

# Recommendations for the implementation of hospital-based HTA in Poland: lessons learned from international experience

**Małgorzata Gałązka-Sobotka**<sup>1</sup>, Iwona Kowalska-Bobko<sup>2</sup>, **Krzysztof Lach**<sup>3</sup>, Aneta Mela<sup>4, 5\*</sup>, Maciej Furman<sup>2</sup>, Iga Lipska<sup>6</sup>

<sup>1</sup>Institute of Healthcare Management, Lazarski University, Poland, <sup>2</sup>Institute of Public Health, Faculty of Health Science, Jagiellonian University Medical College, Poland, <sup>3</sup>National Institute of Cardiology (Poland), Poland, <sup>4</sup>Medical University of Warsaw, Poland, <sup>5</sup>Department of Experimental and Clinical Pharmacology, Medical University of Warsaw, Poland, <sup>6</sup>National Health Fund, Poland

*Submitted to Journal:*  
Frontiers in Pharmacology

*Specialty Section:*  
Pharmaceutical Medicine and Outcomes Research

*Article type:*  
Systematic Review Article

*Manuscript ID:*  
594644

*Received on:*  
13 Aug 2020

*Revised on:*  
24 Dec 2020

*Journal website link:*  
[www.frontiersin.org](http://www.frontiersin.org)

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### *Conflict of interest statement*

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest

### *Author contribution statement*

MGS participated in the study design, methods, collection of the data, quantitative analysis and interpretation of data.

IKB participated in the study design, methods, collection of the data, quantitative analysis and interpretation of data.

**KL participated in the study design, methods, quantitative analysis and interpretation of data.**

AM participated in the study design, methods, quantitative analysis and interpretation of data.

MF participated in the study design, methods, quantitative analysis and interpretation of data.

IL interpretation of data.

### *Keywords*

Decision Making, Hospital management, Health technology assessment (HTA), Hospital Based Health Technology Assessment (HB-HTA), Innovative medical technologies

### *Abstract*

Word count: 260

**Introduction:** The main challenge of modern hospitals is purchasing medical technologies. Hospital-based health technology assessment is a conception used in healthcare facilities around the world to support management boards in providing relevant technologies for patients.

**Aim:** The aim of this study was to update the existing body of knowledge on the characteristics of HB-HTA systems/models in the selected European countries. Insights gleaned from this study were used to inform an optimal approach while implementing HB-HTA in Poland.

**Material and methods:** Firstly, we carried out a systematic review in Pubmed and Embase. secondly we searched for grey literature via the AdHopHTA online handbook and the design book of the AdHopHTA project, as well as literature describing healthcare systems provided by the WHO. Then, we conducted in-depth interviews with HB-HTA experts from four countries. Finally, we selected ten countries from Europe and prepared frameworks for data extraction and analysis.

**Results:** The selected countries (Switzerland, Spain, France, Italy, Denmark, Finland, Sweden, the Netherlands and Austria) are examples of decentralised or deconcentrated healthcare systems. In terms of HB-HTA, they differ in terms of their respective organisational model (independent group, stand-alone, integrated-essential, integrated-specialized), type of financing (internally vs. externally), collaboration with an HTA National Agency and other stakeholders (e.g., Patients' Associations). HB-HTA engages multi-skilled staff with various academic background and operates mainly as a voluntary structure.

**Conclusions:** HB-HTA implementation in Poland should consider practices from experiences in different countries. Each country and each model of HB-HTA has its own strengths and weaknesses. Therefore, Poland's HB-HTA model must be built responsibly, including different healthcare system stakeholders.

### *Contribution to the field*

We wish to submit the original article entitled "Recommendations for the implementation of hospital-based HTA in Poland: lessons learned from international experience" for consideration by the Frontiers in Pharmacology. We confirm that this systematic review is original and has not been published elsewhere and it is although currently not under consideration for publication. Our manuscript was performed in order to investigate the recommendations for the implementation of hospital-based HTA in Poland. We do believe that the findings match the aims and the scope of your journal. The paper should be of interest to all professionals and researchers especially interested in pharmaco-economics, medicine, pharmacology, public health and health management specialist. Thank you for your consideration. We hope our manuscript is highly appropriate for publication in your journal.

### *Data availability statement*

**Generated Statement:** The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

## REVIEW ARTICLE

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#### **Abstract**

**Introduction:** The main challenge of modern hospitals is purchasing medical technologies. Hospital-based health technology assessments (HB-HTAs) are used in healthcare facilities around the world to support management boards in providing relevant technologies for patients.

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**Results:** The selected countries (Switzerland, Spain, France, Italy, Denmark, Finland, Sweden, the Netherlands, and Austria) are examples of decentralised or deconcentrated healthcare systems. In terms of HB-HTA, differences in organisational models (independent group, stand-alone, integrated-essential, integrated-specialised), type of financing (internally vs. externally), collaboration with an HTA National Agency and other stakeholders (e.g., Patients' Associations) were identified. HB-HTA engages multi-skilled staff with various academic backgrounds and operates mainly on a voluntary basis.

**Conclusions:** Strengths and weaknesses associated with various organisational models must be carefully considered in the context of support for decentralised or centralised models of implementation while embarking on HTA activities in Polish hospitals.

**Key words: Hospital-Based Health Technology Assessment (HB-HTA), Health Technology Assessment (HTA), innovative medical technologies, hospital management, decision making.**

## **1. Introduction**

Health Technology Assessment (HTA) influences drug reimbursement decisions are made by respective bodies on the basis of reliable scientific research results from the perspective of a particular healthcare system [1]. An EU health technology assessment organisation network EUNetHTA explains that HTA is a “multidisciplinary process that summarises information on medical, social, economic, and ethical issues related to the use of a given health technology in a systematic, transparent, impartial and robust manner. Its purpose is to provide the information needed to create safe and effective patient-centred health policies and a desire to achieve the best value” [2].

Currently, HTA is an internationally recognised and widely used approach in, e.g., informing decisions on drug reimbursement and pricing. In the European Union, such decisions following the assessment of health technologies are strictly national. Member states independently and separately create their own HTA frameworks with the establishment of a local HTA agency [3]. The main purpose of these agencies is to support healthcare system stakeholders in making decisions on optimal resource allocation.

In 2005, Poland established the Agency for Health Technology Assessment, which serves the Minister of Health as an advisory body by giving recommendations on whether health technologies should be financed [4]. Since 2012, Poland has been an example of a country where no medicine is reimbursed without formal procedures [5]. HTA is an important and formal part of the decision-making process regarding the reimbursement and pricing of new pharmaceuticals in Poland [6].

HTA does not only refer to medicinal products or a function within national health technology assessment agencies. Usually, healthcare facilities, such as hospitals, need a more practical and contextualised assessment related to the use of a specific clinical procedure, medical device, or equipment in their own settings [7]. Hence, a hospital-based health technology assessment (HB-HTA) process is conducted, which applies tools used in HTA processes in the context of individual hospitals. Key reasons for adopting HTA at the hospital level are threefold: i) new challenges (e.g., socioeconomic) have caused changes in

purchasing innovative technologies; ii) hospitals need to stay abreast of new, innovative technologies for which an assessment from a national HTA agency is not yet available; iii) the efficient management of limited resources by hospitals is vital. The major disparities between the traditional HTA at the national/regional level and at the hospital level are: (i) the context (country/region vs. hospital); (ii) informational needs (e.g., a budget impact analysis is far more important than a cost-effectiveness analysis at the hospital level, and also strategic aspects are a newly-identified assessment domain important at the hospital level); (iii) the types of technologies evaluated (assessments of non-drug technologies are conducted more frequently at the hospital level); and (iv) need for a timely assessment associated with a scope of the assessment (a comprehensive HTA is usually conducted at the national level, which takes from one to even two years, while at the hospital level, a mini-HTA is carried out with a usual delivery time of three months) [8]. However, both HB-HTA and national/regional HTA pursue the same goal, that is, to inform decision-making on the optimal resource allocation with regards to investment in health technologies.

Technology assessment units in hospitals are currently present on all continents: from European countries (such as Spain, Italy, Denmark, and Estonia) [9], North America (the USA and Canada), South America (Brazil and Argentina), to Africa (South Africa), Australia, and New Zealand [9]. An EU-funded project, AdHopHTA (“Adopting hospital-based HTA in the EU”), and other initiatives comprehensively characterised technology assessment units from all around the world [8,9]. However, several years have passed since those were published.

Currently, there is no HTA activity in Polish hospitals that the authors are aware of and since the most recent scientific contribution characterising HB-HTA worldwide [8] was published in 2016, our study was designed to update the knowledge in the field and, based on state-of-art knowledge on HB-HTA, lay grounds for informing the optimal model of HB-HTA to be implemented in Poland.

This study was conducted as part of the ongoing research & implementation of the project “HB-HTA-PL” funded by the Polish National Centre for Research and Development (2019-2021).

## **2. Aim of this study**

The study was undertaken to update the existing body of knowledge on the characteristics of HB-HTA systems/models in selected European countries. Insights gleaned from this study will be used to inform an optimal approach while implementing HB-HTA in Poland. This study was conducted as part of the ongoing research & implementation of the project “HB-HTA-PL” funded by the Polish National Centre for Research and Development (2019-2021) [10].

### **3. Materials and Methods**

First, a literature review was conducted to identify developed HB-HTA systems from different regions of Europe, with decentralised hospital management, and with a similar gross domestic product. The following countries were considered for analysis: Switzerland, Spain, France, Italy, Denmark, Finland, Sweden, the Netherlands, and Austria.

The following sources of information were utilised in this study:

#### **A review of literature in medical databases and grey literature**

A review of literature in Medline (via PubMed), and Embase was carried out. Two search strategies were applied (Appendix 1) with a cut-off date of December 29, 2019. The first, more specific, referring only to hospital based HTA search terms, and the second, more sensitive, referring to broadly understood collaboration activities by HTA units/organisations. A time restriction of the last 10 years was applied to capture the most recent developments in the field. Detailed information on the keywords used within the search strategies and the study flowchart based on two search strategies in the Medline and Embase database (according to the PRISMA statement) are presented in Appendices 1 and 2 (Tables 6, 7, 8, 9 and Fig.1, 2).

Additionally, as part of the review, grey literature sources were screened: the AdHopHTA handbook: Hospital-based Health Technology Assessment, The Next Frontier for Health Technology Assessment book: and the WHO Health Systems in Transition database. In the latter, a review of the WHO European Observatory on Health Systems and Policies database, the Health Care Systems in Transition series, was conducted to identify features of the health system models important in the context of HB-HTA development.

Any publication that described the experience or organisational model of a single HB-HTA/unit at the regional/national level or collaboration practices/interactions between HB-

HTA units or collaboration practices/interactions between HB-HTA units and national/regional HTA agencies in the selected European countries were included in the review. Conversely, any publication that characterised national/regional HTA agencies or described any form of collaboration practices/interaction between HTA agencies at the regional/national level were excluded.

### **In-depth expert interviews**

Following the literature review, semi-structured telephone interviews with HB-HTA experts were conducted to address gaps identified in the secondary research as well as to corroborate the findings from the literature review. Four interviews were conducted with HB-HTA experts from Austria, Spain, France, and Denmark. A short questionnaire consisting of five open-ended questions was prepared and sent to the experts ahead of the interviews as stimuli for the conversation:

1. What has changed over the last 5 years in terms of collaboration practices/interactions between your HB-HTA unit and other units/regional or national HTA agencies?
2. Have additional standards or formalisation been developed for HB-HTA in your country?
3. Have new stakeholders relevant from the perspective of HB-HTA appeared? If so, are they a driving force or a barrier to HB-HTA development?
4. What are the major advantages and disadvantages of the HB-HTA model in your country?
5. What is the direction of HB-HTA development and networks created at the domestic and international levels for the future?

Each interview was commenced by providing the background for the research as well as the summary of findings from the conducted literature review. Interviews were prepared by two researchers (IKB, KL) and conducted by one researcher (KL) in October 2019. Interview recordings were used to prepare written transcripts and then analysed by three researchers (IKB, AM, MF).

### **Data extraction and analysis**

Data from the included articles were extracted using a pre-designed analytical framework (designed by KL), whose main purpose was to capture data on the general characteristics of the HB-HTA unit, including its model (according to the nomenclature developed by

AdHopHTA researchers: independent group model, integrated-essential – HB-HTA model, stand-alone – HB-HTA units, integrated-specialised HB-HTA units) [10], including interactions between HTA units in hospitals, and taking into account any collaboration practices with national/regional HTA entities or other entities (Table 1). Pilot extractions were conducted by two researchers (AM, MF) and then checked independently by another researcher (IKB) for accuracy.

**Table 1. Analytical framework for data extractions.**

Analytical frame	Scope
HB-HTA unit organisational model	<ul style="list-style-type: none"> <li>• Independent group,</li> <li>• Integrated-essential HB-HTA,</li> <li>• Stand-alone HB-HTA unit,</li> <li>• Integrated specialised HB-HTA unit.</li> </ul>
Characteristics of HB-HTA unit and its interaction with other stakeholders	<ul style="list-style-type: none"> <li>• Description of activities/interactions</li> </ul>
Level of interaction with other stakeholders	<ul style="list-style-type: none"> <li>• Internal (inside one country)</li> <li>• External (between countries)</li> </ul>
Interaction Type	<ul style="list-style-type: none"> <li>• Informal</li> <li>• Formal</li> <li>• Voluntary</li> <li>• Mandatory</li> </ul>
Stakeholders involved in the interactions	<ul style="list-style-type: none"> <li>• HB-HTA organisational level (stakeholders from various governance and management level, e.g., self-governmental bodies)</li> <li>• Additional important actors involved and their role</li> </ul>
Additional information	<ul style="list-style-type: none"> <li>• All other relevant details</li> </ul>

Source: Own study based on AdHopHTA Handbook.

## 5. Results

30 publications included in the review provided the most recent characterisation of HB-HTA units in the selected European countries. The eight countries, for which information on HB-HTA activity was available, have a decentralised hospital management system, a similar gross domestic product, and established HB-HTA units at select hospitals. In addition to HB-HTA units, national HTA agencies (if any) of the select countries were also characterised in terms of their scope of responsibilities. A detailed description of HB-HTA units and national HTA agencies are shown in Appendices 3 and 4. An analysis of the hospital sector across European countries by Hope and Dexia 2009 and Kowalska-Bobko, I. provides comparable data on hospital governance. Based on the analysis, hospital management systems have been

derived in terms of decentralisation, centralisation, and ‘deconcentration’. It can be concluded from literature and the conducted research, that decentralisation of the health system supports hospital efficiency. The concept of decentralization means the transfer of power from the state level to the level of autonomous territorial self-governments. Decentralisation includes a wide range of scenarios in the EU, with varying degrees as the transfer of powers to elected infra-national bodies. Meanwhile, deconcentration, means a transfer of power from the central level to separate government institutions operating at the regional or local level [11]. Hospital management is decentralised in Belgium, Austria, Germany, Denmark, Finland, Sweden, Spain, Italy, as well as in several Central-Eastern European countries by self-government hospital ownership. Bulgaria, France, Greece and Portugal are, in turn, the countries characterised by a ‘deconcentrated’ hospital management system where central government bodies organise inpatient care. In Poland, the process of decentralization in health care was initiated after the fall of the communist regime and finally consolidated after the separation of three levels of local government – commune in 1990, county and regional self-government in 1999. Municipalities are responsible for primary health care, and counties and regional self-government for hospitals. The regional self-government is responsible also for strategic planning in health care for the benefit of its population, while the governmental deconcentrated regional authorities are responsible for mapping health needs [12].

**Table 2. Selected countries for the analysis of HB-HTA models.**

Country	GDP per capita* [PPP, USD] 2018 [11]	Type of healthcare system
Switzerland	68,060	Decentralised
Spain	39,715	Decentralised
France	45,342	Deconcentrated
Italy	41,830	Decentralised
Denmark	55,671	Decentralised
Finland	46,735	Decentralised
Sweden	53,208	Decentralised
The Netherlands	56,328	Decentralised
Austria	54,454	Decentralised

\* GDP per capita expressed taking into account the purchasing power parity correction (PPP)

Source: Own study based on

<https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD?locations=AT-ES-NL-FR-SE-FI-DK-IT-CH> [13].

A detailed characterisation of each health care system in which HB-HTA is organised within select hospitals is provided below.

## Results

Our review identified differences between the current HB-HTA units in nine European countries. Although healthcare systems are significantly developed in all analysed countries, they represent various approaches to HB-HTA. They differ in terms of the HTA bodies' structure, HB-HTA staff qualifications, and the role of hospital boards in the decision-making process, as well as presenting different HB-HTA models [14,15,].

The countries selected in our analysis of the hospital health technology assessment system have similar GDPs and a decentralised approach to health care management [16]. The characteristics of the analysed countries in terms of similarities and differences of HB-HTA systems have been presented below.

HB-HTA can be analysed and modelled with respect to:

- a. Micro-perspective – organisational practices within HB-HTA units and their level of formalisation, i.e., from independent, less formal teams to specialised HB-HTA units.
- b. Macro-perspective – various complex relationships in a health care system and how they can support the creation of HB-HTA units [17].

While micro-perspective has already been discussed by AdHopHTA researchers [8], we undertook a broader consideration of macro-perspective of HB-HTA to inform the implementation of HTA at Polish hospitals.

**In the micro-perspective**, a key aspect is the level of independence of HTA units in hospitals. HB-HTA units to better organised have to consider different factors:

- Size of the unit;
- Level of development and staff experience in HB-HTA;
- Unit's position with relation to other stakeholders.

The characteristics that best define an HB-HTA unit are the following: 1. **Formalisation.** Procedures and rules organising HB-HTA unit's day to day operations (standard operating procedures and formal documents/guidance). 2. **Specialisation.** This means the extent to which duties and tasks are fragmented into independent roles in the HB-HTA unit. A highly specialised unit is one that can manage various types of HTA processes dedicating specific resources to those processes such as a project team, working on scientific grants, full-time employers and/or specific formal procedures, for example, specific procedures on each type

of health technology to be assessed. 3. **Integration.** This holds for the level of common work between the HB-HTA unit and other healthcare stakeholders inside or out of the hospital. Integration is high if the HB-HTA unit has multiple networks with other actors that are conducting HTA at other institutional levels (i.e., at national or regional levels, the public payer, or universities). 4. **Authority and centralisation of power.** This refers to the authority to take decisions within the HB-HTA unit. When a decision is to be taken, if it is delegated to lower organisational levels in the HB-HTA unit (e.g. to the person responsible for an HTA project), that unit is considered decentralised. Decentralisation is represented when a single clinician is responsible for recommending the technology to be used within a hospital. 5. **Professionalisation.** This refers to the degree of expertise available or training undergone by the HB-HTA unit's staff (their knowledge, experience and education) [8].

Three of these variables – (i) specialisation, (ii) formalisation, and (iii) the level of integration usually defines the organisational arrangements of HB-HTA units. Highly specialised units are more formal because their existence is based on legal regulation. Usually HB-HTA units that existed for a long period of time are more formal and highly specialised. On the other hand, some of the less “mature” HB-HTA units prefer to maintain flexibility, being less specialised, structured and formalised. Integration with other organisations that are conduct in HTA can be based on formal agreements or informal collaborations.

A summary of the analysed countries with a focus on similarities and differences of HB-HTA systems is presented in Table 3. HB-HTA units in the analysed countries have different organisational models based on their respective needs. Some relationship can be observed between the choice of organisational model, its financing, and the existence of a national HTA agency. An integrated-specialised model with external funding seems to be more frequently present for HB-HTA units in those countries where a national HTA agency exists (France, Finland, Sweden, and the Netherlands) [18,19,20] although in several countries the sources of HB-HTA unit funding is both internal and external (France, the Netherlands) [21,22]. Integrated-specialised HTA units at hospitals also more often tend to interact with the payer/insurer or the Ministry of Health (France, Denmark, and the Netherlands) [23,24]. Regardless of the organisational model, most of analysed HB-HTA units have some level of informal interaction with regional governments or hospital district representatives.

**Table 3. Characteristics of the analysed countries in terms of similarities and differences of HB-HTA systems.**

Country / Category	National HTA Agency	HB-HTA model				Source of financing		Stakeholders		
			Stand-alone <sup>2</sup>	Integrated-essential <sup>3</sup>	Integrated-specialised <sup>4</sup>					
	Typical HTA Agency at the national level	Independent group <sup>1</sup>				Internally (from hospital funds),	Externally (scientific grants and regional funds)	National HTA Agency or equivalent	Payer/insurer or Ministry of Health	Regional governments (hospital district representatives)
Switzerland – CHUV	-			✓		✓		✓		
Switzerland – HUG		✓				✓				
Switzerland – EHNV		✓				✓		✓		
Spain – HCB	-		✓			✓				✓
Spain – VR&VM				✓		✓				✓
Spain – HStJD		]✓				✓				✓
France	✓				✓	✓	✓	✓	✓	✓
Italy	✓		✓			✓			✓	
Denmark	-				✓	✓	✓		✓	
Finland	✓				✓		✓	✓		✓
Sweden	✓				✓		✓			✓
The Netherlands	✓				✓	✓	✓		✓	
Austria	✓	✓					✓	✓	✓	✓

CHUV – Lausanne University Hospital; HUG – Geneva University Hospital; EHNV – The North Vaudois Hospital; HCB – The Hospital Clinic of Barcelona; VR&VM – the Virgen del Rocio and Virgen de la Macarena hospitals; HStJD – the Hospital Sant Joan de Deu.

1 – internal hospital units operating as an “independent group” that informally supports managerial decisions on health technologies.

2 – with highly specialised and formalised units within hospitals, operating without strong influences from other external stakeholders, such as national HTA agencies (currently the most frequent model in Europe).

3 – units with limited staff but capable of involving other stakeholders acting as allies in their HTA activities.

4 – units influenced by formal collaboration with the national or regional HTA agencies. Generally, the involvement of HB-HTA units in the technology adoption process is considered good practice and the HTA-based recommendations are closely followed by hospital decision-makers.

From the macro-perspective, undoubtedly, the common feature of the countries analysed is the understanding of the need for networking between HB-HTA and other stakeholders in healthcare. Among the countries analysed, the involvement of both central institutions, such as the public payer or the national/regional HTA agency can clearly be seen. Representatives of hospital districts, i.e. institutions connecting regional healthcare providers, also play an important role. There is much better cooperation among HB-HTA employees in Europe when it is implemented at the regional level. It needs to be highlighted that HB-HTA models need to be adapted to national conditions. This means that all crucial aspects, such as both the external and internal environments, should be considered. Secondly, financing and human resources for the HB-HTA units have to be fixed for this concept to evolve to be more widely implemented into the health system. It should be noted that the HB-HTA system exist in some countries such as Switzerland or Denmark despite the absence of a classic HTA institution at the national or regional level [25].

The analysis of existing HB-HTA models and practices in European countries lays the groundwork for the identification of country-specific practices and scenarios of how the health care systems in the analysed countries can be leveraged in implementing and promoting HB-HTA in the Polish context.

The bottom-up model with support from the regional level in the analysed countries (Spain, Italy, Denmark, and Sweden) has been deemed the most applicable scenario of developing HB-HTA in Poland [26, 27]. In this model, hospitals gain autonomy in making investment decisions on health technologies and they receive professional support from regional HTA (Italy, Spain) [28]. This model is characterised by a strong degree of decentralisation, wherein regions not only own hospitals, but are also responsible for managing and/or financing healthcare services (Denmark, Sweden) [27]. In this case, decentralisation supports

hospital managers of the HB-HTA process by the regions, which collaborate with hospitals respecting their autonomy in making investment decisions.

A second important scenario, represented by Finland, is an HB-HTA unit independent from central institutions and their regulations and procedures, which may stifle hospitals [19]. There are also other possibilities, including a bottom-up initiative featuring large, prominent hospitals as leaders in HB-HTA (Switzerland, France, the Netherlands), or hybrid scenarios, like in Austria [29].

The organisation and financing of health care in Poland indicate its centralised characteristics, which is also true in relation to managing hospitals, which are usually owned by a local self-government unit. Poland's centralised healthcare system is also manifested in the financing of healthcare services by one national payer (the National Health Fund). Given these characteristics, it should be assumed that the most plausible scenarios for implementing HB-HTA would be based on regional or central health care system support. In the former scenario, regional authority at the voivoideship regional level is responsible for hospital care; however, a representative of the central government at the voivoideship level also has a lot of healthcare-related responsibilities (e.g., mapping health needs). At the voivoideship level, there are regional offices of the National Health Fund. In this scenario, the voivoideship authority could play a leading role in regional support of HB-HTA. Nevertheless, the support of other institutions at the regional level would be necessary to successfully implement HB-HTA.

Organising HB-HTA at the central level is inherently associated with stifling its implementation and limiting its autonomy and the level of latitude in shaping its organisation and processes. If implemented in a centralised scenario, HB-HTA at hospitals would need a body that could supervise and monitor HB-HTA and its processes, e.g., the national HTA agency (The Agency for Health Technology Assessment and Tariffs). This is a plausible scenario and its functional effectiveness depends on the relationships between the HTA Agency and hospitals. Respecting HB-HTA's autonomy and mutual support would foster the implementation of such a HB-HTA model.

Plural or hybrid approaches to implementing an HB-HTA model are characterized by bringing together multiple stakeholders, i.e., governmental bodies, local and regional authorities, a national HTA agency, large hospitals, and professional institutions. Austria is an example of a country that utilises this approach for HB-HTA processes. Engaging multiple

stakeholders could pose a serious challenge in Poland when trying to implement HB-HTA. Respecting bottom-up HB-HTA initiatives, it is paramount to consider the optimal means of supporting the initiatives, taking into consideration existing and yet to be created relationships between stakeholders. Austrian HB-HTA functions on a central and regional level. The pioneer of its implementation was a national agency (since 2020, it is the Austrian Institute for HTA (AIHTA), previously the Ludwig Boltzmann Institute (LBI-HTA)), which cooperated with regions responsible for managing healthcare clinics. The need for short and irregular check-ups within the hospitals was pointed out as a result of this cooperation. It should be highlighted that using various methods of assessing medical technologies, such as clinical efficiency analysis or analysis based on international comparisons, proves that the HB-HTA in this country maintains a high level [30].

## **Discussion**

It should also be highlighted that since 2016 there have been scarce publications on the experience of implementing HB-HTA methods in Europe. It is also the main limitation for this article as it is not possible to analyse and discuss the practical experience of particular countries in this field. The only publication that was available in the medical information databases (PubMed, Embase) is the article presenting the functioning of a HB-HTA facility in Kazakhstan, which was established in 2009 [31]. This unit contributed to considerable savings in the hospital's budget by eliminating inefficient technologies. Additionally, it was shown that the introduction of a HB-HTA unit significantly streamlined the decision-making process and hospital management.

From a macro perspective, the analysis results show an increased interest and successful application of HB-HTA methods in countries with decentralised systems of managing hospitals. They point to a high probability of drawing attention to HB-HTA issues in Poland because of the decentralisation of hospital management similar to that in Scandinavian countries, even Spain or Italy, and the need to include regional authorities in the process of standardising HB-HTA in Poland. Because of the dedicated HB-HTA project executed in Poland with the National Health Fund as its leader, it is possible that the target HB-HTA model will include the important role of a system payer in the overall process related to the implementation of HB-HTA. After all, hospitals expect the payer to provide bonuses with regard to funding services based on innovative medical technologies. Centralising the funding for medical services in the Polish healthcare system, similarly to the important system role of

the Agency for Health Technology Assessment, favours the establishment of cooperation standards where important institutions (National Health Fund, AOTMiT) bear the responsibility for HB-HTA development in Poland alongside other actors active in the regions and hospitals. Including AOTMiT in the process of HB-HTA management in Poland will open up the possibility of obtaining the essential opinions issued by this institution that would allow for the implementation of a particular innovative medical technologies in the guaranteed services package. It is assumed that a specific central-local, macro-micro perspective for the target HB-HTA model in Poland will be achieved.

The analysis results for the micro perspective show that the greatest opportunities for organisational growth within hospitals are held by the units already established and active in the area of accessing technologies and expanding innovations. The deepest interest in HB-HTA ideas was displayed by Polish clinical and highly specialised hospitals that have just created units responsible for evaluating technologies and expanding innovations and investments within their organisational structures, similarly to the integrated essential HB-HTA units or stand-alone HB HTA units (see Table 5). Establishing and developing such units in Polish hospitals is essential for having qualified staff that would help the management make the right management decisions. Therefore, it is important to recruit employees working in the health system, who will constitute a human resource for the newly established HB-HTA units. They may come from system institutions, such as the National Health Fund or the Agency for Health Technology Assessment and Tariffs, or from health departments in local government units.

Table 4 below outlines the key strengths and weaknesses of HB-HTA organisational models from both the hospital and healthcare system perspectives, providing arguments for an informed decision on the implementation of HB-HTA in Poland.

**Table 4. Strengths and weaknesses of each HB-HTA organisational model in the context of HTA implementation at Polish hospitals.**

	STRENGTHS		WEAKNESSES	
	Hospital perspective	Health care system perspective	Hospital perspective	Health care system perspective

	STRENGTHS		WEAKNESSES	
	Hospital perspective	Health care system perspective	Hospital perspective	Health care system perspective
<b>Independent group</b>	<ul style="list-style-type: none"> <li>• “Pioneers” advocating/promoting HTA units at hospitals</li> <li>• “Pioneers” promoting evidence-based medicine approach</li> </ul>	<ul style="list-style-type: none"> <li>• Meaning of bottom-up initiatives aligned with internal needs</li> <li>• Consideration of managerial effectiveness</li> </ul>	<ul style="list-style-type: none"> <li>• Unacknowledged importance of HB-HTA among hospital management</li> <li>• Informal HTA process (high level of hospital latitude)</li> <li>• Low level of engagement by “Pioneers” contingent on competence and time capacity</li> <li>• Bias among clinicians with experience in national HTA</li> <li>• Promoting national HTA at the hospital level by clinicians (losing the hospital perspective)</li> </ul>	<ul style="list-style-type: none"> <li>• The absence of activity in HB-HTA</li> <li>• Inability to compare practices</li> </ul>
<b>Integrated-essential HB-HTA unit</b>	<ul style="list-style-type: none"> <li>• Initiating centres of competence in HB-HTA</li> <li>• Synergies in resources and competence boosting the HB-HTA process and decision-making ability</li> <li>• Promoting hospital managerial</li> </ul>	<ul style="list-style-type: none"> <li>• Positive pressure on external institutions with lower competency in HB-HTA</li> <li>• Initiating networking activity with others, e.g.,</li> </ul>	<ul style="list-style-type: none"> <li>• Low general activity level in HB-HTA</li> <li>• Low level of formalisation</li> </ul>	<ul style="list-style-type: none"> <li>• The absence of sufficiently standardised procedures enabling comparisons</li> <li>• Limited outreach of HB-HTA</li> </ul>

	STRENGTHS		WEAKNESSES	
	Hospital perspective	Health care system perspective	Hospital perspective	Health care system perspective
	effectiveness	hospital clinics <ul style="list-style-type: none"> <li>• Creating opportunity to compare HB-HTA reports</li> </ul>		
<b>Stand-alone HB-HTA unit</b>	<ul style="list-style-type: none"> <li>• Formalisation of HB-HTA unit in the organisation chart of a hospital</li> <li>• Capabilities in HB-HTA for hospital managers</li> <li>• Centre of excellence for developing HB-HTA capabilities for healthcare professionals</li> </ul>	<ul style="list-style-type: none"> <li>• Bolstering managerial effectiveness of the hospital</li> <li>• Potential promoting criterion for best managerial practices at hospitals</li> </ul>	<ul style="list-style-type: none"> <li>• Cost of running an HB-HTA unit</li> <li>• Limiting autonomy of hospital managers in making investment decisions</li> <li>• Formalisation of process adversely impacting the willingness to initiate investments in new technologies</li> </ul>	<ul style="list-style-type: none"> <li>• Good practices limited to a particular hospital without outreach</li> <li>• The absence of sufficiently standardised procedures enabling comparisons</li> </ul>
<b>Integrated-specialised HB-HTA unit</b>	<ul style="list-style-type: none"> <li>• More structured approach to making investment decisions</li> <li>• High specialisation in assessment domains (e.g., economic evaluation of health technologies)</li> <li>• Improving</li> </ul>	<ul style="list-style-type: none"> <li>• Ability to compare cost-effectiveness of assessed technologies</li> <li>• Ability to identify good practices in HB-HTA</li> <li>• Improving effectiveness of</li> </ul>	<ul style="list-style-type: none"> <li>• Formal established collaboration practices with the national HTA agency</li> <li>• High level of formalisation in division of work within an HB-HTA unit</li> <li>• Proliferation of organisational structure</li> <li>• Higher administrative</li> </ul>	<ul style="list-style-type: none"> <li>• Integration with national HTA</li> <li>• High standardisation of HB-HTA methodology and processes</li> </ul>

	STRENGTHS		WEAKNESSES	
	Hospital perspective	Health care system perspective	Hospital perspective	Health care system perspective
	<p>the managerial and financial effectiveness of a hospital</p> <ul style="list-style-type: none"> <li>• Potential criterion for more favourable tariffs related to healthcare services</li> </ul>	<p>public resource allocation in the hospital sector</p>	<p>costs</p>	

Authors' own study based on: Sampietro-Colom, L., Lach, K., Cicchetti, A., Kidholm, K., Pasternack, I., Fure, B., Rosenmüller, M., Wild, C., Kahveci, R., Wasserfallen, J.B., Kiivet, R.A., et al., The AdHopHTA handbook: a handbook of hospital-based Health Technology Assessment (HB-HTA); Public deliverable; The AdHopHTA Project (FP7/2007-13 grant agreement nr 305018); 2015. Available from: <http://www.adhophta.eu/handbook>. Access online: 25.05.2020. L. Sampietro-Colom, & J. Martin (Eds.), Hospital-Based Health Technology Assessment: The Next Frontier for Health Technology Assessment (pp. 39-44). Springer. [https://doi.org/10.1007/978-3-319-39205-9\\_4](https://doi.org/10.1007/978-3-319-39205-9_4)

## 6. Conclusions

HB-HTA units are present in European healthcare systems, which differ in terms of centralisation, decentralisation, and deconcentration; however, the absence of such initiatives in the older types of centralised healthcare systems are more likely to embark on HB-HTA activity. HTA units and committees in hospitals are characterised by their multi-skilled staff, including medical and other professionals, such as those in public health, health economics, and bioengineering, among others. Our review found that HB-HTA units/committees cooperate with various healthcare system stakeholders, that is, with payers, insurers, national and regional HTA agencies, and respective Ministries of Health. Interactions between stakeholders and HB-HTA units is often informal and voluntary. The funding for HB-HTA units comes from internal hospital funds and/or external scientific grants. Our analysis of strengths and weaknesses associated with various organisational models from the hospital

and health care system perspective is expected to provide material input in the debate on the future implementation of HTA in Polish hospitals. These strengths and weaknesses must be carefully considered in the context of support for decentralised or centralised models of implementation while embarking on HTA activities in Polish hospitals.

## 7. Acknowledgments

Authors would like to thank Laura Sampietro-Colom, Nicolas Martelli, Kristian Kidholm, and Claudia Wild for sharing their valuable insights on the most recent developments concerning HB-HTA and HTA in general from the perspective of their countries.

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In review