



Health Reform Monitor

Towards the development and implementation of hospital-based health technology assessment (HB-HTA) in Poland: Achievements of an exploratory HB-HTA project from 2019–2022

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ABSTRACT

A comprehensive project exploring the implementation of hospital-based health technology assessment (HB-HTA) was conducted in Poland from 2019 to 2022. This initiative aimed to identify entities that could initiate and manage HB-HTA in the Polish context, including hospitals, the Province Office where was the creation of a new organizational unit the Regional Investment Evaluation Center – was recommended, the national HTA agency, the National Health Fund (the public payer), and the Ministry of Health. Despite the well-structured delineation of roles and stakeholders in the proposed HB-HTA model, its operationalization within the aforementioned institutions has not been realized. Challenges to the implementation of the model include a lack of suitably qualified personnel and a lack of commitment from key stakeholders. However, the late involvement of the national HTA agency and the Ministry of Health, as well as ongoing training and research initiatives in HB-HTA, indicate a growing interest in exploring its benefits. Finally, a central government body (Ministry of Health) will be responsible for coordinating HB-HTA in Poland. This could improve the overall HTA capacity and increase the likelihood of future implementation of HB-HTA in Poland.

1. Background

Concerns about the effectiveness and high cost of established and new medical technologies have led to the establishment of health technology assessment (HTA) agencies or units in many European countries in the last decades [1]. This includes Poland, where a central HTA agency (*Agencja Oceny Technologii Medycznych i Taryfikacji*, AOT-MiT) was established in 2005 to assess the clinical and economic effectiveness of health technologies and make recommendations on their use and reimbursement [2].

Many Health Technology Assessment (HTA) agencies traditionally operate at the national level, such as the National Institute for Health and Care Excellence (NICE) in England. Some regions also have their own HTA agencies, such as the Andalusian Agency for Health Technology Assessment (AETSA). However, increasing economic pressures on hospitals, combined with their vital role as gateways for innovative

health technologies [3], have also led larger hospitals and hospital trusts in some countries to establish their own HTA capacity to evaluate and manage innovative technologies [1]. This has led to the emergence of specialised hospital-based health technology assessment (HB-HTA).

The EU-funded project “Adopting Hospital Based Health Technology Assessment” (AdHopHTA) (2012–2015) played an important role in promoting HB-HTA in Europe, including Poland [4]. The project drew on the expertise and experience of its partner institutions in nine countries (eg. Denmark and Spain) to provide knowledge on HB-HTA and support hospitals and other healthcare institutions to effectively implement HTA and use of new health technologies in their specific contexts. These resources encompassed HTA manuals, toolkits, and databases, including a toolkit for setting up and running an HB-HTA unit [5].

In 2017, the results of the AdHopHTA project were disseminated within the Polish medical community. This included an open letter

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written by Mr Krzysztof Łach, a former employee of one of the coordinating member institutions of AdHopHTA and a Pole. This letter was circulated to key stakeholders in the HTA field in Poland (eg. Ministry of Health and AOTMiT) and various medical university libraries [6]. In particular, the Ministry of Health responded positively to the letter and initiated training programmes in HB-HTA for healthcare administrators.

Later that year, Mr Łach, who was at that time affiliated with the National Institute of Cardiology in Warsaw, championed the introduction of HB-HTA in Poland. In 2018, a consortium comprising the Institute, the National Health Fund (NHF), and Lazarski University in Warsaw successfully secured a grant from the Polish National Center for Research and Development to explore the implementation of HB-HTA in Poland. The objectives of the project included the exploration of different HB-HTA models, the development of a model tailored to the Polish context, and its subsequent testing in selected hospitals, with the ultimate goal of implementing HB-HTA in Poland [7,9]. The project was active from January 2019 to June 2022, culminating in a final conference on HB-HTA organized by the National Institute of Cardiology.

Although the primary objectives of the project have been achieved, the widespread adoption of HB-HTA in Poland has yet to materialize. This article provides an insight into the implementation of the HB-HTA pilot project and examines the view of key stakeholders who have a significant influence on potential national implementation, thus revealing the underlying reasons for the lack of wider adoption of HB-HTA.

2. Policy process, content, and implementation

The HB-HTA project consisted of two phases: the research phase and the phase of preparing the research results for practical application [10]. The research phase started with a comprehensive analysis of HB-HTA systems in Europe and North America and an assessment of the current situation in Poland, which included a survey of large Polish hospitals and in-depth interviews in selected institutions [11].

The construction of six institutional models of HB-HTA was preceded not only by a questionnaire survey and interviews. Theoretical models for the implementation of HB-HTA in Poland were built on the basis of following research works:

- Needs analysis (survey of hospitals in Poland about innovative medical technologies, survey of patients from cardiology and oncology departments);
- Practice analysis (literature review on the functioning of the HB-HTA network in Europe, analysis of hospital health technology assessment reports, assessment of medical technologies implementation analysis, PEST analysis for the implementation of HB-HTA in Poland, analysis of stakeholders, inhibiting and supporting forces for political, economic, social and technological conditions determining the process of implementing HB-HTA in the Polish health care system) [12].

Each theoretical model for the implementation of HB-HTA in Poland was developed according to the same scheme of approach:

1. Identification and role of stakeholders in the HB-HTA process.
2. Identification of key actors and their roles in the HB-HTA process.
3. Stakeholder analysis of their forces (supporting, inhibiting, neutral).
4. Analysis of the consequences and interests of each stakeholder.
5. Relationship between stakeholders.
6. The course of the HB-HTA process, the relationship between entities in the context of data flow, products and services within the model.
7. Analysis of the competence potential of the coordinating unit.
8. General principles: financial aspects, possibilities of maintaining the network.

9. Analysis of barriers and opportunities for the scenario analysed.
10. Summary – differentiation criteria [11].

Building on this work, the consortium developed an initial methodology for hospital-based health technology assessment and six models for implementing HB-HTA. Each model designated a different entity to play a coordinating role: (1) hospitals; (2) Regional Centers for Investment Assessment (*Regionalne Centra Oceny Inwestycji*, RCOI) operating on the province level; (3) the AOTMiT; (4) the National Health Fund; (5) an independent external institution; and (6) Regional Centers for Investment Assessment, which were recommended to operate within the health departments of the province offices, with the support from the NHF and AOTMiT (a mixed model) [13–18]. After further research, the mixed model emerged as the most appropriate for the Polish context. In this model, each institution would take on specific roles; for instance, the NHF would initiate and manage HB-HTA reports, the AOTMiT would provide HTA expertise and maintain a knowledge repository, and the RCOIs would conduct evaluations of HB-HTA reports prepared by hospitals [7].

The second phase was to prepare the research findings for practical application. This included conducting a socio-economic analysis of the demand for HB-HTA in Poland, including the collection of opinions from hospital managers and site visits to selected hospitals and international HB-HTA centers. These findings were used to develop the final HB-HTA methodology and to propose HB-HTA model. During this phase, the consortium identified a skill gap at the regional level (lack of interest in HB-HTA on the part of the province offices responsible for coordinating Covid-19 pandemic activities in the region at the time), which was perceived as a potential barrier to the effective conduct of HTA work. As a result, it was recommended that the role of the Ministry of Health be strengthened with additional coordinating responsibilities [5].

In the preliminarily accepted mixed model of HB-HTA implementation in Poland (Fig. 1), an important role is played by MoH, NHF and AOTMiT, which are responsible for HB-HTA knowledge dissemination and better financing (NHF), hospital certification (AOTMiT) and coordination of activities (MoH). Regional coordination belonged to the RCOI, which has the important task of reviewing the HB-HTA reports prepared by the hospital. The decision to entrust coordination in the region to the RCOI was made in the context of the existing competence of the Province Offices to evaluate major investments in the health sector, a responsibility they have had since the launch of the regional health investment evaluation tool in 2016 (known as the "*Instrument Oceny Wniosków Inwestycyjnych w Sektorze Zdrowia*," or IOWISZ [6]) (Fig. 1).

Following an analysis of the mixed model, in which its strengths and weaknesses were assessed thanks to the exchange of information through the expert panel and the decisions of the Project Steering Committee, the decision to continue working on the basis of the mixed model was maintained. However, in the pre-implementation phase, based on further work of the consortium, it was decided to modify the theoretical model by adding a coordinating role performed by the center managing HB-HTA at the macro level, i.e. the Ministry of Health, and to create the so-called practical model [8,11].

The addition of the coordinating role of the Ministry of Health results from the need to coordinate activities in the field of HB-HTA at the supra-regional level. The exchange of information on solutions implemented in hospitals must, of course, take place within a single province, but there is a need for an entity to develop and, where necessary, regulate HB-HTA at the national level. Based on the project documents and arguments related to the supervisory role towards many actors in the health care system, it was considered necessary to add a coordinating role to the Ministry of Health [11] (Fig. 2).

The final phase of the second stage of the project was dedicated to the practical testing of the proposed solutions through a pilot programme. Seven hospitals, due to their significant contributions in implementing medical technologies, and history of project involvement with Lazarski

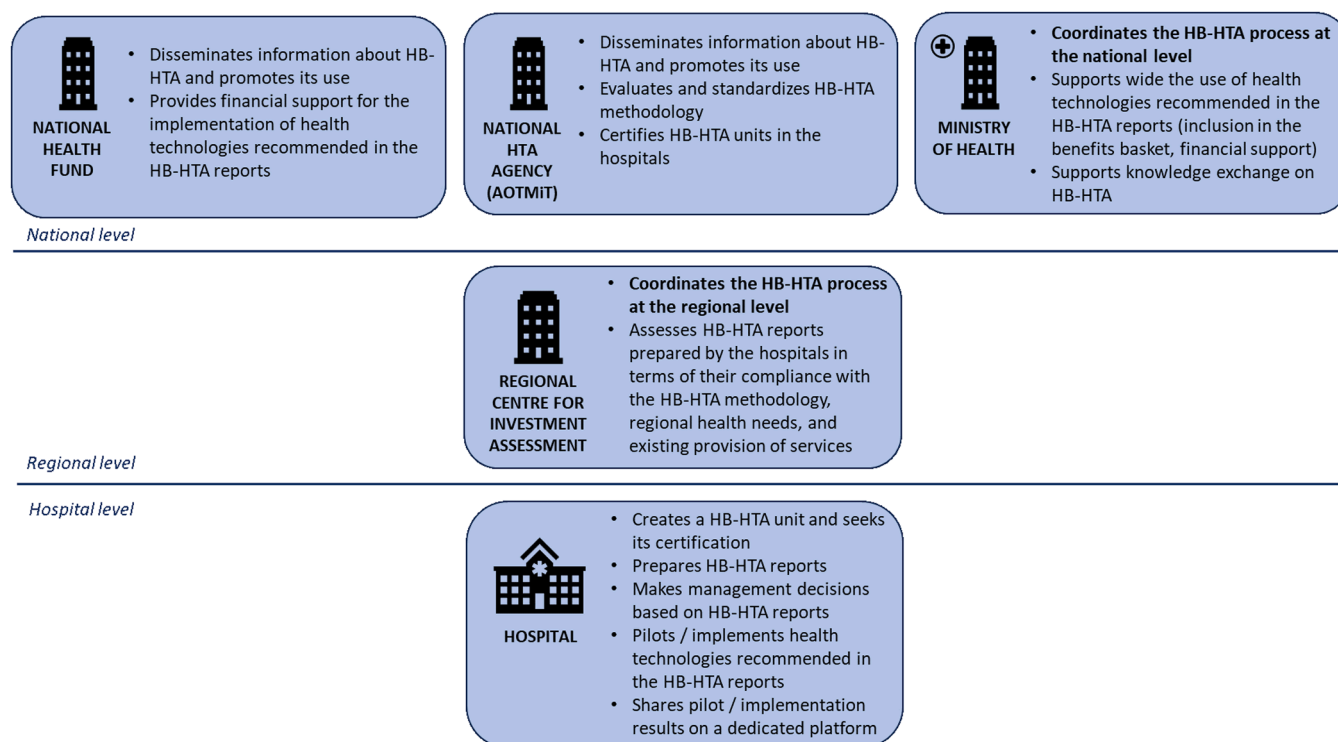


Fig. 1. Key actors in the proposed mixed HB-HTA model and their roles.
Source: Based on [5].

University, were selected (hospitals from Warsaw (3x), Gdansk, Wrocław, Krakow, Lodz).

The personnel in these hospitals received training in HB-HTA facilitated by the Lazarski University. This training capitalized on the knowledge generated in the previous phases of the project. Subsequently, pilot HB-HTA units were established in hospitals and tasked with conducting pilot assessments of medical technologies and preparing HB-HTA reports [10]. The assessed technologies included the integration of the Da Vinci robotic surgery system; the establishment of a center for integrated care of patients with advanced chronic obstructive pulmonary disease (COPD); improvement in the organization and processes of cervical cancer diagnosis; a comparative assessment of implantable electrocardiogram (ECG) recorders versus conventional ECG and Holter diagnostics; an evaluation of bipolar ablation in patients with cardiac arrhythmias; an evaluation of contemporary diagnostic and therapeutic procedures for the management of retinoblastoma in children; and an evaluation of the impact of myocardial perfusion using multi-slice computed tomography, complemented by alternative communication techniques, in the context of ischaemic heart patients [11,12].

At the end of the pilot phase in February 2022, no dedicated HB-HTA units were established in the participating hospitals despite the positive evaluation of the technologies studied and the investments made by these hospitals in these technologies.

3. Stakeholder analysis

The limited adoption of HB-HTA in Poland can be attributed to a general lack of buy-in from key stakeholders, as shown in Fig. 3. In addition, key stakeholders in the mixed model, namely, the RCOIs, the NHF, the Ministry of Health, and the AOTMiT, did not fulfil their expected roles.

Support for the implementation of HB-HTA came mainly from the NHF and university hospitals. The NHF, which had a vested interest in the implementation of HB-HTA as an integral member of the project

consortium, expected that the implementation of HB-HTA would enhance the efficiency of management of public healthcare resources, especially in the area of high-cost medical technologies. The availability of HB-HTA reports would significantly strengthen the Fund's ability to make data-driven decisions, thereby enabling it to exercise greater control over the allocation of resources within the healthcare system.

At the same time, teaching or university hospitals showed a particularly strong commitment to HB-HTA. This enthusiasm is probably due to potential of HB-HTA to secure additional funding for innovative medical initiatives. These types of hospitals tend to use such technologies, extensively, in contrast to province hospitals, and even more so when compared to county hospitals. This disparity contributed to the relative indifference of the latter towards HB-HTA (Fig. 3).

The main reason for the cessation of HB-HTA activities following the mixed model can be attributed to the limited engagement of two key stakeholders: the Ministry of Health, which has significant legislative influence, and the central HTA agency (AOTMiT), which has essential HTA expertise in Poland. Their lack of involvement was largely due to their non-participation in the project consortium. However, it is conceivable that following the presentation of the benefits of HB-HTA at the project's final conference in June 2022, these stakeholders may express interest in initiating a systematic hospital-based assessment of innovative technologies in Poland. Indeed, during this final conference, both AOTMiT and the Ministry of Health contributed to the reports, although they are part of the project consortium, and their involvement in HTA has so far been passive.

Crucially, the Province Offices, which were supposed to play a key role in the HB-HTA process, showed little interest in its implementation. This lack of interest can be attributed to their inability to provide the necessary human, financial, and economic resources necessary for the effective implementation of the HB-HTA process. Province Offices were not involved in activities related to HB-HTA, and during the project they had to deal with the Covid-19 pandemic, and the area of crisis management was the most important for these institutions. This was one of the reasons for changing the coordination of HB-HTA from the level of

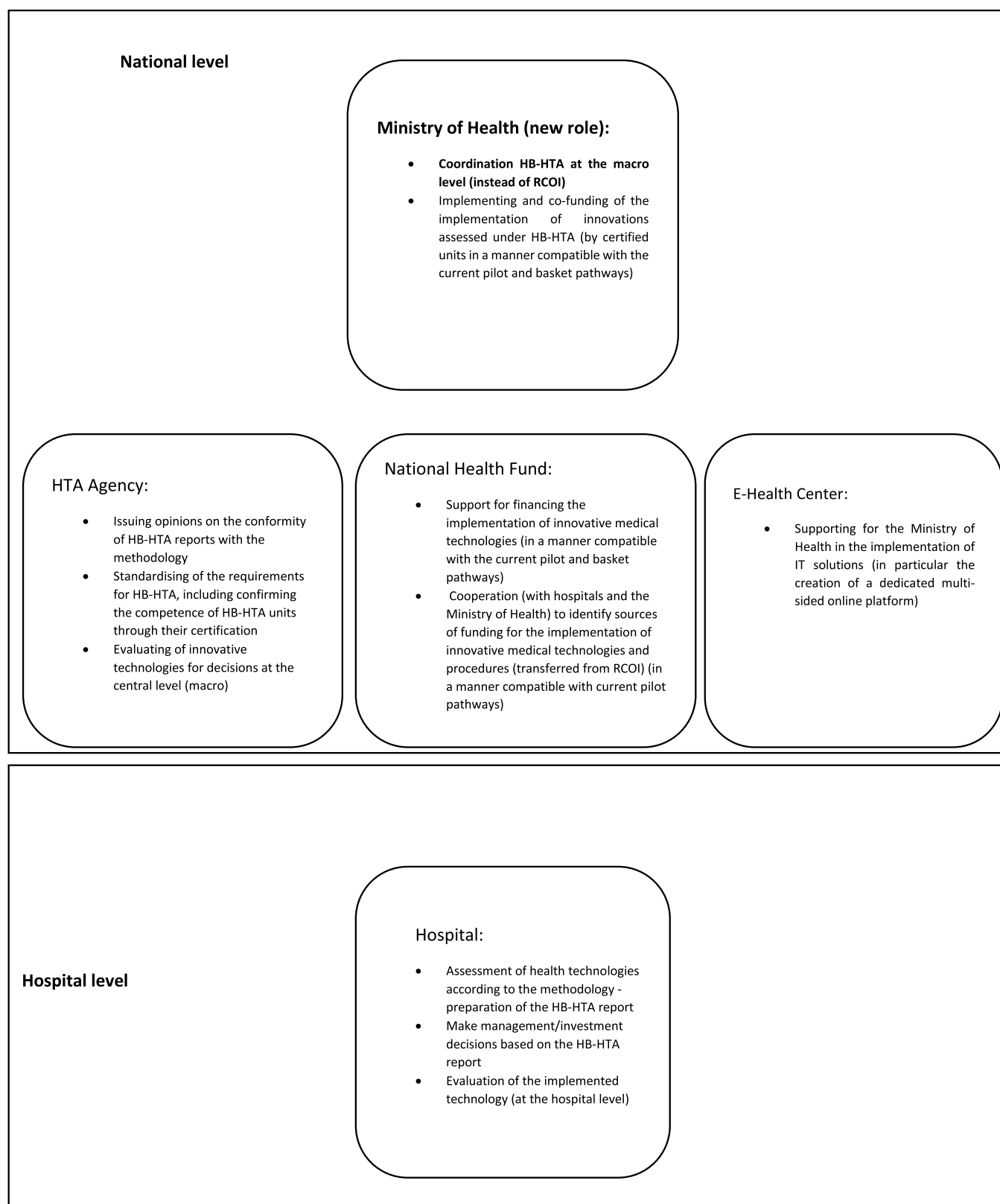


Fig. 2. Tasks performed by institutions in the HB-HTA practical model with coordinating role of the Ministry of Health.

Province Offices to the level of the Ministry of Health in the practical model.

4. Discussion

The establishment of the national HTA agency in 2005 and the introduction of the regional investment assessment tool (IOWISZ) in 2016 have enhanced Poland's capacity to evaluate medical technologies

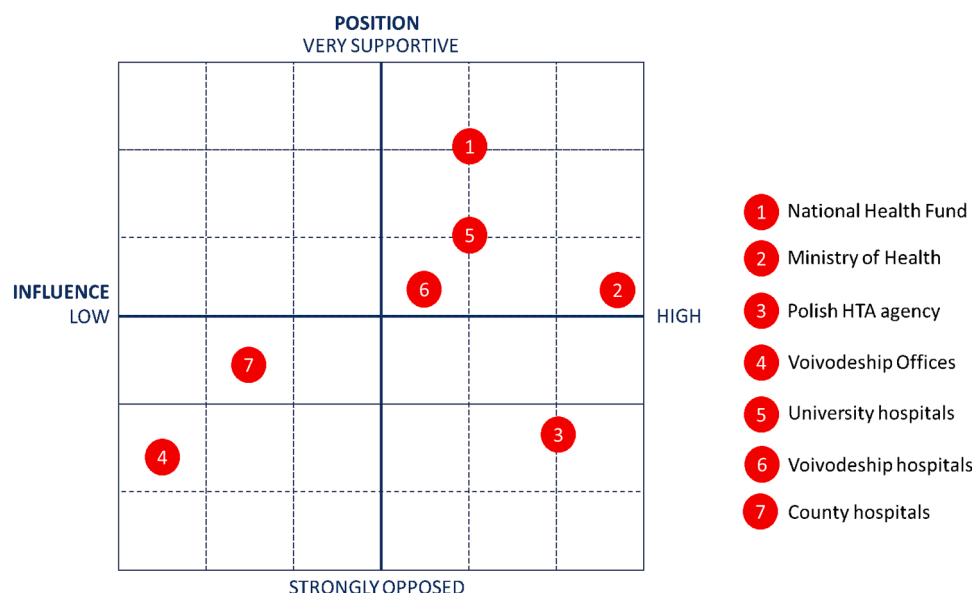


Fig. 3. Positions of the key stakeholders and their influence in the mixed model.
Source: Authors own compilation.

[6]. However, the former is still primarily focused on the assessment of pharmaceuticals, and the latter is primarily focused on assessment of large investments that rely on public funding, including EU funding [6]. As a result, there is a growing awareness that hospital administrators face challenges in accessing essential guidance needed to make informed decisions about the integration of new technologies into their unique healthcare settings [7].

The implementation of HB-HTA is a promising way to fill this gap, especially for hospitals that often adopt innovative technologies. However, the development of HB-HTA in Poland has so far been hampered by lack of resources and to some extent, a lack of willingness on the part of both hospitals and public organisations to implement it [18].

Similar obstacles have been identified in the Czech Republic, where several pilot HTA studies have focused on the evaluation of specific hospital technologies (although they have so far been conducted outside the respective hospitals), but where HB-HTA has not yet been implemented [19]. The main barriers identified included the lack of a unified procedure for evaluating healthcare technologies and the low demand for these types of evaluation from health care institutions and relevant legislation [19].

Estonia serves as an exemplary case among Central and Eastern European countries in terms of commitment to the implementation of HB-HTA. For many years, elements of HTA have already informed analyses and decisions on the reimbursement of medical services by the Ministry of Social Affairs and the Estonian Health Insurance Fund (EHIF). In 2011, as part of the Health Sciences Capacity Building Programme (*Tervishoiuteaduste Võimekuse Edendamise Programm, TerVe*) of the Estonian Research Council, a collaborative HTA initiative was established involving the EHIF, the Ministry, the University of Tartu, the Estonian Hospital Federation, and medical associations, i.e., a mixed model, similar to the one proposed for the Polish context. In the period from 2012 to 2015, these efforts resulted in the commissioning of 25 HTA reports related to hospital settings. The main objectives of these reports were to justify investments in emerging hospital-based health technologies and to evaluate established technologies, such as mammography screening and in vitro fertilization. Topic selection is a collaborative process involving the HTA Council, the Estonian Hospital Federation, medical associations, and the reports are publicly available through an open database (<http://rahvatervis.ut.ee>). The analytical, statistical, and cost data essential for the HTA process are provided by the EHIF and the participating hospitals [4].

An unexpected effect of the implementation of HB-HTA in Poland is low interest in these processes by the headquarters of the HTA agency. HB-HTA processes are therefore closely correlated with hospitals themselves. Hospital managers must look for solutions that ensure effective decision-making. The search for institutional support for them at the central level does not ultimately bring results.

5. Conclusions

The development of HB-HTA in Poland has so far encountered obstacles. These challenges are mainly due to the lack of preparedness for implementing HB-HTA in hospitals and public organizations, characterized by a lack of the necessary training initiatives. Although the exploratory HB-HTA project has not yet led to the establishment of dedicated HB-HTA units in hospitals, there is promising potential for significant progress in this area in the future. Ongoing initiatives in training and research related to HB-HTA, including postgraduate HTA studies at Lazarski University, have the potential to contribute significantly to capacity building in the broader HTA field. The participation of the national HTA institution and the Ministry of Health in some of the HB-HTA activities towards the end of the project may signal a growing interest in exploring the opportunities that HB-HTA can offer.

The future of HB-HTA in Poland is difficult to predict. The possible scenario is that one or several large clinical centers in Poland will specialize in this area, providing also custom services. The HB-HTA team and methodology will also develop in this center/centers. Strengthening competences of HB-HTA specialist is also crucial, which may be achieved by initiated postgraduate study. It is also necessary to constantly evaluate the ongoing HB-HTA processes in Poland, forcing the necessary actions to be taken, which will allow for the permanent professionalization and development of HB-HTA. The example of Poland may help other countries, especially those starting to implement HB-HTA, to shorten the process of HB-HTA implementation and to recognize the key role of the hospital itself in this respect, recognizing mechanisms such as networking or the selection of HB-HTA leader. Proper allocation of competences and structuring of HB-HTA processes will allow healthcare to be better prepared for future crises.

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Małgorzata Gałązka-Sobotka: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Maciej Furman:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Anna Sagan:** Supervision, Software, Resources, Methodology, Formal analysis, Conceptualization. **Iwona Kowalska-Bobko:** Writing – review & editing, Writing – original draft, Supervision, Resources, Methodology, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

None.

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