Laura Sampietro-Colom
Janet Martin *Editors*

# Hospital-Based Health Technology Assessment

## The Next Frontier for Health Technology Assessment

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# Preface

We are delighted to present this internationally contributed book on worldwide initiatives in Hospital-Based Health Technology Assessment (HB-HTA), which is the first of its kind. The idea of writing a book compiling the experiences of hospitals around the world in carrying out and using health technology assessment for managerial decisions originated during the 11th Annual Meeting of the International Society for HTA (HTAi) in 2014. The growing interest in this field and the lack of comprehensive published material on the topic lit the spark in our minds.

When we started, our idea was to gather real-world experiences, within a single publication, on how different hospitals in diverse countries and cultures perform and use HB-HTA. HTA is in itself a context-based activity; therefore, applying HTA in hospitals will also have cross-country and intra-country differences. Taking this into account, we wanted to provide a set of practices that could inspire the development of new HB-HTA programs around the globe. This book is not intended to be an exhaustive source of practical examples, but a representation of relevant examples from different settings.

We are fortunate to include many of the most experienced and knowledgeable writers in this field, who have contributed willingly and on time, and we are most grateful to them for their kindness and commitment.

This book is directed to anyone who wants to initiate or further develop a program of HTA in the hospital setting and to those who want to understand more about the growing HB-HTA momentum. Therefore, the targeted audience is broad, including clinicians, nurses, scientists, public health professionals, hospital managers, national/regional HTA agencies, industry, health service researchers, and policymakers.

We have enjoyed creating this book, and we hope it will serve as a ready-reference among the future of collected HB-HTA resources. Please enjoy, and we welcome your thoughts and feedback for future editions.

Laura Sampietro-Colom — Barcelona, Catalonia, Spain
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# Introduction

# Chapter 1
# Hospital-Based Health Technology Assessment: The Next Frontier

**Laura Sampietro-Colom and Janet Martin**

## 1.1 What Is Hospital-Based Health Technology Assessment (HB-HTA)?

Thanks to the contribution of last century's advances in scientific knowledge and technologies for healthcare, life expectancy and quality of life have increased considerably. Today, there are more than 500,000 medical devices on the market [1] and we are witnessing an annual growth rate of pharmaceutical spending for in-patient care in Europe of 1.5 % [2]. While these health technologies are aimed at relieving symptoms and in some cases to cure diseases, they are generally not 100 % safe (since there is always an associated risk with any health technology) and their level of effectiveness across subgroups may vary. Moreover, new health technologies are often associated with a significant contribution to rising costs for healthcare systems – costs which are not always commensurate with clinical results. This situation is not new for the twenty-first century. In the early 1970s, in response to the notable surge of expensive new healthcare technologies with limited (or non-scientific) evidence regarding their true clinical effects and the unprecedented market pressures for funding, the Office of Health Technology Assessment was created under the USA Health Care Financing Administration in 1976 [3]. Since then, Health Technology Assessment (HTA) has experienced global growth, [4] and the

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processes and methods for HTA have evolved considerably. Today, HTA is defined as a research-based, practice-oriented assessment of the relevant available knowledge on both the direct and intended consequences of health technologies (HTs) and on their indirect and unintended consequences, in the short and long term [5]. The aim of HTA is to provide information for decision-makers on the likely value of HTs [6], and this should be done taking into account the characteristics of the context where decisions have to be made.

Health systems have different types of decision-makers with different mandates working in different contexts, which leads to different informational needs for HTA to address. Therefore, at the governmental level (macro-level), HTA needs to properly inform the design of effective and efficient policies regarding the introduction and allocation of resources in a specific nation or region. This means taking into account the overall characteristics of a country's (or region's) healthcare system (e.g., epidemiology, number and characteristics of healthcare centers, competing priorities, etc.), when deciding if a HT should be covered or reimbursed through governmental (or insurance) funds. Going down a level in the health-system chain, healthcare managers in most hospital settings also have to make decisions regarding the introduction of very different competing HTs considering the idiosyncratic characteristics of the hospital (e.g., profile of patients, HTs already available, organizational characteristics, expertise of healthcare professionals, strategic priorities, etc.) in order to provide safe, effective, efficient, and sustainable healthcare. Therefore, different mandates and different contexts require different HTA approaches. Given the context specificity, this can be most effectively achieved at the local level where the context specifications are understood and where the budget allocation accountabilities become relevant. Arms-length HTA has its place in a national/regional health system, but local HTA is still required to achieve local specificity for the hospital setting.

HTA performed in the hospital in most health systems context for managerial decisions to inform local decisions on the uptake or disinvestment of health technologies is increasingly known as hospital-based HTA (HB-HTA). HB-HTA is not only about producing context-specific and methodologically sound reports for hospitals; it is also a way of organizing HTA activity in hospitals. HB-HTA consists of the implementation of HTA activities "in" and "for" hospitals, which includes processes and methods of organizing and carrying out HTA at the hospital level with a multidisciplinary and evidence-based approach. HTA "in" hospitals means that the assessment process is carried out internally by a team of hospital professionals (e.g., through a devoted internal HB-HTA unit or through internal multidisciplinary committees), whereas HTA "for" hospitals is performed by external bodies. HTA both "in" and "for" hospitals needs to be tailored to the hospital context and needs to be integrated into the managerial decision-making process [7].

The need to provide accurate, context-based information on the value of HTs at the hospital level is not new. The first publication proposing the creation of multidisciplinary committees in hospitals to advise on HTs appeared in 1979 [8]. However, the first real-world experience of such a committee was first described in the literature in 1986 [9]. These committees proved quite popular in hospitals around the globe [10].

Nevertheless, while they used some of the core elements and processes of HTA, they generally did not apply comprehensive methodological standards of evidence assessment, economic evaluation, and local contextualization required by current HB-HTA practices. Therefore, it is important to differentiate what constitutes HB-HTA from other activities performed in hospitals dealing with HTs that do not meet the contemporary definition of HB-HTA, although they may represent important interim steps on the path toward "true" HB-HTA [7]. These activities that are not considered to adequately represent "true" HB-HTA include (a) the use of national/regional HTA reports without adequate adaptation to a hospital's own setting, (b) when a clinical leader acts as promoter of results from a national/regional HTA report not adapted to the hospital setting (a version of the so-called ambassador model) [11], (c) the production of recommendations on HTs by a committee of clinicians and other disciplines at a hospital without appropriate assessment using HTA methods (accepted methods of objective assessment of evidence, resource considerations, and inclusion of other contextual factors), (d) completion of a checklist of questions for assessing HTs without using the quality standards required in an effective HB-HTA process, and (e) using evidence from literature to inform procurement processes (without comprehensive, proper adaptation to hospital needs) during implementation [7].

Since the first non-systematic and limited experiences [8, 9], HB-HTA has spread (especially since the mid-1990s) and a recent survey indicated that the number of hospitals performing HTA at hospitals is growing around the world [10, 12].

## 1.2 Why Hospital-Based HTA Is Important

Hospitals are the main entry point for HTs. Every year, hospital managers face an increasing number of difficult decisions regarding which HTs they should invest in. There is a wide range of HTs, from very costly and sophisticated technologies (e.g., robots) to those not so sophisticated and expensive, but which generate a moderate cost that may impact highly on the overall budget of a specific clinical department (e.g., ultrasound or robot assistance to guide replacement of knee prostheses). In an era of fixed or increasingly smaller effective budgets, more than ever hospital managers have to provide the best care at the lowest possible cost. Therefore, hospital managers need to make decisions that maximize the value generated from each dollar the hospital spends [13], HB-HTA being a way to improve the rationality of the decision-making process on HTs in hospitals [14].

One might think of using HTA reports produced by national/regional HTA agencies for informing decisions for hospital managers, but while these reports are important for HB-HTA and can be used to expedite local HB-HTA, they are insufficiently contextually relevant to help hospital managers to take investment decisions on the value of HTs. In fact, in a number of cases, clinicians and hospital managers perceive these national/regional HTA reports as connected only loosely with their daily clinical and management practices [15], though some arms-length agencies are working specifically to change this mismatch through partnerships with hospitals such as in Canada. The main reasons for this perception are a mis-

match in prioritization of HT elements for assessment [16], different informational requirements [17], and differing response-time needs [18] between policy makers and hospital managers. A study performed in Denmark shows that, in 1 year, only one third of the HTs assessed by hospitals (for investment decisions at hospitals) were also assessed by the Danish national HTA agency, which probably means that prioritization criteria of HTs to be assessed differ from HTA national/regional agencies to hospitals [16]. Additionally, a recent study performed among hospital managers in Europe shows that the informational requirements of policy decision-makers and hospital managers as regards HTA reports vary [7, 17]. Another reason for not always using HTA reports from national/regional agencies is that hospital managers usually need to receive HTA information more quickly than do policy decision-makers, and HTA reports from national/regional agencies frequently work on a longer timescale [18].

Hospitals, especially high-tech hospitals, often require information on emerging technologies for which there is hardly any (good quality) evidence available. These hospitals, in the front line of medical care, frequently want to introduce promising cutting-edge HTs with the assurance that the risk-benefit balance is appropriate, so this type of information must be provided, but it is usually absent from HTA reports from national/regional agencies. Additionally, due to the fact that HTs –of any type– use hospitals as the entrance door to the healthcare system and that it is impossible for national/regional agencies to assess all new HTs, a significant proportion of new HTs that hospitals would like to see assessed are not dealt with by any national/regional HTA agency prior to entry to hospitals (either in the setting of research or clinical practice).

Another reason that makes HB-HTA important today is that in an era of evidence-based clinical practice, the systematic adoption of HTA in hospital decision-making would foster a culture of evaluation leading to clinical practices and management decisions being based on scientific and local evidence [10, 13]. Finally, the involvement of those healthcare professionals (e.g., clinicians, nurses) who request the assessment of the HT will increase buy-in and acceptance of the final results and recommendations provided by the HB-HTA report [7]. Several current HB-HTA practices support this statement: after 5 years of HB-HTA activity, a survey showed that healthcare professionals who participated in the assessment process were 100 % satisfied with both the HB-HTA unit and the process of assessment [19]. Moreover, current practices show that HB-HTA report recommendations are used by hospital decision-makers, as is demonstrated by the fact that four European hospitals have adopted more than 90 % of the recommendations [7]. Several chapters in this book show how HB-HTA is used and benefits clinicians and managers decision-making at the hospital level.

All these reasons highlight the importance of having a system in hospitals to assess HTs with appropriate rigor, objectivity, and contextualization. Table 1.1 shows some of the main features that typically distinguish HTA in hospitals from HTA at a national/regional level.

**Table 1.1** Some differences between HTA at national/regional and at hospital level

| Characteristic | National/regional HTA agency | HB-HTA unit/program |
|---|---|---|
| Types of technologies assessed | Drugs | Drugs |
| | Capital equipment | Capital equipment[a] |
| | Medical devices | Medical devices[a] |
| | Diagnostic tests | Diagnostic tests[a] |
| | Organizational technologies | Organizational technologies[a] |
| Comparator in the assessment | The "gold standard" or the HT most used in the country | The HT that is currently being used in the hospital |
| Information requirements in the HTA report | Description of HT and technical characteristics | Health problem and current use of HT |
| | Health problem and current use of HT | Safety |
| | Safety | Effectiveness |
| | Effectiveness | Organizational |
| | Ethical, organizational, legal and social aspects | Economic evaluation (from hospital point of view, using hospital cost and always budget impact analysis) |
| | Economic evaluation (from societal point of view using average costs) | |
| Primary target audience | Policy makers | Hospital and clinical managers |
| Type of decisions which the HTA report is going to support | Payment, coverage, reimbursement, regulation | Acquisition/investment, strategic alliances, collaborative public-private research, disinvestment |
| Type of HTA report (most often) | Full HTA reports | Hospital HTA (mini-HTA, rapid-reviews) |
| Timescale of the assessment | 12–24 months | 1–6 months (average = 3) |
| Performance of assessment (most frequently) | Scientists at national/regional agency | Scientists at HB-HTA unit |
| | University scientists (commissioned) | Clinicians trained in HTA assisted by HB-HTA unit or university |
| | | Scientists from national/regional HTA agency working for hospital |
| Initiators of the assessment | Policy makers, healthcare payers | Clinicians |
| Capacity of adaptation to local needs | Limited | Frequently total |
| Impact measurement (benefits/outcomes to users) | Usually end-point outcomes (health and social impact), significant funds required | Usually intermediate indicators (satisfaction with HB-HTA unit and its assessments; net present saving or avoided loss from adopting/not adopting HTs) |

Adapted from AdHopHTA [5]
[a]Most often

Nevertheless, since hospitals do not exist in a vacuum and are part of a health system, which frequently [20] and increasingly [21] has a national/regional HTA agency, collaborations between HB-HTA units/programs and national/regional HTA agencies are essential. Currently, there are examples of effective collaborations [7] and a chapter in this book will further elaborate on them (see Chap. "Global Networks in HB-HTA").

## 1.3 Worldwide Approaches to HB-HTA Organization and Performance

HTA should always take into account the context where decisions have to be made. In the same way, the organization of any HB-HTA initiative at the hospital level is highly influenced by the contextual characteristics of the specific hospital. There is no single model of HB-HTA, and while HB-HTA initiatives are more frequently set up in high-tech hospitals, other less technology-intensive hospitals may also choose to support a HB-HTA unit for local decisions. In this book, several experiences with HB-HTA in different countries of the world are presented which highlight how the organization and performance of HB-HTA are being effectively adapted based on the culture, values, and organizational structures and processes of hospitals in different countries.

Although the organization of HB-HTA in each hospital is adapted to the hospital's specific contextual needs, it is possible to extract generalized organizational models from available HB-HTA practices. Eight years ago, the HTAi HB-HTA Sub-interest Group proposed a framework to classify HTA activities performed at the hospital level, which was based on the organizational complexity of the activity and its focus of action [22]. This framework was built from 33 answers given by members of the Sub-Interest Group coming from organizations in Europe ($n=22$), North America ($n=5$), South America ($n=3$), and Oceania ($n=3$). It identified four main HTA activities performed in hospitals: (1) internal committee model, where a multidisciplinary group of healthcare professionals within the hospital analyze the evidence related to HTs (these professionals do not perform this activity full time since they are mainly devoted to providing healthcare); (2) the ambassador model, where a clinician recognized as opinion leader in his/her specialty disseminates the recommendations made by a national/regional HTA agency in the hospitals of a country; (3) the mini-HTA model, where hospitals use a standardized checklist known as mini-HTA which was designed specifically to fulfill hospital informational requirements [23]; and (4) the HTA unit model, which consists of a unit inside the hospital specifically devoted to hospital-relevant HTA and with personnel working on a full-time basis. This framework was relevant and useful when it was produced since, at that time, it was the first attempt to inform how HTA was being organized in hospitals and provided a global collective experience on this issue for the first time [10, 22].

These originally proposed models of HB-HTA require further development to adequately meet the needs of contemporary organizational models and HTA decision-making within hospitals. Additionally, no guidance for good practices on how to organize and perform HTA at the hospital level was available at the time of the survey. It is worth mentioning that this situation differs from that of national/regional HTA agencies, for which principles for good practices were already defined [24]. Recently, under the Seventh Framework Programme, the European Union funded the Adopting Hospital-based Health Technology Assessment in Europe (AdHopHTA-EU) project to carry out research into how new HTs are managed in European hospitals and what the informational needs of hospital decision-makers are as regards investments in new HTs; it also looked into the way HB-HTA is organized and performed at hospital level in Europe [7]. The aim was to develop knowledge and provide experience-based guidance on the principles that should govern good practice in organizing and performing HB-HTA, as well as to provide tools for its deployment throughout European hospitals.

Under the AdHopHTA project, guiding principles for good practices in HB-HTA units have been defined and four macro-trend models of organizing HB-HTA in hospitals have been identified [7]. These macro-trend models are categorized according to the level of formalization and specialization of HB-HTA in the hospital as well as the level of integration in day-to-day hospital activities. The models include (1) independent group, a group of non-full-time hospital professionals who act on a voluntary basis to provide information regarding the value of HTs (in this case, top management is still not fully aware of the relevance of HTA for them); (2) integrated-essential HB-HTA units, small-sized units with non-full-time professionals devoted to HTA, which collaborate with allies – inside and outside the hospital – to produce HB-HTA reports; (3) integrated-specialized HTA units, which despite being specific HTA units inside the hospital, have a certain level of autonomy (they are highly influenced by and collaborate closely with national/regional HTA agencies – these units are formalized inside the hospital and have professionals specializing in the assessment of specific HTs (e.g., medical devices)); and (4) stand-alone HB-HTA units, which are very formalized and integrated in the hospital, with full-time professionals devoted to HB-HTA [7].

The methods and tools used for HB-HTA also differ from country to country, as the chapters of this book will show. Hospitals performing HB-HTA can adapt reviews from outside agencies to their local settings or develop new reviews when information from outside agencies does not exist, to address their local needs. In addition, they can use local information on utilization, outcomes, and cost data to fill gaps in evidence enhancing the usefulness of HB-HTA reports. A frequently used tool for HB-HTA is mini-HTA, although, when comparing mini-HTA performed by different hospitals, it is clear that their quality may vary greatly [16] and must be interpreted accordingly. Nevertheless, when mini-HTA is performed by HB-HTA units fully committed to this task, without undue shortcuts, experience suggests its quality increases considerably while also meeting the shorter timelines demanded by decision-makers [7]. Recently, a quality checklist for mini-HTA performance – that could also be extended to other types of HB-HTA – has been proposed [7].

## 1.4 Conclusion

If hospitals want their healthcare to be of high quality and sustainable, hospital decision-makers need to base their decisions on robust, comprehensive, unbiased and hospital-tailored information, which can be provided through HB-HTA. While HB-HTA is not new, there is now a steady worldwide trend toward increased establishment of HB-HTA activities in hospitals, there is also an increased expectations for HB-HTA to inform decisions for new technologies as well as existing technologies in the hospital setting [12]. This trend may further increase since the approval of the World Health Assembly (WHA) Resolution on universal coverage where HTA is an accepted means to contribute to achieving this [21].

This book is the first attempt to describe how HB-HTA is organized and performed in different countries on a global scale. In doing this, through the experiences described and the additional information provided, its objective is to encourage the adoption and promotion of effective HB-HTA in different hospital settings; while at the same time set out the trends that are envisioned for the worldwide development of impactful HB-HTA in the future.

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# Part II
# HB-HTA Case Studies from Around the Globe

# Chapter 2
# Activity-Based HTA: Hospital-Based HTA Performed by Clinicians with Support and Quality Control, the Sahlgrenska University Hospital HTA-Centrum Experience (Sweden)

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## 2.1 History

In Sweden, decisions about devices and capital equipment, as well as many decisions about drugs, are made at the hospital level. In 2005, the first author (LJ) was commissioned by Sahlgrenska University Hospital and Region Västra Götaland to investigate the need for local assessment of health-care technologies. This was followed by a commission to establish a local assessment unit.

The investigation focused on analysing how local stakeholders formulated their problems and needs, as well as analysing the experiences of existing national and international health technology assessment units that were visited. Local stakeholders supported local assessment, and clinicians stressed their competence in such assessment. Managers and the regional health authority called for a useful decision support tool for the budget process. The 15 HTA units that were visited were mainly national or university units; there were very few local HTA units.

The main problems encountered by existing HTA units were slow implementation and poor understanding of HTA. The main underlying factors seemed to be the poor tailoring of HTA reports to customers' needs, the reports not answering local questions, HTAs often unavailable when needed, and the lack of local ownership. The top priority was thus to address and overcome these factors. In Copenhagen, Mini-MTV (Mini-HTA), a standardised HTA protocol answered by clinicians, was used as a decision support tool in the budget process. The quality was suboptimal [1], but the concept was interesting.

The investigation concluded that local HTA work was needed. To address both the need for high-quality HTA reports adapted to local demands and improved HTA competence, it was suggested that:

- Clinicians be responsible for producing an activity-based HTA for new technologies they wish to use.
- Health-care professionals and managers may nominate technologies for activity-based HTA.
- The head of the department involved must support the nominated question and make working time available for the clinicians to conduct the HTA.
- An HTA support organisation (HTA-centrum) including the Medical Library and a quality assurance process are necessary to enable an activity-based HTA when it is needed.
- Medical librarians could do a major part of the work related to the literature search and selection of articles.
- The activity-based HTA process should be linked to budget requests and research funding.

The Sahlgrenska University Hospital, the Medical Faculty of the University and the health-care organisation of Region Västra Götaland then jointly commissioned the establishment of the suggested activity-based HTA concept. Clinics and institutions were invited to nominate individuals with HTA-relevant competence to a HTA project group, including librarians, and then to nominate questions for activity-based

HTA in order to develop the concept. Activity-based HTA was established by completing eight HTA reports by clinicians with support from the HTA project group during 1 year [2]. A process was defined where the HTA project group gave support, ensured the quality and wrote the conclusions and summary.

Following the investigation, Region Västra Götaland financed a hospital-based regional HTA-centrum organised with the Medical Library in October 2007. The HTA project group formed the basis for HTA-centrum, and a leading evidence-based medicine (EBM) expert (second author, CB) from the project group was appointed head. Suitable external reviewers were identified and invited to participate, and a regional HTA quality assurance board was appointed.

**Box 1: Health Care System Context**

- The Swedish health-care system is publicly funded.
- Hospitals are publicly funded through annual budgets by counties and health-care regions.
- Decisions about the use of drugs, devices and capital equipment are usually made at the hospital level.

## 2.2 Activity-Based HTA: Needs-Led HTA Performed by Clinicians with Support and Quality Control

Our activity-based process is shown in Fig. 2.1. Most of the work of the HTA-centrum employees is performed in the activity-based HTA projects, working together with the clinicians. HTA-centrum staff meetings are held weekly during 2–4 h where newly nominated questions and the progress of ongoing projects are discussed. In addition, PICOs (Population/patient, Intervention/indicator, Comparator/control, Outcome) in projects starting up, as well as conclusions and certainty of evidence in ongoing projects, are discussed (Fig. 2.1).

### *2.2.1 Questions for Activity-Based HTA*

Questions have been nominated by clinicians (81 %) and by the regional health authority or hospital managers (19 %). Nominations are submitted online to the HTA-centrum website (https://www2.sahlgrenska.se/sv/SU/Forskning/HTA-centrum/) and are managed in the following way:

- Incoming nominations are discussed during the following HTA-centrum meeting.
- Usually, the clinician involved is invited to inform the HTA-centrum staff.

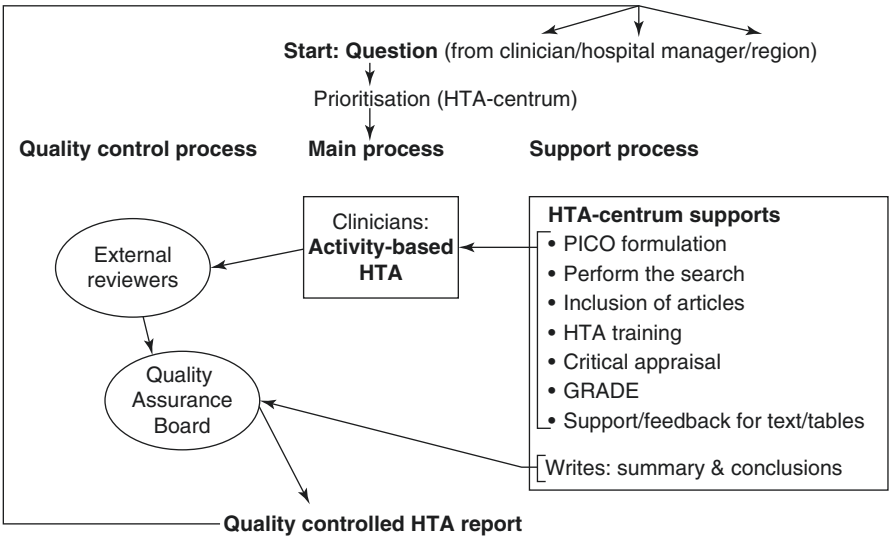


**Fig. 2.1** The hospital-based HTA process, performed by clinicians with support and quality control

- Librarians perform a preliminary literature search.
- The question is discussed again and accepted if it is of interest and published articles are available.
- The head(s) of the clinic(s) assign clinicians to perform the activity-based HTA.

Of all nominated questions, approximately 80 % have been accepted for activity-based HTA, 10 % for rapid HTA (see below) and 10 % have been rejected (usually due to scarcity of published articles or poorly defined PICO).

### *2.2.2 The Standardised HTA Questionnaire*

The questionnaire, initially a slightly modified version of the Danish Mini-HTA translated into Swedish, has been continuously modified based on feedback from the HTA experts and customers (clinicians and managers). Its contents include English and Swedish summaries, the PICO, outcome and summary of findings (SoF) tables, description of the disease/disorder of interest, the currently used health technology, review of the quality/certainty of evidence and safety for the proposed new health technology, ethical consequences, organisational and economy aspects and knowledge gaps. Today, our policy is that all reports are written in English with the format of a systematic review. The Swedish summary is written in plain language suitable for managers.

### 2.2.3 The Role of the Clinicians

An important part of the activity-based HTA concept is that senior clinicians (preferably key opinion leaders interested in using the technology) are involved. These are often the physicians approached by the industry in marketing efforts. By performing the activity-based HTA, the clinicians are trained in HTA and the evaluation of technologies. Through improved understanding of the principles of evidence-based health care, not only the implementation of the HTA in question but also future implementation of other HTA reports may be facilitated. Most clinicians have poor knowledge of HTA and may even be sceptical to HTA prior to their participation in an activity-based HTA, but after completion of the project, almost all are very positive to this way of evaluating knowledge. To date, approximately 375 health-care professionals from all hospital areas have participated in one (or occasionally two) activity-based HTA project(s) and constitute a large and continuously growing HTA competence in the clinical departments.

### 2.2.4 Workflow and Production Lead Times

A production lead time goal of 3 months per completed HTA project was set to facilitate use in budget processes. This goal was initially achieved, but during the years these lead times almost doubled and the process was therefore revised in 2014. During 2015, a lead time of 4–5 months has again been reached in several single technology activity-based HTAs. Today, larger HTA reports involving multiple technologies (e.g. nonsurgical treatment of overweight and obesity) are produced, and such projects necessitate longer lead times.

For a typical single technology activity-based HTA project, there are five project group meetings (meeting duration for all the five meetings in total is usually 17–25 h):

- Start. Basic principles of HTA are presented and PICO is formulated. Deadlines and meetings during the 4–5 months production time are planned in detail (4 h).
- Inclusion of articles. Critical appraisal and checklists are presented (4–6 h).
- Critical appraisal of included articles in consensus. Outcome tables are demonstrated; tabulation work is started. GRADE is presented (4–6 h).
- Conclusions and GRADE. All outcome tables must be finalised and a first draft of the text of the HTA report is to be produced by the project group, prior to this meeting. Conclusions are formulated and the certainty of evidence (GRADE) is defined. The text of the first draft is discussed (4–7 h).
- Feedback. The clinicians have finalised the HTA report, which has been reviewed by HTA-centrum and external reviewers. Finally, revisions have been suggested by the quality assurance board. A final version of the report is discussed and the clinicians are encouraged to give feedback regarding the activity-based HTA process (1–2 h) (Fig. 2.2).

Besides these meetings, the clinicians usually work another 10–30 h reading articles as well as tabulating outcomes and writing the HTA report. For a normal project,

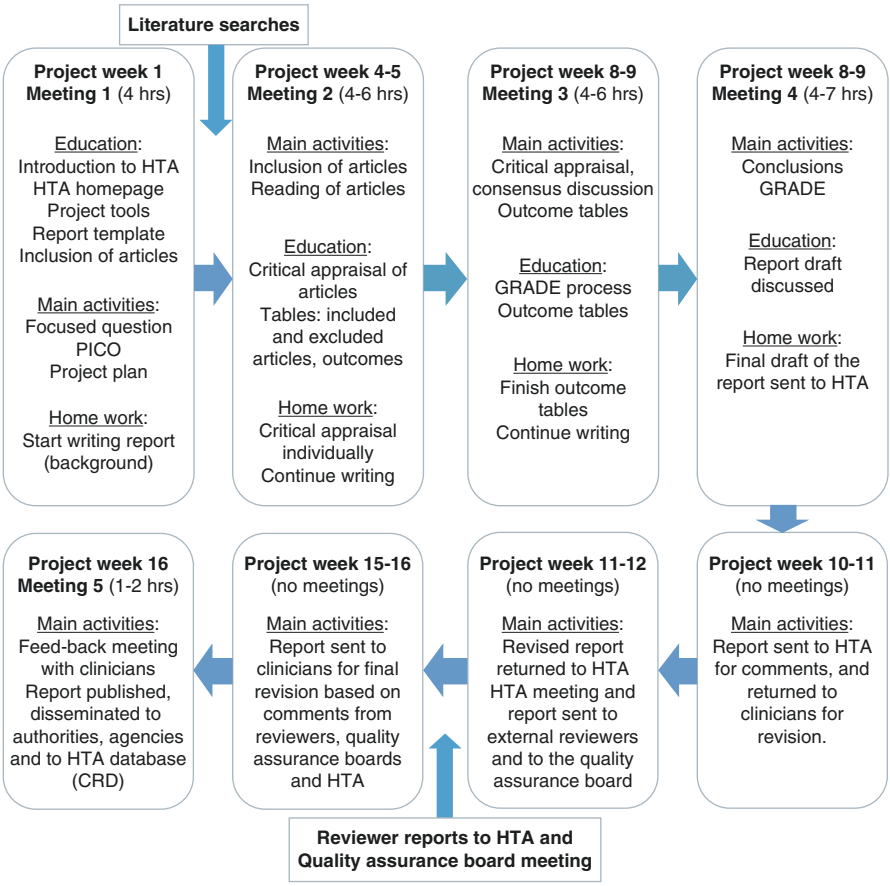


**Fig. 2.2** The project plan for a typical single technology activity-based HTA project, including five project group meetings

the amount of work for the clinicians is median 45 h during approximately 4–5 months. For very large projects, the workload increases. Participation in an activity-based HTA project is regarded as high-level education for the clinicians, and there is no reimbursement for the clinicians' time spent – this is financed by the departments involved. The average number of clinicians participating in each activity-based HTA project has increased by 20 % over the years (from 3.6 in 2008–2009 to 4.3 in 2014–2015).

## 2.3 Tools and Work Principles

The activity-based HTA project groups are usually composed of four to five clinicians (usually at least one MD professor and one MD PhD) as well as of two HTA experts and two librarians from the Medical Library. In order to promote learning and progression during the HTA project, different work tools and resources have been developed.

### 2.3.1 Website, Online Resources and Work Tools

A basic principle in our activity-based HTA process is that the work in a HTA project must be feasible for heavily occupied clinicians. Easily accessible online tools and resources, as well as a possibility to receive support from HTA-centrum at any time during the project, are of great importance and empower the project participants. It is important that participating clinicians are able to work at their location of choice, since they are often heavily occupied by clinical practice. Therefore, different online resources have progressively been developed and made easily accessible via the HTA-centrum website. An example of such a work tool is an empty template of the HTA report, with chapter headings and instructions for authors on what to write in each chapter. Other work tools are checklists for critical appraisal of included articles (available for different study designs). These checklists include AMSTAR, QUADAS and slightly modified checklists from the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU), and have instructions for use. In addition, templates for tables and appendices are provided for included and excluded studies and for outcome tables. Tutorials on how each table is to be completed are also available at the website. The participants can access all previously published HTA reports, to seek guidance about style, format and contents of the report. Altogether, besides the formal project meetings and different checkpoints according to the project schedule, the clinicians can plan their work efforts freely and receive support during the entire HTA project.

### 2.3.2 The Role of the HTA Experts in the Activity-Based HTA Project

The two HTA experts coordinate the project, lead the project group meetings, and guide the participating clinicians throughout the project. The aim of the process is to create an activity-based HTA report, but equally important is to teach HTA principles (‘learning-by-doing’) to the participating clinicians. Therefore it is an objective that resident doctors participate in the projects. During the entire project, the HTA experts supervise and teach the clinicians and try to ensure that the project schedule is followed. After each project group meeting, memos are written by one of the HTA experts and sent to the clinicians, detailing what was done and decided and what is expected from the clinicians until the next meeting.

When an activity-based HTA project is initiated, the HTA experts and the participating librarians guide the clinicians to narrow down the question at issue to form a focused and answerable question. The focused question is formulated according to PICO and focused on patient-related outcome measures. In order to keep the project timeline within a few months, the question needs to be precise and pinpoint the clinical issue. A narrowly focused question also helps the information specialists (librarians) to design efficient literature search strategies with high validity that will retrieve a manageable amount of articles. Also, during the inclusion of articles, the

HTA experts need to keep the project group focused on the question at issue, avoiding the inclusion of articles that do not concur with the PICO.

Critical appraisal of included articles is first done individually and later discussed in a consensus meeting where the entire project group agrees on different aspects related to study quality. The HTA experts lead the discussion and clarify ambiguities that the clinician participants may have encountered during the individual appraisal of the included articles. During this meeting the clinicians are also instructed in how data extraction and tabulation is to be done.

When all relevant data has been tabulated, the project group gathers in a separate meeting for assessment of the certainty of evidence for each outcome, across the studies. The HTA experts teach the GRADE principles and 'walk the project group through' the GRADE process for each outcome.

When a first draft of the HTA report has been written by the clinician participants, the HTA experts revise and return the draft within a few days, at least twice, to the clinicians. Subsequent questions and comments from two external peer reviewers are considered. When the drafting of the report is completed, the HTA report is revised and formally approved during one or occasionally two meetings of the quality assurance board. Based on comments from the quality assurance board, a last revision of the HTA report is done by the clinician participants and the HTA experts.

The final HTA report is published online, disseminated to regional and national stakeholders and abstracted at the Centre for Reviews and Dissemination (CRD) databases (c.f. Fig. 2.2).

## 2.4 Role of the Information Specialists

The Medical Library at Sahlgrenska University Hospital consists of three library units at the three different main hospital units. The Medical Library is organised under HTA-centrum and, in addition to its involvement in HTA projects, caters to the information needs of 16,000 employees at the Sahlgrenska University Hospital. There are currently nine employees at the Medical Library, including the library manager. One HTA librarian is employed directly by HTA-centrum and is in charge of the HTA work done by the librarians.

### *2.4.1 Literature Search*

There are four different literature search strategies that, according to the needs of the project, vary in their degrees of systematic structure:

1. When a question has been nominated for an activity-based HTA, a preliminary/scoping literature search is done to estimate the volume of relevant published studies. At this stage, it is usually sufficient to conduct literature searches only in the Cochrane Library and PubMed databases. This first literature search forms

an important basis for whether a project will be accepted for an activity-based HTA or not. Thus, if no relevant publications are identified in the preliminary searches in these two databases, the literature search needs to be expanded to additional databases in order to ascertain that relevant literature has not been overlooked. HTA-centrum policy is to only include published articles and usually no attempts are made to identify so-called grey literature. However, ongoing clinical trials (ClinicalTrials.gov) are searched for and reported.

2. If the preliminary/scoping literature search only identifies a few publications, the HTA-centrum may decide to conduct a rapid HTA instead of an activity-based HTA report. This necessitates an expanded systematic literature search in several databases, which also ensures that all relevant literature for the project is identified.
3. For an activity-based HTA report, two librarians work with the clinicians and HTA experts. Before the project is initiated, these two librarians independently perform scoping literature searches to identify relevant search terms and study designs of relevant publications and numbers of patients included in the studies, but also to familiarise themselves with the technology at issue.
4. The systematic literature searches are performed by the two librarians – all preparations are done independently but the final searches are conducted together. Although most of the activity-based HTA projects are single technology assessments, the literature search quality is never a matter of compromise. However, the number of databases searched is limited to those that are deemed relevant for the technology at issue. The PubMed or Medline, Embase and the Cochrane library databases are always searched, and depending on the technology in question, PsycInfo, CINAHL and AMED may also be included. In addition, the reference lists of relevant articles are scrutinised for eligible publications.

In general the use of search filters is very limited. Grey literature databases are usually excluded from the search strategy. Language limitations for literature inclusion apply, most often to English (occasionally also German) and the Scandinavian languages, since translation of articles is not done. Depending on the initial volume of relevant literature identified, both nonrandomised and randomised controlled studies may be considered for inclusion. Large case series are included to identify adverse events or complications associated with the technology. However, in some projects, especially if the technology is new and publications are few, case series may be included to shed some light regarding the reported effects on important outcomes.

### *2.4.2 First Selection of Articles: A Major Task for the Librarians*

The two librarians screen and read all identified abstracts as well as all possibly relevant articles in full text. They independently assess the abstracts and make a first selection of full-text articles eligible for inclusion. Clearly irrelevant articles are

excluded in consensus. The remaining full-text articles are sent to the clinicians and HTA experts, who independently read the articles and decide in a consensus meeting which articles are to be finally included. This often extensive work performed by the librarians saves a lot of time for the clinicians and speeds up the activity-based HTA process.

### *2.4.3 Guiding the Clinicians*

Another very important role of the librarians is to participate in guiding the clinicians in formulating answerable clinical questions that can be translated to an efficient literature search strategy. In the early phase, the clinician nominating the question is often invited to the Medical Library to participate in a preliminary/scoping literature search. The experience of this strategy is mostly rewarding, decreasing the number of comparisons and outcomes in the PICO. Altogether, the librarians constitute an important cornerstone of expertise in the activity-based HTA process.

## 2.5 HTA-Centrum Staffing, Products and Production

HTA-centrum currently has ten employees: seven HTA experts, a project leader/assistant, an HTA librarian and a health economist, all working part time with HTA. The staffing is equivalent to 4.5 full-time employees, and the annual budget to run the HTA-centrum is 560,000 euro (includes salaries, facilities, a budget for external reviewers, etc.). All HTA experts working at HTA-centrum are MD or DDS, with a PhD degree, and several of them are professors in medicine, including the head of HTA-centrum. The HTA experts have been individually selected from the clinical organisation due to their competence in HTA/EBM (evidence-based medicine) and research methodology. The HTA experts work part time at HTA-centrum and otherwise within their formal professions. After employment at the HTA-centrum, all the experts have been introduced to the work with HTA project groups, first being deputies in a few HTA projects thereby being introduced to the routines of HTA-centrum including HTA project leading, HTA/EBM education and methodology.

The HTA-centrum contributes to the hospital management with HTA products based on systematic reviews that enable informed decision-making for the structured introduction of new technologies (approximately 90–95 %), as well as for the phasing out of inefficient or harmful technologies (5–10 %). The activity-based HTA reports systematically summarise the scientific knowledge comparing novel and existing health technologies with each other. Many of the activity-based HTA reports have influenced health care, not only in the hospital but in the entire Region Västra Götaland and in other regions in Sweden. After an activity-based HTA, it is

possible for the clinicians that have participated in the project to apply for designated research grants (approximately 300,000 euro per year) for clinical projects aiming to elucidate knowledge gaps identified in the HTA project. Nine activity-based HTA reports have led to a publication in a peer-reviewed scientific journal. HTA-centrum employees are frequent EBM and HTA lecturers within health-care organisations and university institutions.

### *2.5.1 Five Important HTA-Centrum Products*

- The activity-based HTA report is the most obvious and tangible product of the HTA-centrum.
- Teaching HTA ('learning-by-doing') for participating clinicians is equally important.
- A rapid HTA, instead of an activity-based HTA report, is occasionally produced when published research on a specific topic is scarce.
- A statement is made when a question is not accepted for HTA, explaining the reasons for rejection and the results of the systematic literature search.
- EBM and HTA lectures at different levels of undergraduate and graduate studies.

A rapid HTA does not involve clinicians and does not contain the same volume of background information about the technology at issue. It is a brief report of about two pages of information, typically produced by one or two HTA experts and a librarian. A rapid HTA is subjected to a similar rigorous process as a normal activity-based HTA, from a focused question to appraisal of certainty of evidence (GRADE) and a quality assurance board meeting, before it is published on the HTA-centrum website.

### *2.5.2 Reports from the HTA-Centrum and Current Status*

Until September 2015, 82 activity-based HTA reports and 12 rapid HTAs have been published since the start of activity-based HTA. The annual volume of activity-based HTA reports has increased from three published activity-based HTA reports in 2008 to 13 in 2014. Although surgical disciplines and medical devices are dominating among the activity-based HTA reports, they have covered a wide span of topics. A few examples are reports on 'hypoglossal nerve stimulation for treatment of obstructive sleep apnoea', or 'endovenous interventions on varicose veins of the leg', 'teledermatology and teledermoscopy for referrals of patients with suspected skin cancer' and 'clinical decision support systems'. Also disciplines outside of medicine have been covered, exemplified by activity-based HTA reports in dentistry and nursing, such as 'orthodontic retainers' and 'specialist nurse receptions'.

The rapid HTAs have also covered a variety of areas such as ‘treatment of rectal cancer’ and ‘single room or shared room in a hospital ward’.

## 2.6 Impact and Conclusions

### *2.6.1 Lessons Learned Include*

- The concept with activity-based HTA performed by clinicians works very well, but continuous work with improvement of the HTA process is needed to avoid increased project lead times.
- There is a place for rapid HTA instead of activity-based HTA when available literature is scarce.
- The regional health authority nominates fewer, but larger, questions, usually involving whole fields of knowledge (e.g. nonsurgical treatment of obesity) – these projects have longer lead times.
- Impact on decisions is a very important outcome; the hospital managers are responsible for obtaining such data, and the hospital director should annually ask for actions taken by the clinic(s) in response to a certain activity-based HTA report. This has been a slower process to implement.
- Important to invite *all* involved departments to participate in the activity-based HTA report.
- Start report writing early in the project.

### *2.6.2 Main Take-Home Messages*

- Clinicians can successfully be engaged in activity-based HTA work [3, 4]. One important prerequisite is that that they receive adequate expert support.
- Clinicians have accepted and increasingly often use the HTA process.
- A critical mass of HTA experts, who could work part time with HTA, is a necessary prerequisite.
- Librarians can do a lot of the work reducing the workload for HTA experts and clinicians while maintaining quality of the HTA process.
- Participation of HTA experts ensures impartial conclusions and certainty of evidence (GRADE).
- It is a very rare event that a longer process is needed to achieve consensus between clinicians and HTA experts – all activity-based HTAs have ended in consensus.
- The concept of clinicians being primarily responsible for the activity-based HTA report itself, and the HTA experts being primarily responsible for summary and conclusions, has worked well.

- Impact on decisions is not easily studied but there are some indications. Studying the decisions made 1 year after the first 13 activity-based HTA projects [5], a decision in accordance with the results of the HTA, was noted in 12 (92 %).

### *2.6.3 Clinicians' Views on the Activity-Based HTA Process*

According to questionnaires after participation in an activity-based HTA project, the clinicians are very positive (Fig. 2.3). The clinicians' overall impression of the projects as well as the perceived value have been very positive with 100 % of responders scoring between 8 and 10 (on a scale where '1' indicates a very negative impression to '10' indicates very positive). The willingness to recommend a colleague to participate in an activity-based HTA has also been high with all responder scores distributed on scores 7 and 10 (Fig. 2.3).

## 2.7 Visions of the Future

The HTA-centrum has gained wide acceptance among clinicians and decision-makers in the region. The two other major health-care regions in Sweden (Stockholm and Skåne health-care regions) have adopted our principles and started similar HTA

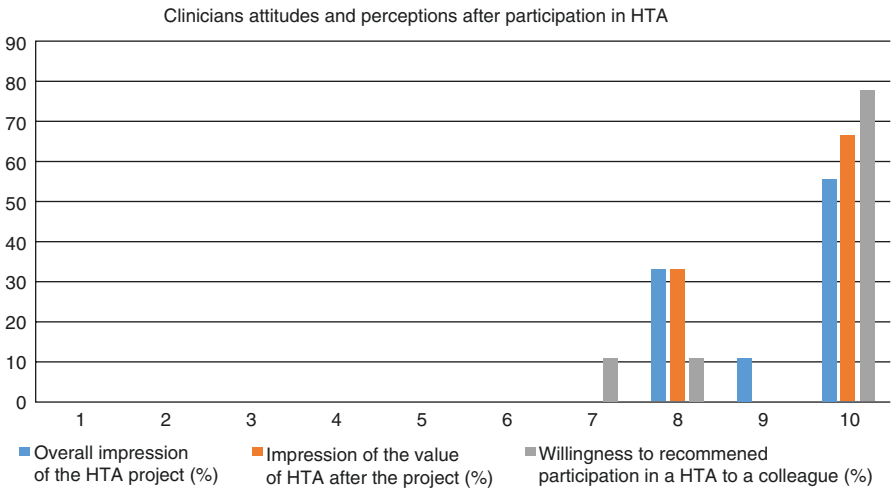


**Fig. 2.3** The clinicians' overall impression and perceived value of the hospital-based HTA projects

activities. We believe that larger hospitals in Sweden, but also in other countries, have the potential to successfully start similar activities.

Collaborations with other regional, national and international HTA- and EBM organisations have positioned the HTA-centrum at an international level in methodological competence.

A challenge for the coming years is to simultaneously maintain future development and to further benefit the health-care organisations in Region Västra Götaland. To achieve this, HTA-centrum needs to make sure that an evaluation process, targeting on the organisational actions taken following a completed activity-based HTA project, is part of routine controlling by the managerial levels. This concerns both the introduction of efficient health-care technologies and the phasing out of inefficient ones.

Altogether, HTA-centrum has established an important collaborative function with the clinical departments for producing objective reports for informed decision-making for the clinical departments, health-care executives and management in Region Västra Götaland.

In the coming years, an important task will be the improved reporting of actions taken as the results of an activity-based HTA. This will fine-tune the processes and provide HTA-centrum's customers with increased value of our end products.

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# Chapter 3
# HTA Activities in Finnish Hospitals

**Risto P. Roine and Iris Pasternack**

## 3.1 Early Health Technology Assessment (HTA) Activities in Finland

The national Finnish health technology assessment agency, Finohta, was established in 1995 within the National Research and Development Centre for Welfare and Health (STAKES). From the very beginning, its task was to support and coordinate HTA-related work in Finland and to promote and mediate high-standard, multidisciplinary assessment research [1, 2]. The early activities of Finohta included marketing the concept of HTA among clinicians and supporting clinical studies, among them randomized trials, financially. Furthermore, Finohta acted as a national clearing house by collecting, analyzing, synthesizing, and disseminating information on national and international HTA studies. Finohta formed a network of 65 clinicians, mainly hospital based, for the purpose of dissemination of information and the identification of research topics [1].

In the early 2000s, it became evident that the dissemination of HTA results to hospitals was not a sufficient way to incorporate HTA results into hospital decision-making for the adoption of new technologies. The culture of HTA thinking in hospitals was also still immature. In some cases, especially in the introduction of new and often expensive drugs into a hospital drug formulary, decision-makers desired unbiased effectiveness and cost-effectiveness information. In contrast, many other types of interventions were adopted without any formal requirement to prove their effectiveness, safety, and cost-effectiveness prior to acquisition.

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**Box 1: Health Care System Context**

- Finland has a National Health System funded through taxes levied by the municipalities. The system, however, is likely to undergo major reform during the next few years.
- Primary care is currently provided and arranged by the municipalities. Specialized health care is funded by the municipalities, but provided through Finland's 20 hospital districts. Some specialized medical care services (e.g., organ transplantations, the treatment of severe burns, etc.) are the special responsibility areas of university hospitals. The budgets of the hospitals are, at the moment, based on historical budgets and activities. From 2019 onward, primary care, specialized care, and social services will be integrated together and the country will be divided into 15 districts responsible for the organization of those services.
- Decisions on the reimbursement of outpatient drugs covered by the public health system lie with the Pharmaceuticals Pricing Board, which answers to the Ministry of Social Affairs and Health. Hospitals usually have Drugs Committees advising on which drugs to include in the list of drugs provided by the hospital. Regarding medical devices and capital equipment, in general, each hospital is free to decide on their investment. However, a recently passed law requires that the introduction of new methods and expensive devices must be harmonized within the university hospital catchment areas to which the hospital belongs.

## 3.2 The Managed Uptake of Medical Methods Program (MUMM)

Decision-makers identified the need to improve the system, as there were marked differences between hospital districts regarding the uptake of new technologies. Influenced by examples of the rigorous assessment of new technologies in other countries, Finohta, together with the 20 Finnish hospital districts, began in 2005 to develop a national approach for the managed uptake of new technologies into Finnish secondary care hospitals. The ensuing new MUMM program started in December 2005 [2–4]. The aim of the MUMM program is to offer critically appraised information for decisions concerning the uptake of new methods in specialized care and to encourage health-care decision-makers to commit to evidence-based practices [5]. The MUMM reviews produced are meant to provide essential material and evidence on methods for the hospital decision-makers.

In the program, the Chief Medical Officers of all hospital districts form a Board which identifies new methods needing assessment based on the proposals submitted using the mini-HTA form [6]. Once a topic is chosen, two or three clinical experts from the hospital districts, together with methodological experts provided

by Finohta, produce a semi-rapid systematic review which is peer reviewed and published in the Finnish Medical Journal. Based on the systematic review, and after an open circulation of the draft proposal for comment, the Board then gives guidance in a traffic light format on the uptake of the technology assessed. A green light is shown to technologies with sufficient evidence on effectiveness and safety, a yellow light is shown to technologies with only limited evidence on effectiveness or safety and for which the use of the technology should be linked to evidence development, and, finally, a red light is shown to technologies with strong doubts concerning effectiveness or safety or the costs of which are considered to be too high [5].

As of June 2015, 49 systematic reviews have been produced in the program and 57 recommendations given based on them (some of the reviews have formed a basis for more than one recommendation). All recommendations are published in the Finnish Medical Journal and on the website of the MUMM program. Members of the Board are also expected to disseminate and implement the recommendations in their respective hospitals. However, as decision-making in Finnish health care is decentralized, the hospital districts are free to decide whether they follow the recommendations or not.

The impact of the MUMM program on the uptake of new methods is difficult to judge due to the lack of specific procedure codes or the inadequate use of appropriate codes. In a study based on quantitative data, the reported numbers of patients treated with six out of seven methods with green lights had increased markedly. The reported numbers of patients treated with methods with restrictions concerning the use of the technology (yellow light) varied: four methods showed increasing use, whereas the numbers of patients treated with six other methods remained constant or decreased. The only technique with a red light that could be tracked from registries did not seem to have spread during the follow-up [7]. In another study surveying the extent to which the processes of examination and treatment within the Hospital District of Helsinki and Uusimaa in 2012 followed guidelines based on evaluated scientific evidence, the MUMM recommendations appeared to be fulfilled moderately well [8].

According to interviews among Finnish health-care decision-makers conducted in 2013 as part of the AdHopHTA project, the MUMM program still appeared to be poorly known and underutilized in hospitals. One obvious reason was thought to be the fact that the results of MUMM reviews are not systematically required or used in the clinics' purchase decisions. Furthermore, some clinics have their own systems to collect evidence and the MUMM program seems to be only one of the possible routes through which evidence is brought into decision-making in hospitals. In addition, the slow assessment process was identified as one of the main barriers of MUMM. As new technologies appear and evolve rapidly, MUMM reviews need to be quicker. An ideal time span for a MUMM review was originally set for 6–9 months, but that has seldom been reached. Furthermore, even a 6-month assessment process may, in many cases, be considered too slow by hospital clinicians eager to start the use of a new technology or drug.

## 3.3 HTA in Finnish Hospitals

There was very little HTA activity in Finnish hospitals prior to their involvement in the MUMM program in 2006. In 2001, the Helsinki University Hospital was the first hospital in Finland to appoint a physician dedicated to assessment of care services provided. The position was first established within the External Evaluation Unit of the hospital which is an independent unit required by law to monitor the economics and appropriateness of services of municipal care providers. The duties of the assessment physician consisted mostly of monitoring services and trying to establish ways to assess the effectiveness of care, rather than being directly HTA related. Later on, the position was moved under the Chief Medical Officer but, even then, HTA work, such as the assessment of new technologies, was not a priority as the hospital did not have any explicit rules requiring an assessment before the adoption of new technologies and, except for the assessment physician, there were no other dedicated resources for HTA work. Most of the assessments were expected to be undertaken in the MUMM program.

Two other university hospitals in the cities of Tampere and Turku followed suit toward the end of the decade and established assessment physician posts with varying roles and expectations. For example, in the Tampere University hospital, the assessment physician was asked to prepare rapid reviews on new technologies, whereas in the other hospitals, this activity was expected to be mainly performed by the MUMM program. Later on, in the early years of 2010s, the remaining two Finnish university hospitals, Oulu and Kuopio, made arrangements to establish posts of assessment physicians, albeit only on a part-time basis in the latter case.

## 3.4 Developments Arising from the New Law

Besides the division into hospital districts, Finland is also divided into five specific catchment areas for the provision of specialized level medical care. Each catchment area includes a hospital district in which there is a university providing training for physicians. The new health-care act, which came into effect in 2011, emphasized the role of these specific university hospital catchment areas in agreeing on the principles of adoption of new technologies. According to the law, the specific catchment areas must agree within their districts on how HTA is arranged and how new technologies are adopted.

To comply with the new law, all of the five university hospital specific catchment areas have mandated that new technologies must be introduced and justified using the mini-HTA form [6]. Subsequent decision-making differs somewhat from one specific catchment area to another, but essentially, if the evidence concerning effectiveness and cost-effectiveness presented by the mini-HTA approach is considered sufficient, the new technology can be adopted. In a case where more detailed evidence is required, most of the specific catchment areas have formed special assessment groups

which may perform rapid systematic reviews to gather more comprehensive evidence. Technologies requiring more thorough evaluation are still intended to go to the MUMM program.

## 3.5 The Current Mode of Operation in the Helsinki University Hospital Regarding New Technologies

Since the end of 2012, the requirement in the Helsinki University Hospital specific catchment area has been that all new costly technologies must be introduced by the mini-HTA approach (Fig. 3.1). When the evidence presented by the mini-HTA form is considered sufficient by the decision-maker (usually medical director of a specialty or, in case of more expensive technologies, the Chief Medical Officer or the hospital board, depending on the cost), he/she can decide that the new technology can be used. However, in a case where there are doubts concerning the effectiveness, safety, or cost-effectiveness of the new technology, the decision-maker can request the technology assessment group of the hospital for a more thorough evaluation. The technology assessment group then usually performs a rapid (within 1–3 months) systematic review, the results of which the decision-maker is expected to take into account when making the final decision regarding adoption. The technology assessment group can also refer the topic to be discussed in the national group of the assessment physicians of all five university hospital district specific catchment areas or to the MUMM program if the technology requires a more thorough evaluation or is of national interest. Although the five assessment physicians, formally appointed by their respective university catchment areas, have a formal role only in their own areas, they try to collaborate and share information as much as possible. Based on consensus they may also give advice as a group, but do not have any formal status as a national group except for having been invited to act as members of the Advisory Board of the MUMM program.

The technology assessment group of the Helsinki University Hospital specific catchment area is led by the assessment physician of the Helsinki University Hospital and consists currently of 12 members and an expert secretary. Eight of the members represent the Helsinki University Hospital district and two each the two other hospital districts of the specific catchment area. Apart from a nursing director and the expert secretary with a nursing background, all other members of the assessment group are medical doctors. As there is no explicit funding for the assessment activity, all members of the group participate in the assessment work on a part-time basis and have at the same time many other duties in the hospital. So far there is no health economist in the technology assessment group, although health economics expertise was considered essential when the group was initially set up in 2013. This means that assessments of new technologies focus mainly on effectiveness. Proper health economic analyses are usually missing and replaced by simpler approaches such as bud-

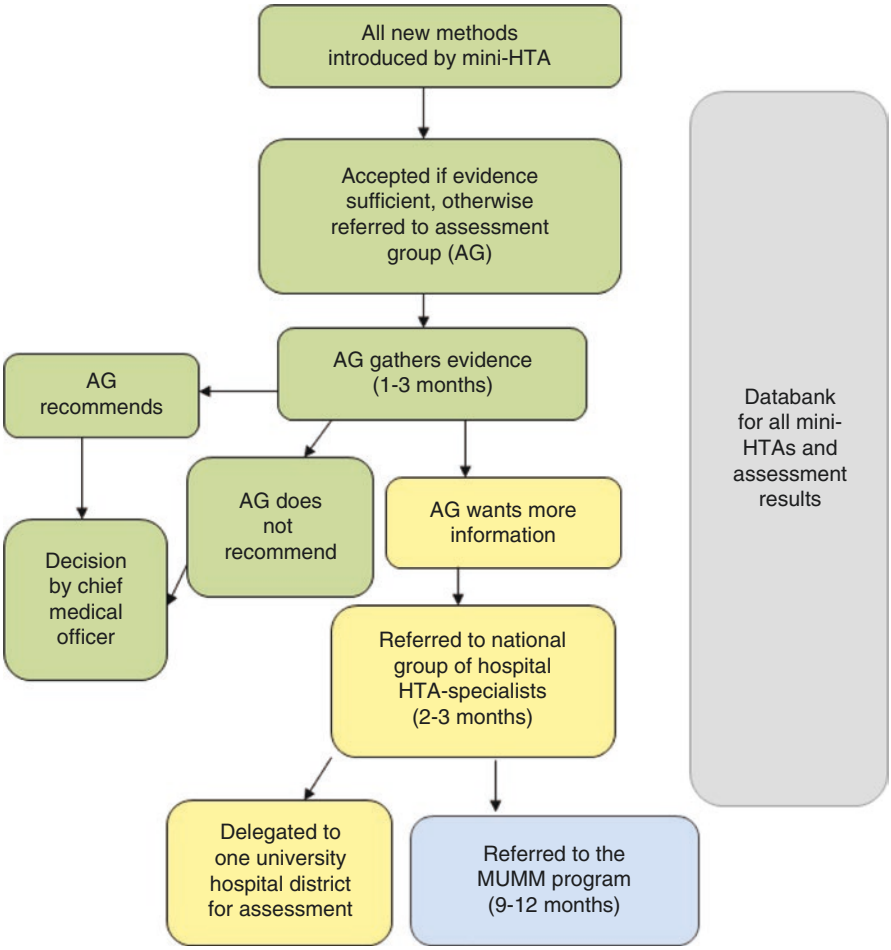


**Fig. 3.1** Mode of operation concerning new technologies in the Helsinki University Hospital specific catchment area

get impact analyses or other cost considerations. The literature searches needed for the systematic reviews are performed by the medical library of the University of Helsinki and the Helsinki University Hospital. Based on the literature review, two designated members of the technology assessment group perform a rapid systematic review which is discussed within the group which then collectively gives its recommendation. The technology assessment groups of the other university hospital districts follow a similar structure although the number and background of the group members may be somewhat different from those of the Helsinki university hospital.

Since the beginning of 2015, the process for assessment in the Helsinki University Hospital has been further consolidated through guidance given by the Chief Medical

Officer of the hospital. The new instructions require that the assessment of new hospital drugs should begin with the mini-HTA approach. The assessment of drugs is now performed by a ten-member drug assessment group based on a former informal group of clinicians set up in the Department of Medicine several years ago. The present drug assessment group consists of nine experts with various medical backgrounds and a pharmacist representing the hospital pharmacy, but has no health economics expertise.

According to the new guidance, decision-makers can decide within their authority (clinical managers have financial decision-making authority when the budget impact is <€100,000, the Chief Medical Officer has authority when the budget impact is ≥€100,000) about the adoption of the new technology when the evidence presented in the mini-HTA is deemed adequate. However, according to the new guidance, further assessment should take place when:

- The budget impact of new the technology exceeds €50,000/year.
- There are safety concerns associated with the new technology, or its effectiveness is uncertain.
- The new technology affects a large number of patients (over 100 per year).
- The new technology has particular societal effects.
- Those contemplating the use of the new technology consider further assessment desirable.

The use of the technologies assessed by either of the assessment groups should be reported in writing back to the group within 2 years after the assessment has taken place.

So far, the technology assessment group has received only a few requests for assessment. The technologies for which assessment was requested include treatment of chondral defects with autologous chondrocyte implantation, facial transplantation, baroreflex activation therapy for hypertension, bronchial thermoplasty for asthma, and Exogen ultrasound healing system for bone fracture nonunion. Some of the suggested topics have been clearly experimental and not easily approached with traditional HTA methods. Consequently, the technology assessment group has so far given assessment-based guidance on only a few occasions and the impact of the activity is thus far difficult to judge.

The drug assessment group has assessed a number of new drugs over the years. The assessments have, however, been less formal and not usually based on systematic literature reviews, but rather on discussions with clinical experts concerning the clinical value of the new drug. As the drug assessment group was formally established only a few months ago, experiences from its new role are still scarce. Moreover, the drug assessment environment of the hospitals may experience some modifications in the near future as there have been discussions about the possibility of harmonizing decisions concerning the uptake of new hospital drugs in Finland by assessments produced by the Finnish Medicines Agency together with individuals from the hospitals. The feasibility and usefulness of this approach, however, are currently being tested and remain to be established.

## 3.6 Conclusions

HTA is only slowly paving its way to Finnish hospitals. The MUMM program has been a good start but has not been able to convince all hospital clinicians of its value. In part, this is due to the relative slowness of the MUMM assessment process, which at its best tends to take a year before the final recommendation is given. There also seems to be some mistrust between clinicians and the national HTA agency as centrally produced guidance does not always align with the needs of the hospitals. Of course it may take years before new practices are widely and unconditionally accepted, but based on current experiences, a more localized, hospital-based HTA (HB-HTA) approach is also clearly warranted.

The new health-care act emphasizing the role of the specific university hospital catchment areas in agreeing on the principles of adoption of new technologies has clearly boosted HB-HTA and led to the implementation of the mini-HTA approach in all five specific university hospital catchment areas of Finland. It has also resulted in the establishment of a fairly similar assessment process in most of the specific university hospital catchment areas and increased cooperation on HB-HTA between the areas [9]. Such cooperation may also form the basis for a common approach concerning the uptake of new hospital drugs, the assessment of which could partially be done in cooperation with the Finnish Medicines Agency.

Although the role of HB- HTA in Finnish hospitals appears to be growing, it is not yet universally recognized and a number of new methods are still taken up without any formal assessment. Bringing the assessment process closer to the clinicians and tailoring the assessments to better serve the needs of the hospitals are likely to improve the impact of HB-HTA. National and local strategies emphasizing the role of effectiveness in health-care decision-making, instead of individual autonomy, must eventually be turned from words to action. This is not possible without a well-functioning assessment process in the hospitals.

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# Chapter 4
# Hospital-Based HTA in Denmark

**Kristian Kidholm and Anne Mette Ølholm**

## 4.1 Introduction

Hospitals in Denmark are owned by the five regions and financed by the public tax system. Private hospitals exist, but public hospitals provide 98 % of hospital treatment. The five regions manage the public hospitals and all physicians are employees at the hospitals and paid fixed salaries.

The hospitals are financed through taxation by a capitation system; thus the regions pay the hospitals a fixed annual budget and the hospitals are expected to stay within that budget. The hospitals have no opportunity for additional funding unless the national government decides to support a special program (e.g., for patients with cancer).

Health Technology Assessment (HTA) was originally performed by the National Board of Health in the form of a limited number of national HTA reports annually but for the last couple of years HTA has been carried out by HTA units at the university hospitals or at the regional level.

Odense University Hospital (OUH) has 1038 beds and 11.280 employees. The total budget in 2014 was € 835 million. The hospital has 40 different clinical departments and is the only university hospital in the Region of Southern Denmark.

The HTA unit at OUH started in 2002 and was the first hospital-based HTA unit in Denmark. The unit was initiated because the hospital management saw a need for improving the basis and evidence for decisions on investment in new health technologies at the hospital. From the beginning the objective was to make HTA "a way of thinking" among the hospital staff and to involve as many clinicians as possible in the production of HTA.

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**Box 1: Health Care System Context**
- Health-care system: Publicly funded and publicly owned hospitals.
- The health care system is financed by the public tax system. The hospitals are financed by the government in a capitation system.
- Investment decisions for new treatments are primarily made at the hospital level, either by the hospital managers or the clinical managers in the clinical departments.

## 4.2 Organisational Characteristics

The HTA unit at Odense University Hospital is located within the Department of Quality and Research in the hospital administration. The HTA unit assists the clinicians in the clinical departments in producing technology assessments of new health technologies. Thus, in most cases, it is the clinicians at the hospital who take the initiative to produce a technology assessment.

The staff of the HTA unit is limited to a manager (health economist), two people with a masters in public health, one person with a masters in health economics, and one person with a masters in clinical engineering. In addition, the unit collaborates with the library at the hospital, which assists with systematic literature searches.

There is no joint commission or board that systematically makes decisions regarding the introduction of new treatments based on the HB-HTAs. Instead the HTAs are used as a basis for decisions either by the head of the specific clinical department or by the board of directors at the hospital.

Recently the HTA unit at Odense University Hospital has also been appointed as a knowledge center for HTA in the Region of Southern Denmark and is now also obliged to assist clinicians and managers from the other three hospitals in the region.

### *4.2.1 Characteristics of the HTA Process*

The main tasks of the HTA unit at Odense University Hospital are:

- Courses in mini-HTA
- Assistance in the production of mini-HTA
- Assistance in larger HTA projects

To engage managers and the clinical staff at the hospital in the production of mini-HTA, we offer regular courses in mini-HTA. During the typically 2-day courses, we describe how to do a systematic literature review; how to assess clinical, patient, organizational, and economic outcomes of new treatments; and how to ensure the quality of a mini-HTAs.

Assistance in the production of mini-HTA is needed because mini-HTA is mandatory at the hospital as the basis for an application for funding and when clinical departments are considering investing in new treatments. Therefore, the clinical departments most often take the initiative to produce a mini-HTA and in some cases ask for assistance from the HTA unit. Typically they need help with how the HTA production process works, who to involve, how to assess the quality and level of evidence of scientific studies, how to assess the organizational aspects, and how to calculate the impact on hospital expenditure and reimbursement of the implementation of a new treatment.

Mini-HTAs [1] at Odense University Hospital contain the following:

1. A description of the technology, clinical impact, and evidence level (questions 1–6)
2. A description of patient perceptions (questions 7–9)
3. A description of organizational impact (questions 10–13)
4. A description of the economic impacts (forms 1–7)

The content is consistent with the national Danish mini-HTA designed by the National Board of Health [2, 3]; however, where the national form has focus on the economic impact at the national level, the mini-HTA form at Odense University Hospital only focuses on the economic impacts on the hospital. This includes an assessment of expenditures for the hospital and the reimbursement to the hospital.

The process of producing a mini-HTA is described in Fig. 4.1 below. After the individual (e.g., a physician) has contacted the HTA unit for assistance with the production of a mini-HTA, a meeting is organized. At the meeting it is determined which departments at the hospital may be affected by the introduction of the new technology and therefore should participate in the development of the mini-HTA. In addition, the primary outcomes of the technology are discussed and whether relevant alternative technologies should be included in the assessment.

After the first meeting, one or two persons begin the systematic literature review, including an assessment of the articles found. The results, including a description of the effectiveness of the technology and the evidence level of the literature, are presented at the second meeting. If the evidence level is insufficient, or if there is no expected improvement in clinical effectiveness found in the articles, the production of the mini-HTA is stopped. If documentation for the clinical effects is lacking, there is no reason to continue working on an assessment of the other types of outcomes of the technology. However, if the articles describe the effectiveness of the technology as an improvement compared to usual care at the hospital, the production of the mini-HTA continues.

The organizational and economic effects of implementing the technology are discussed in the working group at the third meeting. Often the clinical literature does not describe these effects and the assessment is based on the expertise and local knowledge in the working group. Consideration is given to the resources and devices that will be used in the implementation process and how those prices can be found. After this meeting, the HTA unit is often tasked with writing the description

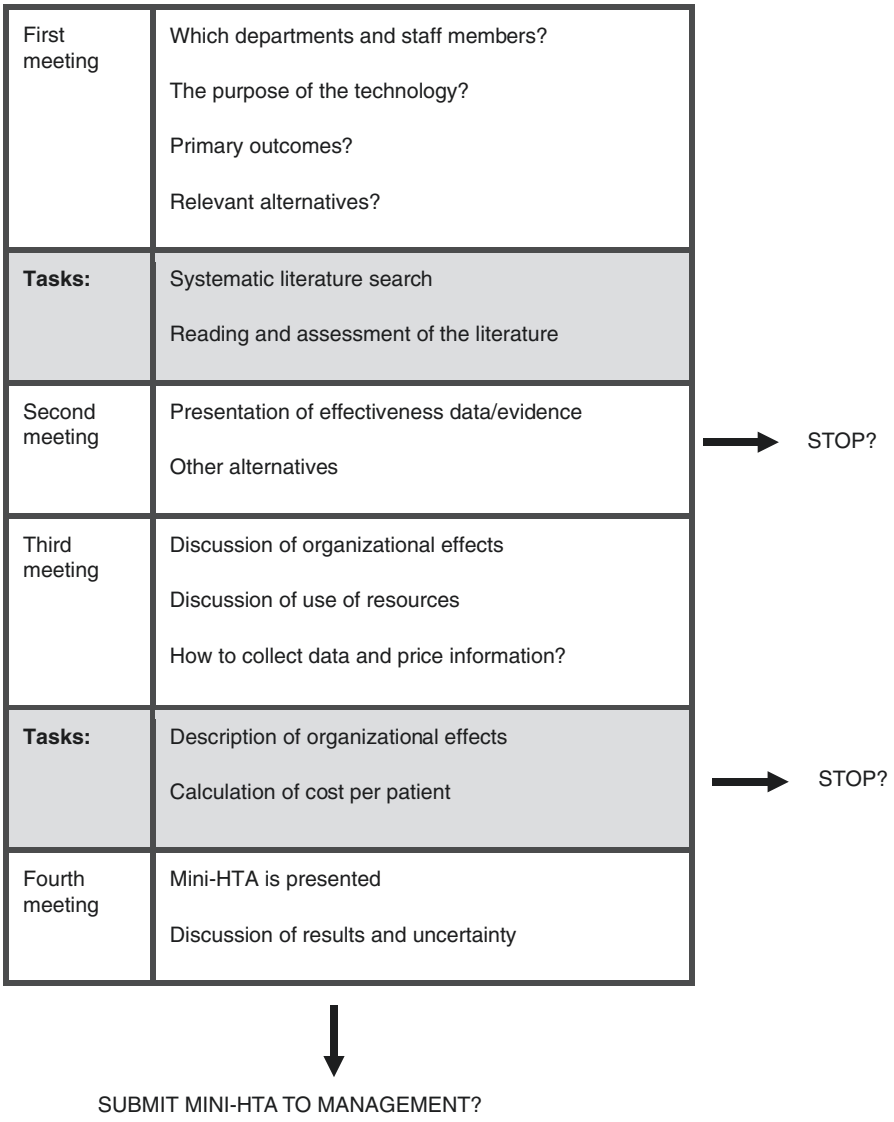


**Fig. 4.1** The process of production of the mini-HTA

of the organizational impact and the estimation of the expected costs of the new health technology.

Finally the results are presented and discussed. This is often done at a fourth meeting. Based on the presentation and discussion of the expected clinical outcomes, patient perceptions, and the organizational and economic impacts, a decision is made in the HTA unit whether to submit the mini-HTA in an application to

the management of the clinical department or the hospital management and ask for funding for the new health technology.

In some cases, clinical researchers at the hospital, often PhD students, have started a large clinical study of a new health technology and then find that an assessment of the organizational and economic outcomes could also be of interest. In that case, the HTA unit assists in changing the clinical trial into an HTA project and ensures that organizational and economic data are collected and reported in accordance with scientific guidelines. This can be a huge task, so it is often necessary to apply for new funding for these projects.

Overall this means that the HTA unit has extensive collaboration with the doctors, nurses, etc. from the clinical departments in the hospital. We use the clinical knowledge and expertise among the clinical staff and their knowledge about how the patients perceive the quality of the health technologies at the hospital. The clinical staff also have detailed information about how the different departments and parts of the staff are involved in the specific treatments and where organizational challenges can be expected when a new treatment is implemented.

The HTA unit is funded partially by the hospital management and partially from external sources. For the last 3 years, the unit has been involved in a growing number of assessments of telemedicine and health IT services. Examples include assessments of home monitoring of patients with COPD and patients with diabetic foot ulcers and IT systems for video conferencing and anesthesia patient recording. This has often been done as a part of large clinical trials of the outcomes of innovative technologies, where the HTA unit is responsible for the assessment of the organizational and economic impact. The funding for these projects often comes from the EU commission and from national Danish funding for innovative technologies.

## 4.3 Impact of HB-HTA

After more than 10 years of work, the HTA unit has had an impact on the view of HTA and evidence-based decision-making within the clinical departments at the hospital. Many clinicians are now trained in the production of mini-HTA and now consider mini-HTA to be a necessary and important basis for decision- making. The use of mini-HTA is now close to being systematic in a number of clinical departments. We have also seen examples of new technologies being rejected because of the lack of a mini-HTA. The annual number of mini-HTAs being produced at the hospital is unknown, but it is estimated to be around 20–40. We have been told that the annual number of mini-HTAs produced by other university hospitals in Denmark is about 40–50 per hospital.

On the other hand, you can still find clinical departments that are not familiar with the use of mini-HTA, and we also sometimes find mini-HTAs that are made too quickly and are of poor quality [4]. Therefore, in the future, we need to consider whether the production and use of mini-HTA should be more systematic.

At OUH we have annual discussions about the content of the mini-HTA form. If, for example, the reimbursement system is changed, this may result in a change in the questions about economic impact in the form. In other years, increased focus on patient safety has resulted in additional questions about patient safety. These changes are needed because the mini-HTA must always reflect the needs of the hospital and clinical managers. Based on the results of the AdHopHTA studies on hospital managers' information needs in decision-making [5], it was decided to add a question about the strategical aspects of new health technologies, but otherwise the mini-HTA form was considered to be largely consistent with the AdHopHTA results.

Why have we been at least partly successful? It is firstly because we are a university hospital with clinical staff familiar with systematic reviews and assessments of evidence and scientific publications; secondly, because staff have full-text access to most scientific journals and can find publications within with help from our local library; and thirdly, because the use of mini-HTA is required by the hospital management and mandatory as a basis for managerial decision-making.

## 4.4 Conclusion

After over a decade of work, the use of HTAs is now generally accepted in the clinical departments and has spread to other hospitals in the region. However, there is significant work still to be done before the use of HB-HTA is systematic.

The mini-HTA form is still considered relevant and a useful tool that is realistic for the clinical staff. However, annual revisions are still needed to ensure that the content is consistent with the needs of hospital and clinical managers.

More information on the work of the HTA unit can be found at http://cimt.dk/en/projects/htaandevaluation/.

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# Chapter 5
# Hospital-Based HTA at Radboud University Medical Centre in the Netherlands: Welcome to Reality

**Gert Jan van der Wilt, Maroeska Rovers, Wija Oortwijn, and Janneke Grutters**

## 5.1 The Role of University-Based Hospitals in HTA in the Netherlands

There are eight university-based hospitals in the Netherlands (ca. 17 Million inhabitants). These hospitals have played, and still play, a key role in the HTA that is carried out in this country. To understand their role in HTA, we briefly describe how HTA developed in the Netherlands.

HTA has been developing in the Netherlands since the early 1980s. The first HTAs were published in 1988–1989 and concerned evaluations of solid-organ transplantation programs (heart, liver) and in vitro fertilization. These were conducted by university-based hospitals and funded by the National Healthcare Insurance Board, now the Health Care Institute (ZIN) [1]. At that time, HTA capacity was being developed at various university-based hospitals (e.g., Erasmus University Medical Centre in Rotterdam, State University of Groningen Medical Centre), rather than in national agencies (such as the Health Council or ZIN). Thus, a decentralized model developed, with studies being conducted in close collaboration between clinicians and HTA researchers.

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An important impetus for HTA conducted by university-based hospitals in the Netherlands was the launch of a national HTA program in 1988. This program, called the Investigative Medicine Fund, was administered by ZIN until 1999. The fund was, in fact, a "coverage with evidence development" program *avant la lettre*. It was launched by the government to gain better control of high-impact innovative medical technologies, such as the cochlear implant for deaf adults and children, extracorporeal membrane oxygenation for neonates, and stem cell transplantation. The program facilitated the establishment of an HTA unit at all eight university-based hospitals. In 2000, the Investigative Medicine Fund was transformed into a national research program for healthcare efficiency research, administered by the National Organization for Health Research and Development (ZonMw) [2]. The program is funded by the Ministry of Public Health, Welfare and Sport for a cycle of 3 years. Currently, the program for the years 2016–2018 is being implemented. The program has a budget of € 29 M [3]. The program has evolved over the years, moving from a more academic focus toward a program that addresses the needs of healthcare professionals, patients, and policymakers. It aims to provide an evidence base for innovative interventions so they can be introduced responsibly and to help ensure that inefficient interventions are no longer used (disinvestment). Researchers can apply for funding either through an open or targeted call. In the open call, proposals can be submitted on (a) early evaluation of promising interventions, either in the context of research or in a single hospital or (b) evidence generation for guideline and insurance coverage. This means that in the open call, there is scope for HB-HTA. In the targeted call, research is conducted that is either linked to conditional funding by ZIN or policy relevant research focusing on efficiency issues [3]. Examples of projects funded by the program that have led to changes in health practice include the use of less mediastinoscopies and thoracotomies in staging patients with lung cancer and a change of IVF practice [4].

In addition to the Health Care Efficiency Research program, university-based hospitals in the Netherlands conduct HTA for investment decisions, as described in this chapter. HB-HTA is also used for investment decisions in cross-border regions, for example, to purchase cyclotrons and laboratories for the production of radiopharmaceuticals for university-based hospitals in the region of Maastricht/Aachen (Netherlands/Germany) [5].

**Box 1: Health Care System Context**

- The funding structure is highly complex. The Netherlands are evolving toward a system of managed competition. All Dutch citizens aged 18 years and older are obligated to obtain healthcare insurance. Healthcare insurance organizations (there are 4–5 of them, resulting from large-scale mergers) are required to accept any citizen as an insuree. The entitlements are laid down legally. Healthcare insurance organizations are risk bearing and mutually competitive. Yet, only part of the costs of healthcare is funded in this way. A large part is through taxes and premiums for long-term care, and another part is covered from private contributions (co-payments).

- Hospitals are funded through a pay-for-performance system. The maximum annual number and the reimbursement for services (a variant of diagnosis-related groups) are negotiated between hospitals and healthcare insurers. University-based hospitals receive additional funding from the Ministry of Public Health, Welfare and Sports and from the Ministry of Education, Culture and Science to cover costs of training, education and research, and development
- Decisions about which drugs, devices, and equipment are funded are made by the Ministry of Public Health, Welfare and Sports. In addition, the National Health Care Institute (ZIN) has a legal advisory task; it hosts the National Appraisal Committee which has an advisory role in reimbursement issues.

## 5.2 Our View of Hospital-Based HTA

Hospital-based HTA (HB-HTA), in our view, does not distinguish itself from general HTA because of the location where it is conducted (hospitals), but because of its perspective. It asks what consequences adopting (or, at least in theory, abandoning) a specific healthcare technology may have for the hospital as an organization. To answer that question, it needs to take into account the context in which the hospital operates. To illustrate what we mean, take the case of photodynamic therapy (PDT) in the treatment of patients with basal cell carcinoma (BCC) as an example. An HTA would typically synthesize the available evidence from RCTs, cohort studies, case-control studies, etc., to draw conclusions whether PDT may be considered a safe, clinically and cost-effective modality in the treatment of BCC. In other words: is it, on the available evidence, plausible to assume that the burden of disease would be reduced and that quality and efficiency of healthcare would be improved, if PDT, rather than other treatment modalities would be used in the treatment of BCC? If this were the case, recommendations would be developed, specifying for whom, when, and under what conditions PDT should be considered in the treatment of BCC. Also, quality criteria might be set up, qualifications might be defined for those who are entitled to use PDT, and arrangements would have to be made for adequate funding of the treatment. In our view, HB-HTA takes the assessment further from here. If it has been established that in general, PDT could be of added value in the treatment of patients with BCC, HB-HTA would seek to answer the question whether this potential value could be realized in the context of a specific hospital in a sustainable way. To answer this question, it will try to find an answer to a number of context-specific questions, including the following:

- Are patients with BCC currently already treated in this hospital? If so, how many and what sort of treatment is currently being offered to these patients? Where and in which department are these patients currently treated (e.g., the department of dermatology, ENT, general surgery, plastic surgery, etc.)?

- Will current treatments be (fully) substituted by PDT? What consequences will this have for the organization and its staff? Will operating room capacity be liberated? If so, are there ways of using this capacity alternatively?
- Would it be necessary to make investments (e.g., in order to purchase the equipment, to train personnel, to make building adjustments, etc.)? Are we likely to recoup those investments? What is the return on investment? What is the remuneration that will be obtained from third-party payers, and how do these compare to variable and fixed costs to the hospital (business case)?
- Who else is offering PDT?
- Could PDT be offered by a specialized nurse, supervised by a dermatologist? Would that be legally acceptable? Are there any risks associated, including liability?
- Who is the manufacturer? Can deals be made regarding purchasing of equipment, training of personnel, and research facilities?
- What is the position of third-party payers regarding PDT? Would it bring competitive advantage to them to cover the costs of this type of treatment?
- Would PDT for patients with BCC offer interesting opportunities for further research, for training residents, medical students, etc.?
- Would this fit into our profile? Is oncology among our spearheads?
- Is the incidence of BCC likely to increase in the near future? Are there any other conditions that could be treated with PDT (e.g., actinic keratosis)?
- Are there any technological developments under way that might render PDT obsolete within a couple of years?
- Could it be argued that PDT is, from a societal perspective, the better option?
- Is it reasonable to assume that patients with BCC should be treated in university-based hospitals? Is it likely that this type of care will be increasingly shifted to primary care?

In other words, HB-HTA aims to answer questions relating to sustainability, feasibility, legal context, work force, funding, economic viability, and the opportunity costs from the perspective of a specific hospital. PDT may be an attractive option in the treatment of patients with BCC from a societal perspective; there may be reasons (related to the specific context) why this is not the case from the perspective of a specific hospital. The opposite may, of course, also be true. HTA, then, provides an indication of the potential value of a healthcare technology; HB-HTA provides an indication of the actual value of the technology in a specific context. The distinction is somewhat similar to the distinction between efficacy and effectiveness: the performance of a healthcare technology under ideal conditions vs. the performance of the technology under real-world conditions [6]. Partly, it is also the reason why it has been argued that the acronym ICER does not stand for Incremental Cost-Effectiveness Ratio, but for Information Created to Evade Reality [7]. The evasion of reality partly derives from the fact that several factors from the decision makers' context are not taken into account in HTA, including budgetary constraints, actual opportunity costs, and limitations in reallocation of resources. HB-HTA aims to

attend to this shortcoming by taking into account the specific local, regional, and national context in which hospital decision makers need to operate.

## 5.3 The HTA Unit at Radboud University Medical Centre

Radboud University Medical Centre is one of the eight university-based hospitals in the Netherlands. Its HTA unit was established in 1993. It is part of the department of Health Evidence, which, alongside HTA, encompasses epidemiology and biostatistics. The unit also participates in the Radboud Centre for Health Economics, a collaboration with the department of Primary Care and the Institute for Quality in Healthcare. The HTA unit consists of ca. 20 researchers; its priority areas are early HTA, participatory evaluation, and global health. Apart from research, it is involved in teaching in the area of HTA, including a master of HTA for students of biomedical sciences, evidence-based practice for students of biomedical sciences, students of medicine and students of dentistry, a Radboud Summer School course on Participatory Evaluation in Healthcare, and an E-learning course on HTA and ethics. It is funded internally by the Radboud University Medical Centre for its teaching activities and externally through grants mainly from the National Organization for Health Research and Development (ZonMw) (e.g., adrenal vein sampling in the diagnosis of patients with aldosteronism; whole exome sequencing in the diagnostic workup of children with complex neurological disease), the National Healthcare Insurance Board (ZINL) (e.g., left ventricular assist devices (LVADs) as a destination therapy for patients with end-stage heart failure; transcutaneous electrical nerve stimulation (TENS) in the treatment of chronic pain), the Health Council (e.g., disinvestment/reinvestment strategies for university hospitals to improve efficiency of healthcare), and the European Commission (e.g., EUNetPaS and INTEGRATE-HTA). Apart from these, the HTA unit aims to contribute to further development of HTA methodology (e.g., development and testing of a tool for the early HTA of medical devices, Bayesian analyses to synthesize complex information in the support of policy making, scoping as a means to collaboratively develop relevant questions for research, and HTA methodology for personalized care).

### *5.3.1 Projects Commissioned by the Hospital Board*

In addition to externally funded projects, the HTA unit conducts projects that are commissioned by the hospital board. These include a wide range of safety, efficiency, and organizational issues, e.g., the cost-effectiveness of helicopter-assisted prehospital trauma care, auditing of pediatric cardiac surgery, and utilization of emergency operating room facilities. Typically, such projects involve activities

where multiple clinical departments are involved (e.g., the departments of emergency care, anesthesiology, intensive care, surgery, etc.). Smaller projects are commissioned by individual departments, e.g., the economic viability of developing a novel renin test using mass spectrometry (department of clinical chemistry). Below, two case studies are presented, illustrative of the type of questions that are being asked, the methods involved, and the results and impact on decision-making.

**Case Study 1: Routine Screening of Patients for Radiotherapy-Induced Carotid Artery Vasculopathy and Related Stroke**

*Background*: At the department of neurology of our hospital, patients were seen with neurological symptoms (carotid artery vasculopathy and related stroke) that were attributed to previous radiotherapy for head and neck cancer. The number of patients that were seen with this type of complications was such that neurologists wondered whether these patients should be routinely screened for radiotherapy-induced long-term vascular complications. Although several reports have been published on the incidence of radiotherapy-induced vasculopathy [8], no reports were found of the clinical and cost-effectiveness of preventative strategies.

*Study commissioned by*: Department of Neurology, Radboud University Medical Centre.

*Methodology*: Decision-analytic modeling (Markov and Monte Carlo). In this model, data on the incidence of vascular complications after radiotherapy from our own hospital were combined with data from the literature on complication rates and effectiveness of cardiovascular risk reduction. Screening consisted of a one-off examination for risk factors, followed by treatment according to national guidelines (e.g., counseling, antihypertensives, and statins). Estimates of costs were based on data from our own hospital, combined with data from the literature. A time horizon of 10 years was used; in a sensitivity analysis, the impact of varying key model parameters (e.g., risk of stroke, health impact and costs of stroke, risk reduction as the result of screening, compliance, etc.) across a wide range of plausible estimates was explored.

*Results*: The results of our modeling study showed that, across a wide range of model assumptions, a one-off screening for risk factors for radiotherapy-induced carotid vasculopathy was unlikely to be cost-effective, given current standards for cost-effective healthcare in the Netherlands.

*Comments*: Although it intuitively makes sense to identify patients who are at increased risk of sustaining radiotherapy-induced vasculopathy, such a preventative strategy is unlikely to be a wise use of a community's resources. It was therefore decided not to pursue this initiative further. If, on the contrary, our modeling study had suggested that this might be a clinically and

cost-effective strategy, next steps would have been an estimate of the number of patients that would be eligible for such one-off screening for cardiovascular risk factors at our hospital annually; optimization of the process (When should the screening be performed, where, and by whom? Would patients with increased risk and who are being prescribed treatment be monitored? How and by whom?); an analysis of costs in relation to what healthcare insurers might be willing to reimburse; etc. In other words, the modeling exercise would have been followed by a business case, asking whether the suggested preventative strategy would be economically viable from the hospital's perspective.

**Case Study 2: Use of Barcode Technology in Preventing Medication Errors in the Operating Room**

*Background*: Medication errors are an important cause of potentially avoidable morbidity and mortality in healthcare. Each year, in Britain and the United States alone, hundreds of thousands of patients are injured, tens of thousands are killed, and billions of Euros are spent on healthcare that is being provided as the immediate result of medication errors [9]. These errors often occur during the preparation and administration of medication [10]. One context where many potentially serious errors are made is the operating room (OR) of hospitals. Recently, technology has been developed that aims to reduce medication errors through barcode scanning of medications, reading aloud the medication, and dosage and printing a label of the appropriate dosage in the appropriate color with Tall man lettering.

While in theory, this type of health information technology is likely to be beneficial in reducing medication errors, adopting such technology in healthcare has proven to be difficult [11, 12]. Two types of objections are typically made to the introduction of safer drug administration systems [13]. A first and important objection is that of denial: no safety devices are needed because the presence of the doctor is seen as the ultimate safety device. This seems to suggest that doctors do not make errors, and safer drug administration systems will therefore not yield any health benefits. A second objection relates to costs. Typically, these technologies require considerable investments. Hospital budgets are constrained, and hospital managers need to choose between a variety of solutions that might improve patient safety, including training and the development and implementation of protocols.

*Commissioning organization/objective*: Department of Anesthesiology; to inform the decision whether or not to implement the new technology in the OR.

*Methodology*: Decision-analytic modeling. The model was constructed based on a review of published literature and consultation of various stakeholders. In the model, errors could be made when preparing or administrating anesthetics in the OR. These errors could be with or without consequences for the patient, and these consequences could be mild or serious. Based on available literature, healthcare costs of errors which had consequences for the patient were set at €1,495. Differences in personnel costs, costs of current labeling technology, and societal costs of error were not taken into account. Two scenarios were drafted: one where the technology prevented all errors, representing the maximum potential health benefit and cost-effectiveness, and a more realistic scenario where the technology prevented 45 % of errors. Sensitivity analyses were performed to explore the impact of changes in the inputs on the results. Results were presented per OR per year and specified for our hospital with 35 ORs and an average of 585 operations per OR per year.

*Results*: Based on the evidence synthesized in our model, we predicted that currently, in our hospital 21 medication errors are made per OR per year. Of these, 11 have consequences for the patient, including 6 with serious consequences. The estimated costs of these errors add up to €16,056 per OR per year. Assuming that the costs of the technology amount to €2,015 per OR per year, the maximum potential cost savings are €14,041 per OR per year. In the more realistic scenario of the technology, where 45 % of the medication errors is prevented, the potential health gain is nine errors, including three with serious consequences. The potential cost savings of the technology in this scenario are €5,210 per OR per year. In total, our model estimated that 723 errors are made each year in our hospital. In the realistic scenario, the technology could save our hospital €182,360 each year. The model also showed that 12 % of the medication errors related to anesthetics in the OR need to be prevented in order to be cost saving (threshold analysis).

*Comments*: The modeling analysis suggests that from a societal perspective, introducing barcode scanning in the OR could be an attractive option, helping to reduce medication errors and associated costs. However, it is not self-evident that this is also true from the hospital perspective. Firstly, implementation may fail as long as key players deny that there is a problem in the first place. Extra efforts may be needed to gauge and, if necessary, correct the views of key players in the hospital. If implementation fails, costs are incurred without appreciable benefits. Secondly, a wide variety of options exists to reduce medication errors, such as better communication, double check systems, and training. Thus, if decision makers decide to make reduction of medication errors a priority, they still need to select among these various options. Often, this is hampered by the lack of comparative data on effectiveness and costs. Thirdly, introducing a novel technology may require changes in clinical practice that are difficult to realize. For example, individual vials need to have barcodes that can be scanned by the technology. This is not yet common

practice in the Netherlands but is expected to be so in a few years time. Until then, barcodes need to be added by the pharmacy to individual vials. Hence, close cooperation between pharmacists, anesthesiologists, and specialized nurses is required. However, probably the most prominent hurdle for implementation of the technology is the funding system in the Netherlands. In this particular case, the department of anesthesiology needs to invest in the technology, but the potential savings will not be realized by the department. On the contrary, when errors are made that result in prolonged hospital stay, the patient enters a different diagnosis-related group with a higher reimbursement rate. Thus, there is no financial incentive for the hospital to invest in measures that aim at further reducing medication errors. An option that might be explored is to share savings among the hospital and the third-party payer. A drawback of this might be that this would unduly advantage hospitals with poor current performance and the administrative costs of implementing such a system may be substantial. However, difficulties that may arise when introducing this technology in a hospital setting need to be acknowledged, and HB-HTA can produce such information that is of crucial importance to key decision makers.

## 5.4 Impact on Decision-Making

Since its inception in 1993, the HTA unit at Radboud University Medical Centre has been called upon by virtually all clinical departments and the board to help them assess the comparative value of a wide variety of healthcare technologies. Increasingly, this is done to support major investment decisions in our hospital. Although we have not explored this formally (e.g., using surveys), the increasing demand and the shift toward supporting investment decisions may be considered an indication of actual impact. This may also be inferred from the *timing* of the HTA. For example, the HTA unit was recently asked to conduct an assessment to support decisions concerning the development of new photospectrometric diagnostic tests. From a hospital perspective, this is an interesting case. The strategic decision to procure novel, state-of-the-art spectrometric technology had been made at an earlier stage by the department of clinical chemistry. The spectrometric device can be used to develop novel diagnostic tests with better test performance than those currently in use. When successful, the development of such novel tests can actually help to recover the initial costs of the acquisition of the spectrometric device. However, the development, standardization, and validation of such novel spectrometric diagnostic tests require substantial further investments. The question is, then: can an estimate be made *in advance* of the likely return on investment? To address this issue, a survey was conducted to take stock of potential areas of application for such novel spectrometric tests. For selected applications, an analysis was made of

the effectiveness gap: to what extent does the current diagnostic practice result in suboptimal health outcomes? Such an analysis reveals the scope for improvement. Taking into account production costs, reimbursement, and volume, an estimate was made of the return on investment of specific decisions [14]. This has resulted in pursuing the development of a selected number of novel spectrometric tests. Another example of impact is the involvement of the HTA unit in prioritizing innovations in hospital care that have the potential of improving quality without incurring higher costs. To support such decisions, business case analyses will be conducted. Increasingly, the involvement of HTA in this type of decisions moves from an ad hoc basis to a more structural type of involvement, e.g., by incorporating HTA as input for the procurement board.

## 5.5 Some Conclusions and a Vision for the Future

University-based hospitals have played a significant role in HTA in the Netherlands. This is not to say that these organizations have been particularly focused on HB-HTA, as defined in this chapter. Many HTAs are aimed at establishing the potential value of a healthcare technology. To examine whether such potential value is likely to be actually realized requires a thorough analysis of the context in which a healthcare technology is to be used. This may involve issues of supply and demand, funding arrangements, cultural aspects, etc. In our view, HB-HTA renders HTA more realistic by taking into account the context in which hospital managers need to make decisions. In doing so, slightly different methods of analysis may be called for, such as Program Budgeting and Marginal Analysis [7]. Currently, HB-HTA in the Netherlands seems to be mostly ad hoc, and not well integrated into decision-making processes at a hospital level. At Radboud University Medical Centre, making HTA a structural element of the Procurement Board is currently being considered. The Procurement Board is chaired by a member of the hospital board. It reviews all major investments (e.g., the purchasing of a da Vinci robot) ex ante. Embedding HTA in this way structurally in a hospital's organization could be an important way to enhance the usefulness of HTA to decision-making in healthcare. It would be an interesting challenge to see how these organizations might strengthen their collaboration in learning how to examine decision-making contexts and what lessons could be learned that apply more generally. Also, it might considerably improve our understanding why national strategies to improve efficiency, safety, and appropriateness of healthcare sometimes fail as the result of insufficiently taking into account local and regional decision-making contexts.

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# Chapter 6
# Hospital-Based HTA in Three Spanish Hospitals

**Laura Sampietro-Colom, Marcelo Soto, Cristina García, and Soledad Benot**

## 6.1 Introduction

The development of health technologies (HTs), especially tests and medical devices, is mainly targeted to hospitals. As main receptors of these technologies, hospitals need to choose the proper mechanisms and procedures that can help them to make sound decision in investments on HTs. The type of mechanisms and procedures chosen depend on the characteristics of the health-care system where the hospital is placed, their own organizational structure, as well as values and cultural determinants.

Health and health care in Spain is stated as a right by the Spanish Constitution, passed in 1978, health being considered both a private and public good. Spain has a National Health System, with universal coverage, free at the point of delivery. The 17 Spanish Autonomous Regions have complete power regarding public health, health-care planning, financing, and provision of health care. Health-care funding comes mainly from taxes, with the exception of small co-payments for ambulatory drugs and out-of-pocket payments for OTC and dentistry. The Spanish public health spending for hospitals and specialized care represents 56 % of the total health-care

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budget [1]. Physicians working at public hospitals are paid by salaries; in some autonomous regions the salary is complemented by a variable payment which aims to encourage quality and productivity. Box 6.1 summarized key elements around hospital funding and mechanisms for introducing health technologies.

**Box 6.1. Key Characteristics of Spanish Health-Care System Around Hospitals and Health-Care Technologies**

- Spain has a National Health System funded through taxes.
- Hospitals receive annual budgets based on historical budgets and contracted activity. The amount of budget received depends on the level of hospital (university hospitals, general hospitals, community hospitals).
- Decisions on drugs covered by the public health system lay on the government of the autonomous region. Hospitals have by law a drugs committee in charge of deciding, from public-covered drugs, which drugs will be included in the list of drugs provided by the hospital. Regarding medical devices and capital equipment, in general, each hospital is free to decide on their investment. Nevertheless, for some very expensive capital equipment that requires extra funding from a public payer (i.e., regional government), consultation with them is required.

Health technology assessment (HTA) has a long history and solid grounds in Spain [2, 3]. Nowadays, seven autonomous regions' HTA agencies (from Andalusia, Aragon, Basque Country, Catalonia, Galicia, Canary Island, Madrid) and representatives from the regional health-care administration of the remaining ten autonomous regions constitute the Spanish Network of HTA Agencies. Its main aim is to answer informational requirements from the Spanish Ministry of Health regarding the feasibility and opportunity of introducing new health technologies in the public health-care portfolio [4]. Nevertheless, the final decision on the introduction of types of medical devices and capital equipment rests at the local or hospital level (depending on the region).

The ways that Spanish hospitals take decisions on HTs are very heterogeneous across the country. In most hospitals, decisions on investing in new medical devices (MD) are made by the chief of a clinical department or by the chief medical officer (CMO) or by the chief executive officer (CEO) based on information provided by the clinician requesting the MD, complemented by some basic economic figures. In some hospitals, a committee for the evaluation of health technologies exists. These committees are composed of physicians from different clinical specialties in charge of deciding which new HTs can be introduced in the hospital; recommendations are mostly based in a narrative summary of scientific information provided, in some cases, by the epidemiology department in collaboration with the clinician asking for the HT. Final decisions are taken by deliberation and consensus. This system constitutes an intermediate step between the nonsystematic and somehow random

mechanism explained above for investment decisions and the most solid and structured base of getting robust information, which is provided by hospital-based HTA (HB-HTA). HB-HTA is a structured, comprehensive, and context-based process to provide hospital decision-makers with the needed information for investment [5]. It follows internationally recognized processes and methods for HTA with a more fit-for-purpose approach [5]. Since HB-HTA is context dependent, its organization and performance varies across hospitals.

Although HTA is very well known by hospital doctors and managers, due to the long tradition of HTA agencies in Spain, HB-HTA is still in its early phases, but is increasingly gaining the interest of hospital decision-makers [6]. No formal mandate in the autonomous regions exists for implementing HB-HTA. This chapter aims to explain the HB-HTA experiences of three very different Spanish hospitals. The Hospital Clinic of Barcelona (HCB) is a high-tech university hospital in Catalonia; it has 4,500 employees (600 physicians) and 666 beds. The hospital has a unique organizational structure. It is organized in nine clinical institutes, each comprising several clinical departments (e.g., traumatology, rheumatology, rehabilitation, maxillofacial surgery), and two institutes that provide support to these nine institutes (i.e., diagnostic imaging institute and biomedical diagnostic institute). Clinical institutes function as small hospitals inside the HCB, each having a clinical director and a financial director. The other hospital is the Virgen del Rocio and Virgen de la Macarena hospitals (VR&VM), which are two university hospitals in Andalusia that recently have merged in a common management. Together they have 12,860 employees and 2237 beds, and are the largest hospitals in Spain. The hospitals are organized in clinical departments that report to the general management of the hospital. Finally, the Hospital Sant Joan de Dèu (HStJD) is a general hospital inside a health-care network (Parc Sanitari Sant Joan de Dèu); it has 292 beds and 800 employees. The hospital provides basic, and some specialized health care, and is organized through clinical departments reporting to general management.

## 6.2 Organizational Characteristics of HB-HTA

Since differences in context exist among hospitals, HB-HTA is differently organized. At the HCB, an HTA unit was created 8 years ago under the Innovation Directorate. This stand-alone HB-HTA unit [5] carries out HTA reports for the 11 clinical institutes of the hospital. Therefore, it is a support structure, working across institutes, which reports directly to CMO and the CEO of the hospital. The team of the unit includes a medical doctor (the head), a health economist, and a public health scientist. The unit works in close collaboration with the clinician asking for the HT and the financial director of his/her clinical institute, making the proper recommendation. Final decisions on the introduction of the HT are taken by the clinical director of the institute based on the recommendation made in the HB-HTA report; no participation in decisions regarding HT from clinicians working in other clinical institutes exists. On the contrary, the VR&VM hospitals' HB-HTA is based on a

joint commission for HTA (coming from the old commission at the VR hospital—from 2002). Members of the commission include clinicians from different backgrounds (internist, pediatrician, rehabilitation, thoracic surgeon, intensivist, pharmaceutical, biochemical specialists) and public health and an epidemiologist specialist. The commission is led by a medical doctor expert in HTA. The commission is in charge of approving or rejecting the proposed HTs that want to enter the hospitals, irrespective of the clinical specialty; in other words, the recommendation is made by the commission, and the final decision is made by the CEO of the hospital. In the same way, the HStJD has an HTA Committee that recommends on any type of HT proposed to be introduced in the hospital. Nevertheless, here members of the HTA Committee include the head of quality, a psychiatrist expert in health economics, the head of research, a nurse manager, a librarian, and a surgeon (the chair of the committee); although each member of the committee represents a specific area of expertise needed for HTA, their main job is clinical practice. The HTA Committee is coached by the head of the HTA Unit at HCB, who attends all the meetings. This committee makes recommendations and raises it to the hospital steering committee for final decision.

Common features from the three hospitals include provenance of the request for assessment, funding of the unit/program, and enforcement of the recommendation on final decision. Requests for new HTs come mainly from individual clinicians, who usually participate in the meetings (either during the assessment or in deliberations); nevertheless, sometimes the request directly comes from the CEO, the CMO, or the financial director. The hospital budget is the main funding source for the HB-HTA unit/program. This funding is mainly for the salary of the head of the unit/program; funds for other members of the team, who are not contracted as clinicians by the hospital, come from competitive grants. Finally, all the recommendations made by the HB-HTA unit/program are advisory and nonmandatory; nevertheless, rarely a recommendation is not adopted by final decision-makers.

Recently, according to the Andalusia Health Services regulations [7], the HTA unit at the VR&VM hospitals has been granted to lead an HTA Provincial Committee (i.e., for the Seville province) which includes representatives of all the hospitals of the province plus professionals of the local administration. This new committee aims to support the local administration on decisions for investment in new HTs. The positive recommendations will be raised to the manager of the local purchasing logistic platform for its acquisition.

## 6.3 Characteristics of the Assessment Process

The person/team that performs the assessment differs between hospitals. The HB-HTA at the HCB is in charge of the entire assessment process. Doctors informally contact the unit for an assessment, and prioritization of assessments is made on a first-in first-assessed basis. Nevertheless, parallel assessments are usually carried out due to demand. Professionals at the HB-HTA unit perform the assessment

(i.e., search and review of the literature, economic analysis, organizational impact, etc.) in close collaboration with both the clinician requesting the HT and the financial director of the clinical institute. Regular meetings are scheduled along the assessment (on average, three meetings per assessment; in the first meeting the scope of the assessment is done), and the final recommendation is taken by consensus based on the results of the HB-HTA report. The same process is followed by the HStJD, with the difference that the assessment is made by the members of the HTA Committee (sharing work on expertise basis) also in close collaboration with the requesting physician. In the case of the VR&VM hospitals, in addition to the HTA tool, an electronic software is used for requesting assessments for specific HTs [8]. The information is complemented by economic and organizational information. Specific selection criteria are used to identify appropriate HTs to be assessed (Fig. 6.1) [9].

Several tools and procedures are used for the assessments. An adaptation of the mini-HTA tool, developed in 2005 [10], is used by HCB and the HSJD. The

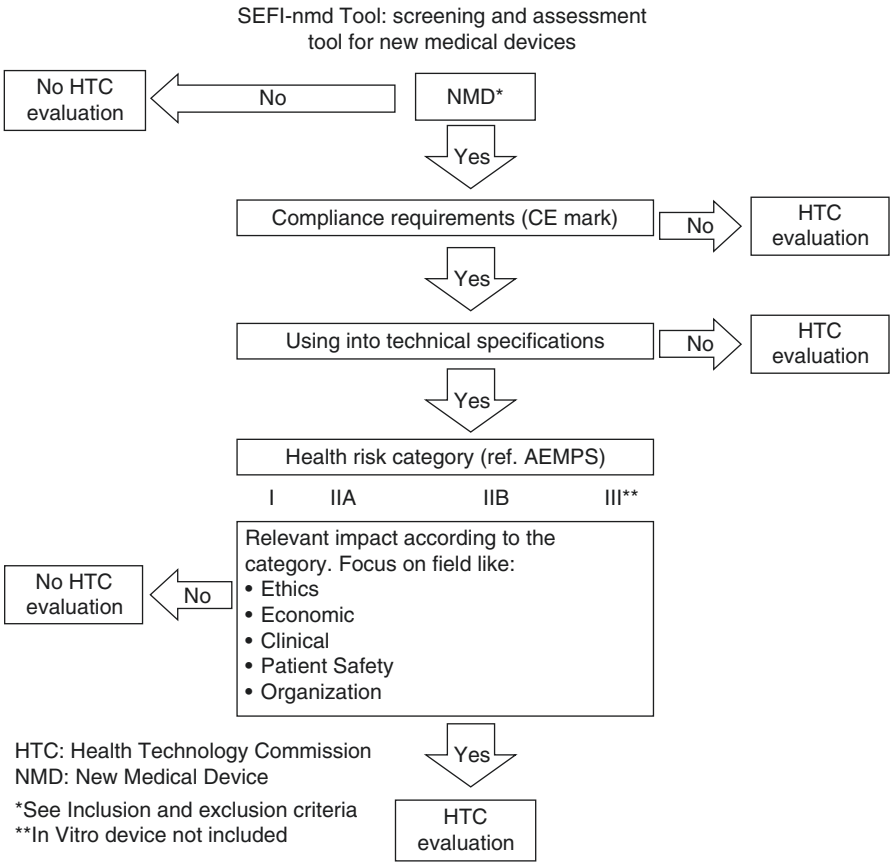


**Fig. 6.1** Selection criteria for health technologies asking for assessment at the Virgen del Rocio and Virgen de la Macarena hospitals [9]

mini-HTA provides hospital decision-makers with comprehensive information including a description of the new HT, scientific evidence, impact on patient, economic impact, and organizational impact [10]. The tool used by the VR&VM hospitals was developed in 1999 by the Andalusia HTA Agency, and recently updated, to help hospitals in their decisions regarding HTs [11].

Methods used to produce the assessment follow conventional HTA methods [12, 13]. All reports made by these hospitals include a review of the scientific literature. Nevertheless, when an HTA report from an national/regional HTA agency already exists for the HT being evaluated, the review of the literature is adopted, with an update of scientific literature, when needed. If no HTA report is available, the review is made from scratch. As regards the economic evaluation, VR&VM hospitals and HStJD mainly carry out cost analysis. The HCB perform all types of analysis including cost-effectiveness (using natural units of effectiveness, e.g., patients corrected diagnosed), cost utility (using quality adjusted life years), cost minimization, and cost analysis. The selection of the economic analysis to perform is influenced mainly by the available evidence on the new HT and its comparator, as well as by the request of the clinician (who is the one who select the effectiveness measures at the beginning of the assessment scoping). All hospitals perform a budget impact analysis, and this is very relevant information requested by hospital decision-makers [5]. Organizational determinants are always included in the HB-HTA reports; this is a key element to inform the final decision since, for example, an HT may appear to be cost-effective, but could impact highly in the organization of care, and, therefore, its introduction could be difficult to implement (e.g., adapting new clinical pathways, changing professional responsibilities, etc.).

Though assessments of HTs are usually done using published data, the worldwide movement to move the inputs from HTA specialists early in the stage of development of the HTs [14], is placing the hospital as a field camp to produce the needed information for HTA. The HCB has set up strategic alliances with several HT developers in the quest to obtain robust and fit-for-purpose HTA information. HTA inputs and methods are included in the clinical trials and in the analysis of their information (e.g., cost-effectiveness analysis). The relevant characteristic of this approach is that the studies are considering real clinical and cost data from a hospital, improving the external validity of results to similar hospitals.

All hospitals mainly assess medical devices (medium and small size), diagnostic tests, and capital equipment. Drugs are assessed exceptionally, since all hospitals have a drug committee, stated by law [15], in charge of assessing and deciding on the new drugs to be prescribed in the hospital. Table 6.1 shows examples of HTs assessed by the three hospitals. The level of innovativeness of HTs to be assessed depends on the type of hospital. For example, HStJD being a general hospital usually assesses HTs that are already available in other hospitals of the region but which are new for them (e.g., laser for prostate cancer), while HCB and VR&VM hospitals being high-tech hospitals usually assess more innovative and sophisticated HTs (e.g., robots). The HTs assessed belongs to the different clinical specialties in the hospital. Percentage of HTs assessed from one or other clinical specialties differs among hospitals. For example, 45 % of the HTs assessed by VR&VM hospitals

**Table 6.1** Examples of health technologies assessed by the Spanish hospitals: Hospital Clinic of Barcelona, Hospital Sant Joan de Dèu, and hospitals Virgen del Rocio and Virgen de la Macarena

| Health technology | Clinical area |
|---|---|
| **Capital equipment** | |
| Frameless stereotaxy | Neurosurgery |
| Intraoperative radiation therapy with linear accelerator (breast cancer) | Oncology |
| Da Vinci robot (prostate cancer) | Urology |
| Robot APOTECAchemo (production oncologic preparations) | Pharmacy |
| MRI screening for breast cancer | Oncology |
| **Medium-sized medical devices** | |
| Deep brain stimulation (Parkinson, other dystonia) | Neurology |
| Semiautomatic metaphase locating and on-screen karyotyping system | Biochemistry |
| Circumferential epithelial RF ablation for Barrett's esophagus | Gastroenterology |
| Autologous platelet gel (for total knee arthroplasty) | Orthopedic surgery |
| Orthosonic system for cemented arthroplasty revision | Orthopedic surgery |
| Extracorporeal shock wave therapy for nonunion long bones | Orthopedic surgery |
| Left ventricular assistive device | Cardiology |
| Implantable medical device for hypertension | Cardiology |
| Electrochemotherapy (melanoma) | Dermatology |
| Laser (prostate cancer) | Urology |
| Video head impulse test (VIHT) (vertigo) | ENT |
| **Small medical devices** | |
| Multigene assay test (for breast cancer) | Oncology |
| Reusable electrosurgical device for bipolar vessel sealing | General surgery |
| **Diagnostic tests** | |
| Diagnostic test for nonalcoholic fat liver disease (steatosis) | Hepatology |
| Diagnostic test for prostate cancer | Urology |
| Point of care test for flu diagnosis | Infectious diseases |
| Point of care test for catheter-related infection | Infectious diseases |
| Diagnostic test for liver fibrosis | Hepatology |

belong to genetic tests (16%), pathological anatomy (15%), and general surgery (14%) [8], while the 46% of the HTs assessed by the HCB belong to the clinical areas of oncology (18%), orthopedic surgery (14%), and neurology (14%) [16]. These differences surely respond to the different contextual determinants; for example, genetic tests were considered by the VR&VM hospitals as key HTs to be assessed, and, therefore, a strict and systematic follow-up and assessment was implemented in these hospitals.

The recommendation from HB-HTA reports in Spanish hospitals provides a range of potential options to support final decision; these options are based on the results provided by the analysis as well as, in some cases, considering the mandate of the hospital. For example, in the deliberations for final recommendations at the HCB, the variable "innovativeness" is very relevant; being a high-tech university hospital, one of its main mandates is to innovate in health care. Therefore, HTs that are new

for the hospital but could already be present in other hospitals of the geographical area could not have a strong recommendation. The range of recommendations provided to hospital decision-makers also differs by hospitals; some examples are as follows: accepted, accepted under specific circumstances (clinical indication and implementation), accepted with negotiation of prices, accepted but need to be followed up (for 1 year or more), accepted under research protocol (purchasing of HT could be done by hospital or through research funds or lending by company), no acceptance, and future assessment needed (reasons: lack of basic requisites, scarce evidence on effectiveness, the HT that could be effective but is not cost-effective).

Finally, at the top hospital decision-making, choices among HTs from different clinical specialties often should be made after assessment. When several HTs are competing for a piece of the hospital annual budget, the top hospital decision-makers should choose on sound grounds coming from the assessments performed. To facilitate these types of decisions, the HCB has elaborated the so-called Matrix4Value, based on the results from the mini-HTA of each HT assessed [17]. This matrix plots the result from the assessments of HTs in a graphic where the *Y*-axis represents the risk for the hospital to introduce the HT (considering the following variables of the mini-HTA tools: staff need, impact in physical space, impact on the organization of health care, incremental cost, net cost, and investment effort for the institute/hospital), and the *X*-axis represents the benefits the introduction of this HT could have for the hospital (including the following variables: safety, clinical benefits, patient impact, cost-effectiveness, quality of evidence, and level of innovation). Figure 6.2 shows an image of the matrix.

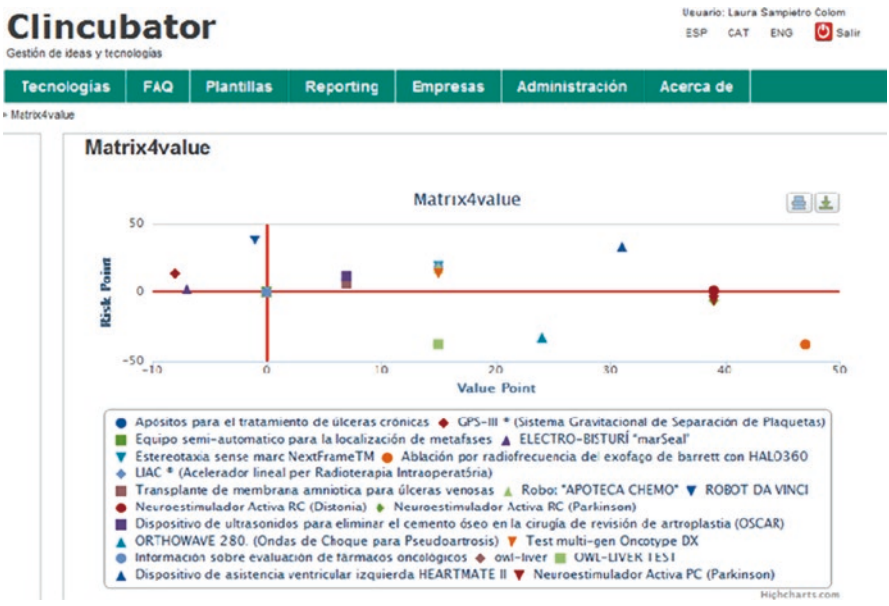


**Fig. 6.2** Matrix4Value: mini-HTA-based algorithm which discriminates across HTs assessed [17]

## 6.4 Impact of HB-HTA

The aim of HB-HTA is to contribute to the improvement of the quality of hospital health care. This contribution will be attained by making HT recommendations that mainly improve patient outcomes, while keeping the economic sustainability of the hospital. However, it is very difficult to evaluate the cause-effect relationship between HB-HTA and clinical outcomes since the achievement of final desired clinical outcomes usually requires a long follow-up, and, therefore, this cause-effect relationship could be confounded or masked by multiple noncontrolled variables [5]. Nevertheless, there are a series of short-term and midterm impact variables that can be measured, which can be surrogates of the positive impact of HB-HTA inside the hospital.

HTA at hospitals is not always understood and used as expected [18]. HB-HTA can contribute to better understanding professionals at hospitals, the real ground of HTA. As an example, after the first assessment, professionals at the HStJD HTA Committee changed their initial economy-focused perception to a more clinical and economical balanced view of HTA. Members were asked to rank the importance of dimensions of HTA in a Likert scale (1 being not relevant and 10 very relevant) before and after the first assessment [19]. Figure 6.3 shows the results.

Satisfaction of hospital professionals that have collaborated in the assessment is also another short-/midterm impact indicator. The HCB made a satisfaction survey

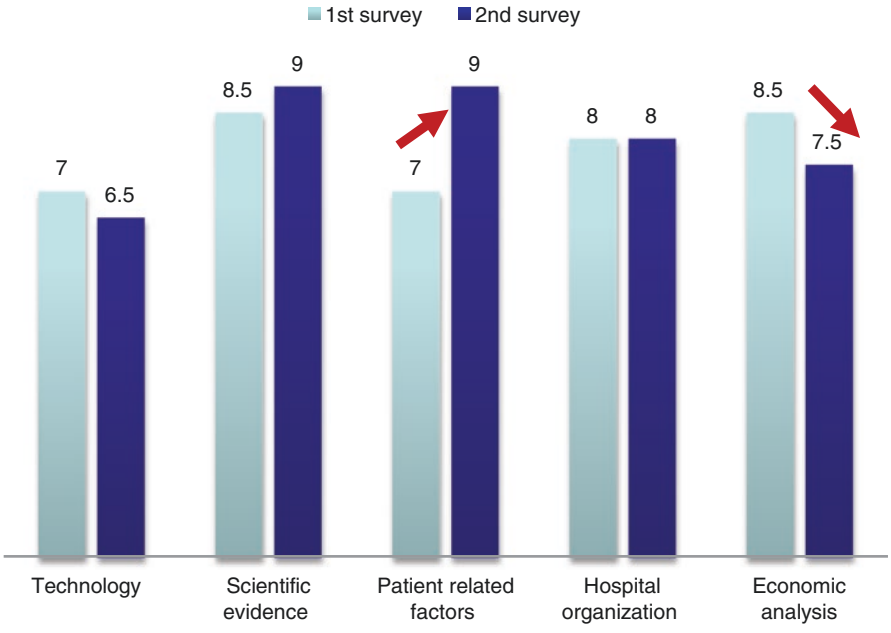


**Fig. 6.3** Perceptions of relative importance of HTA dimensions before and after the first HB-HTA report of the Hospital Sant Joan de Deu' HTA Committee members [19]

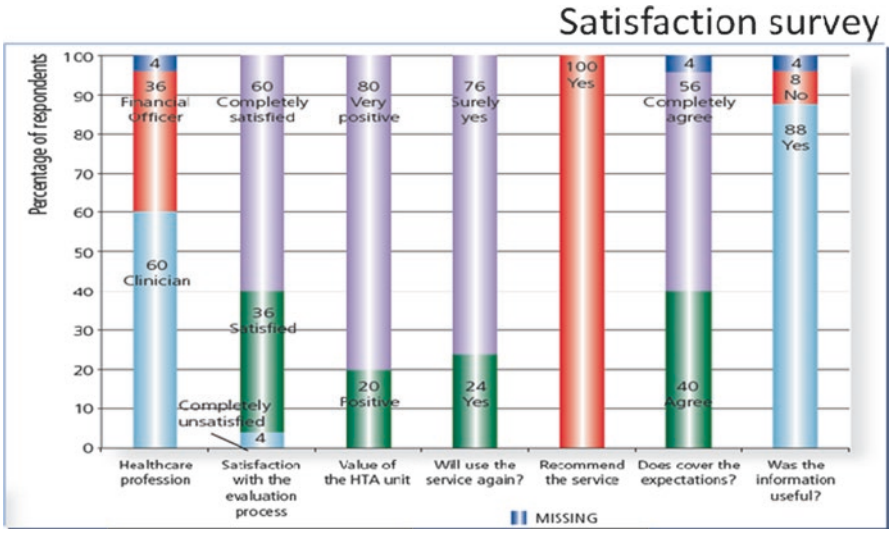


**Fig. 6.4** Results from the satisfaction survey among hospital professionals who have collaborated in HB-HTA reports at the Hospital Clinic of Barcelona [20]

(anonymous) among 24 professionals that collaborated in one or more assessments. The results from the survey showed a high level of satisfaction with the HB-HTA process (Fig. 6.4) [20]. These results show that performing an inclusive, transparent, systematic, and robust HB-HTA process is a passport for accepting any type of result from HB-HTA.

Finally, the economic effect of recommendations provided by HB-HTA is also a long-term impact variable to assess. Projections can be made through modeling. After the assessment of 23 HTs by the HB-HTA unit at the HCB, 12 of them were accepted, and it was estimated that their net present value will yield to €4,100,000 savings for the hospital over the next 10 years. Conversely, 11 HTs were not recommended; if these latter HTs had been introduced in the hospital, they would have generated a loss for the hospital of €13,600,000 over the next 10 years [5].

## 6.5 Conclusion

Although Spain has for long time had several experiences in using HTA at hospital level, in most hospitals these experiences have not always followed what is internationally understood and accepted by HB-HTA [5]. The introduction of HB-HTA units or programs in hospitals represents trade-offs on resource spending. Although, usually, the amount of resources to set up is minimal (frequently equals to the salary of the leader/head of the unit/program), it has a cost opportunity for the hospital, i.e., physicians or nurses will not be hired by investing this resources in an HTA

expert. The scarce resources nowadays in hospitals, as well as the fact that hospitals are being seen mainly as a place for health-care provision, make this trade-off one of the barriers to introduce more HB-HTA units/programs in Spanish hospitals. Other barriers and facilitators have been identified in 2007 through a DAFO study with 21 national and international experts in HTA ($n = 13$ working in HTA agencies; $n = 8$ working in HB-HTA units/programs) [21]. Main weaknesses identified in the mentioned study include the lack of well-trained human resources, lack of knowledge of the relevance and usefulness of HB-HTA for hospitals among clinicians and hospital managers, and lack of transparency in the management, planning, and decision-making process in hospitals. Strengths includes high qualification of hospital professionals regarding research and teaching and its direct access in HB-HTA, tradition in some hospitals of committees for HT evaluation which will make HB-HTA more easily understood, and the performance of HTA in a real clinical setting (using real data) among others, have been mentioned.

The accumulated experience from these three hospitals allows the identification of several success factors that ease the set up and running of HB-HTA units/programs as well as the acceptance of the results from the assessments [20, 22]. These facilitators include the transparency of the assessment process (i.e., discussion of results and uncertainties during the assessment process), the inclusion of the professionals that will use the HT (i.e., involve all actors in hospital that will have a direct relation with the HT), rigor in the assessment (i.e., using the best methods and techniques for each assessment), an assessment process and results that reach an equilibrium between the scientific rigor and the health-care pragmatism, credibility of the professionals leading and working in the HB-HTA unit/program, high-quality HB-HTA reports, HB-HTA activity aligned with the mission and strategic plan of the hospital, and the existence of an explicit support of the top hospital management to HB-HTA.

HB-HTA units described in this chapter are evolving, adapting themselves to constant hospital and environmental health-care changes. Several hospitals in Spain are interested in starting HB-HTA units/programs, but, in general, there is no formal support from national/regional HTA agencies to help on this. Nevertheless, hospitals with HB-HTA units/programs and those interested on implementing them come along in claiming for the need to interconnect hospitals with similar or different experiences in HB-HTA through formal networks [5]. In Spain, a first attempt was done a some years ago in Catalonia trying to build a network of hospitals for HTA (XHATS—Xarxa Hospitalaria d'Avaluació de Tecnologia Sanitaria). A strategic plan of the network was defined and a website created, but it was not implemented due to changing priorities [23]. Recently, the HTA Committee for the province of Seville has been created, and several assessments have already been performed; this experience is worth following and learning from its results. Nevertheless, the creation of HB-HTA network, being local, regional, national, or international, is already a wish. No formal network exists, but internationally there are some seeds toward this direction in Europe (AdHopHTA EU) [5] and in Canada (Pan Canadian network HB-HTA) [24]. HB-HTA networks will help in improving the way HTA is performed and organized in hospitals, through the creation of communities of

practices, to exchange information on specific HTs to be assessed, allowing having quicker answers for hospital decision-makers.

Another trend for HB-HTA observed in one of the Spanish hospitals is the "living labs like" role of the hospital in HTA evidence generation. Traditional HTA has relied on published evidence, but frequently the needed HTA information is not found, often because evidence production have been addressed to answer informational requirements not sufficient for HTA [25]. Industry and HTA professionals are moving the scientific dialog on HTA informational requirements earlier in the developing curve of HTs [26]. Hospitals are the place to help producers of HTs to gather and analyze the required data in the real world.

In conclusion, taking into account that in Spain 60 % of the public health-care expenditure is addressed to specialized health care and considering the experience gathered by HCB, the HStJD, and the VR&VM hospitals, the promotion of HB-HTA units/programs in Spanish hospitals could have a significant positive impact both in the quantity and the quality of the health-care expenditure.

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# Chapter 7
# The "Comité d'Evaluation et de Diffusion des Innovations Technologiques" (CEDIT) in France

**Alexandre Barna, Björn Fahlgren, Emmanuel Charpentier, Clément Taron-Brocard, and Loïc Guillevin**

## 7.1 Why Perform a HB-HTA in France?

Not all technologies are evaluated at the national level, even if a national HTA agency exists (e.g. medical devices). Even if health technologies are evaluated at the national level, conclusions and recommendations are quite global, whereas they need to be locally contextualised in order for hospitals to find all the answers for their specific needs. In addition, new and expensive technologies arrive mainly at university hospitals, which are under immediate pressure from manufacturers, physicians, and patients to adopt them, and a timely evaluation at the hospital level becomes even more useful for decision-makers. Hospitals may also have an interest (medical, economic, organisational) in accelerating the process of assessment and reimbursement at the national level. Hospital HTA units could be involved and help health-care professionals in preparing and submitting the dossiers at the national level (e.g. medical procedures).

**Box 1: Health Care System Context**
France's current health-care system was created progressively after World War II. It is characterised by universal health coverage guaranteed by the health insurance fund, part of a broader welfare and social protection system, based mainly on employer and employee contributions from salaries. This compulsory public health insurance is often supplemented by a private non-for-profit system of health insurance (*mutuelles*). Moreover, a system whose

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eligibility is not based on employment or linked to contributions insures universal coverage for the population (*couverture médicale universelle – CMU*). Out-of-pocket spending represents a small part of the total health-care spending.

Hospitals have a long tradition in France. The system is characterised by the coexistence of public and private hospitals. Both are financed by the health insurance fund, mainly via a DRG approach (*tarification à l'activité – T2A*) where health-care products are financed through the clinical procedure for which they are required. Public hospitals have a certain autonomy in choosing the drugs and medical devices they use, with supervision in some cases by the regional health authority (e.g. expensive drugs or medical devices, authorisation for some equipment). To help hospital decision-makers in choosing health technologies to finance and use, different structures were put in place, such as committees, commissions, and/or innovation units. The CEDIT is one of the most formalised and structured French hospital organisations aiming to undertake HTA as a tool for decision-makers.

## 7.2 History and Structure

The Paris University Hospital (*Assistance Publique-Hôpitaux de Paris/AP-HP*) is a single legal entity (hospital) covering the Paris region. It is comprised of 39 hospital sites, employs 90,000 persons, including 22,000 physicians, and treats more than seven million patients every year.

The Committee for Evaluation and Dissemination of Innovative Technologies (CEDIT) was established in 1982 at the AP-HP, as an advisory structure in matters related to innovation in health care and health technologies. This structure adopted the then new methods of Health Technology Assessment (HTA) and thus became one of the first HTA agencies. By indicating preferable interventions, this process allows access for all to the best health care in an environment of scarce resources.

The CEDIT is a multidisciplinary committee comprised of more than 25 physicians from different specialties, pharmacists, hospital top managers, and headquarter's division directors. The president of the CEDIT (currently Pr. Loic Guillevin) and its members are appointed by the Director General of AP-HP for a 3-year period.

The committee is supported by a permanent scientific secretariat under the supervision of the head of the unit (currently Dr. Alexandre Barna). The scientific secretariat currently employs seven persons with diverse backgrounds, who have completed university training in one or more of the following subjects medicine, public health, dentistry, statistics, and biomedical engineering, before joining the multidisciplinary team. The team carries out prospective analysis of available data, following the aspects relevant for AP-HP (technical, clinical, economical, organisational, ethical, legal, etc.), and proposes strategies aiming at adapting and optimising health-care delivery in the particular context of the AP-HP. The scientific

secretariat, funded by the general hospital budget, is part of the Department of Medical Affairs and Relations with Universities of the AP-HP.

## 7.3 Mission

The CEDIT and its scientific secretariat formulate recommendations for the senior management of AP-HP. The two main missions are:

- Health Technology Assessment: the CEDIT undertakes evaluations to support the decision-making process regarding the acquisition, use, and dissemination of innovative technologies in AP-HP hospitals.
- Horizon scanning: the CEDIT provides awareness and assessment by identifying and evaluating technologies with a high anticipated impact (clinical, economical, organisational) on the hospital.

## 7.4 How the CEDIT Works

The CEDIT acts upon request from the administrative, medical, or paramedical staff of the AP-HP or sometimes on self-request (mostly innovations identified by horizon scanning). The vast majority of requests give rise to an evaluation. Prioritisation is updated regularly with respect to the decision-making agenda of the institution.

The committee undertakes a broad evaluation according to the following two principles. Firstly, it concentrates on medical devices and equipment, but takes into account all health technologies, including drugs, procedures, and even organisations, sometimes all at once (e.g. assessment of therapeutic plasmapheresis comprising an assessment of machines – medical devices and fluids – and drugs and the organisation of the process). Secondly, it undertakes a “full HTA” by taking into account all the aspects of the assessment: technical, clinical, economic, and also the “social acceptability” including organisational, ethical, and legal aspects.

The scientific secretariat performs the analysis, aggregation, and synthesis of all available data (literature, AP-HP specific data, and expert opinions) and then prepares a report including a description of the technology assessed but also of existing alternatives, with the support from members of the committee, ad hoc expert groups, scientific societies, the AP-HP innovation network, other departments of AP-HP (research, finance, medical information system, etc.), and manufacturers concerned, following the four main areas already mentioned:

- Technical assessment: the objective is to verify whether a technology is doing what it was designed for, by describing and analysing the technical characteristics of the assessed technology and its alternatives, but also to help the implementation of an equipment or device into its environment (e.g. surgical robot involving specific constraints on the local organisation).

- Medical, clinical assessment: the objective is to quantify the intrinsic benefit/risk balance of a technology but especially to assess the therapeutic progress (or relative effectiveness) in regard with existing alternatives. For this, a systematic review of publications is performed. In addition, analysis of primary data originating from AP-HP databases can be performed.
- Economic evaluation: to help the decision-makers allocate resources in an optimal way by undertaking mainly economic evaluations but also budget impact analysis. For this part, the CEDIT undertakes the analysis of available economic evaluations. When economic evaluations have to be produced from internal AP-HP data, other dedicated units (e.g. URC-éco) could contribute.
- "Social acceptability" aspect: the objective is to contextualise the scientific data in a precise environment, as the adoption and dissemination of technologies depend on local, organisational, ethical, legal, and "psychological" aspects.

The plenary committee then appraises the value of the technology for AP-HP and issues recommendations which are decision oriented in the context of AP-HP. As such, they are rarely simple recommendations of dissemination or non-dissemination but may frequently state conditions for diffusion, such as previous experience in the domain, the availability of given equipment, and the characteristics of patients to be treated and/or the illness to be addressed. They may also include organisational recommendations, such as regrouping of clinical activities or equipment sharing.

The structure of AP-HP creates an unusual situation for the CEDIT. As it comprises 39 hospital sites, it becomes a sensitive matter deciding how to mutualise and use a health technology among the different health services, when the technology is expensive (e.g. surgical robot) or the target population is very small (e.g. SpyGlass endoscopy). In these cases, the CEDIT seeks to find synergies and can recommend equipment sharing between the different sites (transfer of patients or technology, equipment sharing by different teams) or medical reorganisations.

In France, the evaluation and decision-making processes regarding health-care products are separate. The CEDIT makes recommendations to support decision-making, but is not a substitute to this process. It can thus help policy makers determine which services should be provided. The recommendations of CEDIT are not binding but are followed in practice. Even if it is difficult to measure one's own impact/influence and to determine if the HTA recommendation was the main reason for a decision to be taken, attempts to establish the CEDIT's impact were made in 2006 [1]. According to this study, HB-HTA allows for decisions made in accordance with scientific results, adapted at the local level (evidence-based policy).

## 7.5 National and International Collaborations

Besides AP-HP, several other French university hospitals are adopting the concept and starting to organise HTA units (Lille, Bordeaux, Lyon, etc.). The CEDIT cooperates with these units within a recently established national network on innovation.

This innovation network meets every 3–4 months in order to share experiences, prioritise the work conducted, and avoid the duplication of work. Moreover, an annual congress, the "*Journées Nationales des Innovations Hospitalières*" (*JNIH*), is organised by the national innovation network.

The CEDIT also cooperates with national organisations and institutions such as the Medicine Agency (ANSM), the French National Authority for Health (HAS), the National Insurance Fund (UNCAM), and the Ministry of Health.

At the international level, the CEDIT developed early collaborations and partnerships in the field of Health Technology Assessments and Horizon Scanning. It is a member of the International Network of Agencies for Health Technology Assessment (INAHTA), Health Technology Assessment international (HTAi), and EuroScan. The CEDIT was part of the Advisory Committee of the AdHopHTA European project and also contributes to the assessments realised by the EUnetHTA. The CEDIT is currently enhancing bilateral collaborations with foreign countries or institutions (e.g. University of Tokyo, Medical University of Almaty, Shanghai Hospital Association) and contributes to different events (e.g. Second WHO Global Forum on Medical Devices) as a dedicated part of the international policy of the institution.

## 7.6 Dissemination Activities

The recommendations and opinions of the CEDIT are systematically addressed to the director-general of AP-HP, the president of the medical commission, the directors of AP-HP hospitals, and the physicians and other health-care professionals concerned. The recommendations of CEDIT are non-binding but are nearly always followed by decision-makers.

The HTA reports (in French, with an executive summary in English) are made public on the CEDIT website (http://cedit.aphp.fr/). Chosen assessment reports are submitted for publication to French and international journals. Furthermore, the CEDIT electronic newsletter disseminates early awareness reports and highlights recent assessment reports.

The three most recent assessment reports released in August 2015 are:

- Bioquell® vaporised hydrogen peroxide disinfection system: following an outbreak of *Acinetobacter baumannii* in the burn centre at the Saint Louis hospital (AP-HP), the CEDIT assessed the airborne disinfection based on vaporisation of hydrogen peroxide. The CEDIT recommended that this process should be used as a complement to the current infection control practice (surface cleaning and disinfection), with priority given to the rooms previously occupied by patients carrying a microorganism known for its ability to persist in the environment and presenting a particular resistance to antibiotics;
- Prehospital ECMO for refractory cardiac arrest: this assessment follows a request from an advanced life support unit from Necker hospital (AP-HP) to use the Cardiohelp® device. Because the level of evidence is low and the feasibility has to be confirmed, with no conclusive evidence on efficacy and safety, the CEDIT

recommended that the use of veno-arterial prehospital ECMO at AP-HP should only be made in the context of a clinical trial.

- Fully bioresorbable drug-eluting coronary scaffolds: following the development of stents, then drug-eluting stents (DES), bioresorbable scaffolds are proposed as a third evolution in coronary angioplasty, aiming to reduce the incidence of restenosis and stent thrombosis and to restore vascular physiology. The CEDIT concluded that the technological and clinical development of bioresorbable scaffolds is not yet complete: their possible clinical benefits remain unclear compared with third-generation DES; the impact of arterial physiology restoration has to be assessed over the long term; and their cost-effectiveness has to be established. In this context, there is no compelling reason to hasten the clinical use of these devices before the results of ongoing randomised controlled trials become available.

## 7.7 Lessons Learned: Future Developments

The CEDIT's current role is primarily to provide scientific advice in a timely way to support decision-making. It also supports the importance of publicly sharing the HTA reports conducted (publishing or at least make publicly available as much as possible the assessments it undertakes).

The CEDIT benefits from several strong forces: (i) the multidisciplinary dimension of the team, (ii) the existence of a formalised methodology for the assessment, and (iii) the ability to make local and contextualised assessments and the recently achieved timelines of its assessments and reporting.

Since its creation in 1982, the AP-HP hospital-based HTA agency (CEDIT) connects the concept of evidence-based medicine for clinical practice with the healthcare policy requirements of decision-makers. This role needs both scientific and political skills. It is the background of what could be the answer to the key question of "evidence-based policy".

## 7.8 Agency Information

Website: http://cedit.aphp.fr/

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# Chapter 8
# Hospital-Based HTA in Switzerland

**Jean-Blaise Wasserfallen and Christophe Pinget**

## 8.1 HTA Context in Switzerland

Currently, Switzerland has no national agency for Health Technology Assessment (HTA). The Federal Law on Mandatory Health Insurance (LAMal), adopted in 1996, stipulates that medical technologies should be covered by health insurance if they can be considered effective, appropriate and efficient [4]. The Federal Office of Public Health (FOPH) is in charge of the procedure for the inclusion of medical goods and services in the Mandatory Health Insurance benefit package. The applicants have to complete a detailed request form with information on the new technology, its scientific evidence as well as the expected medical and cost impact. After being reviewed by the FOPH, the dossier is submitted for appraisal to the Federal Commission for Health Insurance Benefits. This expert commission makes a proposal to the Federal Department of Home Affairs, which makes the final decision. This decision is made public in an ordinance [5]. A review of the decisions taken from 1996 to 2013 was recently published [1].

The Swiss Medical Board (SMB) – founded in 2009 – is an independent health technology assessment initiative under the auspices of the Conference of Health Ministers of the Swiss Cantons, the Swiss Medical Association and the Swiss Academy of Medical Sciences. The function of the SMB is to produce HTA reports and to formulate recommendations for health providers and decision-makers. At present, the SMB has no legal power to formulate mandatory decisions and no role in coverage decisions [2].

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**Box 1: Health Care System Context**

- The Swiss health-care system is highly decentralized, under a federal law. The 26 cantons are responsible for the provision of health care for their populations, with communes or municipalities owning some hospitals and holding responsibility for the provision of the social aspects of care. Funding is based on a mix of public (through taxation) and private sources (through mandatory insurance premiums collection, out-of-pocket deductible and copayment).
- Hospitals are either public or private structures subsidised by public funding. The insurance companies pay for 45 % of the inpatient stays, based on a DRG system [8], and 100 % of the outpatient bills, based on a federal tariff [9]. The cantons pay for 55 % of the inpatient stays.
- Decisions to introduce drugs, devices and capital equipment are made by the hospitals, with some limitations imposed by the cantons for expensive capital equipment.

## 8.2 HB-HTA in Switzerland: Three Case Studies

Hospital-Based HTA has been gradually implemented in a few hospitals in Switzerland in response to the increasing cost impact of new medical technologies in a context of limited resources. In the absence of national coordination, different solutions have been implemented in the different hospitals. In the French-speaking part of Switzerland, the Lausanne University Hospital (CHUV) created a dedicated HTA unit inside its medical directorate. Alternatively, the Geneva University Hospital set up an internal committee composed of people interested in HTA, alongside their usual activity. Smaller hospitals rely on the ambassador model for HTA [7].

## 8.3 The Lausanne University Hospital (CHUV) Approach

The Lausanne University Hospital is a public teaching hospital providing care in all disciplines except for ophthalmology. It has 1,400 beds, 1,355 FTE physicians, 3,048 FTE nurses, for a total of 7,846 FTE employees and an annual budget of €1,170 million. Together with the Geneva University Hospital, it covers the whole French-speaking part of Switzerland (2 million inhabitants) for tertiary care, while at the same time serving as the city hospital for Lausanne.

The CHUV created a dedicated HTA unit attached to the medical directorate in 2002, with a 0.5 full-time equivalent (FTE) health economist. This staff allocation was progressively increased to 1.5 FTE over the subsequent years. The unit is entirely funded by the hospital central operating budget. To support external mandates (teaching, research), additional funding is allocated to a dedicated account of the medical directorate, which is used to finance ad hoc tasks.

The main activity of the unit is to conduct HB-HTA for management purposes. The objective is to provide the executive committee of the hospital with relevant information on the medical and economic impacts of introducing a specific technology.

An institutional directive about the introduction and use of new diagnostic or therapeutic procedures (DTPs) sets out the conditions and the pathway to introduce new medical technologies at the CHUV.

This directive mandates that any DTP not CE-marked can be used only under research conditions with external funding. The same condition applies to DTPs not covered by mandatory health insurance. Finally, if the DTP is not yet registered at the CHUV or more expensive than the comparator currently in use, it should be submitted to the HB-HTA process. Investment in medical equipment is submitted to a specific decision-making process, and the HB-HTA unit is only involved when the new equipment has a significant impact on the operating budget of the clinical departments. Finally, the introduction of a new drug is controlled by a specific committee, and again the HB-HTA unit is only involved when the new drug has a significant impact on the operating budget of the clinical department.

The HB-HTA process is initiated by the physician requesting the new DTP. The applicant physician has to complete a request form that describes the clinical pathways with the current and the new DTP, the scientific evidence available and the information on expected medical and economical impacts. A meeting with the applicant physician is systematically organised by the HB-HTA unit to get additional information and to agree on the core data of the assessment.

The HB-HTA unit is then in charge of computing the budget impact and writing the HB-HTA report. The first part of the HB-HTA report describes the technology, the clinical pathways with the current and the new DTP, the indications and the most important results found in the literature. The second part describes the global cost impact of adopting the new DTP. The third part describes the budget impact on the clinical department. This analysis is hospital specific, as it uses the institutional internal funding system to calculate the reallocation a clinical department will need to financially absorb the introduction of the new DTP. Finally, the fourth part defines follow-up criteria for longer-term impact assessment. Once the report is validated by all the stakeholders, it is reviewed by the medical directorate, which issues a recommendation to the executive committee on a separate document.

The formal decision – taken by the executive committee – states whether the DTP is approved for use or not, what financial compensation is provided to the clinical department (if any) and what kind of follow-up is expected. The HTA report with the medical directorate recommendation and the executive committee decision is communicated to all stakeholders and published on the intranet of the hospital.

The HB-HTA unit's activity progressively increased when HTA was made mandatory for any type of new medical device. As a result of this increase in activity, the work force of the unit was increased from 0.5 to 1.5 FTE health economists. DTPs are assessed on a first come, first served basis, with a predefined prioritisation decision system implemented by the medical directorate, if needed.

Besides its HTA activity, the HB-HTA unit is involved in teaching at the University in different programmes about the health-care system (certificates of advanced studies (CAS) in management, economy, public health and masters in business administration (MBA) in health). The unit is sometimes involved in the economic arm of clinical research protocols. Whenever possible, scientific papers are published in medical or economic peer-reviewed journals. In addition, when a physician of the hospital wants to request mandatory health insurance coverage for a new DTP, the HB-HTA unit participates in establishing the dossier needed for submission to the FOPH.

## 8.4 Impact of the HB-HTA Unit Within the Hospital

A review of the HB-HTA unit's impact over a 10-year period was carried out through semi-structured interviews with the relevant clinician for each DTP accepted by the hospital management between 2002 and 2011 [6]. An assessment of the HB-HTA process utility as perceived by the clinicians, the accuracy of the expected medical impact of the new DTP and the compliance with the indications for DTP as defined in the HTA reports was carried out.

Over 10 years, 40 HB-HTAs were carried out, and 34 accepted by the hospital directorate. Of the 28 clinicians in charge of these 34 DTPs, 27 accepted to be interviewed. The majority of them (23/27, 85 %) recognised that the HB-HTA process was useful and necessary.

Five of the 34 DTPs adopted were no longer in use in 2002 (15 %). Of the remaining 29 DTPs, the expected number of patients was accurate in only 11 cases (38 %), higher than expected in 4 cases (14 %), lower in 12 cases (41 %) and not available in 2 cases (7 %).

The observed average length of stay was 61 % longer than expected in the seven DTPs for which an expected LOS was available in the HB-HTA report. The complication rate was higher than expected in two cases, and the success rate lower than expected in three cases.

The indications for treatment as defined in the HB-HTA reports were accurate and mostly respected during the first 3 years after implantation. However, they evolved in 52 % of cases after 3 years of practice (seven restrictions, five broadenings and three modifications of the spectrum of use by combined use of another DTP or by changing treatment type).

Clinician preferences seem to play an important role in DTP proposals, adoption and use, as followers of clinicians who had required the introduction of a DTP were not always sharing their peer's choices. As a result, some of the adopted DTPs were abandoned or seldom used.

Thus, one of the main lessons of this study was the necessity of repeating the HTA at regular intervals, such as a 3-year period. This modification of HB-HTA procedure was introduced in the decisions of DTPs assessed since 2014.

## 8.5 The Geneva University Hospital (HUG) Approach

The Geneva University Hospital is a public teaching hospital providing care in all disciplines. It has 1,804 beds, 1,519 FTE physicians, 4,648 FTE nurses, for a total of 10,277 FTE employees and an annual budget of €1,417 million. Together with the CHUV, it covers the whole French-speaking part of Switzerland (2 million inhabitants) for tertiary care, while at the same time serving as the city hospital for Geneva.

The hospital has no dedicated HTA unit, but has set up a commission for new technologies, which is a consultative body of representatives from several clinical and administrative services. Therefore, this activity does not have a specific funding, as it belongs to each member's mission statement. The commission is mandated by the general directorate to assess expensive technologies. It works in close contact with the leading clinician in the field under examination. This clinician has to fill in a formalised request, with all the dimensions usually involved in a formal HTA. A biomedical engineer provides technical information, and the medico-economic department provides financial information and medico-economic assessment.

The first session of the commission is devoted to assessment of the dossier established by the clinician, in his absence. He is invited to the second session to answer questions and provide additional information if needed. A final recommendation is taken at the third session and transmitted to the hospital's directorate for decision. The hospital has solved the issue of some new technologies not yet covered by insurance reimbursement by setting up a fund dedicated to bridging this period.

The commission for new technology can be mandated only by the general directorate, and as a result all new technologies are not formally assessed before adoption. Two other specific commissions deal with drugs and devices, respectively, but without formal HTA process. These commissions are capable to take the decisions without referring to the hospital directorate.

## 8.6 The North Vaudois Hospital (EHNV) Approach

The regional hospital EHNV is a private structure, subsidised by the canton. It provides care in medicine, surgery (general and orthopaedics), gynaecology and obstetrics and paediatrics, along with an emergency service and an intensive care unit. It has 520 beds, 138 FTE physicians, 627 FTE nurses, for a total of 1,273 FTE employees and an annual budget of €150 million.

The adoption process of a new technology is not formalised in this hospital. It usually follows three different pathways for drugs, devices and equipment, respectively. A physician sends a request to the head of department to initiate the introduction of a new technology. A drug committee provides recommendations for drugs, and a biomedical engineer provides technical information for devices and

equipment. An economist provides financial data for all three categories of technology. An external consultant, usually from a university hospital, is sometimes hired to give recommendations, and the practice of the partner university hospital is also taken into account in the assessment. The medical directorate provides a decision for drugs and simple devices and a recommendation to the hospital directorate for larger equipment. In the latter case, the dossier is discussed at the hospital directorate level (or with the hospital administrative board if the technology necessitates modifications to the buildings), and a final decision is made.

All involved parties recognise that the absence of formalisation opens the way to exceptions, with collaborators trying to introduce new technologies without following the usual process. The process has been improved by hiring a biomedical engineer, who provides useful information about the technology's characteristics.

The hospital directorate is well aware of the hospital's mission and is not willing to adopt technologies which are out of reach of the expertise of its clinicians. At the same time, it is very careful to avoid a private competition in the region, in order to maintain its leadership in hospital and clinical care. The hospital directorate faces relatively great uncertainty in its technology selection and recognises the need for more formalisation, but has not yet been able to face this challenge.

## 8.7 Conclusion

HB-HTA proved useful for the CHUV and for guiding management decisions regarding the introduction or refusal of a new technology. The main advantages of HB-HTA include the fact that it is available on demand, that it uses real patient and economic data from the hospital and that it leads to conclusions that can be directly transferred into practice.

However, technology evolution in clinical practice, as well as clinician preferences, change rapidly, and over- or underestimations of both patient numbers and lengths of stay cannot be totally avoided. This provides a strong argument for repeating HTA at a regular basis. Three years seem to be a reasonable interval.

Other hospitals in Switzerland chose different ways of dealing with the issue of introducing new technologies. The solutions that were implemented seem to play their role, with some limitations, which are acknowledged and tolerated.

Collaboration and exchange of HTA reports between hospitals in the same country or between countries would be interesting. This is nevertheless hampered by the confidentiality agreements surrounding economic data, in particular, the purchase prices of technologies.

In our experience, a HB-HTA unit quickly becomes essential once established in a hospital and is considered a good investment for steering future expenses related to medical technologies. It is thus likely that all countries will eventually follow the example of Québec [3], which mandated the establishment of a unit in every university hospital.

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# Chapter 9
# The HTA and Innovation Unit at the A. Gemelli University Hospital (Italy)

**Marco Marchetti and Americo Cicchetti**

## 9.1 The HTA and Innovation Unit at Agostino Gemelli University Hospital Foundation

In 2000, the HTA Unit (Unità di Valutazione delle Tecnologie - UVT), now the HTA and Innovation Unit (Unità di Valutazione delle Tecnologie e Innovazione), was formally established under the auspices of the Medical Directorate at Agostino Gemelli University Hospital to support informed decision-making in the selection of technologies at the hospital level [1]. Figure 9.1 presents the main characteristics of the Agostino Gemelli University Hospital Foundation.

The HTA and Innovation Unit's primary objective is to provide recommendations on health technology acquisitions to hospital decision-makers through a transparent and consistent evaluation process, and to provide accurate forecasts on the clinical, economical, and organizational impacts of newly introduced health technologies [2]. Decisions on acquisitions must be aligned with the institution's needs and budget available. The unit strives to improve the effectiveness, appropriateness, and efficiency of clinical practices with a quality improvement procedure. The HTA Unit also conducts research projects and training activities in specific areas of interest that have resulted in collaborations with national and international agencies and institutions [3]. In the hospital organizational chart, the HTA and Innovation Unit is currently positioned within the University Hospital Clinical Governance Directorate.

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**Box 1: Health Care System Context**

- Italy has a National Health System (NHS) organized in Regional/Autonomous Province Health Systems. Regions and Autonomous Provinces are responsible for organization and management of Regional Health Care according to a national benefit basket (Essential Levels of Care (LEA)) defining the totality of services, activities, and goods covered by public funds in the context of the NHS [4].
- The Italian NHS is funded through general national taxes. Regional Governments can add additional resources from regional taxes if additional services are to be provided [5].
- Hospitals are reimbursed according to services provided (DRG system for inpatients and outpatient procedure tariff) and hospital functions and services (emergency, university hospitals, etc) [6].
- Decisions on drugs covered by the public health system lay with the National Government through the Italian Medicines Agency (AIFA). Hospitals have a Drugs Commission in charge of deciding which drugs will be included in the list of medications provided by the hospital. As for medical devices and capital equipment, in general, each hospital is free to decide on their investments. Nevertheless, for some very expensive capital equipment requiring extra funds from a public payer (i.e., regional government), consultation with them is necessary.

| | | | | | |
|---|---|---|---|---|---|
| Beds (including 175 Day Hospital Beds) | **1807** | Sqm facilities | **185,000** | 2015 turnover (including Euro 537,000,000 financed by National Health Service) | **Euro 619,000,000** |
| Medical Doctors | **967** | Nurses, auxiliaries, technicians, administrators and other hospital personnel | **4,196** | Employees | **5173** |
| Impatients per year | **60.320** | Day Hospital patients (av. 3 admission per patients/year) | **34.058** | Scientific paper per year | **1,500** |
| Second level Emergency Department (A&E) with a Trauma Center and a Helicopter pad | **1** | Emergency Department visits/admission per year | **70,000** | Patient/year are assisted via helicopter rescue | **500** |
| Delivery rooms | **6** | Deliveries per year | **Over 4000** | Outpatients visits, surgeries and diagnostic | **250,000** |
| Operating rooms | **41** | Surgical operations | **45,000** | Average length of stay in hospital | **7.51 days** |

**Fig. 9.1** Fact and figures 2015 (Source hospital website)

## 9.2 Staff

The HTA Unit employs a technical staff with various competencies. Staff members are comprised of a clinician (Chief of HTA Unit), five health economists, one biomedical engineer, a statistician, a pharmacist, clinicians trained in HTA, and administrative support. Researchers from the Faculty of Economics (High School of Economy and Management of Health System) and from the Ethics Department at the Università Cattolica del Sacro Cuore also participate in some the HTA Unit's programs.

## 9.3 Sources of Funding

The unit receives most of its funding from the hospital budget (four full-time employees). There is an agreement with the High School of Economy and Management of Health System of the Università Cattolica (Alta Scuola di Economia e Management dei Sistemi Sanitari - ALTEMS) that provides funds for one employee. The unit also receives additional financial support from the Italian NHS, scientific societies, and national and international organizations (e.g., Ministry of Health, European Commission) for specific research initiatives. Research projects in collaboration with industry are also performed. These funds are used to pay additional remaining staff.

## 9.4 Process and Procedures

The main goal of the HTA Program is to ensure the introduction and the use of appropriate health technologies in the specific university hospital context through an evaluation process founded on evidence-based medicine and evidence-based health care. Different health technologies are evaluated: pharmaceuticals, medical devices, biomedical technologies, diagnostic tests and organizational procedures. The unit is involved both in the process of technologies introduction and in the process of technologies disinvestment, providing the information for decision-making. The processes for each category of technologies are formalized in internal procedures that explain all phases of HTA process and interaction with the other hospital processes and units (Hospital Pharmacy, Purchasing and Logistic department, Management and Controlling Unit, Hospital Technical Services Department, etc). HTA documents produced by the HTA Unit are used by different hospital decision-makers within the hospital to decide on the introduction or the disinvestment of specific technologies.

Table 9.1 summarizes the activities and products of the unit with a brief description of its role and responsibilities.

**Table 9.1** HTA unit and innovation process and procedures

| Category of technologies | Applicant | Type of recommendations | Product | Role and responsibilities |
|---|---|---|---|---|
| Pharmaceuticals | Any hospital doctor through formal application approved by referred department | Adoption | HTA report | Only the unit is responsible for the assessment of request of introduction of new pharmaceuticals into the hospital formulary |
| | | | | Verifying regulatory status, effectiveness, and reimbursement. Even the existence of other equivalent therapies in the hospital is assessed in collaboration with the Hospital Pharmacy |
| | | | | The report contains a recommendation on the introduction, the denial, or the introduction with restriction of the assessed drug |
| | | | | The Head of the unit is a permanent member of the Commission on Drugs and Medical Devices |
| | Directions | Disinvestment | List of pharmaceuticals to withdraw | Periodically, a working group reviews the Hospital Formulary in order to update the list of pharmaceuticals. A member of the unit takes part in the working group. Other units involved are Pharmacy and Purchase Units |
| Medical devices | Any hospital doctor through formal application approved by referred department | Adoption | HTA report | Only the unit is responsible for the assessment of request of introduction of new medical devices in the hospital list |
| | | | | Conducting an evaluation considering the following dimensions: current use of medical device, regulatory status, effectiveness, impact on organization, economic considerations (budget impact analysis and adequacy of reimburse). The existence of other medical devices available in the hospital is assessed in collaboration with the Pharmacy Unit, the Purchase Unit, and the Management and Control Unit |
| | | | | The report contains a recommendation on the introduction, the denial, or the introduction with restriction of the assessed medical device |
| | | | | The Head of the unit is a permanent member of the Commission on Drugs and Medical Devices |
| | Directions | Disinvestment | List of medical devices or medical procedures to withdraw | Periodically, a working group reviews the hospital list of medical devices, in order to update the list of medical devices and the patient paths. A member of the unit takes part in the working group. Other units involved are Pharmacy and Purchase Units |

| | | | | |
|---|---|---|---|---|
| Medical equipment | Clinical Departments | Investment | Investment plan | The unit is responsible for collecting technology' needs of medical departments, prioritizing requests with an explicit method and providing the investment plan. These activities are performed in collaboration with the Hospital Technical Services Department, Clinical Engineering, the Purchase Unit, and the Management and Control Unit |
| Diagnostic tests | Laboratory | Adoption | Structured advice | The unit is a permanent member of the Commission on diagnostic test introduction and is responsible for the evaluation of clinical, organizational and technical dimensions |
| | | | | The unit provides information on the clinical and patient benefits of new diagnostic tests, and the existence of *any* technical or organizational difficulties for introducing the test |

These hospital-based HTA documents are produced using a robust and explicit methodology and contain all HTA assessment dimensions. Ethical, legal, and social dimensions are included only if needed.

Each report includes the following sections:

- research question
- current use of technology and technical description of the health technology
- legal requirements and regulatory approval status (i.e., CE Mark, FDA approval)
- systematic review of clinical evidence
- alternative devices/therapies in the market which are identified through literature review and clinicians input
- budget cost and organizational impact analysis (includes impact on staffing requirements or training, the need for new organizational models, and facility requirements that are investigated)
- conclusions and recommendations

The HTA reports directly answer clinicians' questions, meet their needs and can support dialogues, increase transparency and consistency, and serve as a tool for different administrative procedures.

## 9.5 HTA and Innovation Unit Production, Recommendation, and Impact

From September 2006 to May 2016, the HTA and Innovation Unit produced 274 reports on medical devices (MDs). On the basis of the information in each report, we provide the decision maker (a commission in the A. Gemelli University Hospital) a recommendation to introduce or to not introduce the assessed MD. In terms of the type of recommendation, the HTA-produced documents issued 81 (30%) recommendations to introduce, 93 (34%) recommendations to deny, and 100 (36%) recommendations of limited use. The level of acceptance of the recommendations and subsequent incorporation into hospital policy is around 66%. Over the 10 years of full functioning of the activity on MDs (2006–2014), the average annual quantifiable savings has been € 660,000 (Minimum Euro 29,.000, Maximum Euro 1,532.000).

Estimation of the net budget impact of these recommendations is quite uncertain. Net budget impact has been estimated by calculating the hypothetical economic impact of the introduction of all of the requested medical devices in respect to those devices actually approved.

For drugs the estimation of the net budget impact is quite difficult when:

- the same drug is approved for many clinical indications.
- its posology is linked to clinical parameters difficult to forecast.
- alternative therapies (for which the actual number of patients under treatment is not available) are available in the Hospital Formulary.

- the drug could be prescribed by many hospital units and not only by the one which requests its introduction in the Hospital Formulary.

Therefore, for drugs per day/patient/year cost of therapy is estimated, while Hospital Pharmacy evaluates if the expected number of patients per year (provided by the requesting clinicians) is realistic.

Decision drivers at the basis of the medical device recommendations are related to:

- effectiveness: existence or absence of evidence to support the use of medical devices in specific target population
- organizational aspects: medical device used by other clinical units and specialities, over and/or under estimation of medical devices needed, and high organizational impact (e.g., operational rooms use)
- budget impact: higher or reduced cost for medical devices requested with respect to the comparator, unsustainable budget impact

Decision drivers at the basis of the drug recommendations are related to:

- *hospital relevance* of the requested drug. Great attention is paid to avoid the introduction in the Hospital Formulary of pharmaceuticals whose prescription is more common at a territorial level.
- *presence of other drugs* approved for the same clinical indication(s) in the Hospital Formulary. The aim is to avoid duplication of equivalent therapies.
- *benefit-risk profile*. Despite EMA approval and national negotiation, the benefit-risk profile is investigated. When evidence for effectiveness, long-term outcomes and pharmacovigilance is available, it is considered and discussed.
- *budget impact*. Cost of therapy per patient and total is estimated and compared with that of similar therapies (drugs and non drugs) already adopted in the hospital. To better monitor its budget impact and prescription, the recommendation foresees in some cases to introduce the drug only with patient by patient request. A further option is to approve a drug for a maximum number of patients per year, or to limit its prescription to specific hospital units.
- *reimbursement status*. The introduction in the Regional Hospital Formulary and other legal requirements able to influence the reimbursement of a treatment for the Hospital are considered.
- *organizational aspects*. Any implication of a new therapy in the hospital organization is evaluated.

In 2015, 58 different medical devices were evaluated:

- 27,6 % (*n*. 16) of them have had a positive recommendation of introduction.
- 39,7 % (*n*. 23) of medical devices requested have had a negative recommendation of introduction.
- in 32.8 % (*n*. 19) of medical devices requested were not introduced.

The reasons of these recommendations are showed in the following table:

| Medical devices evaluated (2015) | Recommendations (absolute value) | Recommendations (% value) | Decision driver |
|---|---|---|---|
| Recommendations of introduction | 16 | 27,6 | Evidence on increasing effectiveness; reducing cost; strategical reasons |
| Recommendations of limitation in use | 19 | 32,8 | Increasing effectiveness not proven but promising; organizational impact |
| Recommendations of denial or suspended evaluation for lack of information | 23 | 39,7 | Absence of increasing effectiveness; unsustainable budget impact; organizational impact; regulatory aspects |
| Total | 58 | 100 | |

With respect instead to the drug evaluation, a total of 67 drugs have been evaluated in the period November 2013 to December 2015.

| Drugs evaluated (November 2013–September 2015) | Recommendations (absolute value) | Recommendations (% value) |
|---|---|---|
| Recommendations of introduction | 16 | 24 |
| Recommendations of limitation in use | 19 | 28 |
| Recommendations of denial | 14 | 21 |
| Recommendations suspended for lack of information | 18 | 27 |
| Total | 67 | 100 |

## 9.6 Dissemination

Reports produced by the HTA Program are actually disseminated internally only (A. Gemelli University Hospital Foundation) due to the sensitive data contained in them. The principal methods of distribution are the hospital's intranet and direct distribution to local health-care professionals. Future plans include publishing a summary of the assessment reports.

## 9.7 Lessons Learned

The hospital-based approach allows a transparent, fair, and consistent decision-making process founded on evidence-based medicine; takes into account the organizational context in terms of formal structure, knowledge, professional skills,

managerial skills, etc.; and permits a more patient-oriented process, as the health needs of patients are taken directly into account in a hospital setting.

The success of the HTA and Innovation Unit can be attributed to the rapid response to requests, taking 0.5 months rather than the usual 12–18 months for a complete assessment, and to the capability to position the HTA process in the operational line in collaboration with the hospital's administration, health-care professionals and all of whom would be affected by decisions.

Another key to the HTA and Innovation Unit's success is the ability to produce an HTA product that goes beyond pure data analysis to make actual policy recommendations.

Disinvestment activities do not represent up to now the main activities of the unit because of the complexity of the disinvestment process and the need for additional resources to perform an added value disinvestment process.

Difficulties in the disinvestment process are related to:

1. the analysis of the hospital medical device consumption database, in terms of device number for the same treatment and total amount of expenditure per type of device
2. identifying objective criteria for defining disinvestment priorities (clinical, economic, etc.)

Coordination with other involved units and stakeholders represents an additional complexity of the process.

Future evolution of HTA Unit foresees increasing activities in disinvestment area.

Long-term, routine follow-up of decision making process based on HTA reports is very important to inform the hospital management about the outcome of its decisions. Only with this information can quality and safety of care be guaranteed.

## 9.8 Future Directions of HTA and Innovation Unit at A. Gemelli University Hospital Foundation

Future evolution of the HTA and Innovation Unit of the A. Gemelli University Hospital is related to increasing activities in assessing technologies at an early stage of development in order to improve the implementation of cost-effectiveness technologies.

Disinvestment activities also represent a major area of work for the future of the HTA Unit.

Finally, the creation of an integrated network that will be able to connect different levels of assessment (macro, meso, micro) will be welcomed. In fact, although small may be beautiful, big is also essential. An optimal system might consist of a coordinated network consisting of large central agencies, affiliated with numerous small peripheral agencies situated in close proximity to end users. The large agencies would have two functions. As at present, they would develop both analyses and policy recommendations for governments and supra-regional health-care delivery organizations. They would also produce technology assessments on any health

topics that could be generalizable. The small, hospital-level, HTA agencies would develop locally relevant policy advice based both on the assessments provided by the central agencies, with incorporation of locally relevant data [6]. In Italy an integrated system of HTA is missing at the different levels macro, meso, and micro, and different new initiatives are addressing the creation of this integrated HTA network.

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# Chapter 10
# Hospital-Based HTA in Turkey

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The Turkish Ministry of Health was established in 1920 [1]. Since the First World War, and throughout the country's transition from empire to democratic republic, Turkey has been struggling with inequities and inadequacies in its health-care system. The Health Transformation Programme (HTP), extending from 2003 to 2013, followed this challenging period and has been a source of major reform in Turkish health care. One of the objectives of the HTP was to deliver health services in an effective, productive, and equal way. This included strengthening primary care services, reorganizing hospital services, and restructuring the Ministry of Health and the insurance system. Significant reforms were achieved in 2008 with the implementation of the Universal Health Insurance (UHI) system [3]. During this time there was both an increased awareness of the need for efficiency and an increased interest in Health Technology Assessment (HTA) [2]. Box 10.1 summarizes the main features of the Turkish health-care system.

## 10.1 HTA in Turkey

Following legislation at the end of 2011, the Department of HTA was established under the General Directorate of Health Research (SAGEM) of the Ministry of Health in 2012. A second HTA unit was established under the Turkish Pharmaceutical

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**Box 10.1. Turkish Health-Care System at a Glance**

- The Turkish health system is financed through a mixed system with features of both the Bismarck and Beveridge models.
- 5.4 % of the GDP was allocated to health spending in 2013. The amount of public funding was 78.5 %. In 2013 Turkey spent the equivalent of USD 941 per person on health [3].
- There has been Universal Health Insurance since 2008 [4].
- Hospitals account for 52 % of all health expenditures in the country [3].
- Hospitals have retrieved global budgeting since 2006. Global budget refers to the amount of progressive payment to be received in return for services which will be provided during a fiscal year.
- The Agency of Public Hospitals was established in late 2012 with the aim of ensuring effective, quality, and efficient management and functioning of the hospitals. This agency has regional general secretaries, and the general secretaries are responsible for understanding the needs and demands of the hospitals in their regions. This brought a complex model of purchasing technologies to the hospitals where some could be purchased directly by the hospital, while others are subject to approval from the general secretariat. Big ticket health technologies might be regulated at the central level.

and Medical Device Agency (TITCK) in the same year. The Social Security Institution (SGK) established its HTA Department in 2013.

SAGEM has completed and published four assessments and has 12 ongoing assessments [5]. TITCK has one published report and has three ongoing reports [6]. While SAGEM is responsible for single or multiple technology assessments, depending on a prioritization process, TITCK evaluates the pharmaceutical market and sets a basis for prioritization. Although there is no legislation mandating that these two teams work together, informal collaborations with individual efforts are present.

SGK is the agency that provides general health insurance for citizens and makes reimbursement decisions about drugs and medical devices. The SGK HTA Department provides advice regarding the cost-effectiveness of new drugs to the Medical and Economic Evaluation Committee (MEEC), which presents an opinion to the Reimbursement Committee by examining the applications about human medicinal products or medical devices, but it has no published assessment, yet [7].

In contrast to many other countries, hospital-based Health Technology Assessment (HB-HTA) started to flourish before HTA at the national level in Turkey. The only HB-HTA unit as of today, ANHTA, was established before the national units [8].

## 10.2 ANHTA: Ankara Numune Training and Research Hospital Health Technology Assessment Unit

Ankara Numune Training and Research Hospital (ANH) has been providing services since 1881 with extensive experience in research and training. It is considered to be the reference hospital in Turkey, and its mission is the provision of high-quality health-care services to individuals, by experienced teams, and with necessary modern technological equipment. ANH has a 1,200 bed capacity and 145.000 $m^2$ closed area in use. There are nearly 5,000 staff in the team, 1,000 being physicians. Health-care services run in 38 different specialties, and residency training exists in 31 specialties. The hospital has an almost 100 million euro budget. It has a high research capacity and is well known with its completed and ongoing outstanding research projects. With its high technology use, reference hospital status, modern equipment, and highly qualified health-care personnel, ANH has a reputation in Turkey and influence on medical practice and health policy [9]. There have been many changes in Turkey's health policies due to the HTP. This program has also changed the way hospitals are managed, with hospitals now having to manage their own budgets. This gives hospitals the responsibility to be more careful about using their resources efficiently [10]. ANH has rapidly understood the importance of hospital-based HTA use in decisions about resource use for technologies [11]. The hospital has been the first in the country to start HTA in hospitals. Although some other hospitals have also been interested in related concepts, the work done until now has not been in a multidisciplinary and structured way, as HTA should be.

ANHTA was established in February 2012 as an administrative unit attached to the hospital chief executive officer (CEO). It is the first, and currently the only, hospital-based HTA unit in Turkey. The unit started with one chair of the unit supported by three part-time professionals. In addition, there were eight people who were voluntarily involved in the improvement of the unit. Over time, the staff increased to three full-time professionals and four part-time members. On the team, there is one nurse with a PhD, an economist, and two administrators besides clinicians from different backgrounds. The staff are supported by continuous training on HTA methods. HTA unit members are selected from the hospital staff who have background on evidence-based medicine and HTA-related fields and who have an interest in improving efficiency in the hospital. As the members of the team are already staff of the hospital, they receive their salaries from the Ministry of Health and the unit does not require any additional funding for the personnel. ANHTA has no external or independent funding for the unit and does not receive any donation from private companies, but is involved in national and international projects. There is a reserved meeting room for the HTA unit within the hospital, where regular meetings take place and the staff can have access to several databases. The unit or its selected members can be invited by the national HTA bodies for HTA assessments and might also be involved in supporting other hospitals in training or assessments.

ANHTA, from the start, has been in close relation with the hospital management to support decisions regarding technology uptake and use. The team has primarily worked on developing the related human capacity for running the assessments, raising awareness, and developing methods. The initial achievement in its first year of establishment was to publish a guidance on HB-HTA where the reader can find the definition of HTA and HB-HTA, aims and place in management. The same guidance also involves "ANHTA mini-HTA" which was developed after serious work on Spain and Denmark examples and adapting them to the Turkish context [12]. The unit's activities are reported annually in March and all HTA reports are printed, whereas abstracts are published at the website [13–15]. The team has organized two international conferences and two national conferences, besides several training sessions where academics, government staff, and industry members have taken part [16]. ANHTA has also been a partner in AdHopHTA, which is an EU-funded project to promote HB-HTA in Europe [17].

HTA is not mandatory in public hospitals in Turkey. ANHTA is the only HB-HTA unit in the country and sets the only directive on HTA in a hospital setting. Hospitals usually finalize their decisions about new technologies by means of a "Commission of Necessities" where the CEO, the hospital manager, clinical directors, and the head nurse are typically members. This is an internal committee model where decisions are not necessarily based on sound evidence.

In ANH, the request for a new technology can come from any clinical department or administrative unit to the "Commission of Necessities," and the decisions about acceptance or a rejection of the requested technology are taken by this commission. The CEO might ask for an HTA report from ANHTA about a requested technology where he feels more evidence and deeper assessment is needed. This is secured mostly for new and expensive technologies. The CEO might also request assessment on existing technologies either for disinvestment decisions or for rationalization of use. This way of working has a balancing effect on the work load of the HTA unit, as the HTA unit has limited resources and needs to be involved in decisions where more impact could be observed. Requests might also come directly from the clinical directors to ANHTA and this follows the below-mentioned HTA directive.

The unit's position and role in hospital decision-making were officially defined by the *Ankara Numune Research And Training Hospital Health Technology Assessment Directive* in 2013. The purpose of this directive was to define the processes and steps of HTA in the hospital. All kinds of health technologies in the hospital are included in the scope of this directive, which is still valid and in effect. The assessment process is rather formalized and is outlined below:

**Proposal Assessment**

1. Requests for assessment of new investments and technologies, or a reevaluation of existing technologies to be used in ANH, will be conducted by completing the HTA application form and submitting the application form to the HTA unit until the last working day of every month. The application form contains the following sections:

Department/clinic making the proposal
Name of the new health technology and necessity for the proposal
Which old technology will be replaced by the proposed new technology
Clinical indications of the proposed new technology
References (if applicable)
Proposal accepted by
Proposal forwarded by
Contact information

**Topic Selection**

2. Assessment requests are evaluated every month in HTA unit meetings, with the hospital CEO in attendance as the Chief of the Evaluation Commission. Decisions are finalized by the next month's last working day.

**Creation of the Project Team**

3. After the acceptance of an HTA proposal, a project team, including experts in the related field and HTA team members, is formed within 15 days. The project team should include at least three members, with a minimum of one mandatory HTA unit member. All members of the project team will be officially notified.

**Scheduling of the Project Teams**

4. The project teams must have at least two regular meetings per month. The team must finalize the assessment 3 months after the approval of the HTA proposal and begin the writing of the final report.

   If the hospital administration believes a technology has significant importance or priority for the hospital and the patients, unique assessment and scheduling strategies can be developed.

**Working Protocol of the Project Teams**

5. The project team takes into account all the social, ethical, organizational, and scientific aspects of the technology and considers the outcomes with the use of the new technology from the hospital's own perspective.

   The report must be prepared in Turkish and according to the guidelines provided in Annex 2 and must include an abstract, executive summary, and the full report. The executive summary will be translated into English when necessary.

**HTA Unit Final Report Control**

6. The head of ANHTA or an elected member of the ANHTA team acts as the head of the assessment commission.
7. Reports from project teams are evaluated regarding methodology, approved, and transferred to the CEO within 15 days.

**Evaluation by Hospital Administration and Executive Process**

8. The final report is evaluated by the CEO and the commission of hospital managers. The decision is reported officially and sent to the related departments,

including the unit who made the proposal. Actions related to the technology or investment are applied within the organizational structure of the hospital.

### *10.2.1 Annual Audit*

ANHTA has regular meetings to monitor outcomes following technology assessments. At the end of each year (late December), a meeting is organized which involves an annual audit regarding HB-HTAs performed during the previous year. If there is a predefined monitoring date and methodology specified in the performed HTA, this measurement is applied.

### *10.2.2 Examples of Technology Assessments from ANHTA*

ANHTA has decided to run its assessments under three subheadings: investment, disinvestment, and rationalization of use of existing technologies. Four assessments have been completed as of today, two for investment decisions and two for rationalization of use of existing technologies. One investment example and both rationalization examples are given below to illustrate their unique methods and impact.

#### 10.2.2.1 Example 1: Rationalizing Use of Human Albumin Solution in ANH

In 2011, the hospital pharmacy department realized there had been a rapid increase in the use of human albumin (HA) in recent years. HA use increased from 1,473 boxes/year in 2005 to 8,406 in 2010, which could not be explained by any change or reason within the hospital. In reaction to this notice, hospital management asked for a commission to explore possible reasons for this increase and to work on identifying the evidence base for rational albumin use. The soon-to-be HTA team members were also invited to this commission that consisted of directors from the HA user clinics and a representative from the pharmacy. The commission carefully reviewed current use of HA by clinics, indications, and trend of use. The costs were also calculated alongside with the consumption. All clinics were informed about their use of HA. The HTA team conducted a systematic review for up-to-date indications of the drug. The commission later discussed the results of the systematic review, identified indications, and approved recommendations for the hospital. This came as a guidance document which was sent to all clinics. The pharmacy started to provide medication according to this guidance. The use was monitored over time and impact was periodically assessed through clinical record review [18].

This intervention of rationalizing a drug use in the hospital was initiated by a notice from the pharmacy, and the 4-year impact (2011–2015) of the intervention is estimated to be 1,837,000 euros. There was a total of 74 % decrease in HA use in the hospital. The intervention was implemented primarily for the purpose of

rationalization, not cost containment, and is not expected to negatively affect patient care. Alternative technology use, such as fresh-frozen plasma, was also followed and no increase of use was observed. The success of this intervention was welcome by the management in its first year and was the primary factor that facilitated establishment of ANHTA in February 2012.

#### 10.2.2.2 Example 2: Efficient Use of Laboratory Services in ANH

A circular from the Ministry of Health at the beginning of 2013 on promoting efficiency in hospital laboratories was the primary facilitator of the project that was run jointly by ANHTA and the laboratory.

This project aimed to define and produce strategies to rationalize laboratory use in ANH and calculate the impact and potential savings in health-care costs. A collaborative action plan was defined by the hospital managers. Joint meetings with ANHTA and laboratory chairs were set, the joint committee invited relevant staff for input, and a hospital laboratory efficiency committee was created, including clinicians from internal medicine, general surgery, family medicine, emergency department, and the laboratory directors of biochemistry and microbiology departments. Literature was reviewed in order to identify strategies used to improve laboratory efficiency. Strategies that would be applicable in local setting were identified for implementation; processes and impact on clinical use and costs were assessed. The team first created a snapshot of the current status by identifying the mean number of ordered tests per patient and total laboratory cost of every department. Laboratory use reports were sent to the departments every month. A hospital meeting was conducted to create awareness, and doctors from various departments were informed about the appropriate use of laboratory tests. A review was also performed to understand how various laboratory tests are used and whether the use was appropriate according to the guidelines or evidence provided in the literature. After the review of techniques used in different settings, implementation barriers and possible solutions were discussed by the committee. The process revealed the unnecessary use and misuse of tests. The test ordering page in the hospital information system was reorganized. The number of ordered tests and total laboratory costs of the hospital was monitored. Numbers of the ordered tests were compared with the previous years' numbers for each month. A significant decrease in test ordering (between 29 and 92.0 %) was observed. The 2-year study savings was equivalent to 488,557 euros. None of the implementations included a prohibition of the laboratory test orders for the clinicians. There was no change in length of hospitalization and hospital mortality in this follow-up period [19].

#### 10.2.2.3 Example 3: Assessment of Setting Up a Bone Bank in ANH

This process began with a request from the hospital management to ANHTA for an assessment regarding the establishment of a Bone Bank in the hospital. The purpose of this study was to assess the convenience of setting up such a facility in the

hospital for the supply of allografts obtained from suitable donors, rather than ready bone grafts that are used in orthopedic surgery, and to provide evidence-based information to upper management to help them decide whether to invest in such a technology. ANHTA mini-HTA was used for the assessment. A systematic literature review was carried out. The experiences of other hospitals currently using this technology were also reviewed. There were several major weaknesses identified including very limited evidence on the efficacy, safety, and cost-effectiveness, for the proposed technology. The experiences of other hospitals were not inspiring, and other issues included the inability to meet demand, a dependency on the old technology, a risk of delay in emergency cases, and the need for accompanying technologies (such as thermal disinfection equipment, storage containers, deep freeze, archival system, etc.). Additionally, the proposed new technology required environmental setup and training for the operating health-care personnel. Finally, it was concluded that there was insufficient evidence in the literature related to the use of Bone Banks; that setting up a Bone Bank in an independent hospital would be more expensive than the currently available technology, and investment in this technology would not be efficient under the current circumstances. The decision was made not to invest in this technology. If the Bone Bank had been recommended, it would have generated a loss of 312,663 TL (104,221 euros) over the next 10 years (a modest calculation that the old technology continues 90 %) [20].

### *10.2.3 Impact of ANHTA*

ANHTA assessed its impact on ANH since its establishment.

The first two projects helped rationalize drug and laboratory use in the hospital and resulted in a savings of 2,242,464 euros in total since ANHTA was established. These two projects also helped the hospital to focus on the "right use of current technologies." The Bone Bank project was a pilot test to improve the Turkish version of mini-HTA. If the Bone Bank had been recommended, it would have generated a loss of 312,663 TL (104,221 euros) over the next 10 years.

All three projects promoted evidence-informed decision-making in the hospital setting and, through the impacts made, proved the benefits of HTA to the hospital management. ANHTA was recognized by the hospital administration as a serious function producing timely assessments and using transparent methodology. With its unique approach, ANHTA managed to involve relevant clinicians in the process, which increased the acceptance of the management decisions by the clinics. The projects up to now allowed increased awareness of HTA within the hospital, as well as increased interest in evidence-informed decision-making. The process allowed for the improvement of multidisciplinary work in the hospital, helped to close the gap between managers and clinicians, facilitated understanding of the local factors, and grew HTA culture in the hospital. Over time, the methods used, the impact

gained, and the appreciation received from the managers and clinicians have increased the motivation of the HTA team. The projects also allowed the team members to improve their knowledge and skills, which was also supported by several training opportunities throughout the years. The mini-HTA process for Turkey and a guidance document were developed about how to run HB-HTA. Both of these set an example for other hospitals in the country.

The impact of ANHTA has expanded beyond ANH. The amount of savings was recognized by the main reimbursement organization in Turkey (SGK) and also the Ministry of Health. Therefore, the reports were recommended for use in other hospitals. Many hospitals contact ANHTA to request training and more information on HTA methodology. The team itself has organized several conferences, has been invited to different conferences as speakers, published abstracts and papers on HTA, and published a book on HB-HTA in order to spread the culture of HB-HTA in Turkish hospitals. Being a partner in AdHopHTA gave ANHTA the opportunity to contribute to promoting HB-HTA in Europe, to learn from the experiences of other hospitals in Europe, and to transfer this knowledge to Turkish context.

### *10.2.4 What Lessons ANHTA Has Learned*

As the first HB-HTA unit in the country, ANHTA has faced several challenges since, and even before, its establishment. An existing HTA culture could speed up HB-HTA in other settings, but it has not been the case in Turkey. When HB-HTA started, HTA at the national level was also in its initiation phase. It has not been possible for collaborative efforts with the national functions, as each function was trying to establish its own human resources and methods. Some informal collaboration has helped these functions to act together in training for human capacity, as human resources have been identified as a major challenge for improving HTA in Turkey [10]. Another challenge while establishing HB-HTA was that there was no local experience and developed methods for local settings. ANHTA has been the first to work on a guidance on how to do HB-HTA and has also developed a mini-HTA template for the Turkish setting. This has been a difficult process but essential for new starters in other hospitals [12].

Despite the challenges, having strong leadership, supported by a strong political will at the hospital level, has allowed HTA to find its place in the hospital. A good team, with several different backgrounds and with an interest in evidence-informed decision-making, facilitated initiation and continuation of the activities of the unit. The first projects were high impact and drew significant attention from the higher authorities and other hospitals, as well as receiving appreciation from the ANH managers. Conferences, abstracts, and publications have been successful dissemination methods [8, 11, 16]. Being a part of projects, such as AdHopHTA, has been a useful platform to learn from the experiences of others in the field and was also a good way to keep the team members motivated.

### *10.2.5 Vision of the Future of HB-HTA for ANH*

The success of ANHTA has been the best way to increase awareness of HB-HTA in the country. ANHTA is the pioneer and is inspired by other hospitals. In the near future, HB-HTA is expected to be a part of the decision-making processes in hospitals in Turkey, whether through the hospitals themselves or through the designed health campuses of the future that will combine several hospitals under one roof. ANHTA's vision is to be the center of excellence with its methods and human resources and to be the training center for HB-HTA in the country. The outcomes of ANHTA's assessments will continue to affect decision-making beyond ANH.

Learn more about ANHTA at www.anhhta.org.

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# Chapter 11
# The Evidence Decision Support Program Within the Surgery Strategic Clinical Network of Alberta Health Services in Canada

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## 11.1 Brief Overview of Our Health-Care System

In Alberta, the health-care system has seen a series of significant changes and is now organized as one health-care service provider for the province, known as Alberta Health Services (AHS). The structure of AHS comprises five administrative Zones/Health Regions, which oversee more than 100 hospitals and a variety of health service programs. The Zones also work in collaboration with several Strategic Clinical Networks (SCNs) [1]. The Surgery SCN is a province-wide network dedicated to delivering surgical care which is "Timely, Safer and Smarter," for more than 4 million Albertans. The Surgery SCN has a core committee made up of more than 30 members including clinicians, researchers, patients, family members, and decision-makers, and one of its subcommittees is the Evidence Decision Support Program (EDSP). The Advisory Committee of the EDSP is an embedded committee of the Surgery SCN within AHS.

This chapter describes the Surgery SCN EDSP.

**Box 1: Health Care System Context**

1. *How is your health system funded*? Alberta Health Services is 100 % publicly funded for hospital and physician care. Out of hospital allied health and pharmaceuticals are funded by private funding/private insurance.

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2. *How are hospitals funded within the health-care system of your country*? Hospitals are 100 % publicly funded. The Zones receive money from Alberta Health Services and each hospital receives a fixed budget. There is a small amount of case/volume funding.
3. *Who is responsible for making decisions about which drugs*, *devices*, *and capital equipment will be funded for the hospital*? The Provincial Ministry of Health is responsible for reimbursement coverage decision on a broad scale. However, there are also many important decisions made by Zones/Health Regions, Strategic Clinical Networks, and hospital administrators, including operating room managers, who may be the designate for internal budget approval funding decisions.

## 11.2 A Short History of EDSP in AHS

In 1997, the Department of Surgery within the former Calgary Health Region (Calgary, Alberta, Canada) recognized the need to have a process to promote a consistent approach for the acquisition of new technology and created an "Introduction of New Technology" policy and an application form. Concurrently, international, national, and provincial health technology assessment (HTA) agencies were producing independent, objective, and high-quality assessments of research evidence to inform large funding decisions, but they could not evaluate the complex and unique needs of each local institution to help decision-makers acquire new health technologies. As a result, the Department refined its technology introduction process and created an Internal Advisory Committee to integrate HTA reports with local information to inform decisions for the introduction of new technologies at the local level. The Evidence Decision Support Program (EDSP, formerly known as the Local HTA Decision Support Program) was born.

With funding from the Canadian Agency for Drugs and Technologies in Health (CADTH) and support from our administration, additional Program improvement and adaptation projects were undertaken. One key project included the development of interactive HTA *education modules* for health-care practitioners in 2005. Other projects followed from 2006 through to 2009. For example, we solicited the participation of additional departments to evaluate the many aspects and components of the Program and collected their recommendations for improvement. We developed sets of *criteria and decision guides* to facilitate the decision-making process and technology prioritization. The goal was to engage all participating departments in an overall *Program adaptation to other settings*. The improved Program was then implemented within the Surgery SCN of AHS.

## 11.3 Program Improvement and Adaptation

Below we describe the three key Program improvements and the adaptation process. Each section explains why the improvement was done, how it was done, and the resulting impact.

### 11.3.1 Education Modules

Innovation is an important part of surgical practice, but its assessment is complex [2–4]. Surgeons typically want to deploy technology as quickly as possible. The system, however, is not able to allow all independent practitioners to make decisions about the introduction of technologies. Dozens or hundreds of independent decisions may lead to huge variation in care and create significant safety, sustainability, and funding issues. Educating managers and physicians is essential to ensure familiarity with the language of technology assessment and support efforts in coordinating and contextualizing requests for new technologies for the local environment. To this end, we created a series of workshops for managers and physicians with the following objectives:

1. Assess pre-workshop knowledge about HTA and current practices for introducing new technologies.
2. Educate physicians and staff about the Program and tools and their application in their area.
3. Evaluate the impact of the educational workshops on the use of the EDSP.
4. Utilize participant feedback from both groups to improve the Program.

As reported by others [5], prior to our education initiative, health-care providers did not feel entirely comfortable with applying HTA findings to their local facilities, thus resulting in a lesser impact of large-scale HTA reports. Pre-workshop knowledge and familiarity with HTA and its application were varied among anticipated users. The majority of managers had little experience, whereas physicians' experience and knowledge of HTA were broader ranging. At the end of the workshops, all participants gained an understanding of HTA and its application in their environment [6–9]. EDSP forms and tools allowed users to have a set of standardized questions to assess requests, engage in evidence and information gathering, and determine areas where implementation issues might occur. Both managers and physicians provided feedback and recommendations, which have been instrumental in Program improvement. The education program was key to facilitate a discussion forum for the successful implementation of HTA at the local level and the refinement of our local EDSP. Education and early and extensive stakeholder engagement were identified as the most important factors for successful implementation of a local program, as also reported for reassessment initiatives [10].

### 11.3.2 Development of Criteria and Decision Guides

Several studies demonstrate that decision-making for introducing new health technologies can be improved not only by gathering scientific evidence on safety and effectiveness but also by using explicit criteria that articulate the health organization's needs, constraints, and values [11–17]. For example, the organization may prioritize technologies that benefit under-serviced or disadvantaged populations and may devalue technologies that treat only rare disease conditions, even though each technology may have good evidence for safety and effectiveness.

Although our initial Program was successful, it lacked explicit criteria to facilitate decision-making. This was identified by both the Advisory Committee and those reviewing the Program for possible use in their own setting [18–20]. This stimulated the development of a multi-criteria decision tool. We used an expert review panel to decide what criteria need to be used to evaluate new health technologies for introduction at the local level, integrated the criteria into the Program to ensure that critical information is systematically gathered for the evaluation process, and used the criteria to create decision guides to facilitate consistency of decision-making process when recommending technologies for introduction at the local level [21].

The final list of Criteria for Technology Evaluation is shown in Table 11.1. It contains 12 criteria (efficacy, population health, standard of care, safety, training, access, service coordination, sustainability, strategic fit, knowledge and research, cost, and economic analysis) grouped into five major domains (health gain, service delivery, strategic fit, innovation, and financial) and 29 sub-criteria clarifying questions. For example, criterion #5 "training" is classified under the "service delivery" domain and is clarified by two sub-criteria clarifying questions including "5.1 Will the technology require health-care provider training?" and "5.2 What is

**Table 11.1** Appendix III: criteria for technology evaluation

| The following criteria can be used for evaluating a new technology for funding or purchase | | |
|---|---|---|
| Domain | Criteria | Sub-criteria clarifying questions |
| Health gain | 1. Efficacy (evidence-based medicine, clinical outcomes, and quality of life) | 1.1 Is there evidence that the technology will improve individual patient short-term (<5 years) gain in health (clinical outcomes and/or quality of life) as compared with the current practice? |
| | | 1.2 Is there evidence that the technology will improve individual patient long-term (>5 years) gain in health or reduce the likelihood of further disease or complications as compared with the current practice? |
| | | 1.3 Can the technology, including risk of adverse events, benefit cases with few alternatives? |
| | 2. Population health (burden of disease) | 2.1 Does the technology address a condition with significant incidence and/or prevalence (burden of disease)? |
| | | 2.2 Is the incidence or prevalence projected to increase or decrease over the next 5 years? |
| | 3. Standard of care | 3.1 Has the technology become the standard of care in other health regions? |
| | | 3.2 Will the technology establish a new standard of care? |

**Table 11.1** (continued)

| The following criteria can be used for evaluating a new technology for funding or purchase | | |
|---|---|---|
| Domain | Criteria | Sub-criteria clarifying questions |
| Service delivery | 4. Safety | 4.1 Is the technology at least as safe as current practice for the patients? |
| | | 4.2 Is the technology at least as safe as current practice for the health-care providers? |
| | 5. Training | 5.1 Will the technology require health-care provider training? |
| | | 5.2 What is the expected time frame for more health-care providers to acquire the expertise to use the technology? |
| | 6. Access | 6.1 Will the technology improve accessibility (i.e., shift services closer to where patients reside; geographic equity)? |
| | | 6.2 Will the technology provide services to underserved population(s)? |
| | | 6.3 Will the technology improve the provision of services at the most appropriate time or decrease wait times? (Timeliness; service efficiency)? |
| | 7. Service coordination | 7.1 Will the technology improve coordination and collaboration with other clinical services or reduce or increase impact on other services (service coordination)? Will the technology reduce load or positively impact other services? |
| | 8. Sustainability | 8.1 How many health-care providers are demanding this technology? |
| | | 8.2 Will the technology be well utilized? How many health-care providers have the expertise to use the technology upon acquisition? Will additional human resources be required? |
| Strategic fit | 9. Strategic fit | 9.1 Is the technology aligned with internal (department/division) strategic goals? |
| Innovation | 10. Knowledge and research | 10.1 Will the technology improve the generation, transfer, and/or application of new knowledge to patient care services? (innovation characteristics) |

(continued)

**Table 11.1** (continued)

| The following criteria can be used for evaluating a new technology for funding or purchase | | |
|---|---|---|
| Domain | Criteria | Sub-criteria clarifying questions |
| Financial | 11. Cost (resources, infrastructure) | 11.1 Will the technology have direct costs (purchase of technology)? |
| | | 11.2 Will the technology have one-time and start-up costs? |
| | | 11.3 Will the technology have ongoing costs? |
| | | 11.4 Will the technology impact other service areas? |
| | | 11.5 Will the technology have alternative or partial funding sources? |
| | | 11.6 Will the technology have environmental costs? |
| | 12. Economic analysis (cost-effectiveness, cost-benefit) | 12.1 Is there evidence to support the cost-effectiveness of the technology? |
| | | 12.2 Is the cost-effectiveness threshold the same for all (e.g., children vs. adults)? |
| | | 12.3 Is there evidence to support the cost-benefit ratio of the technology? |
| | | 12.4 Are any potential cost increases associated with the technology offset by significant improvements in quality of life or other patient outcomes? |

the expected time frame for more health-care providers to acquire the expertise to use the technology?" The criteria list was used to create the Technology Evaluation Worksheet. This tool scores the quality and completeness of information as well as the significance and impact of the technology. As previously described [17], these tools can provide a "visual map" for each criterion, identify any gaps in the evidence and needs for further research, help reviewers focus their comments and recommendations, and make it easier to describe the rationale for the decision.

The criteria list was also used to create a Decision Guideline Tool and a Technology Prioritization Tool. These tools were incorporated into the Program and are available at www.ahs.ca/edsp.

### *11.3.3 Development of Process for Program Adaptation to Other Settings*

Based on our own survey across different clinical departments and other published findings, there is general dissatisfaction with traditional decision-making processes. Our experience with the development of the EDSP suggests that departments or organizations would be better to adapt an existing program to their needs rather than develop one of their own [20]. There has been interest from other departments in our

hospital/health system for a similar EDSP so a project for adaptation and adoption of the EDSP was launched.

A framework was developed for adapting the Program for use by other departments [22]. The framework consists of six steps: (1) development of a Program review and adaptation manual, (2) education and readiness assessment of interested departments, (3) evaluation of the Program by individual departments, (4) joint evaluation via retreats, (5) synthesis of feedback and Program revision, and (6) evaluation of the adaptation process.

Key points identified in this project:

- The distinction between HTA producers and HTA users. The Program does not duplicate efforts of HTA producers; rather it complements their work by acting as the local receptor to use HTA reports. Local data can fill the gap from published literature and improve the generalizability of that evidence to the local setting [23].
- The Assessment of Readiness Tool was a critical element. It required that participating departments demonstrate readiness for change and appoint an EDSP physician leader and an administrative leader.
- We found that the *Points to Consider Questionnaire* ("why, how, who, what, funding") was essential to ensure that all important Program review questions would be systematically discussed by reviewing departments.
- The request that each department appoint an EDSP physician leader and an EDSP administrative leader was crucial to the success of the project. While physicians were more focused on clinical evidence, training and credentialing issues, and other such clinically relevant topics, their administrative counterparts ensured that infrastructure implications, cost, and organizational impact were reviewed.

These initiatives metamorphosed the Program into our current comprehensive EDSP. But how does it work?

## 11.4 Program Description

### *11.4.1 How Does It Work?*

An overview of the Program is shown in Fig. 11.1. The EDSP was created to provide an expert knowledgeable internal governance structure to help local decision-makers appraise new health technologies in a systematic and consistent manner by incorporating research evidence with local operational management information. The Program requires the appointment of an Advisory Committee of health professional(s) who work as an internal governance structure to manage the evaluation process, review the application for suitability, determine whether the application can be approved without further information, and for those technologies requiring further assessment, make recommendations to the Surgical Executive

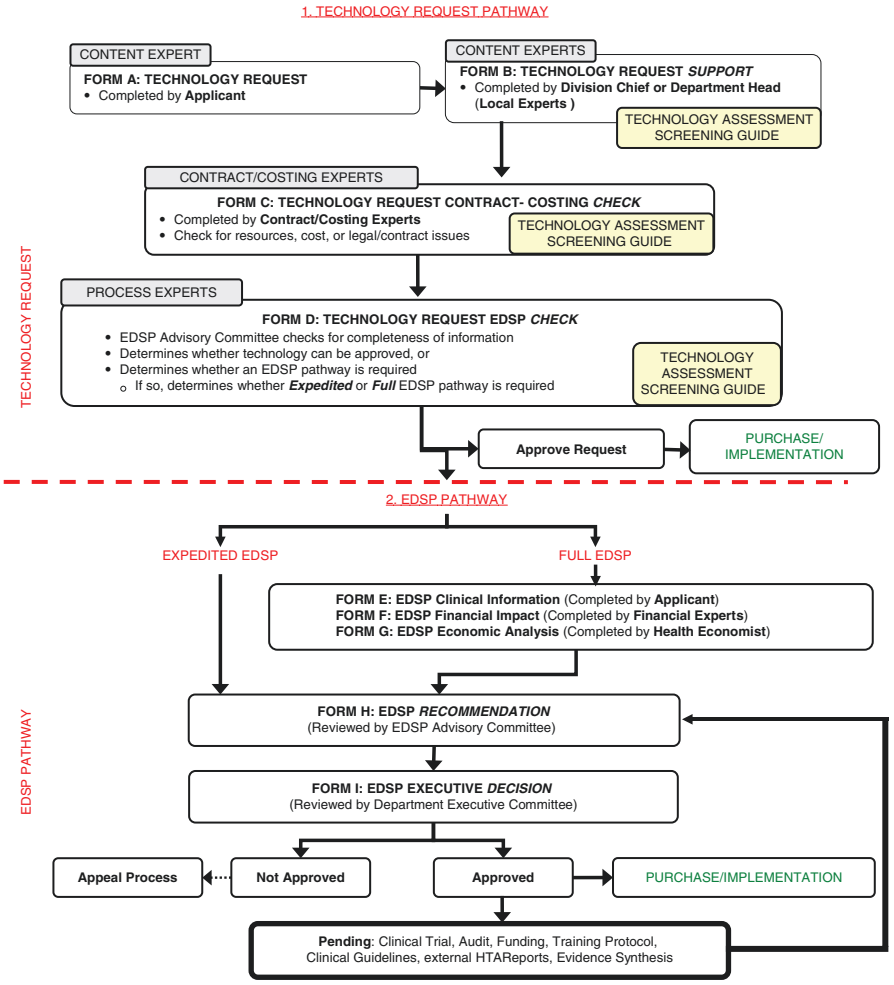


**Fig. 11.1** Overview of the Evidence Decision Support Program. The *Technology Request Pathway* collects basic information about the technology. The EDSP Advisory Committee then either approves noncontentious technologies or refers them for further review by the *EDSP Pathway*. The *EDSP Pathway* is used when additional information and a more complete review are required. The EDSP Advisory Committee then makes a recommendation and presents it to the executive committee, who makes the final decision

Committee for subsequent decision. The Advisory Committee comprises surgeons, a research scientist, patient care/operating room managers, a purchasing specialist, and financial analysts. The Program's tools and processes assist the Advisory Committee in making recommendations about whether and under what conditions the technology would be used. The tools of the Program consist of a *Policy*, *Forms*, and *Appendices*. The *Policy* sets the guidelines for introduction of new technologies, the *Forms* (Table 11.2) collect relevant information about the technology and

**Table 11.2** Forms for the EDSP

| | Form title | Technology request pathway | EDSP pathway |
|---|---|---|---|
| A | Technology Request | √ | √ |
| B | Technology Request Support | √ | √ |
| C | Technology Request Contract-Costing Check | √ | √ |
| D | Technology Request EDSP Check | √ | √ |
| E | EDSP Clinical Information | – | May be required |
| F | EDSP Financial Impact | – | May be required |
| G | EDSP Economic Analysis | – | May be required |
| H | EDSP Recommendation | – | √ |
| I | EDSP Executive Decision | – | √ |

The *Forms* are used to collect information in regard to the safety, efficacy, and organizational impact of selected new technologies and to direct the process flow so that all stakeholders are consulted. The *Forms* are available at www.ahs.ca/edsp

the environment in which it is intended to be used, and the *Appendices* (Table 11.3) provide guides for evaluations and decision-making. Details of the policy, forms, and appendices and how they are used can be obtained at www.ahs.ca/edsp.

There are a variety of similar tools for finding and using evidence about local conditions [24], and as local hospital-based HTA programs continue to evolve, it will be important to constantly review and possibly standardize our tools. As you will see in the impact section below, the EDSP helps inform the optimal use of a technology in the local environment and provides recommendations for local evaluation, monitoring, education and training, local budget, and stakeholder involvement.

## 11.5 EDSP Impact

In 2010, an initial retrospective analysis of the impact of our Program was carried out. Figure 11.2 shows examples of the decisions made on the 68 technology requests between 2005 and 2010. Fifteen of the initial request submissions were incomplete, either because an internal applicant could not be found (the Policy does not allow vendor-initiated requests without an applicant from the Department) or the applicant failed to complete the required forms. Of the 53 complete technology requests, 21 % (11/53) were approved within the Technology Request Pathway. These technologies were deemed to involve only a minor change of practice and approval was given for purchase and implementation. The remaining 79 % (42/53) of requests were referred to the EDSP Pathway for decision by the Surgical Executive Committee. Of these 42 requests, one was approved, 24 were conditionally approved either as “Conditional: Single Case” or “Conditional: Clinical Audit,” 14 were approved only under research use, and 3 had a potential impact beyond the

**Table 11.3** Appendices for the EDSP

| | Appendix title | Description |
|---|---|---|
| I | Technology Evaluation Screening Guide | Gives guiding questions to help determine whether evaluation of a technology should follow the Technology Request Pathway or the EDSP Pathway |
| II | Levels of Evidence | Gives an explanation of the strength (level) of evidence. Used in Form E when providing evidence for a technology's clinical efficacy |
| III | Criteria for Technology Evaluation | Gives a set of predetermined criteria to help evaluate the merits of a new technology being considered for funding or purchase |
| IV | Technology Evaluation Worksheet | Gives a worksheet for members of the EDSP Advisory Committee for reviewing and making recommendations on a technology |
| V | Decision Guideline Tool | Gives guideline recommendations and decisions regarding new technologies. For use by the EDSP Advisory Committee and Departmental Executive Committee |
| VI | Presentation Template | Gives a template for presenting a technology at Departmental Executive meeting to ensure all evaluation criteria are addressed in a consistent and systematic manner. For use by the EDSP Advisory Committee |
| VII | Progress Report | Provides a template for reporting significant follow-up outcome measures to document the performance (benefits) of a technology. For use by the applicant |
| VIII | One-Off Urgent/Emergent Evaluation Process | Gives a draft process for evaluating requested technologies for patients with few alternatives |
| IX | Technology Prioritization Tool | Gives a structured process for rating and ranking several technologies, e.g., when determining which of several technologies should be submitted for funding |

The *Appendices* are a set of guidelines for making decisions at various steps in the process and worksheets for evaluations, reports, and prioritization. The *Appendices* are available at www.ahs.ca/edsp

scope of surgery and were referred to other working groups or the provincial government [25].

Some technologies underwent a second round of review after clinicians presented patient outcome data obtained from locally testing the technology as recommended by the first review cycle. Of four technologies initially approved for clinical audit, one was approved for testing in another setting (ambulatory care as opposed to hospital) and the other three were dropped for failure to outperform the existing standard of care. Of four technologies approved for clinical trial, two were approved for further trial to increase sample size, and two were not approved because of failure to perform [25]. All technologies were also conditionally approved pending funding by impacted operational budgets.

It is important to note that the review of a technology rarely resulted in a "yes" or "no" decision for introduction [25]. Rather, as is the case today, the vast majority of requests were given approval for a limited number of cases with the requirement

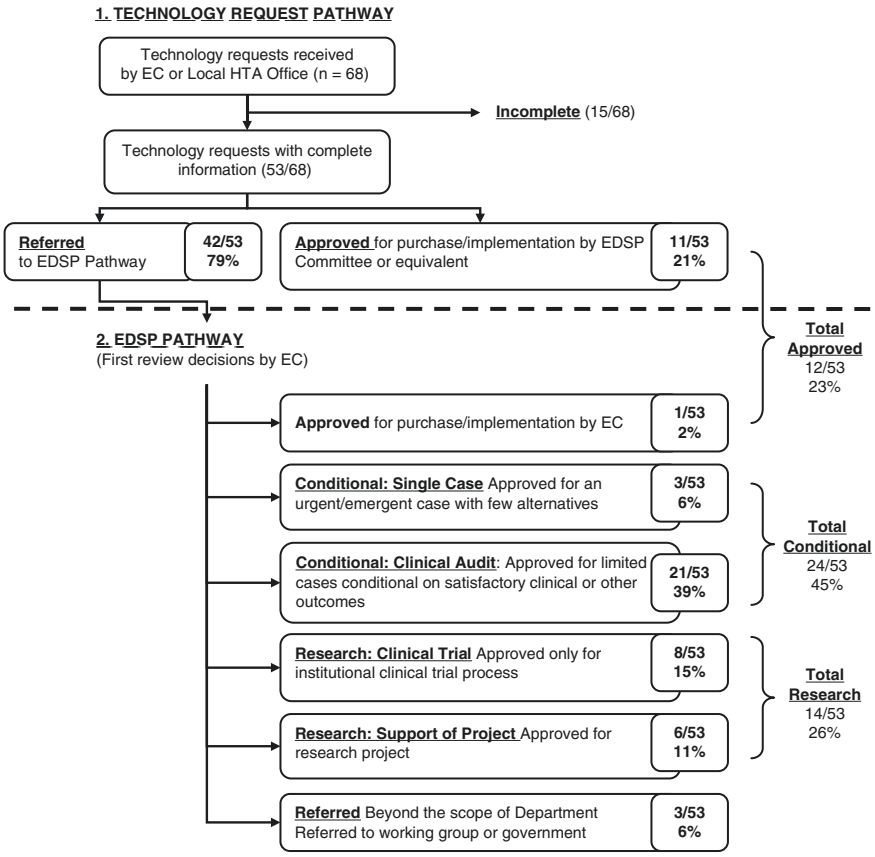


**Fig. 11.2** Examples of decisions made by the Evidence Decision Support Program. The figure lists what decisions were made on the first round of review via the *Technology Request Pathway* and the *EDSP Pathway* between December 2005 and December 2010 (Figure adapted with permission)

to satisfy certain conditions including the evaluation of uncertainty relating to clinical effectiveness, the establishment of some patient outcomes monitoring, the development of agreed-upon clinical evaluation practices, the provision of detailed information about training/credentialing protocols, and the support of hospital budget management. In this manner, the Program prevented the unrestricted uptake of technologies, prevented key patient safety issues, and informed the optimal use of new technologies. Recently, the Program was also used to inform the 3–5-year strategic planning of our surgical services, as surgeons are key players in identifying emerging technologies [26].

Our Program recognizes the need to build evidence and support quality improvement initiatives and offer additional approval options between full acceptance and rejection. New surgical devices or generational updates of existing devices often have little published evidence to support their use [27]. Rather than stifling innovation

and rejecting the technology, which has been a criticism of HTA initiatives [28], the Program attempts to manage risks associated with the limited evidence by setting conditions for technology use, as has been done or recommended elsewhere [29–33]. However, this becomes very challenging with the development of personalized medicine where medical devices are designed to fit specialized and restricted small patient populations at a high cost. Furthermore, while our managers and administrators can evaluate the local budget impact, there is a need for developing cost-effectiveness models on a local level to inform whether and when to adopt a new technology [34].

Local hospital-based HTA programs can help shape various decisions made by several decision-makers and help the management of diffusion and utilization of technologies to optimize use [5]. In fact, Owen-Smith et al. [35] showed that NICE guidance was of more importance and usefulness to managerial than clinical professionals. In a large system that is administratively complex, such as ours, it is difficult to manage the entry of health technologies into the multitude of hospital settings, and we do not know how many new technologies may have entered the system without notification to our Program. It is hoped that with additional engagement and education initiatives, the potential to bypass our Program will be reduced over time.

Overall, the impacts from our EDSP and other local hospital-based HTA initiatives have been seen in a myriad of ways, as outlined here and in the extended literature [15, 25, 36–43].

## 11.6 Lessons Learned

*What works*: The EDSP Advisory Committee that provides an expert governance structure for our local EDSP has several excellent features. First, the Program was designed by surgeons for surgeons, and surgeons are the key players in making recommendations and decisions. The surgeon co-chairs are the "face" of the Program. They also play a key role in identifying emerging technologies [26]. Conflict of interest is avoided by the presence of multidisciplinary members on the Advisory Committee representing various perspectives of the organization and by using expert HTA Agencies (mostly CADTH) to carry out independent and objective evidence reviews. In fact, we know that our Program has prevented the unrestricted uptake of technologies that have been approved elsewhere, indicating that surgeons can ask hard questions about new technologies. Second, any department member is empowered and encouraged to submit a technology request; this bottom-up approach can support a wide array of innovations to achieve ongoing improvement in health, patient outcomes, and sustainability of our health system. Third, the Program is highly collaborative, relying on a multidisciplinary team of physicians, nurses, managers, researchers, and administrators to bring their expertise to the evaluation and decision-making processes that contribute to creating a high performing system. Fourth, the Program encourages innovation while managing risk by offering a range of conditional approvals.

This helps bridge the gap between evidence and practice, a long-standing concern [23, 44–47], by providing a way to incorporate global evidence with local relevance as well as by involving surgeons and operational leaders. We believe that our local EDSP has sufficient versatility to be adapted to a wide variety of regional health authorities.

*There are challenges* to operating a local program, but many of these challenges can be overcome using solutions developed by those leading them [48]. There are several areas where our local EDSP could be improved. As recommended by Mitchell [23], using local data can fill gaps in the published evidence and also improve the generalizability of evidence to the local setting, but to take advantage of local evidence, health systems need to develop and maintain databases of patient outcomes, utilization of services, and their associated costs. Easy access to such prospective databases and registries would facilitate our technology introduction monitoring processes and the local evaluation of safety and effectiveness of novel technologies [4, 29, 49–52]. Within surgical services this will be facilitated by using the American College of Surgeons National Surgical Quality Improvement Program® (ACS NSQIP®) [53] (https://www.facs.org/quality-programs/acs-nsqip), recently installed in five major hospitals in Alberta. It is only when we monitor and are able to evaluate outcomes that patient safety will be optimized when introducing new health technologies [29, 49]. In addition, although there appears to be a general view that involvement of patients and the public is highly desirable in HTAs and many HTA agencies have established some mechanism for seeking input from patients or the public [54–68], our Program lacks both patient and public input. And finally, currently there is concern regarding the uncontrolled introduction of technologies through donation and the degree to which donation processes align with provincial mechanisms for assessment and decision-making on introduction of health technologies. Some technologies may enter the health-care system without being critically appraised. Also, the donation process is driven by philanthropists, and pressures are created that may not be aligned with evidence-informed decision-making, health system priorities, or optimal use of innovation compared to local alternatives. There is a need to review the role of donation in the adoption of health technology and identify a plan to create better alignment with current provincial mechanisms for assessment and decision-making on adoption of health technologies while supporting health technology innovation. There is also a strong need to secure funding for the Program's operation.

## 11.7 Vision for the Future of Hospital-Based HTA

As we have described in our experience with the EDSP, research evidence by itself is limited in the context of medical/surgical devices or innovative services. Effective decision-making must consider and integrate not only context-free (published safety and effectiveness research) and context-sensitive (local needs and constraints)

evidence but also provide an embedded multidisciplinary governance structure (i.e., Advisory Committee) for sharing decisions through meaningful deliberation. This ensures that patients get optimal treatment, while consideration is given to safety, effectiveness, resources implication, training/credentialing, operational feasibility, as well as evidence development and innovation. Within AHS, our future direction is to spread the EDSP to other SCNs and we propose a series of targeted recommendations as our Vision for the Future (Table 11.4).

**Table 11.4** Summary of Lessons Learned and Vision for the Future

| | |
|---|---|
| Leadership, mandate, and governance | Members of the Local EDSP Advisory Committee (physicians and staff) must have the full support of their leaders, have a clear mandate, and be empowered to oversee and operate the Program and adapt it as required |
| Multidisciplinary Advisory Committee | Appointment of multidisciplinary, objective, and trusted personnel to comprise the Local EDSP Advisory Committee is essential |
| Education and engagement of physicians and staff | Education as well as early and extensive stakeholder engagement is the most important factor for successful implementation of a local program. We must aim to simplify our decision-making process and reach consensus faster by engaging, training, and mentoring specialized EDSP Committees and impacted stakeholders in an unbiased, transparent value-based process. We also need to survey and evaluate the experiences, learnings, and sustainability of newly created EDSP Committees |
| Local context | Factors regarding the local context can override positive research evidence but must be taken into consideration, e.g., concerns with budget, access, and availability of trained personnel or other local context factors |
| Budget impact | Our managers and administrators can evaluate local budget impact, but there is a need for developing cost-effectiveness models on a local level |
| Multi-criteria decision tools | The criteria and decision tools used by the Program must be explicit, agreed upon, and freely available. A well-defined criteria tool combines the collective intelligence in one simple, shared tool that shows clinical and financial considerations, safety issues, operational feasibility as well as physician preferences related to a technology under consideration. This enables stakeholders to factor in a variety of competing interests and helps the team achieve collaborative decision-making |
| Clinical audits and outcome measures | When feasible, testing and measuring outcomes using local data prior to technology introduction are hugely important, as technologies often do not perform as well as advertise. Ideally, efforts should be made toward the creation of large (provincial, national, or international) well-designed outcome registries |
| Support innovation | Attempts must be made to manage risks associated with limited evidence by providing funding and resources to support evidence development |
| Strategic planning | There is a need for greater coordination, planning, and management of Medical Devices Procurement in Public Health Services. We must ensure evidence review is fully integrated with surgical service planning purposes (proactive based on needs and interest and ability of local environment) |

**Table 11.4** (continued)

| | |
|---|---|
| Training/credentialing | When new technology is introduced, adequate physician and support staff training/credentialing must be provided to ensure safe and effective use. This is of particular importance for medical/surgical devices |
| Disinvestment | The continued addition of new technologies can result in purchasing inefficiency or patient safety issues. This highlights the urgent need to consider the introduction of new technologies that are specifically linked to disinvestment proposals |
| Putting the patient and public in the center | Collaborative patient-centered care is a priority, and to enable truly patient-centered care, the HTA process must develop some mechanism for seeking input and incorporate the views and experiences of patients |
| Philanthropic donation | There is a need to review the role of philanthropic donation in the introduction of health technology and identify a plan to create better alignment with current mechanisms for assessment and decision-making on adoption of health technologies while supporting health technology innovation |
| Personalized medicine | HTA must anticipate and prepare for personalized medicine because many innovations are focused on small, highly specific patient population at very high cost. This issue can be mitigated when comparing to current effective treatment when available and comparative effectiveness measures are needed. HTA should be used to identify gaps in evidence and inform research agenda and study design for comparative effectiveness research |
| Generalizability | The Program should be freely available to all so that it can be continuously reviewed and adapted to other settings. It is a work in progress and there is a need to keep reviewing and reshaping our tools to fit the needs of the physicians, patients, and managers of our ever-evolving health-care system. Safety, efficacy, and effectiveness integrated to local context are key principles by which we operate to sift through the incoming tide of technologies |
| Clinical pathways and multi morbidity | Further models for HTA need to incorporate how clinical care pathways can be effectively evaluated [69] and could meet the needs of older multi- morbid patients [66] |
| Implementation requirements | Commitment (willingness to adapt and use the Program) |
| | Funding (to support Program operation) |
| | Human resources (to ensure adequate personnel are assigned to support Program operation) |
| | Education (to ensure Program awareness and training of the EDSP Advisory Committee) |
| | Strong link with external HTA agencies (to produce independent, objective evidence reports) |
| | Internal researchers (if possible, to support evaluation and refinement of the Program) |
| | Leadership and mandate (it must be clear who makes the final decisions on the approval of new technologies) |

In conclusion, the further development of local hospital-based HTAs must remain fluid in order to face challenges presented by implementing decisions relating to clinical innovation in the setting/limitations of organizational health-care service infrastructure. Innovation should be introduced with the highest possible level of safety and effectiveness for the patient and consideration of available resources of institutions [70]. Local context with respect to training, usage, and cost must always be integrated with global evidence, regarding safety and efficacy, to ensure the most responsible decisions are made regarding the utilization of new technology.

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# Chapter 12
# Hospital-Based HTA and Know4Go at MEDICI in London, Ontario, Canada

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## 12.1 Background

While individual hospitals are responsible for the majority of drug and technology decisions, relatively few Canadian hospitals have formally implemented HB-HTA, except for the province of Quebec where HB-HTA is mandatory for teaching hospitals. In general, decisions for which devices, tests, medical procedures, surgical interventions, or programs of care will be used in Canadian hospitals are made based on nonsystematic consideration of a "convenience set of evidence" provided by internal advocates or by industry representatives. Few hospitals have adopted an objective, systematic, dispassionate approach to assessing all relevant evidence and economic information to inform which technologies to take up and which to forgo. Despite the existence of external HTA agencies at the national and provincial level, there is still an important gap to be filled by HB-HTA to address contextual issues that are not assessed by external HTA agencies (i.e., competing priorities, local skills and infrastructures, resources, and trade-offs). Moreover, most technologies have not been formally assessed by external HTA agencies before hospitals make

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decisions about whether to adopt them. This chapter focuses on HB-HTA in the teaching hospitals across the city of London, Ontario [1–7].

There are two hospitals in London, Ontario, Canada that provide service to the city and surrounding referral regions. The London Health Sciences Centre (LHSC) is one of the largest acute-care teaching hospitals in Canada providing adult and pediatric services. St. Joseph's Health Care London (SJHC) is also a large teaching hospital in London, with a focus on ambulatory care, chronic care, rehabilitation, and mental health services for adults and children. There are more than 15,000 physicians, residents, and staff providing care for more than 1.5 million patient visits annually. The combined annual budget for LHSC and SJHC is approximately $1.7 billion (Canadian dollars).

**Box 1: Health Care System Context**

- The majority of healthcare in Canada is universally provided and publicly funded through the provincial government.
- Hospitals receive their funding from the provincial government, usually through an annual budget based on historical allocations and/or activity-based funding.
- Most decisions about drugs, medical devices, and medical/surgical procedures are made by the individual hospitals, according to local demands and budget limitations.

## 12.2 Evolution of HB-HTA in the London Hospitals

HB-HTA in the London hospitals evolved over the past 15 years including programs under various names, which have recently been consolidated within the Centre for Medical Evidence, Decision Integrity & Clinical Impact (MEDICI) as a partnership between the hospitals and academia. It is useful to describe the progressive stages of HB-HTA in London, to understand the context for the scope and breadth of the program and approaches to assessment. Appendix 12.1 outlines some of the technologies and drugs evaluated over the course of the HB-HTA program in London, Ontario, and further information is available on our website[1].

## 12.3 Evidence-Based Prescribing Initiative (EBPI): Drug Assessment

- Our HB-HTA program began its earliest roots during a hospital-funded project in 1999 entitled the Evidence-Based Prescribing Initiative within the London Health Sciences Centre [7]. The objective of the initiative was to improve translation of evidence related to drug therapies (whether "new" or "established") into

hospital policy and practice through a process of collaborative systematic review with meta-analysis of the evidence, alongside deliberative discussion about the relevance for our local setting. The evidence-based analyses and deliberative discussions were presented by teams of clinicians together with the EBPI project leader to the appropriate policy committees (usually the drug and therapeutics committee and other relevant clinical, quality, and finance committees) to inform decisions about which drugs should be taken up versus which should be abandoned from practice.

- Initially, new and expensive drugs were the primary focus. But, eventually, drug classes were also reviewed, for the purpose of simultaneous investment and disinvestments within drug classes. In addition, the focus was not only on assessment but also on translation into policy and practice, with evaluation of the impact post-implementation. At any time, three to nine assessment and implementation projects were in progress simultaneously, with one full-time program leader supplemented by a number of clinicians and administrators providing in-kind time.

This innovative approach to knowledge translation was focused on collaborative evidence discovery with the project leader together with hospital practitioners (physicians, nurses, dieticians, respiratory therapists, clinical ethicists, and pharmacists) and managers (budget holders and other hospital policy-makers) to identify, interpret, synthesize, and evidence for high-risk or high-cost drugs in order to improve relevance, buy-in, and ultimately decision translation into practice within LHSC. The success of this initial project resulted in an ongoing program of evidence-based evaluation for drug therapies at the London Health Sciences Centre, resourced primarily through hospital operational funding and supplemented by grant funding and in-kind time from practitioners and trainees.

This initiative introduced a new standard for evidence-informed decision-making at our hospital, ushering in a culture of expectation for rigorous evidence reviews to undergird decisions, and was soon incorporated into the hospital policy-making process for any drug therapy being considered for adoption or disinvestment. A number of drugs assessed in early stages have since become the focus of reassessment, or have been useful to expand into full drug class reviews, with subsequent evidence-based guidelines for internal use.

Some of the assessments culminated in collaboration with the Ministry of Health (MOH) and with the Ontario Hospital Association (OHA) in order to influence drug policy changes in hospitals across the province (drotrecogin alfa, rhAPC; proton pump inhibitors, PPI; intravenous immune globulin, IVIG; biologics for ulcerative colitis). This process also allowed for a few innovative drug price negotiation strategies based on best available evidence, moving us toward evidence-based drug procurement with risk-sharing agreement for selected drug purchase contracts. The EBPI was awarded with two national recognitions: the Innovative Practitioner Award and the Pharmacy Administration Award. In addition, this program was awarded the LHSC Medical Advisory Committee Award (1999) for local impact. Some of the methods and approaches developed during the EBPI continue within our hospital today as a common thread toward assessment of drugs and technologies [1].

## 12.4 High Impact Technology Evaluation Centre (HiTEC): Assessing Drugs, Devices, and Procurement

Eventually, the need to apply evidence-informed decision-making to areas beyond drug therapies was recognized within the London hospitals. As a result, the High Impact Technology Evaluation Centre (HiTEC) was initiated in 2003, with hospital operational funding, grant funding, and in-kind time to perform assessments of drugs and other nondrug technologies as requested by senior hospital leadership, managers, or relevant clinician decision-makers. HiTEC operated as an on-demand request service, to facilitate evidence synthesis and economic evaluations of drugs, devices, and other technologies to inform hospital decisions and procurement processes. In addition, we undertook collaborative projects with Medbuy (a group purchasing provider) to inform negotiations with industry for proton pump inhibitors and erythropoietics. The success of these initiatives was awarded the LHSC/SJHC Medical Advisory Committee Award in 2006 in recognition for evidence-based planning and implementation (knowledge translation) [1].

## 12.5 Evidence-Based Perioperative Clinical Outcomes Research Group (EPiCOR): Assessing Medical and Surgical Procedures

Following the early successes of HiTEC, leaders from other areas of the hospital requested formal collaboration to enable more systematic assessment of anesthesia, surgery, and critical care. As a result, we inaugurated the Evidence-Based Perioperative Clinical Outcomes Research Group (EPiCOR) as an academic and hospital-based collaboration together with HiTEC through a combination of grants, local operating funds, and in-kind clinician support, from the departments of anesthesia and perioperative medicine, surgery, medicine, and pharmacy.

The EPiCOR–HiTEC collaboration also expanded beyond local work at the London hospitals to include international efforts to develop HTAs for surgery, anesthesia, and critical care. In addition, EPiCOR–HiTEC collaborated with international surgical and medical societies to assess innovative hospital technologies and surgical techniques. Through this approach, HTAs, guidelines, and consensus statements were developed for local and international considerations related to adoption or disinvestment in off-pump coronary artery bypass surgery, stentless aortic valves, transmyocardial laser revascularization, surgical ablation of atrial fibrillation, upper gastrointestinal bleeding, percutaneous coronary intervention, minimally invasive mitral valve surgery, video-assisted thoracic surgery, endovascular vein harvest, antibiotic prophylaxis, thoracic endovascular aortic repair, transcatheter aortic valve implantation, and various drugs, technologies, and techniques for blood conservation [8–31].

## 12.6 Centre for Medical Evidence, Decision Integrity & Clinical Impact (MEDICI): Assessing Drugs, Devices, Procedures, and Programs

In 2012, we inaugurated the Centre for Medical Evidence, Decision Integrity & Clinical Impact (MEDICI), which consolidated and further expanded the mandate of ongoing programs and initiatives including HiTEC, EPiCOR, and Know4Go (Appendix 12.2) to foster HB-HTA initiatives locally and beyond while also enabling research, teaching, and service provision through broader collaboration for hospital-relevant HTA. Since HB-HTA provides the "perfect microcosm" to test methods and gain firsthand knowledge of techniques for translating evidence into policy and practice, the mandate of MEDICI has expanded to include research, education, and methods for improving decision-making and knowledge translation. The following outlines the key mandates of MEDICI:

1. *Practice and policy:* To provide timely, contextualized evidence syntheses to enable real-world evidence-informed decision-making related to drugs, devices, procedures, and programs with a special focus on (a) hospitals at the local, regional, national, and international level and (b) global surgery, anesthesia, and perioperative care as an essential component of universal healthcare in the developing and developed world
2. *Education:* To provide educational and capacity-building opportunities in evidence-informed decision-making, health technology assessment, health economics, health policy, and knowledge translation locally, nationally, and internationally in the developed and developing world
3. *Research:* To conduct cutting-edge research to advance the front of health technology assessment, economic analysis, health policy analysis, decision-making science, and knowledge translation in the developing and developed world

A brief outline of MEDICI is provided below. Further information and additional published and internal HTA reports are available elsewhere [1, 8–78].

Currently, the staff of MEDICI includes three part-time positions (director, medical director, health economist) and three full-time positions (one coordinator, one systematic reviewer and methodologist, one research assistant). The three part-time positions also hold other roles, such as teaching university courses and providing clinical services and administrative responsibilities within the university and hospital. Additionally, at any time a number of trainees and visiting researchers contribute to MEDICI activities, including postdoctoral fellows, global health fellows, clinical fellows, medical residents, visiting professors, graduate students (MSc of biostatistics and epidemiology, MSc of applied mathematics, master of library and information sciences), and undergraduate medical and health sciences students. Funding for MEDICI varies annually based on the magnitude and scope of the work requested by the funding partners. Typically, the funders include Schulich School of Medicine & Dentistry, London Health Sciences Centre, St. Joseph's Health Care, Lawson Health Research Institute, internal grants, external grants, and externally

commissioned service contracts from other hospitals, clinical specialty societies, and other governmental or nongovernmental organizations.

HB-HTA services at MEDICI include assessments of technologies, procedures, drugs, and programs through comprehensive systematic reviews or ultra-rapid systematic overviews [1, 7–68]. In addition, when capacity allows, MEDICI supports clinician researchers to design appropriate research to address evidence gaps. Depending on available resources within MEDICI, requests for assessments are accepted through a number of channels, such as through the senior leadership team including the hospital CEOs and other senior administrative leadership, or through clinical leaders including departmental chairs, and directly by physicians or other practitioners. The hospitals have gone through a number of changes in CEOs and senior leadership over the years, resulting in changes in institutional management structures and decision-maker accountabilities. As a result, we have provided HB-HTA for a number of different committees and decision-making units within the hospital in order to remain flexible based on demand and tempered by our available human resources and funding flows. At this time, decision-making for health technology uptake and disinvestment is spread across committees and decision-making structures within the London hospitals, typically organized around clinical departmental structures according to budget accountabilities. At the time of writing, there is no centralized intake process or unified decision-making process for all technology requests for the London hospitals, and we see this as an opportunity for formal research. We are currently seeking grant funding to evaluate the impact of a centralized approach using the Know4Go and IDEAL frameworks [69], both locally and in collaboration with other hospitals in Canada and abroad.

When requests focus on single technology assessment within the local hospitals, we typically use Know4Go to initially map the evidence and resource impacts based on a rapid review of published evidence and local data as a prioritization step to determine whether more in-depth analysis is worthwhile (Appendix 12.2). This rapid pre-assessment allows us to telescope the depth and breadth of the review based on the likely impact of the technology in question. If the pre-assessment suggests that the payback on comprehensive assessment efforts are likely to be commensurate with the potential magnitude of impact of the technology, and if no relevant up-to-date reviews pre-exist from other HTA agencies (including the Canadian Agency for Drugs and Technologies in Health, Health Quality Ontario, and Ontario Health Technology Assessment Committee), we perform “de novo” systematic reviews, meta-analyses, and meta-regressions as the first component of Know4Go. Subsequently, as needed, we determine the contextualized benefit index and local opportunity costs based potentially on local data analysis, economic modeling, sleeper analyses, and a survey of competing priorities. The comprehensiveness of the evidence, economic, sleeper analyses, and trade-off assessments depends on the question at hand, whereby high-stakes decisions receive more time and rigor than low-stakes decisions. In some cases, the evidence and/or economics is so compelling that the Know4Go and decision-making process can be truncated without performing extended analyses. The comprehensiveness and number of reviews conducted also depends on amount of human resources available within MEDICI.

More recently, requests have increasingly focused on more complex “programs” of care (multiple embedded systematic reviews), with crosscutting issues of tech-

nologies, techniques, and institutional issues (i.e., sleepers) embedded within the request (see Appendix 12.1 and Appendix 12.2). While program assessment or "portfolio-wide" assessments can be extremely informative (far beyond single technology assessments), they have also raised significant challenges for a small unit as ours, since program evaluations often represent large and complex assessments that required devoted full-time research resources for several months while reducing our capacity to turn over multiple individual assessments within the annual cycle. Research efforts are required to address this gap.

In addition, we have supported evidence development and research sequencing for innovative early development and evaluation of devices or procedures using the Know4Go Framework (Appendix 12.2) and the IDEAL Framework [69]. Since our HTA process also involves identifying gaps in the evidence base, we have also conducted local randomized controlled trials when existing evidence was insufficient to inform the decision at hand (Appendix 12.1) [35, 41, 51]. However, the latter has been difficult to achieve consistently, due to the resources and timelines required. More commonly, we have conducted local database analyses, scenario modeling, or pragmatic "value of further information analyses" to better inform whether decisions should be (a) "yes" or "no" today or (b) "further research is required *and* is worth waiting for" or (Appendix 12.2).

MEDICI has experienced increasing demand for external consultations and international collaborations with hospitals both in the developing world and in the developed world. Taking on international work and consultations has resulted in less capacity for local projects. This trade-off will be reconsidered over time as we consolidate our expanded service, education, policy, and capacity-building mandate, and as we shift resources to enable efficiencies from locally conducted HB-HTA toward our ultimate goal of a local-global collaboration to reduce duplication, and increase cost-effectiveness and timeliness of HB-HTA through collaborative efficiencies and a formal research program to provide a systematized approach to development and evaluation of HB-HTA methodologies.

As an extension of our local work in technology assessment and knowledge translation, members of MEDICI have contributed to a number of provincial, national, and international initiatives, including Health Quality Ontario Quality-Based Procedures, the Choosing Wisely Campaign, Ontario Drug Benefit policies, the Drugs for Rare Diseases Policy Working Group, Ontario Blood Advisory Committee [70–72], research on decision-making determinants [73], policy advice and white paper on health technology assessment and management for Health Canada, the "Unleashing Innovation: Excellent Healthcare for Canada" conducted by the Advisory Panel on Healthcare Innovation, and the federal health minister's roundtable on healthcare innovations [1]. We have also been invited to expand a number of our local assessments to coproduce national or international surgical society guidelines and priority-setting papers for a number of technologies and techniques (Appendix 12.1).

Given that HB-HTA is particularly relevant to achieving the globally declared sustainable development goal of "universal healthcare provision for the majority of the global population by 2030," MEDICI is now collaborating with the World Health Organization (WHO) Emergency and Essential Surgical Care program to address issues related to global surgery, anesthesia, and critical care services [74–77]. In

2014–2016, MEDICI collaborated with the WHO to address the risk and impact of Ebola virus disease on the provision of surgery services in West African countries. Additionally, we are working with WHO on opportunities to improve access to essential global surgery and anesthesia services while also reducing perioperative and anesthetic-related morbidity and mortality in the developing world through contextualized evidence assessments. Performing HB-HTA to scale with meaningful contextualization and local stakeholder engagement and empowerment will be essential to providing timely guidance on how to achieve this sustainable development goal and may in fact have greater impact on quantity and quality of life and greater return on investment than performing more marginal assessments for newer technologies in the local hospital settings of the developed world.

## 12.7 Impact of HB-HTA in London

In 2012–2014, we performed a return-on-investment (ROI) evaluation of the impact of HB-HTA using Know4Go in the London hospitals. Overall, the ROI was greater than 2-for-1 (i.e., $2 saved for every $1 invested in the HB-HTA program) [1].

In another before-after study of the impact of our approach to HB-HTA using Know4Go to address drug decisions within LHSC, we found that the implementation of Know4Go was associated with reduced drug cost growth in our hospital and reduced total drug costs per patient when comparing the 5 years prior versus 5 years post-implementation (Fig. 12.1). This result was not too surprising, since we had focused especially on performing evidence-based assessments and sleeper assessments for targeted high-cost drugs in 2006 and beyond. During this period, we also developed an annual request for proposals through the drug and therapeutics committee to receive requests for assessments in a coordinated fashion and to elicit sleeper issues that might not be anticipated in prior assessments. We additionally implemented a 24/7 pager system, whereby special one-off requests for non-formulary drugs could be made, which allowed a core team from the Pharmacy & Therapeutics Committee to screen all such requests for approval or rejection on a case-by-case basis. This proved especially important for effective de-implementation of some high-cost drugs (i.e., aprotinin) and for preventing indiscriminate use of newer drugs. It also served as a "horizon scanning" device to foresee the need for upcoming assessments for drugs with increased demand through special request system.

Nevertheless, while the results of our study suggest a possible association of our HB-HTA program on costs (i.e., "bending the cost curve"), these results should not be overinterpreted given the limitations of this study. This study was a retrospective before-after study, likely with many confounders. Association does not prove "causation" since many other changes were likely implemented in our hospital within the same time frame as we began developing and implementing Know4Go. In fact, our Know4Go approach to performing evidence-based assessment, costs, other implementation issues (i.e., social, legal, ethical, institutional factors), and trade-offs was a continued evolution and expansion of our earlier approach to evidence-based assessment introduced during the Evidence-Based

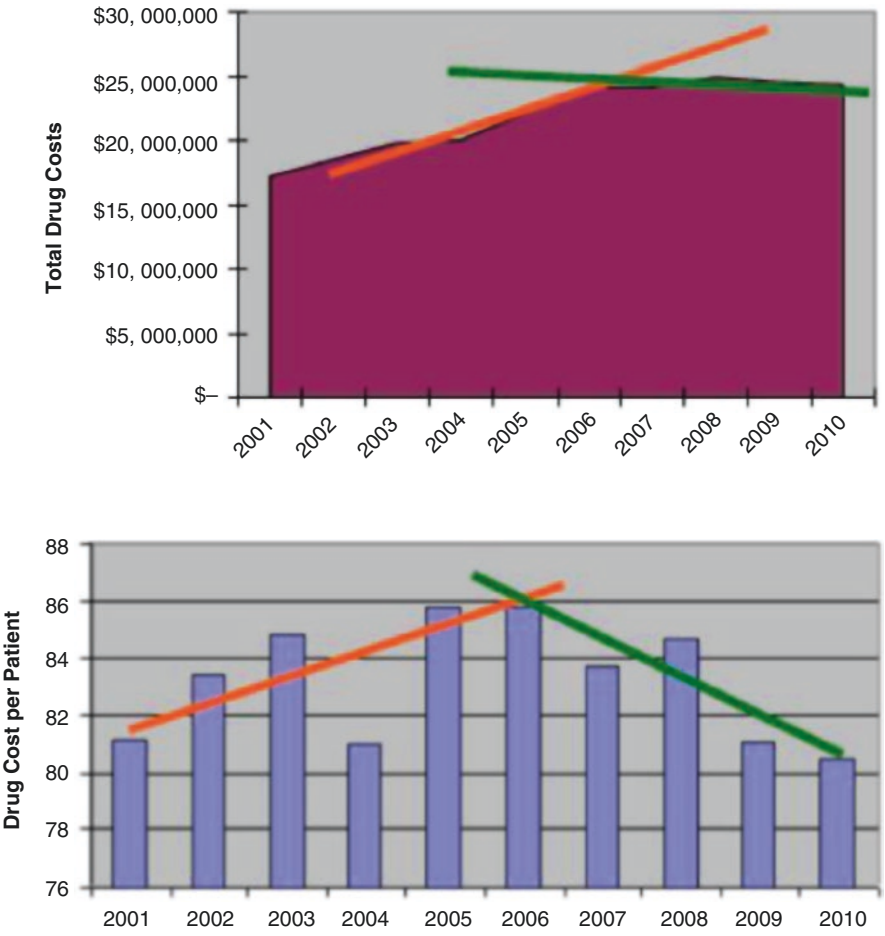


**Fig. 12.1** Drug costs at LHSC pre- vs post-implementation of Know4Go for total drug costs (**a**) and (**b**) drug costs per patient incomplete data was available for 2004 [1]

Prescribing Initiative. As a result, our evolution since 1999 was one of progressively increasing the expectation of comprehensive evidence-based systematic reviews of the evidence. Additionally, it is important to note that Know4Go was not applied in its entirety, or with equal rigor, to all decisions. Due to our limited resources for HB-HTA, we developed a pragmatic approach to prioritizing requests using rapid assessment Know4Go and subsequently assessing subcomponents of Know4Go (at the least, evidence + economics; if pertinent, also assess sleepers and opportunity cost) to address higher-cost or higher-stake drugs more thoroughly than lower-stake and lower-cost drugs. Another concern is that the data from 2004 were incomplete, and we remain uncertain regarding the verity of the drug cost information for that year. Perhaps most importantly, the goal of HB-HTA is not primarily to impact costs. Therefore, a key limitation was that patient outcomes were not measured.

These limitations are similar for many assessments of HB-HTA in the literature, and this highlights the need for more rigorous assessments in the future, such as through adequately powered controlled trials in order to establish increased confidence of the range of impacts of HB-HTA on a variety of outcomes such as clinical outcomes, institutional impacts, costs, and return-on-investment.

## 12.8 Successes and Challenges

The successes of our dynamic approach to HB-HTA include implementing a number of projects and processes that advanced the rigor of decision-making beyond status quo through assessment of evidence, economics, and other contextual factors, as well as quantification of opportunity cost based on a pragmatic approach that can be telescoped based on likely "return-on-additional-effort." These efforts also contributed to a culture of expectation of evidence-based decision-making, of assessing true value, and (increasingly) of assessing opportunity cost through a number of initiatives since 1999.

Throughout the evolution of our HB-HTA services, there have been a number of important challenges. Importantly, our approach to growing a program based on an initial project, and through various versions of a mix of informal or formally recognized service for the hospital setting, has required significant effort, often as an added margin of hours through a "side of desk" approach, while also managing other job titles and clinical or hospital administrative responsibilities. The underlying challenge that is germane to this is the ever-present need to "prove" the value of the HB-HTA unit, often before gaining approval for continued annual operational funding. This constant need to "prove" our worth results in a dual challenge to produce HTA for the hospital proactively while also evaluating the impact of the HB-HTA program and procuring grants to provide funding to expand services and methodologies beyond the core-funded services. This constant need derives from the continual budget shortfall for hospitals in the publicly funded healthcare setting, where demand always exceeds available resources. This growing demand for technology assessments highlights the need for HB-HTA growth, and yet, HB-HTA operating funds must compete directly with direct patient care shortfalls. This is a tough competition to win, given the immediate gratification of offsetting direct patient care shortfalls relative to the more remote and longer-term sustained benefits of an HB-HTA service.

Another challenge is the divergent tug-of-war between rigor of academic methods and timeliness of real-world decisions. The weeks, months, or years required by traditional approaches to HTA with systematic review, meta-analysis, economic evaluation, and post-implementation evaluation or other methods of local evidence generation does not align with the pace expected by decision-maker needs. This challenge is becoming more serious as the volume of evidence and data is growing exponentially, inducing greater efforts to complete evidence syntheses and HTAs. However, decision-makers and academic collaborators who

devote in-kind time (with the hopes of publishing quickly) expect ultra-rapid or expedited systematic review timelines. This challenge is compounded by our approach to HB-HTA where multiple options and post-implementation outcomes need to be evaluated to ensure the predicted effects translated to reality in our hospital. This results in multiple layers of research across multiple topics, and insufficient time to publish all assessments in the peer-reviewed literature. We hope to address this challenge through grant-funded research on expedited methods using rapid crowd-sourced Know4Go.

The counterposing challenge of trading-off quality and precision for timeliness will remain a ubiquitous challenge for HB-HTA until we find better ways of effectively automating our processes and finding other methodologic heuristics which do not jeopardize quality of decision-making and patient care. In our HB-HTA program, rapid reviews with draft trade-off table plots will be our hybrid compromise. However, we need to understand the risks of premature decision anchoring with rapid reviews, given the evolving understanding about risks of evidence reversals with immature evidence. When decisions are prematurely made based on early evidence, reversing those decisions may end up becoming more costly, particularly if the evidence reverses direction, and disinvestment with de-implementation is required.

## 12.9 Future of HB-HTA

Since the future success of HB-HTA will rely on moving beyond our current traditional methods of HTA, we are working on the following areas of future development for our program through grants and service contracts:

*Collaboration, Nationally and Globally*: In 2013, together with CADTH and the Ottawa Health Research Institute, MEDICI co-hosted a national HB-HTA symposium to explore the potential for building a network. We are submitting grant requests to fund this future endeavor to develop collaborative decision-making and integrated knowledge translation for the hospital setting around the globe [2–3]. It is our goal to build an effective national and global network to support hospitals in decisions and KT related to health technology investment and disinvestment to enable efficient innovation and optimal healthcare, whether locally or internationally [2, 3, 78].

*Iterative assessment*, *throughout the life cycle*: Using our Know4Go Framework, we have been exploring ways to move beyond the paradigm of one-off single technology assessments, to progress to dynamic assessment of portfolios of opportunities. To better embrace the world of iterative and evolving assessments throughout the life cycle across a multitude of technologies, a number of methods will need to be further developed including pragmatic Bayesian analysis, pragmatic value-of-information analysis, dual assessment of evidence from clinical trials, along with real-world outcomes, among others.

*Machine learning and cognitive computing to automate aspects of HB-HTA*: Automated efficiencies will be necessary, through technologies such as machine learning and cognitive computing, to ensure that the global evidence base can be identified, collected, synthesized, and made readily available for local contextualization, and so that evidence can be weighed against local considerations and continuous feeds of real-world local data.

*HB-HTA education and capacity building*: Capacity building in HTA skills through training, workshops, and graduate courses (MSc/PhD) will need to be expanded, both in terms of numbers of trainees and also in terms of the scope of knowledge and skills developed. Such capacity-building initiatives need to be accessible both the "users" and "doers" of HTA.

In summary, our collective mantra for the future HB-HTA research and development is:

Share everything; repeat sparingly; adapt often; incentivize problem solving; reward decision-impact and knowledge translation.

## 12.10 Appendix 12.1: Technologies, Drugs, Devices, and Programs Evaluated (Partial List of Selected Assessments, Some Are Ongoing)

| Topic | Category |
|---|---|
| *Devices and procedures* | |
| Off-pump coronary bypass surgery vs on-pump bypass surgery | Procedure |
| Off-pump coronary bypass surgery vs percutaneous coronary intervention | Procedure |
| Aortic valve replacement in octogenarians | Procedure |
| Transcatheter aortic valve implantation (TAVI) vs standard aortic valve replacement surgery | Procedure |
| TAVI vs medical management for patients with symptomatic aortic stenosis ineligible for surgery | Procedure |
| Sutureless aortic valve replacement vs TAVI | Procedure & devices |
| Stented vs stentless aortic valve replacement | Procedure & devices |
| Self-expanding vs balloon-expandable valves for TAVI | Device |
| Knee arthroscopy for osteoarthritis | Procedure |
| Antibiotic-impregnated or antiseptic catheters | Device |
| Video-assisted thoracic surgery (VATS) for lung cancer | Procedure |
| Endovascular vein harvest (EVH) for coronary artery bypass surgery | Procedure |
| Transmyocardial laser revascularization (TMR) | Procedure |
| Minimally invasive mitral valve surgery vs conventional mitral valve surgery | Procedure |
| Orthopedic joint prostheses for hip replacement | Device |
| Orthopedic joint prosthesis for knee replacement | Device |

| Topic | Category |
|---|---|
| Hypothermia for cardiac arrest | Procedure & devices |
| Prehospital versus in-hospital hypothermia for patients with out-of-hospital cardiac arrest | Procedure |
| Prehospital ECG for out-of-hospital myocardial infarction | Procedure |
| Gecko for prevention of venous thromboembolism | Device |
| Tight glucose control for cardiac surgery | Procedure |
| Transesophageal echocardiography, transthoracic echocardiography diagnoses in cardiac surgery | Procedure |
| Surgical tray instrument redundancy reduction | Program |
| Robotic surgery (various indications) | Procedure |
| Patient-controlled vs nurse-controlled analgesia | |
| Transfusion thresholds for ICU and for surgical patients | Procedure |
| Blood conservation | Drug, device, procedure |
| Cell salvage/cell saver technology for blood conservation in cardiac surgery | Device |
| Ultrafiltration for blood conservation in cardiac surgery | Device |
| Miniaturized extracorporeal circuit for cardiac surgery | Device |
| Subglottic endotracheal tubes | Device |
| Prehabilitation for joint replacement patients | Program |
| Safe surgery checklist | Device |
| Appendectomy vs antibiotics for first-line management of uncomplicated appendicitis | Procedure vs drug |
| Lasers for glaucoma | Device, procedure |
| Vertebroplasty | Procedure |
| Thoracic endovascular aortic repair (TEVAR) | Procedure and device |
| Chemoablation for hepatocellular cancer | Procedure |
| Surgical ablation of atrial fibrillation | Procedure and device |
| Teleophthalmology for diabetic retinopathy | Program |
| Drug-eluting stents for PCI | Device |
| Antibiotic-impregnated sutures | Drug/device |
| Sedasys for anesthetic management | Device |
| Collatamp for prevention of surgical site infection | Drug/device |
| Obstructive sleep apnea as a risk factor for perioperative complications | Program |
| Electroconvulsive therapy | Procedure & device |
| Intraoperative neuromonitoring during craniotomy | Device |
| Hepcon, Rotem, TEG monitors for blood conservation in cardiac surgery | Device |
| First Episode Mood and Anxiety Program (FEMAP) | Program |
| Intermittent pneumatic compression devices for VTE prophylaxis | Device |
| Laparoscopic and robotic colonoscopy costs | Procedure and devices |
| *Drugs* | |
| Drotrecogin alfa (activated protein C, rhAPC) for severe sepsis | Drug |
| Amphotericin for suspected or proven acute fungal infection | Drug |
| Voriconazole/posaconazole for suspected or proven acute fungal infection | Drug |

| Topic | Category |
|---|---|
| Proton pump inhibitors versus H2 receptor antagonists for acute upper GI bleeding (PPI) | Drug |
| Sevoflurane, desflurane, isoflurane for anesthesia | Drug |
| Vitamin D analogs for patients with renal failure | Drug |
| NSAIDs for acute postoperative pain | Drug class |
| Drugs for postoperative nausea and vomiting prevention (PONV: 5HT3-antagonists, steroids, promethazine, droperidol, haloperidol) | Drug classes |
| Rivaroxaban, argatroban, dabigatran | Drug classes |
| Digoxin overdose antidote | Drug |
| Once daily aminoglycoside administration | Drug |
| Antibiotic prophylaxis for clean and contaminated plastic surgery procedures | Drug |
| Drugs for treatment and prevention of chemotherapy-induced nausea and vomiting (CINV: 5HT3-antagonists, steroids, promethazine, dimenhydrinate, droperidol, haloperidol) | Drug classes |
| Aprepitant for CINV | Drug |
| Drugs for patients with heparin-induced thrombotic thrombocytopenia (HiTT) (Argatroban, fondaparinux) | Drug |
| Etomidate for rapid sequence intubation | Drug |
| GP 2b3a inhibitors for patients undergoing PCI | Drug |
| Bivalirudin for anticoagulation in cardiac surgery | Drug |
| Fondaparinux for heparin-induced thrombocytopenia | Drug |
| Venous thromboembolism (VTE) prophylaxis | Drugs, drug class |
| Intermittent pneumatic compression for VTE prophylaxis in surgical patients and ICU | Device |
| Patient-controlled analgesia (PCA) vs nurse-controlled analgesia | Device |
| Moxifloxacin for pneumonia | Drug |
| Hyaluronidase for osteoarthritis of the knee | Drug |
| Amobarbital for Wada testing | Drug & procedure |
| Differences among unfractionated heparin products for anticoagulation in cardiac surgery | Drug |
| Insulin glargine | Drug |
| Insulin detemir | Drug |
| Rofecoxib for acute pain and perioperative analgesia | Drug |
| Celecoxib for acute pain and perioperative analgesia | Drug |
| Octreotide for carcinoid crisis | Drug |
| Octreotide for draining fistula | Drug |
| Infliximab for ulcerative colitis | Drug |
| Rituximab for various indications | Drug |
| IV iron for patients with chronic anemia or at risk of acute perioperative anemia | Drug |
| IV immune globulin | Drug |
| Eltrombopag and romiplostim for thrombocytopenia | Drug |

| Topic | Category |
|---|---|
| New anticoagulants (rivaroxaban, dabigatran, argatroban) | Drug classes |
| Drugs for multiple sclerosis | Drug classes |
| Linezolid for methicillin-resistant S. aureus and vancomycin-resistant Enterobacteriaceae | Drug |
| Piperacillin/tazobactam for treatment of suspected or proven infection | Drug |
| Dexmedetomidine vs other drugs for awake fiber-optic intubation (AFOI) | Drug |
| Dexmedetomidine vs other drugs for craniotomy | Drug |
| Dexmedetomidine vs other drugs for ICU sedation | Drug |
| Dexmedetomidine vs other sedation drugs for procedural sedation | Drug |
| Tramadol for acute analgesia | Drug |
| Inhaled nitric oxide for neonates | Drug/device |
| Inhaled nitric oxide for ARDs/ALI in ICU | Drug/device |
| Inhaled nitric oxide for cardiac surgical patients with difficulty weaning from cardiopulmonary bypass pump | Drug/device |
| Aprotinin vs tranexamic acid for cardiac surgery | Drug |
| Sevelamer for hyperphosphatemia of renal disease | Drug |
| Cinacalcet for hyperphosphatemia of renal disease | Drug |
| Myozyme for Pompe's disease | Drug |
| Aldurazyme for Hurler's syndrome | Drug |
| Eculizumab for PNH | Drug |
| Aprotinin for cardiac surgery | Drug |
| Tranexamic acid | Drug |
| Perioperative beta-blockers for preventing atrial fibrillation, stroke, and myocardial infarction | Drug class |
| Amiodarone for perioperative atrial fibrillation | Drug |
| Bevacizumab vs ranibizumab for age-related macular degeneration | Drug |
| Erythropoietin, darbepoetin for patients with renal dysfunction | Drug |
| Hydroxyethyl starches for fluid replacement in surgery and ICU (Pentaspan, Voluven, Volulyte) | Drug |
| Albumin for fluid replacement in surgery and ICU | Drug |
| Crystalloids, IV fluid replacement | Drug class |
| Erythropoietin for perioperative blood conservation for cardiac surgery | Drug |
| *Global HB-HTA initiatives* | |
| Global surgery – capacity development, resource prioritization, safety, and outcomes | Programs, devices technologies, procedures |
| C-section-related maternal and neonatal mortality in developing and developed countries | Procedure |
| Perioperative and anesthetic-related mortality in developed and developing countries | Programs & procedures |

| Topic | Category |
|---|---|
| Ebola virus disease and surgical risks | Procedures & programs |
| Viral hemorrhagic disease and surgical risk | Procedures & programs |
| *Evidence generation and methodologic innovations* | |
| Decision-making framework for technology assessment and prioritization and for research agenda setting (Know4Go) | Methodologic innovation |
| IDEAL Framework in surgery, anesthesia, and critical care to support systematic evidence generation and incremental knowledge translation (multiple technologies, techniques), see www.ideal-collaboration.net | Methodologic innovation |
| Impact of publication bias on HTA | Methodologic innovation |
| Decision-making framework for rare diseases | Methodologic innovation, MoH policy framework |
| Evidence reversals | Innovation and evidence generation |
| Validity and relevance of the evidence base | Evidence generation |
| Quantifying the opportunity cost | Evidence generation Methodologic innovation |
| Mini-VOI (value of further information) analysis | Methodologic innovation |
| Learning curve analysis for new technologies and procedures | Methodologic innovation |
| Supporting systematic searches through machine learning | Methodologic innovation |
| Pharmacist-managed vs physician-managed anticoagulation clinic | Evidence generation (RCT) |
| Disseminating evidence-based guidelines for upper GI bleeding | Evidence generation (RCT) |
| Adding clinical pharmacists to the emergency department team | Evidence generation (RCT) |
| Alfacalcidol vs calcitriol | Evidence generation (RCT) |
| Comparative analysis of IV iron dextran and IV iron sucrose | Evidence generation (RCT) |
| Evidence-informed patient decision-making | Evidence generation (RCT) |

## 12.11 Appendix 12.2: Know4Go Framework

Early in the experience of HB-HTA within the London hospitals, it became clear that the traditional approach to HTA and decision-making was insufficient to meet the needs for local decision-makers for a multitude of reasons [1–4]:

- Evidence alone is essential, but insufficient for decision-making.
- Economic evaluation is essential, but also insufficient for decision-making.
- Additional domains of influence on decisions (i.e., the “sleepers” defined below) also need to be systematically evaluated and contextualized for decision-makers.


**Fig. 12.2** Four domains assessed and contextualized using Know4Go Framework (This work is licensed under the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International (CC BY-NC-ND 4.0) License. To view a copy of the license, visit https://creativecommons.org/licenses/by-nc-nd/4.0/)

- Single technology assessments in isolation add little value to the decision-making process; when in reality, multiple technologies and interactions among them are likely to be important.
- One-off assessments add little value to the decision-making process when technologies (and the evidence) evolve quickly across multiple versions and varied disease applications, with an inevitable learning curve and changing competing technologies, which require iterative assessments throughout the technology life cycle in order to be meaningful.
- Decision-makers and internal advocates are easily distracted by "new" and purportedly "innovative" technologies when there is no explicit process for simultaneously revealing the best value for money among *all* opportunities and options (whether "new" or "old") *for investment and disinvestment.*

We developed the *Know4Go Framework* to address these deficiencies. The Know4Go Framework addresses the contextualized evidence, economics, sleepers, and opportunity cost (Fig. 12.2). Specifically, Know4Go builds on the foundation of traditional HTA components including rigorous evidence synthesis and economic evaluation but also ensures that it goes beyond traditional HTA by systematically addressing decision-relevant issues not addressed by the evidence (i.e., the "sleepers") and by quantifying the opportunity cost of choosing one set of opportunities over another.

The *sleepers* are those domains which may be equally important for guiding decisions and which may prematurely trump the decisions at hand and preempt fair consideration of the evidence and economic considerations if they are not adequately addressed and placed in their appropriate context vis-à-vis the evidence. Specifically, the "sleeper" domains include the *s*ocial, *l*egal, *e*thical, *e*nvironmental/institutional, *p*olitical ramifications, along with *e*ntrepreneurial, *r*esearch/innovation opportunities, and *s*tickiness/reversibility factors (Fig. 12.3).

The sleepers are defined and assessed systematically and collaboratively with stakeholders at the beginning of the decision process to capture the initial emotive reactions to the perceived issues underlying the sleeper domains and again after the

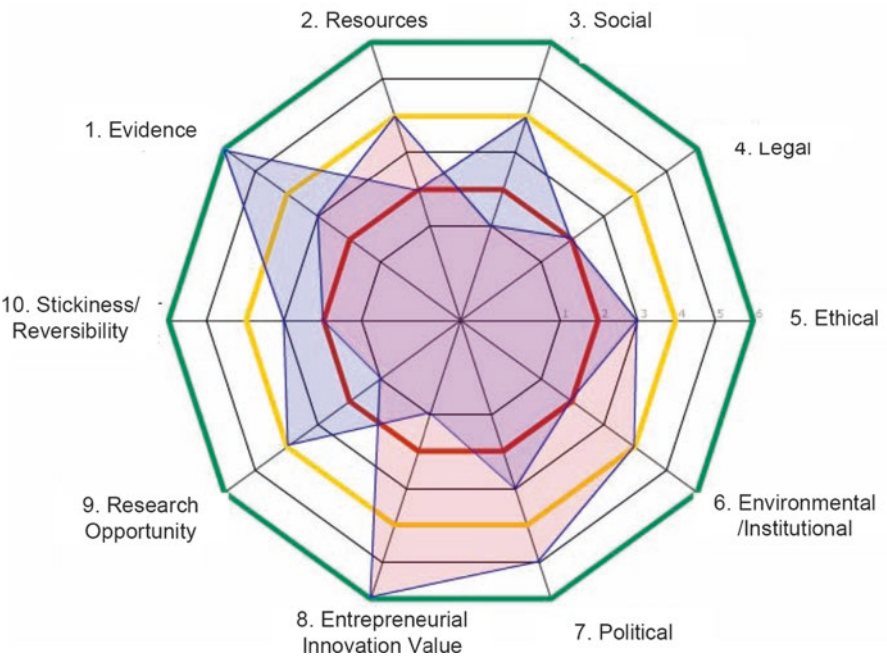


**Fig. 12.3** The "sleepers" (social, legal, ethical, environmental/institutional, political, entrepreneurial/innovation value, research opportunity, and stickiness factors) as rated by differing stakeholders (This work is licensed under the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International (CC BY-NC-ND 4.0) License. To view a copy of the license, visit https://creativecommons.org/licenses/by-nc-nd/4.0/)

evidence and economics have been systematically reviewed in collaboration with the stakeholders to capture the more mature, well-informed contextualized perception of the importance of the "sleepers." This allows stakeholders to define and express their perceptions about the importance of each of the domains of potential sleepers underlying the decision, based on initial "gut" reaction and again after evidence- and economic-informed contextualized reaction. The difference in perceived importance of the sleepers for administrators relative to clinicians is collected by survey and the results presented to the stakeholders via radial plots to outline the amount of discrepancy in perception of the relative importance by the stakeholder groups.

This systematic and visual approach to addressing the sleepers allows for stakeholders and producers of HTA to come to an agreement up front about what issues underlie the decision at hand and the likely perceived weight of importance of that issue on the ultimate decision to be made. In addition, as the HTA progresses through evidence assessment and economic evaluation, the sleeper domains can be repeatedly discussed and placed into a more informed context in light of the evidence and economic issues. Sometimes the perceived weight of importance of the sleeper domains differs significantly from the point of first "gut reaction" to the more informed point of decision-making after the evidence and economic consider-

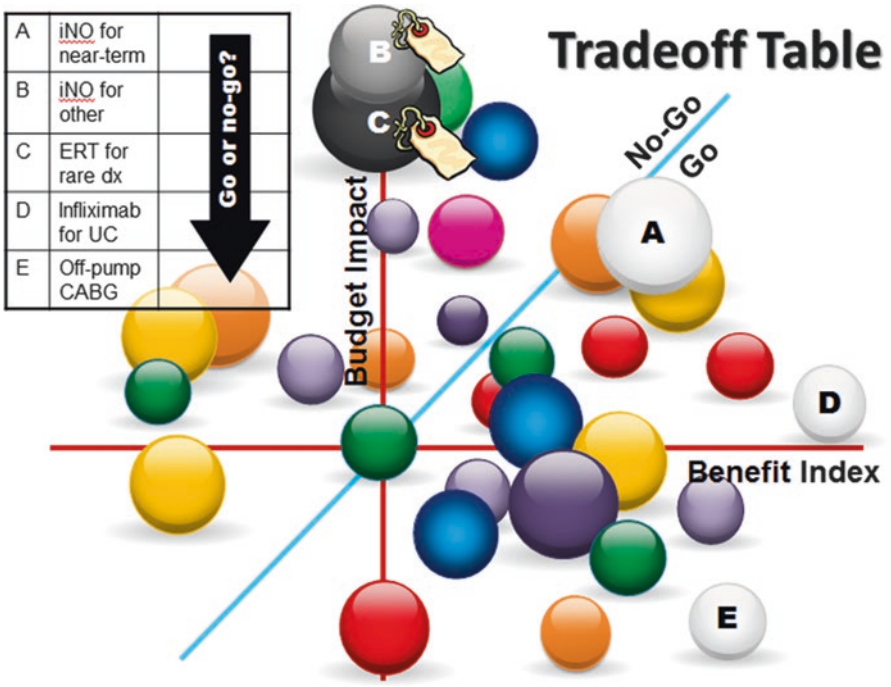


**Fig. 12.4** Know4Go trade-off table (This work is licensed under the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International (CC BY-NC-ND 4.0) License. To view a copy of the license, visit https://creativecommons.org/licenses/by-nc-nd/4.0/)

ations have been brought to bear. Furthermore, defining and evaluating perceptions of the sleepers up front, before the evidence review and economic evaluations have been conducted, also allows the scope of the evidence and economic evaluation to consider formal incorporation of sleeper concepts, when relevant.

Using the Know4Go Framework, once the evidence has been synthesized through systematic review or meta-analysis, the evidence is contextualized to the local hospital perspective (or the health system perspective, depending on where the budget and health outcome accountabilities lie) by converting the evidence to a decision-relevant benefit index. This benefit index derives from number of patients who would likely benefit tangibly from this intervention (using metrics of your hospital's choice) and is based on contextualization of the global evidence base through local data-informed estimates of the number of eligible patients corrected by the absolute benefit and risk derived from the evidence. Furthermore, the local resource considerations and total budget impact for the institution (or the health system, depending on the budget accountabilities) are estimated using local institutional costing data.

Each technology, technique, or drug under consideration is plotted as a ball on the Know4Go trade-off table in order to make transparent the likely benefit gained per resource expended from the institutional perspective (Fig. 12.4). Each ball represents an opportunity (drug, device, procedure, or program), and the size of the ball is telescoped based on the amount of uncertainty regarding the benefit index

and local resource impacts. The colors of the balls are coded based on the relevant clinical programs and interrelatedness of the decisions at hand. Opportunities which fall below the "go, no-go" line which have not yet been taken up into practice are colored as white balls, which represent the opportunity cost (i.e., lost opportunity, not yet implemented) which should be prioritized first for uptake into practice. Additionally, we have added an additional feature within Know4Go to color the ball based on the maturity of the evidence as per the IDEAL Framework [5].

Plotting options on this trade-off table allows greater transparency for decisions to be made about whether a decision should be a "go" or a "no-go." Since we know that generally we are not willing to pay exceedingly more money for exceedingly small benefits, there is a limit which can be defined as the "go, no-go" line. Over time, this "go, no-go" line has defined itself in hospital settings using Know4Go, since the transparency of the Know4Go table has allowed us to regulate our decisions to generally accept the decisions, represented by balls falling under the line, and declining the requests for technologies and programs above the line.

Furthermore, as we progressively plot technologies and programs that already exist within the hospital setting, the trade-off table has become a tool for explicitly identifying disinvestment opportunities (i.e., previous decisions for technologies can be plotted according to their benefit index and resource requirement on the trade-off table and will be above the line if they were low value for money, which reveals an opportunity for disinvestment).

The Know4Go trade-off table also allows for a simultaneous approach to consideration of paired investment–disinvestment opportunities for budget-restricted hospitals considering new opportunities for which there is no available marginal budget. Identifying lower value-for-money technologies that appear above the "go, no-go" line provides a targeted list of technologies from which to disinvest in order to release resources for better investment.

When used appropriately to consider the evidence, economics, and contextualized sleepers, the Know4Go trade-off table becomes a tool to ensure transparency and objectivity in improving value for money for all technologies, drugs, and programs adopted (and disinvested) in the hospital setting. In essence, this becomes an evidence-informed tool to fuel innovation that provides better value for money.

Using Know4Go, we have also found that we can better prioritize requests for new technologies and other innovations in the hospital setting by using the trade-off table as an initial prioritization framework. For example, in previous years when we held an annual cycle of requests for proposals for new technologies and drugs in our hospitals, the volume of requests superseded available human resources to assess each technology using a traditional HTA approach. We used the Know4Go trade-off table to perform prioritization of the submitted technologies using an ultra-rapid review process to anticipate the "ballpark" benefit index and budget impact to plot the "draft" balls. In this way, we could identify requests for technologies which we should not spend further time on, since they provided very low estimated value for money. This is first-draft Know4Go, used as a prioritization tool.

After prioritization of multiple requests, those with highest likelihood of providing worthy value for money (i.e., under the "go, no-go" line) become the focus of detailed HTA, with full evidence assessment, economic evaluation, and sleeper assessment. Full assessment of a proposed technology, procedure, or program may also involve identifying other existing options within the hospital for disinvestment, in order to ensure resources can be released, and the opportunity cost can be minimized.

Know4Go can be used to identify and prioritize a local research agenda. This is an area where HB-HTA units around the world could take a much more proactive approach. Since HB-HTA is in the business of performing evidence syntheses and economic evaluations, with local considerations of competing priorities and detailed consideration of local institutional needs, every HTA becomes an opportunity to highlight the gaps in the evidence base and the gaps in local knowledge. This tabulation of gaps becomes a list of potential "research opportunities," which also can be valued with a predicted benefit and cost (and plotted on the Know4Go trade-off table). This becomes ultimately an expedited "value of further information" analysis, also known as predicting the cost-effectiveness of undertaking research to answer the gaps in the evidence, to prioritize the local research agenda. It can also be embedded within the sleeper assessment (during consideration of the "r" domain for research/innovation) proactively within each opportunity assessment in order to determine whether decisions should be made (in light of the remaining uncertainty) or whether it would be cost-effective and "worthy" (given the time required and likelihood of success in reducing uncertainty to an extent that meaningfully advances decision-making) to consider devoting more resource to research in order to reduce the remaining uncertainty.

Know4Go has been applied to a number of decisions in London and iteratively further developed from its earliest prototype version after learning from application to real-world decisions, in Canada and internationally. Its development and refinement continues, with feedback from those using it in different contexts. At this time, we are seeking grants to study a broader implementation of Know4Go for portfolio-wide assessments of technologies and in hospitals locally and internationally.

**See Also**

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# Chapter 13
# Technology Assessment at SickKids (TASK): A Health Technology Assessment Research Unit Devoted to Child Health in Canada

**Wendy J. Ungar**

## 13.1 Introduction

Technology Assessment at SickKids (TASK) http://www.sickkids.ca/research/TASK/ was established within the Research Institute of The Hospital for Sick Children (SickKids) in 2007 and performs health technology assessment (HTA) of emerging technologies to generate evidence on the cost-effectiveness of child health interventions to inform payers, decision-makers, health practitioners, researchers, and patients and their families. While the importance of HTA has been recognized in recent years in many countries, TASK is the only HTA research unit in the world exclusively dedicated to child health and to the further development of HTA methods for application to child health.

With a primary emphasis on research, TASK is located in the Peter Gilgan Centre for Research and Learning and which is directly affiliated with SickKids. SickKids is a research and teaching pediatric hospital within the University of Toronto and is the largest pediatric hospital in Canada. The SickKids Research Institute is similarly the largest, hospital-based child health research facility in Canada and is committed to improving the health of children globally. With over 225 principal investigators and approximately 2,000 staff, research activity includes basic discovery, clinical trials and applied research in population health sciences, health system research, health technology assessment, and health policy. Research activities are coordinated under seven major research programs which cover the spectrum of child health from the molecular to the population level. Through these programs, scientists are engaged in over 1,000 funded research projects with local, national, and international

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collaborators. Thus TASK is well situated to maximize collaborations to produce high-quality HTAs of emerging child health technologies.

This chapter will briefly describe the unique aspects of HTA in children, describe the structure and processes within TASK for conducting HTA, present the aims of TASK illustrated with examples of completed studies, and share lessons learned and a vision for the future.

## 13.2 Health Technology Assessment in Children

Children possess many unique characteristics that set them apart from adults and that create challenges for the conduct of HTA for hospital-based, community-based, and regional policy decision-making [1]. For example, children are dependent on parents or other caregivers for access to care, demonstrate phases of rapid growth accompanied by dynamic states of cognitive, emotional, and physical development, and manifest unique patterns of acute and chronic diseases [2, 3]. Because of these differences, evidence emanating from studies of effectiveness and cost-effectiveness in adult populations cannot be extrapolated for clinical and policy decision-making in children, and emerging health technologies and interventions need to undergo specific evaluation in children [3].

A challenge for conducting HTA in children is that chronic diseases are relatively rare [2, 4]. This hampers prospective studies designed to detect important differences between intervention groups. The availability of valid outcome measures that incorporate the developmental stages of childhood is also limited [2, 5, 6]. The study of interventions for conditions and disabilities that commence during childhood and continue into the adult years, such as asthma, diabetes, and inflammatory conditions, necessitates long-term models to evaluate cost-effectiveness. Similarly, interventions such as vaccinations – the most common type of intervention in child health [7] – aimed at preventing diseases such as varicella, rubella, and human papilloma virus often require long-term time horizons for measuring costs and health consequences. Data over the long term may not be available or may be highly uncertain. HTA in child health also differs from that of adults in that the consequences of interventions may need to take into account impacts on non-health sectors, especially education and social services [1]. Indeed, the health sector may have only a minor role for common developmental conditions such as autism spectrum disorder [8]. It is also critically important that HTAs in children consider externalities, including parent/caregiver productivity losses, impacts on family quality of life, school performance, and effects on future productivity [1].

As a consequence of the challenges described above, HTA evidence to support new technology adoption decisions for children in hospitals and in the community lags behind that of adults [2, 3]. Methods for child health economic evaluation and HTA need to be improved to ensure that adoption and policy decision-making are evidence based. Some innovative methodological advances that maximize the use of information in evaluating treatment effects in rare diseases include Bayesian and adaptive designs [9–12], randomized placebo phase designs [13], and “n of 1” trials [14–16]. These approaches amplify the efficacy evidence that can be gained from

each research subject, thereby reducing the required sample size. Other innovative research includes the development of child-focused health state preference weights and instruments [17–20] and the study of family effects and the incorporation of parent and child preferences [21, 22]. Such approaches hold promise for ensuring that HTA evidence is available for informed decision-making and that technologies with pediatric indications are not penalized on the basis of lack of adequate evidence [23].

Even when high-quality HTAs can be conducted in children, the HTA evidence is considered alongside other factors in hospital budgetary decision-making. These factors are also unique for children and relate to rules of rescue, equity, family preferences, and the desire to address the needs of vulnerable populations.

## 13.3 TASK Structure and Processes

**Box 13.1. Context for pediatric hospital funding care in Ontario, Canada**

- Health-care delivery in Canada is subsidized by a mix of public and private funding sources. The public system is administered at the provincial level, with each province responsible for the provision of hospital, physician, laboratory, and some allied health-care professional services. Private health insurance covers the costs of medications and some uninsured services for most Canadians. Public provincial drug plans exist for seniors and persons receiving social assistance.
- Children with developmental conditions also rely on publicly subsidized services at the provincial level provided by non-health sectors, including education and community and social services. Many families face large out-of-pocket costs to cover treatments for developmental and learning disabilities.
- In Ontario, each pediatric hospital is funded by the province through a global budget. Additional funding envelopes may be provided for special programs, often covering the introduction of new technologies. Community-based fund-raising campaigns support large capital expenditures. Hospitals have jurisdiction over how their global budgets are spent, but provincial administrators may step in when hospitals incur a deficit.

The funding context for pediatric hospital services is described in Box 13.1. As an HTA research unit situated within a large research institute affiliated with an academic hospital, TASK is entirely funded by competitive peer-reviewed grants from major funding organizations including the Canadian Institutes for Health Research, Genome Canada, and the Ontario Ministry of Health and Long-Term Care. The director is a full-time senior scientist in the program of Child Health Evaluative Sciences in the Research Institute and a full professor in the Institute of Health Policy, Management and Evaluation at the University of Toronto. Grant funding

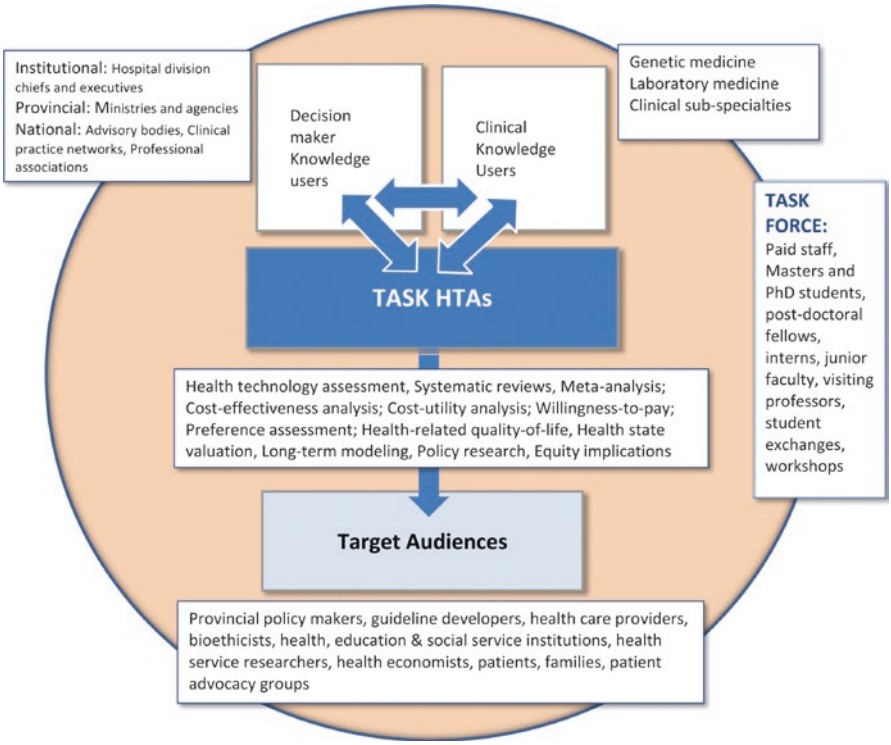


**Fig. 13.1** TASK framework for production of HTA evidence

typically covers salaries for one or two full-time staff, three to five part-time or casual staff, and six to eight masters, doctoral, and postdoctoral trainees. Other members and affiliates of TASK include junior faculty, clinician-scientists, and other research institute staff engaged in health economic and policy research. The conceptual framework for TASK in Fig. 13.1 depicts the policy and clinical decision-maker partners, the types of evidence produced, the targets and modes of knowledge dissemination, and the nature of TASK membership.

As a unit that is entirely grant funded, the research topics are selected in consultation with knowledge users such as clinical division chiefs and clinician-scientists as ones that are salient to the field of pediatrics. This may include the study of specific technologies, such as the use of genomics and biomarkers in the diagnosis of pediatric disease, or focus on specific methodologic issues, such as developing and validating methods for ascertaining preferences for health states in young children. Clinician-scientists working in the area of study are invited to collaborate and grant applications are developed together and subjected to scientific peer review. Upon receipt of funding through a competitive funding competition, HTA studies are executed. Whenever possible, HTAs serve as opportunities for masters and doctoral dissertation research as described below. HTAs that are produced as part of dissertation research are often funded through scholarship support to the student (Table 13.1).

**Table 13.1** Examples of TASK health technology assessments to support decision-making

| Project title | Clinical division partner | Publications | Trainee involvement |
|---|---|---|---|
| *Hospital decision support* | | | |
| Cost analysis of centralized genetic testing using next-generation sequencing | Medical Genetics | In progress | N/A |
| CEA of early intervention with anti-TNFα drugs in Crohn's disease | Gastroenterology, Hepatology, and Nutrition | In progress | Doctoral dissertation of N. Bashir |
| CEA of clinic-based chloral hydrate sedation versus general anesthesia for pediatric ophthalmological procedures | Ophthalmology, General Surgery | Burnett et al., *Br J Ophthalmol*, 2015 | Clinical fellow Rosemary Lambley |
| Cost-effectiveness of a teratology information service in the prevention of fetal malformations | Motherisk | Hancock-Howard RL et al., *Birth Defects Research Part A: Clinical and Molecular Teratology*, 2012 | Doctoral dissertation of R. Hancock-Howard |
| CEA of TPMT testing in children with acute lymphoblastic leukemia. | Oncology, Clinical Pharmacology | Donnan et al., *Pediatr Blood Cancer*, 2011 | Masters dissertation of J. Donnan |
| CEA of implantable venous access device insertion via image-guided therapy versus conventional surgery | Diagnostic Imaging, General Surgery | Hancock et al., *JVIR*, 2010 | Four MSc/PhD students worked on research team |
| Cost-effectiveness of omission of a chest X-ray in the diagnosis of bronchiolitis in infants in the Emergency Department | Emergency Medicine | Yong et al., *Pediatr Pulmonol*, 2009 | Four MSc/PhD students worked on research team |
| Cost-effectiveness analysis of a weekday shift versus a weeknight/weekend shift program for appendicitis assessment | Diagnostic Imaging | Doria et al., *Pediatr Radiol* 2005 | Two MSc/PhD students worked on research team |
| Economic evaluation of ondansetron versus dimenhydrinate for prevention of postoperative vomiting in children undergoing strabismus surgery | General Surgery | Piwko et al., *Paediatr Anaesth*, 2005 | Three MSc/PhD students worked on research team |

(continued)

**Table 13.1** (continued)

| Project title | Clinical division partner | Publications | Trainee involvement |
|---|---|---|---|
| *Community, provincial, national, or international decision support* | | | |
| CEA of next-generation sequencing to aid in diagnosis of autism | Pediatrics, Medical Genetics | In progress | Doctoral dissertation of T. Yuen |
| Systematic review of guidelines for TPMT testing | Clinical Pharmacology | Burnett et al., *Pharmacogenomics J*, 2014 | Two postdoctoral fellows worked on research team |
| Parent willingness to pay for biologic treatments in juvenile idiopathic arthritis | Rheumatology | Burnett et al., *Value Health*, 2014 | Masters dissertation of H. Burnett |
| Systematic review of biologics in juvenile idiopathic arthritis | Rheumatology | Ungar et al., *Semin Arthritis Rheum*, 2013 | N/A |
| CEA of biologics in juvenile idiopathic arthritis | Rheumatology | Ungar et al., *Arthritis Care Res*, 2011 | N/A |
| CEA of a proposed public health policy to reduce tap water scald injuries in children | Pediatric Medicine, General Surgery | Han et al. *Inj Prev,* 2007 | Postdoctoral student lead the project |
| An economic evaluation of asthma action plans for children | Respiratory Medicine, Emergency Services | Polisena et al. *J Asthma*, 2007 | Three MSc/PhD students worked on research team |
| The cost-effectiveness of expanding intensive behavioral intervention (IBI) to all autistic children in Ontario. | N/A | Motiwala et al. *Healthc Policy*, 2006 | Three MSc/PhD students worked on research team |
| CEA of preventing premature mortality and impaired cognitive development in children in developing countries through home fortification | Gastroenterology, Hepatology, and Nutrition | Sharieff et al., *Int J Technol Assess Health Care*, 2008 | Doctoral dissertation of W. Sharieff |
| *Methods research* | | | |
| Task complexity and response certainty in discrete choice experiments | N/A | Regier et al. *J Behav Exp Econ*, 2014 | N/A |
| Use of CEA of pediatric immunization for decision-making in low- and middle-income countries | N/A | Gauvreau et al., *Milbank Q*, 2012 | Doctoral dissertation of C. Gauvreau |
| Parent-child dyad approach to the assessment of health status and health-related quality of life in children with asthma | Respiratory Medicine | Ungar et al. *Pharmacoeconomics*, 2012 | N/A |

For full list of completed studies, see http://www.sickkids.ca/research/TASK
*CEA* cost-effectiveness analysis, *N/A* not applicable, *TPMT* for thiopurine methyltransferase

Deliverables of HTAs include full technical reports, executive summaries, briefing notes, scientific journal publications, and presentations that are disseminated in targeted strategies to relevant stakeholders.

## 13.4 Aims of TASK

The goals of TASK include (1) research; (2) decision support through evidence uptake; (3) education, training, and capacity development; (4) maintaining and expanding partnerships with knowledge users; and (5) continual knowledge transfer and exchange. Each of these goals is explained in greater detail below.

**Research** While HTA agencies typically focus on the *consumption* of knowledge to aid decision-making (knowledge synthesis), TASK focuses on the *production* of high-quality evidence (knowledge generation). Research at TASK includes systematic reviews, meta-analysis, and prospective and retrospective health economic evaluations of emerging technologies. Health economic evaluations may be done alongside clinical trials or may be conducted by constructing conventional decision models, health state transition models, or discrete event simulation models. Models typically incorporate multiple data sources including patient-level cohort or clinical trial data, data abstracted from patient charts and published sources. TASK also conducts studies of preferences and willingness to pay using discrete choice and best-worst scaling experiments. A major focus of TASK is primary research into novel and improved methods for conducting HTA in child health, including novel approaches to quality appraisal [24], health state and treatment preference ascertainment [22, 25], meta-analysis [26], and modeling [27].

An important part of the research mandate is maintaining a catalogue of proposal and report templates, costing protocols, tools and data collection instruments, as well as key hospital contacts and resources that are available to all collaborators. TASK is also responsible for updating and maintaining the Pediatric Economic Database Evaluation (PEDE) database, a comprehensive database of over 2,600 comparative pediatric health economic evaluations published since 1980 [28]. It is the only database of its kind to focus exclusively on child health. This database, updated annually, is in a user-friendly searchable format and is freely available online at http://pede.ccb.sickkids.ca/pede/. A search engine has been created that outputs citation information as well as key study design characteristics. In 2013 the PEDE site was expanded to launch a new application that reports utility weights for pediatric health states. This database includes 1,200 health state utility weights from close to 500 pediatric cost-utility analyses published since 1980 and is the most comprehensive source for pediatric utility weights in the world. These values greatly facilitate the conduct of cost-utility analysis in child health. The PEDE website receives over 20,000 visits per year from users around the globe and has proven to be an invaluable knowledge synthesis tool for health services researchers, health economists, producers of health technology assessments and systematic reviews, and health-care decision-makers.

**Decision Support** TASK is aligned with the mission of SickKids to integrate patient care, research, and learning. Although TASK does not receive funding from the hospital and is not a service unit, TASK generates evidence to assist decisions regarding allocation of technological (medical and surgical) resources at the clinical department and the hospital administrative levels. This work is conducted in collaboration with hospital-based clinicians who have identified specific research questions and who either can provide funding in the form of a research grant or who are part of a TASK-led research grant. Examples of HTAs for hospital-based decision support include a cost-effectiveness analysis of clinic-based chloral hydrate sedation for pediatric ophthalmological procedures [29]; a systematic review [30], cost-effectiveness analysis [31], and assessments of preferences [32] and willingness to pay [33] for biologic response modifiers in polyarticular-course juvenile idiopathic arthritis; systematic reviews [34, 35], meta-analysis [26], cost-effectiveness analysis [36], and full HTAs [37, 38] of thiopurine methyltransferase testing for guiding 6-mercaptopurine dosing; a cost-effectiveness analysis of implantable venous access devices using interventional radiology [39]; a cost-effectiveness analysis of weekday and weeknight or weekend shifts for assessment of appendicitis [40]; and an economic evaluation of ondansetron versus dimenhydrinate for prevention of postoperative vomiting in children undergoing strabismus surgery [41]. In addition to considering the adoption of new technologies and services, hospitals continually review clinical procedures to determine which interventions can be omitted to reduce costs without incurring increased risk to the patient. To this end TASK completed a cost-effectiveness analysis of omitting radiography in the diagnosis of acute bronchiolitis in the emergency department [42].

Many of the HTAs listed above can also be used to inform clinical and policy decision-making at provincial and national levels and inform guideline development and updating. Examples of HTAs produced by TASK to directly support provincial and national policy decision-making include a systematic review on orchidopexy commissioned by the Canadian Pediatric Surgical Wait Times Project [43], an economic evaluation of expansion of autism early intervention services in Ontario used to inform policy changes in delivery of services for Ontario children with autism [8], and an economic evaluation of a legislative policy to reduce the incidence of tap water scalds that resulted in changes to Ontario's Building Code Act [44].

**Training** Being an academic research unit, education and capacity development in the field of HTA are core aims for TASK. As a faculty member and program director for the University of Toronto's international master's degree in HTA, the director of TASK is able to recruit highly qualified applicants to conduct their dissertation research at TASK. Grant applications typically budget for one or more graduate students to conduct HTAs or HTA method research as part of the thesis research. In addition to students from the Institute of Health Policy, Management and Evaluation, students enrolled in graduate programs in the School of Public Health Sciences and from the faculties of Nursing and Pharmaceutical Sciences may train under the supervision of a TASK scientist or collaborator. International postdoctoral fellows have also sought out training at TASK. TASK maintains a monthly learning club, and members participate actively in HTA-related rounds and seminar series within

the university community. TASK has also organized and participated in educational workshops in HTA. Key training objectives are to recruit and provide support for highly qualified graduate students, to maintain an excellent academic training program in pediatric HTA, to provide skills training to colleagues and junior faculty in HTA methods, and to increase the profile of TASK as a source for HTA training in the national and international HTA communities.

**Partnerships and Linkages** TASK serves as a valuable hub to SickKids researchers engaged in HTA or health policy research, many of whom are working in isolation in various disciplines. Formal collaborations exist with clinical staff in the divisions of genetic medicine, laboratory medicine, general surgery, diagnostic imaging, emergency services, respiratory medicine, hematology/oncology, clinical pharmacology and toxicology, pediatric medicine and gastroenterology, hepatology and nutrition, as well as with managers in finance, administration, and decision support. Internal linkages are strengthened through the monthly learning club as well as other educational activities. Most importantly, this internal hospital-based network fosters new ideas and collaborations in the pursuit of future HTA research devoted to children.

As important as the internal linkages are the external connections that have been formed with HTA organizations locally, across Canada, and internationally. Examples include membership in the Toronto Health Economics and Technology Assessment Collaborative, the Canadian Agency for Drugs and Technologies HTA Exchange, the Genome Canada GE3LS Network, and the international coordinating committee for the Ulysses Masters program in HTA and child health interest groups associated with the Canadian Association for Health Services and Policy Research and the Society for Medical Decision-Making. In addition to these networks, members of TASK subscribe to international professional organizations including the International Society for Pharmacoeconomics and Outcomes Research, the Society for Medical Decision-Making, and others.

**Knowledge Transfer and Exchange** The linkages described above are critical for effective knowledge transfer. The value of high-quality evidence lies in its uptake in decision-making. Thus in addition to the agencies listed above, knowledge exchange and transfer occurs with targeted government offices, pediatric networks and healthcare institutions, research organizations, and patient care and consumer organizations. TASK maintains an ongoing dialogue with numerous partners manifest through multiple communication modalities, including website communication, dissemination of electronic newsletters and print materials, organization of educational workshops and special symposia, and ongoing informal communication.

## 13.5 Impact of TASK

TASK has completed over 25 projects across a wide range of clinical and therapeutic areas resulting in over 40 journal publications and technical reports. Current ongoing studies include a cost-effectiveness analysis of early antitumor necrosis factor

therapy in children with Crohn's disease, the use of discrete event simulation to assess the cost-effectiveness of alternative genome-based diagnostic strategies in autism spectrum disorder, a comparative effectiveness and cost-effectiveness study of early intervention models for preschoolers with autistic spectrum disorders, a microcost analysis of next-generation sequencing in child health, a discrete choice experiment assessing the preferences of genetic counselors for preimplantation genetic diagnosis, and HTAs in pharmacogenomics including a series of systematic reviews, a meta-analysis, and an economic evaluation of thiopurine S-methyltransferase testing for averting drug toxicity in pediatric patients receiving thiopurines.

As an active research unit, TASK raises awareness regarding the importance of HTA in children across the institution. Members of the SickKids and University of Toronto HTA community benefit from easy access to HTA tools, costing protocols, study design templates, and sharing of expertise and knowledge. TASK produces HTA evidence of the highest quality for hospital-based decision-making in child health, provides a learning space for high-caliber trainees, and continues to foster new research collaborations. Strong involvement of graduate students in TASK projects has been a highly successful mechanism to produce high-quality evidence while increasing HTA capacity in Canada. Research emanating from TASK also benefits other Canadian pediatric hospitals as well as child health clinical and policy decision-makers locally, regionally, nationally, and internationally. Every TASK study creates a new opportunity for further methodological investigation, and findings from methods research positively impact upon the field of pediatric HTA as a whole.

## 13.6 Lessons Learned and Future Opportunities

Going forward, greater success in ensuring uptake of HTA evidence could be achieved through a more formal relationship with SickKids and through the establishment of a hospital-funded service unit that more directly supports hospital-based allocation decision-making. While TASK has been successful in funding competitions since its inception, subsiding purely on grant funding precludes the hiring of permanent staff and hampers career planning and longevity for those staff members who wish to grow and build careers in child health HTA. It also reduces the ability of TASK to respond to request for HTAs made by hospital staff. Currently there is no requirement for Ontario hospitals to support HTA units. Ontario may learn from other provinces in Canada such as Quebec where such units are mandated.

Another important consideration for future pediatric HTA is greater consistency in addressing the ethical, legal, and social issues that arise from introducing new technologies. Many HTAs produced by TASK, especially those related to pharmacotherapy, explicitly consider whether barriers to access will exist. However, many other ethical issues arise in child health such as whether introducing the new technology will create inequity in adoption and distribution and the challenges in

obtaining a child's and family members' consent. These issues are particularly important for personalized medicine technologies such as next-generation sequencing for screening or detection of childhood disorders.

## 13.7 Conclusion

In an era of constrained health-care budgets, health-care systems are increasingly relying on sound, high-quality evidence of value for money to support budget allocation decisions. Generating the required evidence presents many challenges in child health, requiring researchers to continually refine and improve methods for HTA. It is equally important for researchers to maintain clear communication with decision-makers to ensure that the evidence is understood and utilized. With continued dedication to improvement of HTA methods and to knowledge transfer and exchange, we may evolve toward a reality in which child health policy decision-making is based on the highest quality of evidence.

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# Chapter 14
# The Health Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC) (Canada)

**Maurice McGregor**

## 14.1 Background

In jurisdictions that are endowed with a centralised, authoritarian health services structure, such as the United Kingdom, the development of hospital-based HTA will probably be of little interest. However, in jurisdictions like Canada in which hospitals, limited only by their budgets, largely determine for themselves what services they will provide, much health-care policy is created at the hospital level. In Canada, where curative health services are a provincial responsibility, decisions on the acquisition of technologies of high unit cost such as MRI are made by provincial governments. However, the acquisition of technologies of lesser unit cost is mostly decided at the hospital level. Since hospital budgets account for more than one third of all health-care spending, it is essential that hospitals base their decisions on unbiased, accurate information. However, until 2001 no hospitals had any structured permanent method for acquiring such information.

To meet this need, in June 2001 the McGill University Health Centre (MUHC) created a Technology Assessment Unit (TAU). The MUHC is a single corporate structure consisting of the Lachine General Hospital (LGH), the Montréal Children's Hospital (MCH), the Montréal General Hospital (MGH), the Montréal Chest Institute (MCI), the Montréal Neurological Hospital (MNH) and the Royal Victoria Hospital (RVH). The objective was to create a body that would advise the MUHC "in difficult resource allocation decisions, using an approach based on sound, scientific technology assessments, and a transparent, fair decision making process" [1].

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## 14.2 Structure

The TAU has three distinct roles that determine its structure:

- *The production of health technology assessments* (*HTAs*). Decisions concerning the acquisition or continuing use of a technology should be informed by reliable estimates of the efficacy, risks and costs of that technology and by an awareness of any legal or ethical issues relevant to its acquisition. The development of HTAs that provide such information is the responsibility of a small group of permanent professionals with appropriate expertise, under a director.
- *The development of policy recommendations* (what the institution should *do* in the light of the data presented in the HTA). Such decisions depend on more than data alone. They depend also on such things as the estimated *reliability* of the data, on the *weight* to be given the various data items in arriving at a decision and on the *appropriateness* of the technology in question in relation to the technological sophistication and societal role of the institution in question, the MUHC. Such judgments often have to be highly subjective. The development of policy recommendations is the role of a Policy Committee that is representative of the various components of the MUHC and sensitive to its values.

  The Policy Committee consists of a Chair; five *representative* members nominated by the Association of Nurses, the Association of Physicians, the Association of Allied Health Professionals, the Patients Committee and the Administration; and four *expert* members nominated for their expertise in subjects such as epidemiology, medical ethics and health economics. In addition, two senior representatives of the health-care professionals most affected by the recommendations to be developed are co-opted by the Committee for the duration of each report. As well as serving as full voting members, these individuals provide invaluable professional expertise and, by their participation, promote the "buy-in" of their professional colleagues to the final recommendations.
- *The academic role*. Consistent with its role within a University Health Centre, it is expected that the TAU should, where appropriate, publish its results and contribute to the training of personnel in the field of health technology assessment. Between January 2003 and June 2015, 24 papers (+3 submissions) have been published in the peer-reviewed literature, annual courses in health technology assessment are presented within the programme of the Department of Epidemiology of McGill University and 13 graduate students have served internships in the TAU.

## 14.3 Function

In fulfilling its mandate the TAU has been guided by the following principles: [1]

- *Transparency*. It is believed that acceptance by the community of policy recommendations that will influence patient care, professional acts and shared resources

requires complete transparency. TAU meetings are open, and reports are published in full [http://www.mcgill.ca/tau] shortly after their submission to the MUHC administration.

- *The TAU is advisory*. Responsibility for decision-making rests, as always, with the hospital administration. Nevertheless, the unrestricted availability of recommendations with their supporting evidence and reasoning to all in the MUHC community and elsewhere probably influences the final decisions taken in many cases.
- *Choice of topic*. Consistent with its primary role, most reports are developed in response to requests from the administrative and clinical heads of the institution. The decision to accept a topic for review is guided by such factors as its potential budget impact, suspicion of marginal or unproven effectiveness, unfavourable cost-effectiveness or uncertainty or contentiousness from any cause.
- *Durability of recommendations*. In a field in which the knowledge base is constantly changing, it is essential that recommendations be frequently reviewed and updated when necessary. Of the 76 reports produced up to June 1, 2015, 16 are updates of previous reports. Updates have followed the original reports on average by 5 years (range 3–11 years).
- *Evaluation of impact on policy*. Since the principal role of a report is to inform MUHC policy, failure of recommendations to have impact on institutional decisions would represent wasted effort and budget. At the time TAU was created, the absence of impact of HTA reports on what clinicians actually do was "widely acknowledged" [2]. Accordingly, it was stipulated that "The TAU will conduct a regular follow-up of each HTA policy recommendation that it submits, so as to document the impact it has if any, on hospital policy" [1].

Studies of the impact of reports have been published in 2008 [3] and 2012 [4]. The latter document reviewed the recommendations made in 57 reports produced between January 2002 and December 2011. A recommendation was considered to have been accepted by the MUHC when there was clear evidence that MUHC policy was consistent with the recommendation in question. Of 63 recommendations, it was found that 45 (71 %) had been accepted and incorporated into MUHC policy.

Reasons for failure to accept TAU recommendations varied. Four were "administrative", due to such things as lack of funds or personnel, and one was rejected on legal advice that to not use the technology in question might lead to legal action. Seven recommendations were not incorporated into policy because of failure to identify the administrative responsibility to do so.

*Evaluation of Economic Impact* The objective of TAU reports has not been primarily to save money but rather to achieve the maximum health gain from the money available. However, of the 50 recommendations that advised acceptance or rejection of a new technology, 35 (70 %) recommended outright rejection or highly restricted use. Assuming that in the absence of the TAU report, each of these potential technology acquisitions would have been approved, it was estimated that the average annual saving to the hospital budget attributable to these 35 recommendations was a little over $1 million per year.

## 14.4 Discussion

A potential disadvantage of developing HTAs at sites close to the end user is that it may result in local differences in the services provided by different institutions. This in turn may cause patients to seek those services that are not provided in their own institution elsewhere, so-called postal-code prescribing [5]. This hypothetical danger is minimised by shared use of a common database and by good communication between HTA developers. This has not yet become a problem, but if it were to do so, it would have to be corrected by central authority.

At the present time hospital policy is increasingly "evidence-based". Assuming that this is a desirable trend, to be promoted, we must decide who should collect and analyse the "evidence" and who should interpret the evidence into policy decisions. Since estimates of efficacy, cost and cost-effectiveness are generalisable and applicable across institutions, the collection and analysis of data could be carried out effectively by a centralised, provincial or national HTA agency. However, the development of a hospital's *policy*, what the hospital should do in the light of these data, depends on a knowledge of the institution itself, its state of technical advancement, its concept of its mission, its budget status and the health status of its clientele. All of these make it easier and more effective to develop *policy* at the hospital level.

If policy decisions on the acquisition of health technologies are to be taken locally, who should be involved in this process? The traditional approach of a hospital administration faced with demands of its health professionals to acquire technologies they deem to be "essential" for clinical care is to delegate an individual or group to address each request as it arises. Such an ad hoc group, when lacking in special expertise in the analysis of such data, can be unduly influenced by the clinical discipline that is advocating the acquisition and dependent on data supplied by the vendor. There is then a danger that decisions may be made that unduly favour technology acquisition. Also, when each issue is considered by a different ad hoc group, decisions are more likely to be inconsistent from case to case. We believe that the alternative option, the creation of a permanent group such as TAU, representing all sectors of the institution, applying the same principles to guide each policy decision, has significant advantages [5].

In 2012 an external Review Committee concluded that "TAU has a proven track record of high quality technology assessments which have resulted in cost savings/avoidance for the MUHC, but more importantly contribute to providing high quality cost-effective care for our patients. There is no viable alternative at this time to this unit for providing these types of assessments" [6]. However, there are pitfalls that anyone attempting to institute a similar structure should be aware of. We remarked above that seven policy recommendations of the TAU committee had not been incorporated into MUHC policy simply because of failure to identify the administrative responsibility to carry this out. To avoid this immense wastage of effort, we believe it is important to identify in each report a clinical or administrative individual with the authority to accept the recommendations and to carry them out.

Further information on the TAU and all its reports are available on the unit website [http://www.mcgill.ca/tau].

**Acknowledgements** The value of such a unit is less dependent on its constitution and structure than on the quality of the contributory individuals. The success of the TAU owes much to the integrity, hard work and wisdom of the authors of the reports and the successive members of the Policy Committee (see website). In particular the contribution of the two successive Directors of TAU, Dr. J Brophy and Dr. N Dendukuri, cannot be exaggerated.

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# Chapter 15
# Hospital-Based HTA at the Centre Hospitalier de l'Université de Montréal (Canada)

**Luigi Lepanto**

## 15.1 Introduction

The health technology assessment unit of the Centre hospitalier de l'Université de Montréal (CHUM) was created in 2005 and functioned in collaboration with the Technology Assessment Unit of the McGill University Health Centre until 2008. Since 2008, the HTA unit is independent and is part of the Department of Quality, Evaluation, Performance, and Strategic Planning.

In Quebec, the law on health and social services describes explicitly which activities are required for a hospital to be designated a university health center. These include specialized care, teaching, research, and health technology assessment (HTA). This legal requirement has been instrumental in creating a network of hospital-based HTA units that has been active for several years. In conjunction with the provincial HTA agency, Institut national d'excellence en santé et en service social (INESSS), Quebec has a vibrant practice community that meets regularly and occasionally collaborates on projects.

In Quebec, HTA has been translated as *évaluation des technologies et des modes d'intervention en santé* (ETMIS). In addition to devices, procedures, and drugs, the organization of healthcare services is also an object of evaluation. Although drugs fall under the authority of INESSS, hospital HTA units in Quebec do not routinely evaluate pharmaceuticals.

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**Box 1: Health Care System Context**

- *How is the healthcare system funded?*
- The healthcare system in Quebec is publicly funded.

*How are hospitals funded?*

- Hospitals generally receive historical-based block funding with minor adjustments from year to year. Presently the healthcare sector is being subjected to significant financial constraints.

*Who makes decisions about which drugs, devices, and other technologies will be implemented in the hospital setting?*

- Decisions about drugs, devices, and capital equipment are in the process of being more and more centralized, with government and healthcare organization networks bearing responsibility.

## 15.2 Composition and Mandate

The unit is composed of four full-time staff and a director. There are three research analysts who have advanced degrees in the biomedical or social sciences, as well as degrees or training in health technology assessment. The unit has a full-time administrative assistant.

The director is a clinician who spends 60 % of his time in the administration. In addition to the responsibility of HTA, the director is also involved in the evaluation of clinical performance and is part of the management team of the Department of Quality, Evaluation, Performance, and Strategic Planning. The unit has strong links with the CHUM library services as well as with the CHUM research center. Their collaboration is sought when expertise is needed in specific circumstances. The collaboration with the research center is helpful in obtaining assistance in areas such as biostatistics, economic evaluation, and modeling.

The mission of ETMIS at CHUM is to advise clinical and hospital managers on the adoption of specific medical technologies, procedures, or services. This is accomplished by providing the decision-makers with a synthesis of the current knowledge base. When appropriate, modeling is performed to assess the forecasted impact of the new technology on clinical outcome. Economic evaluation and budget impact studies are also part of the deliverables. Not uncommonly, the unit is also asked to evaluate a technology or procedure that is already in use. At times the object is to reassess clinical and cost-effectiveness, while in other circumstances implementation issues are the focus of the evaluation. In this case, a systematic literature review of implementation studies is undertaken to aid clinicians and managers. A field study can also be organized when appropriate, and although the HTA unit will not perform the study, it will help in identifying the appropriate indicators, often following a literature review.

## 15.3 Mode of Operation

Funding for the unit is drawn from the hospital budget and requests for technology assessments come exclusively from the hospital. Requests are submitted online using a standardized online request form that describes the technology or procedure that needs to be assessed. Information about the technology, the target clientele, the objectives, as well as the anticipated cost must be provided before a preliminary assessment is performed by the unit.

A contact person, who is an expert in the technology to be evaluated, must also be identified by the requestor. This contact person acts as a content expert and is consulted by the HTA analyst during the different phases of the literature review and the drafting of the report. Requests are only accepted from clinical department or service heads or from senior managers. Once the evaluation project is deemed receivable, the project is submitted to the hospital clinical coordinating committee that determines the priority ranking of the projects. This committee is a permanent standing committee that addresses the delivery of clinical services in the hospital. It meets on a biweekly basis. An ETMIS dashboard is available on the CHUM intranet listing the projects the unit is working on, as well as the status of each project.

The reports produced by ETMIS are submitted to a scientific committee whose mandate is to ensure methodological rigor and allow feedback from the hospital membership. The committee members are drawn from both clinical and administrative departments. The committee meets three to four times a year, but also does work asynchronously through electronic exchanges. In addition to the oversight provided by the committee, the intent of submitting the reports to this committee before making them public is to provide the recommendations contained within them with the legitimacy needed. The final decision with regard to the implementation of the recommendations rests with the clinical coordination committee and the concerned department heads. Once the reports have been finalized, they are made public and are available on the CHUM web portal (http://www.chumontreal.qc.ca/patients-et-soins/a-propos-du-chum/les-directions-du-chum/etmis/projets). These reports can be accessed via the CHUM intranet, but are also available via the CHUM internet portal open to the public.

## 15.4 Production

When describing the work done by ETMIS at CHUM, it is useful to divide our reports into three categories based on a temporal perspective. The first category contains knowledge synthesis reports that are essentially a retrospective look at the existing evidence base. They are systematic reviews of the literature and most often address issues such as safety, clinical effectiveness, and cost. Ethical, legal, and organizational issues are always addressed when pertinent.

Two important sections are incorporated into all our reports: present knowledge gap and local experience. Identifying issues that need further research is intended to inspire the pursuit of specific projects by the CHUM research center. The section on local experience is an opportunity for CHUM clinicians to express the view of CHUM experts on the technology or clinical service being evaluated. The local experts' opinion may or may not agree with the conclusions and recommendations of the report. The experts consulted often include the clinical expert who accompanied the analyst during the drafting of the report.

Field evaluations are the second category and these can be seen as real-time evaluations as opposed to retrospective assessments based on systematic literature reviews. Although a literature review forms part of the background work in these evaluation projects, namely, to identify implementation issues and identify pertinent indicators, the focus is on collecting data in the real clinical context. These products aid managers and clinicians in adopting the best strategies for technologies and services that have a proven evidence base and ensure their proper use and implementation. Purported clinical effectiveness and cost can also be confirmed within the context of CHUM.

In collaboration with clinical teams, ETMIS will help in identifying appropriate indicators to assess the impact of a given technology or service. The indicators are chosen from a systematic review of the literature following validation with clinical experts. The use of clinical database mining is privileged in these projects to automate data collection. Close collaboration with the team of health informatics specialists is essential. Healthcare managers have a real need to assess the true impact of implemented technologies in the context of their specific context. Knowledge synthesis and modeling can describe what should happen, but it is essential to assess if the improvements promised are realized. Decisions on disinvestment of older technologies and introduction of innovative technologies are often avoided, not because of bad faith but because of genuine uncertainty. Collecting pertinent information on interventions and patient outcome, in the context of a field evaluation, is important to help managers make these decisions.

Finally, the third category is a prospective outlook and refers to medical decision modeling with economic forecasting. Cost-effectiveness, return on investment, and budget impact studies seek to help managers and clinicians make decisions about purchasing and organization of services. This category of reports is often done, when needed, to supplement traditional knowledge synthesis reports.

In addition to assessing the clinical and economic issues, a concerted effort is made to address other dimensions including the ethical and organizational aspects of a new technology in the context of CHUM. The patient perspective is increasingly recognized as an important element of HTA. The CHUM plans to add a patient representative to the scientific committee reviewing the reports produced by ETMIS.

Lately, the unit has been involved in helping managers confronted with the task of limiting costs. To this end the hospital has adopted a strategy based on appropriateness and quality of care. The hospital HTA unit is uniquely qualified to provide the managers with the information needed to inspire best practices and review the appropriateness of many procedures. Five major themes have been identified in order to help in selecting specific clinical issues to assess. These are (1) overuse of

medical testing, (2) appropriateness of treatment, (3) quality of care and diminution of undesired events, (4) process optimization, and (5) purchasing. The traditional reports produced by ETMIS of CHUM, as described above, will be provided for specific questions arising from an analysis of clinical operations. The hospital has struck a permanent committee to study appropriateness and clinical performance. The director of the HTA unit is a permanent member of this committee.

In a hospital environment, the time taken to produce a rigorous systematic review is occasionally seen as a drawback. This has led to attempts at defining a methodology for rapid reviews or mini-HTA. Generally, we take the time needed to produce a report that is of good quality and that satisfies the appropriate guidelines. When a rapid knowledge synthesis is essential, the same methodology is used, but a limit is put on the scope of the literature search. Only HTA reports and systematic reviews will be included. A synthesis of their conclusions will be provided as well as a general assessment of their quality. If such publications do not exist, then a rapid review cannot be provided. This can be considered a preliminary step and can lead to a more formal systematic review, if needed.

## 15.5 Examples

All reports published since 2007 can be consulted on our web portal. A variety of technologies have been assessed over the years. These include radio-frequency treatment of Barrett's esophagus, vagal nerve stimulation for the treatment of epilepsy unresponsive to medical therapy, percutaneous closure of the left atrial appendage to prevent thromboembolic events, point of care testing in the hospital, hybrid operating rooms (integrated imaging equipment), microscopic trans-anal surgery, chemoembolization of hepatocarcinoma with doxorubicin-eluting beads, and cryoablation of renal carcinoma. Although a majority of our reports address specific medical devices or procedures, we have also enlarged the scope of our work to include the organization of clinical services, management strategies, and health information technology. We have also addressed implementation issues concerning practices or technologies that have been implemented at CHUM. In these cases, the objective is not to assess the technology per se; presumably, the introduction was based on solid evidence. The issue is the actual performance in the context of the CHUM, as well as the identification of barriers and facilitators to successful implementation. In the following sections, a selection of reports produced by the unit will be described in more detail.

### *15.5.1 OPTIMAH*

The purpose of this report was to provide a list of quality indicators that will allow the ongoing assessment of the OPTIMAH (Optimisation des soins aux personnes âgées à l'hôpital) program, an interdisciplinary approach aimed at improving care for elderly patients admitted to the hospital. This program conforms to the objectives

set out in the Quebec Ministry of Health directive entitled l'Approche adaptée à la personne âgée (AAPA). These approaches aim to prevent the loss of functional autonomy caused by avoidable complications in elderly patients admitted to acute care hospitals. These indicators are to help clinical personnel and managers monitor the success of this program in attaining its objectives, as well as guide them in implementing proper policy to achieve the stated objectives. On the basis of this report that lists the indicators that need to be assessed, as well as the degree of difficulty in measuring them, the management and clinical teams are attempting to evaluate the success of the program. They are also seeking to identify implementation issues that either facilitate or hinder the attainment of the objectives of the program.

### *15.5.2 Voice Recognition*

The purpose of this report was to conduct a systematic review of the literature describing the impact of voice recognition on report error rates and productivity, as well as the factors influencing user acceptance. This was done because the hospital was planning to implement this technology and was seeking guidance on an appropriate implementation strategy. Findings reveal the underperformance of speech recognition systems over human transcription; also, the productivity of the user of speech recognition systems is negatively affected by this technology. Studies on the perceived benefits have identified several technical and organizational factors influencing adoption of speech recognition systems. These include user attitudes prior to implementation, adequate training and support, optimization of workflow, as well as gradual and selective implementation. Limiting speech recognition to a specific set of reports based on complexity, as well as encouraging the use of predefined report templates and/or shorter reports, can aid in achieving a successful implementation. The report leads to a systematic review limited to studies looking at voice recognition in radiology departments. The evidence shows that overall gains in departmental productivity are high, but radiologist productivity, as measured by the time to produce a report, is diminished. The findings were recently published [1].

### *15.5.3 Lean Management*

The purpose of this review was to describe the ways in which the methods of lean management and Six Sigma have been implemented in the health sector and identify their effects in an acute care setting. These methods were initially devised in the manufacturing sector with the aim of increasing the efficiency of the production process, as well as ensuring continuous quality improvement. This systematic review was, in fact, a review of published systematic reviews studying the impact

of these management techniques in an acute care setting. The objectives included the identification of specific sectors of activity where these techniques were implemented and of the effects of these techniques. The factors that facilitate implementation, as well as the obstacles to implementation, were described. It is apparent that the majority of the implementations of these management techniques were aimed at specific sectors of activity within a hospital setting. The emergency department, the intensive care unit, the operating rooms, as well as the laboratory services were the sectors most often identified. Lean management and Six Sigma, in these environments, were most often implemented with the objective of improving the efficiency or the quality of processes. The effects generally sought through quality improvement include a decrease in the number of reported errors and incidents, an increase in conformity to established standards and guidelines, and increased satisfaction on the part of patients and health professionals. The economic impact, as well as the impact on clinical outcomes, is poorly documented in the literature. Furthermore, there is little data on the long-term effects of these interventions. This report has helped the CHUM management team identify sectors of activity that could benefit from a lean approach, as well as describe the expected impacts. Although there is very little literature describing failed attempts at implementing these management strategies, a focus on what has been shown to work can help avoid initiating projects that do not have an evidence base to support them. The information obtained in this report served as a basis for the publication of an article [2].

### *15.5.4 Cryoablation of Renal Tumors*

The purpose of this report was to compare the relative efficacy and cost of cryoablation of renal tumors with radio-frequency ablation. The hospital had been performing radio-ablation of the liver, bone, kidney, and various soft tissue tumors for many years, and the need to add this new treatment modality, specifically for kidney tumors, was questioned. The increased access to cross-sectional imaging has resulted in the detection of small renal cell carcinomas early in their evolution, often when patients are still asymptomatic. In most cases, these tumors measure less than 4 cm, and this has spurred the development of less invasive treatment options with the intent of salvaging normal renal tissue and maintaining renal function. The report addressed the specific question of the relative efficacy of cryoablation and radio-frequency ablation, and in this context, there is probably no significant difference in the clinical effectiveness and safety of the two ablative techniques, with the possible exception of tumors situated near the renal sinus where cryoablation is favored. When appropriate, watchful waiting combined with ablation if necessary is a viable approach. The evidence to date, although limited by bias and insufficient long-term follow-up, suggests similar survival rates without metastatic disease for all minimally invasive treatments.

### *15.5.5 Review of Canadian Association of Radiologists (CAR) Guidelines*

This assessment, published as an original scientific article, aimed to critically appraise the Canadian Association of Radiologists (CAR) guidelines on the prevention of contrast-induced nephropathy. The AGREE tool was used to assess the methodological rigor of the guidelines, while the quality of the evidence was assessed by reviewing the articles listed in the bibliography. The following data was collected and tabulated: the type of contrast, the administration route, and the level of evidence (Centre for Evidence Based Medicine, University of Oxford). Rigor of development and applicability are the dimensions that scored the lowest on the appraisal tool. The evidence level of the references cited in the guidelines document is variable, and in the case of intravenously administered contrast, the supporting evidence is scarce and of poor quality. The failure to distinguish between intravenous and intra-arterial injection of contrast agent is a shortcoming and a significant number of the references cited neither the type of contrast (ionic or non-ionic) nor the route of administration is specified. Finally, the lack of attention paid to issues of applicability and the logistics of implementing the guidelines was deemed a shortcoming. In our view, it would be appropriate to revisit the topic of CIN and formulate new guidelines. In conclusion, a formal systematic review of the literature was recommended with data extraction specifically addressing the contrast type and the route of administration, as well as the applicability of any recommendations [3].

## 15.6 Impact

Most of our reports have been produced in the last 5 years so it is difficult to give an appraisal of the impact of our activity. It would be fair to say that the unit has had some modest success as well as some setbacks. The report on voice recognition technology led to a change in implementation strategy, while a number of technologies recommended for adoption were introduced to CHUM. A recommendation calling for limited use of a technology (chemoembolization of hepatocarcinoma with doxorubicin-eluting beads) was not adhered to, and a call for the establishment of a registry to collect real time data was not heeded. This has not been unusual in our setting and the recommendation to establish a data registry when the evidence is lacking or poor in the literature is often ignored. This must be addressed at the administration level. Beyond the impact of the reports, the involvement of the unit in the standing committee on clinical performance based on appropriateness and quality is a significant milestone. It entrenches the activities of the unit in a very important aspect of decision-making and will likely lead to greater resources being injected into HTA activities in the CHUM.

## 15.7 Education

The unit has always been very active in academia. The director is a member of the faculty of the department of hospital administration of the École de santé publique of the Université de Montréal. The unit receives graduate level students on a regular basis and they participate in the ongoing projects of the unit. The unit also offers internships to students enrolled in the Ulysses program, an international master's program in health technology assessment and management that is the fruit of the collaboration of four universities (Université de Montréal, Università Cattolica del Sacro Cuore of Rome, University of Toronto, and University of Barcelona). The unit also offers internships to graduate students in other departments, such as clinical and biomedical engineering. In keeping with the teaching mission of CHUM, the HTA unit considers the teaching of the methods and practice of health technology assessment to all members of the hospital community to be a priority. This will enhance, it is hoped, the quality of care with emphasis on appropriateness and best clinical practices.

## 15.8 HTA and Industry

Lately, the HTA unit of CHUM has had some limited interaction with the medical device industry. University teaching hospitals have often seen collaborations with industry, but the establishment of a framework of collaboration and the application of HTA tools to aid in product development and innovation are a recent development. Knowledge synthesis is the basis of all HTA reports. Although other forms of knowledge gathering and development have been added to the toolkit of HTA, the systematic review of published data on health interventions remains the cornerstone of the HTA approach. It not only informs on the safety and effectiveness of a health technology, but it identifies the knowledge gaps that can then be addressed by other means if necessary. With regard to product development, the systematic review of the disease process addressed by the new product, as well as the safety and effectiveness data of alternative and competing technologies, is of utmost importance. It allows the product developer to know and understand the market and identify competing technologies that will challenge the product they wish to introduce. It will also provide the pertinent benchmarks on safety and effectiveness. Answering all these issues will avoid that the product becomes a solution in search of a problem. Field evaluations in the pre-commercial phase allow rigorous testing of prototypes in an appropriate environment. Human factors are often important determinants of the success of a new technology. Information gleaned from testing in an operational context can have profound implications of decisions concerning product modification and commercialization. It ensures that the product is truly ready for market. For many medical devices, the university hospital environment is well suited for beta testing of new products. The CHUM has a world-class simulation center, and

although the primary purpose is educational, it can serve to test new devices specifically for the evaluation of the learning curve and human factors affecting its use by professionals. Finally, modeling and economic evaluation can help demonstrate comparative advantage, at least hypothetically. Data collected from the appropriate knowledge synthesis, as well as from prototype testing, combined with probabilistic and value of information analysis, can aid in predicting organizational and clinical impact.

In offering HTA services to industry, some caveats must be acknowledged. It is preferable to limit collaboration to technology that has yet to reach market, even if this may involve producing a confidentiality agreement to protect intellectual property. If a device or technology is already marketed, then a traditional arms-length approach is recommended, since any collaboration at this level can be seen as introducing bias. An alternative for technologies that are already commercially available is an unrestricted grant, especially if the evaluation considers a generic technology or a broad class of devices that share the same use. The HTA unit of CHUM recently obtained an unrestricted grant to compare the clinical effectiveness and safety of peritoneal dialysis and hemodialysis. The report concluded that the comparison of peritoneal dialysis and hemodialysis does not demonstrate a clinical advantage (survival, complications, quality of life) of one modality with respect to the other. The report noted that it would be useful to systematically assess the medical, social, and organizational factors that influence the choice of treatment modality.

## 15.9 Future Directions

Although this has long been the mainstay of HTA activity in hospitals, knowledge synthesis and modeling represent only a portion of what ETMIS does at CHUM. The ability to control costs and ensure appropriate care are two challenges facing healthcare organizations worldwide. In a university hospital environment, the pace at which new technologies are introduced, the inability or failure to abandon nonperforming technologies, and the lack of real-life data on outcomes offer a window for hospital-based HTA to make a significant contribution. Although the focus of the evaluation is existing practice and not innovation, the failure to abandon poorly performing practices is an impediment to the introduction of innovative technologies that could potentially offer better outcomes or equivalent outcomes at lower cost. The decision to base cost control measures on the evaluation of the quality and appropriateness of care and the formal involvement of the HTA unit in this process at CHUM is welcome development. The evaluation of other topics not traditionally assessed by HTA units, such as information technology, and the evaluation of the organization of care and the implementation of innovative care are also seen as becoming more important in the future.

Adequate funding for HTA activities remains a challenge and the competition for hospital budget resources is fierce. It is incumbent on us to show that HTA is an activity that has significant added value and that spending on HTA may lead to cost

avoidance and saving when recommendations favor best practices, appropriate care, and disinvestment in nonperforming technologies and practices.

Training in HTA is also of paramount importance. It is a multidisciplinary activity and professionals working in HTA come from different backgrounds. It is nonetheless important to develop a common understanding of the objectives and methods of HTA that will foster an effective team approach. As these teams grow in size and in sophistication, training aimed at preparing managers of HTA to lead such teams becomes necessary. Interaction of these managers with other hospital managers and administrators requires an understanding of management principles as well as an appreciation of the challenges of operating a healthcare organization. Continuing education aimed at healthcare managers and administrators in general is also desirable to foster the development of a culture that promotes appropriateness and best practices. HTA is a necessary ingredient in attaining this objective.

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# Chapter 16
# The Health Technology Assessment Unit of the Centre hospitalier universitaire de Sherbrooke (Canada)

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## 16.1 Description of the Unit

The Health Technology Assessment (HTA) Unit of the Centre hospitalier universitaire de Sherbrooke (CHUS) was created in 2004. A coordinator (middle-level manager) holding a master's degree from the Université de Montréal in health technology assessment and an advisor in technology assessment started the development of the unit under the management of the Director of Medical Affairs and Professional Services. By this positioning, the organization allowed the HTA Unit a proximity to clinicians while keeping strategic relations to senior management. To increase credibility among these groups, approval of HTA reports was under the responsibility of the Director of Medical Affairs and Professional Services (a physician and senior manager).

In 2006, the CHUS created an HTA Department from the original HTA Unit and the Telehealth Service. At that time, the unit's philosophy was characterized by the production of scientific assessment of technologies using experimental evidence presented in literature combined with organizational data with little input from stakeholders. As a specific department, this positioning allowed the unit to be closer to the chief executive officer (CEO) but did not really improve the implication of senior managers.

The CHUS kept moving forward in 2009 by merging advisory divisions including the HTA Unit and Telehealth Services in a newly created Quality Department. Five years later, changes in the philosophy of the HTA Unit were conducted. While at its origin, in 2004, the unit aimed to be a group of independent experts whose

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opinions influenced decisions, in 2014 it was felt that a more inclusive philosophical approach should be developed to increase HTA utility, credibility, and visibility. This new vision was translated into a new mission that involved participation of key stakeholders in the HTA process. In fact, this revision which included a paradigm shift to include more contextual data in the HTA process is now more inclusive of stakeholder's views in the scientific process and development of recommendations. Furthermore, involving stakeholders in a partnership to conduct assessment was found to be a avenue for improving usefulness of HTA while maintaining high-quality evaluation standards. Stakeholder involvement improves contextualization of assessments and facilitates adoption and implementation of technologies in specific organizational settings.

Following adoption of Bill n°10 in February 2015 at the provincial level, the governance of the Health and Social Services system across the Province of Quebec was reorganized, and the HTA Unit of the CHUS left the Quality Department to be integrated in the Administrative Research Department of a new organization resulting from the fusion of the region's health and social services agency and all the region's public healthcare institutions. In the last section of this chapter, the opportunity to develop HTA in a broad network of healthcare and social services with a new concern on trajectory of care will be presented.

### *16.1.1 Team Constitution*

The actual unit is composed by a multidisciplinary team including an administrative officer, a coordinator, 2.5 full-time HTA specialists, and one part-time medical officer. This team has qualification in economics, medical, statistics, mathematics, ethics, epidemiology, computer science, microbiology, clinical and basic research, and HTA, providing very strong skills to address most assessment needs. Appendix I provides a short biography of the HTA Unit members at the end of 2015.

### *16.1.2 Clients*

Requests can be made by all clinicians, professionals, and managers from the Réseau universitaire intégré de santé (RUIS) of the Université de Sherbrooke, representing a territory of more than one million people. Nevertheless, the majority of requests are made by local clients at the CHUS (two tertiary hospitals covering a population of 306,322 people).

From the creation of the HTA Unit to 2014, most requests were provided by clinicians, professionals, and middle-level managers from operational services, with low involvement of executive managers in requesting assessment of technologies.

Gradual changes in the philosophy of the assessment process led to the assurance that requests are supported by all levels of management. A service agreement was developed to expose the mandate, time frame, and responsibilities of HTA Unit and requestors to meet this concern while creating a formalized engagement. To date, the service agreement is signed by the client, the HTA Unit coordinator, and a senior manager. This administrative process has significantly improved the perception of the HTA Unit in reinforcing the mission of HTA across all levels of administration and has played an important role in the use and implementation of the recommendations.

### *16.1.3 Types of Technology Assessed*

Typically, the HTA Unit of the CHUS assesses traditional technologies (medical devices) and healthcare interventions through standard and scientifically recognized methodologies (e.g., systematic review and meta-analysis). Over time, nontraditional technologies have also been assessed according to particular skills and knowledge that characterized the multidisciplinary team of the HTA Unit. In fact, a hospital-based HTA Unit is in a position to address specific local concerns as well as a wide variety of needs that necessitate decision-making. For example, electromagnetic interference with medical device induced by wireless technologies [1] and technologies producing images in the field of telemedicine [2–4] were assessed by literature review and specific laboratory methods. More recently, due to budgetary constraints, assessment of high-cost technologies has increasingly been requested by high-level administration.

The HB-HTA Unit does not address drugs since drug assessment falls under the mandate of the Institut national d'excellence en santé et en services sociaux (INESSS).

### *16.1.4 Production Process*

A scientific production process for HTA was developed to maximize stakeholder involvement, ensure scientific credibility, and respect time frame for HTA production. An algorithm (Appendix II) was developed to help the HTA producers to follow a standardized process while helping all stakeholders to understand the scientific production steps.

Currently, at the beginning of the production process, a scoping committee is formed to assess the needs of the clients, to refine the evaluation question, and to identify stakeholders. Most of the time, stakeholders include one or two managers (department heads and/or directors), a healthcare professional (e.g., nurse, physiotherapist), two physicians (the medical service chief and a specialist in the topic area), a biomedical engineer, and sometimes a member of the administrative staff

(e.g., purchase specialist, computer scientist, database manager). A start-up meeting is conducted with stakeholders to share pertinent information (e.g., key articles and contextual data) and to identify potential pitfalls. Then, the HTA team produces a protocol that is shared with stakeholders for revisions and modifications if necessary (e.g., keywords, primary outcomes, databases). During the health technology assessment, stakeholders are in charge of providing key information (e.g., characteristics of patients, organizational features, human resources needed) and to provide scientific feedback (e.g., results interpretation, cost items to be considered). Numerous interactions are performed between stakeholders and the HTA team to ensure that the evaluation question is well examined and the methodology is technically sound and to contextualize the results. The preliminary results are then reported in a preliminary report. This report is modified and corrected according to the comments of the stakeholders. Preliminary recommendations are then provided by the HTA team, and a recommendation meeting is held to allow for discussion and to ensure contextualization to the organization. Final recommendations and a report are approved by consensus between stakeholders and the HTA team before publication.

### *16.1.5 Connections with Research*

Occasionally, the HTA Unit collaborates in clinical or basic research projects related to healthcare, and other times the HTA Unit is the initiator of research projects. Recent examples of research collaborations include working with endocrinologists to assess the impact of healthy lifestyles in obese patients on fertility and weight loss outcomes (i.e., to assess the cost-effectiveness [5]).

In other cases, it can be a methodological need to improve HTA impact and development that drives these collaborations (e.g., integration of ethics in HTA (see Sect. 16.3.2) and impact of HB-HTA activities [6]). Sometimes, the nature of the evaluation question leads us to conduct research in collaboration with other researchers from different domains (e.g., physicians, engineers, statisticians, physicists, philosophers) to develop tools. Examples of projects initiated include (1) the development of a questionnaire to assess the interdisciplinary functioning of a clinical team (IPC65) [7] and (2) development and assessment of a teletrauma system [8]. Collaborations with researchers are important because they allow knowledge sharing, improving the quality of scientific process while generating new data. Generation of new data has proven to be very important to contextualize the results of HTA products.

### *16.1.6 Unit Funding*

Funding an HB-HTA Unit is challenging for all local organizations in the Province of Quebec. Because no specific additional funding was provided to develop hospital-based HTA in the Province of Quebec when the Ministry of

Health and Social Services mandated HB-HTA as the fourth component of the mission of university healthcare facilities (healthcare, research, education, and HTA) in 1992, each local hospital is required to fund the unit from within its current allocated budgetary framework.

The HTA Unit of the CHUS is no exception. In fact, this situation remains challenging for the ongoing operation of HB-HTA, especially when it comes to field evaluation, because the cost of collecting data in the local clinical setting is very high and requires long-term commitment of resources. To overcome lack of funding, the HB-HTA Unit of the CHUS has mainly obtained external financing to support its field evaluations (e.g., Ministry of Health and Social Services, Regional Health Agencies). No specific process or competitive research proposal has been developed to obtain external funds. In fact, the clients recognized the need of financial support to perform rigorous assessments. Financial support is discussed at the scoping step of the project.

## 16.2 Products and Services

Full HTA reports have remained the gold standard since the origin of the HB-HTA Unit at CHUS. However, in order to address decision-makers' request to shorten the time frame for production, new products have been developed. Currently, the product line includes short reports, as well as brief reviews. During the last year, a shift toward these expedited products that seem to better suit requestors' needs was made. In 2014, for instance, three full HTA reports were published as well as three brief reviews. As of this writing, in 2015, one full HTA report, four short reports, and six brief reviews were produced (http://www.chus.qc.ca/volet-academique-ruis/evaluation-des-technologies/).

The unit has also developed field evaluation in order to address gaps in published data and to better consider local context. Methodological support for managers, clinicians, and any other healthcare professionals is also provide by the HTA Unit. Moreover, a horizon scanning process was developed in 2012 in order to disseminate all HTA production in the Province of Quebec to key people in the network of the CHUS. In addition, HTA internships are also offered since 2013. A detailed description of the aforementioned products and services is presented in the following sections.

### *16.2.1 Full HTA Report*

Full HTA reports consist of a systematic review of the literature, with or without meta-analysis, combined with contextual evidence in order to assess local relevance and applicability. Information to address contextual evidence may be extracted from local hospitals databases and gathered through consultations with many stakeholders.

The whole process usually requires 8–24 months, and reports have a mean length of 50 pages (including references and appendices). The report presents the following outcome: safety, efficacy/effectiveness, organizational and professional implications, and economic issues. Recommendations are produced as described in Sect. 16.1.4.

### *16.2.2 Short Report and Brief Review*

To meet the growing demand in which decision-making has to be taken quickly, two other products quicker to read and faster to deliver were developed.

The first one is a "short report" that includes the same outcome assessment as a full HTA report. However, a narrative nonsystematic review on previously published systematic reviews and on recent primary studies combined with local data is used in order to shorten the whole process (4–8 months is usually needed). Despite this nonsystematic process, this product generally provides sufficient evidence to produce recommendations in a report within an average of 20 pages.

The brief review, which is the other product, is even shorter. The overall process takes 1–4 months and provides a brief assessment of the advantages and disadvantages of a given technology according to the context. A scoping review associated with a short description of the context is used to produce a report without recommendations and within a maximum of six pages.

### *16.2.3 Field Evaluation*

Field evaluation was developed to compensate for the lack of data in the scientific literature and to help decision-making especially when hospital needs are too specific for general use of published evidence or when the technology is at the innovation stage. It is a key element for the HTA Unit of the CHUS and a distinctive orientation compared with other HTA Units in the Province of Quebec. This distinctive research domain was developed in accordance with team skills and expertise and in response to the institutional needs for this kind of research. Data produced using this methodology are combined with literature review to produce a report with recommendations within an average of 50 pages. The overall process requires 8–24 months.

One example of a field evaluation conducted was to evaluate a new interdisciplinary model in orthopedic care. A literature review was unable to provide sufficient data to make a decision about funding this new model of care. As a consequence, it was decided to conduct a clinical study that addresses the impact of this model on access to care, patient quality of life, and cost of care [9].

Some field evaluations have also taken the form of experimental studies [10] and even biomedical equipment development (e.g., infusion pump, confidential unpublished document) and telehealth development [8, 11].

### *16.2.4 Methodological Support*

Frequently, managers, clinicians, and healthcare professionals are faced with a lack of evidence and are not willing to undergo a field evaluation process, considering the time and the costs of such process. In order to ensure that rigorous scientific methodology is used when it comes to measurement, members of the HTA Unit can be involved in a project managed by a healthcare professional. Methodological support is also a good avenue to promote a measurement culture in the organization.

Examples of such interventions include supporting clients in statistical analyses, interpretation of the data, data collection design, participation in a failure and mode effect analysis (FMEA), economic analysis, participation in lean management projects [12], scientific advisory, and root cause analysis, among others.

### *16.2.5 Horizon Scanning*

Healthcare professionals and managers from the RUIS of the Université de Sherbrooke receive a lot of information from various sources, and it is challenging for them to manage all this information. In order to help this group in sorting information, the CEO of the CHUS mandated the HTA Unit to disseminate knowledge concerning new technologies, healthcare interventions, and health services. Horizon scanning was developed by the HTA Unit accordingly. Information produced by all HTA Units in the Province of Quebec and INESSS are examined and summarized in a table within three dimensions: (1) Subject, (2) Objective, and (3) Conclusion and Recommendations. Tables are sent electronically by a mailing list regularly updated. The mailing list started with managers of the CHUS, clinicians, residents, and others professionals and continues to grow year after year by including members of the broad clinical and academic network of the CHUS and RUIS of the Université de Sherbrooke.

### *16.2.6 Internships*

Before 2013, students from the Université de Sherbrooke had been episodically welcomed for an internship at the HTA Unit. Since summer 2013, traineeships are provided on a more regular basis, especially to students in health economics from the

Centre d'Études et de Recherches sur le Développement International (CERDI) in France. The internships last from 3 to 4 months and provide training on the methods of systematic reviews, medico-economic assessment, and HTA scientific process.

The internship offer will be expanded to students in Research in Health Sciences Programs from the Université de Sherbrooke in 2016–2017. Internships are also going to be proposed soon to healthcare professionals, medical students, specialty residents, and fellows, for short periods, or as part of a master's degree in health sciences.

## 16.3 Successes

Since the creation of the first HTA Unit in the Province of Quebec in 2001 (the Technology Assessment Unit of the McGill University Health Center), the successes and impacts of HB-HTA have been gaining momentum in the Province of Quebec, particularly within HTA Units, government, and research units. This section presents key successes and results of an assessment of the impact in decision-making of the HTA Unit of the CHUS.

### *16.3.1 Field Evaluation*

As indicated earlier, field evaluation is a particular method that was developed at the HTA Unit of the CHUS. Since the first project conducted in 2008–2009, skills in this domain have been recognized by other institutions and by the Ministère de la Santé et des Services sociaux du Québec. As an example, a project conducted recently was presented at the 2014 Conference of the American Association of Blood Banks (AABB) and won a prize as a top poster [13]. Other projects were also awarded by regional and provincial prizes or published in scientific journals [8, 9, 14, 15]. This led to other projects requested by different regional health agencies in The Province of Quebec, the Ministère de la Santé et des Services sociaux du Québec, and of course by the CHUS.

### *16.3.2 Partnership in Developing HTA Methods*

Methodological improvement is required to maintain high scientific standards for all HTA producers in order to meet the requirements of rigorous decision-making in organizational settings. A promising avenue in developing methods while ensuring a large adoption in scientific and policy communities is to work in partnership with stakeholders.

An instrument for improved integration of ethical dimensions in the current HTA process is currently in development in partnership with a multidisciplinary team

composed of various stakeholders in ethics and HTA. This project involves the highly credible research team in ethics of the Université de Sherbrooke (Interne3LS) joined by members of the HTA Unit of the CHUS in collaboration with members of the HTA community of practice in the Province of Quebec. This partnership of high scientific credibility has allowed obtaining a 4-year research grant from the Canadian Institutes of Health Research (CIHR) for realizing this project [CIHR #142187].

### *16.3.3 Impact of the Unit on Decision-Making*

A survey conducted in 2013 with decision-makers involved in the HTA process at the CHUS between 2003 and 2012 indicated that 16 out of 23 recommendations (70%) included in 13 HTA reports have been implemented. Among the seven recommendations not implemented, two were accepted in decision-making process, and five were refused by decision-makers. The rejection of recommendation does not mean that the work (published report) was not used as an input for decision-making.

During this survey, face-to-face interviews were conducting by an independent interviewer. The main reasons for not implementing the recommendations by order of importance were administrative reasons (e.g., complexity changes), non-priority recommendation for the institution, lack of resources, failure to identify administrative responsibility to carry out the recommendation, and too late or not at the right time.

## 16.4 Challenges

A hospital-based HTA Unit has to deal with people having various values, experiences, and expertise in a complex environment with many issues. Many factors are involved in policy-making, while scientific evidence is an input among others (Factors Influencing Policy Making in Government [16]). Important challenges that the HTA Unit are faced with are described in this section.

### *16.4.1 HTA Production Challenges*

Decision-makers of the CHUS need useful and timely delivered HTA reports for supporting them in their decisions for implementing new technologies or healthcare interventions for improving healthcare quality and efficiency. They highly value the utility of these reports for their decision process. This utility value is shared and well understood by the HTA Unit members, but it comes in confrontation with HTA producer values such as scientific rigor and professional propriety [17] during the production process.

The need to perform HTA in the window of opportunity for decision-makers has emerged as a challenge over the past few years. As a matter of fact, full HTA reports

that involve roughly 8–24 months for production were increasingly not meeting the expectations of policy-makers. In particular, for decisions that need to be taken quickly, this implies the need to shorten HTA production. This time constraint imposed by decision-makers impinges on the feasibility of producing high-quality reports based on scientifically rigorous systematic reviews. It also reduces time for involving all key stakeholders to contribute to the evaluation of scientific evidence and contextual issues. Time constraints may increase the risk of producing incomplete, partially contextualized reports, lacking full recommendations. This may eventually negatively affect staff adoption and implementation of new technologies and care programs.

### *16.4.2 Perception of the HTA Unit*

Based on the survey conducted in 2013 that covered both clients' satisfaction and the impact of recommendations (see Sect. 16.3.3 for more details), decision-makers agreed that globally HTA reports meet their needs and expectations. Furthermore, decision-makers considered that work done by the HTA Unit is scientifically rigorous. However, the survey results also suggest some disconnections between policy-makers and the HTA Unit. Starting with the scientific terms conveyed by the reports, some policy-makers considered them not easy to grasp. Moreover, a lack of short and clear messages is sometimes noted. When policy-makers were asked about the reason why recommendations were not implemented, they underlined the lack of context-specific evidence. Generally speaking, decision-makers are satisfied with the work carried out by the HTA Unit but are waiting for some improvement, notably shorter production delays.

### *16.4.3 Partnership with Industry*

On some occasions, new technologies need to be assessed locally before they can be integrated widely in a hospital. This is the case for innovative technologies where published evidence is limited. Partnerships with industry may be a solution to create a faster integration of promising technologies. The HTA Unit of the CHUS has tested partnership with industry for some technologies.

One partnership with industry has succeeded with a special project in collaboration with the Université de Sherbrooke. The aim of this project was to develop and assess a system that is able to assist local clinicians in performing surgery procedures on unstable polytraumatized patients using telemedicine [8]. A marketing license resulted from this development partnership.

One of the reasons why a partnership with industry may fail is the insufficient population base in relation to the new technologies to produce evidence. Furthermore, local context is not always suitable to support this kind of HTA process. In fact,

partnership with industry needs to be supported by internal stakeholders who may be reluctant to support this process due to administrative complexity and difficulties in risk sharing with industry. According to past experiences, a third party responsible to manage a good contract is the key to keep independence in scientific production while keeping full capacity to publish the data regardless of whether the results are in favor or against the use of a technology.

## 16.5 Future Needs/Direction

Recently, the Province of Quebec has gone through major changes in the organization of health institutions. In particular, the Government Bill n°10 has resulted in the creation of the Centre intégré universitaire de santé et de services sociaux (CIUSSS) de l'Estrie–CHUS that resulted from the fusion of 14 healthcare and social services institutions. Internal restructuring was consequently conducted including the creation of the Administrative Research Department. This new department now includes the former HB-HTA Unit, three research centers, and a service of knowledge brokering and transfer. This department is responsible for integrating the university mission (research, education, and HTA) in the trajectory of care in a unique and complex setting providing the majority of all kinds of healthcare and social services available for the population. In fact, only few ultra-specialized care are not available across the CIUSSS de l'Estrie–CHUS services.

At this time, the HTA Unit is faced with new perspectives and challenges resulting from this new organization. Chiefly, this represents an opportunity to enhance the development and mandate of the Unit. For example, patient involvement is increasingly considered as an essential input in HTA processes. Contributions of patients can be considered at multiple levels including information (inform and educate patients), consultation (gather information and opinions of patients), or direct participation in HTA activities including prioritization of topics and involvement in HTA committees [18]. However, patient involvement is a major challenge for HTA producers, since it is time-consuming and requires agreement and adoption by all stakeholders involved. There is thus a need to determine how and where in the HTA production process patients' participation is the most useful. To date, patient involvement has been included into only three HTAs at the CHUS. But the unique organization settings in the Province of Quebec and the continued willingness of the CEO and other senior managers of the CIUSSS de l'Estrie–CHUS to integrate the perception of patients in decisions will provide a further opportunity to take a leading position in this development.

Finally, with other partners like the Patient Experience Division, the newly formed Administrative Research Department has a unique possibility to create a full service offer in knowledge management in order to enhance informed decision-making more broadly. The structure of the CIUSSS de l'Estrie–CHUS dedicated to cover the full range of healthcare and social services is certainly an opportunity to expand the utility of hospital-based HTA among this wide setting.

## Appendix I: HTA Unit Team at CHUS

| | |
|---|---|
|  | Christian A. Bellemare, Coordinator, Health Technology Assessment Unit<br>Christian A. Bellemare completed a bachelor's degree in mathematics and computer science and a master's degree in computer science from the Université de Montréal and a master's degree in management from Université Laval<br>He joined the HTA Unit of the Centre hospitalier universitaire de Sherbrooke (CHUS) in 2004 as an advisor in technology assessment. In 2008, he takes the coordination of the HTA Unit to ensure his management while participating in scientific activities in particular in emerging technologies where it contributes to the development of the field evaluation<br>cbellemare.chus@ssss.gouv.qc.ca |
|  | Jean-François Fisette, Advisor, Technology Assessment<br>Jean-Francois Fisette completed a PhD degree in microbiology at Université de Sherbrooke that was followed by a postdoctoral fellowship in neurology at Harvard Medical School and Brigham and Women's Hospital. His primary focus was fundamental research and human health. He joined the HTA Unit of the CHUS in 2011<br>jffisette.chus@ssss.gouv.qc.ca |
|  | Suzanne K. Bédard, Advisor, Technology Assessment<br>Holder of a college degree in medical technology (specialization in molecular biology) and a multidisciplinary bachelor's degree<br>She is a member of OPTMQ and worked several years in the field of basic, clinical, and epidemiological research at the Faculty of Medicine and Health Sciences of Université de Sherbrooke and Research Centre of the CHUS<br>She occupies the Chair of the Multidisciplinary Council of the CHUS since 2005. She joined the HTA Unit of the CHUS in 2007<br>sbedard.chus@ssss.gouv.qc.ca |
|  | Thomas G. Poder, Consulting Executive in Health Technology Assessment<br>Holder of a PhD in health economics, a master in project analysis, and a master in development economics from the CERDI in France. He is an Adjunct Professor at the Department of Economics of the Université de Sherbrooke and a researcher at the Research Centre of the CHUS. His main areas of expertise are the analysis of evidence-based medicine and cost-benefit analysis. He joined the HTA unit of the CHUS in 2007<br>tpoder.chus@ssss.gouv.qc.ca |

Monique Robillard, Administrative Officer

Holder of a certificate in business administration and of a professional certificate of secretary

She worked in administrative support to several teams in the private and public sector. She joined HTA unit of CHUS in 2012

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Pierre Dagenais, Medical Officer

After completing an MD at the Université de Montréal (UdeM) in 1986, Dr. Dagenais specialized in internal medicine (UdeM) and rheumatology (University of Toronto). He then obtained an MSc in Clinical Sciences in 1994 and a PhD in Cellular Biology and Immunology in 1998 (Université de Sherbrooke). For about ten years, Dr. Dagenais served as an Assistant Clinical Professor at a UdeM-affiliated university hospital. He also completed an international master's degree (UdeM) in health technology assessment and management in 2006

Dr. Dagenais joined the Quebec's HTA Agency (AETMIS) in 2005 as a researcher and methodology consultant. He then served as Deputy Scientific Director and became the Director of Methodological Support and Quality at the newly created Institut national d'excellence en santé et en services sociaux (INESSS) in 2011, a position he held until the end of 2014. His work included the production of methodological standards and guides for INESSS researchers. Dr. Dagenais also worked as an Assistant Professor at the Department of Health Administration of UdeM from 2005 to 2015, where he taught evaluation methods in health technology assessment

Dr. Dagenais joined HTA Unit of the CHUS in 2015 as a Medical Officer on various technology assessments and methodological development projects

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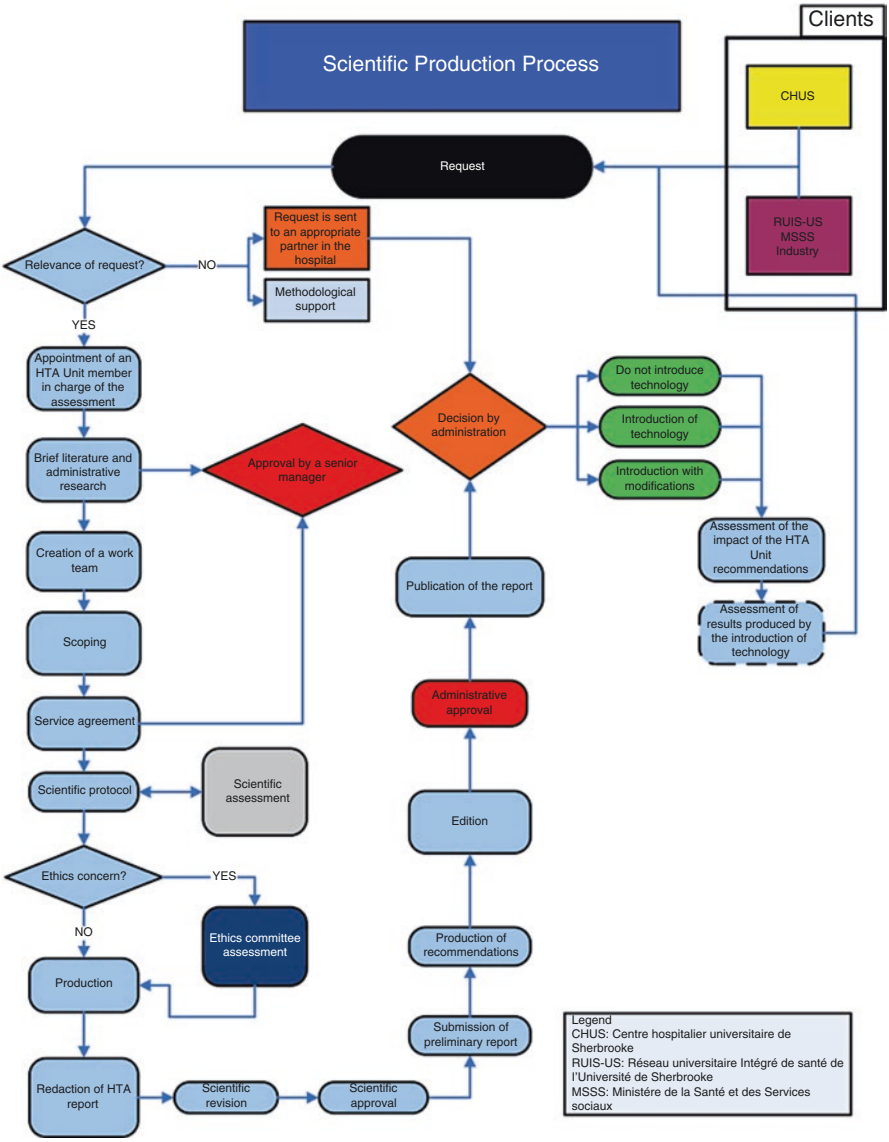
# Appendix II: Scientific Production Process



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# Chapter 17
# CHU de Québec–Université Laval: 10-Years' Experience in Hospital-Based HTA (Canada)

**Marc Rhainds, Geneviève Asselin, and Martin Coulombe**

## 17.1 Overview of the Québec Health and Social Services System

The Province of Québec adheres to a universal access to free healthcare and social services created in 1971 with the State acting as the main insurer and administrator. Most of the funding is generated from taxes collected by the Government of Québec and also from federal government transfers and contributions paid by individuals and employers into the Health Services Fund. The *Ministry of Health and Social Services* of Québec is in charge of maintaining, improving, and restoring the health and well-being of Quebecers by providing access to a set of integrated and high-quality health services and social services. This mission is shared with the institutions of the health and social services network. Mandated by law, academic health institutions must combine missions of care, teaching, research, and health technology assessment (HTA). In addition, four integrated health university networks were created around the four Medical Faculties of the Province of Québec. For instance, the *Université Laval* integrated health network gathers six sociosanitary regions (population: 2M) in order to coordinate specialized care, teaching, research, and HTA and share the expertise of university health centers with smaller hospitals.

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**Box 1: Health Care System Context**

- The healthcare system in Canada is publicly funded at both the provincial and federal levels.
- The roles of the provincial governments in health care include the administration of their health insurance plans and the planning and funding of care in hospitals and other healthcare facilities.
- The government regulates drugs that are available in hospitals and is involved in the authorization of costly health technologies.
- The healthcare centers also make decisions about drugs or medical devices to be funded by the hospitals, via the Pharmacology Committee of the Council of Physicians, Dentists and Pharmacists and the Committee of Medical Equipment, respectively.

## 17.2 Description of the *CHU de Québec–Université Laval*

The *CHU de Québec–Université Laval* was created by the merger of the *Centre hospitalier universitaire de Québec* (CHUQ) and the *Centre hospitalier affilié universitaire de Québec* (CHA) in July 2012. It offers general, specialized, and highly specialized healthcare in a teaching, research, and HTA environment. With its five hospital sites, the *CHU de Québec–Université Laval* is one of the largest university health centers in Canada including 1,767 beds; 14,400 employees; 1,600 physicians, dentists, and pharmacists; 500 researchers; and 1,000 graduate and postdoctoral students. Each year, the number of ambulatory visits and emergency department visits reaches nearly 619,000 and 237,000, respectively, with 66,000 surgeries and 8,400 deliveries.

## 17.3 HB-HTA Unit of *CHU de Québec–Université Laval*

The hospital-based HTA (HB-HTA) Unit of *CHU de Québec–Université Laval* was established in 2006. The Unit is publicly funded by hospital operating funds. The mandate is to support and advise managers, physicians, and professionals in evidence-based decision-making on the best allocation of resources for the introduction or reappraisal of health technologies or clinical practices. The pursued objectives are:

- Evaluate health technologies according to the available evidence to formulate recommendations.
- Conduct activities of exchange and dissemination of knowledge.
- Provide leadership for the development of a culture of evaluation in the institution.
- Contribute to the educational mission of the institution by offering HTA internships and training (e.g., medical residents, Ulysses International Master's program in HTA, master's degree in occupational therapy).
- Participate in research projects, including the integration of patient perspective in HTA activities and the impacts of HTA.

The HB-HTA Unit is part of the *evaluation and patient experience module* of the Executive Office of evaluation, quality, ethics, planning, and legal affairs. The HB-HTA team consists of a medical director, an assistant director, six research officers, and an administrative assistant. Research officers have various academic backgrounds including in epidemiology, social sciences, nutrition, biology, and biochemistry. Two governance committees have been implemented to ensure methodological rigor, transparency in the processes, and the representativeness of stakeholders: the Steering Committee and the Advisory Scientific Committee. The Steering Committee has the mandate to prioritize annually HTA requests from managers, physicians, and professionals; to ensure the usefulness of the evaluation reports; and to receive the annual report of the HB-HTA Unit. The composition of this committee is shown in Table 17.1. The Advisory Scientific Committee has the mandate to review and approve the HTA methods and HTA reports including recommendations and, finally, to contribute to knowledge transfer. It includes representatives from several directions, executive offices, departments, and professional councils (Table 17.1). The HB-HTA Unit reports also to the Committee on Education, Research, and Evaluation of the board of directors of the *CHU de Québec–Université Laval* as an accountability mechanism for the recommendations. In addition, the Unit participates in several internal committees and has strong links with researchers of the institution's research center specialized in Population Health and Optimal Health Practices and external partnerships (Table 17.2). One of them is a panel of representatives in HTA created by the *Université Laval* integrated health network. The mandates are mainly to prioritize HTA questions of common

**Table 17.1** Membership of the HB-HTA unit governance committees

| | |
|---|---|
| *Steering committee* | |
| Chief executive officer | Representative of the research center |
| Deputy general manager of the university and medical affairs | Chair of the central patients committee |
| Deputy general manager of the clinical organization | Deputy director of multidisciplinary services |
| Director of the executive office of evaluation, quality, ethics, planning, and legal affairs | Director of nursing |
| Chair or the council of physicians, dentists and pharmacists | Medical director of hospital services (imaging and laboratories) |
| Chair of the multidisciplinary council | HB-HTA unit comanagers |
| Chair of the council of nurses | |
| *Advisory scientific committee* | |
| Director of the executive office of evaluation, quality, ethics, planning, and legal affairs | Representative of the multidisciplinary council |
| Deputy director of professional services | Representative of the council of nursing |
| Representative of the direction of nursing | HTA researcher of the research center |
| Representative of the council of physicians, dentists and pharmacists | Representative of the central patients committee |
| Deputy director of multidisciplinary services | HTA unit team comanagers and team members |
| Representative of the biomedical services | |

interest among the six sociosanitary regions and promote a culture of evidence-based management and clinical practice at the local and regional levels.

### *17.3.1 HB-HTA* Approach at the CHU de Québec–Université Laval

To meet the needs of its customers and partners, the HB-HTA Unit offers different types of products and services (Table 17.3). The HB-HTA Unit relies to a structured evaluation process that promotes sustained involvement of key stakeholders at each stage of the production and dissemination of HTA projects (Fig. 17.1).

There is an annual call process for HTA projects in which applicants must provide information on the decisional question, the technology (e.g., medical device)

**Table 17.2** List of main internal and external partners of HB-HTA unit

| Internal partners | External partners |
|---|---|
| Committee on education, research, and evaluation (board of directors) | Regional HTA network (Université Laval)[a] |
| Cost driver committee[a] | Provincial community of practice in HB-HTA[a] |
| Committee on evaluation of medical and surgical supplies[a] | Provincial HTA agency: Institut national d'excellence en santé et en services sociaux (INESSS) |
| Advisory committee on medical devices[a] | Quebec Heart and Lung Institute |
| Medical director of hospital services (imaging and laboratories) | |
| Director of professional services | |
| Director of nursing | |
| Director of multidisciplinary services | |
| Researchers in HTA including patient's perspective | |

[a]HB-HTA Unit has a formal committee member

**Table 17.3** HB-HTA unit types of publications

| *Evaluation report* |
|---|
| An HTA produced from a synthesis of knowledge based on an exhaustive review of the literature on efficacy, safety and, if relevant, other HTA dimensions (e.g., budgetary, organizational impacts, legal issues) |
| *Rapid review report* |
| An analysis and synthesis of data produced from a partial review of knowledge based on limited categories of data sources, mainly systematic reviews (SRs) and clinical practice guidelines (CPGs) |
| *Scientific monitoring report* |
| A timely exploration of literature about a published HTA report by the Unit. It takes the form of a critical analysis explaining how this information does or does not modify the current recommendations |

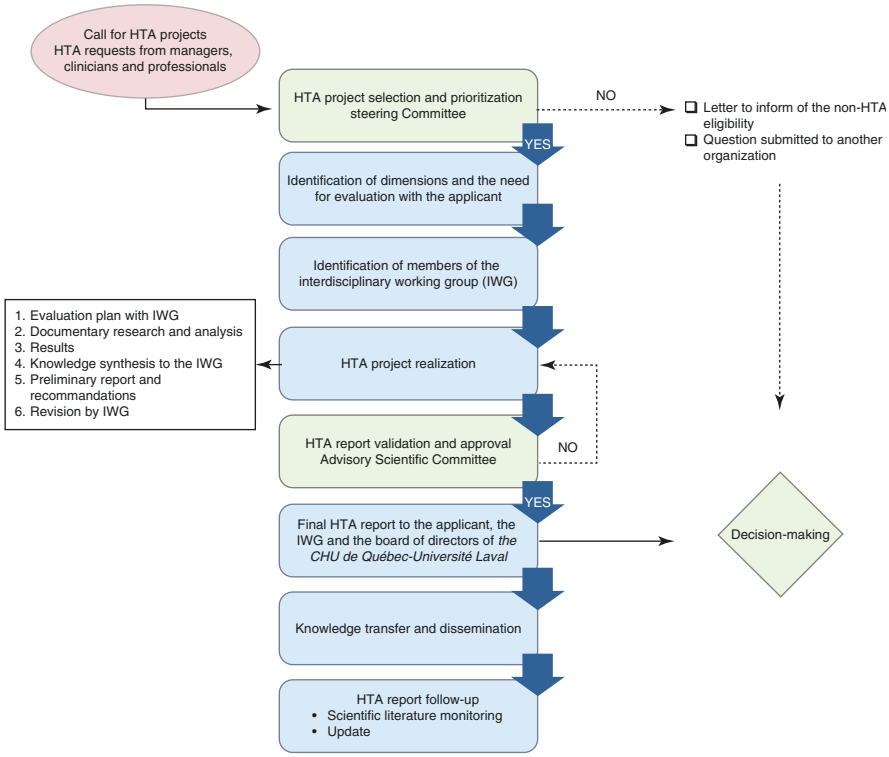


**Fig. 17.1** HTA approach for evidence-based decision-making

or practice to be assessed, the targeted patients, the anticipated advantages and disadvantages of the technology or practice, the impacts on the patients and the organization, the reasons for conducting an assessment, and the deadline of the decision-making process. Prioritization criteria are mainly based on this information. Following an exploratory literature search and first step of go/no-go selection by the HTA Unit leaders, the eligible HTA projects are submitted for prioritization by the Steering Committee which leads to the planning of annual HTA work program.

A new HTA project involves at first the identification of the main issues and needs through discussion with the applicant. A specific interdisciplinary working group (IWG) is then created for each HTA project. The IWG brings together health professionals and managers with various interests regarding the evaluation issues in order to minimize biases associated with intellectual conflicts of interest. The members are involved from the beginning and throughout the HTA process. They contribute to decisional and evaluation question refinement, highlight relevant literature and issues to assess, proposal approval, validate the knowledge synthesis and recommendations, and finally review the HTA report.

A preliminary assessment plan using a predefined template is prepared based on the information from the applicant and the exploratory literature review.

From a simultaneous engineering approach, members of the IWG are invited to improve this preliminary evaluation plan in the context of a first meeting. This approach aims to properly identify the needs while limiting the number of changes in subsequent steps of the evaluation project. The decisional and evaluation questions are reworked in a PICO framework including the definition of the population of interest (P), the intervention (I), the comparator (C), and the outcomes (O). The effectiveness (efficacy) and safety are the main issues to be first considered in the assessment of the health technology or clinical practice. However, to allow a critical judgment on the relevance and applicability of an intervention, information search may extend to additional aspects including budgetary impacts, organizational aspects, as well as ethical, social, and legal issues depending of the HTA context. Furthermore, inclusion and exclusion criteria, study designs to be considered, database sources, and, if appropriate, details concerning methods to collect data on the practice in other institutions are also specified in the plan. The final evaluation plans are posted on the website of the HB-HTA Unit to ensure transparency and rigor in the process.

An advanced search strategy (e.g., descriptors, search dates, filters) is then developed and carried out in multiple databases, including gray literature, for each specific issue to be assessed. Reference lists of eligible studies are also consulted to identify other relevant studies that have not been retrieved with the search strategy. The potential relevant literature is first filtered according to the eligibility criteria based on the title, abstract, and, if necessary, the article's original text. A predetermined hierarchical order taking into account study design and validity of findings is used to prioritize data according to the level of evidence:

I. HTA reports, systematic reviews (SRs) with or without meta-analysis, and evidence-based clinical practice guidelines (CPGs)
II. Randomized controlled trials
III. Observational studies
IV. Case series and case studies
V. Laboratory studies
VI. Expert consensus

Article selection, quality assessment, and data extraction are performed independently by two reviewers. Discrepancies are resolved by discussion with a third reviewer (HTA Unit's medical director) to reach consensus. Methodological quality assessment of SRs and CPGs are performed using validated (e.g., AMSTAR, AGREE) or adapted checklists [5]. Data extraction is performed using a project-specific grid. Additional data are collected on the specific context and local practices at the *CHU de Québec–Université Laval* and, if relevant, from other hospitals in the Province of Québec, in Canada, or elsewhere. Sources of information include written documents such as procedures, instructions or practice guidelines, and survey by questionnaire or interview.

A critical appraisal of all available data on efficacy, safety, security, or other issues is prepared by the HB-HTA Unit team. This knowledge synthesis is shared with the IWG at the occasion of a second meeting to make adjustments to the findings that emerge from the critical review of the evidence and consider their adaptation to the local context of the organization. A preliminary report and the interim recommendations are then developed by the HB-HTA Unit. Members of the IWG are not involved at this point in the development of recommendations in order to limit potential conflict of interest in the HTA process. Members of IWG are invited to review the draft report and to attend a third meeting to discuss the relevance and applicability of the draft recommendations, to propose adjustments or changes, and, finally, to endorse the draft recommendations. In some cases, input from external experts can be sought in the HTA process.

The draft HTA report is reviewed by the Advisory Scientific Committee members and then submitted to a final approval process at the occasion of a meeting. Following the approval of the HTA reports, a project-specific knowledge transfer strategy is carried out and may include both stakeholders from the *CHU de Québec–Université Laval* (e.g., IWG, committees of the board of directors, internal committees) and external partners. All HTA reports are sent to targeted clinical leaders and managers in the facility and available on the website of the HB-HTA Unit. Summaries are published in internal newsletters, provincial HTA newsletter, and, when applicable, reports are submitted to scientific journals and national and international meetings.

### *17.3.2 Summary of HTA Activities at the* CHU de Québec–Université Laval

Between 2007 and 2014, the annual number of reports produced by the HB-HTA Unit increased from 5 to 12 for a total of 54 reports. Over the years, 36 of the 54 reports on various topics included recommendations [5]. Examples of the impact of HTA reports are shown in Table 17.4. In some cases, existing practices were discontinued or modified considering the lack of scientific evidence supporting their effectiveness. In other cases, the introduction of new health technologies was either not allowed or conditional. Several positive benefits associated with the HB-HTA process are observed at the local level including the development of an evaluation culture in the organization and an impact on quality of care. Although the economic impact of HTA reports has not been systematically evaluated, there is some evidence regarding the influence on the organization of care. For instance, the assessment of the microbiological risk associated with multiple-dose injection of contrast media in CT scan [2] and alternatives to seclusion and restraint in healthcare facilities [1] led to annual savings of $ 300,000 and $ 1,000,000 CAD, respectively.

**Table 17.4** Impact of the HTA reports in the *CHU de Québec–Université Laval*

| Topic | Year | Initial applicant | Conclusion | Status |
|---|---|---|---|---|
| Introduction of health technology | | | | |
| Probiotics in prevention/treatment of AAD/CDAD in adults | 2010 | Council of physicians, dentists, and pharmacists | Insufficient evidence | No introduction |
| PET-CT in radiotherapy planning | 2011 | Radiation oncologists | *Esophagus, rectum, cervix* insufficient evidence | No introduction |
| | | | *Lung (NSCLC), head, and neck* limited evidence | Use in the context of a field evaluation |
| Filtered needles to prevent IV glass particles contamination | 2012 | Nursing department | No clear benefit compared with 21G regular needles | No introduction |
| Levodopa-carbidopa intestinal gel in advanced PD | 2014 | Executive office of intensive care, trauma, and neurosciences | Low level of evidence suggest that levodopa-carbidopa intestinal gel could be an effective therapeutic intervention in advanced PD | Conditional introduction |
| Reappraisal of current practice | | | | |
| Microbiological risk with multiple-dose injection of contrast media in CT scan | 2007 | Quality and risk management committee | Reinforce rules of asepsis | Continued |
| | | | Maintain multidose contrast media | |
| | | | Maintain replacement schedule | |
| | | | Stop multiple withdrawals and punctures from contrast media containers | |
| MRI-guided cryotherapy for facet joint treatment in lower back pain | 2008 | Orthopedic surgeon | Insufficient evidence | Withdrawal |
| Bowel preparation in radical cystectomy | 2012 | Uro-oncologists | Strong evidence of no benefit to prevent infections | Withdrawal |
| ICU postoperative management and obstructive sleep apnea | 2013 | Executive office – intensive care and emergency | No clear benefit for routine postoperative monitoring in an ICU for patients with obstructive sleep apnea | Withdrawal and protocol development |

*AAD* antibiotic-associated diarrhea, *CDAD Clostridium difficile*-associated diarrhea, *PET* positron emission tomography, *CT* computed tomography, *NSCLC* non-small cell lung carcinoma, *PD* Parkinson's disease, *MRI* magnetic resonance imaging, *ICU* intensive care unit, *IV* intravenous

In contexts where decisional questions are complex and empirical data lacking, the HB-HTA Unit participation in research projects on patient involvement in the HTA process led to several findings. Taking into account patient perspectives can be critical to support decisional processes both in the stages of identification, prioritization, and development of the evaluation plan and throughout the HTA process. The involvement of the public and patients appears to be an effective approach to improve search relevance, enhance the value of scientific works without compromising rigor, facilitate the implementation of innovations, and increase the external validity of results. In the perspective of implementing best practices in HB-HTA, the process should as much as possible ensure adapting the methodology to take into account the patients' perspectives [3].

The usefulness of HB-HTA recommendations for decision-making and the level of satisfaction of past contributors, administrative and clinical leaders, were measured using an online survey conducted in 2014. A total of 47 professionals completed the survey including physicians, health professionals (nurse, pharmacist, nutritionist, and others), staff managers, and senior managers. Overall, a significant proportion of respondents somewhat or strongly agree that the HB-HTA Unit report had answered the IWG needs (89 %) and had been useful to support decision-making (91 %) and that the recommendations had been used to improve clinical practice or healthcare organization (87 %). The strengths identified by respondents include rigor of the process, availability and staff's skills, findings in connection with the clinical context, and the level of involvement of IWG. On the other hand, some areas for improvement were raised: timeliness, follow-up of recommendations, and number of accepted HTA request per year.

### *17.3.3 The Future of the HB-HTA Unit at* CHU de Québec–Université Laval

The success of HTA relies on multiple key principles as reported by Drummond et al. [4] (Table 17.5). Based on our 10-year experience, some of these principles are critical at the local level to insure an optimal HB-HTA process:

- The credibility of the HB-HTA methods in terms of rigor, bias mitigation, transparency, and scientific independence is essential to facilitate adherence to the recommendations.
- The involvement of stakeholders in all steps of the project. This may lead to greater ownership of the HTA report by IWG, including recommendation implementation and knowledge transfer.
- Understanding the local context is crucial to make sure that findings and recommendations are applicable by stakeholders.
- The timely completion of the assessment in order to support the decision-making process.
- The strong support and commitment of the hospital top management in the implementation of the HTA Unit recommendations and the related change management.

**Table 17.5** Key principles of HB-HTA

| |
|---|
| Structure of HTA programs |
| Goal and scope of the HTA should be explicit and relevant to its use |
| Unbiased and transparent process |
| Include all relevant technologies |
| Clear system for setting priorities for HTA should exist |
| Methods of HTA |
| Should incorporate appropriate methods for assessing costs and benefits |
| Should consider a wide range of evidence and outcomes |
| A full societal perspective should be considered |
| Should explicitly characterize uncertainty surrounding estimates |
| Should consider and address issues of generalizability and transferability |
| Processes for conduct of HTA |
| Should actively engage all key stakeholder groups |
| Should actively seek all available data |
| Implementation of HTA findings needs to be monitored |
| Use of HTA in decision-making |
| Should be timely |
| Findings need to be actively communicated appropriately to different decision-makers |
| Link between HTA findings and decision-making processes needs to be transparent and clearly defined |

Adapted from Drummond et al. [4]

Nowadays, an important and emerging concern in the use of HB-HTA is its close relationship with the challenge of care pertinence and the related evidence-based disinvestment process. Health technologies or medical practices that have been identified, following an HTA process, as offering little value to the patients should be disinvested in order to reduce overdiagnosis and overtreatment and to contribute to quality, safety, and cost control. Greater involvement of HB-HTA at the *CHU de Québec–Université Laval* is expected in the future to identify and assess technologies and practices that provide little or no health benefits. Despite budget cuts, better allocation of resources enabling reinvestment in evidence-based technologies and practices seems to be a major lever in building development capabilities at the local level. Another significant challenge for our HB-HTA Unit will be to develop, when relevant, a systematic approach to carry out field evaluation with evidence development after classic assessment. Using a primary data collection in actual practice conditions is aimed to complete knowledge synthesis carried out in the context of an HTA and contribute to reduce the remaining uncertainties after a HTA process [6]. It would also define the conditions and implementation strategies to optimize the implementation of new technology in a given environment.

In conclusion, our experience in HB-HTA demonstrates the usefulness and positive impacts of HTA produced at the local level to support decision-making. The challenge of care pertinence improvement that health systems and hospitals are facing now and for years to come calls for an enhancement of HB-HTA activities.

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# Chapter 18
# The Penn Medicine Center for Evidence-Based Practice: Supporting the Quality, Safety, and Value of Patient Care Through Evidence-Based Practice at the Systems Level (USA)

**Craig A. Umscheid, Matthew D. Mitchell, Brian F. Leas, Julia G. Lavenberg, Kendal Williams, and Patrick J. Brennan**

## 18.1 Introduction

Hospital evidence-based practice centers (EPCs) are one "structure" with the potential to facilitate the integration of evidence into practice to close "knowing-doing" gaps [1, 2]. In the process, they can support the evolution of their parent institutions into "learning healthcare systems" [1, 3]. The potential of hospital EPCs stems from their ability to identify and adapt national evidence-based guidelines and systematic reviews for the local setting [4], create local evidence-based guidelines in the absence of national guidelines, use local data to help define problems and assess the impact of solutions [5], and implement evidence into practice through information technology (IT) and other quality improvement (QI) initiatives [1, 6]. As such, hospital EPCs have the potential to foster a culture of evidence-based practice at their local institutions and improve the quality, safety, and value of care provided to patients and their families [1, 6].

Formal hospital EPCs remain uncommon in the USA [1, 6–8]. Their numbers have expanded worldwide [9, 10], however, even as national evidence-based practice centers, such as the National Institute for Health and Clinical Excellence (NICE) [11] in the United Kingdom (UK) and the network of 13 EPCs funded by the Agency

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for Healthcare Research and Quality (AHRQ) [12, 13] in the USA, remain vital resources [1]. The growth of hospital EPCs is fueled by the heightened awareness that the value of healthcare interventions often needs to be assessed locally and that clinical guidelines have a greater potential to improve quality and efficiency when they are locally developed [1, 14].

In the USA, integrated health systems and managed care organizations such as Kaiser Permanente have clear incentives to establish hospital EPCs. In these environments, cost-effective care results in obvious savings for the organization [8]. Incentives are also aligned for other hospital types to establish EPCs, since most payers reimburse hospitals using prospective payment systems based on diagnosis-related groups (DRGs). For example, payers will reimburse a hospital a specific amount for treating a patient with pneumonia, regardless of how much the hospital spends on that patient's care. If the hospital provides cost-effective care, they pocket the savings. If not, they lose money [15]. By supporting evidence-based practice at the organizational level, EPCs can also improve publicly reported metrics and pay for performance, potentially resulting in greater market share for the hospital and higher reimbursements, especially with the recent push by payers in the USA toward value-based purchasing [16]. Hospital EPCs that disseminate evidence through computerized clinical decision support (CDS) can also help their organizations meet certification criteria for "meaningful use" of their electronic health records, resulting in further reimbursement increases [6, 17]. Hospital administrators can use hospital EPCs to maximize the value generated from each dollar they spend, which is especially important as the costs of providing care rise in the face of decreasing reimbursements, such as those resulting from healthcare reform in the USA [6, 18].

Despite the potential economic benefits, many US hospitals do not have formal EPCs. Instead, many rely on outsourced or less formal evaluations to inform a relatively narrow set of decisions regarding formularies, technology procurement, and large capital purchases. In many cases, evidence synthesis is the work of individuals or committees who may not have the expertise to appraise or synthesize scientific evidence adequately and may be at risk for conflicts of interest. This is especially the case when evidence synthesis is performed at the level of a clinical department, rather than a hospital, where evaluations may be too narrow in scope and biased toward interventions performed by the department. Such individuals and committees often rely on financial analyses as well as political clout to help them make decisions [6, 19, 20].

In 2006 the University of Pennsylvania Health System (UPHS) created a Center for Evidence-based Practice (CEP) to support the objective integration of evidence into institutional decision-making to strengthen the quality, safety, and value of care provided [1, 6]. In this chapter, we describe the first 9 years of CEP's activities (July 2006 to June 2015), examine its impact on decision-making across the health system, and consider lessons learned and future directions.

**Box 1: Health Care System Context**

- The healthcare system in the USA is insurance based. While the majority of Americans have private insurance, the federal government funds insurance for the elderly, and the federal and state governments fund insurance for adults and children in families with annual incomes below specified thresholds. The federal government also funds the Department of Veterans Affairs, which operates the nation's largest integrated healthcare system, and administers benefits for veterans and their families.
- The majority of hospitals in the USA are nonprofit, but some are for profit. Most funding for hospitals comes from the revenue they generate by providing care to patients. Most payments to hospitals come from insurers. Some hospitals also receive federal, state, and/or county/city funds.
- Hospitals and clinicians are responsible for making decisions about the drugs, devices, and capital equipment they use. These decisions need to be consistent with policies from city/county and state regulators, as well as national regulators such as the Joint Commission and the Federal Government.

## 18.2 Setting

At the time our center was established, UPHS included three acute care hospitals in Philadelphia as well as facilities specializing in skilled nursing, acute rehabilitation, long term acute care and hospice. These facilities invested UPHS with a capacity of more than 1,800 beds and 75,000 annual admissions, in addition to the primary care and specialty clinics serving more than two million annual outpatient visits. In the past year, UPHS has acquired two acute care hospitals in suburban counties, adding 875 beds to the health system. CEP is organized within the Office of the UPHS Chief Medical Officer, serves all UPHS facilities, and has an annual budget of approximately $1 million. Currently, CEP is staffed by a hospitalist director trained in epidemiology, three full-time research analysts, six physician and nurse liaisons who practice at the three Philadelphia hospitals, a health economist, biostatistician, administrator, and librarians, totaling 5.5 full time equivalents.

## 18.3 Mission

The mission of CEP is to support the quality, safety, and value of patient care at Penn through evidence-based practice [1]. To accomplish this mission, CEP performs rapid systematic reviews of the scientific literature to inform local practice and policy, translates evidence into practice through the use of computerized CDS

and clinical pathways, and offers education in evidence-based decision-making to trainees, staff, and faculty [1]. The following sections describe each of these paths to accomplishing our mission.

## 18.4 Rapid Systematic Reviews

CEP has produced over 300 evidence reviews since its inception or about 35 reports annually. Our center has developed and used several different report products to meet our requestors' needs. Over half of reports are "evidence reviews" that consist of a systematic review and analysis of the primary literature. About one third of reports are "evidence advisories" that summarize evidence from secondary sources such as guidelines or systematic reviews. Another report type is the "evidence inventory," which describes the quantity and focus of available evidence, without synthesis or analysis [21]. This report type often serves to help end users decide whether a full review on a particular topic would yield useful results and to focus the scope of full reviews that are commissioned. More recently, we have developed an "annotated bibliography" to provide an annotated list of pathways or policy papers for reports focused on developing care pathways or policy position reports, respectively.

Approximately half of our reviews have examined drugs, devices, equipment, or supplies, while the other half have focused on technology categories not traditionally evaluated by healthcare technology assessment (HTA) organizations, such as processes of care, systems of care, and medical/surgical procedures [1, 22]. The most common clinical specialties addressed by CEP reports include nursing, general surgery, critical care, and general medicine [1]. Clinical departments are the most common requestors of reviews, but chief medical officers from our various entities, as well as purchasing, formulary and quality committees, and increasingly nursing administrators, are also frequent requestors [1]. Interestingly, the proportion of requests from clinical departments has significantly increased in the second half of our center's history compared to the first half, with requests from purchasing committees proportionally decreasing.

The overall report completion time, defined as the time between the date work began on a report and the date a final report was sent to the requestor, is approximately 2.5 months [1]. It has decreased from approximately 3 months in the first half of our center's history to 2 months over the last 4 years [1]. About 15 % of reports include meta-analyses conducted by CEP staff, reflecting the amount and type of evidence available for questions posed to our center, as well as our use of secondary resources to synthesize evidence for decision-making [1].

Reports are disseminated in a variety of ways beyond direct dissemination and presentation to requestors and posting to our center's website. Over 10 % of reports have informed computerized CDS interventions or clinical care pathways (a higher percentage in the last year), about 10 % have resulted in peer-reviewed publications [23–27], and over 80 % have been listed in the Centre for Reviews and Dissemination HTA database at the University of York [1, 28, 29].

### 18.4.1 Impact

To determine the impact of our reports on health system decision-making, we recently conducted a web-based survey of all requestors of the 139 rapid reviews completed in the last four fiscal years of our center's activity (between July 2010 and June 2014) [1]. The 44-item questionnaire collected data on the interaction between the requestor and CEP, report characteristics, report impact, and requestor satisfaction. Seventy-two percent of eligible participants responded. In general, respondents found reports easy to request, easy to use, timely, and relevant, resulting in high requestor satisfaction. In addition, most described the scope of content and the level of detail as "about right." Report impact was rated highly as well, with the "evidence summary" and "conclusions" rated as the most critical to decision-making. Most respondents indicated that reports were consistent with their tentative decision, while fewer suggested that the report changed their tentative decision, and others suggested the report had no effect. The amount of time that elapsed between requestors receiving reports and making final decisions was less than 3 months for most. The most common reasons cited for requesting a report were CEP's evidence synthesis skills and objectivity.

### 18.4.2 Extramural Reviews

Although most of the evidence reviews conducted by our center are for requestors at UPHS, we have contributed to the larger scientific body of knowledge through work performed for organizations outside of UPHS, including the US Centers for Disease Control and Prevention (CDC) and the Agency for Healthcare Research and Quality (AHRQ). This research has addressed topics of interest to UPHS, such as defining best practices in oncology and transplant medicine [30] and preventing healthcare-acquired infections [31]. Our extramural activities began in 2007, when our center collaborated with the CDC to update their guideline development methodology [32]. Since then, we have coauthored multiple infection control guidelines with the CDC [33, 34]. In 2012, we leveraged this experience as well as our previous collaborations with the ECRI Institute, a not-for-profit evidence synthesis organization headquartered in Plymouth Meeting, PA, to win 1 of the 11 AHRQ EPC program contracts. This award allows us to bid on contracts to synthesize evidence to inform national policy in the USA, including practice guidelines and payer coverage decisions. To date, this designation has allowed us to complete ten comparative effectiveness reviews involving 19 faculties at Penn across seven departments, as well as seven divisions within the Department of Medicine. In addition, the contract has given us the opportunity to inform systematic review methods of relevance to healthcare provider organizations, including methods for the development of rapid evidence reviews [35, 36] and methods to help identify the active ingredient(s) in multicomponent healthcare interventions [37].

## 18.5 Clinical Decision Support and Clinical Pathways

When evidence reviews inform decisions about purchasing devices or changing drug formularies, integrating their results into practice is often straightforward. The reviews can be presented to the relevant device purchasing and formulary committees to inform their decisions. However, when reviews involve defining best clinical practices, implementation is much more complex, often requiring the use of more sophisticated dissemination strategies, including the use of computerized CDS tools.

Our center's first experience developing a CDS tool was in response to a pay-for-performance policy between UPHS and a local payer, and involved the development of a system to ensure all patients were assessed for venous thromboembolism (VTE) prophylaxis. An initial step in that process was adapting national guidelines on VTE prophylaxis to our local setting and was the beginning of our center's involvement in the initiative. But it quickly became clear that for such guidance to ultimately impact patient care, a system needed to be developed to ensure use of the guidance. Given this need, our center worked closely with colleagues with expertise in VTE, QI, informatics, and nursing, and ultimately developed a computerized CDS tool that significantly increased the use of VTE prophylaxis throughout the entire health system [38].

That experience, along with other early successes, resulted in the creation of a formal CDS committee in 2010 with the goal of facilitating clinical decision-making consistent with safe, high-quality, and high value care. To accomplish this goal, the committee evaluates and prioritizes new CDS proposals, develops and deploys CDS interventions, and catalogues and evaluates the impact of implemented interventions. The members of the committee include physician, nurse, advanced practitioner, and pharmacy and regulatory representatives from the various health system entities, as well as informatics staff, a data analyst, and a CDS officer to oversee the program. Proposals are prioritized if they address a quality or safety issue relevant to the health system's stated quality strategy, are of general importance to all entities across the health system, and are amenable to a CDS solution. To date, over 30 evidence reports performed by CEP have informed approximately 25 computerized CDS interventions, including interventions targeting venous thromboembolism prophylaxis [38], albumin utilization, urinary catheter management [39], delirium management, red blood cell transfusions [40], vaccine assessments, hospital readmissions [41], severe sepsis [42, 43], ordering of venous access devices, *Clostridium difficile* testing, and selection of target-specific oral anticoagulants.

With the growth of our health system over the past year and the increasing use of bundled payments for episodes of care across the care continuum, there has been greater interest by clinical and administrative leaders in developing agreed-upon clinical care pathways that providers can use to ensure that unnecessary variation in care is reduced and that patients receive the highest quality care regardless of what entity or provider they use at UPHS. Care pathways are often defined as structured multidisciplinary plans of care that translate evidence into local workflows; detail the steps of care in a pathway, algorithm, protocol, or other "inventory of actions"; have a time frame or criteria-based progression (e.g., steps taken if designated criteria are met); and are aimed to standardize care for a specific clinical problem,

procedure, or episode of healthcare in a specific population [44]. Evidence suggests that pathways can improve not only process metrics but also clinical outcomes of importance to patients [45].

Beginning in February 2015, our center took the lead role in consolidating pathways already in routine use across UPHS and posted them on a central website to allow for regular use and maintenance. Most of the pathways are locally developed, but some are pathways from national guidelines that are commonly used in our health system. The website also informs a mobile application, which is available to all UPHS faculty, staff, and trainees. To date, over 60 pathways have been posted to the site. We have just started evaluating how often individual pathways are used, as well as their mode of use (i.e., via website or mobile app).

In addition to hosting, disseminating, and maintaining pathways already in use, our center has begun to collaborate with clinical and administrative leaders to develop pathways to address high-priority clinical issues. Although our center has informally spearheaded such efforts in the past, such as a pathway used by interventional radiology and gastroenterology to make decisions about the care of patients admitted with acute gastrointestinal bleeds, the current efforts are more formal, proactive, and driven by health system strategy and include a review of existing published and unpublished pathways, the development of draft pathways to be reviewed and refined by clinical stakeholders throughout UPHS, the scheduling of initial meetings of key stakeholders to review pathways, and the use of specialized software to facilitate asynchronous review and refinement of pathways by stakeholders. Pathways recently finalized through such efforts include a pathway to assist in the diagnosis of catheter-associated urinary tract infections in those with indwelling urinary catheters and a management pathway for interventional radiology and pulmonology for patients presenting with massive hemoptysis.

Our center has also supported evidence-based resources important to the care of patients but often beyond the budget of our biomedical library. Such resources have included UpToDate (an electronic evidence summary resource covering over 20 specialties), InfoPOEMs (a service that provides daily synopses of the most clinically significant and robust studies in the area of primary care), and VisualDX (a differential diagnosis generator that can help providers diagnose the causes of skin findings and includes over 1,300 diseases with more than 28,000 associated images) [46]. Anecdotally, faculty, trainees, and staff have consistently provided positive feedback about the availability of these evidence resources.

## 18.6 Teaching

A critical element in accomplishing our mission has been the education of trainees, staff, and faculty in evidence-based practice and evidence-based quality improvement. From early in our center's development, we have had the opportunity to lecture and facilitate small group discussions in medical student courses in clinical epidemiology and health policy, as well as direct the clinical decision-making

curriculum. Over the years, we have transformed the medical student clinical decision-making curriculum into a course in evidence-based practice. Specific innovations have included: (1) changing the setting in which students practice critical appraisal of the medical literature from sessions during the decision-making course to sessions that occur throughout their second and third semester preclinical pathophysiology blocks, (2) changing the timing of the decision-making course itself to just before the start of the students' clinical clerkships, (3) developing new discussion sessions in the EBM course emphasizing skills for searching the medical literature and appraising clinical guidelines, and (4) building a new EBM component into the clinical clerkships, such that students can address clinical questions at the point of care and see the impact of evidence-based practice on the care of their patients in real time [47].

Unexpectedly, one of the greatest challenges of modifying the evidence-based practice education from one based in the preclinical years to one based in the clinical years is the limited ability of house staff and faculty to role model and mentor students in evidence-based practice skills. To address these challenges, our center has offered didactics and workshops in various house staff educational programs, such as the Healthcare Systems Leadership and Quality Improvement residency track [48] at our institution. In the last 2 years, we have also created a faculty development program in evidence-based practice for our hospital medicine faculty, who are responsible for house staff and medical student education on the general medicine services across our health system. This program is a monthly meeting where a hospitalist faculty member will briefly present a case, define a clinical question arising from the case that needs to be addressed, discuss how they searched for the answer, appraise the findings from the paper(s) of most relevance, and apply the findings to the case at hand. A similar EBP educational program for advanced practice providers has been developed over the last year. In addition, our center leads a critical appraisal of the medical literature course that is offered as part of a research certificate from our medical school. Students in the course are most often clinical staff in our health system or instructors or junior faculty at the medical school.

In an effort to help our institution and others build capacity for leveraging evidence to improve care, our center has helped develop multidisciplinary workshops that teach clinical leaders the concepts and skills necessary to strengthen evidence-based decision-making at the systems level. These workshops are unique in that they include not only physicians but also nurses, administrators, and librarians and are not only focused on critical appraisal but are more generally focused on addressing clinical problems in need of solutions, searching for and appraising the literature to help address these clinical problems and adapting identified evidence for use in the local setting. The best examples of these evidence-based quality improvement workshops are those offered annually through the New York Academy of Medicine's Teaching Evidence Assimilation for Collaborative Healthcare (TEACH) conference in New York City, USA [49] and the Annual Workshop on Evidence-Based Clinical Practice in Rio de Janeiro, Brazil. To date, 30 of our most promising clinical nurse specialists at UPHS have participated in the TEACH course and have gone on to lead evidence-based QI initiatives on their

local units and across our health system. These alumni have also developed a UPHS EBP Leadership Council that meets monthly, includes leadership of the nursing evidence-based practice and policy committees from across UPHS, and helps address topics of interest to all entities.

Lastly, our center leads a course in systematic reviews and meta-analyses for our graduate students locally, teaches on related topics in other graduate student courses, and provides training in similar topics for national and international audiences.

## 18.7 Lessons Learned

One of the most important contributors to our success has been the support of high-level clinical leadership. In our case, the Chief Medical Officer of our health system had the vision and was the driving force behind our center and has encouraged stakeholders from across UPHS to access our center as a resource. This has allowed us to demonstrate the strength and utility of our center, particularly in our early development [6].

A hospital evidence-based practice center also needs to identify and build genuine relationships and trust with the multiple leaders making clinical decisions and policy across a hospital system. The results of our recent survey support this, as over half cited our objectivity as a reason for accessing our services, underscoring the value of an independent source of answers in an environment where clinical departments and hospital committees can have competing interests. As diverse stakeholders begin to realize a return on investment from the center's activities, the unit can attract further resources to assist in performing rapid reviews and integrate more closely with QI and IT staff to implement reviews of clinical practice and measure their impact [6].

Evidence syntheses must be timely to allow hospital decision-makers to act on the findings [50]. The use of rapid reviews, designed to inform urgent decisions, can help overcome this challenge. Our center reviews require approximately 2 months to complete on average, consistent with the most rapid timelines reported for reviews [51, 52], and much shorter than standard systematic review timelines, which can take up to 12–24 months [52]. Working with requestors to limit the scope of reports to those issues most critical to a decision, using existing reviews when available, and hiring experienced and talented research analysts all help to achieve this balance.

The most apparent trend in the production of our reviews over time has been the relative increase in requests by clinical departments and nursing leadership, suggesting that our center is being increasingly consulted to help define best clinical practices at the service line, unit, or clinic level. This is also supported by the relative increase in reports focused on processes of care, systems of care, and medical/surgical procedures. These findings suggest that hospital EPCs have value even beyond the traditional realm of HTA, which has often focused on drugs, biologics, and devices.

Evidence-based decision-making can be viewed as a threat to innovation, particularly innovations perceived to help medical centers retain or enhance market share. Similarly, providers not educated in evidence evaluation may be resistant to processes informed by evidence. By involving key stakeholders in the scoping and review of reports and informing decision-making in a fair and consultative manner, these negative impressions can be overcome. Moreover, it is important to acknowledge explicitly that evidence-based decisions are not only informed by evidence but are also informed by resource and value considerations, such as how important a particular technology might be to a given market or the outcomes of most interest to patients [6].

Our work has also allowed us to bridge academic and operational leaders from across UPHS, who may be working on local problems and not realize that such problems are of importance to colleagues in similar positions throughout the organization. Our clinician liaisons play a particularly important role here. Operational leaders might also not recognize the local academic expertise that exists on relevant topics. Bridging these diverse operational and academic leaders on evidence syntheses, CDS interventions and clinical pathways has been an important yet unexpected value of our activities.

Identifying and involving the right stakeholders throughout our institution not only reduces redundancies and builds critical mass around institutional initiatives but also greatly increases the buy-in of clinical experts and leaders, the use of our products, and ultimately is a key to successful implementation [14]. Regardless of whether our evidence syntheses yield findings that are novel or dramatically different than what already exists in the clinical literature, the very process of working with a requestor to define the problem, identify other key stakeholders across the institution, and review a synthesis of the existing evidence can result in important practice change.

Lastly, it can be challenging to consider costs when published cost analyses are not available or are not conducted from the hospital perspective. However, when critical to a decision, such analyses can be performed locally and populated with hospital-specific cost data, but it takes significant time to do this work well, so we rarely include cost analyses in our reports. We have also found that there is often an assumption that evidence-based practice will lower costs, because it will expose the weak evidence base underlying new high-priced technologies. In our experience, policymakers are often surprised to find that there can be reasonable levels of evidence underlying new technologies, particularly when those technologies are being used in the treatment of conditions with high morbidity or mortality, like septic shock. They then discover that they have asked for an evidence review because they believe it will support their denial of a new technology, and instead it demonstrates its value. And even when a new technology results in cost savings for the institution, the costs may be borne by one department, while the savings are experienced by another. This can make it difficult to convince local policymakers that a given technology offers good value or savings. To address such challenges, strategies from the corporate side of our organization to reimburse the costs that individual departments incur to realize savings for the institution as a whole can be helpful [6].

## 18.8 Future Directions

One potential limitation of the hospital EPC model is the redundancies or inefficiencies that may result from the independent activities of multiple local centers as compared to a national EPC [6]. Yet, the local nature of this model is also its greatest strength, for it allows centers to address local priorities, take local considerations into account, and use local evidence when gaps in the scientific literature exist [6]. In addition, local centers can complement and strengthen the activities of a national center by providing expertise to adapt, implement, and measure the impact of national guidelines and evidence reviews locally [6, 53]. Moreover, when evidence syntheses from national bodies are not available, hospital EPCs can create evidence syntheses to address their own local questions and list these reports on a nationally coordinated site for others to adapt and implement [6]. Although a centralized clearinghouse for these reports does not exist to our knowledge, we have listed most of our evidence syntheses in a searchable database on our public website, as well as in an international database of HTA reports [28, 29]. We believe there would be tremendous value in the broader use of this database as a "rapid review clearinghouse," similar to how the US government-supported National Guideline Clearinghouse currently catalogues and maintains national and international guidelines of interest to clinicians and policymakers.

Another future direction for hospital EPCs is the expanding definition of "evidence" in this era of "big data." With larger healthcare systems on fully functioning electronic health records for longer periods of time, more local electronic data is available to inform local decisions. Such data is already being leveraged by newly established data science teams and innovation centers within healthcare organizations, to develop prediction rules to identify and prevent healthcare-acquired conditions [42]. How and when such data should be used by local EPCs to inform institutional decision-making is not yet clear.

Advances in rapid review methods and software may also further facilitate the rapid production of systematic reviews. For example, the tool Abstrackr [54] has the potential to expedite title and abstract screening through the use of machine learning algorithms, which can leverage the screening decisions of a trained analyst to predict which titles and abstracts have the greatest probability of meeting inclusion criteria.

The most important limitation of our description and evaluation of our hospital EPC is that our institution may not be representative of the diversity of hospitals and hospital staff across the USA and especially internationally. However, our EPC serves a diverse array of patient populations, clinical services, and service models throughout our multi-entity academic healthcare system, which may improve the generalizability of our experience to other settings.

As next steps, we recommend comparisons with other existing hospital EPCs in the USA [6]. Such evaluations could help hospitals and health systems ascertain which of their internal decisions might benefit from locally sourced rapid systematic reviews and determine whether an in-house EPC could improve the value of care delivered [6]. If these centers prove effective, then start-up and maintenance of these local activities could be supported by incentives from national payers like Medicare and accreditors like the Joint Commission, as well as the local value they create at their own institutions [6].

## 18.9 Conclusion

Our experience suggests that hospital EPCs within academic healthcare systems can efficiently synthesize, disseminate, and implement evidence for a variety of stakeholders; build capacity for the further development, use, and implementation of such evidence; and foster a culture of evidence-based practice. Moreover, our experience suggests that evidence syntheses and dissemination tools impact decision-making in a variety of hospital contexts and clinical specialties. Hospital system leaders seeking to improve the implementation of evidence-based practice at an organizational level might consider establishing such infrastructure locally.

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# Chapter 19
# Medical Technology Assessment at Kaiser Permanente: History and Description of Approach (USA)

**Robin Cisneros, Sandra Arthurs, and Jo Carol Hiatt**

## 19.1 US Historical Context

In the USA, no single, comprehensive system exists to evaluate the evidence for medical technologies or to make unilateral, binding decisions about their deployment and use. Before any medical device or therapeutic agent can be marketed, the US Food and Drug Administration (FDA) must approve the product for sale. The FDA is responsible for assuring basic safety and efficacy, but does not consider comparative clinical or cost effectiveness [1]. Public and private organizations have conducted technology assessment for decades, but their work varies in design, scope, rigor, and how widely it is adopted. No structure exists to enable the efficient use of limited analytical resources and coordination of timely, updated assessments. Notwithstanding the above, the USA does produce many high quality assessments. Increasingly, assessments are published for public use, but private payers, hospitals, nonprofit health systems, and physicians often must conduct their own reviews to meet the specific needs of their organizations. Several publications describe the history and evolution of medical technology assessment in the USA [2, 3, 4].

As reported by Umscheid and Brennan [5], hospital-based technology assessment is a far less familiar concept in the USA than in the rest of the world. Historically, health plans have made nearly all decisions about reimbursement for medical procedures, treatments, and technologies. Most physicians contract with multiple health plans which frequently vary in their coverage of new technologies [6]. Reimbursement ("coverage" by health plans), market demand, and physician preferences are the primary drivers of hospital-level technology decisions. Fee-for-

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service physicians often choose to practice in hospitals that make the desired products and equipment available. Indeed, physicians often dictate what is available, because hospitals that are not part of a larger health system generally cannot afford to alienate any medical staff. This environment has not been conducive to hospital-wide, evidence-based decision-making about the adoption and use of medical technology.

Umscheid and Brennan [5] noted that integrated US health systems such as Kaiser Permanente (KP) may have the most to gain from system-wide hospital-based technology assessment to achieve economies of scale and consistent decision-making regarding coverage and service delivery. This chapter will focus on medical technology assessment (MTA) in Kaiser Permanente and how it addresses the needs of an integrated system.

## 19.2 KP History and Context

Kaiser Permanente is an integrated delivery system providing care in eight states and the District of Columbia. See Figs. 19.1 and 19.2. KP's current medical technology assessment methods developed against a background of 35 years in US healthcare. The discipline of MTA evolved during this same period, as the public and private sectors moved toward encouraging appropriate utilization. MTA has increasingly focused on health outcomes research, the weighing of benefits, harms, and patient preferences; and generally, incorporation of evidence-based medicine.

Kaiser Permanente, founded in 1945, is one of the nation's largest not -for-profit health plans, serving more than 10.7 million members, with headquarters in Oakland, California. Kaiser Permanente's creation resulted from the challenge of providing Americans medical care during the Great Depression and World War II, when most people could not afford to go to a doctor. Innovations KP has brought to U.S. health care include prepaid health plans and integrated delivery system. Physician group practice with salaried compensation allows physicians to focus on preventing illness as much as caring for the sick, and removes incentives for unnecessary interventions.

Kaiser Permanente comprises: Kaiser Foundation Hospitals and their subsidiaries; Kaiser Foundation Health Plan, Inc.; and the Permanente Medical Groups.

**Kaiser Foundation Hospitals (KFH)** A nonprofit, public-benefit corporation that owns and operates community hospitals in California, Oregon, and Hawaii. The corporation owns outpatient facilities in several states; provides or arranges hospital services; and sponsors charitable, educational, and research activities.

**Kaiser Foundation Health Plans (KFHP)** Nonprofit, public-benefit corporations that contract with Kaiser Foundation Hospitals and medical groups to provide services. In our regions that are not hospital-based, they may contract with non-Kaiser hospitals. The Health Plans are the health insurance component of the organization. Each region has its own health plan company.

**Permanente Medical Groups (PMG)** Partnerships or professional corporations of physicians, represented nationally by The Permanente Federation, which contract exclusively with the Kaiser Foundation Health Plans to provide or arrange medical services for members and patients.

**Fig. 19.1** Fast facts about Kaiser Permanente

1. How is your health system funded? (public funding, private funding, insurance-based, out-of-pocket)

   Health care services in the United States are financed primarily by public programs for disabled, elderly and low-income non-elderly people and by Private ("commercial") payers. Individuals and employers pay insurance premiums on behalf of their employees. A growing share of funding comes from out of pocket payments at the point of service. About 70% of Kaiser Permanente's 10.7 million members are covered through employers.

2. How are hospitals funded within the health care system of your country?

   Community hospitals in the United State are generally paid on a per stay (DRG) or per diem basis. As part of a fully capitated health system, Kaiser Permanente's hospitals are budgeted from our total revenues from public programs and private insurance premiums.

3. Who is responsible for making decisions about which drugs, devices, and capital equipment will be funded for the hospital? (i.e., government, hospitals, networks of hospitals)

   At KP physicians are responsible for medical decisions. The Permanente Medical Groups, which provide care for KP members, drive decisions about what medical products and technology KP will use, considering the Federal Drug Administration (FDA) position on safety and efficacy, the available published clinical evidence, and other contract and regulatory considerations. Kaiser Foundation Health Plan and Hospitals make decisions about capital spending with considerable consultation with its Permanente Medical Groups.

**Fig. 19.2** USA and KP Context

Currently, KP's more than 18,000 physicians and 51,000 nurses caring for over 10.7 million KP members share a strong, evidence-based culture.

Throughout the 1980s, KP's MTA activity focused on large capital investments and consideration of new technology deployment. Historical utilization, equipment throughput and capacity, service and maintenance, clinician requests for new technology, and other operational considerations drove forecasts for equipment demand. Serious and more consistent study of "appropriate utilization" began in the early 1990s, heralding an important evolution toward KP's current MTA methods.

KP established the Interregional New Technologies Committee (INTC) in the early 1980s as a nationally coordinated means to provide each KP geographic region and individual Permanente physicians with an objective evaluation of the state of the evidence on select new medical technologies [7]. The INTC compares the safety, efficacy, and effectiveness of the medical technology with current alternative(s). The INTC is led by a physician and includes members (mostly physicians), from each KP region as well as experts in other disciplines from its corporate offices [8]. Regional physician leaders select the physicians to represent them, often selecting physicians with responsibility for new medical technology decisions or experience applying evidence-based methods. KP funds the INTC meeting, staff, and resources internally.

The INTC's scope now includes a wide range of technologies: medical devices and therapies, diagnostic tests, and surgical procedures. KP's Pharmacy and Therapeutics Committee and specialized Biotechnology and Emerging Pharmaceutical Technology Assessment Committee (BEPTAC) assess pharmaceuticals and biologics and are beyond the scope of this chapter.

KP's Southern California region recruited Dr. David M. Eddy in the early 1990s to guide the development of its clinical practice guideline and MTA work. Designing

an explicit, evidence-based approach to collecting relevant published studies, summarizing and comparing results, critiquing study design and statistical methods, and communicating findings were essential to create confidence in the early stages of technology assessment at KP [9]. Dr. Eddy's self-described common sense approach is still the foundation of the INTC's work today: Be conservative when the benefits and harms of a technology are not known, especially when harms could be significant and costs are high [10].

KP manages the entire continuum of healthcare for its population. KP's national and regional MTA activities address the published evidence on procedures, devices, equipment, and other medical products used in all settings of care. This approach considers needs, whether from the hospital, clinic, or home, while achieving the efficiency of a more centralized resource.

## 19.3 KP Needs

The INTC and regional medical technology assessment activities support physicians' needs to stay apprised of an increasing number of published clinical studies, especially of more complex technologies, while bearing in mind the urgency and diversity of patients' needs and the organization's fiduciary responsibility to its membership and communities. Patient safety remains at the root of MTA at KP: a key tenet of the work is ensuring new technologies have been shown to improve the quality of care.

The INTC is advisory only, providing a national source of consistent, unbiased, and comprehensive evidence reviews of many technologies. It is a well-known and highly regarded internal resource. Physicians often request INTC review topics of interest before making regional decisions. Unlike most US health plans, KP does not maintain national, technology-specific coverage policies. Decisions about the medical appropriateness of specific technologies are made within KP's geographic regions, weighing input from its physicians (respective Permanente Medical Group) and nurses, considering its local health plan contracts and regulations, and using the work product of the INTC.

The INTC focuses on the available published peer-reviewed studies, ultimately making recommendations based on the "sufficiency" of evidence to support the technology as a medically appropriate option. "Sufficiency" refers to the preponderance of the evidence from well-designed studies that indicate a benefit of the new technology over the comparison technology. "Insufficient" findings are accompanied by a description of the existing body of evidence and the identified shortcomings in quantity, quality, and consistency of the evidence. The INTC posts the citations of primary clinical studies, along with its presentation materials, minutes, and recommendations, on an internal website. Although the INTC does *not* consider cost when making its recommendations, other KP decision-makers in the regions use the INTC's work when they consider whether to adopt a technology and address its total cost in determining the most efficient deployment strategy.

## 19.4 Evolution of Needs, Scope, and Use

The needs of KP's integrated healthcare delivery system extend across the care continuum, include all specialties of physicians and healthcare professionals, and concern safety and long-term effectiveness.

As a primarily prepaid health system, KP has consistently prioritized preventive care, long-term outcomes, patient compliance with care recommendations, safety in the home and hospital, and lifestyle choices. KP must consider the impact each technology has on its facilities; the use of consumable products; integration with the electronic health record; compatibility with other technologies, environmental impact, workflow, service, and maintenance; and the risks versus benefits of ownership. Failure to understand how a technology changes lives, care delivery, and total costs can create complex problems and safety concerns.

## 19.5 Input and Use

In 1998, KP created an inquiry service for medical technologies. The inquiry service coordinates and collates the responses, using prior work from relevant assessments and incorporates appropriate content from public and private, subscription-based resources. New assessments are created as needed with guidance and input from clinical experts. Although anyone in KP can inquire about a new medical technology or ask for an assessment, most review requests come from patients, Permanente physicians, interregional specialty groups, and clinical teams responsible for technology choices. Physicians work closely with the analysts (or evidence specialists) to define the scope of the literature review, current practice, and the delivery system. They also share their clinical experience and knowledge of the technology.

Based on the available evidence and the clinical needs, the response to an inquiry will be either a "comprehensive assessment" taking 4–12 weeks, or a "time-sensitive assessment" for a patient appeals case with a turnaround time of one to ten business days. The time frame of a comprehensive assessment depends on the extent of the literature and organizational priorities. Supporting physicians with an evidence review to consider in a specific clinical situation is a critical and rather unique application of technology assessment.

## 19.6 Assessment Interests in an Integrated Delivery System

KP has always addressed the assessment needs from all settings of care, especially, the hospital. Since KP is an integrated health delivery system with medical groups, hospitals (KP owned in some regions), ambulatory care entities, and health insurance plan, KP's interests, questions, and concerns around medical technology are

far reaching. While a traditional US health plan must review technologies for coverage purposes and publish a policy for each, KP must also provide education and decision support to its members and Permanente Medical Groups, consider deployment options purchase technology and products, and develop implementation plans. KP's work is just beginning when the evidence assessment is finalized. KP must select, purchase, and maintain necessary equipment and consumables; coordinate with its information technology and facility support; train relevant healthcare professionals and physicians; provide for maintenance and service; determine if ongoing data collection or research is appropriate; manage supplies and inventories; report and respond to safety concerns and recalls; and consider disinvestment when appropriate. It is critical that the available evidence informs the entire decision-making process. If the published evidence is insufficient, the staff must work to communicate findings to the physicians, nurses, and the health plan who may be encountering questions about the technology from patients, colleagues, health plan purchasers, or suppliers. An insufficient finding may prompt a KP research study.

When the evidence is sufficient to determine a technology is medically appropriate, operational, clinical, and business teams at regional and national levels then use key elements of the technology assessment for deployment consideration. For example, clinical trial patient selection criteria may be extrapolated to forecast volumes and plan for appropriate access to the technology, continuing evidence-based decision-making. This process varies by region, although some clinical teams collaborate interregionally. Clearly, evidence is not the sole determinant of medical technology decisions, but a common understanding of what the evidence does or does not demonstrate leads to more informed decisions.

## 19.7 Collaboration and Resources

Health technology assessment is fragmented in the USA; therefore, it is difficult to address the substantial number of complex technology topics in a timely manner. KP monitors the availability of current assessments from a number of American and international technology assessment producers. Through both collegial network and contractual relationships, KP gains insight into the queue of pending assessments. This collaboration helps KP determine when an internal assessment is needed to support timely clinical decisions.

In addition to physician leaders, KP has about nine full-time equivalents (FTEs) in Southern California working on technology assessment, while Northern California has 3 FTEs, the Northwest has 1 FTE, and the INTC has 1.5 FTEs at the national level (all numbers are approximate). Some staff members support other work that requires similar skills or coordination. Most are evidence specialists, trained or expert in epidemiology and biostatistics, and a Masters in Public Health or related field. Staff members work closely with physician committee members and physicians requesting assessments. The national team is responsible for ongoing development of INTC processes and policies, managing external relationships,

and contracts with private technology assessment groups, conducting surveillance of potential topics, and integrating evidence-based work products into other organizational conversations. The national team must also stay apprised of the regional MTA work for information sharing, as those resources address many topics that may benefit from national discussion. While monitoring availability of assessments, the national team is also conducting horizon scanning. Sources include the FDA approval queue, medical literature, and professional meetings. Prioritization of topics considers several factors such as the state of the evidence and timing of regulatory decisions and internal technology planning needs. Permanente physicians' inquiries and input drive the INTC's priorities.

## 19.8 Expanding the Influence of Evidence

For over 30 years, KP has had a network of physician experts working with business partners within and outside the organization to develop medical product standards and national contracts. An inter-regional team of physicians works with technology assessment and sourcing and procurement staff to identify, trial, and select which medical products and technologies they will use throughout all KP regions. The physicians participate in the contract strategy development, product trials, and negotiations. They also meet with suppliers to learn more about new products and technology.

For more than 10 years, this network has used the MTA work to inform its product selections and contract strategies. Sharing this knowledge with additional decision-makers has proven to be very powerful and beneficial to KP and its members. The teams have a much greater understanding of FDA regulation, published studies, and product safety. Additional knowledge has empowered them to define new products versus new technology, drive pricing appropriate to proven effectiveness, and select products and technology demonstrating the greatest benefit to patients and KP. Physicians routinely seek an evidence review before a scheduled discussion of the product or technology with their colleagues and the suppliers. The evidence specialists will access, request, or conduct a literature search to inform those conversations and decisions.

## 19.9 Examples That Illustrate KP Needs and Experience

A partial list of topics discussed by the INTC over the past year best illustrates the breadth of KP's needs: left atrial appendage closure therapy for stroke prevention, alpha defensin and leukocyte esterase tests for diagnosis of periprosthetic joint infection, femtosecond laser-assisted cataract surgery, percutaneous mitral valve repair, antibiotic-coated sutures for colorectal surgery, dopamine transporter imaging with single-photon emission computed tomography (DAT-SPECT) for

diagnosis and management of Parkinson's disease, responsive neurostimulation for epilepsy, and a special report on laparoscopic power morcellation for myomectomy and hysterectomy. Prioritizing topics considers several factors such as the degree of physician interest, the state of the evidence, and timing of regulatory decisions. To provide some data and context, an older topic is most appropriate for the first descriptive example. For the second example, a current topic will illustrate today's challenges, but does not have a conclusion as of this publication.

In 2012, the INTC reviewed technologies designed to prevent unintentional retention of items in patients undergoing surgery. Studies report surgical sponges have the highest rates of retained foreign objects (RFO), in part because they are frequently out of view of the surgical team [11, 12]. Retained objects can be discovered days to years after the initial operation, and symptoms may include pain, infection, sepsis, inflammatory response, mass, bowel obstruction, fistulization, and even death. Bar coding and radio-frequency identification (RFID) tagging of surgical sponges are intended to reduce errors in tracking sponges in the operating room (OR).

The INTC did not find published evidence that isolated bar code and/or RFID technologies could consistently protect against RFOs. Successful trials incorporated these as part of larger quality improvement programs which addressed systems and human factor issues. Data from Mayo Clinic Rochester indicated reduced rates of retained surgical sponges after adopting bar coding; however, process change techniques and training may have contributed more to the reduced rates. It was not clear if the technology, or the focused quality improvement effort, was primarily responsible for the reduction in RFOs. After 18 months of use of a bar code system at Mayo Clinic Rochester, 0 retained sponges were reported. Prior to the new coded sponge system, a retained sponge had occurred on average every 64 days [13].

In addition to the evidence review, the INTC consulted its perinatal and perioperative safety experts regarding a multi-region evaluation they conducted at KP's clinical simulation facility, the Garfield Innovation Center [14]. The evaluation brought together general surgeons, anesthesiologists, obstetrics and gynecologic surgeons, surgical technicians, nurses, operating room leaders and educators, as well as representatives from information technology, procurement, and clinical technology. KP hospitals were very interested in RFO prevention technology, and there was a strong desire to prevent redundant pilots and avoid the purchase and deployment of multiple technologies. Echoing the literature findings, the participants in the evaluation felt that the technologies were advantageous to augment, not replace, manual counting. The evaluators also documented operational and physical considerations discovered during the product trials.

The INTC found the published evidence for RFO prevention technology to be "insufficient" as a stand-alone prevention method of reducing retained surgical sponges, but acknowledged that the technology may be indicated as part of an overall RFO Process Improvement Program. After much consideration of the evidence and the multidisciplinary product evaluations, the operating rooms and labor and delivery departments in KP's two largest regions moved forward to begin deploying RFID RFO prevention technology. This collaborative work was successful in integrating KP's medical technology assessments with other analyses and hospital-based

drivers. The information gathered in the technology assessment process, involving surgeons and patient safety experts, enabled KP to proceed with monitored and coordinated diffusion, to improve patient safety and optimize technology. These KP hospitals made a significant investment in RFID sponges and dressings, along with incorporating the technology into their comprehensive OR safety programs. In the initial year of deployment, one large region was projected to spend over $1 M more for RFID sponges and dressing than it had for the conventional products. Some quality reports indicate that KP hospitals implementing this technology have reduced their RFO rates by at least 50% from pre-deployment rates. However, statistical significance is difficult to establish due to the rarity of RFO events. The aggregate RFO numbers are extremely low for these large regions serving more than seven million patients. The overwhelming majority of hospitals achieve the "never event" goal of zero RFO incidents each quarter. A 2009 study by the Pennsylvania Patient Safety Authority estimates average total costs of caring for each patient with an RFO to be $166,000, including legal defense and other non-reimbursable costs [15].

A second, and very current, example of a technology assessment topic is high-flow humidification (HFH) via high-flow nasal cannula (HFNC). This technology is one of a burgeoning number of devices and technologies focused on patients transitioning from hospital to home, attempting to improve quality of life, and decrease readmission rates. The therapy is intended to increase alveolar ventilation, promote slow and deep breathing, and improve mucus clearance. While there is both current use and active research on adults in the acute setting, the manufacturers also promote the therapy for home use. The manufacturers suggest several indications in the hospital setting. Chronic obstructive pulmonary disease (COPD) is the primary home setting indication under discussion, with a broad range of other pulmonary conditions considered potential candidates. There is also mention in the product literature of the potential use of the technology for scores of patients with restrictive lung disease and difficulty with secretion clearance.

Several factors prompted KP to consider this technology: the product is commercially available; it is being marketed directly to consumers; there is some available evidence; and there is potential benefit for new groups of patients in a different care setting.

Upon receiving an inquiry about the use of the technology in a home-based pilot, the INTC staff consulted the national clinical/business team charged with selecting and purchasing respiratory products to learn more about the current and potential use of the technology.

A preliminary literature review identified some published and unpublished data specific to home use for COPD. One published study included patients with COPD or bronchiectasis that used the device either 1 or 2 hours a day. This publication reported no significant difference between groups in the primary endpoint: exacerbation frequency [16]. However, there was a difference in the primary endpoint: the number of exacerbation days. Preliminary analysis of a randomized, controlled study reportedly favored nasal highflow treatment, but the daily treatment regimen and final results remain unpublished [17]. Intermediate outcomes, such as lung

function, may have demonstrated improvements in these studies, but the INTC is primarily interested in improvement in net health outcomes shown in peer-reviewed published studies. The duration of optimal treatment is also of interest, as well as improvement in quality of life and patient compliance. The literature search continues at the writing of this chapter.

## 19.10 Lessons and Remaining Challenges

The gap between availability of medical technologies and peer-reviewed, published evidence of their value continues to be a significant challenge for making decisions. The number of technologies to consider continues to climb, as does their complexity. National product recalls and safety warnings drive home the need for careful consideration of benefits and harms prior to adoption and the importance of post-market product surveillance. KP has cultivated an evidence-based culture, creating an expectation for evidence-based decision-making across the care continuum. The demand and the rationale for medical technology assessment have never been greater.

KP's national and regional medical technology assessment resources have learned to efficiently manage their limited resources, both internal and external. Selected high quality, external assessments have helped to improve KP's ability to quickly respond to member and physician needs. Internal experience and refinement of recruitment and training of analysts have greatly advanced the quality and coordination of work products. Appropriate timing of assessments is critical to maintaining a credible program that is useful and relevant to clinical and operational decisions.

Introducing evidence reviews into product selection and contracting has been quite successful. The multidisciplinary, national clinical/business teams use this objective information to educate their colleagues, advise product selections, influence supplier negotiations, and inform product utilization. The movement of MTA into these discussions and decisions brings the evidence to the hospital level (or other setting of care) and provides the next set of decision-makers with a consistent, transparent foundation. Because the INTC does not formally consider cost when it reviews the evidence on outcomes, proven technologies are allowed to reach deployment and purchasing consideration without being dismissed a priori on the basis of a financial threshold. Clinical and operational staff can thus influence negotiations over of an effective technology and collaborate on the most appropriate and efficient ways to use it.

Inclusion of physicians and other healthcare professionals in the entire assessment process is a key success factor for KP. Clinical champions inform the assessment framework at the beginning of the process, focusing on the needs of KP patients and the specific needs of KP's integrated delivery system. These same champions then integrate the evidence analysis into decision-making.

## 19.11 Vision for the Future

KP would like to see greater collaboration and coordination of evidence-based assessments in the USA and worldwide. KP has a long history of using credible, external content. While local needs and drivers of technology decisions may vary greatly, the evidence basis to inform those decisions is consistent. Consistent use of evidence-grading systems by technology assessment teams, internally and externally, will also make sharing of assessments easier.

Increasingly easier access to and manipulation of clinical and operational data to inform assessments are an important part of KP's vision. Advances in this area will promote measurement of patient outcomes, faster and consistent spread of effective technologies, and detailed analyses of the benefits. KP will continue to integrate the assessments into new discussions and decisions, close to the point of care. While a hospital-based assessment function at each KP facility may not be an efficient or practical approach, there would be value in developing more formal ambassadors of the MTA work from the clinical and operational ranks at each hospital.

With advances in technology, the electronic medical record, and growing patient expectations to receive care everywhere and on demand, the need for MTA beyond the traditional hospital setting, has never been so great.

## 19.12 Availability of Public Content

KP maintains an intranet site with a list of topics reviewed, presentations and original clinical study citations used in the assessment. Additional links are provided to KP's most commonly used resources, and there is a portal to suggest a topic for INTC consideration. KP offers some of its evidence-based work to the public, although it does not maintain a public website for its medical technology assessments. The Permanente Journal is another public resource describing KP's medical technology assessment program over its history in several articles [7–9]. KP conducts a substantial amount of research, resulting in more than 1300 publications in 2014 and over 4000 ongoing health research studies.

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# Chapter 20
# The Role of Hospitals in HTA in Brazil

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## 20.1 Introduction

The Brazilian public health system, known as the National Health System (SUS), has some unique characteristics (see Box 20.1):

**Box 20.1: Brazilian Public Health System**

- SUS is funded, managed and administered by all levels of government: municipal, state and federal.
- Public health services are available to all citizens of the country (universal coverage). Nevertheless, millions of affluent Brazilians also have private healthcare coverage.
- In 2014, the health insurance services had nearly 51 million participants. The care provided to these beneficiaries generated an expense of U$ 5.83 billion in health care between January and March 2014.[1]

[1] http://www.ans.gov.br/portal/site/informacoesss/informacoesss.asp.

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- Spending in the health sector accounts for 8 % of the gross domestic product, and 60 % of this is spent in hospitals. This level of expenditure is considered insufficient to sustain the largest universal healthcare system coverage in the world.[2] Hospital-based HTA has the potential to dramatically increase the ability of hospitals to efficiently use their health resources.
- Most of the Brazilian Public Health System is funded by reimbursement of procedures or by Diagnosis Related Groups. Some hospitals have annual budgets from the Ministry of Health, states or municipalities.

Hospital-based health technology assessment (HTA) in Brazil is still in its early stages, and the dissemination of HTA evidence and its acceptance in practice have yet to become routine in healthcare management.

In 2000, the Ministry of Health (MoH) created the Department of Science and Technology (DECIT) and made the first attempts at a technological assessment of high-cost medications. In 2008, another important action was the creation of the Brazilian HTA Network (REBRATS) by connecting 15 HTA groups scattered throughout universities, medical schools and teaching hospitals. An HTA milestone in Brazil occurred in 2011 with the passing of Law 12401, which regulated the principle of integrality in the SUS and created the National Commission for Technology Incorporation (CONITEC) [1].

Since 2009, the MoH has created nearly 30 hospital-based HTA. Although with insufficient budget until our days, they have seven obligations:

I. To promote the technical capacity for the inclusion of institutions in the National Network for Technology Assessment in Health (REBRATS)
II. To develop actions for the permanent training of professionals and technicians
III. To encourage and produce research, studies and systematic reviews focused on the use of scientific evidence in decision-making
IV. To coordinate the review of clinical guidelines from hospitals in line with SUS priorities
V. To encourage and enable mentors to guide students and health professionals to teach and conduct research aimed at the evaluation of health technologies
VI. To raise awareness and encourage professionals from hospitals to explore the beginnings of a health technology assessment culture
VII. To strengthen the relationship between teaching and service in the HTA and evidence-based health

[2] Ministério do Planejamento website, "Saúde" (fact sheet, 2002). Retrieved 12 June 2007.

Brazil is a continental country and the largest country in Latin America. There are economic differences between regions, and HTA units work independently. We will present some features of the main centres of Brazilian HTA separately.

## 20.2 NATS-INC

The HTA unit of *Instituto Nacional de Cardiologia* (NATS-INC) in Rio de Janeiro was created in 2009. It is linked to the Department of Research and Teaching, and the team comprises two physicians (one PhD in Epidemiology and one MSc in Health Technology Assessment), one pharmaceutical professional (MBA in Health Economics), one nurse (MBA in Health Economics) and one psychologist (MSc in Health Technology Assessment). The unit also has support from the statistical unit and from trainees.

Our demands come from external sources (MoH, agencies and pharmaceutical industry) and internal requests (Hospital Board).

The unit is supported in part by the hospital (salaries for federal employees and supplies) and in part by the MoH (grants, scholarships, courses, congress, equipment and software). NATS-INC provides informal aid for local decision-making, internal HTA, teaching and research, but the process of HB-HTA is still not well consolidated.

Our methods include quick reviews, systematic reviews, cost-effectiveness analysis, cost-utility analysis and budgetary impact studies.

Until recently, political interest and educational factors were likely the most important barriers that influenced the successful implementation of HB-HTA. Being a tertiary unit accustomed to dealing with modern equipment also hindered the process of incorporating HB-HTA, because health professionals are interested in innovations and, usually, they have limited critical evaluation capacity.

Currently, NATS-INC has been promoting the concept of HTA by sharing its expertise and experience with professionals, policymakers, industry, the health insurance sector, patients and the general population through courses, lectures and manager training. Another priority is capacity building, and in 2013, we developed a master's degree in Health Technology Assessment at Instituto Nacional de Cardiologia.

As an example of our activities, we developed more than 22 technical reports in the last 2 years, most of them for external use (CONITEC–MoH). For example, we evaluated the incorporation of septal occluders for children with intra-atrial communications, including a cost-effectiveness study with positive financial results. This study is available at http://conitec.gov.br/images/Consultas/Relatorios/2014/Relatorio_Oclusores_FechamentoPercutaneo_CP.pdf.

Another recent study [2] (May 2015), published in the International Journal of Technology Assessment in Health Care, was done as a request by a local physician. The specific query was an evaluation of the cost-effectiveness of the new Carpentier-Edwards cardiac prosthesis (aortic and mitral) versus standard bioprosthetic valves

in patients requiring heart valve replacement. The conclusion of this study was that the current data presented in the literature still do not support a clinical advantage for the use of the Carpentier prosthesis over other bioprostheses, and besides that, in Brazil it is approximately seven times more expensive than national prostheses. They were prevented from being implemented into practice based on this HTA recommendation.

The HTA unit is responsible for two websites: one with preferences and economic analysis (www.natsinc.org) and the other with information about *Red de Evaluacion de Tecnologias em Salud de las Americas* (www.redetsa.org).

We highlight as our achieved goals: the partnership with the MoH and the triggered interest of the Hospital Board. Other positive outcomes are developing a local course addressing how to do HTA reports, development of internal capacity for critical appraisal and international partnerships as PAHO, Moffit Center, Euroqol Group and London School of Economics, especially in academic research and applied development methods (multi-criteria decision analysis, preferences and quality of life instruments).

For the future of HB-HTA, we expect a consolidation of the incorporation process, including HTA reports for all significant new technologies.

## 20.3 Conceição Hospital Group

There are five professionals who work at Conceicao HTA Unit. Three are medical doctors and one is a dentist. Three of them are PhD and one of them is a specialist in family medicine. There is also a secretariat. The funding is provided by the hospital, which is funded by the Ministry of Health.

Most of the work that has been carried out is a request by the Ministry of Health and eventually by the local coordination. We have being developing HTA methodology and also quick reviews.

REBRATS (Brazilian HTA Network) identifies our centre as a resource for HTA in primary health care, as it has excellent primary healthcare experience and has developed several related HTA products, following Brazilian guidelines. (These reports are available at: http://189.28.128.101/rebrats/visao/sociedade/estudo.cfm.)

The HTA products include an implementation strategy for hypertension and diabetes in primary health care, guidance on using the ankle–brachial index (BAI) in primary health care, a noninvasive method to monitor 24-h ambulatory blood pressure and cardiovascular disease in primary health care, methods for promoting adhesion of hypertension pharmacology treatment and guidance on obesity, mortality and readmission in patients with cardiac failure.

This unit has completed several research projects and is currently carrying out several others. A list of projects follows:

1. Arthroplasty registries: a comprehensive overview (presented at international conferences). The objective of this overview was to evaluate the application of

local and national knee and hip arthroplasty registries around the world. Conclusion: There is strong evidence that a joint replacement registry is useful as an early warning system for premature device failure, and the study identifies factors associated with positive outcomes.

2. Is Bariatric Surgery Effective in Reducing Comorbidities and Drug Costs? A Systematic Review and Meta-Analysis [3]. The aim of this study was to assess drug use and costs before and after bariatric surgery (BS). Conclusion: BS is effective for the improvement or resolution of comorbidities and has a significant effect on reducing drug use and costs.
3. Impact of Bariatric Surgery on the Saliva of Patients with Morbid Obesity [4]. The aim of this study was to evaluate the impact of bariatric surgery on the saliva of patients with morbid obesity. Conclusion: The results suggest that the salivary levels of mutans streptococci increase following bariatric surgery in morbidly obese patients.
4. Improvement of bacterial sepsis diagnosis in immunosuppressed patients using biomarkers (supervision of a PhD thesis in the postgraduate Epidemiology programme of UFRGS). Objective: Compare the accuracy of PCR and procalcitonin in screening for sepsis in immunosuppressed patients. Conclusion: This systematic review has been developed.
5. Antibiotic prophylaxis in obese patients who submitted to bariatric surgery: A systematic review (submitted for publication). Objective: To review the use of cefazolin in the prophylaxis of surgical site infection in bariatric surgery. Conclusions: The use of cefazolin prophylaxis is recommended; however, further studies are needed to refine parameters such as initial dose, re-dose, time of administration and duration of prophylaxis.
6. Heat-related illnesses during the 2014 heat wave in a general hospital in South Brazil. Objective: To identify the mortality rate in the hospital during the heat wave. This research project is currently under development.
7. Academic detailing and adherence to guidelines for Group B streptococci prenatal screening: a randomized controlled trial [5].

There are several HTA products that have been developed or translated for HTA professionals. These products include:

- Mini-HTA [6]
- Adapte [7]
- Agree II [8]
- GRADE [9]
- Guide of guidelines [10]
- Primary Healthcare Guidelines from the Netherlands [11]

There is another successful initiative: the Professional Masters of Science on HTA. This is a joint venture between Conceição Hospital Group and Federal University of Rio Grande do Sul (https://plone.ufrgs.br/ppgepi/mp_gts). The objective was to educate and train professionals to act as managers in organizations and health systems and to incorporate HTA as a tool for the decision-making process.

Two editions of this MsC on HTA have been developed, and approximately 60 students have finished the postgraduate course. This MsC has received strong evaluations from the examining board and has received a very good score in Masters grade (four out of five). Based on this experience, the unit developed a new postgraduate programme that started in September 2015. It has received strong interest by health professionals in hospitals and elsewhere.

## 20.4 Judicialization: A Gap in the Health System Organization

Judicialization is a challenge in Brazil, and it is related to the growth of spending by the Unified Health System of Brazil in lawsuits even after the regulation of the principle of integrity upheld by Law 12401. Although this law defines the criteria and deadlines for the adoption of technologies in the public health system and regulates which ones can be provided under what conditions by the SUS, magistrates decisions continue to force the public health system to provide technologies that are different from those funded by the SUS [1].

We have seen an explosion of lawsuits and the establishment of a culture of using judicialization as a way to obtain assistance that, for some reason, was not provided by the SUS. Over the past several decades, prescribing doctors, lawyers and the pharmaceutical industry have filed lawsuits against the State and its related institutions [12, 13].

This phenomenon has a multifactorial nature. Below are some factors that contribute, albeit with different weights, to the growth in lawsuits over health actions in Brazil.

1. The understanding of Article 196 of the Federal Constitution. Most of the parties in the lawsuits focus only on the first part of the constitutional article: Health care is everyone's right, and providing it is duty of the State. Considering just this phrase, doctors, patients and judges try to legitimize and legalize their demands. There is an opportunistic interpretation, according to which the State must provide full health care to all, no matter Public Health Policy and related costs [14].
2. Medical education in Brazil is mostly geared towards a liberal interpretation of medicine, even in public universities. It thus creates a disconnection between education, the population's health needs and the reality of professional practice, especially considering that the SUS is the largest employer of the country's health professionals.
3. The forged concept that public policies are bad or have insufficient investment. These concepts are part of an effort to discredit institutions, especially the SUS, by justifying and supporting the judicialization and influencing the judges' decisions [15].

In 2010, the authorities of the National Justice Council approved a recommendation for the Brazilian Courts to seek technical advisers with better knowledge to help judge health care claims [16].

Forcing the public network to fund any and all health provisions can cause serious injury to the administrative order and would compromise the SUS, further restricting medical assistance for the neediest share of the population. Aware that resources in Brazil are not only finite but also scarce, national HTA groups have been supporting CONITEC, summarizing scientific evidence and examining short- and long-term consequences of the incorporation or disincorporation of technologies. The tools for health technology assessment were provided by REBRATS – Brazilian Network of HTA – http://rebrats.saude.gov.br/diretrizes-metodologicas. However, these HTA forms involve populations rather than individuals.

There was a successful experience that started after the Council's recommendation. In 2012, in a province in Southeast Brazil, a team of the teaching Hospital of the Federal University of Minas Gerais (NATS/HC/UFMG) signed a term of collaboration involving the government and the judiciary of the province. According to the terms of this document, the judiciary would ask NATS/UFMG to answer questions about health and well-being that involved medicine, medical devices, medical procedures or other health interventions or exams. The answers were presented in a structured framework and were written in language accessible to the judges, i.e. avoided medical-specific terms.

This document had a summary with the description of the case, a summary of the available literature and recommendations, as well as information about the registry of the technology in the country, an abstract of the principal studies retrieved from the literature and if available, the estimated price of the treatment (including medicines, devices, procedures and exams).

The results were presented within 72 h of the request. The technical documents were then delivered to the applicant judge and made available on the CNJ's website, accessible for inspection by any citizen.

The technical staff that provided this information was composed of ten medical doctors, a librarian specialized in clinical research and an extensive number of ad hoc consultants. The main staff composition was three PhD, four MSc ongoing PhD and three specialists in cardiology, internal medicine and psychiatry, all of them with HTA education.

Between October 2012 and July 2015, NATS staff produced approximately 1,600 documents for Minas Gerais judges. Of those, 1,003 quick answers analysed 1,316 requests for medications.

The growth in demand confirms the programme's acceptance and confidence. There were 6 questions in the first month of the programme and 144 by July 2014. In total, 27.5% of the requested medications were already available from the SUS. Approximately 70% of the treatments requested in lawsuits were considered inadequate or worse than the medication already provided by the SUS. The judges, who now had strong evidence based on the literature, denied many requests. Moreover, there was a huge financial impact, with significant savings. Because many lawsuits were denied and technical assessment for the demands was established, the growth in lawsuits stopped and the number of lawsuits declined even declined in 2014.

Although the evidence-based recommendations and final decision are based on best practices in health care, there is, as a secondary benefit, a financial impact. The

judiciary estimated that these HTA-based answers saved approximately $160,000–320,000 (US) per year without affecting patient care.

In conclusion, HB-HTA has great growth potential in Brazil. The involvement of all stakeholders, including patient groups, clinicians and hospital administrators still needs to be strengthened, increasing HTA understanding and its potential use in relation to hospital demands. The main contribution of HB-HTA may not be in changing the decisions that are ultimately made, but how they are made, with transparency and with systematic opportunity cost judgement.

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# Chapter 21
# Hospital-Based HTA in Argentina: The Hospital Garrahan and Hospital El Cruce Experiences

**Graciela Demirdjian, Rafael Kurtzbart, and Ramon Hernandez**

## 21.1 Introduction

Latin American countries have adopted health technology assessment (HTA) later than the rest of the world, mainly as central macro-level initiatives. In Argentina, the national coordinating HTA unit (Unidad Coordinadora de Evaluación y Ejecución de Tecnologías Sanitarias, UCEETS) was formally created at the Ministry of Health in 2009, with representatives from all ministerial areas including our national hospitals. In 2012, UCEETS joined other state HTA initiatives into a national network, Red Argentina Pública de Evaluación de Tecnologías Sanitarias (RedARETS). Networking has promoted collaboration between centers and has channeled our participation in regional and international networks like Red de Evaluación de Tecnologías en Salud de las Américas (RedETSA) and International Network of Agencies for Health Technology Assessment (INAHTA).

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## 21.2 Overview of the Healthcare System in Argentina

| *Health system funding* |
|---|
| Argentina's healthcare system is divided into three large sectors: public, social security, and private. The public sector has free access and a decentralized scheme with financing and healthcare delivery at provincial or municipal levels with general policy guidance by the National Ministry of Health. The social security sector covers half of the population and is financed through salary contributions of employees under different trade unions; it also involves the coverage of retired workers and disabled people. The private insurance companies are funded through voluntary prepayments by individual contractors, with variable coverage plans according to contribution. In general, the health system is highly fragmented; there is considerable overlapping between sectors and jurisdictions and a significant amount of patient out-of-pocket expenditure |
| *Hospital funding* |
| Funding for hospitals comes from the corresponding healthcare sector. There are national, regional, state, and municipal facilities, as well as hospitals at the private and social security sectors. Hospitals Garrahan and El Cruce are national third-level hospitals funded partly by the National Ministry of Health, and the rest of the budget assigned by the city or the province of Buenos Aires, respectively |
| *Hospital decision-making on health technologies* |
| There is no law for mandatory HTA at hospital level in Argentina. Decision-making on the incorporation and coverage of health technologies takes place at the corresponding administrative level of the facility, with the exception of a few autonomous institutions (as Hospitals Garrahan and El Cruce) with autonomy for budget management and decision-making on health technology acquisition |

## 21.3 Hospital-Based HTA Program at Hospital Garrahan

### *21.3.1 Program Scope*

#### 21.3.1.1 Mission and Structure

The first hospital-based (HB) HTA program in Argentina [1] was created in March 2001 at Hospital de Pediatría "Juan P. Garrahan" (Buenos Aires), a teaching, public-setting, national pediatric referral facility with 500 tertiary care beds, and one of the few hospitals in the country with a self-managed budget. At the time we launched our program, only a few meso-level HB-HTA experiences existed in North America (Canada and the USA) and none in South America. At that time the country faced a deep economic crisis and an unexpected escalation of healthcare costs with a huge impact on hospital budgets. Our administrators understood this was a perfect context for a local HTA project and readily accepted our proposal. The program was aimed at promoting rational evidence-based technologic development and improving the use of existing health technology (HT) at the hospital level. Currently, it involves four main areas: HTA reports to aid executive decision-making for HT acquisition, pediatric clinical practice guideline (CPG) elaboration and implementation,

professional capacity building in research and management, and coaching for health services research (HSR).

The initial unit structure was limited to a part-time coordinator (assigned full-time in 2004), a pediatrician with background training in clinical effectiveness and lengthy teaching experience in HTA-related disciplines such as research methodology, evidence-based medicine (EBM), epidemiology, and biostatistics. Later on, an HTA Committee was formed by hospital professionals selected based on technical skills, willingness to participate, and specialties representing key patient care areas. Their part-time collaboration with the HTA coordinator provides a multidisciplinary look at complex issues such as detecting problems, establishing priorities, selecting expert reviewers, or choosing optimal implementation methods. Currently, it has 12 members: eight physicians (two pediatric clinicians, two neonatologists, one intensive care specialist, one infectologist, one general surgeon, and one radiologist), one biochemist, two pharmacists with pharmacoeconomics skills, and one biomedical engineer; these specialists are not usual constituents of HTA units [2, 3]. The HTA coordinator and some committee members actively participate in other hospital teams in charge of the management of HT (drugs, devices, equipment), quality, career development, and research review board. All of these tasks (including participation in central-level HTA) are funded by hospital operational funds through regular salaries.

Our model is consistent with the general pattern of other reported hospital-based HTA experiences [4, 5], typically a teaching hospital with an HTA unit or multidisciplinary committee dedicated to informing hospital administrators and clinical practitioners on the safety, effectiveness, and organizational impact of a wide range of HT. Our program involves some additional HTA-related activities like continuous and systematic staff capacity building and mentoring of research projects to document the impact of health services initiatives or fill in pediatric evidence gaps [6].

#### 21.3.1.2 Methodology

The assessment cycle is comprised of four main phases: prioritization, evidence synthesis, communication, and monitoring. Priorities are set either by the need of decision-making on the incorporation of a new HT requested by hospital staff, rising costs, or high variability in utilization of existing HT. Professionals applying for acquisition of new HT must fill in and submit a standardized formulary, locally adapted from the Danish mini-HTA [7] and the Spanish GANT [8], which includes vital input information for prioritization, assessment perspective, budget impact, and final decision-making. For HT in use, hospital records and databases provide useful information for serial utilization analysis and continuous monitoring, detection of main users, variability in indications, costs, and changes over time. A systematic review of the relevant evidence follows, including existing HTA reports, published guidelines, meta-analyses or economic evaluations, and gray literature for epidemiological data or industry information. This evidence is comprehensively

analyzed and adapted to the local context, taking into consideration hospital needs and organizational impact.

Communication to hospital administration is delivered by a brief technical or full HTA report or cost-effectiveness analysis from a hospital perspective. HTA reports include a synthesis of the available evidence with minimal raw technical data to allow easy reading and comprehension, a brief conclusion summarizing the status of available information, and a recommendation to accept, reject, or incorporate in a restricted fashion. These recommendations are taken into consideration in decision-making by hospital authorities who are highly committed to the program. To ensure transparency, HTA reports are accessible to staff through the hospital intranet; they are also shared with other HTA centers at a national level through a restricted-access library. This information is sometimes disseminated in a more user-friendly CPG format targeted at pediatric professionals, as utilization guidelines summarizing recommendations for adequate use of HT. The HTA team also coordinates the production of pediatric patient care guidelines which provide a multidisciplinary approach to diagnosis and treatment of complex pediatric diseases. Draft guideline versions are submitted to peer review and expert consensus to promote adherence. All CPGs have an executive summary for quick consultation, and a glossary with MeSH terms linked to PubMed to enable easy searching on related subjects. Implementation is usually tailored to potential users and may involve single or multimode strategies like academic or focus-group meetings, clinical pathways or algorithms, publication of a pharmacy bulletin, or a printed poster with key contents distributed to clinical wards or nursing stations. Full-text CPGs are available both internally and externally via hospital intranet and web page (www.garrahan.gov.ar) and virtual campus (www.garrahan.edu.ar) for easy access by internal and external healthcare professionals.

The final phase is to assess the impact of CPG implementation or HT incorporation. Here again, this may involve various data sources including hospital databases or data collection and analysis by hospital specialists or the HTA team. The continuous monitoring of these measurements not only serves to document the clinical or economic effects of HTA but also as input to induce reassessments, feedback contact with users, or new assessments, reinitiating the cycle.

The remaining two components of the program are aimed at incorporating more hospital professionals to HTA-related activities. Capacity building started with short EBM workshops for staff members and research design courses for residents and fellows under the leadership of the HTA coordinator. These brief courses initiated an evidence-based culture and promoted clinical research at the institution. Later on, in 2006, the need for a more profound and sustainable change among hospital healthcare professionals triggered the idea to start an on-site annual course in research and management for pediatric professionals, directed by the HTA coordinator in collaboration with the Institute for Clinical Effectiveness and Health Policy (IECS) is currently ongoing. Course contents cover fields related to HTA (epidemiology, EBM, biostatistics, HSR, strategic planning and healthcare programs, quality improvement, and economic evaluations), disciplines that are virtually absent during professional grade formation in our setting. A requisite for

certification is the group design of a research or management project; this stimulated other HSR initiatives for which the HTA coordinator provides technical support, the fourth component of our HTA program.

## *21.3.2 Program Performance (2001–2015)*

### 21.3.2.1 HTA Reports

During the last 14 years, the program has produced 30 HTA reports on drugs; therapeutic, preventive, or diagnostic procedures; and institutional programs (Table 21.1). The scope covered effectiveness, safety, cost-effectiveness, and organizational and budget impact. Median time from request to final report was 63 days, ranging from 4 days (rapid technical reports) to 39 months (full HTA reports with utilization review and CPG for users or institutional program assessments). Eight of the HT assessed were already in use; from the remaining 22 new HT, 3 were not recommended for incorporation and two were recommended only for restricted use in specific patient subgroups.

**Table 21.1** HTA reports (Hospital Garrahan 2001–2015)

| |
|---|
| Drugs |
| 1. Effectiveness, safety, and cost of human albumin solutions in pediatric critical inpatients |
| 2. Effectiveness, safety, and cost of intravenous immunoglobulin in pediatric diseases |
| 3. Safety (severe adverse effects) of dipyrone in children |
| 4. Comparative effectiveness, safety, and costs of muscle relaxants in pediatric patients on mechanical ventilation |
| 5. Effectiveness and safety of thymoglobulin in pediatric hematologic and kidney transplant patients |
| 6. Effectiveness and cost-effectiveness of eltrombopag in immune thrombocytopenia |
| 7. Effectiveness and cost-effectiveness of plerixafor for mobilization of stem cells for autologous bone marrow transplantation in the pediatric setting |
| 8. Comparative effectiveness, safety, and costs of horse versus rabbit antithymocyte globulin in pediatric aplastic anemia |
| 9. Cost-effectiveness analysis of palivizumab for prevention of preterm newborn hospitalization due to infection by syncytial respiratory virus |
| 10. Effectiveness, cost-effectiveness, and budget impact analysis of palivizumab prevention in children with congenital heart disease |
| Devices |
| 11. Comparative effectiveness (failure rate) of different brands and models of cochlear implant devices in children |
| 12. Indications and cost of different masks for prevention of influenza and other respiratory virus transmission |
| 13. Effectiveness and safety of paracorporeal ventricular assist devices as a bridge to heart transplantation in children |

(continued)

**Table 21.1** (continued)

| |
|---|
| 14. Effectiveness and safety of intracorporeal ventricular assist devices as a bridge to heart transplantation in children |
| 15. Utilization analysis and clinical and organizational impact after 8 years of incorporation of paracorporeal ventricular assist devices as a bridge to heart transplantation in children |
| Procedures – equipment |
| 16. Cost-effectiveness analysis of polymerase chain reaction versus standard stool culture for diagnosis of *Escherichia coli 0157* in infantile diarrhea |
| 17. Comparative effectiveness, safety, and costs of haploidentical versus hystoidentical bone marrow transplantation in pediatric leukemia |
| 18. Comparative effectiveness and safety of intracorporeal endoscopic versus extracorporeal sound-wave lithotripsy for pediatric urinary stones |
| 19. Effectiveness, safety, and efficiency of pumpless interventional lung assist (iLA) in patients with severe respiratory insufficiency as a bridge to lung transplantation |
| 20. Effectiveness of infantile massage and Reiki techniques |
| 21. Effectiveness and safety of biphasic versus monophasic defibrillators in children |
| 22. Diagnostic effectiveness of optical coherence tomography in pediatrics |
| 23. Organizational impact and efficiency of a computerized quality control system for intensity-modulated radiation therapy |
| 24. Organizational and budget impact of high-performance liquid chromatography tandem mass spectrometry |
| 25. Effectiveness and safety of Alexandrite 755 nm y NdYag 1,064 nm pulsed laser for congenital vascular and pigmented skin lesions in children |
| 26. Effectiveness and safety of UVA phototherapy for refractory skin lesions in children |
| 27. Safety, efficiency, and organizational and budget impact of automatized anesthesia workstations |
| Institutional programs |
| 28. Effectiveness, safety, and economic and potential organizational impact of the implementation of a procedural sedation and analgesia program at hospital level |
| 29. Organizational impact of the implementation of a pay-for-performance program at hospital level |
| 30. Organizational impact of the implementation of a clinical governance program at hospital level |

#### 21.3.2.2 CPG Implementation

From 2007 when we were assigned hospital guidelines, 20 evidence-based pediatric CPGs ("Guías de Atención Pediátrica", "GAP", Table 21.2) were elaborated and submitted to peer review and expert consensus (13 patient care and 7 utilization guidelines), at a rate of 2–5 documents per year. Implementation strategies and tools varied according to subject and main users of the guideline; for example, CPGs on albumin and immunoglobulin were summarized in a one-page pharmacy bulletin with cost information for easy everyday consultation; a poster with highlights of recommendations on infusion pumps was distributed throughout all nursing stations at the clinical wards; face-to-face meetings were held to discuss the adequate use of albumin solutions and infusion pumps with key professional users.

**Table 21.2** Clinical practice guidelines (Hospital Garrahan 2007–2015)

| Utilization guidelines |
|---|
| 1. Use of albumin in pediatric inpatients |
| 2. Use of intravenous immunoglobulin in pediatrics |
| 3. Use of masks during influenza pandemic |
| 4. Use of parenteral infusion pumps |
| 5. Use of transfusions in pediatrics |
| 6. Use of preoperative antibiotic prophylaxis in pediatrics |
| 7. Safe use of potassium solutions |
| Patient care guidelines |
| 8. Clinical care of sodium imbalance in children |
| 9. Multidisciplinary care of children with DiGeorge syndrome |
| 10. Clinical care of pediatric patients with cirrhosis-related ascites |
| 11. Infection care in burned children |
| 12. Dietary care in pediatric chylothorax patients |
| 13. Urological care of pediatric patients with meningomyelocele |
| 14. Clinical care of Duchenne's muscular dystrophy |
| 15. Clinical care of acute renal injury in children |
| 16. Multidisciplinary care of achondroplasia |
| 17. Clinical care of infants with bronchiolitis |
| 18. Clinical care of infantile apparent life-threatening event |
| 19. Clinical care of hemolytic-uremic syndrome |
| 20. Clinical care of potassium imbalance in children |

For these guidelines, an assessment of the clinical and economic impact of implementation was undertaken at some point during the post-intervention period to document guideline compliance, before-after variation in utilization, and expenses or savings attributable to the CPG. For example, during the first year after CPG implementation, albumin consumption and associated annual costs were reduced by 50 % (savings worth $50,000 Argentine pesos) and immunoglobulin by 10 % ($40,000 initial annual savings, $300,000 in the following 2 years given the rise in drug price). General guideline impact is additionally measured by monitoring the number of hits at the hospital website; annual figures round between 1,000 and 10,000 hits per guideline (median 8,399 annual hits), this being the most visited section of the hospital website.

#### 21.3.2.3 Capacity Building

Starting in 2006 and until today, the annual course on research and management was taken by 325 professionals (almost one-third of the professional staff), including pediatric clinicians and specialists, pharmacists, biochemists, physical and respiratory therapists, psychologists, social workers, nurses, and hospital administrators. More than 95 % of the students attained certification through a final evaluation and

77 research or management projects were produced under professor supervision. Many of these group projects were multidisciplinary, and a few even interinstitutional or multicenter in collaboration with other pediatric centers (in 2008 the course opened to outdoor pediatric professionals). They covered a broad range of pediatric issues and methodological designs including clinical research, HSR, quality improvement, hospital programs, and cost-effectiveness analyses. The members of the HTA Committee also participated in an applied course on guideline adaptation by the National Academy of Medicine, during which they produced the basis of a CPG on pediatric preoperative care which has recently been published.

#### 21.3.2.4 Technical Support

Besides course project supervision and participation in the institutional research review board, the HTA coordinator has coached 33 other research projects on hospital programs or quality improvement interventions. Research ideas came from ex-students of the annual course, but also from staff members applying for certification of other specialty postgrad courses or doctoral theses.

#### 21.3.2.5 Educational and Organizational Effects

Along the years, we have observed some additional qualitative changes at least partially attributable to the HTA program: a sustained EBM culture, enhanced multidisciplinary interaction and consensus, encouragement of continuous postgrad education in HTA-related disciplines, and active user involvement in the decision-making process regarding new HT incorporation and utilization review of existing HT. Sustained managerial commitment and support, in-house professional recognition, and outdoor visibility were crucial factors for the sustainability and expansion of our program.

### *21.3.3 Lessons Learned*

#### 21.3.3.1 Achievements (What Has Worked)

Initially, we needed to convince all hospital stakeholders of the usefulness of evidence-based decision-making. Traditionally, decisions were based on medical trends, professional pressure, institutional prestige, expert advice, or budget viability. At the time, experts were suspicious about EBM, and administrators had tough decisions to make in the midst of an economic crisis. Short EBM courses and multidisciplinary consensus activities with opinion leaders proved useful in this initial phase to break some staff resistance [9]. The first HTA report and CPG on albumin use incorporated various hospital areas in the assessment and consensus process,

promoting staff participation, cost awareness, and compliance, while the considerable post-implementation savings were considered highly relevant by hospital administrators at that critical time.

Supervised guideline development also helps clinicians to recognize the economic implications of their prescriptions and to consider efficiency and cost-effectiveness matters for recommendations. Our outdoor influence and recognition as a teaching pediatric referral hospital multiplies the national and regional influence, so it is considered essential to explicitly provide level of evidence and strength of recommendations in CPGs to allow other pediatricians to make rational decisions adapted to their own context.

Progressive staff capacity building in epidemiologic skills and management tools helped maintain the EBM culture and enhanced multidisciplinary involvement in HTA activities [10]. As multiple skills are needed for this task, interdisciplinary work is vital to guarantee a broad and rational approach [11, 12]. Today, there is a rich permanent interaction of the HTA team with the Pharmacy and Medical Technology departments responsible for the purchase and management of hospital HT. Attending regular meetings of hospital committees for the surveillance of drugs, devices, and equipment, the HTA coordinator actively participates in the detection of priorities for assessment and serial utilization monitoring to allow constant reevaluation of the process. This ongoing team task supports credibility and warrants the sustainability of our HTA program [13].

#### 21.3.3.2 Future Challenges (What Has Not Worked…Yet)

We still have some limitations and unresolved issues. First, the HTA unit needs more full-time human resources to cope with the potential demand in a timely manner, shorten response time, and increase CPG production. The technical skills of some of the HTA committee members and the interactive work with other groups help palliate this problem, as most new drug assessments are made in collaboration with the Drug Committee, and some device issues are addressed by the Techno-Surveillance Committee.

Second, specific evidence for complex or rare conditions in the pediatric age is usually scarce, and urgent decisions are often made in conditions of uncertainty, based on insufficient evidence from small case series, extrapolation from adult studies, or expert opinion. In cases where HT are incorporated under these circumstances, we usually recommend a reassessment after a period of specific data collection to document effectiveness in our patients, and also encourage external communication of this new evidence generated by local clinical research.

Third, it is not easy to change physician prescription patterns or maintain guideline compliance over time. Despite our comprehensive and participative HTA approach, a certain degree of professional inertia and resistance to change persists. Experts sometimes feel that guidelines may get in the way of their expertise, and senior professionals may resent being audited or receiving a rejection to incorporate a new HT. Junior staff is often misguided into off-label use of existing drugs or

emerging HT, or question the effectiveness of generic medicines or the quality of less costly brand devices. Moreover, maintaining CPG adherence is a constant struggle in a teaching hospital with a high turnover of residents, fellows, and trainees involved in patient care.

We believe that further end-user involvement in the HTA process may help us overcome all these problems. Our future challenges also include disinvestment strategies, horizon scanning information of emerging HT in the pediatric field to minimize uncertainty in urgent decisions, and proactive participation in the strategic planning for purchase of hospital equipment. Finally, as many of these issues are common to other HTA groups, we consider it essential to maintain national, regional, and international collaboration channels and alliances; a special step was our incorporation to the Hospital-Based HTA Interest Subgroup (HTAi) whose members share our same specific concerns related to undertaking HTA at hospital level.

## 21.4 Hospital-Based HTA at Hospital El Cruce

Hospital El Cruce was created in 2007, as a model hospital for tertiary care or third-level of complexity healthcare integrated to a hospital network. The hospital only receives patients with complex disorders referred by any of the six level 2 hospitals, belonging to the four surrounding municipalities, in the suburban area located south of the autonomous city of Buenos Aires. The hospital is an autonomous institution, free of charge for users who recognized their social right to receive healthcare. It is financed by two Ministries of Health, i.e., the National Ministry and the Ministry of the Province of Buenos Aires. The population of reference comprises approximately 2,000,000 inhabitants, with a low socioeconomic level; hence, technology incorporation is considered an issue of public policy, aimed at achieving equity in the free access to complex medical care (transplants, cardiac surgery and neurosurgery, oncology and hematology, etc.), from which the population mentioned has been historically excluded.

### *21.4.1 Assessment and Decision-Making Process to Incorporate Diagnostic and Therapeutic Equipment*

In 2010, a more formal procedure was initiated to assess the requests for incorporation of new equipment, and the task was assigned to the hospital's Economic Investigation and Assessment Area. An application form for incorporation requests was developed, based on the experiences of the Spanish G-ITESA (Principality of Asturias Healthcare Service), the Agency for the Assessment of Healthcare Technologies of Andalucía, and the HTA Coordination at Hospital Garrahan in Buenos Aires, Argentina. The form is completed by the applicant, with the goal of allowing hospital professionals to critically analyze their own requests for the

incorporation of new technology. They may request help from technical specialists if needed. The application is later analyzed by a multidisciplinary team involving three hospital areas supported by the hospital's own budget: the Quality of Care Area who evaluates efficacy, the Clinical Engineering Area who evaluates patient and operator safety, and the Economic Assessment Area who evaluates cost-effectiveness of the incorporation request as well as the break-even point, which determines the amount of demand required to equal the cost of the various operational alternatives, and particularly the modality that is currently in use. The Assessment Committee undertakes its own literature searches (in addition to the literature about the technology contributed by the applicant) from full-text papers, particularly from systematic reviews and meta-analyses in databases and specialized search engines such as *Medline*, *Lilacs*, *Embase*, *Cochrane, PubMed*, *Trip Database*, *Excelencia Clínica*, *Alquimia* and *RIMA*, using MeSH terms or key words. Then a summary of the best scientific evidence available is provided as a bridge between decision levels and sources of knowledge, thus responding to the information needs of the decision-makers. The economic analyses are always performed locally by the Economic Research Area, considering the demand for the technology requested as well as the various supplies available in the local and international markets.

As to the methodology, once a request for incorporation of technology has been submitted, the hospital management decides on the priority for assessment by the Committee. Concomitantly, as the applicant completes the "guide-form for decision-making," a literature search is undertaken, looking for the evidence that efficacy evaluators will use, as well as evidence on patient and operator safety and cost-effectiveness (although we assign scarce external validity to the latter). The cost-effectiveness analysis is usually performed jointly by the Economic Research Area and the head of the requesting department, since we consider this assessment to be a pedagogic activity regarding the economic aspects, which are not always taken into account by healthcare professionals.

The Committee should recommend the incorporation of equipment only if there is evidence of efficacy, safety, and cost-effectiveness, as shown by the following examples of assessments performed:

- Assessment of laboratory flow cytometry equipment: incorporation is recommended since there is evidence of efficacy, safety, and cost-effectiveness, thus reaching the break-even point, which warrants its purchase rather than referring the test to other hospitals.
- Assessment of different management modalities for chronic patients in the Pediatric Intensive Care Unit (ICU): home care modality is recommended in view of its favorable cost-effectiveness, according to our own analysis.
- Assessment of thromboelastography equipment in hemotherapy: introduction of this technology is not recommended; the application may be reexamined in the future if changes in the evidence regarding avoided morbidity and mortality should occur, from the literature review undertaken by the Committee.
- System for tissue oxygen pressure monitoring in the Adult ICU and Neurosurgery: incorporation is recommended, with a warning that the request may be reexamined

if no change occurs in the evidence regarding avoided morbidity and mortality; the development of a protocol for the assessment of cost-effectiveness was recommended.
- Assessment of automated sample-processing equipment for immunohistochemistry in the Pathology Laboratory: incorporation is not recommended until the number of tests performed can justify the change from manual to automated methodology, since the break-even point that determines cost-effectiveness requires a 100 % increase in the number of assessments performed at the time of evaluation.

### *21.4.2 Assessment of Additions and Deletions of Drugs*

New drugs do not necessarily imply a clinically relevant contribution, cost-effectiveness, or a well-known long-term safety profile. For these reasons, drug assessment and selection must be performed in hospitals, based upon the best scientific evidence available to date. The concepts and methodology of EBM have been incorporated into a standardized process that is transparent, scientifically rigorous and independent, and allows for the dissemination of information. It is becoming an essential activity carried out by the Pharmacy and Therapeutics Committee (PTC) of Hospital El Cruce since October 2008, with participation of the following areas and departments: Pharmacy, Quality, Internal Medicine, Clinical Pharmacology, Pediatrics, and Nursing. This Committee provides advice, consultation, coordination, and information on medicines to be included in the hospital Pharmacotherapeutic Guide (PTG), to help in decision-making. Among the objectives of this multidisciplinary committee that meets periodically are the assessment and selection of additions, deletions, and modifications of medicines contained in the hospital PTG.

The mentioned process begins with the application for inclusion of a new drug requested by a staff physician, who completes a request form and sends it to the Pharmacy Committee, who in turn evaluates the application's priority and commissions a technical report. According to the work methodology, the steps to be followed are:

1. Detection of the problem or need for information for a particular type of patient.
2. Addressing a specific question to be answered using the PICO model (patient, intervention, comparison, outcomes).
3. Search for information, with the aid of the specific question developed into concepts and ultimately into key words. The information search is performed based on a series of strategies, for example, using the 5S pyramid model proposed by Haynes [14]; the search starts at the top or the base (where the databases are located, raw data) according to the time elapsed since the new drug became available.
4. Analysis of the information obtained, following the criteria recommended by the World Health Organization [15] for the assessment of new drugs, based upon efficacy, safety, cost, and convenience. Following these criteria, the best existing evidence available is analyzed using critical reading methodology.

5. The report on the new drug is prepared to help decision-making, based on the model developed by the GENESIS group [16] and adapted to our country. It comprises various sections: identification of the drug and authors of the report, application, description of the drug, pharmacologic action, assessment of efficacy, safety, convenience, cost-effectiveness analysis, conclusions, and references.

With this report, the PTC makes a decision, by consensus, on whether to include the new drug or not in the hospital PTG. This decision will serve as advice to hospital authorities, who will ultimately decide on the inclusion or exclusion of the drug. Subsequently, the requesting physician is informed of the decision and the report is published in order to inform the rest of hospital staff. The time it takes to prepare a report is approximately 2–3 months.

A few examples of reports prepared in our hospital are bevacizumab, prasugrel, terlipressin, Avagard (1 % chlorhexidine gluconate and 61 % w/w ethyl alcohol), desflurane, valganciclovir, and fosfomycin. These reports are available in our hospital website (www.hospitalelcruce.org) under *Pharmacy blog*.

### *21.4.3 Current Impact and Future Directions*

The implementation of a working group on drug selection has led us to markedly improve our capacity to respond to the request for inclusion of new drugs in the hospital PTG. The hospital PTC has worked as a true filter, allowing only the incorporation of those drugs proven to be efficacious, safe, and cost-effective, compared to existing options listed in the PTG. Thus, we have achieved a true control of the new drugs included in the PTG, since decisions considered not only their inclusion or exclusion in the Guide but also their therapeutic role and conditions for their use.

As hospital complexity increases, with the treatment of new disorders and performance of new procedures (e.g., liver transplant), a revision of drugs included in the PTG will be required, as well as drugs that were once excluded, i.e., a new analysis for increasingly precise indications.

In the future, any drug considered for inclusion in the hospital PTG will necessarily have to comply with the established evaluation steps. We wish to share the experience and knowledge acquired with all other healthcare professionals and thus help improve the use of the existing evidence in the decision-making process.

### *21.4.4 Lessons Learned*

We believe that the most important lesson learned is the pedagogical power achieved by accompanying the requesting physician in the process of analyzing the rationale regarding the efficacy as well as the economic aspects of the drug or equipment they have requested. A more mature cultural attitude appears evident the next time those same professionals request an assessment for hospital technology. One of the main

changes we see as a result of this maturation is that they embrace the concept of "opportunity cost," i.e., become aware that if resources are spent on "something," such resources will not be available for other items that might be more beneficial for the overall services provided by the hospital.

For the future, we envision the development of a radial model, with groups working on HB-HTA in all second-level hospitals sharing the network with our third-level hospital, and a committee in charge of assessing the overall network, so that the concept of "opportunity cost" is applied to throughout the network and not just at Hospital El Cruce.

## 21.5 Network Collaboration and Strategies to Promote HB-HTA in Argentina

Our experiences illustrate how public hospitals in developing countries might benefit from the development of HB-HTA initiatives. Managerial commitment and specific capacity building are essential at the starting point, but these initial efforts will most surely prove to be worth the investment. Besides rational and efficient management of the "technologic avalanche," a virtuous circle is produced by promoting interdisciplinary work, local clinical research, healthcare cost awareness, continuous training, and updates. Professional involvement and participation in the HTA process empowers hospital professionals, stimulates critical reading of the scientific evidence, and improves the understanding of the opportunity cost of institutional decision-making. This in turn may generate a positive effect on the rest of the healthcare system through collaboration and networking with other colleagues and institutions.

Today, our HB-HTA programs are evolving and have gained acknowledgment both at hospital and central levels. Our participation in the national HTA unit (UCEETS) and collaborative networks at national (RedARETS), regional (RedETSA), as well as international (INAHTA) levels are extremely useful channels to avoid duplication of assessment efforts, facilitation of advanced training, discussion of methodological issues, and to share concerns.

Hoping to promote HB-HTA in other institutions around the country, we have recently launched a series of workshops on HB-HTA issues. Actually, both 2015 meetings of the Argentine public HTA network RedARETS have been dedicated to HB-HTA, aiming at incorporating more public hospitals to the network (more than 30 just at the city of Buenos Aires). Our basic proactive strategy relies on identifying individuals or groups already carrying out isolated HTA-related activities (such as drug selection, rational device choice, practice guidelines) to integrate them to the network, to provide means for their specific training, and to share HTA documents. We believe these actions will contribute to the spread of HTA countrywide and gradually multiply the impact on the national healthcare system.

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# Chapter 22
# HTA in a Public Hospital in South Africa

**Debjani B. Mueller and Moreshnee Govender**

## 22.1 Introduction

South Africa is a diverse country with a population of 52.98 million, of which approximately 27 million (51.8 %) are female and approximately 25 million (48.7 %) are male [1]. In 2012 the country spent 8.8 % of its GDP on health (approx. USD 18.4 billion), and its per capita expense was USD 982 [2]. The under-resourced public sector serves 84 % of the total population, and the small private sector serves the remaining 16.2 % of the population; however, both sectors spent similar amounts of money (approx. USD 9.2 billion) on its patient population. The South African government has committed to universal health coverage by 2025, which is considered to be critical to improve the health of the population and to compensate for systemic inequalities [3].

The country is divided into 9 provinces and 52 health districts. Eleven percent of the government's budget is spent on public health, which is equitably allocated to the 9 provinces in the form of conditional grants, such as health professional training grants. However, the allocation of the financial resources and the standard of healthcare delivery vary from province to province. Local hospital management has authority over its own operational issues (for instance, regarding budgets and human resources). The role of the local management should not be understated. By allowing a certain degree of local latitude, the system allows greater flexibility and the ability to respond faster to local needs. The private healthcare sector is funded through medical schemes (health insurances) and various donor-funded agencies, which in turn are funded by international governments or agencies widely present throughout the country. The medical schemes used in the private sector have sophisticated tools to measure healthcare utilization. Even though the private healthcare sector in South Africa is well developed and provides premier patient care and services, it is burdened

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by unregulated prices, which may be a consequence of the unsystematic manner of acquisition of high-cost technologies to meet patient demand.

Providers of private health care are dominated by three large hospital groups, whereas the public healthcare sector is typically managed by a referral system: primary health care is provided by clinics and community healthcare centers, secondary care by district and regional hospitals, and tertiary care by central academic hospitals. Furthermore, according to the White Paper on Health Services Transformation (1997), hospital management was designed based on a decentralized model in order to promote efficiency and cost-effectiveness [4]. Box 22.1 summarizes the healthcare system in South Africa.

**Box 22.1: The Two-Tiered Structure of the Healthcare System in South Africa**

*Private* health sector (20 % of the population):

- There are approximately 200 private hospitals.
- Mainly covered by private, voluntary health insurance and out-of-pocket payments [5].
- Comprised of private hospitals, practitioners, and pharmacies.

*Public health sector:*

- Mainly funded from taxes and a minimal contribution from regional government.
- Encompasses national, provincial, and local government.
- Has three categories of hospitals: district, regional, and tertiary (provincial tertiary and national central).
- Entry of patients is usually through primary health care (clinics).
- There are approximately 400 public hospitals, which are funded by the Department of Health.
- At present, the government is using tax-based financing system to fund the public hospitals. 11 % of the total budget is assigned for public health and is allocated and spent by the nine provinces. The national government has the overall responsibility in setting the envelope for allocation of funds to provinces and also decides on the size of the conditional grants – allocation for specific purposes. The provinces then decide on how much of the envelope, topped up with local revenue, will be used for health; they also decide on how much of these resources go to hospitals and to primary health care.
- Demand for sophisticated technologies is driven by department heads and physicians in tertiary and academic hospitals. Standard ordering procedures apply, depending upon the type of the device and if it is listed or not and on tender. Entry of a device in the public sector market becomes difficult when it is specialized or expensive. Decisions on new devices that are required in small quantities and may need a tender for purchase are made on ad hoc basis.

The South African National Department of Health published a framework for Healthcare Technology Policies [6] in 2001, and a regulatory framework was established under the National Health Act (Act No. 61 of 2003).

The framework addresses the following challenge:

> […lack of systematic planning in the acquisition of health technologies, specifically during the procurement and utilization phase has resulted in high levels of inappropriate utilization of health technology and in unnecessary expenditure. This is a phenomenon in both public and private sectors, although the causes differ…….More importantly, there is no coherent system for regulation and assessment of these technologies. The fragmented, inefficient and ineffective manner in which some health technology resources are managed and distributed is thus cause for concern. This observation concerns the public and private sectors and applies to both inter- and intra-provincial institutions, at both local and provincial levels and between academic institutions..]

In 2004 a steering committee – which was later disbanded – was convened by the Department of Health to address these challenges and to drive the HTA agenda in South Africa; the committee had submitted a comprehensive report on HTA structures and mechanisms to be established in South Africa. This report was followed with a draft National Health Technology Strategy document [7] in 2005, which was meant to operationalize the framework.

In 2013, the pharmaceutical market in South Africa had an approximate value of 2.7 billion USD; of this, 15 % was conducted in the public sector, and the rest in the private sector. The current medicine regulatory framework is of a higher standard than that of other health technologies. Even though sufficient information on pharmacoeconomic analysis is not available, it is clear that careful buying decisions about medicines and services are provided. The public sector has recently (2013) adopted the proposed guidelines on pharmacoeconomic submissions [8] for the assessment of new medicines.

The medical device market in South Africa was estimated at USD 1.2 billion in 2013 and is forecasted to grow. The majority of the devices are imported from other parts of the world, and 80 % of South African products are imported to other African countries [9]. However, medical devices do not undergo rigorous price and quality evaluation, even though electro-medical and radiation-emitting medical devices are registered with Radiation Control under Department of Health [10]. Under this scenario, HTA can play an important role as it is a process which summarizes clinical, economic, social, and ethical issues in a transparent and systematic manner with the objective of formulating safe and effective health policies which bring best value to patients and the general public [11]. However, there were no government units conducting formal HTA in South Africa. The Charlotte Maxeke Medical Research Cluster, CMeRC, a translational research unit in partnership with Charlotte Maxeke Johannesburg Academic Hospital attempted to address that gap by introducing HTA to public hospitals in South Africa [12]. A workshop on mini-HTA was conducted for executive officers of hospitals from different provinces. As a result of this workshop, certain forms of HTA are practiced in certain hospitals; however, there is no formal system of carrying out the assessments. Thus agencies or units like CMeRC can facilitate the institutionalization of

HTA in the country. With the gradual introduction of national health insurance [5], it becomes increasingly clear that HTA could play a decisive role and potentially positively impact certain areas (such as service delivery and health policy and extending to include issues as diverse as patient safety, quality of care, and social values).

The two main challenges concerning the introduction of HTA in South Africa were found to be (a) the lack of use of the HTA framework to evaluate health technologies in SA public hospitals and (b) the lack of a health technology decision support tool to guide hospital decision-makers to ensure best diagnostic, therapeutic, and economic outcomes. Thus, the development and integration of a broad HTA framework in policy and planning in order to optimize the management of health technologies in public hospitals will ensure safe and effective delivery of patient care.

## 22.2 Health Technology Assessment in Hospitals

It was observed that setting up HTA units or certain forms thereof in hospitals in the era of Universal Health Coverage (UHC) depends on the infrastructure available and the organization of the health services in a country [13].

A few public hospitals in South Africa practice a limited form of HTA which may consist of committees of specialized professionals working part-time to produce mini-HTAs or utilizing evidence upon which to base decisions. Additionally, ad hoc assessment committees within a hospital may exist. Specific data, however, on this is not available. Individual initiatives taken by clinicians or clinical engineers have been observed in certain cases. These individuals are usually proponents of HTA and have tried to raise awareness of the benefits of using the tool or parts thereof within their department(s).

According to the opinion of the authors, the lack of appreciation of HTA and use of the Health Technology framework, which would provide governmental support in decision-making related to procurement, use, reuse, and disposal of medical devices in policy and planning in almost all South African public hospitals, is the biggest hurdle to establishing formal HTA units. In 2011, a focus group discussion with hospital CEOs [12] had shown that HTA was not being used in public hospitals (personal communication) and also that there was a dire need for a support tool for the purpose of procurement decisions whose results are based on the evidence available. According to Govender et al. [12], the necessity of capacity building programs in HTA is indisputable in low- and middle-income countries, and thus it was found to be necessary to provide regular and ad hoc training to staff as well as external participants. As a support tool for procurement was requested, an adapted version of the Danish Center for Health Technology Assessment (DACEHTA) mini-HTA tool [14] was introduced to the participants of the workshop. The adapted mini-HTA tool was then piloted in those hospitals whose CEOs had participated in the workshop [12].

### 22.2.1 Charlotte Maxeke Medical Research Cluster, CMeRC: Structure and Organization

CMeRC is a translational research center and affiliated with the Gauteng regional departments of Health and Social Development and partners primarily with Charlotte Maxeke Johannesburg Academic Hospital and its cluster hospitals and also with the National Health Laboratory Service.

The cluster is part of the University of the Wits Health Consortium and is a non-profit publicly funded organization. The members of the organization have expertise in clinical epidemiology, family medicine, health economics, medical devices, diagnostics, evidence-based medicine, quality assurance, safety, healthcare management, planning, and policy. It has both full-time and part-time staff and also project-specific consultants. The main objective of CMeRC is to provide comprehensive research, service, and training in translational research through multidisciplinary research programs and thus contributes to the reduction of the burden of diseases prevalent in the South African population. The main areas of its competence include evidence-based health care, clinical research, clinical economics, health technology assessment (HTA) and management, and medical management. Thus the HTA unit is placed within this cluster and is not organizationally placed inside the hospital.

Within a hospital, the assessment requesters are usually department heads, physicians, and nurses. In order to allocate human and financial resources efficiently, it is imperative for the unit to prioritize assessments that are relevant to decision- and policy-makers. The process usually involves various stakeholders within and outside the unit. The unit considers the following criteria to plan and determine its priorities (in descending order):

- Burden of disease (HIV/AIDS and TB; violence and injury; maternal, newborn, and child health; and noncommunicable diseases)
- Level of interest of different stakeholders (health professionals, government, and patient population)
- Clinical and economic impact of the technology
- Budget impact
- Availability of other technologies

### 22.2.2 HTA Product Portfolio

HTA reports are not only prepared for new technologies but also for the analysis of the health technology at any stage of its life cycle. They are needed for established technologies, for which new uses or adaptations are proposed, as well as obsolete technologies.

The methodology that is generally followed in order to create an HTA report begins with the research question and contains a systematic literature review and critical appraisal of the quality of the evidence.

The two types of HTA report that are considered relevant to hospital setting:

- Mini-HTA

  The mini-HTA usually takes 1–2 weeks to complete. The scope is narrow as it covers only the following domains: (a) technology, (b) clinical, (c) organization and social, (d) patient, and (e) economy.

  The process takes place in three steps:

  (a) The requester of the assessment (usually together with the staff of the unit) needs to provide the following information: (1) new health technology and available comparator, (2) other accessories/consumables necessary, and (3) cost of the technology.
  (b) Literature search is limited to two or three databases. As adapted from the DACEHTA mini-HTA questionnaire, the following areas are covered: technical characteristics and organizational aspects. The report is then peer reviewed.
  (c) Conclusion and recommendation are disseminated to the relevant stakeholder, i.e., proposer, board, etc.

- Rapid review

  The rapid review takes place in response to the need for a decision to a specific problem that can be taken quickly. This review can take from a few weeks to 3 months and usually includes the characteristics and current use of the technology, safety and effectiveness issues, and organizational and ethical aspects of introduction of a technology in the setting. However, only a high level of evidence is considered, and the search is restricted to few databases. It sometimes includes financial implications of the use of the technology if requested by the proposer.

### *22.2.3 HTA and Its Link to Life-Cycle Management of Medical Device*

The unit puts emphasis on linking HTA with the various stages of the medical device life cycle (Fig. 22.1), during the incorporation, utilization and disinvestment, and disposal phase.

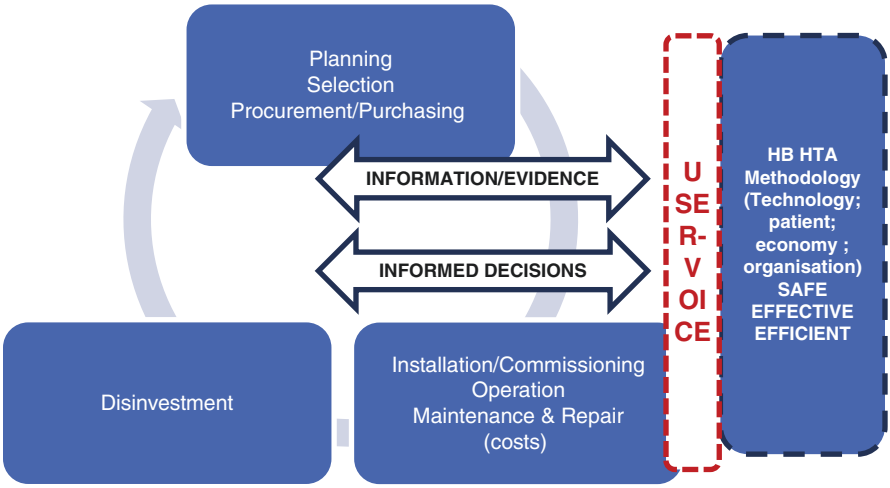


**Fig. 22.1** Where does HTA fit into the life-cycle management of a medical device

Information flow takes place and decisions are made throughout the life cycle of a medical device. Assessments are carried out during the incorporation phase of a technology, evaluating the clinical effectiveness and safety and examining the cost of the technology and its social, ethical, and organizational implications. When a technology has already been introduced into the system, then the assessment criteria also include operational issues such as learning curve, infrastructure, and risks associated with it. Boxes 22.2 and 22.3 show a few examples of reports undertaken by the unit:

**Box 22.2: Effectiveness and Cost-Effectiveness of Clinical Procedures Performed in the Maternity Ward of a District Hospital**

Aim: To assess the effectiveness and cost-effectiveness of clinical procedures performed in the maternity ward of a district hospital.

Result: Normal vaginal delivery (NVD) was found to be the main clinical procedure, which is in line with the district hospital package. The C-section (CS) rate was within acceptable norms, but a significant number of births before arrival (BBA) was of concern and needs further exploration. The majority of the patients who delivered at this unit were black, unemployed, and had no medical aid. Most arrived by ambulance, although it was not clear whether these patients were coming directly from home or were referred by primary health center (PHC) clinics and community health center (CHCs). There was no maternal and perinatal mortality and morbidity during the study period.

**Box 22.2: (Continued)**

Conclusion: This study documented the direct cost of clinical procedures performed at a district hospital. The human resources were the main cost driver. The calculated cost for this study was far lower than the costs prescribed in national health reference price list (NHRPL) for NVD and CS but higher than the Uniform Patient Fees Schedule (UPFS). This report highlighted the need for revising the UPFS.

Recommendation: The resource needs for performing specified clinical procedures (e.g., epistomy) in the maternity section at the district hospital had been recorded. There was no significant association between the mode of delivery and human resources costs per patient. It has provided reasonable indications about the costs of each procedure and the evidence and can be used to determine the costs of each procedure in various district hospitals in the country.

**Box 22.3: Use of Blood Gas Analyzers (BGA) in an Academic Tertiary Hospital**

Aim: To assess the use and annual operating costs of blood gas analyzers located in the critical care area of a hospital.

Result: Blood gas and electrolyte analyzers are the most commonly used point of care testing (POCT) devices at this hospital. As the results of the analysis are critical to the life of the patient, they are located in all critical care areas of the hospital. The costs of POCT devices include purchase cost and (a) staff training costs, (b) implementation costs, (c) ongoing operation cost including program oversight and competency assessment, and (d) total cost per test that includes expected frequency of repeats and errors, calibration, and quality control. In order to be cost effective, appropriate size cartridges must be selected as per the unit's workload.

Conclusion: Selection of a BGA is determined by its safety, suitability, and effectiveness for use. Customization of the test menu for a specific location and workload, ease of use, minimal maintenance, and remote troubleshooting are the factors should be taken into consideration when selecting a BGA. Safety of the patient and the operator should also be taken into account.

The BGAs need to be properly maintained, calibrated, and taken care of by users to prevent errors or inaccurate results leading to wrong interventions resulting in patient-related adverse effect.

Recommendation: The BGAs are cost effective in this hospital when compared to conventional laboratory test considering all other primary factors.

### *22.2.4 Usefulness of HTA in the Local Context*

The recommendations made by the unit are not binding, and thus the intended and the actual uptake of the recommendation may vary. A single solution does not exist when it comes to dissemination of assessment results, e.g., uploading an HTA report on the website may have a negligible impact, and often it is fruitful to have a direct interaction with the requester which leads to further dissemination and implementation, especially when there is a lack of expertise in HTA among the stakeholders and also a lack of understanding of the results. Cases like this lead to the development of improved methodology to showcase the results. Occasionally, a knowledge broker within the unit plays an important role in delivering the product to the relevant stakeholders, ministry, and other decision- and policy-makers. HTA results can also be directed to the board at the regular meeting of hospital clusters.

The DACEHTA mini-HTA tool [14] was adapted and at first applied to assess decisions that had already been made. This study was conducted at the first workshop in 2011 and involved a few South African hospital managers [12]. At that time, this was applied to only few selected medical devices. The mini-HTA tool had been adapted in such a way so that certain questions relevant to the local setting could be incorporated into the tool: for example, (a) technology (Were alternatives considered in terms of specifications? Is a maintenance plan available?), (b) organizations (When was the technology purchased and received at the facility?), and (c) economy (What was the purchasing price? Were consumables used?). Furthermore, it is not only used to aid decision-makers in the procurement of medical devices but also the unit has demonstrated the value of using mini-HTAs [12] retrospectively after the introduction of the technology, a few examples of which are summarized in Boxes 22.2 and 22.3. The retrospective use of mini-HTAs has shed light into the quality of decisions taken in the past and has also highlighted gaps in the management information system [12].

## 22.3 Conclusion

Since the 1980s, there has been a rapid generation and advancement of medical technologies in the face of constrained health budgets. Health systems are confronted with serious challenges to ensure efficiency and to demonstrate value for investment. There is therefore an urgent need to make informed decisions about technologies that are ineffective, or no longer cost effective, or have been superseded by innovations. Public health systems experiencing cost pressures and constrained resources provide challenges to decision-makers considering investments in health technology. South Africa as a developing country is still struggling to provide equal access to healthcare systems for its citizens; the focus of health technology assessment and management on cost-effectiveness, safety, and efficient access to healthcare technologies can lead to improved healthcare delivery and life-cycle management of medical devices.

According to Govender et al. [12], the lack of clear policies and guidelines can result in uncoordinated procurement which also has an impact in service delivery;

unfortunately, this holds true to date. A shortage of trained personnel and a lack of understanding of health technology assessment processes and their impact on the improvement of health care have been detrimental to the advancement of the field in South Africa. Close collaboration and cooperation between CMeRC and various stakeholders and knowledge brokers have played an important role in raising awareness of health technology assessments.

The HTA unit envisions further coordinated effort from the different stakeholders at the national, regional, and local levels which will then eventually result in improved health outcomes.

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# Chapter 23
# Hospital-Based HTA in a Public-Sector Tertiary Hospital in Singapore

**Keng Ho Pwee and Wai Leng Chow**

## 23.1 Introduction: Healthcare and Health Technology Assessment in Singapore

Singapore is a small island-state (718 km$^2$) in Southeast Asia with a population of 5.5 million people [1]. Singapore has a hybrid healthcare system. In primary care, about 80 % is provided by general practitioner clinics, with the remaining 20 % provided by public sector polyclinics which deliver subsidised healthcare services. The reverse applies for acute hospital care, where the seven public sector hospitals account for 80 % of the national supply of acute beds, with the private sector taking up the remaining 20 %. The step-down care sector is run predominantly by community groups and voluntary welfare organisations, several of which receive government subsidies for patients in need. At the national level, health technology assessment is carried out within the Ministry of Health to help inform decision-making and policy development [2].

**How Public-Sector Hospitals are Funded in Singapore**

- Mix of public and private hospital healthcare, with 85 % of hospital beds in the public sector [3].
- Public hospitals receive a hybrid block grant comprising an annual block budget together with piece-rate funding for 70 common conditions based on diagnosis-related groups (DRGs) [10].
- Within the public hospitals, Singaporeans have a choice of the different types of ward accommodation on their admission. Depending on the ward class chosen and means testing, the patient may receive government subsidies of up 80 % of their total bill, with the remainder paid by the patient [4].

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- Singaporeans have a compulsory individual medical savings account scheme, Medisave, which may be used to pay their share of acute hospital bills. This is supplemented by a low-cost catastrophic medical insurance scheme, MediShield. Medifund is a government medical endowment fund that acts as the ultimate safety net for needy Singaporean patients who cannot afford to pay their medical bills despite heavy subsidies, Medisave and MediShield [4, 5].
- Drug [6] and medical implant subsidies are determined by the government.
- The hospital decides which medical devices and capital equipment to procure, subject to the service level agreement it signs with the government. There is an administrative requirement for hospitals to seek approval from the Ministry of Health for purchases of capital equipment costing Singapore $1 million or more.

## 23.2 The Changi General Hospital and Eastern Health Alliance

The Changi General Hospital (CGH) is a 1,000-bed public tertiary hospital. It is part of the Eastern Health Alliance (EHA), one of six regional health systems serving a community of 1.4 million people in Eastern Singapore [7]. Regional health systems are constituted to facilitate integration of care across the care continuum, so that patients receive person-centred holistic care through the delivery of seamless, high-quality healthcare services across various settings, from prevention to acute to step-down and palliative services. The foundation partners of the Eastern Health Alliance are Changi General Hospital, the Health Promotion Board, St Andrew's Community Hospital, SingHealth Polyclinics and the Salvation Army Peacehaven Nursing Home. With the exception of CGH, the rest of the partners are unique entities that report to their own respective Management Boards [8].

## 23.3 How the Hospital is Funded

All public sector acute hospitals and specialty centres are fully owned by the government, although they are run as private companies to give them management autonomy and flexibility [9]. The Singapore Ministry of Health subvents the public sector hospitals with the expected deliverables specified in a service level agreement with each institution. Hospitals receive a hybrid block grant comprising an annual block budget together with piece-rate funding for 70 common conditions based on diagnosis-related groups (DRGs) [10]. In return, the

hospitals deliver subsidised medical services and have to meet specified performance indicators.

## 23.4 Evidence-Based Decision-Making in CGH

There are two main areas where HTA has been incorporated into the decision-making process in CGH:

1. Annual budgeting cycle
2. Introduction of new technology or devices

### *23.4.1 Annual Budgeting Cycle: The Marketplace*

In common with other organisations, CGH has an annual budgeting cycle that allows it to plan how it spends its money to support its strategic objectives. This cycle determines how funds are allocated between competing demands and more importantly is spent on the right items.

An innovative process called the Marketplace exercise was introduced in 2012 as part of the budget planning cycle. Departments intending to start a new service or introduce a new technology within the hospital must submit a proposal justifying the introduction of the new service or technology as well as details of the evidence supporting its clinical effectiveness. The proposer is also required to make a presentation (as a proof of concept) before the hospital (akin to a hospital town hall) that is attended by hospital management and stakeholders and open to any other staff who are interested in the issue being discussed. This allows other services and/or departments that may be impacted by the introduction of the new service/technology to provide inputs as well as raise opportunities for interdepartmental collaboration and/or sharing of equipment and resources.

Through the Marketplace exercise, senior management is given a common platform to review all applications for funding at the same exercise and weigh their relative merits for a more efficient and strategically coherent budget allocation process.

Following the presentation at the Marketplace exercise, proposals that are supported in principle would then be revised to incorporate the various inputs with the final estimated budget. Hospital management may concurrently request a rapid health technology assessment (HTA) on the proposed new service/technology to help inform decision-making (as part of the proof of value). Senior management will then prioritise the proposals for funding based on these inputs.

In the 2015 Marketplace exercise, 31 proposals were submitted, of which 15 were on new services/technologies and 7 rapid HTA reports were commissioned. An example case study of one of the technologies evaluated in the 2015 exercise is shown in the box.

**Case Study: Valveless Trocar System for Advanced Laparoscopic/Robotic Surgery**

The general surgery department had proposed the procurement and use of a novel valveless trocar and insufflator system to improve clinical outcomes for laparoscopic and robotic surgery. Senior management had requested a rapid review of the evidence on the clinical effectiveness and cost-effectiveness of the technology by HSR, EHA.

No relevant systematic reviews, clinical practice guidelines or economic evaluations concerning the use of valveless trocar systems were found. One conference abstract [11] reporting interim results of a randomised controlled trial was found. There were also four non-randomised comparative studies [12–15] comparing valveless trocar systems to conventional insufflation. One non-systematic review on an adverse effect was included [16].

The evidence base for the valveless trocar system was limited and ranged from poor to, at best, moderate quality. Outcomes with regard to operating times and overall intraoperative $CO_2$ consumption were heterogenous. The comparative studies generally showed that valveless trocar system use had more stable intraoperative parameters. Potential benefits are predicated on reduced $CO_2$ use and shorter operating times, however, the evidence for these were limited and not strong. Results from ongoing randomised trials might change the evidence base substantively.

The uncertain evidence base and cost-effectiveness were factors considered in deciding against early adoption of this technology, and hospital management felt it to be prudent to await results from ongoing randomised controlled trials. If subsequently adopted, protocols would have to be put in place to address complications highlighted in the literature, and the budget impact would have to be carefully analysed.

### *23.4.2 Introduction of New Technology or Devices: The Medical Device Oversight Committee*

In 2014, the Ministry of Health instructed all public hospitals and specialty centres to establish medical device committees. The Ministry had issued national standardised lists for three implants: total knee replacements, coronary stents and intraocular lenses. These lists grouped available models of implants into ‘standard’, ‘extended’ and ‘excluded’ categories. Standard implants would be generally available to all patients, extended implants should only be used in patients meeting specific clinical criteria and implants could be excluded on the basis of poorer

**Table 23.1** Terms of reference of the Medical Devices Oversight Committee

| |
|---|
| 1. To serve in an advisory capacity to the Medical Board in all matters pertaining to medical devices and technology-based procedures (MD/TBP), including utilisation, acquisition and safety |
| 2. To assess new applications for MD/TBP and make recommendations to the Medical Board based on the safety, efficacy and cost-effectiveness of the device |
| 3. To review and assess MD/TBP in current use, as directed by the Medical Board, and make recommendations on their future utilisation |
| 4. To make recommendations on the discontinuation and recall of devices to the Medical Board based on safety reports, alerts and updates |
| 5. To make recommendations to the Medical Board on credentialing requirements of new MD/TBP |
| 6. To advise on and formulate policies and guidelines governing the procurement, evaluation and utilisation of MD/TBP |
| 7. To develop an inventory of medical devices and monitor and review utilisation of devices identified in the national standardised list for 'standard', 'extended' and 'excluded' implants and any other devices as directed by Medical Board |
| 8. To be the point of contact with MOH for matters regarding MD/TBP and to provide regular reports as directed by MOH |

performance or unfavourable cost-effectiveness. The medical device committees were intended to oversee the implementation of these national standardised lists and to monitor their utilisation. In addition, the medical device committees should formulate policies pertaining to medical devices and implants in the hospital and review evidence for new medical devices and implants.

CGH formed a multidisciplinary Medical Devices Oversight Committee (MDOC), chaired by a senior surgeon, who is also a deputy chair of the hospital's Medical Board (the governing body for all doctors in the hospital). The MDOC includes senior specialists from relevant medical departments, as well as representatives from operating theatre nursing administration, supply chain management, quality management and members of the health services research (HSR) team. The terms of reference of the MDOC are as shown in Table 23.1.

These terms of reference go beyond those suggested by the MOH: they include MDOC's role in disinvestment – it can make recommendations on the discontinuation and recall of devices – and it is explicit in highlighting credentialing as a tool for managing the use of new technologies.

### *23.4.3 The Pharmaceuticals and Therapeutics Committee*

The MDOC complements CGH's well-established Pharmaceuticals and Therapeutics Committee, which makes decisions on the drug formulary of the hospital. The committee considers evidence of clinical effectiveness and cost-effectiveness in its decision-making.

## 23.5 Enabling Evidence-Based Decision-Making in CGH

### *23.5.1 Who Carries Out HTA in CGH*

HTA is carried out by the Health Services Research (HSR) department. The department has four key areas of focus:

1. Programme evaluations
2. Management analytics and operations research
3. Investigator-initiated research
4. Health technology assessment

The department is fully funded by EHA and CGH and comprises nine staff, who are employees of EHA. The team's mission and vision statements are shown in Table 23.2. Two of the nine analysts focus on HTA as their main portfolio. The rest of the team are also trained in HTA methodology and help perform rapid reviews when many rapid reviews are required in a short turnaround time as part of the annual Marketplace exercise.

### *23.5.2 Management as Main Requestors for HTA*

The HSR team conducts rapid HTA to inform decisions by hospital management. HTA requests usually arise as part of the Marketplace exercise. Ad hoc requests may come from hospital senior management or the chair of the MDOC, for example, when a doctor applies for the use of a device that is new to the hospital.

### *23.5.3 Building HTA Capacity*

In addition to performing HTA, the HSR team also conducts training in HTA methods. Workshops on how to do a rapid review are offered to hospital staff preceding each Marketplace and Health Services Development Programme (HSDP) [1] grant application exercise. These workshops introduce attendees to principles of evidence-based healthcare, how to craft a focused clinical research question, simple literature

**Table 23.2** The EHA HSR team's mission and vision

| Mission |
|---|
| To support evidence-based decision-making and enable knowledge translation through a multidisciplinary research approach to improve care delivery and health of patients and the community |
| Vision |
| To be a leader in generating quality insights for healthcare excellence |

searching, critical appraisal of literature and synthesis of the evidence. They also learn how to submit the appropriate evidence in support of their applications for the respective exercise. Requests to conduct training on HTA at other public hospitals in Singapore have also been fielded.

## 23.6 Summarising the Role of HTA in the Decision-Making Process at CGH

In summary, hospital senior management are the main requesters for HTA in CGH. HTA is conducted by the HSR team as part of a formal process (like the Marketplace exercise or HSDP application exercise) where the prioritisation of resource allocation for new devices/technologies by senior management could be informed by HTA.

The assessment synthesises and clarifies the evidence from the primary literature. This evidence is further appraised by a committee like the MDOC or the Pharmaceuticals and Therapeutics Committee, which takes into account resource availability and impact on existing practice or services, i.e. it contextualises the evidence.

The final decision is taken by hospital senior management, which considers the appraised evidence, as well as business considerations and issues such as staff retention and organisational strategic directions. In cases where management makes an ad hoc request for HTA directly from the HSR team, both the assessment and appraisal is carried out by the team. Figure 23.1 illustrates where HTA fits in decision-making in CGH.

## 23.7 Challenges in Managing Health Technologies in CGH

Traditionally, the choice of treatment or medical device is strongly influenced by factors like where medical practitioners had trained and which models of devices they were used to handling. Establishing governance at the hospital level over individual practitioner's clinical practices will take time and it must include practitioner buy-in. For example, one of the first achievements of the MDOC after its formation was to establish that entry of medical devices for use in the hospital should be centralised and managed by the Supply Chain Management (SCM) department. Whenever the SCM receives a request to purchase a new device/implant, it will check if the device/implant has already been approved. If not SCM will notify the MDOC, which will decide if a formal HTA is required.

Another challenge will be to build a framework for integrating HTA into regular review of care processes so that existing services can be reviewed and updated regularly in terms of its continuing cost-effectiveness and relevance.

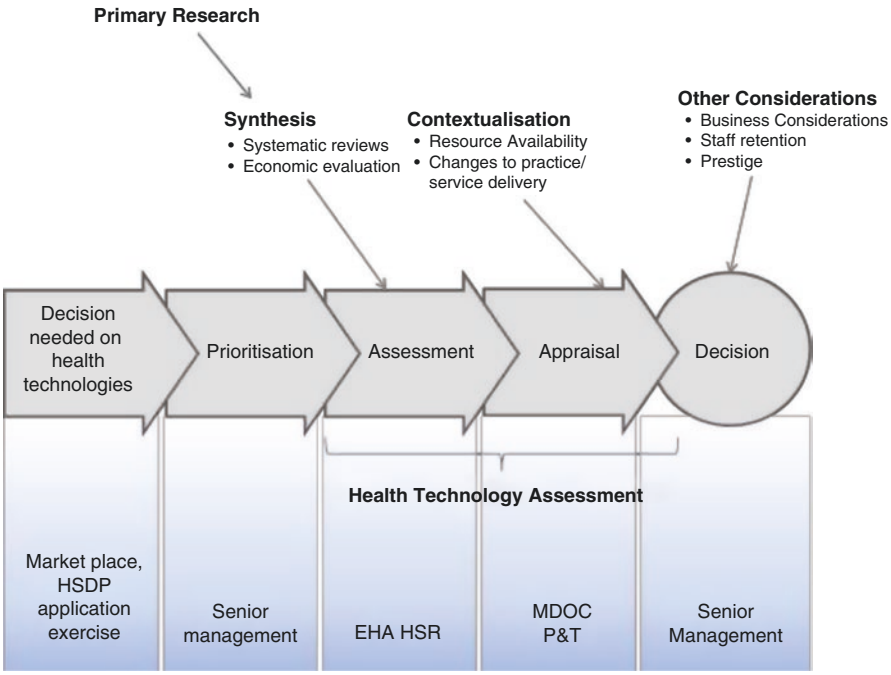


**Fig. 23.1** HTA in decision-making in Changi General Hospital

## 23.8 Aspirations for HTA in CGH and External Engagements

CGH desires to be a centre of excellence for hospital-based HTA. HTA should support evidence-based decision-making at all levels so that demonstrably effective and affordable care is delivered. The use of HTA in CGH is still new – the first use of HTA to support the Marketplace exercise was in 2014, and the MDOC was formed that year too. Notwithstanding this, oral and poster presentations of the HTA work in CGH have been delivered at local and international scientific conferences.

The EHA HSR team has joined the Health Technology Assessment International (HTAi), and the Chair of the MDOC made an oral presentation on the work of the committee at the 2015 HTAi Annual Meeting. Attendance at such events allows staff to network with other hospital HTA practitioners and to learn best practices from around the world. The EHA HSR team has also joined HTAsiaLink, a regional network of HTA agencies in Asia and the Pacific and hosted as well as conducted a workshop on rapid HTA for another network member. We also co-hosted the HTAsiaLink Annual Conference in May 2016 in Singapore. The conference brought HTA users and practitioners from the region to Singapore, allowing local practitioners to exchange ideas and learn from their Asian counterparts.

As part of CGH's effort to improve the hospital-based HTA processes and framework, CGH has also invited international experts in hospital-based HTA, such as Professor Richard King from MonashHealth in South Australia, to engage in discussions with key stakeholders in CGH and make recommendations to improve the current processes for HTA in CGH.

## 23.9 Conclusion

The Changi General Hospital is a public sector tertiary hospital serving the population of Eastern Singapore as part of the Eastern Health Alliance regional health system. A strength of the hospital's planning and budgeting cycle is its Marketplace exercise, an innovative process in which departments desiring to start a new service or use a new technology have to make a presentation of their proposal before hospital management and stakeholders, thereby allowing stakeholders impacted by the new service to be identified and relative merits of many proposals to be considered for efficient allocation of hospital budget.

Health technology assessment is increasingly used in supporting decision-making on new services and technologies. HTA reports may be commissioned to assess technologies proposed at the Marketplace exercise or other grant applications, such as to support Health Services Development Programme applications.

The CGH Medical Devices Oversight Committee was formed in 2014 comprising a multidisciplinary team of stakeholder representatives to oversee the implementation of national standardised lists of medical implants and to monitor their utilisation. In addition, the MDOC formulates policies on medical devices and implants in the hospital and reviews evidence for new medical devices and implants.

The Eastern Health Alliance Health Services Research team conducts HTA for CGH, whether as part of the Marketplace or in support of the MDOC, or at the ad hoc request of hospital senior management. The team also conducts training on HTA methods to hospital staff both internally and externally.

Challenges in implementing hospital-based HTA include the time needed to garner stakeholder buy-in and the need for integrated processes to support governance of new services and technologies.

While only recently introduced to CGH, the hospital aspires to become a centre of excellence for hospital-based HTA.

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# Chapter 24
# Hospital-Based HTA in China

**Li Wang and Fang Zhu**

## 24.1 History of HTA in China

In order to understand the evolving role of hospital-based health technology assessment in China, this chapter will first explain the pace of development of health technology assessment across the country before explaining the hospital-specific component.

Health technologies are essential for a functioning health system. HTA has emerged as an important tool for supporting an effective health system. It aims to ensure the appropriate introduction, use, and disinvestment of health technology. In mainland China, a variety of HTA institutions were established in universities or academic institutes.

The earliest HTA institutions were established by the Ministry of Health's Department of Science and Education with the support from the World Bank, World Health Organization (WHO), and other international organizations (e.g., Cochrane Collaboration, China Medical Board of New York, etc.) in four universities in the 1990s, including State Key Lab of HTA in Fudan University, Appraising Center of Biomedical Engineering Technology in Zhejiang University, Medical Ethic Evaluation center in Peking University, and Chinese Evidence-based Medicine Center in Sichuan University [1]. Each of the four centers had a different focus:

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economic evaluation in Shanghai, medical equipment HTA in Hangzhou, ethics evaluation in Beijing, and evidence-based medicine in Chengdu. With the dissemination of evidence-based medicine and health technology assessment in China, more and more HTA-related institutions were gradually established around the countries, for example, the China National Health Development Research Center (CNHDRC), evidence-based medicine centers or HTA centers in Beijing, Shanghai, Guangzhou, Zhejiang, Lanzhou, Guangxi, Jiangshu, etc.

### *24.1.1 HTA Activities and the Impacts in China*

The most active HTA institutions were the HTA center in Shanghai and EBM center in Chengdu. The Shanghai Center was the first HTA institute to be established (1994) and was approved as Key Lab of HTA by the Ministry of Health (MoH) in 2004 and was furthermore designated as the WHO Collaborating Centre of HTA in 2008 (renewed to January 2018). It has established a few branches in Eastern China (e.g., Guangdong and Zhejiang provinces). The Shanghai center is located in the School of Public health in Fudan University. This center focuses on the assessment of interventions and policies to major public health problems, disease prevention, healthcare system performance, and bioethics evaluation of health technologies [2]. The Chinese EBM center was established as the first EBM center in China in 1997 by the Ministry of Health and was designated as the Chinese Cochrane Centre – the first Cochrane Centre in Asia, by the Cochrane Collaboration in 1999. It was further approved as a Virtual Research Centre of Evidence-Based Medicine by the Ministry of Education in 2002 and designated as the Chinese Clinical Trial Register of WHO International Clinical Trials Registry Platform in 2007 [3, 4]. The EBM center in Chengdu is located in one of the largest hospitals of China (West China Hospital) and focuses on the assessment of medical technologies, health policies, patient safety, and medical education. The Chengdu EBM center has established the Hong Kong Branch of the Chinese Cochrane Centre and over ten subcenters of EBM across the country. The Chengdu EBM center has trained over 10,000 potential contributors and now has a national network of 2,264 Cochrane reviewers from over 25 cities and provinces [5]. Both the Shanghai HTA center and Chengdu EBM center have professional teams for research and education. HTA and EBM are listed in the postgraduate student programs, and books on EBM and medical technology assessment have been published. Courses on EBM and HTA for undergraduate and graduate students have been gradually offered in some medical universities. Hundreds of thousands of health professionals and policy makers have taken part in the continuing education programs of HTA and EBM.

Most recently, a HTA unit was established in China National Health Development Research Center (CNHDRC), focusing on application assessment of high-tech medical devices, surgical procedures, and clinical operative technologies [6]. CNHDRC has cooperated with England's National Institute for Health and Clinical Excellence (NICE) to promote the development and use of evidence-based clinical pathways coupled with payment reform using HTA [7].

HTA institutions in China have already completed some HTA projects and produced HTA reports to support policy making for the MoH and decision-making for medical services. Most of these studies were supported by the MoH, the State Food and Drug Administration (SFDA), and other public funds. The first Chinese HTA report of "evaluation of folic acid strategy for prevention of neural tube defects" was produced by the Shanghai HTA center in 1997 [8].

Health technology assessments of gamma knife and magnetic resonance imaging (MRI), reproductive health technologies (e.g., artificial insemination, in vitro fertilization, prenatal diagnosis, and birth control methods), gene chip, some high-tech medical devices (e.g., Da Vinci surgical system, capsule endoscopy, CyberKnife, etc.), and innovative surgical procedures (e.g., transcatheter aortic heart valve, TAVI) have been completed.

Health technology assessment is used to support policy making in China. By the end of 1990s, the Ministry of Health made efforts to integrate HTA into policy making to improve the quality and efficiency of health care. Now using HTA for supporting policy making is scattered among many administrative areas. HTA work is currently commissioned and used by several government authorities: the State Food and Drug Administration (SFDA), the Ministry of Health (MoH), the State Family Planning Commission (now the three authorities above were merged as National Health and Family Planning Commission (NHFPC)), Ministry of Human Resources and Social Security (MOHRSS), National Development and Reform Commission (NDRC), and their think tanks.

1. *HTA supporting technology regulations and technology licensure mechanism*, including technology permission for use, institution licensure, and workforce licensure. For example, based on technology assessment of assisted reproductive technology, the MoH issued the "Regulations on Assisted Reproductive Technology," "Regulation on Sperm Bank," and the related standards and guidelines in 2001 and the "Administrative procedure of review and permission of assisted reproductive technology and sperm" in 2003 [23]. The MoH issued "Regulation of Prenatal Diagnosis" in 2003 after the HTA report of prenatal diagnosis was finished.
2. *HTA supporting the coverage of included health service,* e.g., essential medicine lists and government procurement catalogue for family planning. Health technology assessment was used for evidence-based adjustment of the national essential medicine list (NEML) [9], which is used for all the primary care institutes across China.
3. *HTA supporting disinvestment of health technologies.* For example, the Ministry of Health disinvested 35 clinical laboratory technologies by using HTA [1].
4. *HTA supporting health resource reallocation.* The Shanghai HTA center assessed gamma knife and MRI using socioeconomic evaluation to help the reallocation of health resource [8].
5. *HTA supporting clinical guidelines.* China National Health Development Research Center has been working with NICE and trying to establish a "China-NICE." [7]. HTA will be used to support the development of clinical guidelines in China.

In addition, SFDA is interested in using HTA for marketing approval (i.e., "registration") of new drugs and devices. Potentially, HTA will be used to support the reimbursement and pricing of basic health technologies (including drugs, surgical procedures, medical devices, etc.) in China. In recent policy documents for adjustment of the essential medicine list and drug reimbursement list, emphasis was put on the role of evidence-based assessment and pharmaco-economic evidence. According to the new healthcare reform requirements, the selection of essential medicines, drug price setting, national formulary, and clinical pathway need to gradually introduce HTA findings. Although this demonstrates, to some degree, that the policy makers have realized the importance and value of HTA, the application of HTA findings to policy making is not yet widespread, and the integration of HTA in the policy-making processes is still in its infancy in China [10].

In Taiwan, HTA has been considered pivotal for supporting decisions and policy making. The non-profit Center for Drug Evaluation (CDE) formed a division of HTA in 2007 and conducts HTA to review the medical products and related services for the Taiwan FDA [11]. It evaluates the new drugs, medical devices, and innovative surgical procedures, facilitates the communication between pharmaceutical companies and the government, and integrates evidence to support the Ministry of Health and Welfare (MOHW) in the policy-making process.

Hong Kong established the Clinical Effectiveness Unit in 1996, administered by the Hospital Authority, to provide current, accurate, and usable information on the safety and efficacy of new/evolving healthcare technologies or management practices that have potential application in HK. Initially, HTA reports from other countries were used for decision-making on technologies. But since 2001, HTA and technology reviews have been carried out. It published 28 HTA reviews which served as the scientific evidence for recommendations to authorities, professionals, and the pharmaceutical industry [12].

**Box 1: Health Care System Context**

1. *How is your health system funded in China?*
    - In China, the health system is administered by the National Health and Family Planning Commission and is jointly financed from public, social, and private insurance and out-of-pocket funding. Various mandatory or opt-in medical insurances exist for urban or rural residents of China, financed through a combination of employment taxes, government subsidies, and individual contributions. Major reform is still ongoing [13].
    - Patient out-of-pocket spending accounted for 34.4% of total health expenditure in 2012 [13].
2. *How are hospitals funded within the healthcare system of your country?*
    - In China, most hospitals and clinics are still government owned, but not all goods and services are paid for by the government. Government subsidies as a share of hospital revenue have been shrinking, and public

hospitals and clinics compensate their expenses by drawing revenue through requiring patient payment for some services, drugs, and technologies.
- Private hospitals also operate within China, operating on private funding and direct patient payment, or insurance payment.

3. *Who is responsible for making decisions about which drugs, devices, and capital equipment will be funded for the hospital?*
   - In China, public hospitals are government-owned and administered provincially. Most decisions are generally made at the individual hospital level, except for the drugs from national medicine lists [14–17] and other medical service lists (e.g., medical exams, surgical procedures or other treatments, standard hospital room, etc.) for reimbursement purposes. These reimbursement lists were made nationally and adjusted by provincial health authorities according to local demands [14–18].
   - The National Development and Reform Commission (NDRC) regulates the ceiling retail price of the essential drugs and other medical services, and the government can also make adjustments to suit provincial needs [19–23].

## 24.2 Introduction of Hospital-Based HTA in China

In the hospital context, it is extremely challenging to perform a comprehensive HTA as the time and other resources are very limited for the decision on the acquisition of a new technology and disinvestment of an old technology. Hospital-based HTA (HB-HTA) has been developed to address the specific challenges of technology assessment in hospital settings. The contextualization of HTA to a specific hospital brings into the assessment process with its unique characteristics, such as the available resources, choice of an available comparator, and the specific organizational patterns of the hospital.

### *24.2.1 Three-Level Management of Health Technology for Hospitals in China*

In China, there are three levels of management for health technologies in hospitals since the "Regulation of Clinical Application of Medical Technology" was issued by the MoH in 2009 [24]. Health technologies are categorized into:

*Level 1*. Safe and effective health technologies – the hospital can ensure the safety and effectiveness in clinical application by regular management. The hospital takes responsibility for the selection and application of Level 1 health technologies.

*Level 2*. Safe and effective health technologies but with some ethical concerns or relatively high risks; the health authorities should control the clinical application. Provincial health authorities are responsible for the approval and management.

*Level 3.* Health technologies with major ethical concerns, very high risk, uncertain safety and efficacy (and clinical research is needed to confirm its safety and efficacy), need for scarce skills or resources, or other special technologies that need strict control and management. The MoH is responsible for approval and management of Level 3 health technologies.

This regulation also defines the process for permission for technology use, institution licensure, and workforce licensure. This regulation mandates the assessment of health technologies for use in hospitals and has facilitated the rational use of new technologies and disinvestment of old technologies in China. Some HTA projects for Level 2 and 3 health technologies have been supported by the MoH, e.g., gene chip, CNS surgery for drug abusers. However, most recommendations and so-called assessments have been based on expert opinion, rather than on "real" health technology assessment based on the current best evidence.

On June 29, 2015, the National Health and Family Planning Commission (NHFPC) terminated the previous process for assessing Level 3 health technologies [25]. As a result, hospitals are now individually required to take responsibility for the organization and management of clinical application of medical technologies. All the medical institutions should be in accordance with the requirements by the "Regulation of Clinical Application of Medical Technology," strengthen the awareness of responsibility, establish and improve the clinical application of medical technology management system, and establish the document system of medical technology assessment and management. If the hospital wants to use Level 3 health technologies in clinical practice, it has to apply to the provincial health authorities. NHFPC sponsored HTA projects to assess some of Level 2 and Level 3 health technologies since 2014 after NHFPC set the priorities and scopes of HTA projects [26].

### *24.2.2 Hospital-Based HTA Units and Process*

Hospital-based HTA (HB-HTA) is not mandated in China. There are very few HTA units located in hospitals. Most of the existing HB-HTA units are funded by hospital operating funds or by research grants from national or regional health authorities. The staff of HB-HTA units in China typically includes administrative staff (e.g., administrative assistant, project coordinator), medical researchers (e.g., systematic reviewers, economists, and statisticians), medical students, and clinicians (usually part-time staff). Sometimes, other stakeholders (e.g., decision-makers, nurses) are involved in specific HTA projects. Patients rarely participate in the HB-HTA in China. The committee members usually include vice CEO (chair of the committee), director of the division of medical affairs, an ethical expert, and chairs of the major

clinical departments (e.g., department of general medicine, department of surgery, etc.), pharmacy, and financial department. However, despite initial efforts to perform HB-HTA, in reality, the so-called "HB-HTA" activities in China are largely based on the expert opinion of the assessment and permission committees of health technologies in hospitals.

Usually health professionals (e.g., physicians, pharmacists, or nurses) request the technology assessment. Sometimes, pharmaceutical companies or medical device companies ask for the assessment. They are required to submit the application to the administrative units of hospitals, e.g., division of hospital medical affairs. The application includes not only information about the technology itself but also the qualification of the health professionals and conditions required for the hospital to ensure support for safe clinical application. After submission, the hospital administrative unit organizes the technology assessment meetings at the relevant department level (e.g., department of surgery if new surgical procedure is applied) and hospital levels. Some of Level 2 and Level 3 technologies were sent to the third-party HTA institutions for assessment. The decision to invest/introduce the technology will be made after the assessment is done either within hospital or by external assessors. If it is approved for clinical use, the applicants are required to establish a team to explore the clinical application. The principle investigator of the team is responsible for monitoring and recording the clinical application and progress. Each year, the team has to summarize the resulting clinical impact of the technology after implementation, by providing the cases performed, alongside a literature review of this technology. The hospital technology assessment committee reviews the program again to decide if it should be continued, expanded for widespread use, or canceled.

### *24.2.3 Case Reports of HB-HTA and Impact*

Most HTA projects have been conducted based on the needs of the MoH or personal interests of researchers and clinicians in China. Some HTA projects played an important role in decision-making, particularly for policy making, as described in the first section of this chapter. Some HTA projects supported decisions of investment/disinvestment of technologies at the individual hospital level, as outlined below.

For example, the MoH Department of Science and Education contracted the Chengdu EBM center for a rapid review to assess the gene chip for diagnosis of hepatitis in 2002. The new gene chip was compared with the enzyme-linked immunosorbent assay (ELISA) test, real-time fluorescence quota PCR (RT-qPCR), and other gene chips with respect to the sensitivity, specificity, accuracy, target DNA sequence, operation complexity, costs, and time per test. The application provided comparative data from a trial of the gene chip versus ELISA and PCR among 66 samples taken from hepatitis B and C patients. Despite no safety and efficacy concerns, there was insufficient evidence to adequately assess the diagnostic efficacy,

and it was costly. Based on the HTA report on the comparative assessment of gene chip versus alternatives performed by the Chengdu EBM center in Chengdu hospital, the MoH declined permission of clinical use of the new gene chip technology [1].

Another case example relates to the assessment of transcatheter aortic valve implantation. Surgeons from one tertiary hospital submitted an application to the provincial department of health to introduce transcatheter aortic valve implantation (TAVI) for high-risk patients with tricuspid aortic valve stenosis. The Provincial Department of Health authorized the Chengdu EBM center to perform a rapid review HTA. The rapid HTA supported the application of TAVI for the applicant hospital, due to the expected benefit-risk ratio derived from best available evidence. Since the first case was treated with TAVI in April, 2012, this team has applied TAVI to treat 100 patients by August 19th, 2015 [27]. The team achieved the "CoreValve Physician Proctoring Program Certificate of Completion" in June, 2014, a paper outlining their experience and outcomes was published by the team in "Nature Reviews Cardiology" in October, 2014 [28].

## 24.3 Lessons and Future of HB-HTA in China

### *24.3.1 Lessons and Challenges of HB-HTA in China*

In China, there are no "real" hospital-based HTA units based on current definitions of HB-HTA elsewhere in the world wherein a devoted unit of experts contribute to ongoing HTA needs of the local hospital setting. Although some HTA institutions have contributed to hospital-based HTA, not all of these hospital-relevant HTA activities exist within the hospital setting for the express purpose of informing local contextualized health technology decisions using the best available evidence combined with local resource considerations and local social, ethical, and organization considerations. Since the decision-making of investment/disinvestment and management of hospital health technologies tends to be largely decentralized in China, and since the purchase and acquisition of new technologies or disinvestment of old technologies are performed more at the regional or local level and less at the central level, there remains a great untapped opportunity for local hospital-based HTA units to serve these local needs. On the one hand, hospitals are facing increased pressures to control budgets and increase their efficiency; on the other hand, there are economic and politic incentives to introduce "new" technologies to hospitals without assessment "barriers." It remains to be seen whether, in this current milieu, HB-HTA will be seen as more urgent and important to decision-makers in both hospitals and health authorities than before.

In China, there are over 986,000 healthcare institutes as of May 2015, including 26,479 hospitals (13,326 public hospitals and 13,153 private hospitals), 921,927 primary healthcare institutes, and 34,992 public health institutes [29]. It would be almost impossible to establish HB-HTA unit for each hospital. The three-level or three-category assessment and management of health technologies is still very effi-

cient and useful for China as an organizing framework. However, the assessment of technologies should shift from expert opinion to the best evidence of HTA, i.e., decision-making based on evidence-informed HTA instead of relying primarily on experts' review.

In a study of 12 HTA institutions in China, the operation of most HTA institutions relied on research funds, and there is no stable financial support from the government [30]. Most HTA institutions work isolated without overall integration nationally and without support for HTA in the legal framework of the national health system. There is no national HTA commission to coordinate HTA activities at the different authorities and different HTA institutions. Lack of awareness of HTA for decision-making exists in most health authorities and decision-makers in hospitals. Decisions are still taken based on (often ad hoc) expert opinion and regulatory requirements. More qualified staff/researchers are required to meet the great need for awareness, education, and performance of HTA in the hospital setting. Overall, the scope of HTA application to date is very narrow in China. There is a huge gap between decision-making and HTA research, and there is no functioning dissemination channel for HTA results [31].

### *24.3.2 Vision of the Future of HB-HTA in China*

China needs to have legislation to promote HTA both nationally and locally. China would also benefit from a national HTA network to share knowledge and to build capacity. China should establish national legal processes of HB-HTA (separate from regulatory approval processes) to ensure a clear understanding of the objectives and how HTA fits within the health system based on local policy, culture, values, and medical practice for a proper and transparent HTA process. Through top-design, the national HTA strategies should be developed with a comprehensive plan for development of methodology, databases, data sharing, and capacity building. National guidelines for HTA and HB-HTA should be developed to standardize the processes and contents of evaluation, and knowledge translation strategies should be established. Stable funding and quality control for HTA projects will be essential. In addition, an early dialogue and full engagement with all stakeholders (including policy makers, industry stakeholders, and patient groups) should also be developed as part of the HTA process. Training and education in HTA (including specific skills for HB-HTA) are needed for the capacity development and for receptivity development in medical students, residents, doctors, and decision-makers. International exchange on experience and lessons learned is very important. Hospitals could use the third-party assessment for technology permission and management. In other words, initially to ensure quality, HB-HTA needs could be fulfilled by working in collaboration with regional or national HTA institutions via collaborative outsourcing. The Chinese government has already realized the importance of HTA and hospital-based HTA, a series of actions have already been initiated. But, much more needs to be done to reach the productivity and impact demonstrated by HB-HTA units in other areas of Asia and the world.

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# Chapter 25
# Hospital-Based HTA: The Australian Experience

**Guy Maddern**

## 25.1 Introduction

Health technology assessment (HTA) within the Australian hospital system has not been introduced in any systematic or consistent fashion. The Australian health insurance system is complex, with almost half of the population carrying private health insurance and the other half being managed by the public health system. This is further complicated by an overlap between payments made for private work by the public insurer as a contribution towards procedures conducted, with supplementation coming either from the patient or the private health insurer. Hotel costs associated with the hospitalisation for private patients are picked up by the private health insurer in most cases. Irrespective of one's insurance status, however, individuals can present to public hospital facilities and have free healthcare provided.

Within Australia, the State jurisdictions are responsible for delivering public hospital care to their residents. The funding stream for this comes largely from the Federal Government paid to the State Governments who then administer the public hospital system. This leads to a number of somewhat perverse incentives in trying to cost shift from the State to the Commonwealth, leading to a complex and difficult system to administer and manage. Into this complexity arrive new health technologies which require assessment at both an Australia-wide level and also a State level and ultimately to the hospital level.

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## 25.2 Technology Assessment

In order to provide information to the health system, a number of organisations and assessment agencies have been put in place. The Therapeutic Goods Administration (TGA) [1] is a Federally based organisation designed to assess devices and technologies as well as drugs introduced into the Australian health system. In almost all cases, devices and drugs would need TGA oversight, assessment and approval before they could be made available to Australian citizens and the Australian health sector. The TGA functions in a very similar fashion to the Food and Drug Administration (FDA) in the United States in its role in determining appropriateness of technologies made available into the health system. Once a device or a drug has approval to be introduced into the Australian healthcare system, it can be purchased by patients, doctors or hospitals if they wish to use the product in the care of their patients. There is, however, no guarantee that rebates will be offered from the public system to support their use. For this to occur, independent scrutiny of the medications needs to occur through a committee that recommends to Government support for medications to be placed onto the national formulary [2, 3].

With respect to new procedures or devices, this needs to go to the Medical Services Advisory Committee (MSAC) [4–6]. MSAC is lobbied by governments, industry and doctors to assess and evaluate new technologies which are then subject to rigorous systematic review and evidence collection in order to determine whether or not the Federal Government, through the national insurance process, will provide support for the intervention. Without inclusion in the Medical Benefits Schedule, it is unlikely that a private health insurer would agree to contribute towards the cost of an intervention. In this way, MSAC acts as a gatekeeper for introduction of new devices and technologies into use even if they have been approved by the TGA.

Supplementing the work of MSAC is a group constituted by State representation known as HealthPACT [7], which functions to evaluate new technologies that have not yet arrived into practice and may well not have even been assessed by the TGA. It has something of a horizon scanning role although on occasions it will look at new technologies that have not yet been reviewed by MSAC but are being lobbied for by patients, hospitals or doctors for introduction into the health system. This organisation has moved from being an advanced health alert organisation to one much more at the near to introduction or recent introduction into the health system.

## 25.3 Hospital HTA

With all of these Federal activities in place, hospital HTA appears in a sporadic and inconsistent fashion within the Australian hospital system. Some large public hospitals have found the need to create health technology assessment units within their organisations to provide timely advice for innovations being lobbied for from within their organisation. These committees are constituted in various

fashions and perform mixed functions. In addition to hospital health technology assessment, State governments within Australia have also formed committees to assess and advise the introduction of new health technologies into the public hospital system. These have varying compositions and varying roles with their State organisation. Some of these committees are charged with the responsibility of actually determining whether or not a device or procedure should be introduced, while others merely provide a recommendation to be determined by the local health authority as to whether or not it wishes to proceed based on budget, volume and cost. An example of the considerations made in decisions for the South Australian Policy Advisory Committee on Technology (SAPACT) is summarised in Table 25.1. These committees are encouraged to interact with hospital health technology groups if they exist at all.

## 25.4 Assessment Processes

### *25.4.1 Drugs*

Within the Australian scene, the Pharmaceutical Benefits Advisory Committee (PBAC) [2] provides the assessment as to whether or not a drug can be introduced into the national formulary. This feeds down to State jurisdictions and hospitals as to the availability of medications. If supported by PBAC, drugs are available at a concessional price to the public, making it highly desirable for these medications to be purchased through the Federal process rather than individual State jurisdictions and hospitals buying direct. When a medication has not been approved by PBAC but has progressed through the TGA, the hospital may elect to purchase it direct but may have to carry the full cost. In many cases this can be substantial, making the availability of expensive chemotherapeutic agents beyond the budget of many public hospital facilities. This is a problem which often leads to delay in being able to bring into practice important new pharmacological developments.

### *25.4.2 Devices*

As stated previously, the TGA will authorise that a device is safe and appropriate to be introduced into the healthcare setting. Public hospitals will have to determine whether they can afford to purchase these devices based on the budget given to them by the State Department of Health. In order to facilitate this decision, health technology assessment committees have developed in many of the larger hospitals. They largely rely on systematic reviews, expert opinion and industry representation to determine whether or not the technology is appropriate for their use. The literature that is used is often taken from overseas studies, in which case

**Table 25.1** Decision-making criteria

| Criteria | Sub-criteria |
|---|---|
| Clinical need | Burden of illness |
| | The burden of illness on society of the target condition to which the technology is applied (e.g. incidence, prevalence, years of life lost, years live with disability, disability-adjusted life years) |
| | Need |
| | The need for the technology compared to the availability of alternatives to manage the target condition |
| Clinic benefit | Effectiveness |
| | Effectiveness compared to available alternatives (measured in terms of relative risk, odds ratios, mortality, survival, morbidity, length of stay, etc.) |
| | The magnitude and direction of the technology's effect should be considered |
| | Safety |
| | Frequency and severity of adverse events specific to the technology compared to available alternatives |
| Value for money | Value for money |
| | A measure of the net cost or efficiency of the technology compared to available alternatives |
| | Can be assessed in many ways including incremental cost-effectiveness ratio (ICER) or incremental cost-utility ratio (ICUR) cost per unit/outcome |
| | Experience from international/other jurisdictions can be used |
| Feasibility of adoption | Economic feasibility |
| | The net budget impact of the new technology |
| | Costs for other system enablers (e.g. information technology, capital works, workforce remuneration/recruitment/training) |
| | Funding implications (statewide/superspecialty status) |
| | Organisational feasibility |
| | The ease with which the health technology can be adopted by looking at other enablers and/or barriers to diffusion |
| | Infrastructure/geographical/clinical services capability framework/impact on other service streams (e.g. rehabilitation services)/ability of applicant to perform field evaluation (where relevant) |
| Consistency with expected/societal/ ethical values | Psychological/social considerations |
| | Broadly shared values in society that bear on the appropriate use and impact of the technology |
| | Ethical considerations |
| | The potential ethical issues inherent in using or not using the technology |
| **Recommendation** | |
| *Recommended*: approved with no further need for assessment | |
| *Restricted recommendation – audit*: approval subject to implementation under audit conditions. Conditions are specific to the technology | |
| *Restricted recommendation – clinical trial*: endorsed, however approval subject to implementation in clinical trial with SA Health Human Research and Ethics Committee approval | |
| *Restricted approval – operational restrictions*: endorsed, however financial or operational restrictions apply | |
| *Not recommended* | |

the context may not always be entirely appropriate, leading to concern that the success of the device reported internationally may not be replicated within the Australian context or in the particular population that is served by the hospital considering these devices. It is often the case that strong representations from particular clinical groups can lead to adoption of new device technology which may prove to be of little benefit to the burden of disease being treated. There is very little published literature available supporting this observation as neither doctors nor hospitals particularly wish to demonstrate inappropriate introduction of new technologies that has occurred. There have been many examples of technologies introduced within the health system that have subsequently completely disappeared from contemporary practice, indicating perhaps undue haste in their adoption within the health system [8].

### *25.4.3 Procedures*

Procedures represent an even greater problem for health technology assessment within the hospital context. A new procedure can be introduced that has no particular link to a drug or a device but is exploiting existing devices and/or medications and some new form of surgical intervention that is thought to bring clinical gain to the patient. MSAC may or may not have considered this procedure; however in the public health system no rebate is required for its practice; therefore awaiting an MSAC review is not necessarily required.

Within Australia, almost all surgeons are Fellows of the Royal Australasian College of Surgeons. This organisation has set up the Australian Safety and Efficacy Register of New Interventional Procedures in Surgery (ASERNIP-S) to help review new procedures and devices that become available to surgical practice [9, 10]. This organisation has been functioning now for in excess of 16 years and has been able to provide authoritative guidance to hospital HTA committees. In particular, it has published guidance on the introduction of new health technologies into a hospital environment [11]. This guidance proposes to provide general direction to hospitals and health services about the assessment of new surgical procedures and the factors that should be considered prior to their introduction. In this document a new surgical procedure is defined as one that has not previously been used in that particular hospital or health service and represents a significant departure from previous practice. It recognises that often the decision about whether to introduce a new surgical procedure is a balance between the desire to advance knowledge and increase experience with the potential risks of new procedures.

Even if new procedures have been thoroughly evaluated elsewhere, they may not have been assessed under particular local conditions. Any decision should also include an assessment of whether the new procedure is intended to replace or complement an older procedure and the perceived advantages of new versus old. It further points out that the introduction of a new procedure has an opportunity cost. It will consume resources that would have been used elsewhere and a judgement

needs to be made about the benefits of the new procedure and the diversion of resources away from existing procedures. It asks some important questions:

- Has the technique been previously evaluated?
- How reliable is the evaluation?
- How wide ranging or complex is the procedure?
- What training and experience are required to introduce the procedure or technology into the hospital?

Appropriate clinical governance needs to be in place and a formal application needs to occur as well as an acknowledgement of the resource utilisation, predicted demand and the consent process that should occur for patients. An understanding of the learning curve, the consent process and the monitoring that will occur when the procedure is brought in needs to be assessed. These questions are placed into a simple questionnaire that needs to be filled out by the individual or group wishing to introduce a new procedure or technology into a hospital and this can be assessed by the hospital-based HTA organisation. It is, of course, entirely suitable to modify this approach if the hospital has particular requirements or concerns regarding the information being sought.

### *25.4.4 Systems*

The systems surrounding the delivery of healthcare within countries, states and hospitals represent an important and increasing area of research and analysis. Hospital-based systems of care can be delivered in efficient and effective ways or can be extraordinarily wasteful and poorly focussed. Largely, systems of care are delivered either by States within Australia or at the local hospital level. If, for example, a hospital wishes to move to an increased utilisation of day surgery, then appropriate systems of early placements of the procedure during the day, appropriate follow-up after the operation, home nursing and availability of 24 hour support need to be put into place for these initiatives to be successful. These types of system approaches have been either left to clinical units within a hospital or sometimes individuals to establish.

Hospital health technology assessment bodies, when they exist, are the ideal venue to have such initiatives assessed and critiqued prior to their introduction. Unfortunately, within the Australian health system, system changes are often introduced without such evaluation and it is only when they fail to deliver the promised benefits that they may come to the attention of the hospital or the State jurisdiction. Often these changes can be introduced without necessarily employing additional staff or, indeed, incurring additional cost but whether or not the care is genuinely improved by them can be poorly evaluated or, indeed, completely opaque to the system. Mechanisms should exist for such changes to be evaluated by hospital HTA and this can only occur if such an organisation exists within the hospital and if it is,

in fact, aware of the change that has occurred. It is particularly in this area of systems control that hospital HTA seems to still be struggling.

### 25.4.5 Practitioner Control

Hospitals require systems of developing credentialling and scope of practice for doctors working within their jurisdiction. This has been a relatively new development within the Australian healthcare system and is not always well understood by either the hospitals or the practitioners working within it. Credentialling is the process by which an individual practitioner is evaluated as to whether or not they are capable and competent to conduct certain interventions. For example, a general surgeon may be considered competent to conduct laparoscopic surgery of the upper gastrointestinal tract but not necessarily to conduct colorectal laparoscopic surgery. Similarly, colonoscopies and endoscopies may not always be appropriate for an individual practitioner to perform, depending on their prior training.

Overlaid onto this "credentialling" process is the "scope" of practice. While an individual may be competent to perform certain procedures, a hospital may not necessarily be appropriately equipped or resourced to permit these procedures to be conducted. For example, maybe in a smaller regional hospital, operations such as oesophagectomies and liver resections would be entirely inappropriate. A surgeon visiting such a hospital may be credentialled to perform these operations but the scope of practice at that particular hospital would not permit the surgeon to perform these procedures at these sites. An understanding of the interplay between credentialled and scope of practice is still sometimes leading to confusion and this confusion can also be shared by hospital HTA bodies if they are not fully aware of the skill set of the practitioners available at their site.

### 25.4.6 Cost

Adding to this complexity is the issue of the funding for these interventions. It needs to be understood whether or not the funding has come from the recurrent budget of the hospital, whether there is additional funding from the State or whether, in fact, the funding has come for the procedures or the devices from industry. Industry-funded interventions, while permitting the early introduction into a health system, have the disadvantage of denying it to the system if the support of industry is withdrawn. Industry funding, when delivered as a marketing tool, is probably unhelpful and should be appropriately warned against by a hospital health technology assessment committee. If, on the other hand, industry funding is provided as part of a trial to assess the efficacy and suitability of the technology into the local health system, this can be supported but should probably be conducted under the supervision of an

ethically approved study. These types of questions and solutions are well served within a hospital HTA committee.

## 25.5 Conclusions

Hospital health technology assessment within the Australian hospital system remains at best haphazard with no clear unifying guidelines as to how such committees should be constituted or how they should operate. This is in part due to a lack of appreciation of the role of assessment of new interventions, procedures and drugs into a system but also because the resourcing for such activities has been poorly supported.

It is unrealistic to have formal health technology assessment structures in place for hospital HTAs within Australia but State jurisdictions can certainly provide such support which hospital committees can then draw on. This has also not occurred in any consistent fashion around the country. Some States have excellent State-based HTA groups; others have poorly constituted and resourced organisations. The process of health technology assessment is very much left to champions within hospitals and the local health system to push for appropriate appraisal of interventions being put forward.

Within the Australian hospital system, if mechanisms can be found to introduce a new technology or procedure without going through a health technology assessment, this will be the likely direction taken. It is only when blocks are put into place that resorting to either a State or hospital health technology assessment agency is likely to occur.

As of 2015, the health technology assessment agencies within hospitals are very much seen as a place of last resort rather than the first port of call for introduction of improvements that may be available to community that serve.

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# Chapter 26
# Hospital-Based HTA in New Zealand

**Anita Fitzgerald, Stephen Streat, Caroline McAleese, and Stephen Munn**

## 26.1 Background

In New Zealand there are well-defined pathways for the registration, assessment, funding and procurement of pharmaceuticals for the hospital setting and ambulatory setting. Applications for the registration of new medicines are evaluated by an advisory committee and recommendations to approve the registration of such new medicines are in accordance with the terms of the Medicines Act 1981. Submissions are thereafter made to the Pharmaceutical Management Agency (PHARMAC) which undertakes evaluations of safety, efficacy and cost-utility and these evaluations are then scrutinized by the Pharmacology and Therapeutics Advisory Committee (PTAC), made up of subcommittees of interested clinicians. Recommendations with priority weightings are made for funding, allowing costs to be contained at a national level.

Unlike pharmaceuticals, medical devices are not required to be evaluated by a regulator for safety, efficacy or cost-utility evaluation nor are there tracking requirements for implantable devices. Because there has been no centralised process for evaluating medical devices by HTA, distributors and manufacturers attempt to disseminate devices by marketing directly to clinicians in the hospital setting. Similarly, decisions about the use of diagnostic equipment and test kits and new medical and surgical services (which are often introduced in conjunction with a medical device or diagnostic equipment) are usually made by hospital managers on the basis of affordability and/or the ability to cost-shift or are approved by hospital procurement units without evaluation.

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Since 2005, the Auckland District Health Board (Auckland DHB) in New Zealand with an annual budget of around NZD$2 billion and 10,000 staff has operated a hospital-based HTA committee evaluating a wide variety of new health technologies. Since 2014, the scope of the Committee has increased to accommodate the interests of three adjacent DHBs (Waitemata, Counties Manukau and Northland) and is called the Northern Region Clinical Practice Committee (NRCPC). The Committee is made up of 12 clinicians with representatives from all four DHBs, chosen for their clinical expertise and ability to analyse evidence dispassionately and apolitically and are supported by analytical, economic and administrative staff.

**Box 1: Health Care System Context**

*How is your health system funded*? Public funding.

*How are hospitals funded within the health-care system of your country*? Hospitals are funded regionally through district health boards (elected and appointed members).

*Who is responsible for making decisions about which drugs, devices and capital equipment will be funded for the hospital*? Decisions about the funding of drugs are made by a specific drug-buying agency called PHARMAC which conducts formal HTAs. Devices and capital equipment funding is controlled at hospital level, usually by senior management on the advice of expert clinicians.

## 26.2 Submission Process

Requests for HTAs come from a wide variety of sources, although the majority originate from the Chief Medical Officers (CMOs) who request assessments to support decision-making about the implementation of new technologies. Other protagonists include individual clinicians, small groups from within hospital departments, procurement staff and occasionally medical device companies. The NRCPC approach is to compare patient pathways (current vs. proposed) using the best available evidence for safety, efficacy and cost-utility, and where available, current local costs with those anticipated if the new health technology were to be implemented. To date, technologies analysed have included medicines, medical devices, diagnostic tests and services; the Committee has judiciously avoided more distantly related health technologies such as information systems or support services such as human resources. Over the past year, in response to the need for time-critical evidence-based decision-making within the hospital, the Committee has also begun producing technology briefs; detailed literature reviews of the published data reporting safety and efficacy but often with limited information about costing. Further examples are provided later in the chapter.

Submitters wishing to have their technology assessed by the Committee can access a toolkit available on the hospital intranet. The toolkit walks protagonists through the submission process, from preliminary discussions with hospital units and management staff to making a formal submission to the NRCPC. Informal discussion with the NRCPC chair person is most often the applicant's first engagement with the Committee and provides an opportunity to discuss the new technology and whether a submission to the NRCPC is required. Once this route has been decided, applicants are asked to complete a submission document which requires information about the clinical pathway, best available evidence for effectiveness, safety, cost-utility and the best estimate of resources (operating capital, costs, staff and space). NRCPC support staff often assists applicants with their submissions, particularly with drafting patient pathways and obtaining cost data.

Having received a formal submission, the NRCPC conducts an independent search of the literature and reviews the best available evidence. Two Committee members are nominated to review the submission and evidence in detail. A formal meeting then takes place where the applicants are invited to present their proposal to the Committee and address questions from the Committee members, following which they leave the meeting and the Committee hear from the two Committee members who reviewed the topic in depth.

To assist in the comparison of dissimilar health technologies applied in different medical disciplines at different DHBs, the NRCPC developed a scoring tool (Fig. 26.1). The score given to each HTA or technology brief depends on cost-utility, predicted health improvements and the quality of evidence (based on the levels

| Patient outcomes | Procedure costs | | Quality of Evidence | | | |
|---|---|---|---|---|---|---|
| | | | A | B | C | D |
| Outcomes improve or remain unchanged | Procedure costs will be reduced | Cost neutrality expected within 12 months | 100 | 90 | 40 | 30 |
| | | Cost neutrality expected within 1–2 years | 90 | 80 | 35 | 25 |
| | | Cost neutrality expected within 1–5 years | 60 | 50 | 30 | 20 |
| Outcomes improve | Procedure costs remain unchanged | | 60 | 50 | 30 | 20 |
| Significantly improved survival | Procedure costs will increase | | 40 | 30 | 20 | 10 |
| Significantly reduced morbidity | | | 20 | 15 | 10 | 5 |

**Fig. 26.1** NRCPC scoring tool

of evidence used by the Scottish Intercollegiate Guidelines Network[1]). In addition to the scoring tool, editorial notes are discussed to contextualise the agreed score and to explain the NRCPCs interpretation of the evidence.

The NRCPC routinely recommends submissions be implemented or declined or that they have interim approval with data collection and audit of that data at 1–2 years. The latter often occurs when there are uncertainties about efficacy, but no (or very few) safety concerns, or where there are uncertainties about whether the proposed costs are reproducible in the hospital setting. In these cases, management responses often require protagonists to undertake a limited number of cases and collect data for audit.

The process for producing technology briefs is less formal in that the briefs are produced in-house and either circulated via e-mail or presented to the Committee face to face.

Once completed, both the traditional HTAs and the shorter technology briefs have been prefaced by advisory letters to the CMOs of all four DHBs containing the score, editorial comments and the recommendation agreed by the NRCPC.

## 26.3 Submissions Over 10 Years

While the NRCPC is an advisory Committee, for the most part, decision makers at Auckland DHB have made decisions concordant with the recommendations of the NRCPC (Fig. 26.2). Low-scoring submissions (<30) are often declined, whereas high-scoring submissions (>60) have not been declined to date. The interim approval (with data collection) strategy has had variable outcomes based on the willingness of the implementing clinicians to collect accurate data about both costs and outcomes. Of the 13 technologies for which the NRCPC has recommended interim approval with data collection, 5 were subsequently implemented, 3 remain unfunded, 3 were declined and follow-up was not possible for 2.

Examples of high-scoring submissions include: sacral nerve stimulation for faecal incontinence, bevacizumab treatment of diabetic macula oedema, fetoscopic surgery for twin-to-twin transfusion syndrome and the Barrx Flex® (formerly HALO) system for radiofrequency ablation of the lower oesophagus. Examples of submissions receiving mid-range scores include: photodynamic therapy for cholangiocarcinoma, long QT syndrome genetic testing; IgE testing for food allergies and outpatient ORL laser treatment of polypoid lesions. Examples of low-scoring submissions include: pre-filled midazolam syringes (in the preoperative area), percutaneous pulmonary valve placement, rituximab treat-

[1] Scottish Intercollegiate Guidelines Network. SIGN grading system 1999–2012. http://www.sign.ac.uk/guidelines/fulltext/50/annexoldb.html

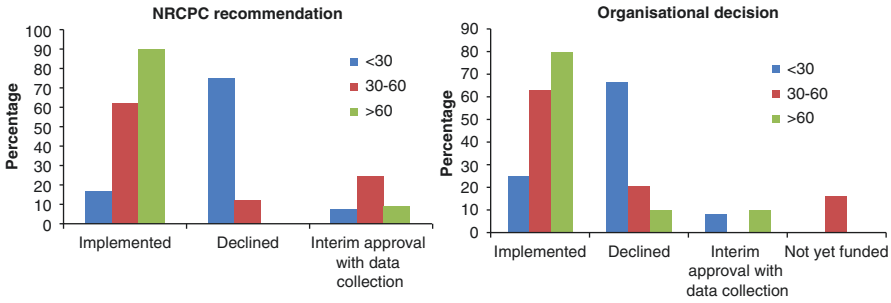


**Fig. 26.2** NRCPC submissions over 10 years (2005–2015)

ment for SLE, home humidification for xerostomia and high-dose intravenous vitamin C for severe respiratory illness. Over the last couple of years, the NRCPC has seen resubmissions of previous technologies where either better evidence for the proposed technology has become available or a local study has provided more data about efficacy and/or cost.

There have been 84 submissions over the 10-year period of operation; the following are two examples illustrating two different types of submission: lab tests and clot retrieval for patients with proximal anterior circulation occlusion.

### *26.3.1 Lab Tests*

LabPlus is a government-funded diagnostic laboratory serving central Auckland and is the major referral laboratory for the North Island of New Zealand. It receives approximately 4,000 specimens and performs approximately 15,000 tests per day. Audits had revealed markedly skewed distributions of test requests for vitamins and minerals, with a few requestors accounting for a disproportionately large share of the tests. In this group, it appeared that tests were mainly being used for screening in a generally well population. A consensus position on the appropriate indications for tests and on restriction waivers for certain categories of requestors or patients was reached by conducting a literature review, consultations with relevant specialists as well as GP representative groups and by formal submission to the NRCPC. The development of policy documents explaining the reasons for test restrictions, the development of fact sheets about the restricted tests and vetting of test requests by consultant chemical pathologists resulted in a marked reduction in the number of tests performed with the implementation of restrictions (Fig. 26.2). No adverse clinical events resulting from the new policy were reported to the laboratory. As a by-product of streamlining and ensuring the service were not overwhelmed was the considerable opportunity for disinvestment. Table 26.1 outlines reduction in the number of tests and the associated cost savings.

**Table 26.1** Outcomes of test restrictions on savings

| Test | Number of tests pre-restriction (per month) | Number of tests post-restriction (per month) | % decrease | Cost per test (NZ$) | Savings per year (NZ$) |
|---|---|---|---|---|---|
| Serum zinc | 662 | 136 | 79 % | 22.19 | 14,0063 |
| Serum copper | 176 | 82 | 53 % | 22.19 | 25,030 |
| Serum selenium | 62 | 21 | 66 % | 22.19 | 10,917 |
| Blood mercury | 56 | 27 | 52 % | 22.19 | 7,722 |
| RBC magnesium | 117 | 0 | 100 % | 16.64 | 23,363 |
| DHEAS | 733 | 100 | 86 % | 13.1 | 99,508 |
| Insulin | 406 | 126 | 69 % | 14.2 | 47,712 |
| Homocysteine | 245 | 52 | 79 % | 16.24 | 37,612 |
| Lipoprotein(a) | 140 | 32 | 77 % | 32.93 | 42,677 |
| 25-Hydroxyvitamin D | 2,906 | 458 | 84 % | 16.58 | 487,054 |
| SHBG | 739 | 212 | 71 % | 10.72 | 67,793 |
| Total | | | | | 989,452 |

### *26.3.2 Clot Retrieval for Embolic Stroke*

A recent submission to the NRCPC involved investigating the provision of a clot retrieval service at Auckland City Hospital for the northern region DHBs. Compelling evidence indicated that clot retrieval within approximately 6 h in patients with proximal anterior circulation occlusion was associated with significant improvements in the modified Rankin scale related to neurological disability and a decrease in mortality in some of the studies. An Australasian trial including patients randomised from Auckland City Hospital reported that patients in the intervention arm had slightly reduced hospital costs and that estimates of nursing care costs for the severely disabled indicated further savings. The NRCPC debated the practicalities of establishing a regional service, considered the inter-district revenue flow between organisations and asked questions about resource use, particularly the ability of current interventional radiologists to provide this service on a 24-h basis. The submission was supported, on the proviso that audit data be made available to the NRCPC following 2 years of data collection; a service delivery model is currently being discussed with funders.

## 26.4 Post-implementation Issues

Implementing recommended advice is an activity that has not received a lot of attention in terms of monitoring or following up. The reporting structures within the hospital, while clear in principle, are often not as clear when it comes to follow-up after an extended period. The most difficult category of advice to monitor post-implementation is the promising technologies for which the NRCPC has suggested

interim approval with data collection. Some technologies in this category, for example, vagal nerve stimulation for intractable epilepsy, have had managerial support withdrawn because data collection was poor rather than an absolute conviction that the technology itself was not beneficial or cost effective.

Recently the NRCPC has begun to consider ways in which the NRCPC could assist protagonists to implement their new technologies in ways that are amenable to audit. The NRCPC is aware of cases where significant "indication creep" occurred or where the new technology was used well outside the bounds of the indications which had received managerial approval. One such case was intravitreal bevacizumab, an anti-VEGF agent for patients with diabetic macular oedema. Good quality evidence showed that patients are twice as likely to see significant and real visual improvement if an anti-VEGF agent is used compared to standard care. The submission scored highly based on the good quality evidence identified, the protagonist estimates of the proposed number of patients treated over 1 year and the assumption of cost neutrality being reached within 1–2 years. There was concern about "eligibility creep", that is, patients receiving bevacizumab who didn't meet the inclusion criteria outlined in the submission and the NRCPC advised interim approval with data collection. An audit was conducted over a 2 month period and showed that almost five times as many patients were receiving bevacizumab as anticipated. Forty percent of the eyes treated did not meet established entry criteria and in 20 % the treatment was almost certainly futile. Additional patients were identified who were being treated with bevacizumab without any established indication. Since then, the number of procedures have been reigned in and have stabilised somewhat; however if such an audit had not been undertaken, there was a real chance of not only costs spiralling out of control but of potentially doing more harm than good for some of the patients involved.

The NRCPC will continue to consider its role in the post-implementation audit of new technologies and over time the NRCPC plans to develop ways to monitor post-implementation activity.

## 26.5 Pursuing Disinvestment Opportunities

In 2013 the NRCPC attempted a "grass-roots" approach to optimising decisions about new technology and potential disinvestment activities. Following the global financial crisis in 2008, Auckland DHB and all other DHBs in New Zealand were asked to make hefty financial savings with all clinical units expected to show cuts in their operating budgets. In the past, mandated savings were realised in the form of crude cuts to back office functions such as administration and infrastructure support. The NRCPC attempted to provide assistance whereby clinical departments could, with the Committee's help, analyse their current practices and suggest areas where eligibility criteria could be tightened (especially for expensive interventions) or services withdrawn so that these required savings could be realised without crude cut backs.

A presentation by Dr Josep Pique of the Hospital Clinic, University of Barcelona, at the 2012 HTAi conference was pertinent to the NRCPC's deliberations about

potential disinvestment activities because in Barcelona it had a similar operating budget and served a similar-sized population as Auckland DHB. Dr Pique detailed a process whereby Spanish clinicians were asked to realise cost savings from their operating budgets in return for 50 % of the savings. Reducing costs provided the necessary funds to invest in new technology by "creating windows of opportunity to incorporate new techniques or products without increasing the total budget of the institution."[2] Based on successful implementation in Barcelona, Auckland DHB management agreed to the idea of allowing 50 % of savings to be kept within hospital units. Over the course of 6 months, NRCPC representatives visited several hospital departments with the intention of inviting discussion about current practices and creating awareness of the potential for retaining 50 % of savings for investment in new technologies. Despite its best intentions, the NRCPC was not well received. The majority of departments were already under pressure to produce cost savings and did not welcome the prospect of additional work in the form of NRCPC submissions to their already busy schedules. "The prospect of retaining savings did not seem to be a big enough carrot, nor was there anyone with a large enough stick."

## 26.6 The Future

The future of the NRCPC is promising. Introducing shorter technology briefs has increased the demand for high-quality evidence-based summaries and has made evidence-based decisions more accessible without requiring the time or expertise to carry out a full submission. It has also allowed decision makers rapid access to the NRCPC advice whereas previously this may have taken months to achieve. The compromise is that often there is insufficient published cost data available. Without estimated local costs provided in a full submission, it is difficult to allocate a score. Another compromise is that protagonists do not get the same opportunity to engage with the evidence and cost data with the NRCPC members; while there is certainly a place for technology briefs conducted in-house, it has left some protagonists frustrated when they do not receive the recommendation they were hoping for and the opportunity to discuss the new technology with the group has passed.

The NRCPC is currently exploring a new method of hospital-based HTA, focussed primarily on disinvestment. This involves proactively identifying opportunities where the NRCPC can detect and limit medicines prescribed, medical devices used, diagnostic tests undertaken or services that provide little or no health benefit to patients. In the past these opportunities have arisen within the traditional submission process where opportunities for disinvestment have been a by-product of the HTA process. By accessing local patient data and costs, assessing current evidence and developing a case for disinvesting, the NRCPC hopes to be able to provide benefit to the organisation in the coming years.

[2] Pique JM. Optimizing the introduction and use of innovations in a hospital under a crisis environment. Health Technology Assessment International; 2012; Bilbao, Spain; 2012

# Part III
# Networks and Collaboration

# Chapter 27
# Networks in Hospital-Based HTA

**Iris Pasternack and Krzysztof Lach**

Do hospitals network with each other, nationally, regionally, or internationally, in health technology assessment? What is understood by networking and what does it consist of? Are there perceived benefits of collaborating through networks? These issues are dealt with in this chapter.

Networking implies collaboration of some kind, which could be demonstrated by shared services, joined programs, umbrella organizations, or even merged functions. Canadian hospitals have categorized the networking or alliances between hospitals based on the level of coordination and formality required to maintaining them, the level and balance of centrality of the shared function for the organizations, the level and symmetry of commitment in terms of resources, and the level of uncertainty [1]. Røttingen et al. [2] have categorized networking between HTA units in terms of levels of collaboration:

- Ad hoc contacts with no formal interaction.
- Formal processes for sharing information or data.
- Formal processes for involving other parties in commenting on plans and drafts. The decisions remain in the party that requests the comments.
- Formal processes for involving other parties in producing a defined task within the HTA process. The decisions remain in the party that offers involvement in production.
- Joint HTA projects with regular input from both parties and shared leadership. The decisions are made collectively.
- Functions merged with one decision-making entity.

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There are few examples where hospitals have established specific national or regional networks to help hospitals in starting and maintaining HTA activities [3]. In France, the professionals and departments of the university hospital of the Paris region collaborate with each other in HTA matters. A national network for innovation and HTA helps the French university hospitals to start HTA units. In Finland, each of the five university hospital districts has nominated a specific person experienced in HTA to a formal network. With regular meetings, the members of this network communicate and support HTA production in hospitals. In Denmark, the current informal networking between hospitals is all that is left from the original formalized collaboration between the hospitals and the national HTA agency, which in some instance lost its position and ceased to exist.

According to a survey performed in 2008, hospitals with HTA activities frequently network with universities and health policy institutions, either formally or informally [4]. Networking with national or regional HTA agencies is even more frequent and has been recognized as a guiding principle for good practices in HB-HTA, according to the research carried out from 2012 to 2015 within the AdHopHTA project [3, 5].

Almost all hospitals with a hospital-based HTA function network with national or regional HTA units [3, 4]. These activities started to appear in the early 2000s. The interactions are typically permanent but informal. However, in some countries or areas, such as Finland, Norway, Basque country in Spain, and Quebec in Canada, there are systemized collaborations between hospitals and HTA agencies, with formal organizational structures. Moreover, in Norway and in Quebec, the collaboration is mandatory. In other cases, although there are no formal assignments for collaboration, specific agreements are set up for single assessment projects. Although informal, the networks frequently employ appointed persons responsible for coordinating the interactions.

Even when there is no actual HTA function within the hospital, networking occurs. National or regional HTA agencies inform hospitals of planned and ongoing projects as well as their end results. Relevant topics for HTA are sometimes discussed together and hospital clinicians act as subject experts in the HTA reports performed nationally or regionally. Hospitals, in turn, have helped in getting access to their registries. There are examples where national HTA agencies have provided methodological and even financial support to hospital clinicians to perform randomized trials or systematic reviews.

Examples of networking between hospitals and national or regional HTA agencies in several European countries and in Canada are briefly discussed in Figs. 27.1 and 27.2 [3].

Though collaborative activities take place between hospitals and national or regional HTA units, they are also initiated and nurtured beyond these levels with trends for their internationalization. In circumstances where a group of hospitals interact with regional and national HTA units, it becomes natural for the hospitals to interact among themselves to increase the overall impact of HB-HTA. In Quebec, Canada, a group of hospitals share their knowledge and experience in HB-HTA as well as some sections of HTA reports striving for the establishment of a community

for good practices in HTA carried out locally. In Catalonia, Spain, due to emerging interest in assessing technologies in hospitals and in order to promote the use of HTA methodology, foundations for the creation of the Catalan Network for HB-HTA (XAHTS) have been laid.

Cross-country interactions with global outreach include networks such as Health Technology Assessment International (HTAi) with its subgroup for hospital-based HTA which has operated since 2001. The subgroup serves as a forum for focused discussions among its members. The AdHopHTA project (2012–2015) brought together actors in hospital-based HTA for the first time, and provided a substantial boost for further networking, e.g., in the form of maintaining a shared database for assessment reports.

## 27.1 What Do the Networks Do?

The concrete forms of interactions between hospitals and national or regional HTA agencies were investigated in 12 countries during the AdHopHTA project [3]. Interactions occur in different ways, forms, and intensities. In its simplest form,

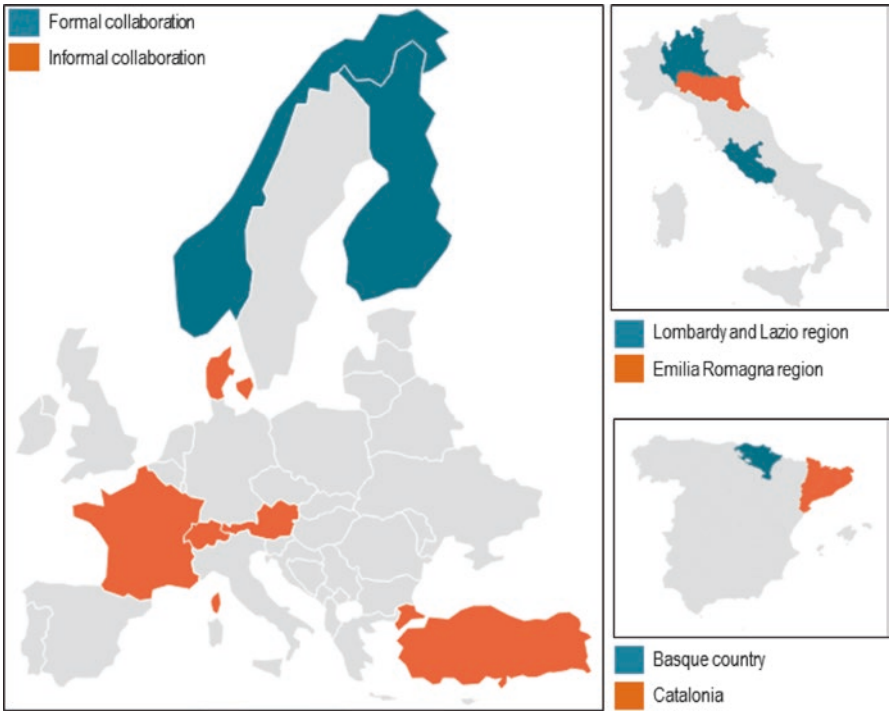


**Fig. 27.1** Networking between hospitals and national or regional HTA agencies in several European countries

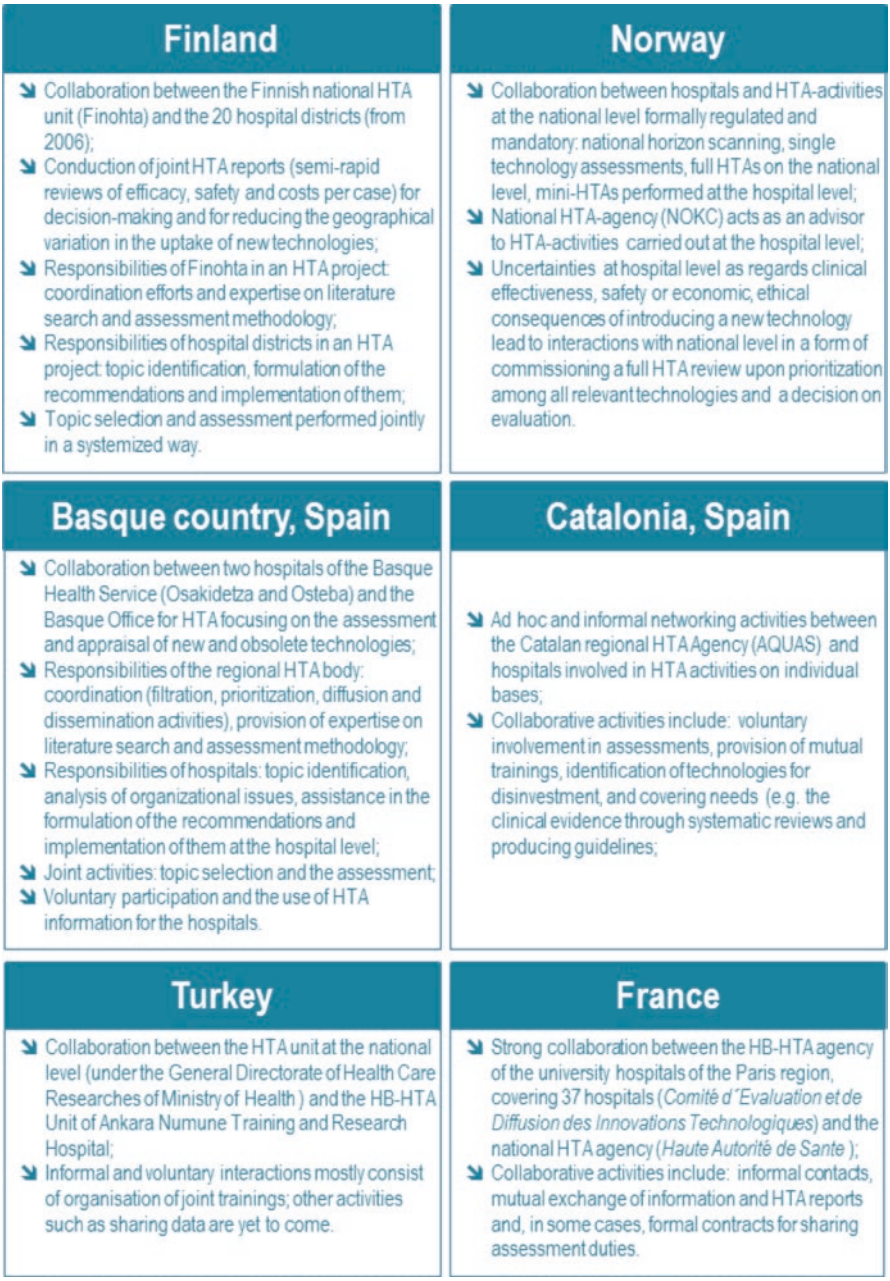


**Fig. 27.1** (continued)

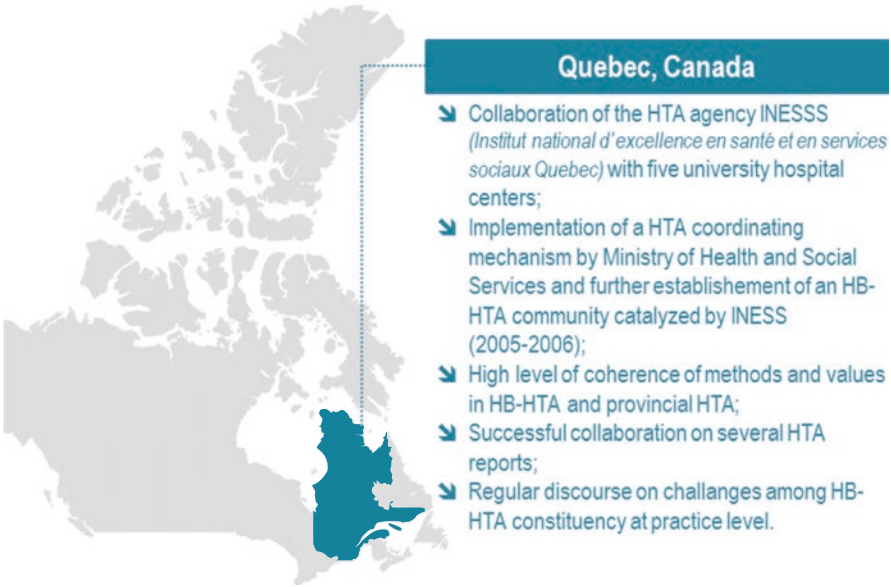


**Fig. 27.2** Networking between hospitals and regional HTA agencies in Canada

networking means sharing of documents or methodological and clinical expertise. There are joint efforts for training in HTA methodology and co-production of HTA reports, and also shared efforts in topic identification and publication. Some countries have had collaborative efforts in dissemination of technologies, reimbursement and pricing, and industry interactions. There are examples of providing mutual strategic or political support (Table 27.1).

The overall attitude toward networking is positive, both from the viewpoint of the hospitals and the HTA agencies and irrespective of the depth of the collaboration. The perceived advantages of collaboration include avoiding duplicate work, acceleration of HTA production, and an increase in the quality of HTA reports. The exchange of views and the specific perspectives of hospital-based HTA enrich the national HTA reports as well. However, there are also differing perceptions about involving hospitals in assessment. Some HTA agencies perform assessments intentionally in isolation of hospital influence, and only the results are delivered to hospitals.

A shared database for HTA reports of hospitals and national or regional HTA agencies seems to be a rarity. The AdhopHTA project participants were asked whether such a database would be useful. The project participants welcomed such a database development in general, but raised also important suspicions. Some suspected that confidential information, either patient data or commercially confidential information of agreements and prices, would hinder the use of such a database. Another reason for hospitals not to take over such a database is fear of criticism; the high methodological standards typical for national and regional HTA reports are not usually met in hospital-based HTA reports, at least in the beginning. National and

**Table 27.1** Activities shared or performed jointly by hospitals and national or regional HTA agencies

| |
|---|
| Exchange of documents: HTA reports and other information |
| Training principles and methods of HTA |
| Topic identification and prioritization for HTA projects |
| Horizon scanning |
| Identification of inappropriate or obsolete technologies |
| Informing about planned or ongoing HTA projects |
| HTA production |
| Finding experts for HTA projects |
| Methodological advice or support |
| Sharing information services, library services, help in getting articles |
| Sharing hospital data (on indications, clinical outcomes, and costs) |
| Appraisal and making recommendations |
| Commissioning or joint production |
| Joint publications |
| Financial support |
| Providing strategic or political support to each other |
| HTA-industry collaborations (e.g., early scientific advice) |
| Advice for reimbursement and/or pricing |
| Performing external evaluations of each other |
| Providing practical advice for dissemination of technologies |

Source: Reproduced with permission from Sampietro-Colom et al. [3]

regional HTA agencies also raise the expected problems in quality as a barrier. The resources required for the generation, updating, and quality control of such a database may become significant challenges.

## 27.2 What Hinders Networking and What Makes It Easier?

Facilitators and barriers of collaboration between hospital-based and national or regional HTA units have been examined during the AdHopHTA project [3]. Hospitals are stronger in scanning the horizon for emerging, potentially useful technologies, and national or regional HTA agencies are stronger in resources and may have more experienced staff to perform HTA. The position of hospitals as the entry point of new technologies, and also perhaps as a depository of obsolete technologies, and their obvious need of HTA information for rational decision-making make them a logical partner in networks of HTA. Economic restrictions have been considered as main drivers for collaboration between hospitals and national or regional HTA agencies in the future. Improving the quality and equity of care through such a collaboration is another motivation.

Transparent processes and informal, personal contacts were recognized as facilitators of collaboration by AdHopHTA partners. Pragmatic solutions, such as using the existing structures and resources in hospitals, as well as tailoring and minimizing HTA to be relevant and "good enough" for hospitals, seem to be other facilitators specific for hospital contexts. Formal and systemized collaboration was preferred over informal ad hoc contacts both by the hospitals and the national or regional HTA agencies. However, many respondents of the survey emphasized the importance of informal personal contacts, particularly in the beginning of the collaboration. Proper coordination is considered vital. The dominant perception seemed to be that it is the task of the national or regional agencies to provide the coordinative activities, i.e., the necessary infrastructure and administrative support for collaboration. However, the leadership should rotate and unilateral dominance should be avoided. Multidisciplinary participation, mutual trust, and respect were considered essential to improve collaboration. A general shortage of public funds has been considered as one of the main drivers, not only for extended use of HTA in decision-making but also for collaboration between HTA producing entities. Legal requirements or binding regulations to perform and use HTA for decision-making seem to be helpful for supporting collaboration between hospital-based and national or regional HTA.

The most frequently cited barrier of collaboration between hospital-based and national or regional HTA units was the general lack of knowledge and culture of HTA in hospitals. The lack of legal regulations and national policies to use HTA in a systematic way seems to be a particularly relevant barrier, in addition to competition between hospitals and clinicians' fear of losing their professional autonomy. For example, a shared topic identification and selection process, which in itself is considered a useful form of collaboration by many, may become a barrier. Being open about topic selection can sometimes harm a hospital if it reveals the plans of a hospital to purchase a technology and competing hospitals hurry in order to be the first hospital with the technology. Imbalances in expectations and power are typical barriers of good collaboration where two parties interact. Ease of use and comprehensibility of the HTA products are not traditionally valued high in HTA good practice models, but they were particularly strongly underlined by AdHopHTA partners as barriers of collaboration. The high methodological standards that characterize good HTA functions can paradoxically become a barrier for collaboration between hospital-based and national or regional HTA.

There are additional issues which could be anticipated to be important for collaboration, although not mentioned by the interviewees during AdHopHTA project. Clear definitions for mission, vision, and values are probably important for any collaboration. Supporting flexibility and creativity in collaboration, as well as rewarding participants and ensuring sufficient education, orientation, and satisfactory career development for them, are likely facilitators of collaboration.

## 27.3 Why Networking Becomes Essential

It seems obvious that certain HTA functions require coordination across hospitals or geographical areas in a country, or even across countries. These are typically instances in which very expensive technologies or technologies targeted to rare diseases are considered for implementation, or when the technology requires specific skills or premises not widely available. Furthermore, if there are particular ethical concerns or patient relevant aspects in the implementation of a technology, collaboration between hospitals and national and regional HTA communities is warranted.

Hospitals collect data on processes, treatment indications, clinical outcomes, and costs. Although this sort of data is of utmost importance for evaluating technologies, it is not always available to national or regional HTA units. On the other hand, hospitals do not always have the capacity, time, and skills to use the data to a full extent. Access to, and knowledge of, the data may be in just a few hands within the hospitals and not necessarily to anybody involved in the HB-HTA function. Strict rules ensuring data protection and confidentiality of patients or business further complicates access. Furthermore, efficient use of hospital data would require standardized data collection in order to yield comparative information from other areas nationally or internationally. This would allow for learning from others and for identifying the best ways to implement the technology, as well as for improved resource planning on a national level. Hospital-based and national or regional HTA functions could together target these issues and develop formal processes and rules for access to information in hospitals' clinical and financial databases. Flexible use of the databases should be guaranteed without jeopardizing confidentiality of the information.

Often with new technologies, at the time of the implementation decision, there is very little evidence available. In those instances, a temporary or conditional decision to fund the technology together with a plan for data collection may be warranted. National or regional HTA agencies and hospital-based HTA units could collaborate more in designing what kind of data should be collected to fill the evidence gaps and how and what could be considered as sufficient efficacy and safety to support permanent decisions. At the moment, statements in HTA reports, based on published literature, that only refer to insufficient evidence may not be considered helpful in hospitals. Detailed guidance on how to generate evidence in the hospitals themselves would be a further step that would benefit from close collaboration between hospitals and HTA agencies. Furthermore, collaboration in clinical trials has been suggested.

Implementing a technology in hospitals may have consequences to primary care too. Monitoring of patients after a hospital stay takes place often in primary care and has, therefore, organizational and cost consequences there too. Involving primary care in the collaboration between hospital-based and national or regional HTA has consequently been suggested. Moreover, the role of patients and citizens in decision-making in health care is becoming more and more important.

## 27.4 A Possible Step Forward?

Observing more apparent movements toward tightening the collaboration between organizations carrying out HTA at national or regional level (RedETSA, HTAsia-Link) and more efforts made to harmonize HTA process in the EU (EUnetHTA), it becomes a natural step for HB-HTA to not only intensify interactions between national or regional HTA bodies but also to establish constituencies of HB-HTA (e.g., Pan-Canadian Network, AdHopHTA). Regional (country level) or macro-regional (e.g., Europe) networking activities are more likely to appear (local HTA) from technical and coordination reasons; however, a second layer of interactions between these regional networks globally (global HTA) could form an interesting forum for sharing experiences on how generalizable global knowledge (clinical effectiveness) and local context characteristics resonate with different assessments, appraisals, and decision-making outputs ("Glocal" HTA).

When it comes to benefits from the existence of regional HB-HTA networks, the most evident one is the promotion of a culture of harnessing objective measures to inform investment decisions in health technologies or, at least, supporting the procurement process. Other advantages have been extensively discussed in this chapter.

Existing hospital networks seem a viable and, most importantly, a readily available vector for carrying the collaborative HB-HTA activities also considering limited financial resources and geographical proximity. At global level, there is already a common forum possibly strapping future interested networks (ISG on HB-HTA of HTAi).

A potential HB-HTA network consisting of hospitals that already have an HB-HTA unit or program would require clear governance, mission, vision, and values that drive the initiative. A proposal on how these could be formulated is briefly discussed in Table 27.2.

Regardless of the model and operational methods of future networks, the AdHopHTA project has delivered a characteristic that epitomizes successful collaboration between bodies inside the network. It is expected that networks will collaborate pursuant to a mutually agreed mission, vision, and strategy fuelled by established values. Clearly defined responsibilities and roles would save irksome consequences stemming from the lack of coordination across levels. Moreover, adequate funding would prevent competition between levels. Individuals within bodies of the network who possess HTA expertise and are trained in leadership and effective communication coupled with openness to informal contacts, are expected to contribute to streamlined collaboration between bodies. Another requirement for successful collaboration is the conduction of HTA activities together, which saves time and resources. All the above can be considered as building blocks of successful collaboration, and they are instrumental in bringing outputs that are useful for creating repositories of HTA knowledge and, ultimately, for decision-making [3].

**Table 27.2** Proposed mission, vision, and values for a potential HB-HTA network

| Potential HB-HTA network | | |
|---|---|---|
| Mission | Vision | Values |
| Promoting HB-HTA in hospitals around a macro-region (e.g., Europe) | Becoming a role model for hospitals interested in creating an HB-HTA unit to inform decisions on investment in innovative and effective technologies in a strategic way, contributing to patients' care and healthcare systems | *Transparency* in processes and methods involved in different activities |
| Increasing the visibility of HB-HTA with an impact on an agenda of the macro-region | | *Excellence* ensured by implementing the highest standards and practices in HB-HTA and striving for the continuous improvement |
| Creating a forum for exchanging experience and expertise on HTA at hospital level in the macro-region | | *Integrity/independence* from stakeholders and other health sector actors as well as by welcoming evaluation and implementation of change when necessary |
| Facilitating cooperation between organizations and individuals active in HB-HTA as well as with other existing HTA networks | | *Responsiveness* to the needs of society/the community by a collaborative effort of members to foster positive relationships with other colleagues and related institutions in the macro-region and worldwide |
| | | *Innovation* by challenging itself to be innovative in its work |

Modified from Sampietro-Colom et al. [3]

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# Part IV
# HB-HTA from Stakeholders Point of View

# Chapter 28
# Hospital-Based HTA from Stakeholders' Point of View: View from Hospital Stakeholders

**Kristian Kidholm**

## 28.1 Introduction

The main users of HB-HTA are the clinical and administrative managers at the hospitals who need a basis for decisions on whether to invest in new treatments at the hospital. As it is described in this book – Sampietro-Colom et al. [1] – a number of hospitals around the world have started using HB-HTA, and many hospitals have demonstrated positive impact of this approach. However, to what degree does the content of HB-HTA products comply with the need for information by the decision makers? This question has not been studied at an international level before the AdHopHTa project was carried out, and below the results will be described.

The aim of the studies was to assess hospital managers' need for information when making decisions on investment in new treatments. For this purpose, three studies were carried out: a systematic literature review, see Ølholm et al. [2]; an interview study with a small sample of European hospital managers, described in Kidholm et al. [3]; and a questionnaire survey with a large sample of European hospital managers.

The results are presented in the table below. The table below describes (with green colour) to what extent the information included in the nine domains in the EUnetHTA core model – see [4] – was assessed as important parts of the basis for decision makers by the hospital managers themselves. In the literature review, 14 studies of hospital managers' need for information were found. These studies indicate that information about the health problem of the patients, the clinical effectiveness, the economics and the organisational and the strategical and political aspects of new treatment was most frequently considered as important by hospital managers.

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**Table 28.1** Results from studies of hospital managers need for information in decision-making

| Domain | 1. Literature review | 2. Interview Study | 3. Questionnaire survey |
|---|---|---|---|
| D1: Health problem and current use | | | |
| D2: Description and technical characteristics | | | |
| D3: Clinical effectiveness | | | D3.1 Outcome/effect size<br>D3.2 Quality of evidence |
| D4: Safety aspects | | | |
| D5: Costs and economic evaluation | | | D5.1 Societal point of view<br>D5.2 Hospital point of view |
| D6: Ethical aspects | | | |
| D7: Organisational aspects | | | |
| D8: Social aspects | | | |
| D9: Legal aspects | | | |
| D10: Political and strategic aspects | | | D10.1 Strategic aspects<br>*D10.2 Political aspects* |

The domains in green colour are the five domains considered the most important in each study

The last and tenth domain in the table is not part of the EUNetHTA core model, but was developed and added in the literature review, because a number of articles describe that hospital managers were including strategic and political issues when making decisions on investment in new treatments. Strategic issues are understood information on, e.g. the fit between a given health technology and the research strategy and local values of the hospital or prestige and competition among hospitals. Political issues are understood information on, e.g. the alignment between the decision to invest in a given technology and the local political climate. The relevance of information on especially the strategic aspects associated with the introduction and use of a given new health technology was confirmed in both the interview study and the questionnaire survey.

The interview study with 54 hospital managers and the questionnaire survey with 163 hospital managers gave similar results, as the table below describes. The major difference is that in both these studies, information about the safety aspects was considered as the most important by the decision makers (Table 28.1).

## 28.2 Implications for HB-HTA

### *28.2.1 HB-HTA Should Be More Focused on Fewer Domains*

As described above, the results from the three studies indicate that not all domains in the EUnetHTA core model are considered equally important by hospital managers. Information about the health problem of the patients and the clinical

effectiveness, the safety, the economics, and the organisational and the strategical and political aspects of new treatment was most frequently considered as important by hospital managers in the studies.

This could indicate that the relative importance given by hospital managers to the different types of information differ from those given by national/regional HTA agencies, as described by Sampietro-Colom et al. [5] and Ehlers et al. [6]. Hospital managers need information with focus on the impact on the hospital, whereas national HTA organisations must produce assessments with a more societal perspective and include information on ethics and social and legal aspects.

### *28.2.2 HB-HTA Should Include Information on Effects on Clinical Outcomes and Level of Evidence*

The results from the systematic literature review did show that the third domain (D3) dealing with "clinical effectiveness" includes decision criteria concerning on 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. The results showed that both dimensions were considered important parts of the basis for decision-making by a majority of the respondents. Thus, both the size of the effect on clinical outcomes and the level of evidence of the studies behind the results should be included in HB-HTA.

### *28.2.3 HB-HTA Should Focus on Economic Impact on the Hospital*

The results from the literature review and the interview study made it clear that the economic aspects include both decision criteria concerning traditional health economic analyses with a broad societal perspective (e.g. cost-utility analyses) and more narrow budget impact analyses with a hospital perspective (e.g. costs and budgetary constraints).

In the systematic literature review, the majority of identified decision criteria concerning the economic aspects associated with the introduction of a new treatment concerned the narrow hospital perspective. In the interview study, it was not always clear whether the respondents had a broad societal or a more narrow hospital perspective in mind when asked about the economic aspects of new treatments. However, one third of the 39 respondents indicating information on economic aspects of new treatments as highly important referred only to the economic impact on the hospitals by using terms like "budget impact", "financing", "reimbursement", "billing" and "DRG".

Therefore, in the questionnaire survey, the questions about economics were divided into information from a "societal point of view" and a "hospital point of

view", respectively. The results showed that 52 % of the respondents was considering the hospital point of view as among the most important informations, whereas only 25 % was considered information on economics from a societal point of view as the most important. Thus, the three studies indicate that HB-HTA should have a hospital point of view when describing the economic impact of new treatments.

### *28.2.4 HB-HTA Should Include Information on the Strategic Aspects*

The domains of EUnetHTA's Core Model cover the majority of information needed by hospital decision makers when they are to make decisions on whether or not to invest in a new treatment. However, perfect consistency was not observed as decision criteria dealing with strategic and political issues were identified in the systematic literature review as well. These were classified under a tenth and new domain named "political and strategic aspects".

In the interview study, the respondents were asked to rank the most important domains, and the strategical and the political aspects of a new treatment were separated into two different domains. The results were that 9 % of the respondents was considering the strategical aspects as among the five most important domains in decision-making, whereas only 4 % was considering the political domain as among the most important. This indicates that HB-HTA should include information about potential relations between investing in a new treatment and, e.g. the hospital research strategy or competitive advantages for the hospital.

## 28.3 Conclusion

To increase the use of HB-HTA as the basis for decision-making at hospitals all over the world, we must ensure that the assessments on one hand comply with the principles of HTA by being multidisciplinary, systematic and evidence based and on the other hand give the hospital managers the information they need, both with regard to the content of the information and the timing of the information. The studies described above provide a basis for further development of HB-HTA to ensure that goal. However, many questions still remain unanswered and more studies are needed of how HB-HTA should be produced, what HB-HTA should include and differences in the need for information in different countries, different hospitals and among different types of hospital managers.

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# Chapter 29
# Hospital-Based HTA from Stakeholders' Point of View: View from Industry

**Grégoire Mercier, Camille Dutot, Nicolas Martelli, Anne Josseran, and Christophe Roussel**

## 29.1 Introduction

Hospital-based health technology assessment is aimed at improving decision-making regarding investments for new health technologies in hospitals. In the worldwide context of budget constraints, HB-HTA is gaining momentum as a tool considered interprofessional and favoring evidence-based managerial decisions. The acknowledged limitations of the regional-/national-level HTA processes in terms of scope, complexity, cost, and timeliness reinforce this recent trend.

At first glance, HB-HTA can be viewed as an additional hurdle by the drug and medical technology industry. However, it can be part of a new market-access strategy focused on innovations delivering high value to hospitals and to the health system. To that end, all stakeholders – including the industry – need to have a clear picture of the HB-HTA process and informational needs. In other

Note from the Authors The view presented in this chapter has been mainly inspired by the position of the French industry of medical devices. Consequently, the points discussed in this chapter might not be fully representative.

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words, the industry could and should be a privileged partner in the development of HB-HTA worldwide.

As a matter of fact, the drug and medical device manufacturing sector is highly diverse. Health technologies range from drugs to medical equipment, and companies vary greatly in size and experience, from start-ups to well-established globalized ones. Depending on its own features, each company might have different expectations and a different role to play.

In the following sections, we are going to analyze to what extent companies are incorporating HB-HTA in their market-access strategy, to depict the opportunities and challenges of HB-HTA for the industry, to present experiences and tools illustrating collaborations between industry and HB-HTA units, and to propose some perspectives.

## 29.2 Insight from Industry

### *29.2.1 What Is the Level of Awareness Among the Industry Regarding HB-HTA?*

The awareness and knowledge of HB-HTA encompass two aspects: "What is the level of general understanding of HB-HTA principles and definition?" and "What is the level of concrete knowledge of the HB-HTA process within a hospital?" Both vary greatly between companies according to their size, history, and portfolio.

Generally, the culture of HTA and HB-HTA tends to spread into large and globalized companies through their market-access departments, whereas smaller companies do not necessarily have much knowledge because they are less likely to dedicate specific resources and competences there. However, HB-HTA knowledge varies substantially across small- and medium-sized enterprises (SMEs) according to the portfolio and to the background of each company. For instance, start-ups usually have a better understanding of the local HB-HTA process and have more methodological support opportunities from hospital departments. This might be explained by some geographic proximity or by the fact that they usually develop new medical devices with local partners. Some other SMEs having reached fundraisers are more likely to be helped by contract research organizations (CROs) and consultancies. Bigger companies often have a more comprehensive overview of the health-care system and usually directly target HTA agencies.

Raising the level of awareness and knowledge might precisely be one of the roles of the unions/associations of drug and medical technology manufacturers (e.g., EUCOMED, EFPIA in Europe, or national unions). This could be achieved by organizing events in partnership with hospitals or by spreading information about HB-HTA.

### *29.2.2 Which Feedback from Industry on HB-HTA Process?*

Regarding the insight on the concrete HB-HTA process, the prevailing view of the industry is that:

- HB-HTA approaches are extremely heterogeneous between hospitals and, in some cases, within a hospital depending on the contact person.
- HB-HTA units occasionally refuse to exchange with the manufacturer, because they are afraid it might affect their critical thinking and their objectivity.
- Hospitals sometimes do not cover the full range of clinical and technical expertise to correctly assess innovations.

From the industry perspective, transparency of HB-HTA process is one of the main issues, and there is a need for an open dialogue with HB-HTA units.

Involvement of industry in the HB-HTA process depends on the goal pursued by the hospital: if the aim is to establish good practice guidelines at the hospital level, then there is little chance manufacturers would be involved. In contrast, when considering adoption of a new technology, manufacturers are more often informed that one of their products will be assessed. However, the communication does not always happen formally by the HB-HTA unit itself, but sometimes on an indirect way, e.g., by a clinician they are in touch with. Furthermore, results of the assessment are not always published or communicated to them. These circumstances prevent manufacturers from having some insight on the HB-HTA process, its timeline, and the assessment criteria used. In fact, a greater transparency would be desirable for both sides as it would help manufacturers to better understand hospital expectations and then to bring relevant data to justify the added benefit of their technology. With clear explanations of the decision, especially when adoption is rejected, it would also be easier for manufacturers to raise funds to develop specific studies that will address hospital requirements.

Regarding the assessment methodology, the industry raises the issue of the perspective chosen. Indeed, limiting the assessment to strictly hospital-centered outcomes might prevent a full recognition of the broader value of medical technologies. Although it is the mission of the hospital to provide comprehensive health benefits to the community, industry fears that a hospital might be incentivized to favor "profitable technologies" in the assessment process. For instance, a reduction in the readmission rate can theoretically be seen as a reduction in hospital revenue in most countries, although this has undoubtedly a positive impact on the patient and on the society as a whole.

HB-HTA criteria finally appear to be quite similar among hospitals, regardless of the size. However, even if there is a common basis of criteria, when it comes to their relative weight along with hospitals priorities, this remains difficult to capture for industry.

## 29.3 Opportunities and Challenges for the Industry

### *29.3.1 Toward Hospital Market Access New Opportunities?*

The development of HB-HTA methods and tools is a new step toward hospital autonomy and toward a reinforcement of hospital decision-making power on health technology adoption.

However, for industry, health technology adoption by hospitals remains rarely considered as a proper market-access opportunity. HB-HTA submission mainly depends on the type of technology and its innovation grade.

Firstly, the most common scheme for manufacturers is to target funding by regional/national health system. Thus, health technology adoption at the hospital level is usually considered as a preliminary step which allows for real data collection to support the assessment process at the regional/national level. In this case, attention is paid to target at first hospitals with key opinion leaders or specialists of the discipline and hospitals with a great pool of potential eligible patients.

Secondly, HB-HTA activities are often restricted to innovative and expensive technologies. For other technologies, procurement process is often based upon a basic economic or RFP approach, often without formal assessment of clinical evidence. It is then difficult for manufacturers to consider HB-HTA submission as an opportunity to reach the market if they have no clue on the eligible criteria to enter such a process, or are not invited to make a submission to the relevant people at the appropriate time to support the decision-making process.

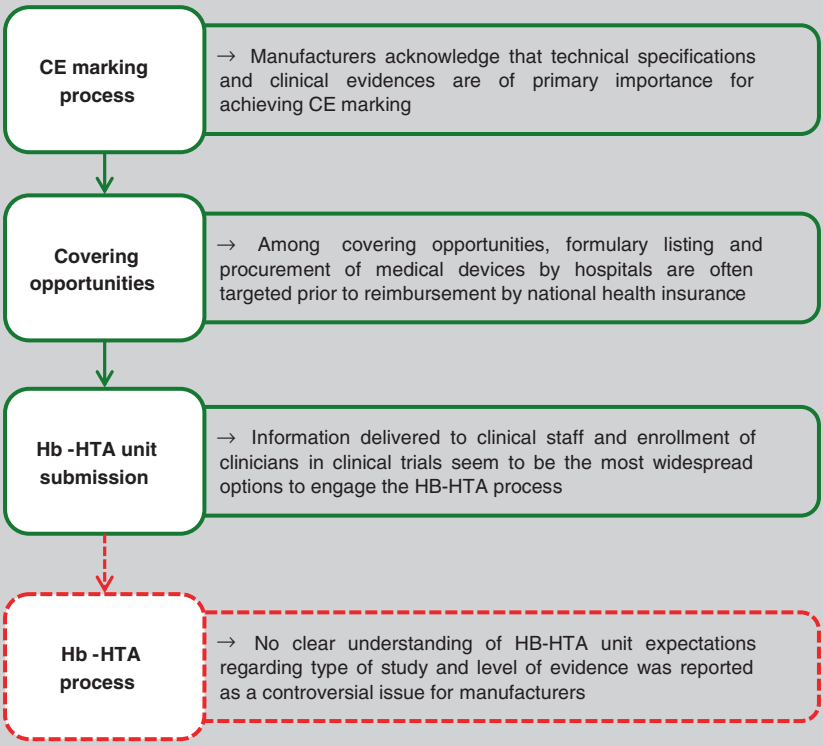
Above all, the expectation from industry regarding HB-HTA activities is not so much a new gate for hospital market access, but rather an opportunity to undertake cooperative primary research within the local context, especially for new and emerging technologies. In this case, HTA might be understood as a process of applied clinical research on new technologies that has to be spread out over time: a first level of evidence has to be provided to start the process up (safety data as a minimum). Then further data could be generated through industry/hospital partnership, along with implementation of the new technology. Results from a pilot survey on the industry point of view about HB-HTA are summarized in Box 29.1 [1].

**Box 29.1. HB-HTA from Industry Point of View: Results from a Pilot Survey**
In 2014, a prospective pilot survey based on the insights of five people from medical devices industry was conducted. The aim was to compare their hospital market-access strategies and to determine whether or not a prevailing trend would arise.

The survey focused on innovative medical devices and consisted in a two-round questionnaire through a mini-Delphi approach. At the first round, four dimensions were explored by each participant: (i) CE marking process, (ii) covering opportunities, (iii) submission to Hb-HTA unit, and (iv) Hb-HTA

process. At the second round, each participant was asked to challenge his initial position according to the summary of feedbacks collected over the first round.

As illustrated in the following graph, convergent positions were only reached on the three first topics:




According to the panel, medical devices adoption at hospital level is a valuable covering opportunity for innovative technologies. However, Hb-HTA unit expectations still remain unclear and manufacturers wish they could be more involved in the Hb-HTA process.

### *29.3.2 Interaction Between Regional/National and Local HTAs*

The interaction between local and regional/national HTAs is variable depending on the type of the health product, the country or the region concerned, the industrial resources, and so on. Firstly, the strength and type of interaction will be more

or less strong depending on whether the product is reimbursed or not by the coverage system of the country. Thus, for manufacturers, the main interest of local HTAs is that they will potentially generate local data which could be thereafter used to build a dossier for a regional/national refund application. Indeed hospitals are uniquely able to measure the organizational impacts which are sometimes difficult to identify and quantify at a regional/national level. The local approach can offer valuable insights for the authorities that examine manufacturers' requests. In addition, if a product has been introduced in a hospital after a HTA process, there is sometimes a period of follow-up and monitoring to measure the long-term impact of the technology. Data generated are also very informative for manufacturers which could use those in the perspective of a renewal of a regional/national refund. Then, some manufacturers can view local HTAs as training before a more comprehensive HTA at the national or regional level. This is an opportunity to understand what the potential weaknesses of the dossier are and how to improve it before a national/regional submission. However, this implies that hospitals state the reasons for refusal which seems not always to be the case. Finally, the interaction between local and regional/national HTAs highly depends on the industrial resources. As stated above, SMEs do not have enough staff in order to manage the coordination of both activities, i.e., following local HTAs and their potential results and also submitting a full application for a national/regional HTA.

### *29.3.3 Variability Across Hospitals and Countries*

Level of cooperation between hospitals and industries varies widely between countries or regions, but also depending on the size of both organizations and the reimbursement system. Firstly, the HB-HTA culture is not equally distributed in every country and sometimes within the regions of a given country or even within hospitals of a region. This is partly due to the degree of centralization in health-care system. Thus in countries or regions where HB-HTA activities are largely implemented, the industries are aware of the major importance of these processes to ensure market penetration. Consequently, level of cooperation with hospitals is much more likely to be high in such countries or regions. In addition, the density of health industry also varies across countries and regions. A high density of health industry within a region is surely a favorable environment to the development of cooperation. Finally, the size of hospitals and companies seems to be an important factor to take into account. Big hospitals such as university or teaching hospitals are more likely to develop strong HB-HTA activities and to establish real cooperation with companies. For example, the university hospital of Lyon (France) has set up a program for helping small and medium enterprises in the development of clinical trials for their medical device [2]. Conversely, big companies are able to provide services and expertise to hospitals that SMEs cannot offer.

## 29.4 Cooperation Between the Industry and HB-HTA Units: Experience and Tools

### *29.4.1 From Assessment to Implementation: Breaking Organizational Silos*

Some medical devices are intended to be widely used in hospitals and could potentially replace several current equipment. Devices for dependent patient cleansing (ICU, geriatrics, etc.) are a good example for this.

The challenge is easy to depict with a concrete example: going from time-consuming, nonstandardized, multi-product, patient cleansing procedures to quick, standardized, mono-product, cleansing process. According to the manufacturer, this could be achieved thanks to a new impregnated device that cleans, moisturizes, and protects the skin at the same time.

In this example, qualitative surveys have been performed together with micro-costing studies within different health-care facilities (hospitals and nursing homes). It is important to notice that involvement from top management to nursing staff and caregivers has been critical to get relevant outcome.

Although the outcome was in favor of the new device for both staff satisfaction and time-saving, market-access strategy of this new medical device was still facing a big issue. Implementing this new protocol required several changes to the existing situation: adding a new device, replacing other devices, saving budget related to topical drugs, and saving human resources time. Overall, five different budgets were affected (Table 29.1).

The wide impact of this technology made data collection and analysis difficult. Indeed, purchasers are more concerned by their budget constraints, and capturing the whole impact on clinical practice and organization remains a secondary objective. Thus, breaking organizational silos, if comprehensive value brought by innovation is demonstrated, is certainly necessary but usually represents a big challenge.

**Table 29.1** Budget impact of a new medical device per hospital department

| Department | Budget | Impact | Inc/decrease |
|---|---|---|---|
| Pharmacy | Medical devices | Adding a new MD |  |
| Pharmacy | Drugs | Reducing topical cream consumption |  |
| Hospital store | Commodities | Reducing mattress protector, washcloth, soap |  |
| Human resources | Nursing staff/caregivers | Workload, time saving |  |
| General services | Water/laundry | Reducing laundry and water consumption |  |

### *29.4.2 A Decision Support Tool Tailored to Targeted Population*

Models of HTA organization may vary from mini-HTA (individual) to HTA unit [3]. As a result, hospitals sometimes lack dedicated team or specific expertise. However, understanding value brought by an innovation may require a broad range of expertise on technical, economic, and even organizational impacts.

Yet, for each expertise domain, methodology may differ and outcome comprehension may not be necessarily obvious. The following is an example that illustrates a stepwise and collaborative approach of a medical device manufacturer whose goal was to provide decision-makers relevant tools depending on available local expertise.

This example is about a catheter securement device. Its distinctive feature is the capability of a sustained release of an antiseptic at the insertion point. It is intended to reduce catheter-related bloodstream infection (CR-BSI), associated with a severe prognosis (attributable mortality rates up to 11.5 %) and with high costs (increased antibiotics use and length of stay) [4, 5].

Classically, the manufacturer started with a randomized controlled trial (RCT). The study demonstrated a significant CR-BSI risk reduction of 60 % [6]. Despite this result, a strong demand came from hospitals to consider economic aspects. Actually, CR-BSI are relatively rare events (1–3.1 per 1,000 patient/day) [7] and decision-makers needed this health economic outcome to invest into a new device, more expensive than the ones currently used.

A health economic study has been then performed in collaboration with hospitals [8], fed by RCT results. Formally, it was a cost-effectiveness analysis based on non-homogeneous Markov-Chain Monte Carlo simulations comprising eight health states. The main endpoint was the cost per patient with CR-BSI avoided. The model, designed according to French health economics guidelines [9], showed that the new device was more cost effective than the actual strategy. Although this approach offered more robust estimates including uncertainty quantification (probabilistic sensitivity analysis, confidence intervals), model complexity made it rather ineffective for some hospitals.

The decision was taken to design a straightforward budget impact tool so that people in charge of the assessment could quickly master it. This seems paradoxical since such a tool is less robust: calculation using average/median values, neither confidence interval nor probabilistic sensitivity analysis.

As a conclusion, one may guess purchasers need to trust the decision support tool provided by the manufacturer. Their adherence is tightly linked to model readability and transparency. The more complex the model is, the more it will “cost” the hospital to make use of results and the less its “utility” will be perceived by decision-makers. Finally, a balanced trade-off between robustness and “usability” has to be found in order to facilitate the transaction.

### *29.4.3 A Standardized HB-HTA Form Fulfilled by the Industry*

At the Public Assistance – Hospitals of Paris (Assistance Publique – Hôpitaux de Paris, AP-HP), the medical device committee (Comité des dispositifs médicaux stériles, CODIMS) is responsible for assessing innovative sterile medical devices for the AP-HP hospitals' group (38 centers). The medical device committee acts upon request from medical staff of the AP-HP only and never from device manufacturers. The technology assessment is based on three main documents: (1) a report of the scientific secretariat of the CODIMS which collects and synthetizes evidence on the technology, (2) recommendations of the French HTA agency (HAS) when they do exist, and (3) a form describing general therapeutic interests of the technology and completed by the device manufacturer. The items of the form describing general therapeutic interests are presented in Box 29.2. In addition, the device manufacturer must also provide a technical note on the technology and administrative documents such as the CE mark certificate, the launch dates, price offers, etc. The three main documents are then submitted for opinion to medical experts and a representative committee.

Device manufacturers are thus involved in the preparation of the dossier for the technology assessment. Nevertheless there is no direct participation of device manufacturers in the final analysis. Moreover, the reliability of all information provided is checked by the scientific secretariat before any submission to medical experts and the representative committee. The example of the CODIMS of the AP-HP shows that the participation of device manufacturers is still limited in the process of HB-HTA. They are only asked to provide updated information on the technology evaluated and are not regarded as an "active stakeholders" in the process.

**Box 29.2: Form Describing General Therapeutic Interests of the Technology (CODIMS, AP-HP)**

- *Characteristics of the population*
  - Prevalence of the disease
  - Target population
  - Population already treated
  - Potential number of patients for the AP-HP
- *Therapeutic interests*
  - Claimed indications
  - Effectiveness
  - Safety (adverse events and their severity)
  - Risk-benefit balance of the technology
  - Severity and consequences of the disease
  - Burden of the disease
  - Expected beneficial effect of the technology on the disease
  - Place in the treatment of disease

- *Comparators*
  - Comparative studies on effectiveness, safety, and global benefits (quality of life, convenience of use, etc.)
  - Description of the current treatment of the disease
- *Summary of clinical studies*
  - Tables summarizing all clinical studies available on the technology

## 29.5 Perspectives

While it is clear that industry has a deep knowledge about their technologies, it is also obvious that hospitals are well placed to work on their organizations. Thus, from the industry perspective, cooperation with hospitals is essential to guarantee the quality of local HTAs. Hospitals need reliable and detailed information on the health technology to perform a proper assessment. However, all information is not publicly available and there is a risk that hospitals might not take into account important data in the assessment process. Collaborative HB-HTA can produce several benefits in a market where information asymmetry is the rule. It might be a good way to gain more information thanks to early dialogues or to generate new evidences when not available initially. This would allow for both a quick access to innovation and an increased knowledge level.

From hospital perspective, asking information from manufacturers can be done in a transparent way. For example, an agreement on confidentiality, intellectual property, and data ownership can be signed by both parties. There is an implicit danger of manipulation of the better resourced on the less resourced part. To prevent this from happening, defining processes, schedules, roles, and specifications in advance helps. Even if it is perceived as too slow from the better resourced part, trying to impose new processes, schedules, roles, or specifications should be a no-go. Then, local data and HB-HTAs performed by hospitals are very important information for industries. Most of the time, companies do not have any access to hospital data. This is unfortunate, because this information could be used to improve the product, to build a dossier for a regional/national refund application, or to help hospitals in the assessment. Some companies could help hospitals to analyze their local data by conducting economic evaluations, for example. However, this cannot be offered by all companies, especially the smaller ones. Then these services would not concern all health technologies, and industries do not wish to be a substitute for HB-HTA units. Finally, it is hard for companies to identify the relevant stakeholders involved in the HB-HTA process within hospitals. The clear identification of representative interlocutors could also improve the relationship between industries and hospitals. In addition, because different professions use different kind of wordings, matching players from both sides with similar backgrounds helps, i.e., medical director and medical director.

In conclusion, companies would like to engage in stronger cooperation with hospitals in their HB-HTA processes. They could be more involved in the discussion, but with no decision-making power as a condition for participating. This could be based on a greater mutual transparency, but in a flexible and effective way without creating additional bureaucracy. Thus, it must be clear from the beginning for both sides if the process is about negotiation or collaboration.

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# Chapter 30
# Involving Patients in Hospital-Based HTA: Experiences, Approaches, and Future Directions

**Marie-Pierre Gagnon, Janet Wale, Durhane Wong-Rieger, and Russel McGowan**

## 30.1 Introduction

Policy makers, healthcare managers, and HTA producers are increasingly interested in exploring strategies for involving the public and patients in HTA activities [1, 7]. While public involvement in HTA can be a response to the need for more transparency and accountability in decisions regarding funding of drugs, devices, and healthcare procedures [1, 20], patient involvement in HTA can be seen as a way to enhance the relevance of the technologies and services that are provided by considering end users' needs and values [8, 23]. Experiential knowledge regarding a particular health condition or the use of a given technology can be gained through patient consultation, including direct patient input [12, 30]. Furthermore, involving patients in health decision-making promotes their empowerment and can improve adherence to therapy and/or reporting of adverse effects, which could ultimately improve their health and well-being [30, 33].

In the field of HTA, a number of initiatives exist to support public and patient involvement, but most of them have been conducted at the national or regional level [17, 22]. There is equal need for involving patients in HTA at more local levels, such

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as in hospitals, to ensure that they can influence decisions regarding health technologies in these settings.

The purpose of this chapter is to provide an overview of current knowledge and experience regarding patient involvement in HTA at the hospital level. First, the rationale for involving patients in HTA at the hospital level will be discussed. Second, two experiences of patient involvement in HTA activities at the hospital level are reported. Third, a conceptual framework for guiding patient involvement in HTA at the local level is presented. Finally, future directions for supporting patient involvement in hospital-based HTA (HB-HTA) are discussed.

## 30.2 Why Should Patients Be Involved in HTA at the Hospital Level?

Many countries have started to develop systems that support decision-making at the local or institutional level, such as at within hospitals [24]. Thus, many hospitals are interested in implementing HTA methods because they could facilitate decision-making regarding the acquisition, implementation, or discontinuation of technologies or interventions within the hospital [14]. Health authorities increasingly urge individual healthcare organizations to be involved in quality and efficiency improvements of their healthcare delivery processes. The idea is that such improvements at a local level should affect quality, safety, and efficiency of health care at higher levels. As a result, many decisions regarding health technology acquisition, diffusion, and disinvestment are now made within the hospital [10]. In the context of scarce health resources and growing healthcare expectations, health authorities demand that healthcare organizations improve their levels of efficiency and effectiveness and that decisions regarding health technologies (prioritization, investment, adoption, and disinvestment) be carried out at the local or hospital level [15].

Moreover, decision-makers, managers, clinicians, and other healthcare providers are increasingly asked for scientific evidence to be included in their practice and organizational processes [10]. The establishment of more proximally located HTA units is viewed as a strategy to improve the relevance and timeliness of HTA recommendations and, ultimately, to facilitate their uptake. Also, it is recognized that the organizational context should be taken into account when assessing a technology since the opportunities and advantages that emerge from a technology depend on the available resources and skills within a healthcare organization [5].

The importance of patient and public involvement (PPI) is increasingly acknowledged in various types and areas of healthcare decision-making, from policy and research through to service delivery. Patient involvement in HTA at the hospital level is not yet implemented in many jurisdictions or hospitals. A systematic review [17] found 24 studies about patient or public involvement in HTA at the local level. Two main purposes for patient or public involvement were identified. First, patients or their representatives were consulted in order to generate evidence about their

perspectives, experiences, or preferences about a health technology or a clinical intervention. The rationale for this type of involvement is that patients have experiential knowledge on living with a health condition that needs to be considered when making decisions about the introduction or removal of health technologies. The second domain was direct involvement of patients or public representatives in the HTA process where they could take part in one or several steps of the HTA process, which are topic identification and selection, prioritization, formulation and scoping of the evaluation question, evidence assessment, as well as dissemination and implementation of HTA recommendations.

## 30.3 Experiences in Patient Involvement in Hospital-Based HTA

As hospital-based HTA (HB-HTA) is being extended in several jurisdictions, patient involvement in this context remains relatively less well documented. Two cases are presented here in order to provide different examples of current practices involving patients in HB-HTA. Then, this section highlights that patient involvement in HB-HTA is still limited globally and discusses some of the challenges that this involvement currently faces.

### *30.3.1 The Case of Monash Health, Australia*

In Australia, healthcare decision-making at the local level is devolved to individual states and territories. Health policy on consumer, carer, and community engagement in local health services and public hospitals is set by the states and territories. Their mandate includes defining the engagement frameworks and strategies for involving community advisory committees (CACs) or reference groups for local area health services and public hospitals. As an example, the Victorian Health Issues Centre is funded to resource consumer and community involvement in public hospitals in the state of Victoria through training and support of the individual hospital officers employed to support the CACs [37].

Health consumers also participate in public hospital safety and quality programs. Hospitals are accredited at a national level through the National Safety and Quality Health Service (NSQHS) standards, which were developed by the Australian Commission on Safety and Quality in Health Care [4] to improve the quality of health care in Australia. Standard 2 addresses “partnering with consumers” in service planning, designing care, service measurement, and evaluation.

In states where it is legislated that the public hospitals have CACs, or reference groups, these committees are a subcommittee of the board to ensure that the community, carer, and patient voices inform strategic direction. Generally CAC members

have experience, personally or through their families, in care provided by the hospital. Hospitals also engage and train volunteers to assist in various programs. CAC members, volunteers, and present or past patients and carers may be nominated to hospital committees.

Not all hospitals have active health technology assessment committees. The states of Western Australia, South Australia, and Queensland assess new technologies for their public hospitals at a state level. Where these committees have a consumer representative, this is generally through the state or territory health consumer organization. Drugs are assessed separately to medical devices, diagnostics, and services. These committees are overseen by the state or territory health departments. In New South Wales and Victoria, individual hospitals have new technology committees. Consumers have a clearly identifiable role, to oversee and increase the transparency of decision-making on technologies that are available in a given hospital, to increase accountability to the community, and to ensure delivery of the care that people want and are comfortable with. Thus consumers have the opportunity to influence decision-making through membership of the committees.

Monash Health is a large hospital service in Melbourne, Victoria. The New Technology and Clinical Practice Committee was instigated in 2002 to consider the introduction of a new technology (or clinical practice), change in use of a technology (including in a new patient group) together with the resource implications, impact on other areas of service delivery, training and credentialing (parameters for use), and disinvestment of technologies with low or no health gain. The HTA committee is chaired by a senior medical director, involves medical heads of department, and reports to the Executive Management Committee. The work of the committee directly influences practice within the local health service.

For a new technology to be considered, it has to be approved by the Australian regulator (Therapeutic Goods Administration) or is available with special access approval. The committee is however an early adopter of new technologies, before they have undergone formal assessment by the national Medical Services Advisory Committee (MSAC), that is, before any formal cost-effectiveness analysis based on a clearly defined usage within the Australian health system. Other such committees may require prior MSAC approval, as in the ACT.

Two consumer representatives have been on the committee since its beginning. They are members of the CAC or have been patients within the hospital. These consumer representatives are considered vital to the role of the committee. In the early years, the consumers were mainly concerned about information for patients, but now that they are more familiar with their roles, they are active throughout the meetings. The consumers can utilize the health service Centre for Clinical Effectiveness to assist them at any time and do so.

Clinical feasibility (resource implications, impact on other services, credentialing, and training), access and equity, and legal and ethical implications are also taken into consideration. The new service is monitored for a period of 2 years before it is considered standard practice, with regular reporting of audits of its use and notification of any serious adverse events. The audits are generally approved by the Human Research Ethics Committee as quality assurance activities.

### *30.3.2 The Case of the Centre Hospitalier Universitaire de Québec, Canada*

Canada has a decentralized healthcare system where each of the ten provinces and three territories is responsible for the provision of health and social services to its population. Within these jurisdictions, healthcare decisions are also made at the regional (i.e., health regions) or local level (i.e., the hospitals and other organizations providing care and/or social services). Since 1992, university hospitals in the province of Quebec (Canada) are mandated by law to conduct HTA activities [9]. Quebec is the Canadian province with the greatest number of hospital-based HTA units, with all five university hospitals and other health and social service centers implementing their own HTA programs. Other Canadian provinces also have local or hospital-based HTA activities, such as Alberta with the Local HTA Decision Support Program and Ontario with the High Impact Technology Evaluation Centre at the London Health Sciences Centre [9].

The emergence of HB-HTA units in Quebec represents a unique opportunity for increased user involvement in HTA. Involving patients at this level is different from involving them at a national level, notably because of the close relationships between service users and providers and the existence of organizations such as user committees. In fact, according to the Quebec Act respecting health services and social services [31], a users' committee has to be established for each institution, and each institution must allocate to it a special budget provided for that purpose. The users' committee is composed of at least five members elected by the users of the institution. The main functions of the users' committee are to (1) inform users of their rights and obligations; (2) foster the improvement of the quality of the living conditions of users while in a healthcare institution and assess the degree of satisfaction of users regarding the services provided by the institution; (3) defend the common rights and interests of users or, at the request of a user, defend his or her rights and interests in an appearance before the institution or any competent authority; and (4) accompany and assist a user, on request, in any action he or she undertakes, including the filing of a complaint.

The HTA unit (HTAU) of the Quebec University Hospital Centre (CHU de Québec-Université Laval) was set up in 2006. It aims to provide health managers and clinicians with the best available evidence to support decision-making on new services or technologies and to foster the emergence of a culture of evaluation within the hospital. The HTAU relies on two administrators (one physician and one manager) and six full-time research officers entirely dedicated to evaluation activities. Moreover, to ensure rigor and transparency in the HTA activities, the unit relies on two committees. The orientation committee is in charge of proposing annual orientations on evaluation projects and prioritizing HTA activities. The scientific committee's role is to validate HTA products and recommendations. One patient representative is involved in each of these committees and participates, with other members, in decisions that are made regarding the prioritization of HTA topics and the approval of HTA reports. However, there is no formal structure to

involve patients in the conduct of HTAs on specific technologies or modes of delivery.

As of 2009, a collaborative research program is being developed by the HTAU of the CHU de Quebec and researchers interested in patient and public engagement [14, 18]. Three externally funded research projects have allowed the involvement of patients in different stages of the HTA process. The first project provided a knowledge synthesis of international experiences of patient and public involvement in HTA at the local level [19] and an environmental scan of stakeholders' perceptions regarding patient involvement in HB-HTA. A second project involved health-service users in an HTA on alternative measures to restraint and seclusion for hospitalized or institutionalized adults [18]. Based on the results of this research, a third project involved patient representatives in the identification and prioritization of HTA topics in the field of cancer [14]. These collaborations between researchers and decision-makers have allowed the development of a framework to guide patient involvement in HTA at the local level. This framework is presented in the following section.

These examples notwithstanding, patient involvement does not seem to be the current norm or a proposed standard in the development of HB-HTA, as evidenced by what is NOT included in principles or priorities. For example, a recent survey of 46 hospitals across 15 regions in Italy revealed that almost half (467 %) had official HTA Commissions. Almost all (95 %) considered clinical principles to be important, and most (70 %) said it was important to consider economic principles, but less than one fourth (22 %) said social principles were important and none indicated that patient perspectives or patient impact were primary [6]. Not surprisingly, reports of the emergence of hospital-based HTA in low- and middle-income countries (LMIC) make no mention of patient involvement [3, 26].

More surprisingly, the Periodic Report Summary 1 from the European Commission's pioneering project, Adopting Hospital Based Health Technology Assessment in EU (AdHopHTA), also makes scant mention of patient involvement. Based on 38 case studies of existing HB-HTAs, the authors concluded that "Information that hospital managers value most are clinical evidence, economic aspects, safety and organizational aspect." This report also mentions that ethical and legal information was less relevant for HB-HTA than for national HTA and that budget impact was more important in HB-HTA than societal cost-effectiveness. On a positive note, AdHopHTA proposes inclusion of patient representatives in the Expert Panel to review the Handbook and Toolkit prior to finalization [2].

## 30.4 A Framework for Patient Involvement in HTA at the Hospital Level

Based on a systematic review of the literature on patient participation in HTA at the local/hospital level [17] and interviews with HTA stakeholders in the province of Quebec [18], a reference framework was developed to inform decision-making and

| | Phases in the HTA process | Objectives of the involvement | Level [1] / Type of participants [2] Information flow(→) | Methods or activites (examples) |
|---|---|---|---|---|
| Selection of topics | **Submitting assessment requests** | Get suggestions form patients about needs in assessment | **Consultation** / «specialists» HTA producers ← patients | Methods to collect information or opinion from patients: focus group, web, phone lines. |
| | **Prioritizing topics** | Have the patients' perspectives about priority topics | **Participation**/ «generalists» HTA producers ←→ patients | Commitees of priorisation<br>Citizen jury<br>Focus groups in a specific field |
| Evaluation | **Elaborating evaluation plan** | Have the patients' perspectives about the definition of the research question, issues, dimensions to be evaluated, to improve the accuracy and applicability of the assessment | **Participation**/ «generalists» or «specialists» HTA producers ←→ patients | Participation in a workgroup with other stakeholders<br>Participation in a separate groupe or in adhoc committe |
| | Collecting evidence (Literature) | | | |
| | **Collecting new data or contextualization** | Obtain informaiton on the impact of technology evaluated and the context of its implementation | **Consultation**/ «specialists» HTA producteurs ← patients | Collect of data from patients with various qualitatives or quantitatives methods |
| | Analyses and syntheses | | | |
| Final report and recommandations | **Discussion and approbation of report/ Making recommendations** | Obtain informaiton on the impact of technology and the context of its implementation in order to improve the accuracy and applicability of recommendation / Encourage implementation and adoption of recommendations | **Participation**/ «specialists» patients ←→ producteurs | Participation in a workgroup with other stakeholders<br>Participation in a separate groups or in ad hoc committe |
| Diffusion | **Communication and diffusion of results** | • Promote information, accountability and autonomy of patients<br>• Encourage implementation, acceptability and adoption of recommendations | **Information**/ «specialists» HTA Producers → patients<br>**Consultation**/ «specialists» HTA Producteurs ← patients<br>**Participation**/«generalists» or «specialists» HTA Producers ←→ patients | Dissemination to report and recommandations to patients<br>Consultation or participation of Patients' representatives to the development of the information material and to its diffusion |

1 **Level of participation**
**Information**: dissemination of HTA results to patients
**Consultation**: collect primary data among patients or ask them about their needs, views or preferences
**Participation**: actively involve patients in the HTA process as partners

2 **Type of participants:**
•« specialists» : patients (including their relatives and representatives) directly affected by the technology that is evaluated
•« generalists» : patients who represent all actual or potential service users who may be represented, for ex by members of a users' committes

**Fig. 30.1** Patient involvement in HTA at the local level

practice on patient involvement in HTA [16]. This framework was inspired by other conceptual frameworks for patient and public involvement in HTA or health decisions in general [20, 29, 32, 36]. The framework was recently validated among representatives of different groups involved in HTA, including HTA producers, managers, clinicians, and patients [16].

The framework (Fig. 30.1) illustrates models of user involvement defined by the *steps* of the HTA process (*when*), the *objective* of the involvement (*why*), the type of *people involved* (*who*), and the *mechanisms* of user involvement (*how*). The first stage of the HTA process is the selection of evaluation topics and comprises the suggestion and prioritization of topics. The second stage, evaluation, is made up of several steps. It includes protocol development, review of evidence, contextualization or collection of primary data (if relevant), analysis and synthesis of results, the final report, and recommendations. The communication and dissemination of results represent the third and last stage of the HTA process.

Regarding the people involved, a distinction was made between "specialist" and "generalist" lay people, similar to that made by other authors between patients and the public [20]. A specialist refers to health-service users or patients, namely, people who are, or have previously been, users of health services directly affected by the technology that is being evaluated. User family members and user representatives, such as community groups that represent

user interests, are also included in this category. Generalists include people who represent all potential or current service users, such as users' committees, but who do not have experience of the specific health condition targeted by the assessment.

Different mechanisms of involvement include the levels of user involvement and the activities for involving health-service users. The three levels of user involvement presented in the framework correspond to those defined by Rowe and collaborators [32]: (1) information, related to the communication of HTA, results to health-service users; (2) consultation, which includes different ways of asking users about their values, perspectives, needs, and/or preferences in order to inform the different phases of the HTA process; and (3) participation, which includes different mechanisms that can be put in place in order to actively involve health-service users in the HTA process.

This framework was applied and validated in a project that aimed to implement and evaluate interventions involving service users in a specific HTA: the assessment of alternative measures to restraint and seclusion among hospitalized adults and those living in long-term care facilities in the regional integrated health network of Université Laval in Quebec [18]. According to interviews conducted with managers and HTA producers, the proposed framework was considered a useful means to inform and raise awareness among decision-makers and practitioners concerning different options for patient involvement in HTA. They also believed that this framework could support the planning and implementation of patient involvement initiatives in the hospital context. Patient representatives appreciated that the framework included consideration for user involvement in all stages of the HTA process. However, some respondents found that the framework was more a theoretical model rather than a practical tool and it required explanations in order to be understood.

## 30.5 Different Types of Patient Involvement in the HTA Process

### *30.5.1 When to Involve Patients in the HTA Process?*

In the proposed framework, patient involvement can take place at each step of the HTA process. Many respondents believe that user representatives should participate as much as possible in all steps of an assessment. They should, therefore, consider themselves full participants and familiarize themselves with the HTA process. According to the two broad domains for patient involvement in HTA, consultation and direct participation, consulting service users about their experience, needs, or preferences regarding the evaluation topic is essential in order to foster health care and services that are focused on their needs.

### 30.5.2 Why Involve Patients in HB-HTA?

The direct participation of user representatives in the HTA process, through their involvement in working groups, for example, is seen by many of the managers and coordinators who were interviewed as a direct way (through the discussion) to get their perspectives and feedback on HTA results.

User representatives find their participation in workgroups or committees very relevant because they can bring experiential knowledge, which is radically different from the knowledge of clinicians or managers. Furthermore, involving patients and their representatives by informing them of the HTA results and recommendations could enable them to better understand the interventions and services they receive. They can then judge the interventions and services in this light. As such, involvement could improve informed decision-making and support informed consent regarding the utilization of health technologies.

According to interviews, consulting patients about their experience, needs, or preferences regarding the evaluation topic is essential in order to foster the health care and services that are more focused on their needs. In the specific case of mental health and geriatric care, this attention to the lived experience of service users is particularly relevant since patients often have to live with technologies (e.g., psychiatric drugs, meals, and daily care in long-term care facilities) for a long time or on a frequent basis.

### 30.5.3 Who Should Be Involved?

People directly affected by the technology (patients or users) should be consulted in the data collection process. These people who have a direct experience of living with a particular condition are our "specialists." Family members and other significant people could also be considered in this category. According to the interviews, the basic criteria for selecting patient representatives to participate in an HTA working group are being involved in the community related to the topic (e.g., a community group) and having experience as a service user while having enough distance from the experience related to the technology that is being evaluated to contribute effectively. The person should also exhibit good teamwork, openness, and communication skills.

With respect to direct participation, patient group representatives are considered to be relevant participants in an HTA working group. They possess a good knowledge of the issues and experiences of the members of their organization and are able to easily get information from the members. Also, being elected by group members, they are seen as trustworthy and have the legitimacy to represent the common interests of the group and not to present their personal opinion.

### 30.5.4 How Patients Can Be Involved in HB-HTA?

One source of patient input is in the form of "patient-reported" outcomes, increasingly requested in the form of validated patient-reported outcome measures (PROMs), in part because these data are easier to summarize, analyze, and replicate [35]. However, patients sometimes complain that the quantitative reported PROMs do not adequately capture their perspectives, with researchers recommending blending of quantitative and qualitative methods [27]. For some technologies, HB-HTAs could also adapt the "patient submission" template used by HTA agencies reviewing innovative drug technologies. The *Patient Group Submission Template* was adapted by the HTAi Interest Group on Patient and Citizen Involvement [34].

Qualitative methods, including focus groups, are an appropriate consultation strategy because of the wealth of information and nuances that can result from interactions among participants. In particular, a key element of the success of patient consultations is when focus groups are facilitated or co-facilitated by a person who has experience related to the topic (such as a representative of a community group or a peer worker). The organization of public meetings to consult service users and the use of more formal processes such as citizen juries have also been suggested as effective methods to gather patients' perspectives. It is important to consider particular strategies to reach vulnerable and illiterate people in order to gather their care experiences.

The active participation of user representatives in HTA could also enable appropriation and dissemination of results during the action. Besides, user participation in the dissemination of HTA results could help inform researchers about the needs and priority research topics for users.

Different means of communicating HTA results to patients have been suggested. A brochure or leaflet summarizing the key points can be developed in plain language, ideally with the help of communication specialists and taking into account the level of health literacy of the targeted audience. However, according to our study, patient representatives favored in-person meetings.

### 30.5.5 Barriers to and Facilitators of Patient Involvement in HB-HTA

One of the main barriers to user involvement relates to the recruitment of patient representatives for consultation or direct participation in the HTA process. Participants can be difficult to recruit because of the sensitivity of some topics (e.g., fear of any stigma attached to mental health), and the lack of awareness of certain HTA topics by both users and their relatives can limit their understanding of the technology being assessed.

Although participation of the same user representatives throughout the HTA process seems advantageous since it allows them to become familiar with the whole

HTA process, it can also be very demanding for participants. Some of the factors that can affect the success of user participation include their lack of preparation, a lack of clarity regarding their role, a lack of tools, and/or the use of language that is too technical, scientific, or hermetic.

User representatives considered that facilitation of the focus group by a representative of a patient group or a peer-support worker was a key element of success. Working with patient groups or associations constitutes a promising strategy to bring together researchers and patients in the organization of consultations and the recruitment of user representatives. These groups are highly trusted by their members and their cooperation for the recruitment of participants can be an effective strategy. It may also be a good idea to vary sources of recruitment for user consultations (e.g., via users' committees, advertisement at points of care, or through managers or care providers).

With respect to user participation in a working group, it is important to recruit a sufficient number of user representatives to ensure that their expertise is represented in a similar proportion to that of other experts. Respondents also favored smaller working groups, thus also enabling the participation of users to have an impact. User representatives delegated to committees should be provided with initial training, including basic information on HTA, the specific topic that will be evaluated, and the basic skills required to participate in a working group.

## 30.6 Discussion

Patient and public involvement (PPI) in hospital-based HTA (HB-HTA) is increasingly being proposed to promote more transparent decisions regarding the allocation of scarce healthcare resources, to integrate the unique value that experiential knowledge brings to the understanding of the effects and impact of a health technology. As shown in this chapter, there are several ways in which patients and the public can engage in HTA at the local or hospital level. However, the evidence is still limited on the effects that this involvement has on the decisions made. Rigorous evaluations of PPI experiences are required from around the world. Collaboration between researchers and knowledge users (including patient and public representatives, HTA producers, clinicians, and healthcare managers) is suggested as an avenue to provide contextualized evidence on the various experiences of PPI in HB-HTA.

The distinction between the "patient user" and the "public consumer" often is not maintained in many HTA frameworks and/or processes. This "muddling" leads to inconsistency and confusion as to "whom" to involve as well as "how" and "why" to involve and, most importantly, how to use the input (evidence) provided. For example, the *Evidence Brief on HTA in Ontario* [21] defines a "patient" as an "individual with experiential knowledge about living with an illness or condition who can provide valuable perspectives about the intended or unintended consequences of current or future health technologies" and a "public" as "individuals who can

contribute broad social values regarding the efficiency or fairness of a technology." However, throughout the remainder of this report and in its recommendations, patient and public engagement in HTA is used without any differentiation [21]. It is important that community groups or citizen councils not be used as substitutes for patient group representatives or disease-specific groups. Preferences submitted by patients who are direct users or beneficiaries of health products or services have different relevance than those of the potential users or societal representatives. However, identifying and engaging patient users may be more challenging for HB-HTA than HTA agencies assessing therapies or interventions for specific illnesses or chronic diseases.

The conceptual framework that is proposed in this chapter can be used in order to guide the planning, implementation, and evaluation of PPI in HB-HTA because it covers the various steps of the HTA process as well as the main questions relevant to and of interest for effective PPI (When? Why? Who? How?).

The different strategies or mechanisms to integrate users' values and perspectives as presented in the framework have to be considered in relation to the local context where their relevance and applicability can be assessed. People directly affected by decisions should be involved alongside other stakeholders (policy makers, healthcare managers, clinicians, researchers, etc.) in shaping public policies. If a clear distinction has to be made between the use of information on users' values and preferences and their direct involvement in the decision-making process [25], both have their place in HTA at the local level.

Restricting involvement to direct participation raises concerns about the identification of participants who can represent the range of user experience; it may also eliminate input from marginalized and vulnerable populations [25]. As pointed out in our study, the consultative approach makes it possible to consider the views of a variety of participants who do not necessarily meet the requirements for participation in HTA committees [16]. It is important to find ways to reach users in their diversity, including vulnerable people and those that present specific challenges, such as cognitive problems, in order to better answer the needs of the population and to improve health care. Moreover, incidental patient users of hospital technologies may be more difficult to identify, recruit, and engage than patient representatives with chronic illnesses who may belong to patient groups and have a continued and vested interest in being informed and ensuring access to appropriate technologies.

The proposed framework could be useful in informing decision-makers and practitioners on the different purposes of patient involvement in HB-HTA and provide some consistency in the classification and description of involvement activities. Moreover, it can support practice regarding patient involvement at the different steps of HB-HTA by informing practitioners and health managers about the different approaches and strategies for involving patients. However, there is a need to develop instruments to guide practice and support decision-making on how to implement these different user-involvement mechanisms. Thus, structured tools are necessary to help managers plan patient involvement in HB-HTA activities. Also, a better evidence base is needed to persuade providers and managers to place greater

emphasis on patients' views when they are making decisions about health technologies and services.

Furthermore, these evaluations face important conceptual and methodological challenges, from the definition of user involvement to the measurement of its effects. Healthcare professionals and service users understand and practice user involvement in different ways based on their individual ideologies, circumstances, and needs [13]. The simple question of the choice of the outcomes utilized as indicators of the success of user involvement depends on the different perspectives of the key stakeholders [13].

Typical scientific evidence (i.e., based on rigorous experimental design) is currently lacking for the effectiveness of PPI interventions on health care and health outcomes. A Cochrane systematic review [28] found some evidence to support the effectiveness of involving users in the development of patient-information material. In fact, material that was produced with input from patient representatives was perceived as more relevant, readable, and understandable to patients. In order to promote PPI in HB-HTA, evaluating current experiences remains a priority to strengthen the evidence base. There is a need to develop alternatives to experimental methods and to consider factors that contribute to the success of different models of user involvement, which could enhance our understanding of the best methods to involve users [11].

## 30.7 Conclusion

This chapter provides an overview of the current landscape regarding patient and public involvement (PPI) in hospital-based HTA (HB-HTA). As both patient involvement and HB-HTA are expanding in many jurisdictions, the knowledge base is expected to grow in the coming years, and it is recommended to look for updated versions of this document. It is hoped that the present chapter provides some clarification of these concepts and offers guidance to people interested in promoting greater patient and public participation in decisions affecting health care.

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# Chapter 31
# Clinician Perspectives on Hospital-Based HTA

**Davy Cheng and Janet Martin**

## 31.1 Background

> Healthcare is a complex adaptive system. We need to work with the system, not against it, to bring about change. (Sir Muir Gray, www.bvhc.co.uk/solutions/)

The success of any hospital-based health technology assessment (HB-HTA) program depends on many stakeholders, but without buy-in from physicians and other members of the clinical team, HB-HTA will fail to reach its full potential. Physicians and clinical team members have great influence on which drugs, technologies, and techniques are used in the hospital setting, due to their pivotal role in hospital decision-making from the micro-level (individual/patient level clinical practice) to the meso-level (institutional policy/standard) and ultimately to the macro-level (national or governmental guidelines/standards).

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## 31.2 Clinicians as Technology Influencers

At the micro-level, clinicians ultimately make decisions at the patient bedside about which technologies, drugs, and procedures will be used. Patients differ in their clinical presentation and in their ultimate needs and values. For this reason, individualized decision-making rather than "one-size-fits-all" decision-making is required. At the meso-level, clinicians often serve as leaders and influencers in policymaking for the hospital setting, including for quality oversight, clinical management, and institutional policy implementation. Furthermore, clinical teams are the end users of the drugs and technologies, and are necessarily the experts in their delivery to treat patients. Clinicians also build research programs and world renown through the innovative development and use of drugs, technologies, and techniques in order to further enhance healthcare toward better outcomes for the future. With this triple influence at the patient level, institutional level, and global level, clinicians become one of the most important players (or naysayers) in setting the pace for technology uptake and abandonment.

## 31.3 Managing Clinician Perceptions and HTA Capacity

Depending on how the HB-HTA program is organized and operationalized, it may be perceived by clinicians as either helping or hindering patient care. If HB-HTA is organized to primarily serve and answer to the priorities of budget holders, managers, and planners, it may be perceived (rightly or wrongly) as a hindrance to overall patient care, with undue focus on cost-cutting and organizational efficiency. On the other hand, if HB-HTA is conducted to primarily serve the agenda of industry, it will be perceived by clinicians as biased and unduly advancing development of technologies and drugs which may be of low value to the reality of the hospital's gravest needs.

From the clinician perspective, HB-HTA needs to be conducted in a fair and transparent manner, with continuous opportunity for clinician involvement in the identification and prioritization of topics for assessment, and with a collaborative approach between the HTA producers and the clinicians as "experts" and "end users" to ensure that the evidence synthesis and economic evaluations are conducted in a manner that is meaningful and relevant. Clinicians are unaware of HTA activities performed at a national level or performed outside of the hospital setting, often because such HTAs are presented in a manner that is less accessible and relevant to the practicing clinician (large reports, with lots of data and generalizations that are difficult to apply to the local setting, where different skills and competing alternatives may make the external HTA reports a moot point).

## 31.4 Capacity for Clinician Involvement

As reiterated throughout the case examples provided in this book, clinician involvement in HB-HTA remains one of its greatest strengths toward achieving buy-in and local relevance. Hence, methods to enhance and maximize the effectiveness of clinician engagement should be the subject of future exploration. Clinicians in hospitals may have limited interest or understanding of the HTA process, until they have had opportunity to be involved in a successful local HTA process. To prepare clinicians for the journey of producing a locally relevant assessment of technologies, opportunities to educate clinicians and trainees on the rationale and methods of HB-HTA will be essential.

Educating students and upcoming generations of clinicians should also be a priority, since increased in future ambient knowledge of HB-HTA will enhance the capacity of hospitals to collectively move the agenda forward toward better decision-making, and ubiquitous understanding of the need for rigorous evaluation before technologies are taken up or abandoned in the hospital setting. Increasing educational opportunities, through workshops, certifications, and graduate courses or masters/PhD programs devoted to HTA, evidence-based decision-making, critical appraisal, systematic review, meta-analysis, health economics, biostatistics, clinical epidemiology, clinical trial design, and evidence generation should be provided in a clinician-friendly manner.

## 31.5 Risks of Clinician Involvement

Clinician involvement in HB-HTA is essential [17], and yet this comes with a mix of potential risks and rewards that will need to be managed across the institution if an HB-HTA program is to remain viable over the course of multiple decisions with unlimited technology demands and severely restricted budgets. Due to the nature of clinical practice innovations and the pressure for academic recognitions for innovative progress and research, some clinicians may be unduly invested in getting a "yes" recommendation for any technology assessments related to their area of expertise.

This pressure may be particularly strong for technologies and procedures related to a clinician's international renown. In some cases, this can place undue pressure on those conducting the assessment and may place the assessment at high risk of bias. To some degree, this risk of undue pressure is analogous to "moral hazard," whereby a "yes" to technologies with vested interests to a small group of clinicians will mean a "no" to other technologies of other equally vested clinicians. Maintaining an objective process, with transparency, and broad involvement of stakeholders so that there are no disparities of power in determining the overall institutional priorities are key.

While an appeal to altruism may be sufficient for many clinicians to contribute to HB-HTA, clinicians may also respond to appropriate incentives such as peer-reviewed publications and other academic recognitions as a direct output of the HB-HTA process, to ensure that their in-kind time devoted to HB-HTA is duly recognized. If possible, when clinicians are part of an HB-HTA process to identify opportunities for reducing low-value interventions through disinvestment, they should share in the benefits from the savings through commensurate opportunities for investment. Otherwise, those who are most helpful in identifying disinvestment opportunities may also feel punished as "losers" in the process of identifying things that their department will give up, while others will be the "winners" of subsequent investments made possible by the released funding.

## 31.6 Understanding the Technology Hype Cycle

Clinicians, administrators, patients, and lay citizens alike are vulnerable to the technology "hype cycle" mentality in healthcare (Fig. 31.1). With each new introduction of a technology or innovative procedure in healthcare, the raised expectations for the "new" (and presumed "better") technology trigger often translate to a rushed and overexuberant uptake of the technology into practice. However, this hyperbole encourages premature uptake, before adequate evidence that has accrued to allow assessment of the worthiness of the new technology relative to available alternatives has been undertaken, and before contextualized assessment of the need for supportive processes and other interrelated issues such as local skills, protocols, and safety measures are adequately ensured [5, 14].

Premature uptake often results in the new technology failing to reach our inflated expectations and may even cause more harm than benefit. As a result, the technology may rapidly fall out of favor and even be a risk of unnecessary abandonment if the "plateau of productivity" cannot be achieved within reasonable time and effort. This "hype cycle" repeats itself time and time again, with the allure of each new technology introduced to the imaginations of clinicians and hospitals looking for easy solutions to very big programs. HB-HTA needs to arrest, or slow, this technology hype cycle, so that the hyperbole (both "over" and "under" the plateau of productivity) can be smoothed, and realistic expectations based on best evidence are made clear as the evidence evolves throughout the technology development and implementation. Achieving the "plateau of productivity" more efficiently should be the goal of HB-HTA, rather than responding to the whims of clinician and patient advocates for every hyped technology prior to adequate evidence upon which to make a reasoned decision.

The Minister of Health in Ontario, Canada, has released the "Excellent Care for All Act**,"** which proposes to "reduce wide variations in clinical practice, reduce inconsistent adoption of best practices, guidelines, and protocols" by "strengthening the focus on quality, value, and evidence-based care in Ontario [19]." Other

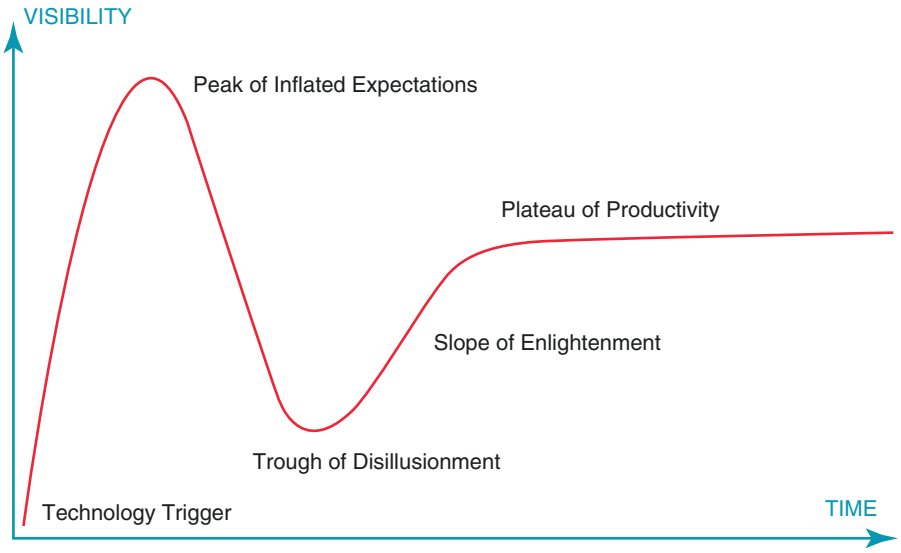


**Fig. 31.1** Technology hype cycle (Reproduced with permission from Jeremykemp at English Wikipedia, the copyright holder of this work, under the following licenses: GNU Free Documentation License, Version 1.2 or any later version published by the Free Software Foundation)

jurisdictions worldwide have begun to work in a similar vein, to ensure that the full potential of the available array of technologies, devices, drugs, and programs are identified and made available to the people efficiently. Without coordinated entry to the healthcare system, new technologies will never reach their full potential, and the opportunity costs will be high [13].

## 31.7 Clinicians Facing Trade-Offs in Healthcare

The culture of medicine has changed over the past 20 years to espouse the need for an evidence-based approach [21]. Simultaneously, the expanding demands coupled with declining resources have also ushered in an increased awareness of the limits of hospital budgets, and the need to objectively face the need to make trade-offs in healthcare, within available budgets:

> On one hand, there is the pressing need to do all that we can to justify the increasing costs and efforts expended to implement new drugs, technologies and techniques into practice. On the other hand, we need to respect that we cannot (and should not) do it all, especially if the new techniques or technologies will achieve only marginal benefits, at best, and at greater risk and cost compared with the existing status quo.

> There is a limit, in terms of available resources: money, space, people, time, and effort. Evidence-based health technology assessment (EB-HTA) is not necessarily a means for cost-cutting, since the best available evidence may suggest that the newest most expensive option is truly the best, and that the payback is worth the incremental costs required. Thus, EB-HTA provides guidance to ensure that resources are not wasted, and that every dollar expended improves value for money.
>
> Status quo is no longer an option in sustainability of healthcare system. Physicians are often entrusted as gate-keepers of the healthcare resource utilization and expenditure. How can we continue to practice decision-making on a whim, opinion, or something less than due diligence to the best available evidence? [5, 13, 14]

In many regions of the world, as in Canada, there has never been a time in history of medicine where the political milieu has been so fertile for building the scientific basis for health policy. The recent Choosing Wisely campaign is timely in focusing the attention of physicians and patients on the inappropriate use of tests, treatments (drugs, technology), and procedures [12]. The campaign began in the United States in 2012 and now has spread to many countries around the world and has made us more aware of the shift in evidence from evolving research that even established practice adopted from highly cited clinical research may become contradicted or be proven less effective than initially proposed [11].

We need to understand why physicians are not following clinical practice guidelines and address the root causes [3]. The main barriers in HTA uptake can be attributable to (i) knowledge (lack of familiarity or awareness of practice guideline or evidence); (ii) attitude (lack of agreement with guidelines, outcome expectancy, self-efficacy, motivator); and (iii) behavior (patient factor, environment factor such as time, resource, infrastructure, or reimbursement). Our experience in hospital HTA and implementation, particularly in perioperative surgical and anesthesia care, led us to add (iv) skill (lack of technical training opportunity or learning curve to retool particularly in technology-intensive areas such as critical care and surgery) [1, 2, 4–9, 13–18].

In summary, externally produced HTAs often do not get adequate dissemination and uptake to frontline practicing physicians. To effectively evaluate technologies for translation to the local hospital, context requires local physician champions, buy-in, and accountability in order to maximize the impact and relevance to patient care. Transformational sustainable change in frontline clinical practice requires organization-physician partnership and engagement with technical tools and adaptive work [10]. Our experience in HB-HTA in Canada has been similar to that expressed by many HB-HTA units in this book: clinicians remain an important stakeholder group without whom success in knowledge translation will not be achieved. With clinicians involved in HB-HTA, the valleys of challenge can be more easily surmounted across the clinical translational continuum, starting even from the mountain of basic biomedical research to clinical science (through upstream HB-HTA during technology development) and ultimately to clinical practice and healthcare decision-making to patients (through assessment and reassessment of mature technologies for investment or disinvestment) [1, 5].

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# Part V
# Lessons Learned

# Chapter 32
# Hospital-Based HTA in 31 Organizations Worldwide: What Are the Lessons Learned?

**Americo Cicchetti, Marco Marchetti, Janet Martin, and Laura Sampietro-Colom**

## 32.1 Introduction: Aims of the Chapter

The use of health technology assessment (HTA) as part of the decision-making process at national, regional, and international levels has evolved considerably over the past 40 years.

Hospital-based health technology assessment (HB-HTA) can be considered as one possible approach to enhance the use of HTA for managerial decision-making in hospitals and other healthcare organizations and to improve the use of evidence, complemented with local information, to inform clinical practice in the "real world."

The aim of this chapter is to provide readers with a broader analysis of different models of HB-HTA presented within this book and to extract some "lessons learned" from these experiences. Additionally, it aims to give some insights on what should be considered when setting up a new HB-HTA program.

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Finding an ideal model for HB-HTA is not the aim of this exercise. In fact, organizational theory and managerial practice during the last 50 years suggest that organizational models should be designed based on an analysis of specific contextual factors of the organization. Many contextual factors, including characteristics of the environment, the strategic conduct, the operational dimensions, the geographical setting, as well as the dominating organizational culture and values, affect the appropriate choice of technologies and resulting organizational design to incorporate the chosen technologies. Consistent with this "contingent" view [1], we are not looking for an ideal organizational model for HB-HTA. Each experience can provide managers and policymakers with useful insights and suggestions if analyzed in its own context, rather than searching for the idealized "one-size-fits-all" model.

## 32.2 Organizational Models for HB-HTA

Since the seminal experience of application of the HTA logic to support managerial decision-making in the Assistance Publique – Hopitaux de Paris, thanks to the establishment of CEDIT in 1982, many healthcare organizations around the world are implementing institutional HTA programs or initiatives. In the past, only a few surveys have tried to capture these experiences in different geographical contexts. The first worldwide survey was carried out by the HB-HTA interest sub-group of HTAi in 2008 [2]. This survey identified four types of HTA activities carried out in hospitals based on their focus of action and organizational complexity, categorized as follows: ambassador model (clinicians recognized as "opinion leaders" play the role of ambassadors of the HTA "message" inside the hospital), mini-HTA (clinicians carry out the assessment process filling a checklist), internal committee (a group of clinicians who perform reviews of evidence to provide a recommendation on HTA), and HTA unit (formal organizational structure based on specialized HTA personnel in hospital) [2]. This survey was useful to depict the variety of organizational solutions and ways of application of HTA around the world. Nevertheless, the survey was not able to fully capture the characteristics of the processes, the quality of the products, or the impact of each unit's activity.

Other surveys were launched in the years to come in single countries. Examples come from two surveys launched to assess the diffusion of HB-HTA and its impact on hospital decision-making in Italy. These surveys were promoted by Ce.Ri.S.Ma.S. (Centre for Healthcare Management Studies and Research) and by FIASO (Italian Federation of Healthcare Organizations) in 2013. The most recent results regarding HB-HTA organizational models come from AdHopHTA, a European-funded research project under the 7th Framework Program [3]. Its results show macro-trends in HB-HTA organizational models, which have been identified through the analysis of seven HB-HTA units in Europe: Hospital Clinic de Barcelona (HCB), Ankara Numune Training and Research Hospital (ANH), University Hospital of Lausanne (CHUV), Hospital District of Helsinki and Uusimaa (HUS), Odense University

Hospital (OUH), Fondazione Policlinico Universitario A. Gemelli Università Cattolica del Sacro Cuore (UCSC), and one from New Zealand (Auckland City Hospital located in the Auckland District Health Board in New Zealand).

To identify macro-trends in organizational models, a case study methodology was used, based on the analysis of five key organizational variables: (1) formal structure and use of authority, (2) centralization/decentralization of decision-making power, (3) specialization of labor, (4) formalization of procedures used in the units, and (5) level of personnel qualification. In addition, the case descriptions were further organized by two key structural variables: (1) formalization/specialization of the HB-HTA unit and (2) level of integration with other HTA bodies at national/regional levels. Results of this analysis lead to a framework describing four main organizational models of HB-HTA. Figure 32.1 shows these models [3].

| | | **Level of integration** | |
|---|---|---|---|
| | | *High-Mid* | *Mid-Low* |
| **Level of structuration** | *Formal and specialized* | Integrated specialized HB-HTA program/initiative (e.g. HUS, OUH) | Stand-alone HB-HTA program/initiative (e.g. UCSC, HCB) |
| | *Informal and essential* | Integrated-essential HB-HTA program/initiative (e.g. CHUV) | Independent group (ACH) |

| | |
|---|---|
| *UCSC* | UVT-Policlinico Gemelli |
| *HCB* | Hospital Clinic Barcelona |
| *ANH* | Ankara Numune Training and Research Hospital |
| *OUH* | Odense University Hospital |
| *HUS* | Helsinki University Hospital |
| *CHUV* | University Hospital Lausanne |
| *ACH* | Auckland City Hospital |

**Fig. 32.1** Organizational models of HB-HTA units defined by their level of integration, formalization, and specialization (Source: AdHopHTA handbook, reproduced with permission). (1) Independent group, a group of non-full-time hospital professionals who act on a voluntary basis to provide information regarding the value of HTs – in this case, top management is still not fully aware of the relevance of HTA for them; (2) integrated-essential HB-HTA units, small-sized units with non-full-time professionals devoted to HTA, which collaborate with allies – inside and outside the hospital – to produce HB-HTA reports; (3) integrated-specialized HTA units, which despite being specific HTA units inside the hospital, have a certain level of autonomy, are highly influential, and collaborate closely with national/regional HTA agencies – these units are formalized inside the hospital and have professionals specialized in the assessment of specific HTs (e.g., medical devices); (4) stand-alone HB-HTA units, which are highly formalized and integrated in the hospital, with full-time professionals devoted to HB-HTA and not influenced by national/regional HTA agencies (7)

These four groups should be considered ideal types, recognizing that none of them is able to fully capture the complexity and variety of possible organizational arrangements. Nevertheless, the model communicates, at least, the richness of available solutions to run an HTA program/initiative within a hospital. The model can also describe a sort of organizational life cycle for HB-HTA programs/initiatives. During start-up, units are typically informal and less connected with the external environment (independent groups). People work part-time, on a voluntary basis without strong formal endorsement from management, applying informal procedures. The presence or absence of national/regional HTA bodies, acting as hubs of an HTA network, influences the evolution of the unit towards an integrated or a stand-alone solution. The evolution towards a more mature HB-HTA program/initiative is characterized by increasing levels of formalization and structuration in the processes and by a progressive alignment between strategies and goals pursued by the HB-HTA program/initiative and hospital-level strategies. In this evolution, the HB-HTA program/initiative gains internal and external legitimization until it is fully recognized as a key factor for the hospital's development strategies and is also considered to be a partner at the national/regional level. Table 32.1 outlines the organizational characteristics and trends of HB-HTA units identified recently through AdHopHTA research [3].

## 32.3 Analyzing HB-HTA Programs/Initiatives Around the World

Previous chapters of this book have described worldwide experiences in HB-HTA. Thirty-one HB-HTA experiences have been surveyed in Canada (seven cases); Spain and Switzerland (three cases per country); USA, Argentina, and Brazil (two cases each country); and France, the Netherlands, South Africa, Italy, Denmark, Turkey, Sweden, Finland, Australia, New Zealand, China, and Singapore (one case per country). Six continents are represented for a total of 18 countries. These experiences have been analyzed (using a qualitative methodology) and classified according to the four organizational models identified in AdHopHTA. Table 32.2 shows these results.

Other key organizational trends in the HB-HTA practices described in this book can be identified:

(a) *Mission and organizational structure of HB-HTA programs/initiatives*: the mission of most HB-HTA experiences is to support managerial decisions (27 over 31 practices described) although some of them also report a broader mission (e.g., promote innovation, support clinical practice guidelines). Regarding the formal organizational position of the HB-HTA unit, most of them report directly to the board of trustees or to specific internal commissions, while fewer report directly to the CEO or the CMO of the hospital.

(b) *Connection with other HTA initiatives at the national/regional level*: 26 out of 31 hospitals report either formal or informal collaborations with other players in the healthcare system during the assessment process. Two types of integration have been reported: vertical integration among HB-HTA units and regional/national level HTA bodies (or international collaborations) and horizontal inte-

**Table 32.1** Organizational characteristics and trends in HB-HTA units

| Characteristics of HB-HTA | Trends in HB-HTA functioning |
|---|---|
| Mission (how it is defined by the HB-HTA program/initiative) | (a) Managerial support to decision-making |
| | (b) Assessing health technologies |
| Position in the organizational structure of the hospital | (a) CMO (Chief Medical Officer) (most) |
| | (b) CEO ($n=1$) |
| | (c) Quality and directorate research ($n=1$) |
| Funding source (public) | (a) External (e.g., competitive grants, contract with other organizations) (main source for most) |
| | (b) Internal (from hospital) (few from hospital budget for most) |
| Role of HB-HTA in the decision-making | (a) Mandatory (most units) |
| | (b) Recommended |
| Role after the assessment | (a) Procurement (acquisition) phase (few) |
| | (b) Implementation of recommendation (few) |
| Background of professionals in the unit | (a) Clinicians, health economists, public health (most) |
| | (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) |
| Dissemination of the activities performed by HB-HTA | (a) Internal (clinical rounds, word of mouth, information send to clinical departments, broadcast e-mail, presentation at the hospital board meeting) |
| | (b) External (media, national journals, newsletters, websites, courses, events/conferences) |
| Prioritization of health technologies for assessment | (a) Specific criteria (few) |
| | (b) First-in-first assessed (most) |
| Types of health technologies assessed (in order of frequency) | (a) Medical devices |
| | (b) Medical equipment |
| | (c) Diagnostic tests |
| | (d) Procedures (clinical and organizational) and drugs |
| Performance of the assessment | (a) By professionals in the HB-HTA program/initiative |
| | (b) Shared between clinicians (e.g., literature review) and the HB-HTA program/initiative (e.g., economic analysis + supervision of work by clinicians) |
| | (c) By clinicians supported and supervised by the HB-HTA program/initiative |
| Scope | PICO (all) |
| | Type comparator: gold standard and technology available at hospital |
| Recommendations included | (a) Yes (most) |
| | (b) No |
| Characteristics of recommendation | (a) Advisory (always) |
| | (b) Mandatory (few) |

(continued)

**Table 32.1** (continued)

| Characteristics of HB-HTA | Trends in HB-HTA functioning |
|---|---|
| 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) |
| Dissemination of the HB-HTA product/assessment | (a) Internal (e.g., intranet/database: complete assessment, abstracts, or summaries of the assessment) (most) |
| | (b) External (e.g., database open to other hospitals) (few) |

*Source*: Reproduced with permission [3]

gration across HB-HTA units. In seven cases only, links were based on formal agreements or specific institutional arrangements with a national, regional, or provincial level HTA body.

(c) *Leadership*, *staff, and professional competencies*: in most cases, the leader of the unit is a physician. The number of FTEs ranged from 1 to 14.5. In some cases, the HB-HTA program was established without full-time personnel. The typical "stand-alone" HB-HTA unit has three to five FTEs with multiple professional competencies ranging from clinicians to biomedical engineers. In most HB-HTA experiences, public health specialists and librarians seem to provide a key competence; health economists and specialists in organizational analysis are less common.

(d) *Operative procedures and assessed technologies*: in most cases, the clinician asking for the health technology is the professional who initiates the assessment process, usually with the support department head or the CEO, CMO, or CFO. In most cases, professionals working at the HB-HTA program produce the HTA reports; in other cases, the HB-HTA unit supports clinicians who are responsible for performing the HTA or, less frequently, complement their tasks (e.g., performing the economic analysis). Regarding decision-making, in 16 out of 31 institutions providing this information, the final decision is made by the CEO or by the hospital's board of directors. Regarding the technologies to be assessed, medical devices (28/31), medical equipment (28/31), procedures (23/31), and drugs (22/31) are assessed in the sample of cases presented in this book.

(e) *HTA products delivered*: many hospitals (19/31) produce short-mini-assessment reports. Additionally, many units use the mini-HTA label to indicate a short report of few pages. Some units are also involved in the production of full HTA reports where all domains are assessed. Finally, in few cases, the HB-HTA program/initiative produces organizational-clinical practice guidelines as direct support for clinical practice.

## 32.4 Setting Up a New HB-HTA Unit

As shown in this chapter, there is no "one-model-fits-all" way of organizing and doing HTA at the hospital level. Nevertheless, from all the current HB-HTA experiences shown in this book, some hints and trends can be extracted. The information

**Table 32.2** Thirty cases of HB-HTA in the world: organizational models

| Acronym | Name of the hospital | Country | Name of the unit | Establishment (Year) | Model |
|---|---|---|---|---|---|
| **AP-HP** | Paris University Hospital | France | CEDIT | 1982 | Stand alone |
| **Hospital Garrahan** | Pediatric Hospital Garrahan | Argentina | HTA Committee | 2001 | Stand alone |
| **UCSC** | Policlinico Gemelli | Italy | HTA and Innovation Unit | 2001 | Stand alone |
| **CHUM** | Centre Hospitalier de l'Universitè de Montréal | Canada | HTA Unit | 2005 | Stand alone |
| **CHU** | CHU de Québec - Université Laval | Canada | HB-HTA Unit | 2006 | Stand alone |
| **EPCs** | University of Pennsylvania | USA | Penn Medicine Center for Evidence-Based Practice (CEP) | 2006 | Stand alone |
| **Sick Kids** | The Hospital for Sick Children - Peter Gilgan Centre for Research and Learning | Canada | Technology Assessment at Sick Kids (TASK) | 2007 | Stand alone |
| **HCB** | Hospital Clinic Barcelona | Spain | HB-HTA Unit | 2009 | Stand alone |
| **Numune Hospital (ANH)** | Ankara Numune Training and Research Hospital | Turkey | ANHTA | 2012 | Stand alone |
| **Hospital El Cruce** | Hospital El Cruce | Argentina | Assessment Committee -(MDs, equipment, procedures)<br>Pharmacy and Therapeutics Committee (Drugs) | 2010 (Assessment Committee)<br>2008 (Pharmacy and Therapeutic Committee) | Stand alone |
| **KP** | Kaiser Permanente | USA | Interregional New Technologies Committee (INTC) | 1980 | Stand alone |
| **China (HB Unit Overview)** | Overview Very few HTA units | China | General description of HB-HTA Unit | NA | Stand alone |
| **Helsinki Univ Hospital** | Helsinki University Hospital | Finland | HTA Group coordinated | 2001 | Integrated specialized |
| **OHU** | Odense University Hospital | Denmark | HTA Unit | 2002 | Integrated specialized |
| **CHUS** | Centre hospitalier universitaire de Sherbrooke | Canada | Health Technology Assessment (HTA) Unit | 2004 | Integrated specialized |
| **Sahlgrenska** | Sahlgrenska University Hospital | Sweden | HTA-Centrum | 2007 | Integrated specialized |
| **Eastern Health Alliance** | Changi General Hospital | Singapore | Health Services Research (HSR) department | 2014 | Integrated specialized |
| **SSCN** | Surgery Strategic Clinical Network of Alberta Health Services (AHS) | Canada | Evidence Decision Support Program (EDSP) | 1997 | Integrated specialized |
| **Lausanne (CHUV)** | University Hospital Lausanne | Switzerland | HTA Unit | 2002 | Integrated essential |
| **CMJAH** | Charlotte Maxeke Johannesburg Academic Hospital | South Africa | Charlotte Mexeke Research Consortium (CMeRC) Unit | NA | Integrated essential |
| **VR&VM** | Virgen del Rocio&Virgen de la Macarena Hospitals | Spain | Joint Commission for HTA | 2002 | Integrated essential |

**Table 32.2** (continued)

| Acronym | Name of the hospital | Country | Name of the unit | Establishment (Year) | Model |
|---|---|---|---|---|---|
| **Radboud Hop** | Radboud University Medical Center | The Netherlands | HTA-Unit | 1993 | Independent group |
| **McGill University Health Centre (MUHC)** | Lachine General Hospital (LGH)Montréal Children's Hospital (MCH), Montréal General Hospital (MGH), Montréal Chest Institute (MCI), Montréal Neurological Hospital (MNH) Royal Victoria Hospital (RVH) | Canada | Technology Assessment Unit (TAU) | 2001 | Independent group |
| **Centre for Medical Evidence, Decision Integrity & Clinical Impact (MEDICI), formerly HiTEC** | London Health Sciences Centre, St. Josephs Health Care, Lawson Health Research Institute, Western University | Canada | Technology Assessment & Knowledge Translation Unit | 2003 | Independent group |
| **Mon Health** | Monash Health | Australia | New Technology and Clinical Practice Committee | 2002 | Independent group |
| **Auckland DHB** | Auckland City Hospital | New Zealand | HB-HTA Committee - Northern Region Clinical Practice Committee (NRCPC) | 2005 | Independent group |
| **NATS-INC** | Instituto Nacional de Cardiologia | Brazil | HTA unit | 2009 | Independent group |
| **Conceição Hospital Group** | Conceição Hospital Group | Brazil | HTA unit | NA | Independent group |
| **HStJD** | Hospital Sant Joan de Dèu | Spain | HTA Committee | NA | Independent group |
| **Geneva Univ Hospital (HUG)** | Geneva University Hospital | Switzerland | Commission for new technologies plus Specific Committees for drugs and devices | NA | Independent group |
| **Vaudois (EHNV)** | North Vaudois Hospital | Switzerland | Drug committee for drugs, Biomedical Engineering for equipment and devices | NA | Independent group |

provided above and the related tables and figures could help newcomers in their planning and initial steps to set up a HB-HTA unit or program in their own context.

The AdHopHTA project has also developed 15 guiding principles for good practices to organize and perform HB-HTA [3]. From these principles, a subset has been considered to be a fundamental core (see Fig. 32.2).

## 32.5 Lessons Learned from HB-HTA Practices

From the 31 experiences of applying HTA at hospital level, several key success factors and things to be avoided have been identified. Table 32.3 summarizes some of the most relevant items from this cumulative experience.


**Fig. 32.2** Core elements when establishing an HB-HTA unit (Sampietro-Colom et al. [3], reproduced with permission)

### *32.5.1 What Has Worked?*

- *Competence and training*. The presence of well-trained and motivated people in HTA and easy access to scientific journals and other informational resources are key factors for a successful experience in HB-HTA.
- *Transparency and rigor*. Transparency and rigor of the assessment process is considered as one of the major success factors for a HTA hospital-based unit.
- *Legislative framework*. Legitimation of HB-HTA unit by law, where it is present (e.g., Quebec), is considered a facilitator.

**Table 32.3** Lessons learned from current HB-HTA practices

| What has worked (successes and enablers) | What has not worked barriers and areas for improvement |
|---|---|
| Competence and training of people | Cultural barriers |
| Transparency and rigor | Political interests |
| Legislative framework | Limited scope of HTs assessed |
| Multidisciplinary team | Informational barriers |
| Top management commitment | Lack of systematic stakeholder input |
| Clinician involvement | Lack of resources |
| Researcher/manager collaboration | Lack of interorganizational coordination |
| Clear roles and explicit methodology | Lack of monitoring post-implementation |
| Timeliness | Internal use variability |
| Patient involvement | Lack of formal mandate for HTA in hospitals |
| Stakeholder and industry interaction | |

*HTs* health technologies

- *Multidisciplinary team*. Diversity in the cultural and professional backgrounds of unit's personnel is considered a key success factor for many hospitals around the world.
- *Top management commitment*. A clear and formal endorsement from top management team is key to ensure genuine collaboration from clinical departments and other hospitals' units. These conditions are considered fundamental to increase the use and acceptability of recommendations produced by HB-HTA programs/initiatives.
- *Clinicians*' (*users*) *involvement*. Many of the units highlighted the importance of active end-user involvement (clinicians, nurses) in the assessment process. Continuous education programs that incorporate an evidence-based medicine approach for clinical decision-making are key to promote the diffusion of a positive cultural attitude toward HTA.
- *Research/management collaboration*. University collaboration, especially in the case of academic medical centers, raises the opportunity to have access to specific and broad competencies that may be lacking within the available HB-HTA unit staff and resources. This can ensure greater robustness and increase acceptability of recommendations.
- *Clear role of the HB-HTA unit and explicit methodology*. Clarity of the role played by the HTA initiative/program within the hospital organizational processes (e.g., in procurement process) and the existence of a formalized methodology for assessment is important in order to reduce internal conflicts and improve impact of recommendations.
- *Timeliness*. Having timely HB-HTA reports is highly appreciated by many hospital managers.
- *Patient involvement*. Only in two cases was direct and systematic involvement of patients and consumer representatives in the HTA process reported, and in both cases, it was considered as a key factor for success.

- *Stakeholder and industry interaction*. In a few cases, engagement with industry and other business stakeholders was reported as a way to gain extra financing for clinical activities and to find competencies that are not usually available in the hospital.

### *32.5.2 What Has Not Worked*

- *Cultural barriers*. One of the most common problems reported by HB-HTA units is the presence of cultural barriers. For some hospitals, especially in countries where the HTA is not well established at a national level, lack of a widespread HTA culture across the country is considered an important barrier. The lack of physician and managerial awareness and training in HTA are suggested to contribute to this cultural barrier.
- *Political interests*. In those countries where political power has the most influence on hospital decision-making, the use and the impact of HTA is more difficult.
- *Informational barriers*. Lack of available global and contextual information for performing specific assessment of hospital technologies remains an important barrier. This is specially the case for relevant cost data and real-world data, which are essential for performing a useful contextualized HB-HTA.
- *Limited types of HTs assessed*. Hospitals seem to be mainly devoted to assessing new technologies in their adoption phase, whereas reassessment of preexisting technologies already in use in the hospital setting is less common. Some of the latter may represent better opportunities for assessment due to their lack of effectiveness and inefficiencies relative to better alternatives; therefore, preexisting technologies should be routinely considered for disinvestment. In particular, efforts provided by clinicians in contributing to the detection of technologies and clinical procedures to be withdrawn remain insufficient in many HB-HTA programs/initiatives to date. A more structured and proactive disinvestment process may produce financial savings for hospitals and other areas of the healthcare system.
- *Systematic stakeholder inputs*. Input from patients and other stakeholders beyond the usual hospital-based multidisciplinary decision-makers is rare, and many hospitals and HB-HTA units indicated a willingness to invest in developing broader stakeholder engagement in the future.
- *Lack of resources*. A lack of resources to maintain the required HB-HTA activities is reported as a problem in half of the cases. This lack seems to affect productivity more than the quality of the assessments. Specifically, it reduces the potential impact of the HB-HTA program/initiative due to lack of resourced capacity to produce information within the most ideal window of opportunity for decision-makers.
- *Interorganizational coordination*. The need for more effective coordination among multiple HB-HTA/HTA programs and initiatives in the same country or region is reported in some cases. This coordination is expected to contribute to economies of scale and better use of limited resources for HTA.

- *Monitoring*. Since the primary focus of most HB-HTA programs/initiatives is on the adoption phase of newer technologies, a lack of attention and processes is reported for monitoring the real impact of the technologies after their introduction. There also remains a general lack of efforts to understand the impact of the assessments on overall indicators of hospital performance (productivity, effectiveness, outcomes, efficiency).
- *Internal use variability*: The use of the results of HB-HTA in the same hospital may differ from department to department, and the resources available to assess all technologies vary considerably; therefore, hospital decision-making is not uniformly based on HB-HTA recommendations. This may cause concern for inequities and differences in thresholds of rigor for decision-making across departments.

## 32.6 Hospital-Based HTA: An Emerging Role in the HTA "Ecosystem"

The experiences of HB-HTA gathered in this book show that in the vast majority of cases, HTA programs/initiatives at the hospital level are mainly devoted to support decision-making (clinical or managerial) within the institutions to which they belong and rarely is their activity oriented to supporting decision-making outside of the hospitals' borders.

The experiences presented in this book provide a broad picture of the use of HTA logic at the hospital level. In the comments proposed by authors, it seems clear that the HB-HTA programs/initiatives provide important support to optimize managerial processes and organizational performance: quality of care, budget sustainability, productivity, and smoothing of processes may be positively affected by a systematic use of HTA when introducing or withdrawing a medical technology or a clinical procedure. All organizations suggest that HTA enhances the level of rationality in managerial decision-making in hospitals by avoiding or reducing internal conflicts, political bargaining, and excessive individual discretion in decision-making in favor of a more objective and transparent evidence-based decision-making model, explaining the tendency to shift toward a "managerial HTA" decision-making approach.

In general, the development of HB-HTA seems to be related to a process of progressive dissemination and integration of HTA into the clinical and managerial world. HTA should not be perceived as something that is accessible and understandable only for insiders, but it should become a fundamental part of clinical work and an organizational process to be mastered by hospital managers along with other stakeholders in the decision-making process required for an effective and efficient technologically advanced healthcare system (e.g., strategic management, managerial accounting, procurement, clinical leaders, and even patients and representative citizens).

On this basis, HB-HTA contributes significantly to delivering value to healthcare systems worldwide, increasing the appropriateness of resource use and making systems (public and private) sustainable. At present, HB-HTA seems able to produce "local value," as it has been confirmed in many of the 31 cases presented in this book. HTA hospital programs/initiatives are operating as "stand-alone HB-HTA units" or through independent groups. In order to translate the "local value" to greater global impact, HB-HTA programs/initiatives should be interacting and integrating along the HTA "supply chain"; contributing to international, national, regional, and provincial HTA efforts; and offering to the system the unique knowledge about the impact of healthcare technologies in the "local contexts." The role of HB-HTA programs/initiatives, in this manner, could evolve assuming two different "missions." On one hand, hospital HTA programs could continue to operate as they mainly did up to now, integrating globally produced HTAs with local evidence and data to provide intelligent support to managerial and clinical decisions (i.e., local contribution and impact). On the other hand, they should also share locally produced evidence with international, national, and regional HTA bodies (and networks such as EUnetHTA) and regulatory bodies (such as EMA or Health Canada) adding value from the local "real-world" analyses and experience to the work produced by these agencies/organizations.

In this fashion, the HB-HTA programs/initiatives could assume a clear positioning and role within a glocal (global+local) "HTA ecosystem," highly needed, to fully manage the life cycle of health technologies in a worldwide environment where challenges and efforts for healthcare systems are evolving together, with optimal interoperability and cooperation and maximal impact.

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# Part VI
# Looking to the Future

# Chapter 33
# Looking to the Future of Hospital-Based HTA: The Next Frontier

**Janet Martin and Laura Sampietro-Colom**

This book represents the first attempt to provide a collated description of the global experience in hospital-based HTA across 18 countries and 6 continents. It is clear that there is an emerging global movement afoot to increase HTA activity at the local level in order to ensure that hospitals' decision-making needs are addressed within required timelines and that relevant institutional considerations and other contextual issues are adequately addressed. Despite the growth of government-related and other external HTA agencies in recent decades, the persistent gap between production of arms-length HTA reports and relevance and timeliness for decision-makers in the real-world hospital setting has become increasingly clear. HB-HTA has been proposed as a solution to bridge this disconnection since local HTA can specifically address issues of relevance, context, and institutional decision-maker timelines. Furthermore, HB-HTA can serve as an ally for national/regional agencies in transferring nationally produced HTA information and guidance to the real-world setting, through proper adaptation to local context characteristics. For this reason, we have entitled the book *The Next Frontier for HTA*, insofar as HB-HTA represents the natural progression from arms-length HTA, to a locally integrated relevant HTA, which spans decision-makers and the knowledge translation context to improve HTA reach and overall impact.

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## 33.1 HB-HTA Is Growing

The recent growth of HB-HTA uptake is a clear signal that hospital decision-makers recognize the need for local HTA expertise to increase effectiveness in decision-making and to ensure maximum value is extracted from each dollar expended. Demand for HB-HTA is likely to increase even further as fiscal restraints tighten, while health technology options multiply, and patients' expectations are intensified. Indeed, the promise of new technologies is exciting and often involves potential lives saved or quality of life gained, sometimes with potential for cost savings to be released back into the system for better uses. Nevertheless, not all "good" things can be adopted. Choices must be made.

Achieving these promises of better outcomes or better value for money in the contemporary hospital setting will require a constant force of applied expertise in HB-HTA to ensure the "best" technologies from among the many "good" technologies are selected and implemented and that low-value technologies are disinvested and de-adopted so that health technology can deliver on its promise of better value for money at the hospital level.

As shown throughout the chapters of this book, the resounding finding across each country is that the capability of national HTA efforts to "reach" hospital HTA decision-makers remains limited; it is only through local HB-HTA that a deep knowledge of the local setting (including local budget trade-offs, competing priorities, local skills and cultural aspects, strategic priorities, and effective engagement of the right stakeholders) can ensure adequate relevance and meaningful knowledge translation. This is simply not achievable from an arms-length perspective.

## 33.2 But Not Growing Fast Enough

While HB-HTA is growing in recent years, most decisions for drugs, devices, procedures, and programs in the hospitals still remain unaddressed by HTA, simply because there remain insufficient HTA skills and resources to do so. An immediate challenge to securing resources for HB-HTA relates to the constant budget shortfall in hospitals, which essentially forces hospital budget holders to trade off whether to direct limited resources toward investing in direct patient care needs (nurses, doctors, hospital beds) versus spending it on HTA capacity (to advise on how to invest in patient care needs). Developers of HB-HTA will need to further innovate in order to overcome the lack of capabilities and capacities inherent in the local setting to meet the future needs of hospital decision-makers and to demonstrate the added value of investment in local HTA.

The pace of health technology development has outpaced severalfold the pace of our traditional methods of HTA to synthesize evidence and provide meaningful advice. Traditionally, HTA has been based on largely manual methods for identifying relevant scientific evidence, extracting the relevant data into statistical software

for analysis and modeling, followed by manually combining this information with local resource considerations and other contextual factors, before manually producing a report that details the analysis and its implications for the local decision-makers. Depending on the type of scientific evidence available, and the need for local data generation from within the hospital setting through clinical trials or database analysis, time requirements for traditional HTAs may vary from hours to months, or even years. Admittedly, the most informative and impactful technology assessments should be conducted iteratively over the course of years, in order to capture emerging data before the decision to introduce the technology and then to capture real-world outcomes during the early post-implementation and continuing through the maturation and obsolescent stages. With the increased pace of new technologies requiring consideration for investment and the flip side of established technologies requiring consideration for disinvestment, our current approach to HTA will need to change to effectively embrace this overload and meet the challenge with meaningful analyses in the time required by decision-makers.

## 33.3 Innovations for HB-HTA to Build Even Greater Impact in the Future

The case studies provided within the chapters of this book provide tangible examples of the impact of HB-HTA across a variety of indicators, including improvements in local decision-making rigor, hospital efficiencies, patient outcomes, sometimes with significant cost-savings, or potential costs averted. These impacts are laudable. Yet, even more impact could be attained if we are willing to further innovate beyond our traditional approach to HB-HTA provision.

A selection of innovations likely to catapult HB-HTA to the next level of impact are proposed below:

1. *Global and local collaboration across HB-HTA units:*
    - Likely one of the greatest opportunities for efficiency will be for hospitals with HB-HTA units to openly collaborate to share ideas and assessments and to prevent unnecessary duplication of work across hospitals.
    - HB-HTA units should consider collaborating on the identification of topics for assessment, delegation of the "global evidence" synthesis (generalizable across institutions), and shared development of templates and tools for contextualization.
    - Sharing experiences regarding successes and failures of different methodological approaches to assessment, disinvestment, and evaluation of knowledge translation and other local HB-HTA impacts would further advance the science of HB-HTA. In addition, collaborative research locally and globally would facilitate rigorous assessment of HB-HTA impacts across settings.

- Creating communities of practice to build capacity, skills, and support for professionals working in HB-HTA.
- Creating HB-HTA "hubs" to mentor and collaborate with other hospitals interested in implementing HB-HTA programs but with insufficient experience or resources to do so. The hubs could act either as advising or supporting local teams in developing and prioritizing assessments, decision-making, or translating decisions to practice.
- Programs to build awareness and skills in both producers and users of HB-HTA (i.e., hospitals' CEOs, VPs) through innovative educational programs and mini-sabbaticals to ensure decision-makers and producers are able to maximally integrate HB-HTA into the hospital setting.

2. *Prioritization of Topic Selection*

- Since HB-HTA will never be resourced sufficiently to address all decisions related to technologies, HB-HTA units should collectively develop methods for deciding which technology assessments are likely to bring the highest return on time invested. This will ensure that the most important technologies are assessed, while lower-value assessments are queued for later assessment if time and resource allow.
- Broader priority setting of a list of emerging technologies could also be more efficiently achieved through collaboration across hospitals to collectively and iteratively identify emerging technologies and trends on a regional basis, as well as on a global basis.

3. *Simultaneously consider Technologies for Investment and Disinvestment*

- Since hospital budgets rarely have a margin of available dollars for investment, it will be equally important to identify technologies of lower value for disinvestment whenever new technologies are proposed for investment. Every dollar committed to a new technology will need to be displaced from somewhere else in the system, unless additional dollars are available within the budget (a rarity in hospital settings reliant on public funding).

4. *Automated Evidence Synthesis and Data Analysis*

- Since traditional methods of evidence synthesis and incorporation of local clinical and economic information will not be able to keep up with the pace of decision-making and the growth in information (including local information available through electronic clinical records and data warehouses in hospitals), HB-HTA needs to develop new ways of automating evidence identification, knowledge synthesis, and data analysis.
- Gleaning from progress in the fields of cognitive computing and artificial intelligence will be essential for HB-HTA to keep up with the pace of demand.

5. *Broader Stakeholder and End User Engagement*

   - A significant value-added aspect of HB-HTA lies in the ability to directly involve end users and other stakeholders in the process to increase buy-in, relevance, receptivity, and knowledge translation. HB-HTA will need to ensure that its definition of "stakeholders" is sufficiently broad to maximize this opportunity.
   - Involving patients and the community in the process ensures that the values and preferences of the patients and community are considered and integrated. This is an important challenge for HB-HTA where many decisions are made at the bedside and where competing or opposing objectives between individual patient needs and overall population or system needs may be felt most acutely, imposing new ethical challenges to address.
   - Involving clinicians and administrators throughout the process of assessment is one of the main characteristics of HB-HTA which brings credibility and receptivity to the process and its results. This distinguishing feature should be further developed and fostered in the future to ensure the full potential of HB-HTA is reached.
   - Future attention needs to focus on appropriate ways to engage with industry, and other partners for the purpose of improving relevance of the assessments, while also ensuring the HB-HTA methods, remain unfettered by relationships that affect transparency and freedom to invest/disinvest in the best set of opportunities for the local setting.
   - This area remains a particular challenge, due to the overarching need for objectivity in the HB-HTA setting, juxtaposed with the need to have a working relationship with industry in order to achieve complete access to evolving evidence related to their technologies.

6. *Broader Definition of Evidence*

   - It is widely recognized that evidence from clinical trials alone is insufficient to adequately inform decisions for update and disinvestment of technologies. This is especially relevant for hospitals where clinical practice usually differs from those in the "ideal settings" where clinical trials have been done.
   - Information from other domains, such as strategic considerations for the hospital, institutional impacts, environmental impacts, and a number of other potential implications that depend on the type of technology and trade-offs being assessed may be important, depending on the technologies being addressed.
   - A broad definition of "allowable" evidence should be considered in order to ensure the decision is adequately informed by relevant aspects. Furthermore, involving experts from other domains, such as social workers, management specialists, bioengineers, clinical ethicists, and new professional profiles coming from the new disruptive technologies (e.g., genomics, information systems, e-health, etc.), may be required to integrate these concepts.

7. *Expanding assessments to consistently include post-implementation data collection:*
    - HB-HTA needs to expand its remit beyond only providing up-front advice, based on best available scientific evidence; assessment of whether the predicted impacts translated to the real world after implementation of the recommendation will be an essential future component of high-value HB-HTA.
8. *Moving assessment upstream*
    - Earlier assessment of technologies may improve the ability of HB-HTA to impact on uptake (or not) of emerging technologies, before they are entrenched in the field. This is particularly challenging, since early assessment requires evaluation based on insufficient and emerging evidence that requires appropriate types of deliberation and repeated assessment as the evidence grows and matures throughout the product life cycle.
    - Earlier assessment may also increase opportunities for better alignment of evidence generation with the needs of hospital decision-makers and end users of the technology if the early assessments are conducted in a collaborative way – with opportunity for feedback between developers of the assessment methods, developers of the technology, end users of the technology, and the ultimate decision-makers (funders, implementers, and managers of the technology).
9. *Iteratively repeating assessment throughout the life cycle*
    - Regardless of the time of initiation of assessment (prior to market entry, after market entry, after dissemination to practice), HB-HTA initiatives should consider that iterative assessment, rather than only one-off assessment, will likely provide better information across the technology life cycle (from pre-market to post-market through to obsolescence). Iterative assessment may provide more timely consideration of appropriate interventions to determine whether the predicted efficacy and safety have actually been translated to the real-world setting. Furthermore, an iterative approach to early assessment that respects the need for continued generation of evidence during initial stages of implementation through obsolescence should allow for better decisions about which innovations to take up versus which to abandon (more efficient and timely investment in innovation).
10. *Evidence generation through pragmatic clinical trials*
    - One of the distinguishing features of HB-HTA is that it allows unprecedented opportunity for local evidence generation, through data collection within the hospital setting in close collaboration with clinicians and end users at all stages of the technology life cycle. It also allows for potential involvement in clinical trials to ensure the range of outcomes, duration of assessment, and other contextual factors that are incorporated into local

research, which further ensures relevance of the evidence for HB-HTA and local decision-maker needs.

- As HB-HTA grows, there has been an upswing in interest to more systematically generated local evidence of rigor through conducting pragmatic clinical trials in the hospital setting. The benefits of pragmatic clinical trials have been described extensively (PRECIS). This methodology has been of increasing interest to HB-HTA given the potential for generating rigorous evidence through an approach to enrolling patients and collecting data that poses fewer barriers than the traditional clinical trial approach and that more realistically reflect the range of real-world outcomes while simultaneously allowing questions of comparative effectiveness to be addressed with greater rigor than retrospective cohort studies and other traditional database reviews.
- Hospital-based pragmatic trials may provide a more efficient means to fill evidence gaps and may add significantly the efficiency of contextual data generation.

11. *HTA-informed procurement*

- Procurement of technologies and supplies in the hospital setting often involves a traditional business-dominated approach to requests for proposals and setting contracts with providers-based price and "fit" of the technology services offered by vendors with preexisting technologies and services within the hospital setting. Traditionally, procurement services have not systematically considered the evidence for comparative effectiveness and/or relative cost-effectiveness among the options for technologies and supplies under consideration, and as a result, decisions may be suboptimal.
- Evidence-informed procurement, and more recently HTA-informed procurement, has become the focus of recent innovations in procurement approaches for local hospitals and for "buying groups" represented by clusters of hospitals. HB-HTA has an important role to play in implementing HTA-informed procurement to ensure the technologies and supplies chosen represent the best value for money in their context and that contract renewals are systematically anticipated with timely HTAs to inform ongoing decisions about technology uptake and disinvestment.
- This area also represents opportunity for further development in innovations in HTA to inform what types of contracts and bundled services should be pursued to maximize value for money and whether shared accountability and risk-sharing agreements could be systematized within contract cycles that ensure technology and service providers.

12. *Hospital-based technology incubation and technology transfer*

- HB-HTA also provides opportunity to work with local clinicians and others who are developing innovative technologies in the hospital setting to demonstrate the potential value of the health technology through appropriate early assessment methodology using local data and other institutional and contextual issues, combined with modeling and iterative updates.

- Such an approach may foster local technology incubation and innovative start-ups and may further facilitate successful patents and licensing of new technology that is relevant to hospitals. Particularly with a coordinated approach across HB-HTA units to enhance timelines and sample size for evaluation, the role of HB-HTA in technology incubation, validation, and ultimately successful technology transfer could lead to more efficient technology development in the future.

13. *HTA-informed local research agenda*

- Since HB-HTA involves evidence synthesis, combined with local data evaluation and exploration of local factors, HB-HTA is uniquely positioned to identify gaps in the global evidence base and gaps in the local evidence base.
- This unique knowledge provides an opportunity for innovative HB-HTA producers to more effectively inform the local research agenda, by defining local gaps in evidence and providing analyses to inform which local research should be prioritized to address the most important gaps with efficiency.
- In addition, HB-HTA may build on emerging frameworks such as the IDEAL collaboration to set out the required level of research required for the progressive stages from the idea stage through the development, exploration, assessment, and long-term evaluation of technologies and techniques.
- Such an approach could improve the efficiency by which local gaps in evidence are addressed and may improve cost-effectiveness of the local research enterprise.

14. *Innovative growth models for HB-HTA*

- Since hospitals often benefit measurably from HB-HTA yet HB-HTA units often struggle to find sufficient sustainable funding in an environment where public hospitals are chronically fiscally constrained, hospitals and HB-HTA units should agree on a growth model that incentivizes both parties to succeed in their service contract. In particular, hospitals should agree and allow HB-HTA units to reap some of their benefits to fund their own growth commensurate with their returns on investment.
- Or, another growth model could be proposed based on hospitals investing 0.5–1 % of their technology budget on building HB-HTA in order to inform which technologies should be taken up and which should be forgone. This investment will likely reap severalfold in return to the hospital, and investment in HB-HTA should grow annually based on such returns in order to better address health technologies over time.
- The HB-HTA unit that proves itself worthy should be fostered with growth investment, as long as the return on investment (ROI) is likely to be greater than other opportunities for funding.

15. *Evaluation of impact of HB-HTA*

- The case studies in the preceding chapters of this book suggest that HB-HTA provides significant benefits in hospital processes and cost-savings for many,

but not all, hospitals. These preliminary observational results provide impetus for studying the impacts more formally, not only to explore the types and magnitudes of impacts, but also to explore the factors that are predictors of success.

- Until HB-HTA dares to study its impacts with a higher level of evidence (such as through externally evaluated program evaluation rather than through self-reflection alone, or through prospective time series or perhaps even randomized controlled evaluation) and provides a coherent voice and coherent approach for providing decision support and for measuring impact, HB-HTA will likely continue to operate on a sporadic basis with some hospital funding local HTA, while others oblivious to the benefits and return on investment (ROI) will continue without building their own local capacity for HTA.
- Collaborative and coordinated program evaluation across a variety of HB-HTA units and settings would provide significant strength to such an evaluation of impacts and predictors of outcomes.
- One of the barriers to assessment is securing funding from research agencies to conduct formal research on HB-HTA initiatives, since this is often perceived as supporting operational costs of an existing program. For this reason, HB-HTA producers will need to develop approaches to program evaluation that align with research funders' priorities.

Do hospitals with HB-HTA fare better than those without? Is HB-HTA the best use of hospitals' limited funds? Or, to put it another way, of all options for hospitals to spend their limited resources on, does HB-HTA provide the best value for money? Theoretically, HB-HTA stands to be one of the best possible uses of hospital funds, to the extent that it provides best possible solutions to the ongoing conundrum of deciding which technologies, drugs, devices, and procedures will provide the biggest bang for the buck among the crowded lineup of options vying for funding (available resources).

Many of the case studies quoted within these chapters suggest that the ROI is far greater than 1, which means that for every dollar spent on internal HB-HTA, there will be greater than $1 in return. If this is true, then investment in HB-HTA on a broader scale should be considered and should be formally prioritized for immediate implementation to ensure hospitals are providing the best possible complement of technologies within their limited set of resources.

In order to maximize this investment, broader collaboration along with innovations in evidence synthesis and breadth of evidence definitions will expand the leading edge of this next frontier in HTA sooner rather than later. Hospital-based HTA has created new impetus for getting evidence into decision-making and practice, in context, and in collaboration with the end users. When conducted in its true intention, HB-HTA provides a living example of integrated knowledge translation (iKT).

Since there is not enough HTA resource to span all needs, collaboration between arms-length agencies and hospital-based agencies could provide opportunities to cover more topics while also ensuring greater buy-in and uptake of the

recommendations. Innovations in pragmatic trials, procurement, technology incubation, and research feedback loops combined with cognitive computing will lead to greater efficiencies in technology uptake and disinvestment for the ultimate purpose of optimizing patient outcomes and patient experience.

We look forward to future updates on HB-HTA over the coming years, with outcomes and innovations that likely exceed our current perception of the world of possibilities.

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