers
DRUGS	• Need for substantial additional financing	• Need for substantial additional financing • No clear or formalised decision-making process
PROCEDURES	• N.A.	• Lack of internal consensus on the technology

Duration of the health technology adoption process

The variability of the duration[1] of the health technology adoption process in hospitals with an HB-HTA unit is generally lower than in hospitals without such a unit (from a few weeks up to 2 years versus weeks to 3 years). HB-HTA units have better control over the circumstances that may increase the adoption period (e.g. organisational impact, economic impact, etc.).

The duration of the process seems to be affected mainly by the type of health technologies to adopt – it takes more time for medical equipment to be adopted as compared with medical devices and drugs (Table 4). The time required for reimbursement decisions may delay the process, whereas urgent situations and external pressure e.g. from industry, may accelerate the process.

TABLE 4
DURATION OF THE HEALTH TECHNOLOGY (HT) ADOPTION PROCESS.

SOURCE
38 case studies undertaken in Spain, Italy, Turkey, Switzerland, Austria, Estonia, Denmark, Finland and Norway (Cicchetti et al. 2014).

TYPE OF HT	HOSPITAL WITH HTA UNIT	HOSPITAL WITH NO HTA UNIT
MEDICAL EQUIPMENT	**6-36 months** • Initiator: clinician • Main actors: clinician, HTA unit, management board • Decision-maker: CMO/CEO/ management board	**2-48 months** • Initiator: clinician • Main actors: clinician, management board, nurse coordinator, CMO • Decision-maker: CMO, CEO, management board, financial department
MEDICAL DEVICES	**5-12 months** • Initiator: clinician • Main actors: clinician, HTA unit, financial department • Decision-maker: CEO	**1-60 months** • Initiator: clinician • Main actors: clinician, CMO • Decision-maker: CMO, CEO, management board, financial department
DRUGS	**3 months** • Initiator: pharmaceutical committee • Main actors: nurse coordinator, CMO, head of clinical division • Decision-maker: head of clinical division	**12-24 months** • Initiator: clinician • Main actors: clinician • Decision-maker: head of clinical division
CLINICAL PROCEDURES	**6 months** • Initiator: clinician • Main actors: clinician, HTA unit, financial department • Decision-maker: head of clinical division	**24 months** • Initiator: Clinician • Main actors: clinician, nurse coordinator, CMO, financial department • Decision-maker: financial department

2.2.2 HOSPITALS WITH AN HB-HTA UNIT VALUE ORGANISATIONAL AND MEDICAL/CLINICAL COMPETENCIES.

Ideally, HTA requires a multidisciplinary team of professional profiles (medical/clinical, economic, technical, organisational, legal, ethical, political, nursing). However, when performing HTA at hospital level, some of these competencies are perceived by hospital managers and clinical decision-makers as more relevant than others for the assessment process. Medical and clinical competencies are perceived as the most relevant; followed by economic and ethical competencies. Figure 1 summarises the perspectives of hospital managers and clinical managers on how relevant they consider the different professional competencies involved in HTA (in absolute terms, not relative to other competences).
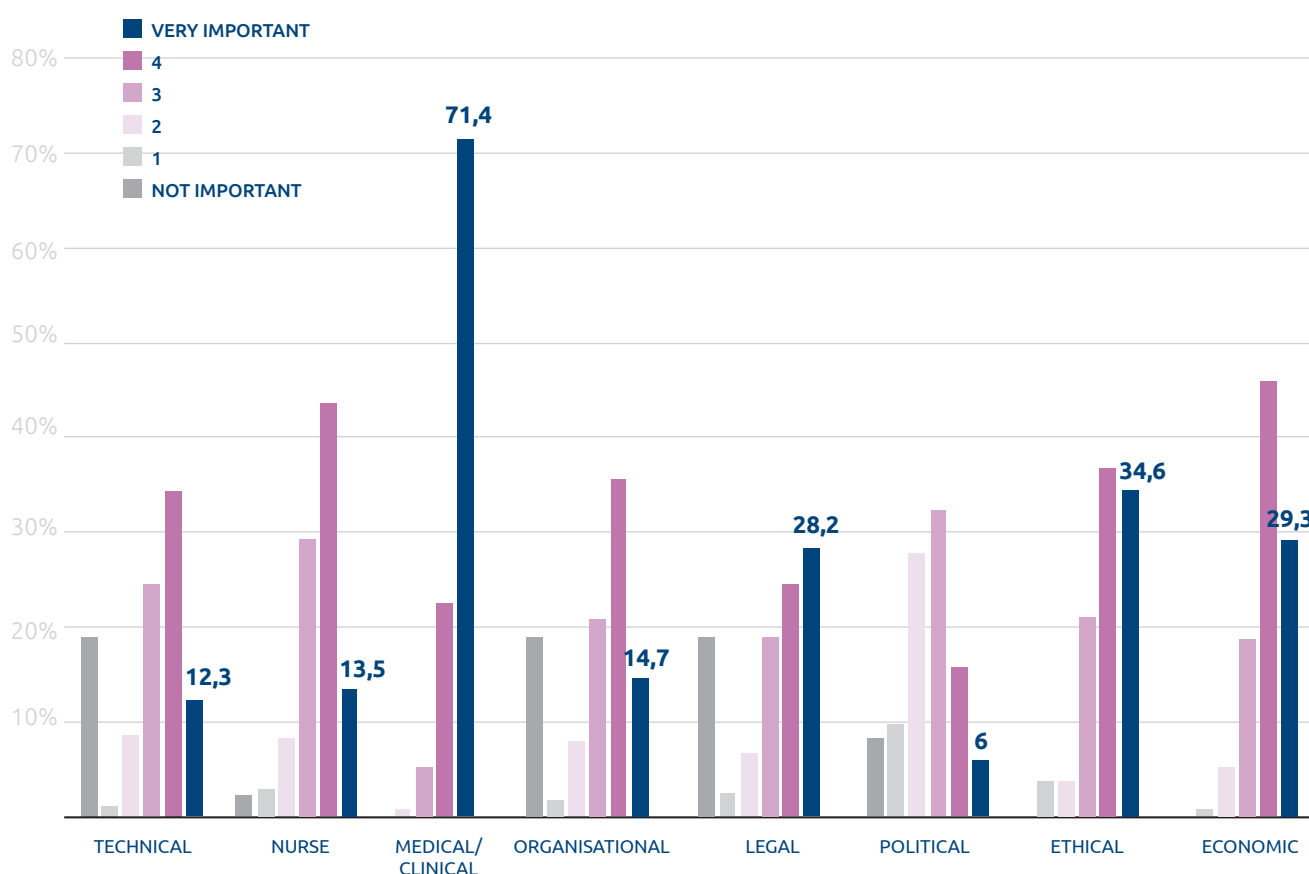
FIGURE 1
RELEVANCE OF DIFFERENT COMPETENCIES INVOLVED IN THE EVALUATION OF HEALTH TECHNOLOGIES.

Q13. Please indicate on a scale from 0-5 how relevant you find the following competencies in evaluating new technologies in general (e.g. drugs, medical devices, diagnostic tests, surgical treatments or organisational procedures) at your hospital.

Perception of the relevance of professional profiles also differed between hospital managers and clinicians. Hospital managers consider economic, technical and ethical background profiles to be of absolute higher relevance. Relating the latter, clinical managers do not score it as high as managers since they most probably assume that the ethical approach is already included as a part of the medical/clinical assessment.

Some differences were also observed between hospitals with or without HTA activities, as hospitals with HTA units gave more importance to organisational and medical/clinical competencies.

2.2.3 INFLUENCE OF DIFFERENT ORGANISATIONAL ATTRIBUTES IN THE DECISION-MAKING MODELS FOR THE ADOPTION OF HEALTH TECHNOLOGIES.

The organisational decision-making model of adoption of health technologies in hospitals can be described using the Contingency Decision-making Framework (See Box 1). The "problem" can be understood as the clinical, strategic and organisational needs and the "solution" is the technology that best satisfies those needs. The assumption was that HTA finds its natural location in the "Managerial Science Model", since the systematic analysis of information and the evaluation of possible technological alternatives are part of the HTA process.

Definition

Box 1. The Contingency Decision-making Framework (Daft 2007)

The Contingency Decision-making Framework aims to describe different models of decision-making according to different parameters that affect the final decision. This model is based on two dimensions.

1. **Consensus on the problem:** the level of agreement within a decision-making group on a certain problem (ranging from total agreement to total disagreement). When managers agree, there is little uncertainty. When managers disagree, organisation direction and performance expectations are in dispute, creating a situation of great uncertainty.

2. **Technical understanding of the solution:** the level of understanding and agreement about how to solve the problem and reach organisational goals. This variable ranges from complete agreement and certainty to complete disagreement and uncertainty about cause-effect relationships leading to the solution of the problem.

The crossing of the 2 dimensions allows us to identify four different models of decision-making.

- **The Managerial Science Model:** characterised by a high certainty of both consensus on the problem and understanding of the solution. It corresponds to the rational approach used by a single manager. In this Model, the decision-making process generally follows a logical sequence, which goes from the evaluation of the problem by means of analytical tools until the decision is taken. Throughout this process, alternatives are compared and the best solution is chosen. In the Managerial Science Model, the decision-maker follows a rational approach and evaluates all the possible solutions in a systematic way.

- **The Carnegie Model:** recorded in those situations characterised by high uncertainty about problems and priorities. Thus, negotiation and compromises are used in order to reach a consensus on the solution which seems to immediately satisfy criteria of efficacy. Discussions, debates and coalitions in the organisational context are implemented in order to achieve a consensus. This model is applied in those organisations having a decision-making process based on managerial coalitions.

- **The Incremental Decision Process Model:** applied in those situations in which problems and performance standards are certain, but technical solutions to solve the problems are vague and uncertain. Thus, in order to address the problem, a rational approach is not applicable, and the manager uses previous experience and judgment to take the decision. In the organisational perspective, this model is equivalent to a single manager solving problems by means of trial and error. This model is applied in those contexts involving a decision-making process which is composed of several steps. These steps lead, through incremental decisions, to the resolution of the problem. Given the nature of this process, managers could come up against barriers or meet with failure, but might finally acquire the necessary knowledge.

- **The Garbage Can Model:** characterised by high uncertainty about both problems and solutions. In this critical context, managers can use inspiration – which can be defined as an innovative behaviour far from logical sequences – or can apply some imitative behaviour, as well as implementing the other methods previously listed in the models above.

FIGURE 2
THE CONTINGENCY DECISION-MAKING FRAMEWORK

SOURCE
Adapted from Daft 2007

CONSENSUS ON THE PROBLEM

CERTAIN | UNCERTAIN

UNDERSTANDING OF THE SOLUTION

CERTAIN

INDIVIDUAL
Rational approach, comparison of alternatives

ORGANISATION
Managerial Science Model

INDIVIDUAL
Negotiation, formation of coalitions

ORGANISATION
Carnegie Model

INDIVIDUAL
judgement, trial an error

ORGANISATION
Incremental Decision Process Model

INDIVIDUAL
Negotiation, inspiration and imitation

ORGANISATION
Carnegie or Incremental Process Model evolving towards a
"Garbage Can Model"

UNCERTAIN

The case studies performed for different types of health technologies in the AdHopHTA research project have made it possible to define a trend in the decision-making models for adoption of health technologies in hospitals. Box 2 summarises the type of decision-making models observed according to type of health technologies and the organisational characteristics of the hospital. For most of the technologies studied, the decision-making process followed a Managerial Science Model, except for the case of drugs, where the decision-making process followed a typical Carnegie Model.

Box 2. Organisational decision-making models for adoption of health technologies in hospitals

The table below summarises the type of decision-making models according to type of health technologies (medical equipment, medical devices, drugs and organisational procedures) and the organisational characteristics of the hospital (size, institutional profile and the existence of an HB-HTA unit), observed in the case studies performed in the AdHopHTA project. In the table, the colour intensity of the cells indicates the strength of the model in terms of consensus on clinical, strategic and organisational needs (i.e. the consensus on the problem) and type of the health technology to be adopted (i.e. the level of certainty about understanding the solution):

• In the case of the Managerial Model (M), the darkest colour means that the model is strongly rational, being characterised by strong consensus on both needs and solutions to be adopted.

• In the case of the Carnegie Model (C) the darkest colour means that the process is characterised by strong consensus on the solution (i.e. the technology to be adopted), but low consensus and uncertainty on the clinical, strategic and/or organisational needs.

• In both cases, the mid tones and lightest shades indicate moderate and low intensity of the prevalent mode.

TABLE 5
ORGANISATIONAL DECISION-MAKING MODELS FOR ADOPTION OF HEALTH TECHNOLOGIES IN HOSPITALS.

SOURCE
38 case studies undertaken in Spain, Italy, Turkey, Switzerland, Austria, Estonia, Denmark, Finland and Norway (Cicchetti et al. 2014).

		ORGANISATIONAL ATTRIBUTES					
		HOSPITAL SIZE		LEGAL STATUS		HB-HTA UNIT	
		BIG	MEDIUM /SMALL	PUBLIC	PRIVATE	YES	NO
TYPE OF TECHNOLOGY	MEDICAL EQUIPMENT (N=22)	M	M	M	M	M	M
	MEDICAL DEVICE (N=10)	M	M	M	M	M	M/C
	ORGANISATIO-NAL PROCEDURE (N=2)	M	M	M	M	M	M
	DRUG (N=4)	C	C	C	(1)	C	C/I

M = Managerial Science Model | **C** = Carnegie Model | **M/C** = Borderline situation between Managerial and Carnegie Model | **C/I** = Borderline situation between Carnegie and Incremental Model | **(1)** = No case study available
Grades of intensity: Managerial Model ■■■■■ | Grades of intensity: Carnegie Model ■■■■■

In the case studies performed, it was observed that the type of technology to be adopted influenced the decision-making model in following way:

- **Medical equipment**. In half of the case studies (11 cases out of 22), the decision-making process was mainly inspired by a managerial rational approach (Managerial Science Model = M). However, in three cases the decision-making process was incremental and in three cases the decisions tended to emerge as a result of a dynamic interaction among powerful coalitions (Carnegie model = C). In five cases, the decision-making process was on the "borderline", between Carnegie and Incremental.

- **Medical devices**. In the majority of cases (8 cases out of 10) the decision-making process followed a managerial-rational approach.

- The decision-making process behind the introduction of **drugs** is more heterogeneous and, in general, less rational, and in accordance with the Carnegie Model.

Other attributes observed that affect the decision-making process on a health technology (HT) adoption include:

1. **Complexity and cost of a HT**. In general, it seems that the more complex and costly the technology is, the more rational the decision-making concerning its adoption will be. Such a trend is observable in the case of most of the medical equipment characterised by a high level of complexity and for those medical devices whose adoption requires great effort and resources.

2. **Level of innovation of a HT.** Conversely, the adoption of very innovative technologies (e.g. radioactive seed implants for the treatment of prostate cancer) is affected by a higher level of uncertainty and this decreases the level of rationality in taking the decision. Indeed, the decision-making models range from those in which the decision is based on the role of powerful organisational coalitions (Carnegie) to those in which no specific rational approach is visible (Garbage Can Model).

3. **Legal status.** Some organisational attributes have also proved to play a certain role in defining the decision-making model occurring in the introduction of new medical technologies. The legal status (private versus public) of the hospitals plays no great role in defining the decision-making model.

4. **Size of hospital**. The same occurs with hospital size. Both these dimensions seem not to affect the type of decision-making model.

5. **HB-HTA unit.** The presence of an HB-HTA unit seems to increase the level of rationality in decision-making since the Managerial Science model is prevalent.

Key observations:

- Hospitals with an HB-HTA unit manage better the process of adoption of health technologies.

- The length of the adoption process is affected by the type of technology, however the use of HTA in hospitals seems to control risk factors associated with delaying the duration of the adoption process.

- Notably, HB-HTA units have a paramount role in the process of adoption of very complex technologies that require significant organisational changes and/or economic investment.

- The process for adoption of medical equipment, devices and procedures is characterised by a "rational approach and the comparison of alternatives" (Managerial Science Model). However, the adoption of drugs is characterised by "negotiations and coalitions" to reach the final decision (Carnegie Model).

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MANAGEMENT OF HEALTH TECHNOLOGIES IN HOSPITAL THROUGH THE USE OF HB-HTA – EXAMPLES

Box 1. HB-HTA and drugs – room for a collaborative approach in hospital drug formulary management *(example from Italy)*

HB-HTA has been widely recognised as a relevant method for systematically evaluating health technologies in hospitals. The health technologies most frequently addressed by HB-HTA are medical devices (big ticket equipment), medical equipment (medium- and small-sized equipment), and healthcare interventions or programmes. Drugs are scarcely considered by HB-HTA units, probably because of the strict national and regional regulations controlling their introduction. However, a recent survey performed by the European Association of Hospital Pharmacists revealed that most European hospitals employ their own hospital drug formulary, meaning that concerns about the introduction of drugs are faced also at an organisational level and that a role for HB-HTA in the evaluation of drugs can be developed (EAHP survey 2010). In Italy, most of the decisions concerning drugs are taken at the national level by the Italian Medicines Agency (AIFA), which is responsible for the introduction of drugs, their pricing and their reimbursement regimes. However, because of the progressive decentralisation of competences on the organisational arrangement of healthcare and of related financial responsibilities from the national to the regional level, there are several examples of regional HTA for drugs from the last decade. However, little evidence is available on how HTA of drugs is managed in the hospital context, even in those hospitals already employing HTA in the evaluation of devices and further procedures. An exception to this trend is the "A. Gemelli" University Hospital in Rome, which established the first Italian HB-HTA unit in the year 2000. Mainly devoted to the assessment of medical devices, this HB-HTA unit started to play an integral role also in the process of introducing new drugs in the hospital in 2013. This process starts with the request formulated by clinicians to introduce a new drug into the hospital drug formulary. The hospital's Committee for Drugs and Technologies (COFT), which collects these requests, bases its decision on the collaborative expertise of the HB-HTA unit and the hospital pharmacy. Published evidence, pharmacoeconomic studies and hospital-specific data on comparators already included in the Hospital Drug Formulary are taken into account in the evaluation of the new drug's efficacy, safety, cost and organisational implications through this rapid cooperative assessment. The HB-HTA unit brings its expertise into this teamwork process from its long-standing collaboration with the Italian Medicines Agency, while the hospital pharmacy brings detailed knowledge of internal organisational and clinical needs. These joint rapid assessments provide a strategic tool to support the hospital's COFT decisions, which liases between clinical needs and budget constraints. In addition, the HB-HTA unit recently suggested monitoring new drugs after their introduction. In a pilot project, the hospital pharmacy started with two recently introduced drugs, keeping track of their prescriptions and the resulting expenditures. These will be compared with the clinicians' estimates laid out in their proposals prior to introduction, and will inform the evolution of the hospital drug formulary at a later stage.

In 2014, 18 drugs were evaluated. Four of them were approved; the positive decision was suspended for three drugs until the decision of the regional committee responsible for the Regional Drug Formulary is produced. Two other drugs were approved only under a regime of per patient request with closed monitoring on the appropriateness and number of requests. All the other requests were assessed and rejected by the COFT.

To meet budget constraints and guarantee appropriateness, the HB-HTA unit and COFT also promoted drug class review to guide hospital drug utilisation. The first trial was with new oral anticoagulants (NAOs). The HB-HTA unit conducted a rapid comparative assessment on approved indications, risk-benefit profile, therapy costs, clinical guidelines and pharmacoeconomic studies relating to a special population of patients. Finally, clinical experts and the COFT defined which category of patients in the hospital NAOs should be prescribed for.

Furthermore, to guarantee an updated hospital drug formulary (HDF), and also to avoid unnecessary duplication of active principles for the same clinical indication, a revision process is under way. The HB-HTA unit, the hospital pharmacy and the pharmacology unit are redefining the format and the content of the HDF. First, drug purchases submitted since 2010 were analysed to identify those drugs reported in the HDF which are no longer prescribed. Then the same database was used to identify drugs not discussed in the COFT, but regularly requested from the hospital pharmacy. It was decided to automatically insert these in the HDF or to discuss their use with clinicians. Comparison of the regional drug formulary with the HDF is under way.

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Box 2. Role of HB-HTA in strategic investment
(an example from Catalonia, Spain)

HB-HTA takes into consideration context-specific strategic aspects of a health technology (HT) as relevant informational need for a final recommendation on investment in given health technology. Traditionally, national and regional agencies do not recommend reimbursing HTs for which there is little evidence of good quality or HTs which are still under clinical research. Yet, at the hospital level these HTs might be considered because of strategic impact.

Hospital Clínic de Barcelona considers adopting the Intra-Operative Radiotherapy using the Linear Accelerator (IORT-LIAC®) owing to its promising features over the traditional treatment*.

The IORT-LIAC® is purchased from hospital funds but introduced under the research protocol.

In the light of scarce but promising scientific evidence on advantages of IORT-LIAC® treatment, an economic evaluation is carried out showing potential cost-effectiveness of the treatment.

A financial analysis is undertaken revealing the IORT-LIAC® assumable for the hospital.

The hospital negotiates with the payer to finance the procedure (IORT) using the new technology (LIAC®).

The payer agrees to pay the highest available rate for this type of treatment.

Investment in the IORT-LIAC® under the research protocol for the Hospital Clínic was perceived as strategic, since no other hospital in Spain has introduced the technology and the mandate of the Hospital Clínic is to be an innovative healthcare centre.

* IORT-LIAC® is an innovative HT targeted at a specific population of patients, offering advantages over the traditional treatment (external beam radiotherapy after breast-conserving surgery), such as a single treatment session instead of 30 and a high rate of overall patient satisfaction. At the time the technology was adopted in Hospital Clínic de Barcelona, evidence of its clinical effectiveness was scare and of low quality. Nevertheless, using IORT-LIAC® in the target population seemed to have a positive trend in terms of efficacy and patients' overall quality of life.

Box 3. Role of HB-HTA in optimisation/disinvestment
(example from Italy)

In the last few decades, HTA has mainly been applied in the decision-making process on the adoption of health technologies. Nevertheless, an important and emerging area of interest relates to the application of HTA methods to the process of disinvestment. Disinvestment can be defined as "the full or partial withdrawal of resources from health technologies and practices (pharmaceuticals, medical devices, diagnostics, procedures, treatments, and other clinical, public health, and organisational interventions) that are determined to offer low value to the health system and/or patients relative to alternatives" (HTAi Policy Forum 2012).

One example of applying HB-HTA to a disinvestment approach came from the "A. Gemelli" University Hospital, which experienced a Proactive Disinvestment Process (PDP) for the surgical meshes used mainly for inguinal hernia repair. The PDP approach consists of a first step, in which technologies to be withdrawn are identified by the HB-HTA unit by means of (i) routine HTA activities; (ii) an annual review of International, national and regional HTA reports. The second step is the assessment, carried out by the HB-HTA unit through literature review, questionnaires submitted to clinicians and hospital data analysis. Finally, the appraisal step is applied; this consists of a proposal and discussion for disinvestment (using reports or producing guidelines). Finally, after discussion, the decision is made by the top management. This PDP approach was applied to the case of surgical meshes.

In 2012, the hospital faced a serious financial crisis, mainly due to the financial crisis that the third payer (Lazio Region) was facing. Moreover, systematic increasing expenditures for medical devices occurred, together with an increasing complexity in managing surgical medical devices, and in logistics in particular. These devices in fact had to be allocated among multiple surgical teams within an operating block with 33 operating theatres. Another motivation to start the disinvestment process was related to the observed variability in clinical practice and related outcomes, mainly with reference to those procedures in which more devices were available. So the basic idea was not exactly to disinvest, but rather to rationalise the number and the nature of devices used by clinical departments. During 2011, surgical meshes were among those technologies to be "selected out", since more than 70 meshes for hernia repair were available on the market. They can be classified into different categories according to their materials and composition, their pore size, their weight and shape. Data analysis and literature reviewed showed the importance of rationalising the use of surgical meshes in the "A. Gemelli" Hospital: the literature review also showed that from both surgeons' and patients' points of view the meshes should have had certain characteristics, considered necessary for the wellness of the patients, such as minimal adhesion formation, excellent tissue ingrowth with minimal shrinkage, no infection or fistula formation, etc. So, clinicians were asked to identify which of the meshes could be "selected out": a questionnaire, adapted from the Guideline for not funding existing health technologies in healthcare systems (Ibargoyen-Roteta et al. 2009), was used. One of the clinicians selected the "flat and three-dimensional heavy-weight mesh for inguinal hernia repair" as the technology to be withdrawn: there was still consensus about the limitation of the use of these technologies. A comparison between heavy-weight meshes (HWMs) and light-weight meshes (LWMs) showed that LWMs were associated with a similar risk of postoperative

complications, a reduced risk of developing chronic groin pain and a lower risk of developing other groin symptoms. In this situation, three sources (literature review, data analysis and questionnaire submitted to clinicians) concluded that the limitation of this HWM was desirable: its use was reduced by 65% in 6 months, according to the guideline prepared by the HB-HTA unit and approved by the hospital's Committee for Drugs and Technologies (COFT). Now attention is being paid to this withdrawal in terms of clinical outcomes and costs. The major lesson learnt from this experience was that barriers and problems, such as clinicians' habits, the lack of evidence, administrative efforts (due to the re-negotiation of contracts with vendors), the time consumed in the adoption process and data collection, can be overcome through clinicians' engagement and by creating incentives. Moreover, a dedicated procedure, synergy with routine HTA procedures and transparent criteria and methodological rigour improve the success of this process.

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2.3 ORGANISATIONAL MODELS OF HB-HTA UNITS

This section of the handbook aims to explore the organisational models of existing HB-HTA units in order to understand their varying structure, processes and outcomes. It describes the general characteristics and trends in organisation and functioning of HB-HTA units. Information was collected through a semi-structured interview within a number of HB-HTA units across Europe[1] with the additional perspective of New Zealand.

2.3.1 MACRO-TRENDS IN ORGANISATIONAL MODELS OF HB-HTA UNITS

Organisational arrangements of HB-HTA units depend on several variables, such as the size of the unit, the stage of development of the unit (mature vs. early stage/start-up), their mission, vision and orientation (internal vs. external), professional competencies, and the collaboration with national or regional HTA agencies.

However, the characteristics that best define an HB-HTA unit are the following:

- **Formalisation.** This refers to the extent to which rules and procedures (i.e. written protocols) are used to govern the activities of the HB-HTA unit.

- **Specialisation.** This concerns the extent to which tasks and duties are divided into separate roles in the HB-HTA unit. A highly specialised unit is one that is able to manage different kinds of HTA processes (e.g. HTAs for drugs or devices or a three-year investment plan for health technologies) dedicating to those processes specific resources (e.g. a project team) and/or specific formal procedures (e.g. specific procedures per each type of health technology to be assessed).

- **Integration.** This refers to the level of coordination occurring between the HB-HTA unit and other organisations within or outside the hospital. Integration is high if the unit is creating multiple linkages with other organisations that are doing HTA at other institutional levels (i.e. at national or regional level) (Daft 2007).

- **Authority and centralisation of power.** This refers to the authority to take decisions within the HB-HTA unit. When decisions are delegated to lower organisational levels in the HB-HTA unit (e.g. to the person responsible for an HTA project), the unit is considered to be *decentralised*. When decision-making is done at the top level (e.g. by the head of the unit), the HB-HTA unit is *centralised*.

- **Professionalisation.** This refers to the degree of training of the employees in the HB-HTA unit.

Three of these variables, namely (i) formalisation, (ii) specialisation and (iii) level of integration seem to be particularly relevant and tend to characterise the organisational arrangements of HB-HTA units. Moreover, highly specialised units tend to be more formalised. Usually "mature" HB-HTA units tend to be more formalised and highly specialised. On the other hand, some of the less "mature" HB-HTA units prefer to maintain flexibility, being less specialised and formalised. Integration

with other organisations that are doing HTA can be based on formal agreements or informal collaborations.

The combination of formalisation plus specialisation and level of integration allows us to identify four different types of HB-HTA units (Figure 1), which are described in the paragraphs that follow.

		LEVEL OF INTEGRATION	
		MID-LOW	HIGH-MID
LEVEL OF FORMALISATION AND SPECIALISATION	INFORMAL AND ESSENTIAL	1. Independent group	2. Integrated-essential HB-HTA unit
	FORMAL AND SPECIALISED	3. Stand-alone HB-HTA unit	4. Integrated-specialised HB-HTA unit

FIGURE 1
ORGANISATIONAL MODELS OF HB-HTA UNITS DEFINED BY THEIR LEVEL OF INTEGRATION, FORMALISATION AND SPECIALISATION.

1. Independent group
These units operate within the hospital as an "independent group" that provides support for management decisions in a fairly informal way. In general, this is the first stage of the development of an HB-HTA unit. In this scenario, the hospital top management is not usually fully aware of the usefulness of HTA as a support for decision-making and some "pioneers" are acting on a voluntary basis; they are not dedicated full time to HTA, but are working to demonstrate how an HTA approach could be useful to the hospital management.

2. Integrated-essential[1] HB-HTA units.
These are units of small size, with a limited number of staff members, but who are able to involve many other actors and "allies" in their activities They are embedded in a system of collaborations that include universities and research centres that can provide the complementary competences and workforce needed.

3. Stand-alone HB-HTA units.
These are mainly acting internally within hospitals and are not strongly influenced by the national or regional HTA organisations. They are generally more mature HB-HTA units with usually highly formalised and specialised procedures.

[1]
By the term "essential" we mean a unit of small size with few staff members. Because of the limited number of professionals, staff members are required to perform multiple tasks. When necessary, external organisations are involved in the work.

4. Integrated-specialised HB-HTA units.
  They act and are embedded in a context characterised by the presence of national or regional HTA organisations. Consequently, even if they have a certain level of autonomy, the functions of the HB-HTA unit are influenced by the formal collaboration with the national or regional HTA agency. They have high levels of formalisation and they have professionals dedicated to specific HTA tasks (e.g. assessment of drugs, assessment of medical devices etc.).

These four groups should be considered generic models as none of them is able to capture the real complexity of HB-HTA units belonging to one of the four categories. Furthermore, many HB-HTA units may fall in between these generic models presenting borderline characteristics of organisational attributes. Nevertheless, the descriptions above communicate, at least, the richness of the solutions available for running an HB-HTA unit within a hospital.

The classification also describes a sort of organisational life-cycle for HB-HTA units. Start-up units, in general, are informal and less connected with the external environment (Independent groups). People are working part-time, on a voluntary basis without strong formal endorsement from management and with informal procedures. The presence or absence of a national or regional HTA body acting as the hub of an HTA network may determine the evolution of the unit towards an integrated or a stand-alone unit.

The evolution towards a more mature HB-HTA unit is generally characterised by increasing levels of formalisation and specialisation in the processes and by the progressive alignment between the strategies and goals pursued by the national or regional HTA activity and the hospital-level strategies. In this evolution, the HB-HTA unit gains internal and external legitimation until it is fully recognised as a key actor in the hospital's development strategies and is also seen as a partner at national or regional level.

2.3.2 MICRO-TRENDS IN ORGANISATIONS AND PERFORMANCE OF HB-HTA UNITS

HB-HTA units are characterised by numerous features regarding their structure, processes and outcomes. The main micro-trends observed in the HB-HTA units analysed are summarised in Table 1 below.

CHARACTERISTICS OF HB-HTA	MICRO-TRENDS IN ORGANISATIONS AND PERFORMANCE OF HB-HTA UNITS
Mission (as defined by the HB-HTA unit)	a. **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) b. **Assessing health technologies** (in this case, there is no formal commitment to integrate the assessment results in the final decision-making process)
Position in the organisational structure of the hospital	a. CMO (Chief Medical Officer) – *most* b. CEO b. Quality and Research Directorate c. Research and Innovation Directorate

CHARACTERISTICS OF HB-HTA	MICRO-TRENDS IN ORGANISATIONS AND PERFORMANCE OF HB-HTA UNITS
Funding source (public)	a. External (e.g. competitive grants, contract with other, public or private organisations*) – *most cases* b. Internal (from hospital budget) (in most cases there is little funding support from the hospital budget)
Role of HB-HTA in decision-making	a. Advisory – *most cases* b. Mandatory
Role after the assessment	a. None – *most cases* b. Procurement (acquisition) phase – *few cases* c. Implementation of recommendation – *few cases*
Background of professionals in the unit	a. Clinicians, health economists, public health – *most cases* b. The same as a) plus nurses, bioengineers, and other allied health professionals
Careers opportunities	a. Formal (specific plans for development) – *none* b. Informal (e.g. ad-hoc conferences, courses, etc.) – *most cases*
Staff dedication in the HB-HTA unit	a. Part time – *most cases* b. Full time
Dissemination of the activities performed by the HB-HTA unit	a. Internal (clinical rounds, word of mouth, information send to clinical departments, broadcast email, presentation at the hospital board meeting) b. External (media, national journals, newsletters, websites, courses, events and conferences)
Prioritisation of health technologies for assessment	a. Based on specific criteria – *few cases* b. First-in-first assessed – *most cases*
Types of health technologies assessed (in order of frequency)	a. Medical devices b. Medical equipment c. Diagnostic tests d. Procedures (clinical and organisational) and drugs
Performance of the assessment	a. By professionals in the HB-HTA unit involving closely clinicians and hospital managers b. Shared between clinicians (e.g. literature review) and the HB-HTA unit (e.g. economic analysis + supervision of work by clinicians) c. By clinicians supported and supervised by the HTA unit
Scope	a. PICO (patient, intervention, comparator, outcome) – *all cases* b. Type Comparator: gold standard and technology available at hospital
Recommendations included	a. Yes – *most cases* b. No, just results (e.g. clinical or economic) of the assessment are presented
Role of HB-HTA in decision-making	a. Advisory – *always* b. Mandatory – *never*
Impact of the recommendations on the final decision	a. High – *most cases* b. Low

CHARACTERISTICS OF HB-HTA	MICRO-TRENDS IN ORGANISATIONS AND PERFORMANCE OF HB-HTA UNITS
Assurance of transparency during the assessment	a. Internal reviews – *often* b. Step–by–step, explicit (e.g. published or shown to clinician) c. External review – *less frequent*
System/approach to assure independence of assessment	a. Informal – *most* b. Systematic
Dissemination of the HB-HTA product/assessment	a. Internal (e.g. Intranet-database: complete assessment, abstracts or summaries of the assessment) – *most cases* b. External (e.g. database open to other hospitals) – *few cases*
Measurement of impact of HB-HTA unit	a. None – *most cases* b. Non-systematic – *few cases* c. Systematic – *never*

* Funding of the HB-HTA units' activities may give rise to a conflict of interest. To address this issue, in some of the HB-HTA reports, authors declare a conflict of interest.

TABLE 1
TRENDS IN ORGANISATIONS AND PERFORMANCE OF HB-HTA UNITS.

Key observations:

- The organisations of HB-HTA units may evolve from an informal support for management decisions (an "independent group") to a formally organised and more integrated unit.

- Currently, the most frequent model in the EU is a type of formalised and specialised HB-HTA unit acting internally within hospitals and not strongly influenced by the national or regional HTA organisations ("stand-alone HB-HTA unit").

- The mission of HB-HTA units is mainly to support hospital managers in decisions about the adoption of health-technologies.

- Most frequently, HB-HTA units assess medical devices and equipment.

- The involvement of HB-HTA units in the adoption process is almost always advisable and their recommendations are closely followed by hospital decision-makers.

- Professional profiles usually present in all units are clinicians, health economists and public health specialists.

- The team and characteristics of the assessment process vary from unit to unit, but in all cases clinicians (i.e. the users of health technologies) are involved.

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2.4 WHAT INFORMATION DO DECISION-MAKERS NEED WHEN ADOPTING NEW TECHNOLOGIES?

[1]
The term "hospital decision-maker" is understood to mean both hospital manager / hospital director and clinical manager / head of a clinical department.

This section describes the informational needs of hospital decision-makers[1] regarding technology investment. In order to understand what information is key for decision-making in hospitals, an extensive literature review was carried out followed by face-to-face interviews with hospital managers, clinical managers and nurse coordinators affiliated to different types of hospitals (university, research & training, and small- to middle-sized hospitals). This research was complemented by a large-scale web survey of 339 hospital healthcare professionals.

2.4.1 BACKGROUND

The objective of any HTA is to support the decision-making process on the adoption of or disinvestment in health technologies. Therefore, 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, this means that the content of the HTA reports should address the informational needs of hospital decision-makers.

There are numerous examples of guidelines on methods and tools for producing HTAs, including the type of information requested. One of the most widely used is EUnetHTA's Core Model© developed mainly by national HTA agencies. The Core Model© includes a large number of possible elements of assessment grouped into nine different domains (Lampe et al. 2009). Table 1 describes these nine domains.

EUnetHTA'S CORE MODEL DOMAIN	EXPLANATION
D1: Health problem and current use of the technology	Target population, target condition, current management of the condition, utilisation, regulatory status
D2: Description and technical characteristics of the technology	Features of the technology, investments and tools required to use the technology, training and information needed for utilising the technology
D3: Safety	Patient safety, occupational safety, environmental safety, safety risk management
D4: Clinical effectiveness	Mortality, morbidity, test-treatment chain, change-in-management function, health-related quality of life, quality of life, patient satisfaction, patient safety, test accuracy, benefit-harm balance
D5: Costs and economic evaluation	Resource utilisation, measurement and estimation of outcomes, examination of costs and outcomes, characterising uncertainty, characterising heterogeneity, validity of the model(s)
D6: Ethical analysis	Beneficence/non-maleficence, autonomy, respect for persons, justice and equity, legislation, ethical consequences of the HTA
D7: Organisational aspects	Health delivery process, structure of healthcare system, process-related costs, management, culture
D8: Social aspects	Individual, major life areas, information exchange
D9: Legal aspects	Autonomy, privacy, equality in healthcare, autorisation and safety, ownership and liability, regulation of the market

However, the extent to which the Core Model© domains cover the informational needs of hospital decision-makers is not fully known. The background knowledge, methods and scientific evidence used in HB-HTA are usually the same as those used for undertaking HTA at national or regional level. Nevertheless, preliminary evidence from hospitals shows that the assessment tools and the information required for decision-making at hospital level differ from those used at national or regional level (Cicchetti et al. 2008). Therefore, if HB-HTA aims to be of use to hospital decision-makers, it is crucial to know their informational needs. In AdHopHTA, a multi-method approach was used to study the informational needs of hospital decision-makers and how they related to the nine domains of EUnetHTA's Core Model.

2.4.2 THE DOMAINS OF EUnetHTA'S CORE MODEL COVER THE INFORMATIONAL NEEDS OF HOSPITAL DECISION-MAKERS TO A LARGE EXTENT

Hospital decision-makers were asked to describe their most important informational needs when deciding on a health technology investments. The results showed that EUnetHTA's Core Model© domains cover the informational needs of hospital decision-makers to a large extent. However, hospital decision-makers also expressed a need for information on political and strategic aspects which are not covered by the Core Model©.

Table 2 shows these results, the five most relevant EUnetHTA domains identified through each method used to establish hospital decision-makers' informational needs are highlighted in green.

TABLE 2
RESULTS ON THE RELATIVE IMPORTANCE OF THE 10 DOMAINS IN THE THREE STUDIES.

SOURCE
Literature review, interview study (N=53 respondents) and questionnaire survey (N=163 respondents) performed in Spain, Italy, Turkey, Switzerland, Austria, Estonia, Denmark, Finland and Norway (Kidholm et al. 2014, Kidholm et al. 2015, Ølholm et al. 2015).

EUnetHTA DOMAIN (D)	METHODS USED TO IDENTIFY HOSPITAL DECISION-MAKERS' INFORMATIONAL NEEDS		
	LITERATURE REVIEW	INTERVIEW STUDY	QUESTIONNAIRE SURVEY
D1: Health problem and current use			
D2: Description and technical characteristics			
D3: Safety aspects			
D4: Clinical effectiveness			**D4.1** Outcome/effect size
			D4.2 Quality of evidence
D5: Costs and economic evaluation			**D5.1** Societal perspective
			D5.2 Hospital perspective
D6: Ethical aspects			
D7: Organisational aspects			
D8: Social aspects			
D9: Legal aspects			
D10: Political and strategic aspects *New domain identified in AdHopHTA and not included in the Core Model ©*			**D10.1** Strategic aspects
			D10.2 Political aspects

In dark color the most important EUnetHTA domains identified by each method.

2.4.3 RELATIVE IMPORTANCE OF EUnetHTA'S DOMAINS FOR HOSPITAL DECISION-MAKERS

The relative importance given by hospital managers to the different domains used in the assessment may also differ from the importance given by national or regional HTA agencies (Sampietro-Colom et al. 2012, Ehlers et al. 2006).

Overall, consistently identified by the different research methods used as being the most important for hospital decision-makers (Table 2) was information on:

- the health problem and current use of the health technology (D1);

- the clinical effectiveness of the health technology (D4);

- the cost of the health technology (D5), especially from a hospital point of view; and

- safety (D3), organisational (D7), and political or strategic aspects associated with the introduction and use of the health technology (D10), especially strategic aspects.

As a consequence of the results of the systematic review and the terms used in the interview study, three of the ten domains were split into two groups each in the questionnaire survey in order to get a more precise picture of the informational needs of hospital decision-makers:

- The domain covering *Clinical effectiveness* (D4) was divided into information on *Clinical outcome/effect size* and *Quality of evidence*, respectively.

- The domain covering *Costs and economic evaluation* (D5) was divided into information from a *Societal point of view* and a *Hospital point of view*, respectively.

- And finally the domain covering *Political and strategic aspects* (D10) was divided into information on *Political aspects* and *Strategic aspects*, respectively.

Again, the results of the questionnaire survey with regard to relative importance did not differ significantly from those found in both the systematic literature review and the interview study. Information on the costs of a given health technology from a hospital point of view was more relevant to hospital decision-makers than from a societal point of view, and this corresponded well with the fact that the majority of the identified decision criteria regarding the economic aspects in the literature review concerned the narrow hospital perspective and that the majority of respondents indicating economic aspects as highly relevant in the interview study referred only to the narrow hospital perspective. This also underlined the relevance of dividing the fairly broad domains into smaller groups to get a more detailed picture of the informational needs of hospital decision-makers.

Furthermore, the fact that information on the strategic aspects associated with a given new technology were considered more important by hospital decision-makers than the political aspects in the questionnaire survey corresponds well with the fact that when hospital decision-makers were directly asked about these aspects in the interview study, the majority of their replies were related to the strategic goals of the hospital itself.

2.4.4 THE NEW DOMAIN – POLITICAL AND STRATEGIC ASPECTS

The domains of EUnetHTA's Core Model© cover the majority of the information needed by hospital decision-makers when they have to make decisions on whether or not to invest in a given health technology. However, not everything is covered. In all three methodological approaches used, managers identified a need for information on political and strategic issues, but there is no domain in the Core Model dealing with these aspects.

The literature review already identified the need for information related to the strategic aspects associated with the introduction and use of a given technology. These were classified under a new tenth domain named *Political and strategic aspects*.

Definition

> By **strategic issues** we mean, for example, the alignment between a given health technology and the research strategy and local values of a hospital, or prestige and competition between hospitals on a specific technology or health problem.
>
> By **political issues** we mean, for example, the alignment between the decision to invest in a given technology and the local political climate (understood as the political decisions and announcements made by local politicians in e.g. the municipality or the county council).

The results from the interview study showed that when hospital decision-makers were directly asked about political and strategic aspects, a majority of their replies were related to the strategic goals of the hospital itself including research strategies, competition with other hospitals, profile building and investment strategies.

> **Examples of quotes related to political and strategic issues from the respondents in the interview study**
>
> Examples of political issues:
>
> • "Political decisions often overrule everything else. Of this we are certain."
> • "Political aspects are growing in importance in Finland."
>
> Examples of strategic issues:
>
> • "Even if we do not like it, political/strategic considerations are very important because if one wants to be a pioneer in the field, one has to be the first to adopt a new technology."
> • "Strategic aspects are key to becoming an authority in Spain and Europe."
> • "Political aspects no. But hospital strategic aspects are relevant."
> • "In Finland politics affect only the budget, but in our hospitals we have our own strategy."
> • "Relevant information is also if a technology is profile-building or not."

2.4.5 THE TWO DIMENSIONS OF CLINICAL EFFECTIVENESS

Results from the systematic literature review showed that the domain related to *Clinical effectiveness* (D4) contained decision criteria concerning, on the one hand, clinical outcomes (e.g. quality of life) and effect sizes (e.g. patient impact), and on the other hand characteristics of the evidence (e.g. quality of the evidence). This domain was therefore divided into two separate dimensions in the questionnaire survey.

2.4.6 THE TWO DIMENSIONS OF ECONOMIC ASPECTS

The fifth domain related to *Costs and economic evaluation* (D5) contained both (i) decision criteria concerning traditional health economic analyses with a broad societal perspective (e.g. cost-utility analyses) and (ii) narrower budget impact-analysis with a hospital perspective (e.g. costs and budgetary constraints).

In the systematic literature review, the majority of the decision criteria identified relating to the economic aspects associated with the introduction and use of a health technology concerned the narrow hospital perspective.

In the interview study, it was not always clear whether the respondents had a broad societal or a narrower hospital perspective in mind when asked about the economic aspects of health technologies. However, one third of the respondents who indicated that information on economic aspects of a health technology was "highly important" referred only to the economic impact on the hospitals by using terms like "budget impact", "financing", "reimbursement", "billing" and "Diagnosis-related group (DRG)". On the other hand, fifteen percent of the respondents explicitly stated that both a societal and a hospital perspective on the economic aspects of a health technology were needed.

2.4.7 IMPORTANCE OF INFORMATION AMONG DIFFERENT ACTORS IN THE HOSPITAL

Following the findings from the literature review and the interview study, the questionnaire survey included 13 final domains. Five of these domains were identified as the most important both by the clinical and the hospital managers: *Clinical outcome effect size* (D4.1); *Safety* (D3); *Quality of evidence* (D4.2); *Health problem* (D1) and *Economic - hospital point of view* (D5.2). However, the last two of these domains, were ranked differently: while hospital managers ranked information on economic aspects from a hospital point of view (D5.2) higher, clinical managers gave more importance to information on the health problem of patients (D1). In addition, political aspects were only ranked as important in relation to the others by hospital managers. Table 3 summarises these findings.

TABLE 3
FIVE MOST
IMPORTANT
DOMAINS IN
DECISION-
MAKING
BY TYPE OF
MANAGER.

SOURCE
questionnaire survey
(N=163 respondents)
(Kidholm et al. 2014,
Kidholm et al. 2015).

NOTE
Total share of
respondents
indicating five types
of information that
they consider the
most important as a
part of the basis for
decision-making on the
use of new treatments
in general (e.g. drugs,
medical devices,
diagnostic tests,
surgical treatments
or organisational
procedures).

DOMAINS OF THE AdHopHTA SURVEY	CLINICAL MANAGER	HOSPITAL MANAGER
D1: Health problem	**74%**	**51%**
D2: Technology characteristics	16%	19%
D3: Safety	**82%**	**77%**
D4.1: Clinical outcome effect size	**84%**	**74%**
D4.2: Quality of evidence	**74%**	**72%**
D5.1: Economic - societal point of view	24%	23%
D5.2: Economic - hospital point of view	**42%**	**61%**
D6: Ethical	24%	19%
D7: Organisational aspects	11%	30%
D8: Social	11%	5%
D9: Legal	26%	21%
D10.1: Strategic	26%	35%
D10.2: Political	0%	7%

Key observations:

- Hospital decision-makers require/demand information on the clinical effectiveness, economic, safety and organisational aspects of the technology being assessed.

- Assessment of the economic aspects focuses on the impact for the hospital and includes budget impact and reimbursement issues. This analysis could be complemented with societal cost effectiveness analysis.

- Strategic aspects of a health technology investment for hospitals are a new assessment domain demanded by hospital decision-makers.

- Hospital decision-makers seldom find information on the social, legal and ethical aspects most important.

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2.5 TYPES AND QUALITY OF HB-HTA REPORTS

This section aims to show the variety of HB-HTA reports produced for or by hospitals in Europe and their quality. The information comes from a sample of the HB-HTA reports used in decision-making on investment in new health technologies in various countries as well as on their quality assessment.

2.5.1 TYPES OF HB-HTA REPORTS

Decision-making on investment in health technologies requires tailored information meeting hospital decision-makers' needs, which is delivered through the HB-HTA report. However, the characteristics and type of the HB-HTA report about a new health technology depend on several issues i.e. the health problem in question, the

abundance of evidence and its quality, the life-cycle and maturity of the technology as well as the type of technology. For instance, when an emerging technology is considered for investment, the existing evidence may be scarce or lacking, so the HB-HTA report will probably present only brief information in the form of a checklist.

Delivering the results of the assessment at the "right time" in relation to the subsequent decision-making process affects the size of the HB-HTA report and the amount of information included. If there is little or no time pressure, the report can include more parameters and comprehensive information; if the time available is short, only key information will be included. Similarly, when there are a lot of requests from end-users in clinical practice (healthcare professionals), the HB-HTA report, due to the shortage of time, will most probably include only key information.

Available resources may influence the type of HB-HTA report produced, especially when resources are limited in terms of staff available to draft the HB-HTA report. The type of report may likewise be determined by the specific culture of the hospital (e.g. some decision-makers ask for brief information while others may require extensive information).

All this in turn gives rise to a great variety of HB-HTA reports as an input for hospital decision-making. Currently available HB-HTA reports vary in features (such as length, type of assessment report used, assessment domains being addressed) as well as in ultimate target audience, specific goals and staff involved. From this vast landscape of reports, it seems that two particular types of HB-HTA reports are the most common: short and structured mini-HTA reports and more broad and comprehensive full HB-HTA reports.

- **A mini-HTA report** is a short and structured assessment of the prerequisites for and consequences of using a specific health technology for a specific group of patients at hospital level. It is often delivered in the form of a checklist containing a number of questions (e.g. 15-25) related to the clinical, safety, economic and organisational implications of the health technology in question. Answers to the questions provide a brief overview and (part of) a basis for decision-making for a proposal to introduce the health technology at a hospital. A mini-HTA is typically *retrospective*, based on a review of relevant literature (not necessarily systematic) and expert opinions.

- **A full HB-HTA** report is a comprehensive, interdisciplinary, systematic assessment of the prerequisites for and consequences of using a specific health technology for a specific group of patients at hospital level. Both direct and indirect, intended and unintended, short- and long-term consequences are properly addressed. The health technology in question is considered using a broad approach focusing on all important aspects of the health technology, including clinical, safety, economic, organisational, ethical and social aspects. The assessment is based on both primary data, produced for the specific purpose, and secondary data, e.g. an exhaustive and systematic literature review carried out in accordance with established guidelines.

At the same time, there is a wide range of HB-HTA reports that are positioned in between these two types of HB-HTA reports when it comes to content, scope, structure and use of time and resources (Table 1).

TYPE OF HB-HTA REPORT	FEATURES OF THE HB-HTA REPORT
List of technologies for potential disinvestment	**Objective:** carried out to review hospital drug formulary and hospital medical devices list for potential disinvestment.
	Target audience: hospital decision-makers (medical management, head of pharmacy, head of purchase unit, chief financial officer).
	Types of HTs assessed: medical devices and drugs.
	Production period: usually 4 weeks.
	Staff-effort: 2 senior professionals (10% of FTE each).
	Deliverables: an MS Excel sheet.
Mini-HTA (using clinical trial data or routinely collected data)	**Objective:** carried out *prospectively* to contribute to primary research on clinical efficacy and cost-effectiveness of innovative technologies (integration of HTA methods and tools into clinical trials).
	Target audience: manufacturers of the health technology, clinicians, hospital managers looking for support in strategic planning of investments.
	Types of HTs assessed: technologies just entering the market, especially medical equipment, medical devices (large-/medium-/small-sized) and diagnostic tests assessed in order to inform decision-makers on aspects or information not yet available from current clinical studies.
	Production period: estimated 52-78 weeks.
	Staff-effort: several professionals from the HB-HTA unit (10-15% of FTE*) and clinicians.
	Deliverables: • a 23- to 24-page report including primary data on clinical efficacy and safety, costs, cost-effectiveness, budget impact analysis; • a 6- to 8-page scientific manuscript submitted to a scientific journal.
Technical input	**Objective:** carried out as a joint initiative of HTA doers and users (hospital committees) to manage the introduction of specific health technologies used across different clinical departments (units).
	Target audience: hospital committees embracing clinicians of different medical specialties.
	Types of HTs assessed: usually medical equipment, medical devices or drugs at a very early stage of development (emerging health technologies).
	Production period: estimated 4 weeks.
	Staff-effort: several professionals from the HB-HTA unit (10-15% of FTE).
	Deliverables: a 3- to 6-page document with a decision on whether the health technology needs to be studied under a clinical trial (primary research, RCT or others) or should undergo the assessment process.

TYPE OF HB-HTA REPORT	FEATURES OF THE HB-HTA REPORT
Medico-economic analysis	**Objective:** to assess the budget and the medical impact of a technology in question.
	Target audience: an executive committee of the hospital (decision-makers).
	Types of HTs assessed: medical devices (therapeutic, diagnostic) and drugs.
	Production period: estimated 18 weeks.
	Staff-effort: one professional from the HB-HTA unit (FTE).
	Deliverables: a 2- to 4-page document encompassing contextual medical impact of the new technology, economic assessment, impact on the workload and non-work-related charges, impact on the budget of the hospital and clinical division, budget reallocation needed, follow-up procedure.
Semi-rapid HTA	**Objective:** to provide evidence-based background information for decision-making in national hospitals of Finland.
	Target audience: hospital decision-makers in all national hospitals in Finland.
	Types of HTs assessed: all types of health technologies excluding drugs.
	Production period: usually 52 weeks (from 32 to 72 weeks).
	Staff-effort: 2 HTA experts and 1 information specialist from the national HTA organisation as well as 2-3 clinicians from hospitals.
	Deliverables: a 15-page document encompassing a description of the health technology and the condition, clinical effectiveness, safety, costs per case, and organisation of care from a national viewpoint.
Rapid systematic review	**Objective:** to provide an evidence-based background for hospital decision-making on different health technologies.
	Target audience: hospital decision-makers.
	Types of HTs assessed: medical equipment, medical devices, clinical procedures, drugs and others.
	Production period: 6-12 weeks.
	Staff-effort: HTA expert and clinical expert (1 week each).
	Deliverables: a 6-page document summarising clinical efficacy, safety and unit costs.

TYPE OF HB-HTA REPORT	FEATURES OF THE HB-HTA REPORT
Drug assessment	**Objective:** to provide an evidence-based background for hospital decision-making on drugs.
	Target audience: hospital decision-makers.
	Types of HTs assessed: drugs.
	Production period: 2-4 weeks.
	Staff-effort: 1-2 clinical expert (1 week each).
	Deliverables: a 2- to 4-page document encompassing relevant information retrieved from literature (not necessarily systematically) supplemented with an expert opinion.

FTE – full time employment (approximately 40 working hours per week)
* Equivalent to one professional from the HB-HTA unit working for estimated 8 weeks fully dedicated to carrying out the report. HB-HTA professionals work on few projects in parallel.

The choice between doing a mini-HTA or a more comprehensive HB-HTA will often involve balancing the need for quality and thoroughness against requirements of resources and speed and timing of the assessment in the given situation (Danish National Board of Health 2005).

2.5.2 QUALITY OF HB-HTA REPORTS

Healthcare decision-makers, including hospital managers and heads of clinical departments need timely and tailored information of high quality to make a decision on investment in health technologies. Consequently, hospitals across Europe have started to produce HTA as an input for decision making themselves (Sampietro et al. 2012). However, a potential concern is whether the quality of HTA produced by hospitals considering introducing a new health technology is sufficient to support sound decisions.

HB-HTA reports typically combine relevant information on the clinical outcomes coming from the scientific evidence with the context-specific organisational and economic implications of a new health technology, thus providing tailored and timely information for hospital decision-makers (Sampietro et al. 2012). HB-HTA reports may not necessarily have to meet the same quality requirements and approaches as national or regional HTA reports. On the other hand, HB-HTA reports may need to include additional information requested specifically by hospital decision-makers.

A number of guidelines on how to produce high-quality HTA as well as checklists to be used for the quality assessment of HTA already exist (Busse et al. 2002, Hailey 2003, Drummond et al. 2008, Kidholm et al. 2009). However, the focus of these tools rests primarily on the HTA addressed in national or regional contexts. Only the checklist developed by Kidholm et al. focuses on the quality of HTA from a hospital perspective.

The need to have a high quality HB-HTA report, based on both a robust methodology and the experience of European HB-HTA experts, has led to the development of a checklist with criteria for obtaining a high-quality HB-HTA report. This important advance, applicable across hospitals in different countries, is also a means to contribute to the improvement of transparency and consistency of HB-HTA reports.

!

Definition

What is the checklist for high-quality HB-HTA reports?

The checklist is intended as a guide for both decision-makers using HB-HTA reports as a basis for investment decisions and for HB-HTA doers keen to deliver high-quality reports. The checklist is generic and thus applicable across different types of HB-HTA reports and different countries. The checklist should be seen as complementary to the more detailed worldwide guidelines available on how to conduct HTA, but focusing on HB-HTA.

The final checklist includes 26 questions to help to prepare or review an HB-HTA report, grouped in the following categories:

- Basic information (questions 1-5).

- Methods & reporting (questions 6-12).

- Results within domains (questions 13-23).

- Discussion & recommendations (questions 24-26).

The questions on the checklist contain only brief details of a number of important points related to HB-HTA reports.

The checklist is available online in the AdHopHTA toolkit for hospital-based Health Technology Assessment (http://www.adhophta.eu/toolkit).

2.5.2.1. Quality performance of the HB-HTA reports.

In order to assess the quality of current HB-HTA reports, nine HB-HTA units were asked to choose one report they considered of high quality for the quality assessment. These reports should be considered as best cases, not necessarily representative of all types of HB-HTA reports.

The nine HB-HTA reports were evaluated looking at the presence, or absence, of each of the 26 items on the quality checklist.

- **Items dealing with Basic information (questions 1-5):**
  Most of the HB-HTA reports include information on the authors (Q1, 98%) and define the scope of their reports (through PICO question i.e. Population, Intervention, Comparator, Outcome) (Q5, 100%). About half of the reports provide a brief summary (1 page or less) of the assessment (Q4, 56%). Only a third of the reports include a statement on whether the report has been internally or externally reviewed (Q3, 33%) and even fewer on the presence of conflicts of interest (Q2, 22%).

- **Items dealing with Methods & reporting (questions 6-12):**
  The results of the HB-HTA reports are generally presented in a well-structured way (Q11, 100%) and all the reports include a list of important references (Q12, 100%). A review of relevant literature is often carried out (Q6, 89%) and methodological details of the literature review (Q7, 67%) and level of evidence of included information (Q10, 78%) is often provided. However, a statement on the quality of included information (e.g. by using a checklist to assess the internal validity of included literature) is often missing (Q9, 33%).

- **Items dealing with Results within domains (questions 13-23):**
  The majority of the HB-HTA reports include information on clinical effectiveness (Q13, 89%), safety issues (Q14, 78%) and economic aspects, including the perspective of the economic assessment (Q15, 100%) and a quantitative presentation of costs (Q17, 78%). However, the different types of cost elements involved (Q16, 67%) and implications for hospital reimbursement (Q18, 67%) are described only in two-thirds of the reports. The same applies to the organisational consequences both inside (Q19, 67%) and outside (Q20, 67%) the hospital department, and information on additional influencing factors (Q23, 67%). Most of the HB-HTA reports lack information on patients' experience of the given technology and its consequences (Q21, 33%), while all reports lack information on the strategic aspects (Q22, 0%), e.g. to what extent investment in the new technology is consistent with the research strategy of the hospital (the relevance of strategic aspects as an informational need of hospital managers is described in section 2.4).

- **Items dealing with Discussion & recommendations (questions 24-26):**
  The findings of the HB-HTA reports are only superficially discussed (Q24, 33%), whereas recommendations from the assessment (Q25, 78%) and suggestions for further actions (Q26, 89%) are more fully covered.

In summary, this critical evaluation of a convenient sample of HB-HTA reports across Europe reveals that there is a great variation on how well the requirements of the quality checklist are met – both between countries and between the different criteria. Nevertheless, the calculated quality score of HB-HTA reports varies between 0.50 and 0.92 (mean = 0.67), and three reports obtain a quality score of 0.80 or above. Overall analysed HB-HTA reports are of moderate quality (with three exceptions of high quality), although there is room for improvement, especially in the description of conflicts of interests, the quality of included information, the patients' experience and the strategic implications of introducing a new technology. Discussion of findings in the assessments is another area with potential for advancement.

The results of the quality assessment should be approached with caution. When assessing the quality of HB-HTA reports, the different criteria in the checklist were given equal weight. In principle, this implies that each criterion on the checklist is equally important for the quality of HB-HTA reports. This is hardly the case, since hospital decision-makers find information on the clinical, economic, safety, organisational and strategic aspects of a given technology most important (the relevance of these aspects for hospital managers is highlighted in section 2.4). If this relative weight had been considered in the evaluation, the results would obviously be different.

How do the resource use and comprehensiveness of HB-HTA report affect its quality?

Comprehensiveness of the HB-HTA reports (number of pages[1]) and the staff-effort invested in their production seem to correlate with the quality of HB-HTA reports[2]. Despite the great variance in both the staff-effort invested and comprehensiveness, it appears that the higher the quality score of an HB-HTA report, the greater the amount of staff-effort invested and the more comprehensive the report is. (Table 2). This can be seen by the fact that the average number of pages and the average amount of staff-effort invested for the 3 HB-HTA reports with the highest quality score (reports 1, 2 and 4) are higher than the average score for the whole group of reports.

1
As a proxy for the comprehensiveness of the HB-HTA reports, the total number of pages in the reports was counted, including front page, table of contents, glossary, bibliography and appendices.

2
Overall quality score from applying the checklist to the HB-HTA report.

HB-HTA REPORT	FORMAT	STAFF-EFFORT (no. of weeks)	COMPREHEN-SIVENESS (no. of pages)	QUALITY (% of positive ratings)
Report 1	Checklist	14.3	42	0.84
Report 2	Checklist	N/A	15	0.80
Report 3	Text report	2.0	17	0.52
Report 4	Text report	10.8	54	0.92
Report 5	Text report	8.7	21	0.50
Report 6	Text report	4.3	6	0.56
Report 7	Text report	4.3	25	0.69
Report 8	Text report	N/A	14	0.62
Report 9	Checklist	0.6	5	0.62
Mean	-	**9.0**	**22.1**	**0.67**

TABLE 2
OVERVIEW OF SPECIFIC HB-HTA REPORTS FORMATS, AMOUNT OF STAFF-EFFORT INVESTED IN PRODUCING THESE REPORTS (in weeks), COMPREHENSIVENESS (total number of pages) AND QUALITY OF THESE REPORTS (proportion of positive ratings).

Nevertheless, there are some considerations to take into account. First, when submitting HB-HTA reports, the majority of authors declared that it was very difficult to provide an estimate of effort invested, since this information typically is not routinely recorded. Moreover, the amount of time and staff-effort necessary to carry out the assessment depends largely on the amount of available evidence for the specific technology. The estimate may include time used for searching and reviewing literature for some of the HB-HTA reports but not for others. All this makes the estimate of resources used highly uncertain and thus the results should be interpreted with caution.

Secondly, as a proxy for comprehensiveness of the HB-HTA reports, the total number of pages in the reports was counted. The total number of pages depends on many factors, including the level of detail in the analysis and the complexity of the technology being assessed, and thus a great variation in comprehensiveness of the HB-HTA included reports was found. In some reports, complete search histories are included and in others are not, which may explain some of the variability. This makes the estimate of comprehensiveness of the HB-HTAs highly uncertain and these results too must be interpreted with caution.

In summary, the great diversity in the reports submitted demonstrates that HB-HTA can be done in many ways – of varying quality and comprehensiveness and with a disparate use of resources. Hospital decision-makers need accurate, relevant and timely inputs for decision-making, but these objectives may be in conflict with each other (Kidholm et al. 2009). According to the numbers in table 2, striving to achieve

the highest level of quality may well have a price in terms of resource use, i.e. the higher the quality of information, the greater the use of staff-effort, and hence the greater the cost. As an example, report 3 obtained a relatively low quality score of 0.52 but required only two weeks of staff-effort to produce it, compared to report 4, which obtained a much higher quality score of 0.92, but also used more than five times as much staff-effort to produce it (10.8 weeks), (cf. Table 2). Whether the increase in quality of included information is worth the additional cost of staff-effort must be decided by an assessment of the specific case. It is up to hospital decision-makers to balance this trade-off between high quality information, low resource requirements, timeliness and usage.

Key observations:

- There is no one type of HB-HTA report. The reports range from almost full HTA reports to simpler checklists of questions without the deep level of detail.

- Though there is variability in the quality of the HB-HTA reports evaluated, overall they are of moderate quality. Therefore, there is potential for improvement in their quality.

- HB-HTA reports also vary in other parameters, such as comprehensiveness and staff-effort invested in producing them. However, it seems that the higher the quality score of a HB-HTA report, the greater the amount of staff-effort invested and the more comprehensive the report is.

- There is a need for an increased focus on quality assurance in HB-HTA reports. However, this must be done without compromising the timeliness of these.

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2.6 COLLABORATION EXPERIENCES BETWEEN HOSPITALS AND NATIONAL OR REGIONAL HTA AGENCIES

This section aims to describe the extent and patterns of collaboration between HB-HTA units and national or regional HTA agencies in Europe. Information was retrieved from the AdHopHTA countries and regions[1] (n=12), plus Belgium, France (Paris) and Canada (Quebec). Collaboration with HTA agencies is presented here from the perspective of existing hospital HTA units and some additional hospitals without an HB-HTA unit. Some of the findings, such as perceptions of barriers to collaboration, do not necessarily represent only the viewpoints of the HB-HTA units, but those of the hospital management in general.

The number of HB-HTA initiatives is increasing worldwide (Martelli et al. 2013). HTA agencies exist in many countries and regions, but their output is not necessarily adjusted to the needs of the hospitals. On the other hand, HTA agencies usually have longer experience and more resources to perform high quality assessments. Therefore, joining forces in collaboration is very likely to be beneficial for hospitals.

In a majority of the European countries analysed, there are informal interactions of HTA activities between the HTA agencies and the HB-HTA units. However, some of these countries are characterised by having several regions with a high degree of autonomy (e.g. Spain and Italy), and therefore some regions may have a formal system of interaction, whereas other regions in the same country may have only an informal system. Table 1 shows existing patterns of collaboration in the European countries studied.

Definition

Formal system: nominated persons, formal process for sharing information, feedback and participation, joint projects, merged function.

Informal system: ad hoc contacts only.

TABLE 1
PATTERNS OF COLLABORATION BETWEEN THE NATIONAL OR REGIONAL HTA AGENCIES AND HB-HTA UNITS.

SOURCE:
Questionnaire survey with 24 respondents from AdHopHTA partners' countries and regions (Arentz-Hansen et al. 2013, Pasternack et al. 2014).

FORMAL SYSTEM	INFORMAL SYSTEM
Between the national level and hospital level: • Norway • Finland • Italy ("A. Gemelli" University Hospital) **Between the regional level and hospital level:** • Spain (Basque country) • Italy (Lombardy and Lazio region)	• Spain (Catalonia) • Austria • Switzerland • Turkey • Denmark • Italy (Emilia Romagna region)

2.6.1 COLLABORATIVE EXPERIENCES OF HB-HTA UNITS AND HTA AGENCIES IN EUROPEAN COUNTRIES AND CANADA

Austria

A designated HB-HTA unit exists in only one of the nine hospital districts of Austria. Austrian federal states own most of the hospitals. Since 2006 the national HTA function is covered mainly by a publicly funded non-university research institute, the Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA). All the major players in Austria's healthcare sector are represented on the Institute's board: the nine federal states, the main association of the Austrian Social Security (uniting insurances for health, accident and pension) and the, federal ministry of health. Austria does not have a national HTA strategy. Collaboration between national HTA and HB-HTA units is not formalised and takes place mainly through the annual agenda set by the nine federal states, which jointly shape the LBI-HTA's annual work programme. Information about on-going HTAs and final HTA reports is available to the public in full via the LBI-HTA website. HB-HTA reports have to be accessed informally. The interaction between HB-HTA and the national HTA agency is voluntary and ad hoc through personal networks. Formalising the cooperation between the national HTA agency and HB-HTA units is not currently envisaged in Austria.

Belgium

Belgium has no formal programme for HB-HTA. It is unclear whether HTA initiatives are taken at the hospital level or not and if they are, what they consist of. Collaboration between hospitals and the Belgian Health Care Knowledge Centre (KCE) is limited to the involvement of experts from hospitals in the national HTA agency. They can be involved either as stakeholders or as external experts with experience of a particular technology or disease. Like every citizen, organisations or institution in Belgium, hospitals can submit study proposals to the national HTA agency. This helps to identify priorities for HTA, but submission of a proposal does not guarantee execution of the study, as the number of proposals is always higher than the number of HTAs that can be executed in any one year. Sometimes, hospitals also contribute to national HTAs by sharing hospital data. Information flowing from the national HTA agency to the hospitals includes the published recommendations regarding a hospital technology; the list of planned and on-going studies at the KCE; and presentations about methods and/or work on specific technologies at seminars organised by professionals (including hospital associations).

Denmark

Collaboration between Odense University Hospital and the Danish national HTA unit started in 2002. At the hospital level there was a desire to introduce HTA as a tool for planning and prioritisation, and collaboration arose initially with the aim of drawing lessons from the national level. Since then, the national contribution has gradually been downscaled leading to an informal collaboration with hospitals on an ad hoc basis. It has mainly involved exchange of knowledge and information at national HTA meetings and conferences and in a few cases joint projects at the national level. Participation in and the use of HTA in general is voluntary at hospital level, and the large national HTA unit is now de facto closed. Besides the HTA unit at Odense University Hospital there is a regional HTA unit (HTA & Health Services Research in Århus) in one of the five regions in Denmark (Central Denmark Region). They mostly do national and regional HTAs. The HTA unit in Århus is also the co-ordinator for the national work of HTA on behalf of Danish Regions.

Estonia

In 2011 HTA collaboration was set up by the Estonian Health Insurance Fund (EHIF - the main healthcare purchasing body), the Ministry of Social Affairs, the University of Tartu, the Estonian Hospital Federation and the medical associations in the framework of the *TerVe* health promotion research programme. Elements of HTA had already been used in the analyses and decisions on reimbursement of medical services for years by the Ministry and EHIF. According to the Estonian healthcare programme, 25 HTA reports will have been commissioned in the period between 2012 and 2015. The main objectives are to justify investments in new health technologies and also to evaluate some established technologies (e.g. mammography screening and in vitro fertilisation). Topic selection is carried out by the HTA council in collaboration with the Estonian Hospital Federation and the medical associations. Reports are published in an open database (http://rahvatervis.ut.ee/). The analytical, statistical and cost data needed for HTA are provided voluntarily by EHIF and the collaborating hospitals.

Finland

Collaboration between the 20 hospital districts and the Finnish Office for Health Technology Assessment (FinOHTA) started in 2006 with the goal of preparing joint HTA reports on new health technologies. The aim was to bring evidence directly into decision-making, and reduce the geographical variation in the uptake of new health technologies. Topic selection, assessment and appraisal are organised in a systematised way with a shared organisations including a secretariat, a triennial board and an operational advisory council. A new expert team is established for each joint HTA project, based on informal contacts. Tasks are divided in the following way: FinOHTA has responsibility for coordination efforts, and provides expertise on the search for relevant literature and assessment methodology; the hospital districts are responsible for topic identification, formulation of the recommendations, and implementation of these. The topic selection and assessment are performed jointly. The product is a semi-rapid review of efficacy, safety and costs per case. The use of the HTA reports by hospitals is voluntary, i.e. there is no mandatory rule to implement the recommendations.

France

There is a strong tradition of collaboration between the regional HB-HTA Agency, CEDIT (Comité d'Evaluation et de Diffusion des Innovations Technologiques) and the national HTA agency which had already started before the establishment of the Haute Autorité de Santé (HAS) in 2004. The HAS is the national HTA agency whose task is to carry out assessments mainly for reimbursement and pricing of technologies in France (drugs, medical devices and procedures). CEDIT is the HB-HTA agency of the university hospitals of the Paris region, covering 37 hospitals, established in 1982. It is responsible for formulating advice for the dissemination of technological innovations in the hospitals and for horizon scanning. Collaboration between CEDIT and HAS includes informal contacts, mutual exchange of information and HTA reports and, in some cases, formal contracts for sharing assessment duties.

Italy

Collaboration models in Italy can be of various types because of the complex decentralisation of the country. There is great regional diversity since the regions are very autonomous. Based on examples from three regions, it can be observed that there has been ad hoc and informal collaboration between hospitals in the Lazio region and the regional HTA Agency (ASP Lazio) since 2009, and its successor, the regional HTA unit, since 2013. Moreover, the HB-HTA unit of the "A. Gemelli" University Hospital has established a formal and systematised interaction with the

national HTA agency and has a longstanding collaboration with the Italian Medicines Agency (AIFA).

Collaboration with hospital HTA units and the regional HTA programme in Lombardy is not systematised. It consists of providing information on emerging technologies or problems. Hospitals produce mini-HTAs or pre-assessment reports which are then further developed at regional level. Collaboration in Lombardy is mainly informal and voluntary.

In the Emilia Romagna region, the regional HTA agency maintains contacts with hospital managers in order to coordinate the HTA activities, but the HTA reports are performed only at regional level.

Norway

A new system strongly recommends that health technologies are introduced into the Norwegian hospitals through a systematic evaluation, particularly regarding clinical effects and safety. Established in Norway in the period 2012–2014, the system is based on consensus between the four regional health authorities, the Norwegian Directorate of Health, the Norwegian Knowledge Centre for the Health Services (NOKC), the Norwegian Medicines Agency, and the Ministry of Health. The system comprises a national horizon scanning function, single technology assessments and full HTAs on the national level, as well as mini-HTAs performed at the hospital level (HB-HTA). Collaboration between hospitals and HTA activities at the national level are formally regulated and mandatory. Clear criteria exist for when hospitals should interact with the regional and national levels after the completion of a mini-HTA.

Likewise, the national HTA agency in Norway, NOKC, has the responsibility to assist and provide advice to HTA activities at the hospital level. Completed mini-HTAs are published in an open-access national database. If, after the completion of a mini-HTA, uncertainty still exists regarding clinical effectiveness or safety, a more comprehensive evaluation of the technology in question may be performed at the national level. This is also the case when economic or ethical consequences of introducing a new technology are unclear. In such cases, a so-called "Commissioner's Forum" where all parties are represented, prioritises all relevant technologies, and decides which technologies the national HTA agency should evaluate through full HTAs.

Quebec, Canada

Collaboration between the provincial-health-system-level HTA agency INESSS (*Institut national d'excellence en santé et en services sociaux*, Quebec) and five university hospital centres in Quebec started in 2001. The number of HB-HTA units has increased continuously over the last decade with currently around 10 active HB-HTA units and another 10 newly established HB-HTA units in health and social service centres. In 2005, an HTA coordinating mechanism was set up by the Ministry of Health and Social Services and in 2006, the creation of a community of practice in HB-HTA was initiated by INESSS. These well-functioning collaboration structures and now well-established collaborations have led to a high level of coherence of methods and values between HB-HTA units and provincial HTA. All the HTA reports are publicly available and challenges for HB-HTA are regularly discussed at the community of practice level. Several HTA reports have benefited from collaborations between HB-HTA units and INESSS. Quebec is the only jurisdiction worldwide where HB-HTA unit is mandated by law as part of the mission of university health and social service centres.

Spain

As described above, collaboration models in Spain can be different due to decentralisation and high level of autonomy of Spain's regions:

> Catalonia

Collaboration between the Catalan regional HTA Agency (AQUAS) and hospitals involved in HTA activities started on individual bases and at different points in time beginning in 1990. Clinicians from the collaborating hospitals have since been involved in several assessment projects with the regional HTA agency. Generally, requests made are of a technical nature or about information on the clinical area where the technology is to be employed. The first formal HB-HTA unit was established in 2008 in the Hospital Clínic de Barcelona. A cooperation agreement was signed between the two institutions, which expressed their willingness to collaborate and help each other. In the first years of collaboration, members of the regional agency taught in the HB-HTA course organised by the new HB-HTA unit. Since then, collaboration has been ad hoc and informal.

The epidemiology department of another Catalan hospital, the Hospital de la Santa Creu i Sant Pau, also collaborates with the regional HTA agency in the identification of technologies for disinvestment and improved appropriateness of healthcare. This department gives support in the assessment of technologies requested by clinicians in its hospital, being responsible for reviewing the clinical evidence through systematic reviews and producing guidelines. In very few cases a comprehensive HB-HTA is carried out.

In 2012, the regional HTA agency laid the foundations for the creation of XAHTS, the Catalan Network for HB-HTA, in response to the emerging interest in assessing technologies in hospitals and to promote the use of HTA methodology. However, the implantation of the network has come to a halt due to lack of resources.

> Basque Country

Collaboration between two hospitals of the Basque Health Service (Osakidetza) and the Basque Office for Health Technology Assessment (Osteba) was established in 2010 with the mission of producing joint HTA reports on new and obsolete technologies. The aim was to provide evidence for decision-making at the hospital level and give advice on the public procurement processes at hospital and regional levels, increasing the interaction between health professionals and the regional HTA agency. The collaboration consists of topic selection, prioritisation, assessment and appraisal through joint activities including commissioned-research and joint-research teams. Research teams are defined ad hoc related to the technology to be assessed and the degree of expertise required for each joint HTA project is based on informal contacts. Tasks are divided in the following way: the regional HTA agency (Osteba) has responsibility for coordination efforts and provides expertise on search for relevant literature and assessment methodology, including ethical, legal, social and organisational issues (ELSOI) as well as economic analysis. The hospitals are responsible for topic identification, analysis of the information retrieved, organisational issues and help in the formulation of recommendations and their implementation at the hospital level. Topic selection and assessment are performed jointly. The reports used are mini-HTAs including clinical, economic and ELSOI aspects depending on the topic. Participation and the use of HTA information are voluntary for hospitals.

Switzerland

Switzerland does not have a national HTA agency, but the Swiss Network for Health Technology Assessment (SNHTA) supported by the Federal Office of Public Health was created in 1999 in the form of an association. Its role is to promote the use of HTAs in Switzerland and to serve as a platform of exchange between Swiss government agencies, university institutes and university hospitals. SNHTA members usually meet twice a year to discuss HTA matters and Swiss HTA policy.

Switzerland is a confederation of 26 cantons and each of them is responsible for setting up a healthcare system able to meet the health needs of its population. As a consequence, HTA is also decentralised with varied organisational patterns. The SNHTA has no operational function apart from allowing health authorities to stay in touch with HTA specialists. Participation is voluntary and members are heterogeneous with respect to organisation and interest.

Turkey

Turkey established its first HTA unit at the national level under the General Directorate of Health Care Research of the Ministry of Health in 2012. The first HB-HTA unit (ANHTA) under Ankara Numune Training and Research Hospital was also established in the same year. An HTA unit in the Social Security Institution followed in 2013. Although there is informal interaction between these two units, there is no formal or systematised form of collaboration. The interaction could be considered as voluntary and would mostly depend on individual efforts. The most common form of collaboration is on the training side, where staff of these units may participate in joint training. There is no example of collaboration yet on the prioritisation of topics, library services, finding experts, or sharing data. There is no financial relationship between these units.

2.6.2 TYPES OF COLLABORATIVE ACTIVITIES

The most frequently mentioned types of collaborative activities between HB-HTA units and HTA agencies in the countries and regions analysed are presented in Table 2; the most frequently reported activities are first.

TYPES OF COLLABORATIVE ACTIVITIES	THE NUMBER OF COUNTRIES OR REGIONS FOR WHICH THIS ACTIVITY WAS REPORTED
Exchange of documents: HTA reports and other information	12
Training sessions on principles and methods of HTA	11
Finding experts for HTA projects	8
Methodological advice or support for HTA projects	8
Providing mutual strategic or political support	7
Informing each other about planned or on-going HTA projects	6
Jointly carrying out or commissioning of health technology assessments	6
Sharing expert input (in any task)	6
Joint publications	5
Topic identification and prioritisation for HTA projects	4
Sharing hospital data (on indications, clinical outcomes and costs)	4

TYPES OF COLLABORATIVE ACTIVITIES	THE NUMBER OF COUNTRIES OR REGIONS FOR WHICH THIS ACTIVITY WAS REPORTED
HTA agency facilitating collaboration between hospitals	4
Information services, library services, help in obtaining articles	3
Preparing recommendations (based on HTA results) for decision-making	3
HTA-industry collaborations (e.g. early scientific advice)	3
Financial support	3
Horizon scanning	3
Sharing software or tools	2
Advice on reimbursement and/or pricing	2
Performing external evaluations of each other	2
Identification of inappropriate or obsolete technologies	1
Providing practical advice for dissemination of technologies	1

TABLE 2
TYPES OF COLLABORATIVE ACTIVITIES BETWEEN HB-HTA UNITS AND NATIONAL OR REGIONAL HTA AGENCIES.

2.6.3 BARRIERS AND FACILITATORS IN COLLABORATION BETWEEN HB-HTA UNITS AND HTA AGENCIES

The most frequently cited barriers to collaboration were the general lack of knowledge and culture of HTA in hospitals. The lack of legal regulations and national policies on using HTA in a systematic way in hospitals seems to be a particularly important barrier, as are competition between hospitals and clinicians' fear of losing their professional autonomy. The high methodological standards which characterise good national or regional HTA agencies can paradoxically become a barrier for collaboration between HB-HTA units and the HTA agencies. Adapting the traditions of the HTA agencies, which often produce long and complex reports, to the needs of hospitals, which require rapid and pragmatic solutions, can be a challenge.

Legislation or directives to mandate HTA in decision-making processes were considered an apparent facilitator for collaboration between HB-HTA units and HTA agencies. Formal and systematised collaboration was preferred over informal ad-hoc contacts. However, many respondents of the survey emphasised that informal contacts between individuals are important for collaboration as well. Multidisciplinary participation, mutual trust and respect were considered essential to improving collaboration. Pragmatic solutions, such as using the existing team and decision-making structures and resources in hospitals, as well as tailored and relevant HTAs that are "good enough" for hospitals, seem to be additional facilitators specific to hospital contexts.

The full list of barriers and facilitators in collaboration between HB-HTA units and national or regional HTA agencies is presented in Table 3.

BARRIERS	FACILITATORS
THE ASSESSMENT PROCESS	
• Difficulties in getting access to and using hospital data for HTAs • Lack of balance in collaboration: HTA agencies dominate too much • National or regional HTA agencies typically assess technologies at a later stage of evidence development than hospitals would require • HTA report production in national or regional HTA agencies is too slow for hospitals • Lack of evidence in HTA reports, which reduces the motivation for collaborative HTA projects • Too much methodology from hospital perspective in HTA reports produced by HTA agencies or in collaboration with them • Mini-HTA form is too complicated for hospital use • Language of HTA is perceived as difficult in hospitals	• Performing assessments together or commissioned by the other • Temporary coverage decisions followed by re-assessments (push for additional evidence generation in hospitals) • Transparent expert identification and selection process in collaborative HTA projects • Using existing networks, e.g. specialist associations for nominating experts or hospital management teams for appraising evidence • Sharing hospital data on indications, costs and clinical outcomes in HTA work • Shared database or other form of active sharing of HTA reports and information • A collaborative process for identifying HTAs which require updating and a process for updating them • Attracting and training newcomers: capacity building • Shared training sessions • Shared research projects (primary studies) • HTA agency facilitates national or regional networking of hospitals • Shared efforts to enhance international networking • Communication through bulletins and reminders • The HTA topics are relevant: affect many people and have financial significance • The content of the HTA report is tailored for hospitals to include information on organisational and patient issues and costs • The volume of the HTA report is reduced: only the relevant information needed for decisions is included • HTA reports adequately cover the organisational requirements (skills, continuous training, facilities and changes in work processes needed) and cost consequences (budget impact) of implementing the technology • More information on patient aspects • Standards for appropriate quality of HTA reports are determined (to overcome the problem of (i) insufficient quality and (ii) slow production due to too high methodological standards) • HTA reports are easy to access

BARRIERS	FACILITATORS
LEADERSHIP & STRATEGY & PARTNERSHIPS	
• A general lack of culture and knowledge of HTA in hospitals • Top-down governance of collaboration. Centrally planned and organised collaboration has been perceived as redundant • Lack of a national policy for HTA that clarifies the roles of HB-HTA and HTA agencies • No legal requirements or regulations to use HTA* • Lack of managerial commitment to collaboration, mainly from the side of the hospitals • Lack of formal governance structure of the collaboration • Perception of clinicians losing their autonomy • Competition between hospitals • Lack of funding both in HB-HTA and HTA agencies as it may create unfruitful competition • Differing interests and priorities in HB-HTA and HTA agencies	• Good reputation of the organisations which coordinates the collaboration (could be either a hospital or an HTA agency or the organisations which hosts the HTA agency) • Legislation or regulation which mandates or requires the use of HTA • Formal structures for collaboration • Informal, personal contacts • Availability of dedicated coordinators for collaboration • Shared horizon-scanning function • Alerts on obsolete technologies • Sharing information on planned and on-going projects
RESOURCES	
• Lack of methodological expertise in people participating in collaboration • Lack of information specialist who could work for the collaborative project • Role conflicts and mistrust between partners from HB-HTA and HTA agencies	• Skilled and credible HTA teams • Multidisciplinary HTA teams: both doctors and nurses, but also other professional groups join in • Good personal relationships, mutual trust and appreciation, and sufficient communication between the collaborating parties • Good project leaders in collaborative HTA and other projects
IMPACT	
• HTA is not used routinely in decision-making in hospitals • Public visibility and recognition of HTA in general are low	*None*

* represents a lack of facilitation rather than a barrier as such

SOURCE
Questionnaire survey of AdHopHTA partners' countries, regions and three additional countries or regions (Belgium, France, Quebec/Canada), two case studies from Finland and Norway (Arentz-Hansen et al. 2013, Pasternack et al. 2014)

TABLE 3
BARRIERS AND FACILITATORS IN COLLABORATION BETWEEN HB-HTA UNITS AND NATIONAL OR REGIONAL HTA AGENCIES.

Key observations:

- There are interactions and collaboration, although usually informal, between hospital-based HTA units and national or regional HTA agencies.

- Sharing documents and training are the most frequent forms of collaboration, but individual expertise and political support are shared as well.

- The most obvious barriers to collaboration are the general lack of culture and voluntary nature of using HTA in hospital decisions. Different expectations regarding timeliness and methodological quality of HTA reports have been identified as a barrier too.

- Formal organisation for collaboration is deemed necessary by most, but informal interactions are considered important to create trust.

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2.7 GUIDING PRINCIPLES FOR GOOD PRACTICES IN HB-HTA UNITS – STEPS IN DEVELOPMENT

This section aims to describe the process followed in the AdHopHTA project for the identification and final selection of criteria for good practices that HB-HTA units should ideally comply with. It also aims to inspire or contribute to the development of a final framework of guiding principles for good practices in HB-HTA units.

2.7.1 A HEALTHCARE BUSINESS EXCELLENCE MODEL WAS SELECTED AS THE BASIS

Good practices in HB-HTA units should cover all the criteria necessary to organise and run an HTA unit in a hospital as well as those necessary to perform a high-quality assessment. In the AdHopHTA research project, the EFQM model was used to guide the identification of the HB-HTA units' good practices criteria. The EFQM model[1] (EFQM 2003) is a recognised business excellence model used by the management level of many hospitals (Vallejo 2006). It is composed of 9 criteria grouped under "enablers" (how organisations undertake key activities) and "results" (what is being achieved and how it is measured). The enablers' criteria are: leadership; people; strategy; partnership and resources; and process, products and services. The results criteria are: people results; customer results; society results; and business results. Good practices in HB-HTA units should include criteria in all these categories.

2.7.2. GOOD PRACTICE CRITERIA WERE IDENTIFIED THROUGH LITERATURE REVIEW

The review of the scientific literature showed what guidance was available for good practices at national or regional HTA agencies. Although no guidance was found on good practices for hospital-based HTA units, there were articles describing the characteristics and running of HB-HTA units. HB-HTA experiences are less frequently described in the literature as compared with national or regional HTA, probably due to the fact that HB-HTA is a newer area of HTA deployment which has only just started to become widespread.

The criteria identified for guiding good practices at national or regional HTA agencies were compared with criteria described for HB-HTA units. Some criteria were mentioned in both settings when organising or carrying out HTA. Nevertheless, some of them were more frequently discussed than others in the literature, which may indicate their greater or lesser importance to either national or regional HTA or HB-HTA. Therefore, the number of citations was considered as a surrogate for importance and the criteria were ranked accordingly. Additionally, when looking at the position of criteria for both HB-HTA practices and national or regional practices, it was observed that some criteria were ranked the same (i.e. no difference in ranking position or one position of difference). Table 1 shows these results.

1
The **EFQM® Excellence Model** is a non-prescriptive framework for organisational management systems, promoted by EFQM (formerly known as the **European Foundation for Quality Management**) and designed for helping organisations in their drive towards being more competitive. Regardless of sector, size, structure or maturity, organisations need to establish appropriate management systems in order to be successful. The EFQM Excellence Model is a practical tool to help organisations do this by measuring where they are on the path to excellence; helping them understand the gaps; and then stimulating solutions.

CRITERIA	NUMBER OF TIMES MENTIONED IN LITERATURE (PLACE IN RANKING)	
	HB-HTA PRACTICES	NATIONAL OR REGIONAL HTA PRACTICES
Response time: HTA are delivered on time (S)	7 (1)	4 (7)
Identification and engagement of all stakeholders (inclusiveness) (PPS)	6 (2)	13 (1)
Hospital perspective should be taken into account when performing the assessment (P&S)	6 (2)	3 (8)
Conducting of HTA with the appropriate methods, tools and competency (PPS)	5 (3)	9 (3)
Establishment of a system for setting priorities (S)	5 (3)	5 (6)
Clear task descriptions regarding professionals working on the HB-HTA initiative and good recruitment process (Pe)	5 (3)	4 (7)
Clear definition of mission, vision and values which guide the initiative (L)	4 (4)	3 (8)
Funds earmarked for the HTA initiative (P&R)	4 (4)	1 (10)
HTAs have to be unbiased and transparent (S)	3 (5)	11 (2)
Identification of key allies and external partners to cover needs (P&R)	3 (5)	7 (4)
Clear governance (L)	3 (5)	3 (8)
Adaptability/self-learning/generalisability (S)	3 (5)	3 (8)
Policy for sharing knowledge, information and resources (S)	3 (5)	1 (10)
Link between HTA and decision-making (BR)	2 (6)	6 (5)
Independence (S)	2 (6)	3 (8)
Relevance of HTA to its use (S)	1 (7)	9 (3)
Customers' right to appeal results/recommendations (PPS)	1 (7)	6 (5)
Impact measurement (PPS)	1 (7)	6 (5)
Clear communication policy (internal and external) (S)	1 (7)	5 (6)
Definition of the goal and scope of the assessment (PPS)	0 (8)	6 (5)

Corresponding EFQM criteria: (**L**) Leadership; (**S**) Strategy; (**Pe**) People; (**P&R**) Partnerships & Resources; (**PPS**): Processes, Products & Services; (**PeR**) People Results; (**SR**): Society Results; (**BR**): Business Results. / **Color figures:** the three first in the ranking. **Color shadow:** criteria that were ranked in the same position (±1) by both national or regional HTA agencies and HB-HTA units.

The three most important criteria for HB-HTA were different from those observed in national or regional HTA agencies. These differences may underpin the fact that dissimilarity in context (hospital vs. national or regional) implies different needs when organising and carrying out HTA. "Responding on time" is a critical element in the performance of HB-HTA units, and so it was ranked in the first position. Additionally, the importance given to the criteria "identifying and engaging all stakeholders" and "adopting the hospital perspective when performing the assessment" both ranked in the second position, showing the importance of customising the assessment to the hospital context. These most important criteria identified for HB-HTA were more related to organising the process of the assessment, making sure to answer hospital context needs, than to the methodological aspects of the assessment itself, showing the dynamism and pragmatism needed to undertake HTA at hospital level. The third ranking position corresponds to the need to have a "prioritisation system" for choosing the health technologies to be assessed, and "skilled professionals to perform the assessments". Both criteria also imply the need for a pragmatic approach in a setting where multiple competing health technologies are being introduced into clinical practice and resources are scarce both for health technologies and for contracting professionals to carry out the assessment. High quality assessments ("Conducting of HTA with the appropriate methods, tools and competency") were also considered relevant and were placed in third position.

National or regional HTA agencies also include the need to identify and involve all stakeholders in the assessment process as an important criterion (ranked in the first position); the other criteria placed in the first three positions were related to the method of the assessment itself rather than to the organisation of the assessment process. Therefore, criteria such as "HTAs have to be unbiased and transparent", "HTA should be relevant to its use", and "Conducting of HTA with the appropriate methods, tools and competency" were found in the second and third position. All of these criteria are necessary for performing a methodologically good assessment.

There were two good practice criteria that were specific for HB-HTA: "To support evidence development" and "To carry out assessments for disinvestment" (Poulin et al. 2012).

All the criteria identified in scientific articles related to good practices in national or regional HTA agencies and in papers showing HB-HTA experiences can be classified under the two big categories of the EFQM® (enablers and results). Nevertheless, only one generic EFQM-model criterion "Impact measurement" was directly addressed in the literature. For all the other EFQM® criteria, HB-HTA specific adjustments need to be performed.

2.7.3 THE GOOD PRACTICE CRITERIA WERE FURTHER REFINED BASED ON VIEWS FROM HB-HTA UNITS AND HOSPITAL MANAGEMENT

A focus group involving eight HB-HTA stakeholders, including managers, industry representatives, HB-HTA representatives, a patient representative, and an HTA representative, identified 25 additional relevant criteria to be considered for good practices (see Table 2).

ENABLERS	
LEADERSHIP	• **Leaders** of the HB-HTA unit act as a role model, promoting the unit inside and outside the organisation (formal and active leadership)
STRATEGY	• The strategy of the HB-HTA unit is defined based on the **culture and strategy of the hospital**, as well as on its vision, mission and values • The HB-HTA unit's strategy is **linked to national, regional and European HTA strategies**
PEOPLE	• The organisation has clearly stated **career development plans**, related training programmes and other actions favouring the development of skills and abilities • There are frequent encounters and/or joint spaces allowing for interaction between the HB-HTA unit, its customers and other relevant stakeholders, creating a **good working environment** and a joint working culture
PARTNERSHIP AND RESOURCES	• The HB-HTA unit has adequate space, equipment, materials and technological support • There is a strategy for seeking additional funds for the development of additional evidence when gaps in knowledge are identified
PROCESSES, PRODUCTS AND SERVICES	• Patients are involved in the assessment process (hospital level) • Assessment results and decision taken are communicated to patients • There is a **follow-up process** on how results are implemented

RESULTS	
CUSTOMER RESULTS	• Customers **value** HB-HTA • Customers' **expectations** are met by the HB-HTA unit • Customers are willing to **repeat and recommend the service** by the HB-HTA unit
PEOPLE'S RESULTS	• People working for the HB-HTA unit are **satisfied** with their work, development and professional fulfilment, motivation and sense of belonging • People working for HB-HTA unit value their **opportunities for professional growth** within the field, such as networking
SOCIETY RESULTS	• Professionals within the hospital and relevant people outside the hospital are aware of the **need for and usefulness of the HB-HTA** unit • Relevant **stakeholders are informed** of the use and benefits of HB-HTA • HB-HTA is widely known and/or this knowledge is actively generated via scientific papers, other publications, specific training and scientific meetings
BUSINESS RESULTS	• HTA results have an impact on the technology **adoption process** and its implementation • Demands are satisfied • There is some degree of recognition achieved (reputation & market position) • HB-HTA complies with its budget • There is a return on investment (costs of HB-HTA unit compared to benefits generated) derived from the assessment • Productivity indicators are available • HB-HTA contributes to the overall performance of the hospital in terms of: achievements of benefits/health outcomes to end-users (patients/overall population), and operational efficiency

The complete list of criteria identified by both the literature review and the inputs of the HB-HTA unit, HTA stakeholders and hospital managers, was carefully analysed (e.g. looking for consistency in definitions, redundancies in concept, etc.). This step resulted in a final list of 42 criteria for good practices in HB-HTA units.

2.7.4 CONSENSUS ON THE IMPORTANCE OF THE IDENTIFIED CRITERIA WAS SOUGHT FOR

The 42 identified criteria which were considered important for good practices in HB-HTA based on literature and insights from HB-HTA stakeholders were subsequently exposed to the views of a wider sample of hospital managers and heads of clinical departments as well as of professionals with expertise in HTA and patient representatives in a Delphi panel (N=48). Table 3 shows the importance rating as well as the level of consensus found in this panel for the 42 criteria.

TABLE 3
GUIDING PRINCIPLES FOR GOOD PRACTICES IN HB-HTA UNITS BY LEVEL OF CONSENSUS AND IMPORTANCE RATING.

SOURCE
Delphi survey (n=36 participants) (Danglas et al. 2014)

(*) importance of guiding principle was assessed from 1 (less important) to 6 (very important) with the average rating of 4.86 (most important means higher than 4.86).

(**) The top 2 measures rated on the 6-point Likert scale were identified and the percentage of answers summed: more than 80% in the top 2 measures was considered as high consensus; between 70% and 80% in the top 2 measures was considered as medium-high consensus; between 60% and 70% in the top 2 measures was considered as medium consensus.

		IMPORTANCE RATING*	
		MOST IMPORTANT	LESS IMPORTANT
LEVEL OF CONSENSUS**	HIGH	1. Mission, vision & values 2. Place in the hospital's organisation 5. Role of HB-HTA unit in the technology adoption process 6. System for prioritisation of health technologies 8. Capacity to learn from experience and adapt 10. HB-HTA unit's independence 14. Good working environment and culture 18. Link to key allies, network and partners 19. The assessment process of health technologies 21. Unbiased and transparent assessment process 22. Involvement of stakeholders 26. Follow-up process on implementation of results 35. Impact of HTA results on adoption and implementation process 36. Schedule compliance (timely delivery of results) 42. HB-HTA unit's impact on society	9. Generalisability of the HB-HTA process 30. HB-HTA unit's staff satisfaction 38. External recognition (reputation & market position)
	MEDIUM-HIGH	3. Active leadership role 7. Communication strategy 12. Established human resources' profiles 16. Specific budget covering operational costs 25. Process of disinvestment 27. Customer's perception on the HB-HTA value 32. Awareness of the relevance of HB-HTA unit 33. Communication to stakeholders	4. Strategy of HB-HTA unit aligned with hospital's strategy 13. Career development plan 15. Adequate facilities 17. Funding strategy 28. Meeting customers' expectations by HB-HTA unit's 29. Positive reviews on HB-HTA unit's work 31. Perceived career opportunities at the HB-HTA unit 34. Wide dissemination of generated knowledge 39. Budget compliance 40. Derived return on investment (ROI) 41. Availability of productivity indicators
	MEDIUM	*None*	11. Link between HB-HTA unit and HTA strategies at different healthcare levels 20. Assessment customised for specific hospital setting 23. Patients' involvement 24. Communication of results to patients 37. Demand satisfaction

2.7.5 DEFINING THE FRAMEWORK AND THE GUIDING PRINCIPLES FOR GOOD PRACTICES IN HB-HTA UNITS

A content analysis of the criteria, aimed at grouping the criteria around similar concepts, and discussions with experienced HB-HTA units, was used to define dimensions for the final HB-HTA framework of the AdHopHTA project. This framework has four dimensions and 15 guiding principles, which summarise the identified criteria.

The assessment process (dimension 1) lies at the centre of the good practice framework. This is the keystone necessary to achieve the main objective of any HB-HTA unit, which is to provide the high quality information needed by hospital decision-makers. The assessment process is driven, governed, and facilitated by leadership & strategy & partnerships (dimension 2) as well as supported by adequate resources (dimension 3). The conjunction of these three key dimensions leads to the overall performance of the HB-HTA unit, with its expected positive impact of creating value for hospital decision-makers, as well as indirectly for society (dimension 4). The guidance and tools for a pragmatic application of these guiding principles are available in the Toolkit for HB-HTA.

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3

GUIDING PRINCIPLES FOR GOOD PRACTICES IN HB-HTA UNITS

3

GUIDING PRINCIPLES FOR GOOD PRACTICES IN HB-HTA UNITS

This chapter provides guiding principles for setting up good practices to achieve excellence in hospital-based HTA. Following and achieving these principles will foster the founding and running of HB-HTA units in hospitals.

HTA required by hospitals can also be performed by organisations external to the hospital. In order to achieve excellence in HB-HTA, external organisations are encouraged to act in accordance with specific guiding principles devised for HB-HTA units to provide hospital decision-makers with the high-quality information they require (see "HTA *'for'* hospitals" section in Table 1).

This chapter presents the guiding principles and subsequently gives examples of the current practices at various HB-HTA units and HTA organisations[1] as regards each principle. Whenever practices at HB-HTA units comply with the guiding principles, they can be considered good HB-HTA practices.

Adherence to the whole set of guiding principles sets up a benchmark for HB-HTA since it represents the ideal performance of HB-HTA units and organisations that have achieved excellence. However, a set of core guiding principles as essential requirements for founding of and running HB-HTA units can be selected from the whole set of guiding principles (see Table 2).

The guidance and tools for a pragmatic application of these guiding principles is available in the AdHopHTA Toolkit for HB-HTA (Figure 1).
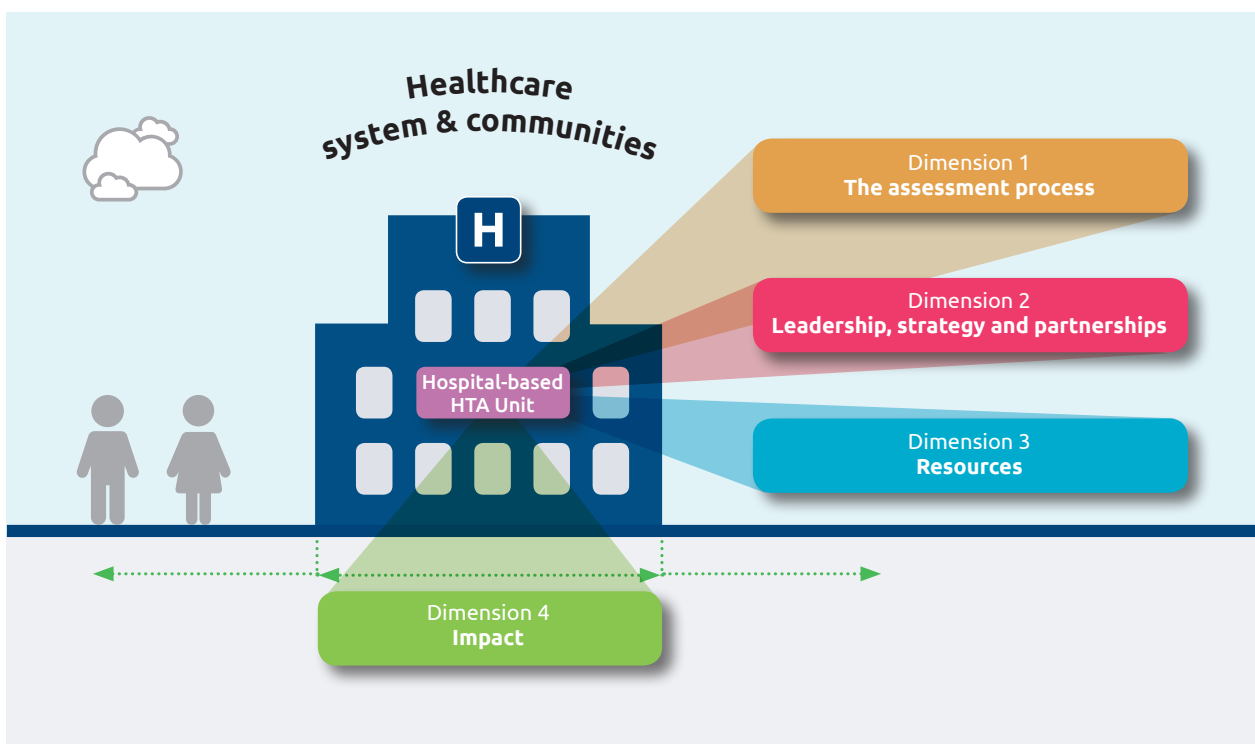

FIGURE 1
Graphical representation of the four dimensions influencing HB-HTA unit's good practices (AdHopHTA Toolkit for HB-HTA)

Guiding Principles

Dimension 1: THE ASSESSMENT PROCESS	**1**	**HB-HTA REPORT: SCOPE, HOSPITAL CONTEXT AND INFORMATIONAL NEEDS** The HB-HTA report clearly states its goal and scope, reflects the hospital context and takes into account the informational needs of hospital decision-makers.	HTA *'FOR'* HOSPITALS
	2	**HB-HTA REPORT: METHODS, TOOLS AND TRANSFERABILITY** The HB-HTA report is performed systematically using good practice methods and appropriate tools. It should be done in a way that can be adapted by other hospitals (transferability).	
	3	**HB-HTA PROCESS: INDEPENDENT, UNBIASED AND TRANSPARENT WITH STAKEHOLDER INVOLVEMENT AND COMMUNICATION** The HB-HTA process involves all relevant stakeholders. It is conducted in an unbiased and transparent manner, ensuring independence and it is properly communicated to hospital stakeholders.	
Dimension 2: LEADERSHIP, STRATEGY AND PARTNERSHIPS	**4**	**MISSION, VISION AND VALUES AND GOVERNANCE** The mission, vision and values of the HB-HTA unit are clearly defined, and are coherent with the hospital's overall mission and strategy and allow for clear governance of the HB-HTA unit.	HTA *'IN'* HOSPITALS
	5	**LEADERSHIP AND COMMUNICATION POLICY/STRATEGY** Clear leadership at the top of the HB-HTA unit acts as a role model when striving for excellence and defining and promoting a good communication policy/strategy.	
	6	**SELECTION AND PRIORITISATION CRITERIA** Criteria for the selection of technologies to be assessed are clearly stated.	
	7	**PROCESS OF DISINVESTMENT** The process for identifying and evaluating technologies for potential disinvestment is defined and established.	
	8	**IMPROVING THROUGH INNOVATION** There is a willingness to improve in the light of experience and a capacity to learn and innovate.	
	9	**KNOWLEDGE AND RESOURCE SHARING** There is a clear policy and mechanism for sharing knowledge, information and resources.	
	10	**COLLABORATION WITH HTA ORGANISATIONS** The HB-HTA unit collaborates with regional, national and European HTA organisations.	
	11	**LINKS WITH ALLIES AND PARTNERS** Key allies and partners are proactively identified and proper interaction between them, staff at the HB-HTA unit, customers and other relevant stakeholders, is facilitated.	
Dimension 3: RESOURCES	**12**	**SKILLED HUMAN RESOURCES AND CAREER DEVELOPMENT** Well-defined profiles and skills for human resources, recruitment policies and career development plans are established.	
	13	**SUFFICIENT RESOURCES** Financial resources are sufficient to cover operational costs and ensure an appropriate place of work.	
Dimension 4: IMPACT	**14**	**MEASURING SHORT- AND MEDIUM-TERM IMPACT** Short- and medium-term impact is measured and maintained.	
	15	**MEASURING LONG-TERM IMPACT** Long-term impact is measured and maintained.	

TABLE 1
GUIDING PRINCIPLES FOR GOOD PRACTICES IN HB-HTA UNITS.

HTA **'IN'** HOSPITALS means that the assessment process is carried out internally by the team of hospital professionals (e.g. clinicians, HB-HTA unit) and always leads to taking managerial decisions on health technologies; whereas HTA **'FOR'** HOSPITALS is performed by external bodies on the basis of different lines of actions such as consultations, temporary contracts, freelance activities or projects. However, both HTA "in" and "for" hospitals need to be tailored to the hospital context and serve for managerial decisions.

Core Guiding Principles

Dimension 2:	**4**	**MISSION, VISION AND VALUES AND GOVERNANCE** The mission, vision and values of the HB-HTA unit are clearly defined, and are coherent with the hospital's overall mission and strategy and allow for clear governance of the HB-HTA unit.
Dimension 3:	**13**	**SUFFICIENT RESOURCES** Financial resources are sufficient to cover operational costs and ensure an appropriate place of work.
Dimension 2:	**5**	**LEADERSHIP AND COMMUNICATION POLICY/STRATEGY** Clear leadership at the top of the HB-HTA unit acts as a role model when striving for excellence and defining and promoting a good communication policy/strategy.
	6	**SELECTION AND PRIORITISATION CRITERIA** Criteria for the selection of technologies to be assessed are clearly stated.
Dimension 1:	**1**	**HB-HTA REPORT: SCOPE, HOSPITAL CONTEXT AND INFORMATIONAL NEEDS** The HB-HTA report clearly states its goal and scope, reflects the hospital context and takes into account the informational needs of hospital decision-makers.
	2	**HB-HTA REPORT: METHODS, TOOLS AND TRANSFERABILITY** The HB-HTA report is performed systematically using good practice methods and appropriate tools. It should be done in a way that can be adapted by other hospitals (transferability).
	3	**HB-HTA PROCESS: INDEPENDENT, UNBIASED AND TRANSPARENT WITH STAKEHOLDER INVOLVEMENT (AND COMMUNICATION)** The HB-HTA process involves all relevant stakeholders. It is conducted in an unbiased and transparent manner, ensuring independence. Note: the part on "communication" of this guiding principle is not considered as core.
Dimension 3:	**12**	**SKILLED HUMAN RESOURCES (AND CAREER DEVELOPMENT)** Well-defined profiles and skills for human resources, recruitment policies are established. Note: the part on "career development" of this guiding principle is not considered as core.
Dimension 2:	**10**	**COLLABORATION WITH HTA ORGANISATIONS** The HB-HTA unit collaborates with regional, national and European HTA organisations.

TABLE 2
CORE GUIDING PRINCIPLES – ESSENTIAL REQUIREMENTS FOR FOUNDING OF AND RUNNING HB-HTA UNITS ARRANGED IN ORDER OF IMPORTANCE (according to AdHopHTA research results).

Dimension 1
THE ASSESSMENT PROCESS

Excellent HB-HTA units design, manage, carry out, review and improve the assessment process to generate valuable, tailored information for hospital decision-makers. The assessment report should be relevant and reliable, carried out in an unbiased and transparent manner with involvement of stakeholders. Assessment results and recommendations should be properly communicated to hospital stakeholders.

Guiding Principle 1

HB-HTA REPORT: SCOPE, HOSPITAL CONTEXT AND INFORMATIONAL NEEDS

The HB-HTA report clearly states its goal and scope, reflects the hospital context and takes into account the informational needs of hospital decision-makers.

SCOPE OF THE HB-HTA REPORT

To ensure the quality and clarity of HTA reports, the scope needs to be clearly stated at the very beginning of the assessment process. This means clearly defining:

TECHNOLOGY:

the name and type of the technology, described in enough detail to distinguish it from other comparable technologies;

INDICATION:

the intended use of the technology in the hospital:
1. Is it meant for treatment (first line/second line), prevention, screening, diagnosing or monitoring a condition, or determining prognosis?
2. What is its role and position in the treatment pathway?
   a) Does it replace or add-on an existing technology?
   b) Is it an interim or an end-solution (e.g. an artificial heart as an interim solution for a transplant)?
   c) Does it direct the use of other tests or treatments (e.g. triage tests and companion diagnostics)?

the target condition, with a brief description of the disease or health condition (of certain grade or severity) to be affected by the use of the technology;

the target population, which is typically a subgroup of all the individuals who have the target condition (e.g. of certain age or sex), or who are at (low/high) risk of having or getting the condition.

COMPARISON:

the name and type of a relevant comparator, which can be a another technology (including watchful waiting) or an alternative indication (i.e. alternative population or alternative way of using the technology) currently in use in the hospital.

OUTCOMES:

the benefits expected to be achieved through the use of the proposed technology, which may relate to direct or indirect benefit for patient, staff, organisation, or regarding costs.

This scoping activity should always be inclusive and performed with end-users in clinical practice (i.e. hospital healthcare professionals) and hospital payers of the technology. This will ensure that the clinical condition, the use of technology and the selected comparator are related to the specific context of the hospital. Moreover, it will contribute to selecting meaningful outcomes both for clinicians and financial managers. For example, a measure of Quality-Adjusted Life Years (QALY), used in the economic part of the assessment report, may be meaningful for health economists, and relevant for some clinicians, but healthcare managers might experience difficulties in applying it (McGregor 2006) and may prefer natural measures of cost-effectiveness (e.g. avoided hospital readmissions).

Definition

TICO question relevant for the technology assessment

Technology:	What is the proposed technology?
Indication:	What are the: target disease, target individuals and purpose of use of the technology?
Comparator:	What is the technology currently used in the hospital (or selected as an alternative for comparison)?
Outcomes:	What are the relevant outcomes expected from using the proposed technology?

Using the TICO question for scoping does not differ conceptually from the traditional PICO (patients, intervention, comparator and outcome) question used in HTA and in HB-HTA. However, AdHopHTA recommends the use of the TICO question as it fits better in the hospital context.

Current Practices

Current practices: scope of the HB-HTA report

Professionals at HB-HTA units define the scope of the HB-HTA report using the classical PICO structure: patients, intervention, control, outcome (hospitals such as HCB, GUH, OUH, CHUV, ANHTA, HUS and SUH, and HTA organisations such as CEDIT and NOKC).

The comparator is the technology in place in the hospital. A range of clinical, economic and organisational outcomes are defined in the scope. Some hospitals involve both end-users (physician requesting the technology, nurses, bioengineers, and planning professionals) and the financial manager (i.e. the person in charge of economic resources of the clinical department) when defining the scope of the assessment to be performed in the hospital. Involvement of other stakeholders is described in detail under guiding principle 3.

HOSPITAL CONTEXT OF THE HB-HTA REPORT

Consideration of the local context's characteristics when producing an HB-HTA report is crucial for assessing the economic and organisational impact of a given technology. Cost and availability of trained staff may even override the positive results derived in other hospitals (Poulin et al. 2012). Safety and clinical effectiveness are less dependent on the local context. Clinical and economic information related to the hospital context should be incorporated into HTA reports to complement global evidence; this information could (i) come from hospital databases or (ii) be produced within the framework of a clinical research study. The latter also contributes to the issue of scarce or unavailable evidence, a problem frequently faced by university hospitals in which introduction of technologies is considered at a very early stage of their development. Nevertheless, incorporating local evidence into HB-HTA in a comprehensive and systematic manner is not a standard practice and would require specific infrastructure (Mitchell et al. 2010).

Current Practices

Current practices: hospital context of the HB-HTA report

HB-HTA units take into account the hospital context, e.g. by consulting the economic manager of the clinical department for real hospital healthcare cost data to include in the economic analysis (hospitals such as CHUV, HCB and OUH). Additionally, HB-HTA units have carried out several data collection activities jointly with clinicians to produce the clinical and cost data needed in the assessment.

HOSPITAL INFORMATIONAL NEEDS

The EUnetHTA Core Model answers the informational needs of policy decision-makers (Lampe & Mäkelä 2008, Lampe & Pasternack 2008, EUnetHTA 2015). Nevertheless, while this type of information is important for hospital decision-makers, there is some key information that is of utmost value for them and not covered by this Core Model. The AdHopHTA mini-HTA template shows that any HB-HTA report has to provide information on the following domains: health problem and current use of the technology; clinical effectiveness; safety; cost and economic evaluation from the hospital point of view; organisational aspects and strategic aspects. Figure 2 shows the relevance of the different domains from the perspective of local hospital decision-makers versus national and regional HTA institutions (Kidholm et al. 2014, Kidholm et al. 2015, Ølholm et al. 2014, Ølholm et al. 2015).

It is important to notice the inclusion of an additional domain (the political and strategic aspect) not taken into account by the EUnetHTA Core Model but perceived as relevant by hospital decision-makers. This domain deals with the need for information on aspects related to the strategic goals of the hospital. Thus, it has to be taken into account when valuing the investment or introduction of the health technology assessed into the hospital (e.g. technology not yet available in the country but with which the hospital wants to be pioneer in the field).

DOMAINS	HTA CORE MODEL **EUnetHTA**	HB-HTA CORE MODEL **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
D5.2 Hospital point of view		••• **most important**
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		
D10.1 Political aspects		• relevant
D10.2 Strategic aspects		••• **most important**

FIGURE 2

HTA INFORMATIONAL NEEDS: NATIONAL AND REGIONAL
VERSUS LOCAL HOSPITAL DECISION-MAKERS.

Current Practices

Current practices: hospital informational needs

The majority of existing HB-HTA units and HTA organisations carrying out assessments for hospitals address the most relevant domains to meet hospital decision-makers' informational needs (hospitals such as HCB, GUH, OUH, CHUV, ANHTA, HUS and SUH, and HTA organisations such as CEDIT and NOKC). Informing decision-makers on strategic aspects remains a challenge as it is addressed superficially or not at all.

HB-HTA REPORT: METHODS, TOOLS AND TRANSFERABILITY

The HB-HTA report is performed systematically using good practice methods and appropriate tools. It should be done in a way that can be adapted by other hospitals (transferability).

USING APPROPRIATE METHODS AND TOOLS

To be of quality and relevance, methods chosen in the HB-HTA should follow internationally recognised standards for HTA. The need to use suitable methods and tools in the management and execution of HTA is confirmed by numerous studies (Lafortune et al. 2008, Goodman 2012, Gagnon et al. 2011, Lavis et al. 2008, Battista 2006, McGregor & Brophy 2005). Multinational HTA organisations have developed tools for ensuring good quality HTA reports and to support their quality assessment, such as INAHTA's 17 question checklist and EUnetHTA's Core Model (Lampe & Mäkelä 2008, Lampe & Pasternack 2008, EUnetHTA 2015, Hailey 2003).

These models are valid for national or regional HTAs, but are not specific for HB-HTA reports. The HB-HTA reports need to be presented in an executive and timely manner to hospital decision-makers (Sampietro-Colom 2012). Hence, HB-HTA reports may not necessarily need to reflect the same methodological approaches as the reports developed by national and regional HTA institutions. For example, systematic reviews of evidence always constitute the basis of a full HTA report produced by national and regional agencies, which usually increases the time required to produce it. However, HB-HTA frequently uses external HTA reports, if available, as a starting point for contextualisation (Gagnon et al. 2011).

HB-HTA reports need to specifically answer the informational needs of end-users in clinical practice. For example, national and regional economic evaluations ask for a cost-effectiveness analysis (CEA) from a societal perspective, while HB-HTA assessments should provide a CEA taking into account the perspective of the hospital. Moreover, budget impact analysis is often required in hospitals, but is not usually presented in national and regional HTA reports (Kidholm et al. 2014, Kidholm et al. 2015, Ølholm et al. 2014, Ølholm et al. 2015).

The assessment tool used in hospitals (e.g. AdHopHTA mini-HTA template), should ensure the robustness of the results.

Definition

The AdHopHTA quality checklist for HB-HTA reports

A quality checklist for HB-HTA reports has been developed and is available in the AdHopHTA toolkit. This checklist has 26 questions about the quality of an HB-HTA report and is organised in four sections:

1. Basic information – 5 questions about:

- quality of the scoping (TICO),
- declaration of conflicts of interest,
- presence of a review process, summary and contact information.

2. Methods and reporting – 7 questions about:

- explicitness and transparency of the methods applied, e.g. in search,
  review process and appraising the quality of the original studies,
- presence of reference list,
- clarity of reporting.

3. Results within domains (assessed items) – 11 questions about:

- availability of quantitative information on effectiveness and safety,
- presence of relevant organisational and economic information, including
  a description of the perspective of the analysis and the implications
  for hospital reimbursement,
- presence of information on strategic implications,
- inclusion of patient perspective.

4. Discussion and recommendation – 3 questions about:

- limitations, uncertainties,
- presence of recommendations.

(→ the quality checklist can be found in the AdHopHTA toolkit for HB-HTA)

This checklist is intended for initial guidance on how to conduct assessments of health technologies tailored to hospitals, and should not exclude the consideration of more detailed available methodological guidelines. It can also be used for the quality assessment of existing HTA reports carried out at a hospital level.

Current Practices

Current practices: using appropriate methods and tools

Review of available external HTA reports is a common practice in HB-HTA units (hospitals such as OUH, GUH, HCB and ANHTA). This information is updated with primary studies published after the release of the external HTA report if needed. HB-HTA units provide an economic evaluation taking into account the perspective of the hospital. Budget impact analysis is frequently performed – in about two thirds of reviewed HB-HTA units. Some HB-HTA units compare published economic models with their own hospital practice when developing the economic evaluation. This requires adjusting the baseline analysis, or "reference case", to the profile of patients in the hospital (such as HCB). The majority of HB-HTA units assess the quality of information or data included in their reports by using different tools; indicating levels of evidence is the most frequent method. The use of different checklists for the assessment of internal and external validity of included literature is declared less frequently.

HB-HTA REPORT TRANSFERABILITY

An HB-HTA report should be produced in a way that allows its transfer to other hospital settings. Transferability (i.e. the potential adaptation of an available assessment report to a specific context) should be differentiated from generalisability (i.e. the ability to directly apply the results of an HB-HTA report from one hospital to other hospitals). The latter, at the hospital level, is unlikely to happen mainly because an HB-HTA report is context-based, i.e. it includes characteristics of a population, disease and provider (e.g. types and skills in clinical practice, existing guidelines, experience, quality of care, culture and values of the hospital, the patterns of technology use) and methodological characteristics of the assessment (e.g. costing methodology, prices, discount rates, relevant outcomes considered) (HTAi 2014). This hospital context component may preclude direct adoption of the recommendations stated in an HB-HTA report to another hospital.

Nevertheless, an HB-HTA report can be transferred and adapted to another hospital's context. For this, the assessment requires explicit reporting and a clear description of the definition of the assessment's goal and scope (e.g. population characteristics) as well as methods used to produce the assessment report. Clear reporting of the assessment's goal and methods makes it possible to carry out the necessary adjustments to the report being adapted to another setting. The AdHopHTA quality checklist and other guidance documents, such as the EUnetHTA adaptation toolkit (EUnetHTA 2011) can be of help in making reports transferable.

HB-HTA experience from Canada shows that certain elements of HB-HTA reports can be transferred, such as results from a systematic review (if it is of high quality) in such a way that these results can be used as a starting point for HB-HTA in another setting (Gagnon et al. 2011). Other information that could also be used as a starting point is the section on the organisational implications of introducing the technology in the hospital. Moreover, the economic model used in the assessment could also be transferred if patterns of care do not greatly differ between hospitals. Information on on-going and completed projects as well as knowledge and know-how on the hospital-based process may also be transferrable (Gagnon et al. 2011).

Current Practices

Current practices: HB-HTA report transferability

Assessment reports performed by existing HB-HTA units provide the information necessary to ensure the transferability of their reports to other hospitals quite exhaustively. In the AdHopHTA research project it was shown that HB-HTA reports clearly define and describe their goal and scope (by means of the PICO question) along with reporting on methods used (i.e. details of the literature search such as key search terms, databases, selection criteria and study flow diagram) (see section 2.5). In addition, the assessment reports include authors' contact information which facilitates obtaining missing details (if needed) for carrying out adjustment in the course of adapting the assessment report to another setting.

Guiding Principle 3

HB-HTA PROCESS: INDEPENDENT, UNBIASED AND TRANSPARENT WITH STAKEHOLDER INVOLVEMENT AND COMMUNICATION

The HB-HTA process involves all relevant stakeholders. It is conducted in an unbiased and transparent manner, ensuring independence and it is properly communicated to hospital stakeholders.

INVOLVEMENT OF RELEVANT STAKEHOLDERS

Failure to involve relevant stakeholders at an early stage in the process may lead to undesirable consequences, such as delays in the adoption of new technologies (Bennie et al. 2011), non-acceptance or loss of credibility of both the results of the assessment and its process (Hutton et al. 2008). Therefore, before starting the assessment, key stakeholders should be identified and invited to participate in the process. A planned engagement process helps to balance the vested interests of participants and also contributes to the enhancement of quality, since it will capture the full range of perspectives on the value of the technology being assessed (Stafinski et al. 2011). It will increase the probability of the assessment's results being accepted and implemented. In addition, it helps to anticipate the range of effects (e.g. unintended, indirect or long-term impact) that the technology and the final decision on investment may have (Moharra et al. 2009, Tantivess et al. 2009, Watt et al. 2012, Boenink 2012).

At the hospital level, internal stakeholders are mainly of three types: those who are going to decide on the investment (i.e. managers and procurement professionals), healthcare professionals (i.e. clinicians, nurses, pharmacists, therapists) and patients. The literature shows that most hospitals with HTA activities involve healthcare professionals in the process (McGregor & Brophy 2005, Stafinski et al. 2011) and this is seen as a key success factor for the HB-HTA initiative (Gagnon et al. 2011, Gallego et al. 2009). Participation guarantees that the report is locally relevant, with full appreciation of all clinical aspects (McGregor & Brophy 2005), and ensures support for the assessment's results and their implementation (McGregor 2006).

The literature also highlights the need to involve patients in the assessment process (Poulin et al. 2012, Bridges & Jones 2007, Gallego et al. 2009, Barham 2011, Gagnon et al. 2012). They can provide new or improved evidence on personal experience about specific technologies (Barham 2011), as well as information on the value of the technology-related outcomes from their user perspective (Gagnon et al. 2012). The results of the AdHopHTA research show that the involvement of patients in the assessment process is identified as relevant and perceived as one of the key challenges for developed HB-HTA units striving for excellence. However, there are very few empirical evaluations on the benefits of patient or public involvement in HTA (Gagnon et al. 2012). Thus, there remains considerable scope for future research and improvement in the involvement of patients in the assessment process.

External stakeholders may include society, industry and policy-makers (i.e. national or regional authorities). Involvement of the public in general is also mentioned in the literature (Abelson et al. 2007) but not raised in HB-HTA.

Current practices: involvement of relevant stakeholders

Current practices regarding relevant stakeholders' involvement in the assessment process may differ from country to country as regards both the type of participants and the character of their involvement. In some HB-HTA units, the assessment team is in principle composed of the clinician, who asks for the technology and the professionals from the HB-HTA unit (hospitals such as OUH and HCB). This differs from other hospitals, where instead of an actual HB-HTA unit there is a fixed team of 5-10 clinicians and a nurse with knowledge of the evaluation methods available for the assessment (for example HUS). In other hospitals, the assessment team also includes professionals from the pharmacy, financial, procurement and clinical departments (for example GUH). In some units, the manager of economic resources of the clinical department is always part of the team (for example HCB).

The assessment team, regardless of its kind, not only meets at the scoping phase of the assessment, but frequently participates throughout the whole assessment process. Clinicians may perform different functions in the assessment process i.e. discussing and validating preliminary results produced by the HB-HTA unit's professionals (hospitals such as HCB and OUH) or producing the clinical part of the assessment themselves (for example OUH) or the whole report with support from a hospital team of experts in HTA methodology (hospitals in Norway with support from a national mini-HTA resource group run by the national HTA organisation i.e. NOKC). The final decision on recommendation based on the HB-HTA report is taken with the agreement of all participants involved. Sometimes the final HB-HTA report is submitted as a scientific publication to a peer-reviewed journal.

Most HB-HTA units lack experience on how to involve patients in the assessment process. When available, information on patients' perceptions of the technology to be assessed is incorporated from scientific literature into HB-HTA reports, although it is not a systematic and widespread practice in current HB-HTA units. Other practices include asking patients about, for example, their quality of life, satisfaction and overall experiences with the health technology studied during the assessment process (for example OUH).

In current HB-HTA units, industry is not involved in every assessment process; industry involvement occurs when some scientific literature or evidence required during the assessment process is not available. HB-HTA units contact the industry to obtain unavailable literature or evidence, have it explained to them and discuss the results of the assessment (when asked to do so by the clinician requesting the health technology) (for example HCB). Additionally, when production of evidence is needed, the HB-HTA unit collaborates closely with clinicians contacted by industry to carry out research activities on innovative health technologies. The results of these activities (e.g. clinical trials) often serve as an input for future HTA analyses. Regarding policy-making involvement (e.g. when selecting large medical equipment for regional accessibility), guiding principle 10 presents some clues.

UNBIASED AND TRANSPARENT ASSESSMENT PROCESS

The need for a transparent and unbiased assessment process is highly valued in hospitals (Gallego et al. 2009, Gagnon et al. 2011). It is identified as a key success factor for an HB-HTA unit (Gagnon et al. 2011) and for the use of its reports (Attieh & Gagnon 2012) by contributing to the transparency of the assessment process. Following the quality standards defined for HB-HTA reports (see section 2.5) is also a means of ensuring transparency and avoiding bias in the assessment process. Moreover, the quality checklist for HB-HTA reports includes reporting: (i) evidence gathering and interpretation, and (ii) conflict of interest disclosure. Both these items have been identified as a means of minimising bias (Goodman 2012, Niederstadt & Droste 2010).

Current Practices

Current practices: unbiased and transparent assessment process

Mechanisms used by hospitals to ensure transparency and an unbiased assessment process differ. Some hospitals document every step of the assessment process and put this information into the intranet of the hospital so that anybody interested can see the results from the assessment as well as how the decisions have been taken (for example ACH). Other hospitals carry out internal reviews of the assessment and send them to an external colleague of the hospital for review (hospitals such as OUH and GUH). In Norway, all mini-HTAs are reviewed by external experts from another hospital (HTA organisation such as NOKC). The external review can also be carried out by several professionals with different backgrounds, i.e. the reports performed by the HB-HTA unit are reviewed by the clinician requesting the assessment, the head of the clinical department involved, the head of the finance department, by a medical bioengineer and the medical director if needed (for example CHUV). Less formal systems are also used by some hospitals, such as working transparently through the involvement of all interested parties during the assessment and complying with the quality items for a good HB-HTA report (hospitals such as HUS and HCB).

INDEPENDENCE OF THE ASSESSMENT PROCESS

Ensuring independence from particular interest groups is one of the seven recommendations that emerged from a worldwide study of best practices and is well understood by the HTA community (Goodman 2012, Lavis et al. 2008). Independence should be ensured from suppliers of the health technology being assessed, but also from potential users of the technology and the funding body of the HTA programme (Bodeau-Livinec et al. 2006). At the hospital level, where technology providers are continuously interacting with clinicians, and where decisions are to be made very close to the bedside, the maintenance of independence in the assessment process is critical. Therefore, HB-HTA units should also seek to ensure the independence of their assessments.

COMMUNICATION TO HOSPITAL STAKEHOLDERS

A good understanding of the results from the HB-HTA by all stakeholders is crucial and needs good communication, which has been identified as a key success factor (Gagnon et al. 2011). The major immediate audience for HB-HTA findings in the hospital are the clinician requesting the technology, the professional in the financial department and the healthcare manager who will make the decision (being either the head of the department, CMO, CEO or other hospital professional). These professionals usually either use different languages for similar concepts or have different levels of knowledge about technicalities in the clinical area (for economists) or in the economic area (for clinicians). The HB-HTA unit should ensure that both types of information presented in the HB-HTA report are understood by all those who are going to use them for decision-making.

Dimension 2:
LEADERSHIP, STRATEGY AND PARTNERSHIPS

Excellent HB-HTA units have leaders who shape the future, acting as role models in accordance with the unit's values and ethics. The leaders ensure that proper and strategic relationships are developed within the hospital and with external key institutions and organisations. Policies and plans are available and deployed to deliver the strategy of the unit, including clear mechanisms for chosen technologies to be assessed and for knowledge and resource sharing. There should be a positive attitude towards adapting to a changing environment.

Guiding Principle 4

MISSION, VISION AND VALUES AND GOVERNANCE

The mission, vision and values of the HB-HTA unit are clearly defined, and are coherent with the hospital's overall mission and strategy and allow for clear governance of the HB-HTA unit.

MISSION, VISION AND VALUES

Like any other department in the hospital, the HB-HTA unit should have an explicit mission. It should be coherent with the hospital's mission and its strategic planning (Haselkorn et al. 2007), as well as with the hospital's values. Mission and vision should enlighten the strategy of the HB-HTA unit. This is considered a success factor for HB-HTA (Gagnon et al. 2011). Consistency between the HB-HTA unit and the hospital in terms of mission, vision, values and strategy is especially important for newly established HB-HTA units, as the whole idea of the HB-HTA may backfire in the face of conflicting missions, visions and values. It has already been shown that a lack of an explicit linkage of the HB-HTA unit to hospital policy regarding assessment of new technologies could carry the risk that other units in the hospital might produce assessments of low quality (Kidholm et al. 2009).

Current practices: mission, vision and values

The mission of any HB-HTA unit is in principle to provide hospital decision-makers with the information they need when deciding about health technologies; it could be expressed in different ways or be formalised through different hospital documents. Some hospitals express the mission in general terms such as "providing information to hospital decision-makers about new and existing health technologies" (hospitals such as GUH and HCB); while others are more explicit in their mission i.e. "to ensure that the hospital would only use effective and cost-effective interventions" (for example HUS). Whatever the case, it is important that the stated mission is explicitly linked to the role of the HB-HTA unit in the hospital (and not as another aim of the hospital) which is to provide information to hospital decision-makers and ensure its quality. This is achieved in hospitals in different ways, for instance by adhering to a specific document or directive on how new health technologies should be introduced in the hospital, stressing the need for the clinician to contact the HB-HTA unit (for example CHUV). Another way is linking the need of an assessment to the HB-HTA unit in the strategic plan of the hospital (hospitals such as HCB, ANHTA and GUH).

GOVERNANCE

Healthcare organisations require explicit rules for governance and authority, and this also applies to HTA organisations (Moharra et al. 2009, Goodman 2012). In the case of hospitals, clear governance of the HB-HTA unit consists in: (i) designating its place in the general organisation of the hospital, and (ii) defining how its work is related to or connected with hospital departments. As to the former, the most desirable option for any HB-HTA unit is to have a clear position in the organisational chart of the hospital. Relations of the HB-HTA unit with other hospital departments unit are particularly important when it comes to the adoption of new health technologies. The HB-HTA unit should play a role in the assessment of health technologies before their introduction into clinical practice in the hospital. Finally, there should also be a clear definition of who makes the final buying decision; this has been identified as a success factor for HB-HTA (Rosenstein et al. 2003).

Current practices: governance

Most HB-HTA units have a clear position in the organisational chart of their hospital. Some of them are formal bodies working directly for the CEO (for example ANHTA), come under the CMO (for example ACH) and others are placed under the Research and Innovation Directorate directly linked to the CEO (for example HCB). Current HB-HTA units play differing roles in the adoption of health technologies in hospitals. While in one hospital it is mandatory to consult the HB-HTA unit any time a new health technology is considered for introduction in the hospital (for example GUH), in others, this activity is voluntary, although highly recommended, especially for high cost and sophisticated healthcare technologies (hospitals such as OUH and HCB).

Guiding Principle 5

LEADERSHIP AND COMMUNICATION POLICY/STRATEGY

Clear leadership at the top of the HB-HTA unit acts as a role model when striving for excellence and defining and promoting a good communication policy/strategy.

LEADERSHIP

Good leadership is the soul of any organisation, department or unit. Well-defined and active leadership in HTA organisations is considered to be an important prerequisite for their organisational climate and improved performance (Lafortune et al. 2008). HB-HTA leaders, apart from being visible and promoting HB-HTA activity inside the hospital, should engage actively and personally in communication activities with current and potential customers (i.e. those requesting an assessment); encourage and support transparency and accountability of the assessment process; and be creative to sustain and promote the HB-HTA unit and its staff.

Current Practices

Current practices: leadership

Leaders of HB-HTA units at different hospitals work closely with heads of clinical departments. This relationship aims not only to identify technologies to be assessed, but also to make the clinicians aware of the support that the unit can provide them with in introducing health technologies (hospitals such as GUH, HCB and HUS). Leaders of HB-HTA units co-operate with heads of departments to define projects of common interest, including the introduction of HTA methodology in clinical trials, and promote HB-HTA in their national and international clinical scientific societies (for example HCB).

COMMUNICATION POLICY/STRATEGY

Visibility of the HB-HTA unit can be enforced through good policy/communication strategy. This should include internal activities, mainly addressed to professionals at the hospital, as well as external activities, addressed to stakeholders outside the hospital (e.g. national or regional HTA programmes, other HB-HTA initiatives, scientific societies, patient associations, mass media etc.). Internal and external communication policies allow for an improved organisational climate and performance, coordination of activities, dissemination of knowledge, understanding of and collaboration with end-users in clinical practice, as well as the building up of their capacity (Lafortune et al. 2008, Battista et al. 2003, Tantivess et al. 2009, Battista 2006).

Current Practices

Current practices: communication policy and strategy

Active communication inside the hospital includes making hospital clinicians and managers more aware of the potentialities of HB-HTA. The value of HB-HTA is communicated through specific courses on HB-HTA and lectures for several hospital departments (hospitals such as GUH and OUH), or by presenting specific case-studies and the HB-HTA unit itself in clinical rounds of clinical departments (i.e. patients' bedside sessions with healthcare professionals held on an everyday basis) (hospitals such as OUH and HCB).

The passive internal communication tool most used by hospitals is the website, where full HB-HTA reports are available, both in the intranet of the hospital and on the hospital's general website (hospitals such as ANHTA and OUH). Other hospitals keep the HB-HTA reports only in the intranet with little or no access for external people (hospitals such as CHUV and ACH). Another instrument for internal communication is including information about HTA activities in a specific newsletter (for example GUH) or printing all the HB-HTA reports and distributing them widely (for example ANHTA).

External communication activities performed by HB-HTA units include several options. Some units advertise both HB-HTA in general and themselves in national medical journals (for example ANHTA); others include chapters dealing with HB-HTA in books and journals addressed to national healthcare managers (for example HCB). Most hospitals publicise HB-HTA and participate in national and international conferences, either by invitation as a speaker or by presenting results from the assessments.

Another way to make an HB-HTA unit visible is to collaborate with other hospitals in setting up an HB-HTA unit; this may include acting as host to professionals from these hospitals who want to learn about HB-HTA (for example HCB). Some HB-HTA units' leaders acts as coaches attending monthly meetings of a committee for HTA in a community hospital supporting the assessment process (for example HCB).

Guiding Principle 6

SELECTION AND PRIORITISATION CRITERIA

Criteria for the selection of technologies to be assessed are clearly stated.

Scarce resources and increasingly expensive health technologies call for prioritisation of technologies to be assessed; establishing explicit mechanisms to determine technology selection is considered indispensable for the efficiency of any HTA organisation (Moharra et al. 2009, Lafortune et al. 2008, Poulin et al. 2012, Goodman 2012, Juzwishin et al. 1996, McGregor & Brophy 2005, Golan et al. 2011, Rubinstein et al. 2009, Stafinski et al. 2010). Strategies for defining technologies to be assessed vary across organisations. For HB-HTA, screening guides (checklists) with specific criteria are available (Poulin et al. 2012, Gagnon et al. 2011). Nevertheless, in practice it is often not a systematic and formalised process but rather a pragmatic, ad-hoc activity. However there are established scientific methodologies followed by some HB-HTA units (McGregor & Brophy 2005).

Current practices: selection and prioritisation criteria

Different approaches are used to select technologies to be assessed in hospitals. In some hospitals, the choice of topics is prioritised according to urgency, potential budget impact, the uncertainty of health benefits to be expected, concerns about the level of proof of the health benefits, and the presence of significant legal or ethical issues (for example MUHC) (McGregor et al. 2005). In other hospitals, prioritisation of all suggested topics for HTA is made at monthly meetings by an HTA council of researchers, clinicians and leaders representing all departments (for example OUH).

It is necessary to distinguish between the prioritisation criteria for the assessment of technologies and the criteria applied to establish which technology should be introduced first. The most often used prioritisation criterion for the assessment of technologies in HB-HTA is the "first in first assessed" rule. HB-HTA units should answer requests made by hospital decision-makers or clinicians promptly, and they should also deal with the requests in order of receipt. Some HB-HTA units have further explicit criteria in addition to order of receipt of requests, such as the relevance of the process of care where the technology should be established, the effort and amount of work needed for each evaluation, and the number of assessments coming from the same clinical department or ward (for example GUH). Other more context-based criteria are used by hospitals, such as prioritisation by the urgency shown by the clinician (for example CHUV and GUH). Units with scarce resources may prioritise requests according to the income earmarked for performance of assessments (hospitals such as OUH and HCB).

Regarding the prioritisation criteria for the introduction of technologies within the hospital, such as medical equipment to be considered in the Investment Plan, a multi-criteria analysis can be applied, assigning different weights to each criterion and a final score determining a ranking of priorities. The criteria applied in the GUH are the following:
1) The presence/absence of the technology in the hospital, as well as its level of obsolescence;
2) The relevance of the activities related to the technology to be introduced;
3) The impact of the technology on the organisation (on the staff and on physical infrastructure);
4) The strategic potential of the technology.

Guiding Principle

7

PROCESS OF DISINVESTMENT

The process for identifying and evaluating technologies for potential disinvestment is defined and established.

Considering hospitals' scarce resources for investment in new technologies, the HB-HTA unit's role is also important in identifying and evaluating those technologies that have little or no benefit to health. Partial or total removal of resources allotted to technologies with limited therapeutic benefit prevents an inefficient allocation of resources and makes it possible to re-invest those resources in other HTs of greater benefit to both hospital and patients (Poulin et al. 2012, Elshaug et al. 2007).

A structured process of identification and assessment of HTs for disinvestment is becoming an increasing need for hospitals, especially taking into account the fact that the worldwide economic situation does not make forecasts of budget increases in healthcare in the near future very likely (Henshall et al. 2012). However, experiences in applying this guiding principle into the HB-HTA are scarce and not always systematic.

Current practices: process of disinvestment

Disinvestment activities at hospitals are undertaken due to budget cuts and include gathering information by the HB-HTA unit on current coverage status in different countries for expensive drugs prescribed in the hospital (for example HCB). This information is mostly used to limit the application of the technology to its appropriate use, to target the use of technology to those patients who will benefit the most, and to negotiate prices with industry. Other hospitals apply HB-HTA to the disinvestment of surgical meshes for inguinal hernia repair through a Proactive Disinvestment Process (for example GUH).

Guiding Principle 8

IMPROVING THROUGH INNOVATION

There is a willingness to improve in the light of experience and a capacity to learn and innovate.

Good performance of HTA processes depends on positive attitudes to change in the light of experience, answering the needs of a changing environment, and a capacity to learn and innovate (Lafortune et al. 2008). Good performance of HB-HTA units should in turn also include a capacity to learn from experience and look for innovative ways to adapt to a hospital in a changing environment. This would require a system of self-evaluation and monitoring (Poulin et al. 2012, Juzwishin et. al 1996, Battista 2006).

Current practices: improving through innovation

Most HB-HTA units do not use formal and structured systems to review their performance and to adjust to new requirements on a periodic basis. Like their clinical peers in the hospital, who quickly adjust their patterns of care to new patient needs, most follow a pragmatic approach supervising closely in an ad-hoc way both the running of the HB-HTA unit and the assessments produced, and proposing appropriate changes when needed. In some instances there is an external review from hospital directors, where supervision of activities and performance of the HB-HTA unit is carried out and new areas where work is needed are identified. In one of the hospitals (ACH), the head of the HB-HTA unit meets every three months with the CEO to discuss progress and arising needs (e.g. to work in disinvestment).

Guiding Principle 9

KNOWLEDGE AND RESOURCE SHARING

There is a clear policy and mechanism for sharing knowledge, information and resources.

The HTA community is aware of the need to collaborate with other professionals nationally and internationally as a mechanism to share knowledge and experience among HTA peers. Knowledge of the impact of HTA-based decisions as well as the results from assessments should also be disseminated to other stakeholders such as policy makers, researchers, industry, patient and consumer organisations (Attieh & Gagnon 2012, Andradas et al. 2008). Hospitals with experience in HB-HTA should share their experience with other hospitals looking for systematic approaches to health technology adoption and management (Juzwishin et al. 1996). Collaboration and coordination is more important when resources are scarce. HB-HTA units are usually small, and their staff (including the leaders) are often not fully devoted to this activity. The heads of HB-HTA units are also engaged in other hospital activities; they may take part in clinical research (OUH), advise in technology transfer activities (HCB); be involved in the transplantation department (ACH), deal with flow of information activities and reorganisation of hospital laboratories (GUH), or work as general practitioners (ANHTA).

HB-HTA units in Europe collaborate on an informal basis. Exchange of information on management and running of HB-HTA units and information on on-going health technology assessments is not systematic. This lack of systematisation is mainly due to the small size of these units, usually with a heavy burden of work, and slender resources to organise systematic collaboration. The creation of a formal network of HB-HTA units in Europe could contribute greatly to a more efficient and effective exchange of knowledge and information among current units, as well as to an appropriate transfer of knowledge to other hospitals. On a smaller scale, the province of Quebec (Canada) set up a network of healthcare centres performing HTA thus creating a "community of practice" where knowledge, experience and content of assessments is shared and exchanged (Gagnon et al. 2014).

Current Practices

Current practices: knowledge and resources sharing

Sharing of knowledge and information from current HB-HTA unit activities is done internally (i.e. within the hospital) and externally (i.e. at a national and international level). Most HB-HTA units engage the clinician requesting the health technology during the whole assessment process. These engagements not only provide key information on how to design and carry out the assessment properly, but are also a way to teach healthcare professionals basic HB-HTA concepts and methods. Other knowledge transfer activities performed inside the hospital include HTA courses organised for internal staff of the hospital on request (hospitals such as OUH and HCB). Other HB-HTA units undertake teaching activities for clinicians on what the evaluation process is and how to request an assessment (for example GUH). Courses outside the hospital, for a wider audience, are also held by several HB-HTA units. They include holding national training days on HTA to raise awareness of it at other hospitals (for example ACH), bringing HTA courses into MBA programmes (for example OUH), collaborating with other schools (for example GUH with the Graduate School of Health Economics and Management) or organising post-graduate master programmes and courses on HTA (for example GUH).

Knowledge of HB-HTA can also be shared by consulting and advising hospitals new to HTA how to organise their work. An example of this practice occurs in one of the recently established HB-HTA units, which invites other European HB-HTA units to teach their professionals (for example ANHTA). Another HB-HTA unit coaches a newly-created HTA Committee in a community hospital on how to organise and carry out the HB-HTA work in the hospital (for example HCB). The unit also shares the HB-HTA reports with them, as baseline information, for those health technologies already assessed by HCB and being requested by a clinician from the community hospital. Knowledge sharing also takes place through the publication of full versions or selected parts of completed HB-HTA reports.

Finally, knowledge is also shared internationally. All HB-HTA units in AdHopHTA are members of the Interest Subgroup of the international society for Health Technology Assessment (HTAi). During the annual meetings, HB-HTA units present both results from their assessments as well as policy and strategic work. It is also a place for establishing informal contacts among the worldwide HB-HTA community. The leaders of HB-HTA units are usually invited to national and international conferences organised by different stakeholders (e.g. patients' associations, healthcare managers' associations, industry) to present their work in the field, which is also a way to share knowledge and experience.

Guiding Principle 10

COLLABORATION WITH HTA ORGANISATIONS

The HB-HTA unit collaborates with regional, national and European HTA organisations.

National and regional HTA organisations are well established both in Europe and around the world (WHO 2001). Hospitals with HTA units usually operate in countries where a national or regional HTA organisation exists. Although their mandates, end-users of assessment results and decision-makers differ, there is a common field of work where synergies and economies of scale can be promoted. Moreover, although decisions taken based on HB-HTA results will immediately affect the hospital, in the long term they will also affect the surrounding community and the whole healthcare system. Therefore, it is advisable for the HB-HTA unit to have a line of collaboration with national or regional HTA organisations that facilitates mutually respectful collaboration. This collaboration may include issuing joint guidelines on how to proceed when there is a contradiction between recommendations given at the hospital and those developed at the national level.

There are several prevailing requirements for successful collaboration between HB-HTA units and national or regional HTA organisations, including good leadership, competent personnel, better use of resources, strategic and political support across levels and relevant outputs. Leadership and governance should clearly define the basis and the strategy for collaboration. Similarly, roles and responsibilities should be defined and adequate funding secured. Savings may be achieved through sharing resources (e.g. a library), exchanging knowledge (e.g. training) and networks. And, finally, collaboration should aim at customising information that hospital decision-makers need, but also considering some requirements to HB-HTA reports from national or regional HTA organisations (i.e. quality, accessibility to reports) (Arentz-Hansen et al. 2013, Pasternack et al. 2014). Figure 3 shows the building blocks for a successful collaboration.

THE BUILDING BLOCKS OF SUCCESSFUL COLLABORATION ARE:

- Good leadership
- Competent people
- Fluent processes across levels (national/regional and hospital)
- Relevant outputs

SEE MORE INSIDE!

FIGURE 3
PORTFOLIO OF REQUIREMENTS FOR COLLABORATION BETWEEN HB-HTA UNITS AND NATIONAL OR REGIONAL HTA ORGANISATIONS.

SOURCE
Arentz-Hansen et al. 2013, Pasternack et al. 2014.

LEADERSHIP AND GOVERNANCE SHOULD ENSURE

- regulations that require the use of HTA at all levels
- clear definition of mission, vision and values of collaboration
- mutually agreed strategy and managers` commitment to collaborate
- clearly defined roles and responsibilities across levels
- adequate funding that prevents competition between levels

THE INDIVIDUALS WHO COLLABORATE SHOULD

- have appropriate HTA knowledge, including methodological skills
- be trained in project leadership, communication and knowledge transfer
- have access to relevant databases, IT support and administrative assistance
- be open to informal contacts and express mutual respect across levels

BETTER USE OF RESOURCES THROUGH COLLABORATIVE PROCESSES SUCH AS

- sharing HTA reports, data and library resources
- training in HTA methodology
- joint identification of relevant HTA topics
- exchange of competence and networks
- providing strategic and political support across levels

USEFUL OUTPUTS OF COLLABORATION SUCH AS

- joint HTA reports that are directly useful for decision making in hospitals, i.e.
  - to the point and usually brief tailored for hospitals and to include information on the organisation, costs and patient aspects
  - methodologically "good enough"
  - clear and easy to read
- database for easy sharing of HTA information
- improved communication between partners and reduced duplication of HTA work

Current practices: collaboration with HTA organisations

Collaboration between national or regional HTA organisations and HB-HTA units takes place both formally and informally. In countries with legislation or directives mandating the use of HTA in decision-making, linkages between HB-HTA and national or regional HTA are stronger or are perceived as more useful. For example, the Managed Uptake of Medical Methods programme (MUMM) in Finland fosters collaboration of all hospital districts in the country with the Finnish HTA Office. This programme has been prioritising health technologies for assessment and producing evidence for hospital decision-making for nearly ten years (Mäkelä & Roine 2009). A new system that strongly recommended the introduction of health technologies linked to an assessment process was set up for the period 2012-2014 in Norway. This system included the performance of mini-HTA by hospitals and its storage in a national database. Here, the collaboration of the national HTA agency with hospitals was to assist them and provide advice on HTA activities (NOKC 2014). Other formal collaborations deal with producing HTA reports for drugs aiming to support decisions on the allocation of economic resources (a hospital such as the GUH collaborates with the Italian Medicine Agency —AIFA— within the Italian National Healthcare Service). In this case the HB-HTA unit's role is to (i) perform systematic analyses of scientific literature on the effectiveness and cost-effectiveness of specific drugs; (ii) develop pharmacoeconomic studies on the epidemiological, economic and social impact of specific pharmacological groups used within the National Healthcare Service and regions; and (iii) support the national or regional organisation in the implementation of the HTA process at national level.

In other instances, exchanging information, reports and jointly performing assessments is a well-recognised and long-standing practice between the HB-HTA unit and national or regional organisations (an HTA organisation such as CEDIT —the HTA unit for the hospitals of the Paris region— and HAS, the French National Authority for Health). Collaborative practices also take place when national or regional organisations act as umbrella and facilitator of all the HB-HTA initiatives existing in the healthcare centres of the country or region (e.g. INESS —Institut national d'excellence en santé et en services sociaux— in the province of Quebec, Canada).

HB-HTA units are also informally linked with national or regional HTA organisations in different ways, forms and intensity. Informal collaborations do not only include sharing of documents or expertise, but also mutual strategic or political support. There are also joint efforts in training and capacity building in HTA, and shared efforts in topic identification and prioritisation to improve efficient use of resources. In some countries HB-HTA and national or regional HTA organisations have collaborated in reimbursement and pricing and industry interactions. Among remaining miscellaneous types of collaboration between national or regional HTA agencies and HB-HTA units there are: coordination activities across hospitals in the case of a very expensive new technology targeted at a few clinical cases or with specific skill requirements or premises not widely available; development of formal processes and rules to access information in hospitals' clinical and financial databases to use the data to a full extent for HTA reports; and additional data collection as a requirement of temporary approval of a health technology.

Guiding Principle 11

LINKS WITH ALLIES AND PARTNERS

Key allies and partners are proactively identified and proper interaction between them, staff at the HB-HTA unit, customers and other relevant stakeholders, is facilitated.

The strength of HTA processes arises from the integration of the efforts of partners in multiple and diverse disciplines in order to produce knowledge that will assist decision-makers (Poulin et al. 2012, Battista 2006). Partnerships are made through alliances with external organisations or people in order to be able to draw on resources from them or from other services (e.g. a library). HTA organisations at national level collaborate with other agencies and academic institutes in both developed and developing countries (Tantivess et al. 2009). An HB-HTA unit also needs to proactively identify key allies and external partners, not only to cover unmet needs and produce the required knowledge, but also to formally or informally obtain the strategic and political support needed to ensure sustainability of the unit. Partners can be domestic (i.e. in-hospital or close at hand), national or international.

HB-HTA units have a clear mandate in the hospital and are usually created and supported by the top management. The few resources devoted to the unit should be perceived by other clinical departments as worthwhile. Therefore, HB-HTA units should have key allies inside the hospital who support and contribute to their work. Although the unit could work for any department inside the hospital, the concentration of an important part of the unit's work in a specific clinical department may help at the beginning to consolidate the position of the unit. To maintain and foster domestic allies, it is important to have systematic and proper interactions with them and be responsive to their requests for collaboration. Interactions usually occur through specific assessment projects, where these allies are customers of the HB-HTA unit. In these cases, interactions involve multiple systems (e.g. emails, conference calls, meetings).

Strategic allies can also be sought outside the hospital, either at other hospitals in the region or country or at the national or regional HTA agency (the latter is described under guiding principle 10).

Seeking allies and partners outside the country is also important for knowledge growing, experience sharing and the unit's sustainability. The formal or informal exchange of information among HB-HTA units helps to consolidate any unit in any hospital. HB-HTA units around the world are informally supporting each other and building firm alliances. The AdHopHTA research project is one example of a collaborative effort of HB-HTA units and HTA organisations supporting this activity. Most HB-HTA units independently have contacts with other units outside their countries and continent, and some are trying to build collaborative efforts to support the creation of HB-HTA networks in their continents (e.g. exchange of information of the basis for a Pan-Canadian HB-HTA network and an EU HB-HTA network).

Current practices: link with allies and partners

In-hospital domestic partnerships are established by some existing HB-HTA units by close collaboration with the IT department, which is one of unit's main supporters (for example OUH). At other hospitals, there are joint work efforts on different projects by the HB-HTA unit and laboratory and diagnostic imaging departments making these important allies inside the hospital (for example HCB). Other HB-HTA units identify main allies in the hospital management group and organise periodical meetings with them to present the HB-HTA unit's activity and results and define future work (for example ANHTA).

In the immediate surroundings of hospitals, most HB-HTA units have domestic alliances to cover unmet technical needs, for example, systematic searches done by the librarian of the hospital or the university.

In the case of HCB, partnerships outside the hospital are set up through close interactions of the HB-HTA unit with other domestic hospitals, scientific societies and companies that work closely with a clinician. The unit is coaching and mentoring the development of an HTA Committee working in a regional community hospital. Moreover it also supports the development of similar HB-HTA units in other high-tech, tertiary hospitals in the country (e.g. Virgen del Rocío in Andalusia and Cruces in the Basque Country). Welcoming staff from other hospitals for a short training period is another means of setting up and maintaining alliances (for example HCB).

Dimension 3:
RESOURCES

Excellent HB-HTA units plan, manage and value the utilisation of their various resources (information, human, technical and financial resources) to ensure that the HB-HTA unit and its staff have the necessary resources, competencies and empowerment to support the HB-HTA strategy and the assessment process.

Guiding Principle 12

SKILLED HUMAN RESOURCES AND CAREER DEVELOPMENT

Well-defined profiles and skills for human resources, recruitment policies and career development plans are established.

HUMAN RESOURCES AND RECRUITMENT POLICIES

The HB-HTA unit, like any other professional organisation, should have a basic organisational structure i.e. core staff with specific profiles working on a full-time basis as well as ad-hoc experts needed to work on specific aspects of a particular project. The structure of staff involved in HTA reflects the multidisciplinary nature of HTA. The most apparent competences involved in assessment projects on a full-time basis in HTA organisations include health economists, public health specialists, biomedical engineers, sociologists, documentalists and management professionals. Other staff profiles covering consulting roles (ad-hoc basis) in the assessment project include ethicists and biostatisticians. The research conducted in the AdHopHTA project showed that in an HB-HTA unit, the basic staff should cover competencies in medicine, epidemiology and public health, and economics.

Professionals are the main asset of any organisation and their selection and proper management is an essential part of the organisation's success. Therefore, establishing explicit criteria for hiring staff, giving clear job descriptions and designing mechanisms to encourage team work is advisable (Moharra et al. 2009, Lafortune et al. 2008, Poulin et al. 2012, Goodman 2012).

Current Practices

Current practices: human resources and recruitment policies

Most HB-HTA units' staff comprises exclusively professionals devoted to assessment of health technologies (hospitals such as CHUV, OUH, GUH, HCB, ACH and ANHTA). HB-HTA units in Europe also look for any ad-hoc expertise required among their hospital colleagues and outside the hospital. Some HB-HTA units, mainly made up of medical doctors, economists and public health specialists, involve clinicians and other professionals working at the hospital (e.g. bioengineers) when performing the assessment (hospitals such as CHUV, HCB and OUH). If the assessment project requires external collaboration, it is sought at the university level (for example ACH, rarely in GUH). In a few instances, when the internal staff is not available to perform requested assessments, external specialised manpower is engaged to carry out the assessments (for example

HCB); this always happens with the collaboration and under the supervision of the leader of the HB-HTA unit.

Some of the HB-HTA units in Canada include a range of hospital professionals: physicians, planning department representatives, quality improvement department coordinator, hospital ethics committee chair, clinical engineering department director, and representatives from the public health sciences and applied sciences in medicine department (Technology Assessment Working Group, Alberta University Hospital, Canada) (Juzwishin et al. 1996). In one United States hospital, the unit's professional staff structure comprises two hospital coordinators, two research analysts who perform evidence syntheses, health economists, six clinical liaisons, a librarian and an administrator (University of Pennsylvania Health System) (Luce & Brown 1995).

Newly-funded HB-HTA units do not necessarily follow an explicit and formalised procedure to advertise and select professionals to work on their assessments. Instead they invite hospital professionals with specific interest, or defined skills, to collaborate on the HB-HTA projects (hospitals such as ANHTA and HUS). In more developed HB-HTA units, their leaders define specific job descriptions and make the final decision on candidate selection (hospitals such as ACH and HCB). The selection process is supported by the hospital human resources department. The position is usually advertised on the hospital website and also through social media or specialised international web spaces (e.g. B-value, HTA group in LinkedIn). Some HB-HTA units, because of national rules, have a very formalised and strict advertisement and selection process (for example OUH). The information about the position is clearly written and posted widely in several dissemination media (e.g. hospital website, newspaper). The final decision on candidate selection is taken jointly by the head of the HB-HTA unit and a team of hospital professionals.

CAREER DEVELOPMENT PLANS

Successful HTA programmes require appropriate education and training strategies, which should be targeted at expertise and staff qualifications. Some HTA organisations in Europe invest a lot in training and education in order to overcome the lack of trained staff in the organisation (Moharra et al. 2009). The same applies to HB-HTA units, which should ensure the development of workers' skills and abilities through a proper career development plan. It should be mentioned that, in some cases, education goes beyond the unit's staff as it seeks to ensure programme awareness and training of advisory team members (Poulin et al. 2012). The availability of properly skilled staff and the existence of mechanisms to update their knowledge and skills ensures the production of high quality assessments and increases the confidence of hospital decision-makers in the results received.

Current Practices

Current practices: career development plans

HB-HTA units in Europe have mainly informal career development plans. Most heads of units identify potentially interesting training activities on an ad-hoc basis and offer them to staff, or are responsive to proposals from staff, but no formal career development plans are available. At one of the European HB-HTA units (OUH), there is a formal and explicit process for career development. The head of the unit arranges annual meetings with staff to recognise and understand their expectations as regards professional development and their interest in training activities (including attendance of meetings). Members of staff's interests and background are evaluated along with the availability of

Guiding Principle 13

SUFFICIENT RESOURCES

Financial resources are sufficient to cover operational costs and ensure an appropriate place of work.

The availability of stable funding to support the operation of the HB-HTA unit is crucial (Poulin et al. 2012, Goodman 2012, Battista et al. 2003). The availability of specific resources devoted to HB-HTA is seen as a factor in the successful development of this activity (Gagnon et al. 2011) and is considered to play a fundamental role in increasing the probability of success of the HTA unit at the hospital. Limited availability of financial resources is seen as a major barrier to the successful implementation of any HTA programmes (Attieh & Gagnon 2012). Insufficiently funded HB-HTA units may run the risk of poorer performance because of having to devote time to looking for external funds instead of spending it on internal affairs. Hospital managers, especially those in a more senior position in the hospital, need to be aware of the basic needs of an HB-HTA unit, which are not usually as great as other clinical departments in the hospital, and be sensitive to them. Clinicians asking for support from the HB-HTA unit should also know about the need to have proper funds to carry out the work. Therefore, HB-HTA units should convey this message when presenting (at any opportunity) either the unit or the results from an assessment inside the hospital. The HB-HTA unit should have an allotted budget ideally coming from the hospital, aimed at maintaining a core structure and covering its operational costs. Once basic support from the hospital is granted, HB-HTA units should subsequently devise a strategy for seeking additional funds for the proper running of the unit when the economic support of the hospital is not enough, or when an increased workload is foreseen. Additionally, HB-HTA units should take advantage of different research grant opportunities, which can considerably augment their often scarce financial resources. Finally, looking for funds to support the development of additional evidence to support decision-making is perceived as good practice (Poulin et al. 2012).

Current Practices

Current practices: sufficient resources

Most European HB-HTA units do not have a specific budget assigned by the hospital, which mainly provides the working space and covers the salary of the head of the unit (hospitals such as OUH, HCB, ACH and ANHTA); although some hospitals do also pay for hiring staff such as clinicians, health economists and public health specialists (hospitals such as CHUV and GUH). In some instances, if additional funds are needed, a request is made to the medical directorate and these are often successfully obtained (hospitals such as CHUV and ACH). Most HB-HTA units look for complementary sources of funding. Some units work with hospital clinical departments on those projects that have economic resources assigned (hospitals such as HCB and OUH); others also look for funds through public research calls and, in rare cases, some carry out consultancy work. Some HB-HTA units participate in research projects funded by national or regional authorities (for example GUH). Learning from experience, it is recommended that the HB-HTA unit employs at least professionals such as a clinician and economist paid directly from the hospital's budget since these two profiles are complementary.

Dimension 4:
IMPACT

Excellent HB-HTA units achieve their main aim, which is to be useful to hospital decision-makers. They also show their value for their customers and the hospital in identifying key performance indicators of what the HB-HTA unit is achieving (short-, medium- and long-term indicators) in relation to its mission and activities. Results, experiences and perceptions from the perspective of the staff, customers and community at large should be measured and appropriate feedback provided.

Guiding Principle 14

MEASURING SHORT- AND MEDIUM-TERM IMPACT

Short- and medium-term impact is measured and maintained.

IMPACT MEASUREMENT

An HB-HTA unit should prove that its work is valuable for the hospital, (i.e. it should be accountable to the hospital) (Battista et al. 2003). Impact measurement of any HTA activity has been identified as good practice (Granados et al. 1997, Moharra et al. 2009, Lafortune et al. 2008, Bennie et al. 2011), nevertheless monitoring activities are rare among HTA organisations (Neuman et al. 2010). Impact measurement at hospital level can be carried out in several ways. One short-term indicator is the use of the assessment report by those who have to make a decision. By definition, there should be a clear link between HTA and decision-making (Health technology assessment 2009), be it at policy or healthcare level. In other words, HTA results have to be used in the decision-making process and must be relevant to decisions; recommendations have to be followed. Assessment reports from the HB-HTA unit have a clear and targeted customer and, therefore, assessment results are always valued and taken into account in decision-making by those who request the assessment inside the hospital; this may be different from the recommendations provided by national or regional HTA bodies, where results are usually perceived by clinicians as being far removed from their reality (McGregor 2006).

Another important indicator consists in checking if recommendations made by the HB-HTA are followed by the final decision-maker, who is not always the clinician who is asking for the technology. It is worth mentioning that not all the HB-HTA units make a final recommendation; some produce an assessment report with evidence, and the final recommendation and decision (i.e. appraisal) is made by either the CMO or heads of clinical departments (CHUV, OUH). On the other hand, other HB-HTA units state a clear recommendation in their reports (HCB). In this case, the recommendation is communicated to the head of the department or to the CMO or CEO who takes the final decision. Nevertheless, it should be remembered that final decision-making could be influenced by other subjective but relevant factors for the hospital (e.g. strategic alliance with industry) and, therefore, even if rarely, the final decision may differ from the recommendation stated in the HB-HTA report. Finally, another factor affecting the final decision, that may differ from the recommendation of the HB-HTA report is the lack of budget for the investment.

Current practices: impact measurement

Functioning HB-HTA units perform a check on the use of the HB-HTA report in decision-making and on the correspondence between the decision made and the report recommendations. For some technologies assessed, certain indicators are defined and monitored through records (for example GUH).

Recommendations provided by HB-HTA units are adopted by hospital decision-makers to a very high degree, the correspondence between recommendation and decision is very high (99% and 100% concordance in hospitals such as GUH and ANHTA, and CHUV respectively).

FOLLOW-UP PROCESS

Implementation of the decision made based on the HB-HTA should also be monitored. After a positive recommendation is given and the decision is taken, the level of follow-up and monitoring can vary and depends on the resources available. Usually, HB-HTA units are small and have no resources to closely follow-up the implementation of their recommendations after a positive decision. Follow-up is necessary as health technologies are developing rapidly and indications can evolve over time. Nevertheless, in practice follow-up is usually carried out on an informal basis through contact with clinicians in charge of the new technology adopted.

Current practices: follow-up process

Some HB-HTA units perform a follow-up of their recommendations through an annual audit on the results of the implementation of specific assessments (hospitals such as ANHTA and ACH). An example of follow-up performed in one of the European hospitals (ANHTA) consisted in the implementation of a new strategy for efficient laboratory use by reorganisation of test ordering in the Hospital Information System. Monthly follow-up of the implementation throughout a one year was set up to collect important data for an economic evaluation. A 10% decrease in unnecessary laboratory tests was one of the outcomes. Another benefit of the follow-up process was an increase in awareness of the HB-HTA unit among clinicians, which led to a greater number of new requests for the assessment of health technologies.

FINANCIAL OUTCOMES

HB-HTA should also demonstrate that it generates economic value for the hospital. Therefore, financial outcomes should also be measured. Some hospitals measure the global impact of the recommendations coming from HB-HTA in financial terms for the hospital. Another financial indicator consists in demonstrating the amount of money obtained from external financial sources (e.g. from specific contracted projects, from public grants) and how this contributes to the sustainability of the HB-HTA unit. Performance indicators, such as productivity, can also be used. Productivity measures the ratio of output to resources used and therefore it gauges how efficient a particular organisation is (Lafortune et al. 2008). Productivity can be measured by volume or quantity of activities performed according to a pre-defined set of activities (e.g. reports, number of dissemination activities, training activities etc.). Nevertheless, it is worth taking into account the fact that productivity should be linked to quality and usefulness of products, which can be measured by customer satisfaction.

Current practices: financial outcomes

One of the HB-HTA units (HCB) systematically updates the net present value for the hospital of health technologies which have been recommended and those that were rejected. This is internally compared with the cost of running the HB-HTA unit, which yields an indirect estimation of the efficiency of the unit.

Productivity measurement (e.g. number of health technologies assessed by the HB-HTA unit, length of the preparation period of an HB-HTA report) is not an activity systematically performed currently by any HB-HTA units.

CUSTOMER SATISFACTION

Customer satisfaction is a key indicator of the impact of an HB-HTA unit's performance; however, it is not usually formally measured by most HB-HTA units. Normally, the level of satisfaction is informally perceived by the head of the HB-HTA unit through periodic interactions with clinicians and collecting their views on the overall experience on co-operation with the unit. In general, for all the HB-HTA units participating in AdHopHTA, the satisfaction level is very high; the work done by the unit is perceived as very good.

Current practices: customer satisfaction

Formal measurement of customer satisfaction performed in an HB-HTA unit involves a satisfaction survey of all hospital professionals who collaborated in the assessments carried out at the unit. The satisfaction survey is anonymised and topics asked about include satisfaction with the assessment process as a whole, fulfilment of expectations, the usefulness of the report and recommendations, and willingness both to use the service provided again and recommend it to a colleague (for example HCB).

HUMAN RESOURCES SATISFACTION

Good quality of assessments is achieved by having qualified staff, and several HB-HTA units devote time to proper staff recruitment and continuous career development (see guiding principle 12). It is key for running HB-HTA to measure staff's perceptions of their job and satisfaction as regards career development opportunities. The capacity to attract and maintain human resources is seen as good practice in any HTA organisation (Lafortune et al. 2008). The HB-HTA unit should be attractive to talented professionals and able to ensure their satisfaction and continuity in the organisation.

Current practices: human resources satisfaction

Some HB-HTA units periodically carry out formal written assessments of job satisfaction (for example OUH annually, CHUV periodically). The others explore it in informal ways or through indirect indicators, such as retention (for example ACH). Retention is an indicator of job satisfaction among volunteer clinical collaborators shown by their willingness or reluctance to continue collaborating with the HB-HTA unit and reviewing reports (hospitals such as HCB and OUH).

TIMELY DELIVERY

Timely delivery of assessment results is another key principle for any HB-HTA unit since it is also a factor influencing customer satisfaction. Timely responses are crucial to generating impact and ensuring the usefulness of HTA outputs (Lafortune et al. 2008, Attieh & Gagnon 2012, Andradas et al. 2008). Promptness in processes allows the information to be available when decisions have to be made. Timely delivery of HB-HTA reports is especially relevant for hospitals, where decisions in real-life situations have to be taken more quickly than at national or regional level (McGregor & Brophy 2005). Therefore, a timely answer is considered a success factor at hospital level (Gagnon et al. 2011, Juzwishin et al. 1996, Luce & Brown 1995, Gallego et al. 2009).

Current Practices

Current practices: timely delivery

All the studied HB-HTA units deliver answers from HB-HTA reports on time, and since end-users of the technology (i.e. clinicians) are involved during the whole assessment process or are closely informed about it, they have constantly updated information on the assessment results.

EXTERNAL IMPACT

Finally, impact of the HB-HTA unit's work outside the hospital should also be measured. This measurement includes the perception of the value of its work, the external outreach in terms of scientific and professional activities as well as mentoring and training external partners (the former is also addressed in guiding principle 11). Indirect indicators can be used to explore the value given by external professionals, such as the frequency and number of requests for talks on HB-HTA in general and about the experience of the unit specifically, as well as requests for training activities or collaboration in other activities related to health technology.

Current Practices

Current practices: external impact

Most HB-HTA units are perceived as valuable vis-à-vis the aforementioned indirect indicators, even if they were recently founded (for example ANHTA). HB-HTA units have multiple requests from other hospitals and scientific societies in their country to talk about their experience and produce training activities (hospitals such as ANHTA, GUH, OUH, HCB and CHUV). Certain units have developed educational courses on HB-HTA that are included in several formal educational activities (e.g. MBA, International Master in HTA-Ulysses, etc.) (hospitals such as GUH, OUH and CHUV). One of the units (HCB) has also been requested by an association of hospitals in the region (the Catalan Hospital Union) and individual hospitals as well as healthcare managers' associations to show the value of HB-HTA and its own experience. Scientific outreach, and training activities, can also be measured by papers in scientific journals and presentations at national and international scientific meetings. Most HB-HTA units have a long track record of this. Professional outreach could also be shown by collaboration of the leaders and the staff of HB-HTA units in activities related with the development and management of health technologies requested by private or public health organisations. (e.g. development of procurement methodology, mentorship in programmes for innovation production, talks to private companies, etc.).

Guiding Principle 15

MEASURING LONG-TERM IMPACT

Long-term impact is measured and maintained.

Monitoring the HB-HTA unit's contribution to overall hospital performance in terms of achievements of expected outcomes to patients is also advantageous. HB-HTA might also be expected to increase the ability of hospitals to use their resources efficiently (Attieh & Gagnon 2012). This long-term measurement is difficult to perform since it requires devoting considerable resources, which are usually scarce in HB-HTA units. Furthermore, proving a direct cause-effect relationship between an HB-HTA unit's performance and hospital impact is very challenging in a hospital environment. There could be a lot of confounding variables that can distort impact results. This also happens at national or regional HTA level where no study has examined the impact on final outcomes understood as the benefits and costs for the healthcare system of the additional information provided by HTA (Lafortune et al. 2008). In an excellent HB-HTA unit, it is recommended that at least the hospital impact of specific assessed HTs is measured.

Finally, another challenging measurement is the impact of the work of the HB-HTA unit on communities. Since hospitals function in a community and in a wider healthcare system, any decision made at the hospital level will affect the immediate community and, in the long term, the healthcare system. This type of impact measurement can include indicators on how the work performed by HB-HTA contributes to the quality of life of a population, environment protection, preservation of global resources, and efficient use of limited resources in the healthcare system. HB-HTA activity can also have a range of impacts on quality of care, on the way information systems are developed and used, on the way health systems are managed, and how resources are allocated and used. Although chosen as a guiding principle for good practice, this type of measurement is extremely difficult and is not currently performed by any HB-HTA unit.

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4

FURTHER DEVELOPMENT OF HB-HTA IN THE FUTURE: RECOMMENDATIONS FOR THE EUROPEAN UNION

4

FURTHER DEVELOPMENT OF HB-HTA IN THE FUTURE: RECOMMENDATIONS FOR THE EUROPEAN UNION

4.1   INTRODUCTION

This chapter aims to give an overview of the history and current state of EU health policies, institutions and initiatives relevant for HTA activities in order to reach a better understanding of the need to incorporate HB-HTA into EU policy. It also proposes recommendations on how HB-HTA could be encouraged and how a European HB-HTA Network could be established, fostering HTA activities at the hospital level and contributing to the creation of a comprehensive EU HTA ecosystem.

4.2   EU POLICY AGENDA FOR HTA

Economic development has been the foremost aim behind the creation of the European Community and then the European Union, and health affairs did not move up the European agenda until the end of the 1980s, in reaction to the HIV/AIDS epidemic, the contaminated blood scandal and the cancer of one of Europe's most prominent leaders (Rosenmöller 2005). Since then, consecutive European health programmes have addressed health issues in Europe, starting with the framework of action in public health in 1993 (European Commission 1993), bringing together a series of parallel actions previously implemented separately and establishing a recognised position for public health activities at the European level. The subsequent Public Health Programmes 2003 – 2007 (European Commission 2002), followed by 2008 – 2013, and 2014 – 2020 programmes, have been supported by the European Commission as the main instrument with which to implement the EU health strategy (European Commission 2005, European Commission 2011).
The current EU Health Programme came into force on 21 March 2014 with the main objectives of addressing health promotion and systems issues, but also including a set of health technology (HT) topics which are:

- to promote health, prevent diseases and foster supportive environments for healthy lifestyles taking into account the health in all policies' principle;

- to protect Union citizens from serious cross-border health threats;

- to contribute to innovative, efficient and sustainable health systems; and

- to facilitate access to better and safer healthcare for Union citizens.

Here, HTA has been addressed with specific objectives:

- to use HTA to contribute to innovative and sustainable health systems; and

- to support the European Voluntary Network on HTA (on the basis of criteria set out under Directive 2011/24/EU) (Council of the European Union 2011).

Despite the specific references to HTA and explicit mentioning in the EU health strategy, the role of HTA at the hospital level is not referred to.

HTA is also an emerging topic on the EU research agenda, and with growing significance. In 2011, the EU 7th Research Framework Programme (FP7), which included a call point on new methodologies for HTA, put HTA on the research agenda for the first time; as a result, 4 projects were co-founded[1]. Horizon 2020, the new Research and Innovation Programme, as part of the Innovation Union, recognises the importance of HTA, including HTA aspects in a series of the Health, Demographic Change and Wellbeing calls. However it does not address the crucial need for more evidence on how HTA can support the further development of value-based efficient healthcare at the system and institutional level.

4.2.1 THE CREATION OF A NETWORK FOR HTA IN EUROPE

Following the Sachs report on Macroeconomics and Health (Sachs 2001), European policy makers realised the crucial interaction between health, health systems and the economy. A study looked into the essential impact that health and health systems have on the economy, stressing the importance of economic evaluation for decision-making and the role of health technology assessment (Suhrcke 2003). Since then, HTA (and its use) has been fostered at EU level by support for networking and collaboration between EU agencies, as well as other actions.

One of the first actions supported by the European Commission was the EUR-ASSESS project (1994-97), which, for the first time, brought together the existing European HTA organisations to cooperate in the establishment of a common and consistent understanding of HTA, and also to identify the need for information sharing among European countries (Banta et al. 1997, Banta et al. 2000). Following the recommendations of EUR-ASSESS and HTA Europe, the European Collaboration for HTA/Assessment of Health Interventions Project (ECHTA/ECAHI) was launched for the period 2000-02, with the main objective of developing a means of collaboration for HTA activities in Europe (Jonsson 2002). One of the main conclusions of the project was the need to establish a permanent coordinating body to facilitate European collaboration on HTA.

In 2004, the European Commission, along with the Ministers of Health from EU Member States, decided to establish a sustainable network for HTA and proposed several steps starting with a three-year project supported by the EU Public Health Programme: the European network for Health Technology Assessment project (EUnetHTA), which then led to the EUnetHTA Network[2]. The project was established in 2006 to create an effective and sustainable network for HTA across Europe, at national and regional level, that could develop and implement practical tools or provide reliable, timely, transparent and transferable information to contribute to HTA in EU Member States. The strategic objectives of the EUnetHTA project were:

- to reduce duplication of effort in order to promote more effective use of resources;

- to increase HTA input to decision-making in member states and the EU in order to increase the impact of HTA;

- to strengthen the link between HTA and healthcare policy making in the EU and its Member States; and

- to support countries with limited experience of HTA.

In July 2008, the European Commission issued a communication on a proposal for a directive on the application of patient rights in cross-border healthcare (European Commission 2008), in which the part on HTA was based on the framework proposed by EUnetHTA. HTA advanced considerably on the European policy agenda, particularly when the Patient Rights Directive 2011/24/EU came into force on 24 March 2011 (Council of the European Union 2011). The Directive established a number of areas for EU-wide co-operation in healthcare. In particular, Article 15 addresses HTA and invites the European Union to support and facilitate HTA cooperation and the exchange of information among member states working within a voluntary network connecting national authorities responsible for HTA: the HTA Network.

The HTA Network was officially presented at the EUnetHTA conference that took place in Rome on 30-31 October 2014 (EUnetHTA 2014). The HTA Network aims to support cooperation between national authorities or bodies responsible for HTA, gathering together all Member States, Norway and Iceland. A wider group of stakeholder representatives is associated with the Network as observers. The Network is responsible for the strategic governance and the long-term planning of HTA cooperation in the EU (EUnetHTA 2014), while EUnetHTA, by its Joint Actions[3] (JA1 and JA2), provides technical and scientific support to the Network by producing and testing common tools for HTA.

The HTA Network aims to provide a framework for HTA assessment in an efficient, structured and systematic way. It focuses on sharing resources and tools for evidence-based decision-making on cost-effectiveness, tackling health inequalities and increasing access to new medicines and treatments.

4.3 AN HB-HTA STRATEGY FOR THE EU

The prominent position of HTA on the EU health agenda is firmly established as a result of the long history of support from Member States and the EU. However, until now, European coordination efforts in HTA have basically involved national and regional organisations without specific consideration of the hospital level. In fact, before the AdHopHTA project, no coordination of or formal contacts between hospital-based HTA initiatives existed. Nevertheless, there were some informal contacts mainly initiated under the Hospital Based HTA Interest Sub-Group created within the HTAi as well as a workshop dedicated to hospital decision-makers organised by the ECHTA/ECAHI project (European Collaboration for Assessment of Health Interventions, 1999-2001)[4].

HB-HTA initiatives provide early identification of emerging health technology issues and answer hospitals' need for timely information to support decision-making. They further play a role in adapting existing HTAs, completing them as necessary with local data and context considerations. Thus, being a bridge for effective transfer of HTA results from the international, national or regional level to the hospital. A better collaboration with and involvement of HB-HTA units within the European HTA scientific and professional network would result in a more comprehensive approach across the different health system levels reducing duplication of effort and facilitating cooperation and information sharing.

To ensure that HB-HTA is represented as a specific branch of the HTA community, and to allow for better collaboration between HB-HTA units, we would recommend the creation of a European Network of HB-HTA to foster HTA at hospital level. The network would aim to be complementary to other HTA networks and resources already active in the EU and would work closely with them on issues of common interest.

The following section describes how this network could be envisaged.

4.3.1 ESTABLISHING A EUROPEAN HB-HTA NETWORK

The European HB-HTA Network would be made up of European hospitals already having an HB-HTA unit or interested in creating one. Additional members could be representatives of relevant national or regional institutions, not-for-profit organisations and other stakeholders with an interest in and the desire to contribute to HB-HTA in Europe.

A) MISSION

The European HB-HTA Network would be established to foster HB-HTA in European hospitals and elsewhere, increasing the visibility of HB-HTA with the subsequent impact on the EU health agenda. It would act as a platform for exchanging experience and expertise on HTA at hospital level in Europe, fostering co-operation and facilitating liaison between organisations and individuals active in HB-HTA across Europe and internationally, as well as with other existing HTA networks.

B) VISION

The European HB-HTA Network could be a reference point for hospitals desiring to develop an HB-HTA unit to facilitate decisions on adopting innovative and valuable technologies in a strategic way, to the benefit of patients and healthcare systems in Europe.

C) AIM AND OBJECTIVES

The aim of the Network would be to contribute to the creation of a real European HTA ecosystem supporting innovative hospitals and HB-HTA initiatives in Europe as well as promoting collaboration with worldwide HB-HTA initiatives.

This mission would be achieved through the following strategic objectives:
- to provide an arena for HB-HTA experts and other interested health professionals, healthcare providers, patients and industry and other networks in the field of HB-HTA to share professional expertise, exchange knowledge and shape the European hospital-based health technology assessment agenda;

- to share existing HB-HTA experiences and reports with the aim of promoting HB-HTA excellence in all settings with a view to improving both the creation of HB-HTA units and process and product assessment and their appropriate use (knowledge brokering);
- to create a framework within which cooperative research, development, implementation and evaluation of scientific and methodological tools for HB-HTA can be undertaken;
- to cooperate with national and regional HTA agencies and institutes to complement knowledge and activities;
- to link with the HTA Network and similar worldwide HB-HTA networks and initiatives for knowledge sharing and mutual advancement and improvement in the field; and
- to raise awareness of HB-HTA in Europe, its visibility in terms of potential contribution to high quality health systems and its place in the European health and technology agendas and also to foster the spread and implementation of HB-HTA initiatives throughout Europe and beyond (globally).

Table 1 below gives an example of a possible Business Canvas for the European HB-HTA Network which aims to enable sustainable European collaboration on HB-HTA.

D) VALUES

Transparency
- The Network will ensure transparency in the process and methods used in the different activities carried out.

Excellence
- Members of the Network will work together to discuss, develop, research and implement the highest standards and practices in HB-HTA.
- The Network will strive for excellence in all aspects of its work because of the importance of its mission and its leading position in the field of HB-HTA.
- The Network will take responsibility for quality. Each member of the Network will deliver excellence, strive for continuous improvement and respond vigorously to change.

Integrity/independence from stakeholders and other health sector actors
- The Network will consistently perform at the highest level of ethical and professional behaviour.
- The Network will be accountable for its actions and will act with honesty and fairness in its job.
- The Network will maintain integrity by welcoming evaluation, implementing change when necessary and consistently improving to remain a trusted resource.

Responsiveness (to the needs of society/the community)
- Members of the Network will work together to foster positive relationships with other colleagues and related institutions in the EU and worldwide.
- The Network will communicate openly and honestly with other peer organisations and interested individuals.

Innovation
- The Network will consistently challenge itself to be innovative in its work and members will be passionate about learning and integrating new information.
- The Network will always strive to improve and innovate.

KEY PARTNERS

- **National and regional HTA agencies**
- **Health ministries**
- **Academic institutions**
- **Patients' associations**
- **HTA associations and networks**
- **Industry**

KEY ACTIVITIES

- **Handbook and toolkit**
- **Platform for networking**
- **Newsletter**
- **Annual conferences**
- **Database**
- **Working groups**
- **Advocacy/lobbying**
- **Research**

KEY RESOURCES

- **Expertise/Body of Knowledge/Hands on Experience**
- **Enthusiastic partners, existing network**
- **HB-HTA units**
- **Motivated, well established team**

VALUE PROPOSITIONS

- **Support & network**
- **Good practices**
- **Visibility**
- **Efficiency**
- **Sustainability**
- **Accessibility**

COST STRUCTURE

- **Administrative costs (registration, staff, etc.)**
- **Events**
- **Database maintenance**
- **Website**
- **Training**

TABLE 1
EXAMPLE OF A POSSIBLE
BUSINESS CANVAS FOR THE
EUROPEAN HB-HTA NETWORK

CUSTOMER RELATIONSHIPS

- Trust/transparency about Network activities
- Rapid response in providing advice or guidelines

CHANNELS

- Events
- Meetings and working groups
- Publications
- Database
- Newsletter
- Policy papers

CUSTOMER SEGMENTS

- HTA and HB-HTA professionals
- Healthcare providers (professionals and hospitals)
- Industry
- Healthcare payers
- Patients and healthcare consumer organisations
- Citizens
- Policy makers (EU or national)

REVENUE STREAMS

- Membership fee
- Fundraising
- Partner support
- Generation of revenues through products, services (access to database, consultancy services, accreditation), etc. to externals/non- members
- Government subsidies
- Grants (Horizon 2020, etc.)

4.4 OTHER RECOMMENDATIONS

The ultimate goal of HB-HTA is to increase the quality of healthcare in populations by contributing to a sound decision-making process around the adoption of health technologies at hospital level.

The strategy presented in the previous sections is of paramount importance in achieving this goal. However, releasing the potential of HB-HTA in full requires a wider set of accompanying actions of a varied nature. When properly orchestrated in the context of the detailed strategy presented in this section, these accompanying actions can have a profound effect on successful adoption while ensuring long-term sustainability.

A non-exhaustive list of accompanying measures is briefly presented below.

4.4.1 EUROPEAN LEVEL

HB-HTA should be adopted as a persistent theme in the EU agenda given its centrality to a number of activities related to the health domain that are supported by the European Commission:

- First and foremost, HB-HTA should be incorporated with its own unique identity into the wider family of European HTA initiatives. HB-HTA units are situated in a privileged position to cover the last mile of HTA reports, becoming the natural aid to making wise investment decisions in healthcare technologies at the point of care.

- This singularity of the focus of HB-HTA could be further acknowledged within the wider family of HTA initiatives by obtaining the support of the EU in creating an HB-HTA network. The current AdHopHTA consortium could be the seminal group for such an initiative.

- Regional authorities and related existing regional associations such as EUREGHA would be in an advantaged position to disseminate and further push these EU promoted networks among their members establishing liaisons between interested institutions and widening the impact of these networking activities.

- Last but not least, HB-HTA should be present in the calls in the production of the H2020 Work Programmes. Indeed, because of its closeness to the point of care, HB-HTA is a much needed component in the undertaking of research work dealing with the adoption of services and technologies in the health domain. Furthermore, HB-HTA can support the processes of development and transference or licensing of innovations generated at hospital level, an area on the rise in many institutions, as already happens in some countries (e.g. MaRS EXCITE programme[5] Ontario, Canada).

Several areas of need for research have been identified in the AdHopHTA project. These include:

Developing HTA models and tools to support technology transfer activities in healthcare centres

Healthcare centres are the cradle for innovations. Ensuring that ideas are promptly captured, managed and assessed is a key for a successful outreach of innovations into society. There is a trend in developing both Tech Transfer (TT) units and HB-HTA units in EU hospitals, with the same aim (i.e. promote the access to society of "right" innovation). Consequently, a research action on the synergic collaboration of technology transfer & business development units and HB-HTA units is needed. This research should aim at investigating on HTA models and tools that could help TT units in their work. Moreover it should generate knowledge regarding models of work of both units and mechanisms for proper interaction to learn from each other and delineate good practices. Finally, it should also provide with information on how this pragmatic and collaborative very early HTA is perceived and implemented in real life by its target users (producers of innovation - researchers on breakthrough innovations in hospitals and industry).The results of this research should result in a set of tools and processes that help to identify, assess and promote sustainable innovative ideas/products generated at hospital level to be transferred into society.

Evidence-based procurement in healthcare centres

HB-HTA is an informative tool for hospitals when deciding to invest or not in innovative technologies. Nevertheless, how this information is translated into the procurement process in healthcare centres is not known. The new EU Directive on procurement (European Union 2014) calls for using new type information ahead of cost, which usually is included in HB-HTA reports, but currently scarcely used. Research is needed to: identify the current and expected role of evidence, and other type of information, in the procurement process and how HTA can help; perform a benchmarking of current HTA/procurement EU models; define the proper methods to use different types of evidence; produce tools for a pragmatic implementation of the EU directive requirements; and investigate the role of stakeholders in the process (e.g. hospital procurement staff, bioengineers, clinicians, industry, patients). The results of this research should provide with pragmatic solutions and tools to implement the new Directive in healthcare centres.

Fostering high value innovation through HTA

Results from HB-HTA reports can include positive recommendations for innovative and high value health technologies (HTs). Most of the times these HTs represent a breakthrough that poses challenges to health systems, and specially to hospitals, to adopt mainly because they require adaptation, modification or complete change on existing healthcare practices. HTA can be a convenor of all parties on how healthcare systems need to develop to get value from innovation. The research focus here should be set on methods and mechanisms to promote the adoption of innovative breakthrough HTs through the use of HTA, including the identification and analysis of available accelerating mechanisms or programs in EU, as well as to search about the role of stakeholders in different steps of the process and to propose successful models.

Promoting innovation in healthcare centres through disinvestment of outmoded health technologies

Current constrains in economic resources of hospitals make it imperative to disinvest in some health technologies thus making room for innovative solutions. The proposed research area should bring new light on different aspects related to the application of disinvestment in hospital setting. In particular, research activities could be aimed at: (i) investigating how European hospitals face the problem of disinvestment; (ii) understanding the methods and the tools applied in disinvestment; (iii) identifying the role of stakeholders in this process; (iv) providing clarification on the role that HTA could play. The results of this research should provide with a menu of methodological and practice options to implement disinvestment in EU healthcare centres.

Improving mechanisms for real world data collection and analysis required for HTA

Both regulatory and national/regional HTA organisations require real world data (RWD) for their assessments on health technologies that want to access market. Nevertheless, how to get these data is not clear. Moreover, healthcare centres, potential providers of data, are not properly prepared for this task. The proposed line of research should look at what the information needs from regulators and HTA are, examine the limitations and potentialities of current information systems (clinical and economic) in healthcare centres in EU, and find solutions to overcome the limitations for RWD gathering.

Patient and industry involvement in hospital-based HTA

In most EU countries, hospitals take their own decisions on the purchase of HTs, especially equipment and medical devices. Although patients and citizens are the current and future end-users of HTs in hospitals, they are scarcely involved in the assessments process. The same applies to the industry, which as manufacturers of HTs are deeply knowledgeable about the characteristics of their products, however they are not involved systematically in the assessment process. How patients and citizens are to be involved in decisions concerning investment in HTs at hospital level, specifically how they can contribute to HB-HTA, is another area that needs to be studied, as is the question of how manufacturers of HTs are to be involved in the assessment process given their knowledge and experience of the use of HTs in other hospitals locally, nationally, and internationally. Decision-making at hospitals is surrounded by important ethical, organisational and financial challenges and hospital decision-makers are in need of clear directions and solutions. This is an under researched area that needs attention.

4.4.2 MEMBER STATES

Many EU regulations and directives require adoption by Member States. This can translate into the development of the appropriate legal framework (or modification of a previous one) and/or the definition of strategic policies that further develop this framework. Member States can also develop their own regulations to address some specific needs. Some possible initiatives that could facilitate wider adoption of HB-HTA are as follows:

- Support for the creation of HB-HTA units by developing regulations and policy documents highlighting their value in the process of valorisation and transfer of innovative technologies to hospitals. Hospitals are the main cradle for innovative

health technologies, especially medical devices and clinical procedures. HB-HTA can help a hospital's technology transfer or innovation unit in identifying potentially valuable innovative technologies, contribute to their valorisation and transfer process, and play a part in demonstrating their value throughout their life cycle.

- Support for HB-HTA from national and regional HTA agencies. Agencies could act as facilitators and as an umbrella for creating "HB-HTA communities of knowledge and good practices" in their territory.

- The development of specific budget lines to fund research work undertaken by HB-HTA units in order to gain a better understanding of what HB-HTA can achieve in each country.

- Regulatory early scientific advice for industry developers could be performed jointly by national or regional HTA and HB-HTA representative reflecting viewpoint of the latter.

4.4.3 STAKEHOLDERS

Most European states are carrying out reviews of their health policies in order to better address the Triple Aim goals (Berwick et al. 2008): better health of the population, an excellent patient experience and reduced per capita costs of healthcare. To be successful, such policies have to impact different stakeholders and agencies all along the healthcare chain. HB-HTA can be a very welcome ally in this process, but this requires raising awareness of its role across the whole range of actors and disciplines.

Therefore, and adopting a wider perspective, awareness activities should be sensibly promoted to reach all groups:

- Decisions on innovations and investment taken in hospitals have an impact on the recipients of the services provided, i.e. the patients. There is an urgent need to strengthen their involvement in HTA because traditionally it has been very minor. The HTAi subgroup of patient and citizen involvement[6] has created a template which is intended to act as a guide for HTA organisations. Implementing similar initiatives at hospital level would enhance the communication exchange between patients and the HB-HTA unit. This is also in line with the rising concept of "patient-centred medicine" (Bardes 2012).

- Equally, the activity of managers and health professionals, and also professional development, is influenced by the type of decision adopted at the hospital. But they themselves can and must be active parts in HB-HTA processes, while at the same time reaping its benefits. So, involving them in activities to identify how they can better participate in the process of assessment of technologies at hospital level is a crucial step. As a pre-requisite, HB-HTA has to be understood by these groups and specific training activities have to be addressed to them.

- Making these and other stakeholder groups — such as the medical device industry or the pharmaceutical industry— more knowledgeable about the role of HB-HTA units would result in greater motivation for them to have an active contribution in the HB-HTA activities at a European, national, regional or institutional level.

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APPENDIX 1:
AdHopHTA MINI-HTA TEMPLATE

This section introduces a management and decision support tool named "AdHopHTA mini-HTA template" to be used as structured assistance to perform the assessments of health technologies in hospital contexts. The tool constitutes an evolution of the mini-HTA developed by DACEHTA and integrates the AdHopHTA partners' experience and research, specifically:

- the results of studies on the informational needs of hospital decision-makers;

- the checklist for quality assessment of HB-HTA reports;

- a review of other European mini-HTA/HB-HTA templates.

The template consists of 28 questions concerning the prerequisites for and consequences of using (new) health technology at hospital level. The answers to the questions provide a brief, written basis for decisions. The purpose is to provide (part of) the basis for decision-making on a proposal to introduce a specific new health technology or in connection with changes in the indications for the use of existing technology. It is intended to be a flexible tool adaptable to local conditions and the current requirements of hospital decision-makers.

It is advisable to upload completed assessments using the templates to the AdHopHTA database in order to avoid duplication of work (The database can be accessed through the AdHopHTA website: www.adhophta.eu/database).

AdHopHTA MINI-HTA TEMPLATE

QUESTION 1: SUMMARY

1- Summary of effects

Please provide a short summary (in bullet points, maximum 1 page) describing why the assessment of the technology is being undertaken (rationale) and the effects and safety of the technology/proposal (main results). Compare these to similar effects of comparator(s).

Please include also the recommendations of the assessment, if any.

QUESTIONS 2-7: *BASIC INFORMATION*

2- Who is the proposer of the technology?

Please specify who proposed the acquisition / implementation of the specific technology (e.g. industry, company, hospital, departments, individual).

3- Who are the authors of the HB-HTA report?

Please specify the names of the authors of the HB-HTA report including appropriate contact details for provision of further information (hospital, department, e-mail address, phone number, date).

4- Are other parties/stakeholders involved in the proposal?

Often it is beneficial to discuss a proposal with e.g. a local drug or device committee, other affected hospital departments or relevant cooperation forum. Please state with whom the proposal has been discussed, if with anyone, and the conclusion reached.

5- Are there any possible conflicts of interest?

Please state any possible conflicts of interest for both authors of the HB-HTA and other parties/stakeholders involved in the proposal.

6- Has the HB-HTA report been reviewed (internally or externally)?

Please state whether the HB-HTA report has been reviewed or not. If it has, was the review internal or external? An internal review may be carried out by e.g. HTA experts or healthcare professionals inside the hospital. An external review may be carried out by partners outside the hospital, e.g. healthcare professionals from another hospital or region or by industry representatives.

7- Define the goal and scope of the HB-HTA report (TICO)

Please define the goal and scope of the HB-HTA report in short using the TICO abbreviation (technology, indication, comparison and outcome).

ELEMENT	QUESTIONS	INSTRUCTIONS
T TECHNOLOGY	**Technology:** What technology will be assessed?	Please state the name of the technology and describe the type, classification, dosage, frequency, timing, duration and setting of the technology. If relevant, please specify whether the technology is compatible with the current IT-system of the hospital.
I INDICATION	**Target disease:** What condition/ disease is targeted? **Target population:** What population/ group of patients does it concern? Who should receive the treatment/service? **Intended use:** What is the purpose of use of the technology?	Please describe the disease or condition which is targeted. Please describe the target population in terms of e.g. age, gender, education, ethnicity, level of risk etc. Please specify the number of patients per year. Please describe whether the technology is used for prevention of or screening for the target condition; for diagnosing the target condition; for treatment of the target disease; for treatment selection, evaluating prognosis, monitoring, rehabilitation or for other purposes.
C COMPARISON	**Alternative technologies/indications:** What are the alternatives to the technology/intervention? What is the technology/intervention compared to? E.g. usual practice at the hospital (available technology), conventional practice (gold standard), none/placebo, another population, dosage or mode of use?	Please describe all possible alternative technologies and highlight which specific alternative the technology/ intervention is compared to in this assessment. Please specify the name of the alternative technology or indication used as comparator.
O OUTCOME	**Relevant measureable outcomes:** What relevant endpoints/outcome measures are used? E.g. change in mortality, morbidity, side effects, quality of life, cost-effectiveness, length of stay, number of (re)admissions, ICER, budget impact, costs per correct diagnoses etc.	Please describe all relevant and important outcomes for this technology and indication and highlight which specific outcomes are included in this assessment.

QUESTIONS 8-12: GENERAL METHODOLOGICAL ASPECTS & REPORTING

8- Has a review of relevant literature been carried out (by the hospital or by others)?

A mini-HTA should to a large extent be based on documented knowledge. If a review or assessment of relevant literature or HTA reports has been carried out, please provide details of the search, review and assessment of this (date of search, key search terms, databases, selection criteria, number of hits, flow diagram etc.).

9- Is additional material/data included in the HB-HTA report?

If additional material or data is included please describe the sources of the data or material and the process for gathering it. Additional material or data can be, for example, local register data, activity data, interview data, data from the manufacturer, non-published data etc.

10- What is the quality of information/data/studies included?

Please specify the types of studies included and make an assessment of the quality of the information or data included, e.g. by means of a checklist for the assessment of internal or external validity of literature included (e.g. potential problems with bias, sample size, transferability etc.).

Please rate the strength of the evidence using a relevant evidence hierarchy.

A rating of the strength of the evidence using an evidence hierarchy can be used as a sole instrument in a "fast track" process when the timeframe for the assessment is very tight. In normal circumstances, an assessment of the quality of information/data included is however mandatory.

11- List of references

Please provide a list with the most important references.

12- Are there any ongoing studies of the effect of the proposal/technology?

Please specify any ongoing studies of the effect of the proposal/technology.

QUESTIONS 13-23: RESULTS WITHIN DOMAINS

When describing results of the assessment within the different domains below, please compare the results to similar results/effects of the relevant comparator(s).

Clinical effectiveness
13- What are the clinical effects of the proposal/technology?

Please describe the clinical effects of the proposal/technology, e.g. on the health of the patients (e.g. mortality, morbidity, disability/functional capacity, health-related quality of life, pain) or on the length of stay, number of admissions etc. The clinical effects should as far as possible be quantitatively described (e.g. response rate, average number of years of life gained per patient, number of QALY gained) by at least one relative measure (RR, OR, RRR) and one absolute measure (ARR, NNT/NNH). If the clinical effects are expressed as intermediate end-points (e.g. change in SBP, DBP) please describe how these end-points are linked with relevant final end-points.

Patient safety
14- Are there any potential adverse effects associated with the proposal/technology?

Please describe any potential adverse effects associated with the proposal/technology with regard to e.g. timing, severity and frequency. The risks, side effects and other adverse effects should be assessed against the benefits of the technology. These disadvantages should be compared with the disadvantages of current practice and any other possible alternatives.

Economic aspects (1/4)
15- What is the additional or saved annual cost for the hospital?

Please specify the direct additional or saved cost per year for the hospital if the proposal/technology is implemented. Please describe the types of costs included – both start-up costs (e.g. equipment, rebuilding, training/education etc.) and running costs (e.g. staff salaries, maintenance of equipment etc.) should be included. Costs should be presented quantitatively. Additional or saved costs in other departments of the hospital should also be included.

Economic aspects (2/4)
16- What are the implications of the proposal/technology for the reimbursement of the hospital per year?

Please specify the implications for hospital reimbursement per year. Implications for hospital reimbursement may be estimated using the number of patients, discharges, outpatient visits, bed days, DRG-weights etc. Implications for reimbursement should be presented quantitatively. Implications for reimbursement in other departments of the hospital should also be included.

The relevance of this question may depend on the specific financing scheme of the hospital.

Economic aspects (3/4)
17- Which additional or saved costs can be expected for other hospitals, sectors etc.?

Please specify whether the proposal/technology causes additional expenses or savings for other hospitals, regions, sectors or for the patients. Costs should be presented quantitatively.

Economic aspects (4/4)
18- Has an economic evaluation of the proposal/technology been carried out from a societal point of view (by the hospital or by others)?

Please specify whether a societal economic evaluation (e.g. cost-effectiveness analysis, cost-utility analysis etc.) of the proposal/technology has been carried out. If so, by whom and what were the main results? The economic effect of the proposal/technology should be quantitatively presented.

Organisational aspects (1/2)
19- What are the organisational consequences *inside* the hospital department?

Please describe any organisational consequences *inside* the hospital department associated with the introduction of the proposal/technology, e.g. physical space impact, workload and workforce implications, impact on staff regarding information, education/training, working environment and organisation of work, working hours etc. When can the proposal/technology be implemented/introduced in the hospital?

Organisational aspects (2/2)
20- What are the organisational consequences *outside* the hospital department?

Please describe any organisational consequences *outside* the hospital department associated with the introduction of the proposal/technology. A proposal/technology will often entail changes in the cooperation with other hospital departments or healthcare sectors. If so, please describe in what way this is expected to affect the departments/service functions or sectors, e.g. altered patterns of cooperation, differences in workload, changes in criteria for referral etc.

Patients' perceptions

21- What is the patients' experience of the proposal/technology and its implications?

Please describe the patients' experience of the proposal/technology and its implications, e.g. satisfaction, compliance, empowerment etc. This information may be found in the scientific literature or be collected by interviewing relevant patients in the hospital.

Strategic aspects

22- Are there any strategic implications associated with the introduction of the proposal/technology?

Please describe any strategic implications associated with the proposal/technology, e.g. fit between the proposal/technology and the research strategy, the local values of the hospital or national/regional healthcare strategies; implications for prestige and competition among hospitals in connection with the proposal/technology etc. Can the proposed technology be considered an innovation compared to current practice? If so, how?

Other potentially important aspects

23- Are there any other important aspects associated with the proposal/technology that should be considered?

Please describe any additional influencing factors associated with the proposal/technology, e.g. ethical implications (access, equity etc.), social implications (family dynamics, occupational status, early return to work etc.) or legal implications (FDA-approval, CE marking etc.). These considerations should be compared with usual practice and other possible alternatives.

QUESTIONS 24-28: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

24- Discussion of uncertainties

Please describe and discuss the uncertainties in the answers to the questions above. Are there any possible limitations to the methods/approaches used or sources of bias from different types of evidence? Are the patients in the included studies similar to the patients in clinical practice (transferability)? Do the results point in the same direction? The implications of some uncertainties can be illustrated in a sensitivity analysis.

25- Has the proposal/technology been implemented in other hospitals, in this country or internationally?

Please indicate if the proposal/technology is being used –or is planned to be used– elsewhere. Depending on the nature of the proposal/technology it may be relevant to explain why increased decentralisation is considered to be necessary.

26- Is the proposal/technology recommended by any other relevant national/international institutions or organisations (e.g. the national board of health, relevant medical associations/societies, EMA, AMA, NICE etc.)?

If yes, please specify by whom. Please state any recommendations.

27- Based on the assessment of the proposal/technology, what are the recommendations?

Please describe any recommendations from the assessment of the proposal/ technology. Should the new technology be introduced in your hospital?

28- Are there any suggestions for further actions?

Please specify any suggestions for further actions, e.g. a new scientific study of the effect of the proposal/technology, other research projects, quality assurance initiatives, monitoring of the effect and safety of the proposal/ technology, updating the review of literature after a period of time etc.

APPENDIX 2:
PROCESS OF DEVELOPMENT OF THE HANDBOOK

PROCESS OF DEVELOPMENT OF THE HANDBOOK

This handbook is one of the final results of the AdHopHTA (Adopting hospital-based Health Technology Assessment in the EU) research project funded by the European Commission under the 7th Framework Programme (Grant Agreement 305018).

This appendix summarises the research activities undertaken in the course of the AdHopHTA project that have led to the results presented in this handbook.

Partners involved in the project included six university hospitals, one training and research hospital, two national HTA agencies and a business school:

- Hospital Clínic de Barcelona – Fundació CLINIC per a la Recerca Biomédica (FCRB), Spain (*coordinator of the project*).

- Odense University Hospital (OUH), Denmark.

- Centre Hospitalier Universitaire Vaudois (CHUV), Switzerland.

- University of Helsinki and Helsinki University Hospital (HUS), Finland.

- Tartu University Hospital (TUH), Estonia.

- Università Cattolica del Sacro Cuore (UCSC) – University Hospital "A. Gemelli", Rome, Italy.

- Ankara Numune Training and Research Hospital (ANH), Turkey.

- Norwegian Knowledge Centre for the Health Services (NOKC), Norway.

- Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA), Austria.

- Center for Research in Healthcare Innovation Management (CRHIM), IESE Business School, Spain.

2.1 OVERALL DESCRIPTION OF METHODS USED TO DEVELOP THE HANDBOOK

The content of the handbook is comprised of:

i. facts and evidence from the research done on HB-HTA under the AdHopHTA project;
ii. an understanding of HB-HTA coming from the experience of AdHopHTA partners;
iii. experiences of other professionals working in HB-HTA units or working in HTA for hospitals in the EU.

A graphical overall summary of the multi-method approach used for producing the knowledge and information presented in the handbook is shown in Figure 1 below. Later, a more extensive description of each activity is presented.
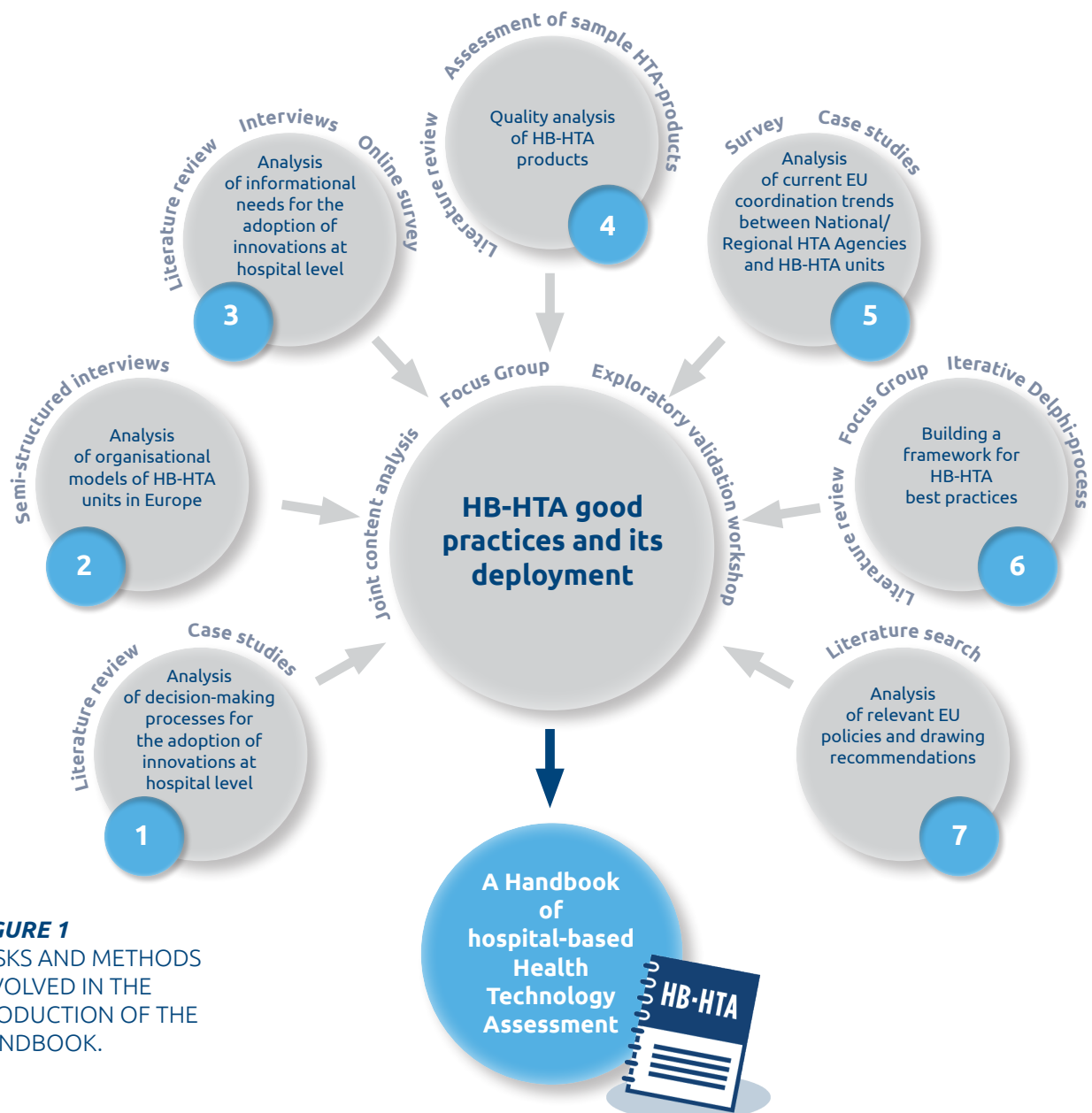
FIGURE 1
TASKS AND METHODS INVOLVED IN THE PRODUCTION OF THE HANDBOOK.

Literature review **Case studies**

Analysis
of decision-making
processes for
the adoption of
innovations at
hospital level

1

Aims of this task:

- To describe the adoption of technologies in healthcare with specific focus on the hospital level with and without an HB-HTA unit.
- To understand the adoption process of different types of health technologies in partners' countries.
- To provide an overview of the current processes of health technology adoption across European countries participating in the research.

Methods involved:

- **Literature review** of databases (Medline, Scopus, Embase, ISI Web of Knowledge, Cochrane Library Plus, CRD database, Tripdatabase, Google Scholar) resulting in 59 articles selected and reviewed out of 730 records found on the relevant topic.

- **Face-to-face interviews** with hospital and clinical managers from 32 hospitals across Europe: university/research and training hospitals with an HTA unit (N=8); university/research and training hospitals without an HTA unit (N=12); small to middle-sized hospitals without an HTA unit (N=12). Additional interviews with nurse coordinators affiliated to 19 hospitals. A convenience sample of hospitals was selected from the AdHopHTA partners' countries. The partners were asked to identify two respondents from each type of hospital, resulting in six respondents per country. Additionally, partners were asked to select two nurse coordinators in two different hospitals from the convenience sample.

- **Large scale web-based survey** of 339 sampled professionals invited to participate, 163 replied to the questionnaire (response rate = 49.1%) – hospital managers (N=98), clinical managers (N=47), other position (N=18). A convenience sample of respondents affiliated to hospitals with and without HTA unit was selected from the AdHopHTA partners' countries. Pre-defined criteria for selection of respondents were as follows:

  - hospital managers;
  - clinical managers;
  - both private and public hospitals;
  - minimum 25 participants from each country;
  - hospitals of all sizes, but a minimum of one hospital manager and one clinical manager from each of the five biggest hospitals in each country;
  - respondents who had participated in the face-to-face interview-survey in the spring of 2013 about different types of information needs could not participate – in these cases, managers at the same organisational level or from the 6th or 7th biggest hospitals in the country were selected;
  - managers from hospitals familiar with HTA and not familiar with HTA.

- **Case studies** – 38 case studies from project partners describing the decision-making process on the adoption of the following health technologies:

  - Medical equipment: Positron Emission Tomography - Computed Tomography (PET-CT), Positron Emission Tomography (PET), Computed Tomography (CT), Spiral Computer Tomography (spiral-CT), Robotic Surgical System, Light Intraoperative Accelerator (LIAC), Ion-Coupled Plasma Mass Spectrometer (ICP-MS), Intraoperative Neurophysiological Monitoring (IONM), Neuromonitoring, Electrocardiogram (ECG), Hybrid Operational Theatre, Intra-Coronary Optical Coherence Tomography (OCT), Intra-Operative Radio-Therapy (IORT) with Linear Accelerator, Remote Magnetic Navigation System for ablation of cardiac arrhythmias.

  - Medical devices: Portable Ultrasonography Device, Servo Feedback Hypothermia Device, Transcatheter Aortic Heart Valve (TAVI), Intra-Aortic Balloon Pump (IABP), Kyphoplasty, Radioactive seed implants for the treatment of prostate cancer.

  - Drugs: medical treatment of Dupuyten's contracture, Vemurafenib.

  - Clinical procedures: Extracorporeal Photopheresis, Atrial fibrillation outpatient clinic.

Case studies were based on information collected through questionnaires from the convenience sample of hospital managers and clinical directors. Each AdHopHTA partner was asked to choose HTs adopted in the last three years and belonging to the following categories:

1. Medical equipment (big technologies);
2. Medical devices (middled-size and small technologies);
3. Drug or Diagnostic tests (small technologies).

Further requirements for selection of technologies in different types of sampled hospitals were as follows:

- two HTs (one big and one small) within a university hospital/research and training hospital with an HTA unit;
- two HTs (one big and one small, if possible the same as above) in a university hospital/research and training hospital without an HTA unit);
- technology (big or small, indifferently) in a small/middle-sized hospital (i.e. community hospital).

At least five case studies from each country/partner should have been carried out.

2

Analysis
of organisational
models of HB-HTA
units in Europe

Semi-structured interviews
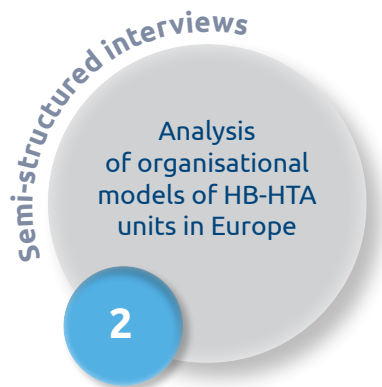
Aims of this task:

- To explore the characteristics of organisational models of HB-HTA units among AdHopHTA partners.
- To provide a set of generic models based on the research performed.

Methods involved:

- **Semi-structured interviews** answered by a convenience sample of hospitals with an HB-HTA unit selected from AdHopHTA partners' countries and by one hospital outside the project (Auckland City Hospital, New Zealand) – in total seven HB-HTA units from different hospitals.

3

Analysis
of informational
needs for the
adoption of
innovations at
hospital level

Literature review   *Interviews*   *Online survey*

Aims of this task:

- To review the empirical studies that analyse which information hospital managers and clinical managers require for making decisions on health technology investments, and the relative importance they assign to this information.
- To understand and determine which information European hospital managers and clinical managers need and what information they find most important as a basis for decision-making on investments in new health technologies.

Methods involved:

- **Literature search** of databases (PubMed, Embase, Cochrane Library and Web of Science). 14 articles were selected and reviewed out of 3,206 records found on the relevant topic.
- **Face to face interviews** (*following the same approach as described in task 1 above*).
- **Large scale web-based survey** (*following the same approach as described in task 1 above*)**.**

Assessment of sample HTA-products

Literature review

Quality analysis of HB-HTA products

4
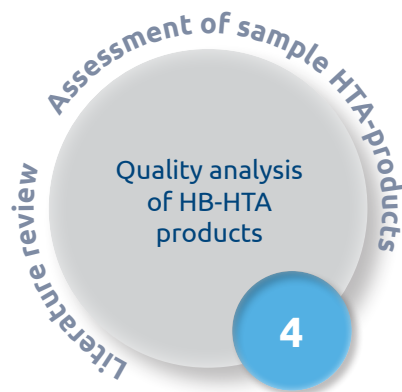
Aims of this task:

- To define what a good quality HB-HTA report is.
- To assess the quality of current HB-HTA reports to identify what improvements are needed to ensure they are of the best quality.

Methods involved:

- **Systematic literature review** (peer-reviewed and grey) on the characteristics that define high quality HTA reports. From over 4,500 records identified in Medline, Embase and Cochrane databases, four relevant articles met the requirements of the review.

- **Analysis** of a convenience sample of HB-HTA reports developed by HB-HTA organisations and units across Europe, both from the AdHopHTA partners' countries and others (N=9 countries). AdHopHTA partners were requested to choose one of their best reports for this task (according to their own adjudication). Other selection criteria for the HB-HTA reports were as follows:
  - carried out from a hospital perspective;
  - produced for <u>or</u> by hospitals;
  - used to inform a decision whether or not to invest in a new technology.

Survey   **Case studies**

Analysis of current EU coordination trends between National/ Regional HTA Agencies and HB-HTA units

5
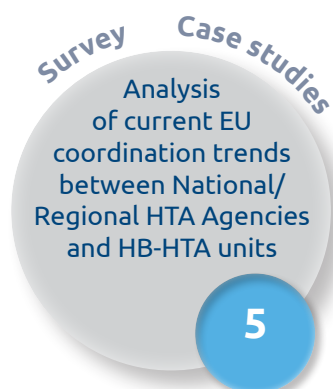
Aims of this task:

- To map and analyse current and potential paths of cooperation between national or regional HTA agencies and HB-HTA units in each of the respective AdHopHTA partners' countries.
- To extract and describe a set of parameters predicting successful collaboration and to provide a portfolio of patterns for successful collaboration.

Methods involved:

- **Case studies**. A Finnish case study based on: (i) 12 non-structured interviews with hospital clinicians, staff of the Finnish National HTA Agency and Finnish Medicines Agency and external stakeholders; (ii) information from 38 interviews with hospital managers (N=13), chief physicians (N=12) and nursing directors (N=13) from five university hospital districts in Finland about knowledge of the MUMM programme. A Norwegian case study based on results from an extensive national consensus process preparing the establishment of the new system for the introduction of new health technologies in Norway (NOKC 2014). In both case studies a convenience sample of respondents was selected from the two AdHopHTA partners' countries.

- **Questionnaire survey** – 24 respondents (HTA doers from HB-HTA and HTA national or regional agencies, administrative/management or combination of both) from a convenience sample of respondents from nine AdHopHTA partners' countries and three additional countries or regions (Belgium, France, Quebec/Canada). AdHopHTA partners were asked to select at least two persons in their country with knowledge and competence within HTA and/or hospital-based HTA (HTA leaders or doers). One person should work preferably in a unit at the national/regional level and the other should work at the hospital level.

Aims of this task:

- To identify a business excellence framework in healthcare suitable for adaptation to an HB-HTA unit.
- To update current scientific knowledge on best practices for national or regional HTA agencies and compare this with HB-HTA practices.
- To collect the views of key global HB-HTA professionals and other key opinion leaders on components for good practices in organising and carrying out HB-HTA.
- To achieve a consensus on key elements that should drive good practices in HB-HTA units.
- To check on the feasibility and practical relevance of the key elements for HB-HTA good practices and their place in the deployment process.

Methods involved:

- **Literature review** on (i) the identification of specific business excellence frameworks used in healthcare to be adapted to design an HB-HTA business excellence framework; (ii) characteristics of defined best practices in undertaking and reporting HTA in national or regional HTA agencies as well as of the characteristics of practices in settings performing HB-HTA. For the latter, a search

of multiple databases (Medline via PubMed, Trip Database, CDR, NLM Gateway, ISI Web of Knowledge) yielded 774 records, from which 52 articles were included for further analysis.

- **A pilot dry-run application** of the selected business excellence framework to the HB-HTA unit of the Hospital Clínic de Barcelona in order to test and adjust the framework. A further check was performed with HB-HTA units and organisations of AdHopHTA partners. The tests consisted in checking the different dimensions, concepts and definitions to fit the framework, and identifying issues and challenges to be considered in its application.

- **Focus group** on the resulting framework of good practices for HB-HTA units conducted with members of the AdHopHTA Advisory Committee, representing international organisations and European hospitals (N=8). The objective was to explore the adequacy of the framework and identify potential elements lacking in the adaptation of excellence to HB-HTA.

- **Delphi survey** on the importance and/or the desirability of a set of elements and concepts supporting the deployment and improvement of HTA units in the hospital context as part of the framework that can constitute an HB-HTA good practice. From a convenience sample of 44 global HB-HTA and key HTA experts selected by the AdHopHTA partners, 36 participated in the first round of the Delphi questionnaire, 27 in the second round. The round on deployment information was answered by 28 experts.

Literature search

Analysis of relevant EU policies and drawing recommendations

7

Aims of this task:

- To identify the current state of HTA EU policies and analyse how they can be better fine-tuned to foster the implementation of HB-HTA in Europe in order to create a comprehensive HTA ecosystem in the EU.

Methods involved:

- **Literature search** on current EU policies directly related, or directly affecting, a future collaborative EU effort in HB-HTA. Information sources included: EU legal documents (EuroLex), public documents from agencies, associations and interest groups at the EU level. Additional insights came from existing European associations.

A Handbook of hospital-based Health Technology Assessment

HB·HTA

Aims of this task:

- To produce a body of knowledge for decision-making on managing technology at hospital level through the use of HB-HTA.
- To define a set of guiding principles for the adoption of good practices in HB-HTA units.
- To provide clues for supportive policies for the adoption of HB-HTA in European countries.

Methods involved:

- **Literature review** to gather relevant examples of handbooks and toolkits in a general healthcare field and in HTA. From the extensive search in medical databases (Medline through Pubmed, Cochrane Library, TripDatabase, Centre for Reviews and Dissemination) and grey literature sources (International Network of Agencies for Health Technology Assessment (INAHTA), multinational/global HTA projects i.e. Euroscan, EUnetHTA), 12 examples of handbooks dealing with general healthcare (N=9) and HTA (N=3) were identified as relevant for defining the handbook of HB-HTA.

- **Joint content analysis** of the results from previous tasks to elicit the set of pragmatic guiding principles and parameters to be part of the handbook.

- **Group discussions** to deliver on the proposed principles for good practices in HB-HTA with the AdHopHTA project partners to establish the final set of principles.

- **Local validation interviews** with a convenience sample of respondents (one hospital manager and one clinical director) from the nine AdHopHTA partners' countries. Among the pre-defined selection criteria for respondents was involvement in the decision-making process on the adoption of health technologies in hospitals. Data was collected through questionnaires and further used to validate the HB-HTA handbook (and the accompanying toolkit for HB-HTA) and to guide the AdHopHTA partners before the validation workshop.

- During the preconference workshop at the HTAi annual meeting (Oslo, 2015,), an **exploratory validation workshop** with a convenience sample of 10 global leaders in HTA (both doers and users) who had never been involved in the project activities was carried out to check the feasibility and comprehensiveness of the defined set of guiding principles for good practices in HB-HTA units as well as general views on the project outputs. Profiles of the HTA leaders included:

  - Medical director of a university hospital;
  - Head of the economic evaluation unit at a university hospital;
  - CEO at a university hospital;
  - Head of global HTA scientific strategy at a company of biotechnology industry;
  - Chief physician for HTA at a university;
  - Owner and Senior Consultant at a consultancy company;
  - Professor/head of department at a university hospital;
  - Global Vice President of Health Economics, Policy and Payment at a medical device company;
  - Researcher at a research consortium;
  - Patients' representative.

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Ølholm AM., Kidholm K., Birk-Olsen M. et al., 2014. D2.2: Quality assessment of hospital-based HTA products. Confidential Deliverable; The AdHopHTA Project (FP7/2007-13 grant agreement nr 305018).

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APPENDIX 3: HISTORY OF HB-HTA

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HISTORY OF HB-HTA

Health systems all face the challenges of rationally allocating scarce resources to satisfy ever rising demands, due to costly medical innovations on the one hand and an ageing population on the other (Rechel et al. 2009). Ensuring sustainability and facilitating access to innovation in the era of rapid technological development were the drivers for the inception of health technology assessment (HTA) in the 1970s in the institutionalised form of the United States Congress Office of Health Technology Assessment at Washington D.C.

In 1985, the United States and Europe took measures to establish the *International Society on Technology Assessment in Health Care* (ISTAHC). The aim of the society was to encourage research, education, cooperation and the exchange of information on the clinical and social implications of healthcare technologies. Discussions in the early 1990s focused also on joint ventures with other societies, collaboration with the World Health Organisation (WHO) and the World Bank, and how to provide a forum for agencies to meet and exchange HTA results, which in 1993 led to the establishment of the International Network of Agencies for Health Technology Assessment (INAHTA) by several of the early European HTA agencies. INAHTA currently embraces 54 organisations from 31 countries around the world, including 32 organisations from 17 European countries. INAHTA's members mainly consist of government agencies with the aim of producing knowledge for the decision-making process at the macro- (policy), meso- (management providers) and micro- (clinicians) level (Granados 2005).

In 2004, ISTACH was reformed into the Health Technology Assessment international (HTAi) (Banta et al. 2009). HTAi is the global scientific and professional society for all those who produce, use or encounter HTA, whose aim is to act as a neutral forum for collaboration and the sharing of information and expertise with members from 59 countries and six continents.

The International Information Network on New and Emerging Health Technologies (EuroScan International Network) was formally established in 1999. The aim of the new collaboration was to enhance the exchange of information on new and emerging technologies amongst members.

In Europe, action in the field of HTA started more than twenty years ago. The first national HTA agency was established by Sweden in the 1980s and since then many countries have followed the Swedish lead in creating HTA-related institutions or agencies (Velasco et al. 2008).

Since the origins of HTA, the use of its main principles in decision-making processes has evolved significantly internationally with very well developed procedures and methods of HTA at macro- (policy) level (Kristensen & Sigmund 2007, Lampe & Pasternack 2008, Lampe & Mäkelä 2008). The historical contexts of European countries and regions and their diverse policy and healthcare systems, resulted in different approaches to HTA and its institutionalisation in agencies at a regional

and national level. Despite this heterogeneity, national and regional HTA agencies have realised the importance of joint cooperation, supported and developed at international and European level. International Networks such as HTAi, INAHTA, EuroScan (Simpson et al. 2009), and Regional Networks (European Network HTA – EUnetHTA), have contributed to this development. Today, many governments around the world have already adopted HTA.

The first publication discussing the need for creating a multidisciplinary committee within hospitals to assess the appropriateness of acquiring new health technologies appeared in 1979 (Mamana 1979), although the experience of these committees was described for the first time in 1986 (Millenson & Slizewski 1986). These early committees used some of the core elements of the HTA process; however they did not apply the current comprehensive standard method of HTA.

Nowadays, HB-HTA is unevenly present in Canada, the USA, Australia and Europe. In Canada, for instance, four university hospitals in Quebec have an HTA programme by law (Gouvernement du Québec 2006) (McGregor & Brophy 2005). HTA programmes can also be found in other Canadian hospitals (e.g. Calgary, Edmonton, London, Toronto). One of these hospitals, the McGill University Health Centre, in its first four years of existence (2001-2005), assessed 16 very different health technologies, helping the hospital to decide on proper investments and to achieve savings of over three million Canadian dollars (McGregor & Brophy 2005).

In the USA, a formal HTA programme has been adopted by the University of Pennsylvania Health System (Mitchell et al. 2008) and, until recently, the Veterans Health Administration operated its own HTA centre (Veterans Health Administration 2008).

In Australia, hospitals in different regions have HTA programmes or committees and the group of hospitals in Melbourne has established an HTA programme (King 2003). Furthermore, hospitals and regional services in Queensland, Western Australia and South Australia also have internal committees for the assessment of innovations (personal communication from Prof Guy Maddern, Surgical Director of Australian Safety and Efficacy Register of New Interventional Procedures-Surgical – ASERNIP-S, the Australian HTA programme).

One of the first "hospital" HTA agencies in Europe, the CEDIT (Comité d'Évaluation et de Diffusion des Innovations Technologiques), was established in 1982 at APHP Paris (Assistance Publique Hôpitaux de Paris), constituting the first example of a hospital-based agency for the assessment of medical technology. Hospital-based HTA (HB-HTA) has developed further since the mid-1990s, particularly in northern Europe, Italy, Spain, Canada and Australia (Cicchetti et al. 2008). Currently, there are different HB-HTA initiatives aimed at informing decisions on the introduction of or investment in innovative health technologies. Table 1 below summarises European HB-HTA initiatives.

TABLE 1
LANDSCAPE OF EUROPEAN
HB-HTA AT A GLANCE.

COUNTRY	HB-HTA INITIATIVE(S)
AUSTRIA	The Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA), responds to requests from two different health policy bodies responsible for investment and planning in hospitals (Mad et al. 2012, Wild et al. 2014): • The Regional Hospital Corporations, which it provides with assessment on indications and appropriate use of very expensive health technologies and early assessment of emerging health technologies. There are 9 Regional Hospital Corporations in Austria (one per region) owned by the regional governments. • The Ministry of Health, which it provides with (i) assessment of hospital interventions before their inclusion in the benefit package, and (ii) support on disinvestment decisions.
DENMARK	• HTA used by most university hospitals for decision-making on adoption of new health technologies (Ehlers et al. 2006, National Board of Health 2005). • Mini-HTA (one of the types of HB-HTA reports) widely used as a decision support tool in the hospital sector: by 66% of hospitals and 27% of clinical departments (Kidholm et al. 2009).
FINLAND	• Collaborative project created by the National Agency (Finnish Office for Health Technology Assessment – FinOHTA) called the Managed Uptake of Medical Methods programme project – MUMM project (Mäkelä & Roine 2009) embracing Finnish hospitals. This project is aimed at promoting HTA in hospitals and proactive identification of innovative health technologies that will seek funding in the short-run.
FRANCE	• A network of 37 hospitals – The Assistance Publique Hôpitaux de Paris (AP-HP). • Committee for the Assessment and Diffusion of Technological Innovations (i.e. CEDIT, Comité d'évaluation et de diffusion des innovations technologiques) founded in 1982 with the aim of advising decision-makers in AP-HP regarding the advisability of introducing innovative health technologies into their hospitals. It is responsible for formulating advice for diffusion of technological innovations in the hospitals and for horizon scanning. • Transformation of CEDIT's Scientific Secretariat into an innovation hub (2010).
ITALY	• Development and growth of HTA through HB-HTA at the San Matteo Hospital in Pavia (Lombardy Region), the University Hospital in Udine (Friuli Venezia Giulia Region), Bambino Gesù Children's Hospital and the HTA Unit at the "A. Gemelli" University Hospital (Lazio Region). • Inception of Italian Health Technology Assessment Network in 2003 bringing together all hospital experience in HTA (NI-HTA). • Foundation of the Italian Society of HTA (SIHTA) through approval of a consensus charter named "Carta di Trento on HTA". The charter includes principles that should guide HTA activities in the Italian context and comes from the initiatives of Italian HTA experts and stakeholders. • Establishment of the Italian Health Policy Forum in 2010, formally linked to the Policy Forum established at the HTAi.
NORWAY	• Pilot programme of The Norwegian Knowledge Centre for the Health Services (NOKC) aimed at introducing mini-HTA in their hospitals and creating a database where all mini-HTA reports performed by any hospital will be available (Arentz-Hansen et al. 2011).

COUNTRY	HB-HTA INITIATIVE(S)
SPAIN	• Committees for the Evaluation of New Technologies at some of the hospitals comprised of clinicians who voluntarily devote their time to analyse requests for investments in health technologies in their hospitals (supported by the epidemiology department of the hospital which performs the literature review). • Uneven adoption of formal and structured HB-HTA initiatives by hospitals. • Several examples of high-quality HB-HTA initiatives e.g. Hospital Clínic de Barcelona (Sampietro-Colom 2011, Morilla-Bachs et al. 2011), de Valme University Hospital Seville (Briones et al. 2009).
SWEDEN	• HTA conducted at the national/regional level; assessments being done mainly by university hospitals (Sahlgrenska University Hospital and Örebo University Hospital 2012) (L. Jigevärt, personal communication, April 30, 2015).
SWITZERLAND	• Long-standing HTA initiative at the Lausanne University Hospital (CHUV) (Pinget et al. 2014, Wasserfallen et al. 2004).
TURKEY	• The Department of HTA was established in 2012 under the Ministry of Health's General Directorate of Health Care Researches, responsible for HTA at the national level. • First HB-HTA unit in the country (ANHTA) was established under Ankara Numune Training and Research Hospital in 2012. • ANHTA produced mini-HTA and guidelines for HB-HTA and published them through their website in 2013.

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ACKNOWLEDGEMENTS

ACKNOWLEDGEMENTS

The authors would like to thank the following people for their contribution to the development of this handbook:

1) RESEARCHERS FROM OUR ORGANISATIONS THAT HAVE PARTICIPATED IN DIFFERENT PHASES OF THE PROJECT DEVELOPMENT:

Albert Alonso, Marcelo Soto, Ester Angulo - Fundació CLINIC per a la Recerca Biomédica (FCRB), Spain

Domenico Addesso[1], Angelica Carletto[2], Silvia Coretti[1], Giuseppe D'Amico[1], Rossella Dibidino[3], Alessandra Fiore[1], Carmen Furno[3] - [1]Università Cattolica del Sacro Cuore, Rome (UCSC), Italy; [2]Italian Medicine Agency, Italy; [3]"A. Gemelli" University Hospital, Italy

Janne Buck Christensen - Odense University Hospital (OUH), Denmark

Lucile Danglas, Marçal Farré, Olena Tigova - Center for Research in Healthcare Innovation Management (CRHIM), IESE Business School, Spain

Marisa Warmuth - Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA), Austria

Nurullah Zengin, Fatma Meric Yilmaz, İsmail Ercan Bal - Ankara Numune Training and Research Hospital (ANHTA), Turkey

Urmas Siigur - Tartu University Hospital (TUH), Estonia

2) THE MEMBERS OF THE ADVISORY COMMITTEE OF THE PROJECT:

Alexandre Barna - CEDIT, Committee for the assessment and diffusion of technological innovations, Paris (France)
Liuska Sanna, Valentina Strammiello - EPF, the European Patients' Forum
Roberto Grilli, Luciana Ballini - EUnetHTA, European Network for HTA
Hans-Peter Dauben - EuroScan International Network, the International Information Network on New and Emerging Health Technologies
Henk Groen - HTAi, Health Technology Assessment international
Irina Cleemput - INAHTA, the International Network of Agencies for Health Technology Assessment
Roisin Boland - ISQua, International Society for Quality in healthcare
Johan Nordenadler - Karolinska University Hospital, Sweden
Carlo Favaretti - SIHTA, Italian Society of HTA
Lennart Jivegård - HTA Centrum, Sahlgrenska University Hospital, Sweden
Geoffrey Wilson - COCIR, European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
Lluis Bohigas, Victoria Wurcel - EDMA, European Diagnostic Manufacturers Association
Pascale Brasseur - EUCOMED, European Medical Technology Industry Association

3) THE PANELLISTS OF THE VALIDATION WORKSHOP THAT TOOK PLACE IN THE HTAi OSLO 2015 CONFERENCE:

Kim Brixen - Odense University Hospital, Denmark
Erik Fosse - The Intervention Centre, Oslo University Hospital, Norway
Alicia Granados - Global HTA Strategy, Genzyme, United States
Tuija Ikonen - Hospital District of Southwest Finland, Finland
Grégorie Mercier - Economic Evaluation Unit, Montpellier University Hospital, France
Debjani Müller - Charlotte Maxeke Research Consortium, South Africa
Mitch Sugarman - Medtronic, United States
Enrico Zampedri - "A. Gemelli" University Hospital, Rome, Italy
Maya Züllig - Züllig Consulting, Switzerland
Russell McGowan - Patient representative, Australia

4) THE PARTICIPANTS OF THE DIFFERENT FACE-TO-FACE INTERVIEWS, THE DELPHI PROCESS AND THE LOCAL VALIDATIONS THAT FORMED PART OF THE ACTIVITIES OF ADHOPHTA AND THAT ALLOWED COLLECTING MANY OF THE DATA ON WHICH THIS HANDBOOK IS BASED:

Agnes Aart - South-Estonian Hospital, Estonia
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5) THE 163 PARTICIPANTS OF THE AdHopHTA LARGE SCALE SURVEY THAT PROVIDED THEIR INSIGHTS TO INFORMATION REQUIREMENTS AND DECISION-MAKING PROCESSES AT THEIR HOSPITALS.

GLOSSARY

GLOSSARY

Health Technology Assessment (HTA) – a multidisciplinary, research-based and practice-oriented assessment of the effects and consequences of a health technology (i.e. clinical benefits, economic and organisational impact, social, ethical and legal implications) in the short and long term. The aim of HTA is to provide answers to the specific questions asked by decision-makers on the likely value of health technologies and assist healthcare professionals, providers and payers. Methodological rigour and inclusiveness are required when collecting and analysing context-specific information for an HTA report.

"Health technology assessment is the systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policy making in health care. HTA contributes to answering questions from decision makers in areas and organizations related to health policy and/or practice."
(INAHTA)

"Health Technology Assessment (HTA) is a field of scientific research to inform policy and clinical decision making on the introduction and use of health technologies. (…) HTA is a multidisciplinary field that addresses the clinical, economic, organizational, social, legal, and ethical impacts of a health technology, considering its specific healthcare context as well as available alternatives. The scope and methods of HTA may be adapted to the needs of a particular health system, but HTA processes and methods should be transparent, systematic, and rigorous. In health systems throughout the world, HTA plays an essential role in supporting decision making."
(HTAi)

"Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method."
(EUnetHTA)

"Health technology assessment (HTA) refers to the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform a policy decision making."
(WHO)

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

HTA "in" hospitals means that the assessment process is carried out internally by the team of hospital professionals (e.g. clinicians, HB-HTA unit) and always leads to taking managerial decisions on health technologies; whereas HTA "for" hospitals is performed by external bodies on the basis of different lines of actions such as consultations, temporary contracts, freelance activities or projects. However, both HTA "in" and "for" hospitals need to be tailored to the hospital context and serve for managerial decisions.

Health technology – the application of available knowledge in the form of intervention that can be used by healthcare professionals in health promotion, prevention, screening, diagnosis, treatment of disease, rehabilitation or long-term care to improve health.

Health technologies include medical devices, medical equipment, medicines, diagnostic and clinical procedures, e-health interventions or public health activities and organisational systems.

Hospital decision-maker – hospital manager / hospital director and clinical manager / head of a clinical department.

Managerial decision – in the context of this handbook, this means an action taken by the hospital decision-maker regarding a technology in question after an assessment report. It may concern accepting a new technology to be implemented in the hospital, rejecting a new technology that offers no clinical benefit or is not affordable or disinvesting in an outmoded technology. It can also involve other types of strategic decisions regarding a health technology under assessment.

New technology – technology which has not yet been commonly adopted in the healthcare system or established in widespread use (at an early stage of diffusion, early post-marketing or in the launch stage).

Innovative technology – novel technology (e.g. procedure, equipment, medicine) which is a true innovation with a completely new way of action and proven potential value developed to address medical conditions, foster the improvement of quality of life or enhance the efficiency of a healthcare system. Technology deemed to be an innovation can be described as a technology that has not existed previously or is more cost-effective, safer or simpler than the former technology (standard of care).

Medical devices (small or middle-size technologies) – a wide range of products, e.g. materials, instruments, apparatus or machines, which have an impact on healthcare service delivery and are used for human beings, alone or in combination, for medical purposes (prevention, diagnosis or treatment of disease).

Unlike medical equipment, medical devices include non-renewable assets, e.g. implantable devices, disposable or single-use products.

Medical equipment (big technologies) – medical equipment includes technologies requiring a long-term amortization and is subject to inventory. Medical equipment can be used for human beings, alone or in combination with any accessory, medical consumables or supplementary medical equipment.

Clinical procedures – interventions undertaken by healthcare professionals on patients for health improvement, diagnosis, treatment or rehabilitation of medical conditions, grouped by clinical specialty and compliant with the international classification systems (following e.g. ICD-9 and ICD-10).

Obsolete health technology – any health technology, in specific indication, deemed to appear significantly inferior to other alternative interventions in terms of clinical benefit, safety or cost-effectiveness (e.g. demonstrated to be non-cost-effective, redundant or used in incorrect indication).

Disinvestment – a process of the complete or partial withdrawal, restriction or substitution of resources for existing health technologies considered to be obsolete, ineffective or have comparatively low added value. Disinvestment activities are aimed at optimisation, re-allocation and re-investment of available resources without reduction in the quality of care.

Valorisation – a chain of iterative processes in which the initial step is associated with the creation of adequate value for yet unpublished knowledge. Valorisation is thus associated with technology transfer activities, as a repeatable cycle of sub-processes, where the knowledge can be disseminated to society, translated and adapted into new or improved products.

Technology transfer – a process of the transfer of knowledge and innovation to facilitate further development and commercial application. The process of technology transfer comprises, inter alia, the identification of new technologies and evaluation of their potential value, securing and management of the protection process (e.g. patents), market research and creation of commercialisation strategies of technologies to be used by private sector or start-up companies to communicate healthcare innovations.

FOR OTHER RELATED TERMS PLEASE CHECK:

HTA glossary
http://htaglossary.net/HomePage

HTAi consumer and patient glossary
http://www.htai.org/fileadmin/HTAi_Files/ISG/PatientInvolvement/Glossary/HTAiPatientAndConsumerGlossaryOctober2009_01.pdf

Cochrane glossary
http://community.cochrane.org/glossary/5#letterd

National Information Center on Health Services Research and Health Care Technology (HTA 101) glossary
http://www.nlm.nih.gov/nichsr/hta101/ta101014.html

ABBREVIATIONS OF HOSPITALS AND OTHER ORGANISATIONS PERFORMING HB-HTA USED IN THE HANDBOOK

HCB – Hospital Clínic de Barcelona (Spain);

GUH – "A. Gemelli" University Hospital (Rome, Italy);

CHUV – Lausanne University Hospital (Switzerland);

ANHTA – Ankara Numune Health Technology Assessment Unit (Turkey);

HUS – Helsinki University Hospital (Finland);

OUH – Odense University Hospital (Denmark);

TUH – Tartu University Hospital (Estonia);

ACH – Auckland City Hospital (New Zealand);

SUH – Sahlgrenska University Hospital (Göteborg, Sweden);

MUHC – McGill University Health Centre (Montréal, Canada).

CEDIT – Committee for Evaluation and Diffusion of Innovative Technologies (Paris, France);

NOKC – The Norwegian Knowledge Centre for the Health Services (Oslo, Norway).

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