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Hospital-based health technology assessment of innovative medical devices: insights from a nationwide survey in France

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Abstract

Objectives: To better understand the process of hospital acquisition of innovative medical devices (MDs) and the hospital-based health technology assessment (HB-HTA) pathways in France, an in-depth study based on a quantitative approach is needed. The aim of the present study was to assess through a national survey how HB-HTA is currently implemented in French hospitals and to identify its level of formalization.

Methods: A quantitative online survey was conducted among hospitals performing HB-HTA in France, with a focus on the acquisition of innovative MDs for individual use. The survey, conducted between March and June 2022, was developed by a scientific board composed of members of the French-speaking Society for HB-HTA.

Results: Sixty-seven out of 131 surveyed hospitals with HB-HTA activities responded, including 29 university hospitals, 24 nonprofit private hospitals, and 14 local hospitals. Sixty-one respondents (91 percent) reported the existence of a process dedicated to evaluating innovative MDs; of these, 16 declared that their hospitals had a formalized unit with HB-HTA activity. These units were more frequently found in larger hospitals with more than 500 inpatient beds (n = 16, p = 0.0160) and in university hospitals (n = 12, p = 0.0158). No hospital reported any collaboration with HAS, the French national HTA agency.

Conclusion: A diverse range of HB-HTA organizations with different structural levels exist in France for MD procurement linked to the category of hospitals. The study highlights the need for recognition of HB-HTA activity at the regulatory level in France and for direct collaboration between HTA activities performed at local and national levels.

Introduction

With limited healthcare resources on the one hand and ever-increasing in number yet costly therapeutic innovations on the other, access to innovative medical devices (MDs) is a major challenge for European countries (1;2). Many countries have implemented processes to incorporate evidence-based assessment in policy decisions on medical technologies (3;4). In this context, health technology assessment (HTA) helps decision makers render more efficient the use of limited resources by providing high-quality information on the clinical efficacy, cost-effectiveness, and broader impact (including social and ethical impacts on patients) of health technologies such as MDs. This multidisciplinary process allows a complete overview of the MD evaluation, considering organizational, economic, legal, social, and ethical aspects together with a clinical and technological assessment (5;6). HTA can be conducted as a centralized process on a national level, or as a decentralized process at regional/local levels often in hospitals where it is referred to as hospital-based HTA (HB-HTA) (6).

In France, the scientific evaluation of MDs undergoes a highly centralized process. The French national health authority (Haute Autorité de Santé, HAS) was established in 2004 to manage all HTA activities nationwide, and provides support on decisions concerning the eligibility for reimbursement of MDs for individual use. However, the HAS manages to assess only a small proportion of the vast number of new health technologies developed in the rapidly evolving field of MDs. In contrast, the procurement of MDs in France is entirely decentralized and methods demonstrated in French hospitals, whether they are private or public, are similar

across all categories. Each hospital or hospital group assumes the responsibility for acquiring healthcare technologies or drugs for their patients in accordance with the regulations outlined in the French commercial code (7). As a result, individual hospitals or purchasing groups engage in direct price negotiations with medical device manufacturers. Meanwhile, French hospitals are faced with ever-growing demands for innovative and often costly medical devices that may not yet have been evaluated by the HAS at the national level. As such, many hospitals, especially university hospitals (UHs), have been compelled to develop their own HTA systems (8;9).

There is no single model for HB-HTA. In 2007, the international working group Health Technology Assessment International (HTAi) identified four main HB-HTA approaches according to two variables (focus of action and level of complexity): the mini-HTA, the internal committee, the HTA unit, and the ambassador model (10). Although these four categories help capture general HB-HTA models around the world, this classification considers neither those many HB-HTA systems combining together all four models, nor the goal and specific organizational process of the HTA within a particular organization (5). Indeed, many different solutions exist for achieving HB-HTA, and it is very difficult to fully characterize them through these "simplified" categories.

The European project AdopHTA, aimed at enhancing HB-HTA practices, provided recommendations for good HB-HTA and proposed a description of the models observed in European countries. As a result, in 2018, an additional classification was suggested based on the combination of formalization and specialization of HB-HTA with the level of integration at the national, regional, and provincial levels as a criterion (11–13). Four distinct options have emerged from this classification: integrated specialized HTA unit, standalone HTA unit, integrated-essential HTA, and independent group unit. In 2020, Gałazka-Sobotka *et al.* also proposed five criteria for defining the highest level of HB-HTA structuration. These five criteria are as follows: (i) formalization with standard operating procedures; (ii) specialization with full-time employers and/or specific formal procedures; (iii) integration between the work of the HB-HTA unit and that of other healthcare stakeholders inside or outside of the hospital; (iv) authority and centralization of power at a high level in the unit (e.g., nondelegated decisions to lower organizational levels in the HB-HTA unit, e.g., to the person responsible for an HTA project); (v) professionalization with a high degree of expertise available or training undertaken by the staff of the HB-HTA unit (14).

In France, no in-depth investigations into HB-HTA models have yet been performed, although some studies have been done to explore and improve existing models. In 2015, a study conducted to explore HB-HTA activities in French UHs, focusing only on MDs for individual use, identified three major types of HTA processes for adopting new MDs: MD committees, innovation committees, and "pharmacy and management" processes. HTA units were also part of these models, supporting MD and innovation committees in technology assessment (9). In 2017, a complementary study comparing the topics evaluated in a Danish mini-HTA model, proposed the use of a mini-HTA model in French UHs. They found that mini-HTA would be compatible with and also potentially beneficial to the French system (8). However, it is worth noting that these studies had some limitations: They utilized a qualitative approach and only considered data from university hospitals, which may limit the applicability of their results to all types of French hospitals.

It is also worth mentioning that some literature references concerning the French model are no longer relevant. Indeed, one publication in 2016 featuring 31 case studies examining HB-HTA methods in various countries highlighted the example of the "CEDIT," which stands for the Committee for the Evaluation and Dissemination of Technological Innovations, of Parisian university hospitals. However, since the dissolution of this committee in 2016, there has been a dearth of literature exploring the French version of HB-HTA, with limited data available on the subject (4). In addition, one recent publication emphasizing the limited evidence regarding the influence of HTA on the procurement of medical devices did not include France (15). The specific mixed model (centralized evaluation, decentralized procurement) used in French hospitals was therefore not described in this study. The authors called for further research to better understand the link between HTA and procurement.

Very little is therefore known about HB-HTA processes for MDs in nonprofit private and local hospitals in France. In addition, some elements that could help describe the organization of HB-HTA processes more specifically are currently unknown, such as the level of formalization of the HB-HTA units identified in the 2015 study, the type of data used for MD assessment, and the degree to which HB-HTA reports are shared among hospitals and with the HAS.

To better understand the process of hospital acquisition of innovative MDs for individual use and HB-HTA procedures in France, a quantitative approach based on a large panel of French hospitals is now required. The aim of this study is to assess how HB-HTA is currently implemented in French hospitals and to identify its level of formalization.

Methods

Survey design

A quantitative survey, based on those developed following good practice described in the literature (16), appeared to be the most suitable solution for collecting original data on HB-HTA in French hospitals. The one thus developed among professionals practicing HB-HTA in France for the procurement of innovative MDs for individual use was named GRETAH ("orGanisation des Réseaux d'Evaluation des Technologies de sAnté en milieu Hospitalier"). It was developed and validated by a scientific board composed of members of the French-speaking society of hospital-based HTA (Société francophone pour l'évaluation des technologies de santé – SF-ETS). A preliminary questionnaire was conceived and tested by two professionals in order to refine its content. Open-ended questions and closed questions covering six topics were included in the final questionnaire (available in supplementary file 1). The six topics were as follows: type of institution (3 questions), organization (16 questions), communication (6 questions), evaluation (12 questions), collaboration (3 questions), and funding (1 question). Some questions required a response, while others were not mandatory. The survey was expected to take about 10 minutes to complete.

SF-ETS members' second role was to define a list of healthcare centers to be contacted in which HB-HTA activity for innovative MDs was plausible. As a result of this process, a first broadcast list was conceived excluding centers in which innovative MDs were unlikely to be introduced, such as long-term care facilities. At this point, the aim was to identify the professional likely in charge of or involved in the HB-HTA process within each healthcare center. Subsequently, to widen the distribution of the survey, the

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2020 yearbook of all French hospital pharmacists was used to identify healthcare centers. In France, the hospital pharmacist is legally responsible for the management and procurement of sterile MDs for individual use, so we assumed that hospital pharmacists would be aware of the existence of a dedicated evaluation system for MDs.

The final survey targeted different categories of health facilities, such as local hospitals, teaching hospitals, and nonprofit private hospitals. Of note, in France, most cancer treatment institutions are nonprofit private hospitals. The survey was performed in Google Forms, and an invitation was emailed to potential professionals identified by the SF-ETS panelists as detailed above. The data collected in this survey were kept anonymous, but respondents could leave their contact information, allowing us to contact them for further details if needed. The survey was conducted between March and June 2022. The representativeness of hospitals included in the study was estimated based on the number of hospital stays for acute care per year per category of healthcare centers. These data were extracted from the "SCAN Santé" Web site of the French hospital care information agency (Agence Technique de l'Information sur l'Hospitalisation, ATIH).

Statistics

Responses to each question were summarized using descriptive statistics. Continuous and categorical variables were expressed as median and percentage when appropriate. Categorical variables were compared using chi-squared tests. For statistical comparisons, hospitals were categorized into two groups: UHs (for university hospitals) and non-UHs (for nonprofit private hospitals and local hospitals). The test for differences in responses according to type and size of healthcare center was performed using Pearson's chi-squared test or Fisher's exact test when the sample sizes were too small. A standard significance level of 0.05 was used for the statistical tests. The questionnaire data were processed using Excel software (Microsoft Office 2016). All analyses were performed through scripts developed in the R software (version 4.2.1, June 2022).

Results

Characteristics of the healthcare centers included in the survey

We issued 131 invitations to take part in the survey, and 67 (51 percent) professionals responded from a diverse range of 67 French hospitals: 29 UHs, 24 nonprofit private hospitals, and 14 local hospitals. Of these, 52 (78 percent) were large hospitals with more than 500 inpatient beds. The 67 responders from 67 different hospitals represented 42 percent of the healthcare supply in France in terms of bed numbers. Of all French hospitals, the survey included 91 percent of UHs, 21 percent of nonprofit private hospitals, and 12 percent of local hospitals.

Technology assessment and decision-making processes

A total of 61 centers out of the 67 (91 percent) responders reported the existence of a dedicated process for the evaluation of innovative MDs, including at least the existence of a multidisciplinary committee involved in the selection process for adopting new MDs for individual use. Of these 61 hospitals, 16 (24 percent) also declared having an "HTA unit", that is, a scientific committee in charge of summarizing evidence on MDs. This HTA unit comprises at least five members for 44 percent of these hospitals and is multidisciplinary in all: 16 (100 percent) units include a pharmacist, 14 (88 percent) a physician, 13 (81 percent) a surgeon, and 8 (50 percent) a health economist. Among these 16 units, 11 (18 percent) are associated with an innovation committee and the other five are the "scientific secretaries" of MD committees. In addition, the professionals in 38 percent of cases (six hospitals) reported the existence of these units for over 10 years. However, out of the total number of units surveyed, only one unit (6 percent, 1 out of 16) reported having dedicated full-time HTA experts within their team. All reported HTA units were in larger hospitals (no unit in hospitals <500 inpatient beds) ($p = 0.0160$) and were more frequent in UHs than in non-UHs ($p = 0.0158$) (Table 1). Table 2 provides the descriptive variables relating to the questionnaire responses of the 16 surveyed hospitals with HTA units.

For the decision-making process, among the 61 centers with an HB-HTA process, 52 (85 percent) professionals reported the existence of a plenary commission for the evaluation of MDs, 39 (64 percent) of which are MD committees as described in the French Public Health Code since 2010. These commissions make recommendations concerning sterile MDs used within the hospital and review requests for new MDs. They are all multidisciplinary (100 percent), and 77 percent have hospital decision makers (managing director, financial managers, etc.) as permanent members and 46 percent include an evaluator with expertise in health economics assessment. This last expertise was not associated with hospital size ($p = 0.0860$) or hospital category ($p = 0.1386$) (Table 1).

Characteristics of HB-HTA procedures

The evaluation requests for MD assessment (multiple-choice question) primarily come from physicians or surgeons (100 percent of respondents, 60 out of 60). A considerable amount come from pharmacists, accounting for 72 percent (43 out of 60) of the respondents. Other professionals, such as manufacturers themselves (13 percent, 8 out of 60) and biomedical engineers (5 percent, 3 out of 60), may also be involved. A small percentage of requests may come from various other medical and paramedical health professionals, including dentists, nurses, physiotherapists, and others (5 percent, 3 out of 60). Commission meetings are scheduled between one and four times a year in 48 percent of cases (25 out of 52 respondents), more than four times a year in 33 percent (17 out of 52 respondents) of cases, and as needed in 19 percent of cases (10 out of 52 respondents).

A financial decision threshold exists in 17 plenary commissions (33 percent) for costly, innovative MDs. The existence of this threshold makes the plenary commission's opinion conditional on external validation by a hospital manager, such as a financial manager. The decision threshold varies widely among hospitals, from €5 K to €50 K (median = €40 k). The presence of this financial decision threshold was not associated with either the size ($p = 0.1525$) or the type of hospital ($p = 0.2428$) (Table 1). One particular finding concerns the existence of specific grants for costly innovative MDs, which encourages the acquisition of innovative and costly MDs and is generally conditional on prior evaluation by a HTA unit or at least a multidisciplinary committee. These grants were found in 26 percent (16/61) of the surveyed hospitals performing HB-HTA and more frequently in UHs (grants in non-UHs = 2/38 [5 percent], grants in UHs = 15/29 [52 percent], $p = 0.017$) (Table 1).

Regarding the communication of the final decision, access to the full HTA report is given to the medical professionals who requested

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Table 1. Characteristics of HB-HTA processes according to the size and category of healthcare center

	Healthcare center size		Small *versus* large hospitals	Categories of healthcare center		University hospitals *versus* non-university hospitals
	Small hospitals < 500inpatient beds N = 15 n (%)	Large hospitals ≥ 500 inpatient beds N = 52 n (%)	*p*-value[a]	Non-university hospitals N = 38 n (%)	University hospitals N = 29 n (%)	*p*-value[a]
Existence of a structured evaluation unit	0 (0%)	16 (31%)	0.0160	4 (11%)	12 (41%)	0.0158
Presence of skilled evaluators for health economics assessment	2 (13%)	22 (42%)	0.0860	10 (26%)	14 (48%)	0.1386
Existence of a financial decision threshold	6 (40%)	11 (21%)	0.1525	7 (18%)	10 (34%)	0.2428
Notification of the final decision to the manufacturer	4 (27%)	33 (63%)	0.0474	22 (58%)	15 (52%)	0.2968
Consideration of the national assessment for HB-HTA process	5 (33%)	19 (37%)	0.2145	10 (26%)	14 (48%)	0.1208
Existence of a reevaluation process	6 (40%)	33 (63%)	0.3117	16 (42%)	23 (79%)	0.0092
Dedicated funding to innovative MDs	1 (7%)	16 (31%)	0.0846	2 (5%)	15 (52%)	0.0017

Abbreviations: HB-HTA, hospital-based health technology assessment; MD, medical device.
[a]Pearson's chi-squared test or Fisher's exact test.

Table 2. Characteristics of HB-HTA processes for the 16 surveyed hospitals with a HTA unit

	Number of HTA units surveyed N (%) Total = 16 respondents (100%)
Number of members in the unit (single possible response):	
< 5	7 (44%)
Between 5 and 10	3 (19%)
Between 11 and 15	5 (31%)
>15	1 (6%)
Professional categories of members of the HTA unit (more than one answer possible):	
Pharmacists	16 (100%)
Surgeons	13 (81%)
Doctors	14 (88%)
Health economists	8 (50%)
Engineers	6 (38%)
Nurses	4 (25%)
Epidemiologists	3 (19%)
Other categories	7 (44%)
Existence of full-time members in the HTA unit	
Yes	1 (6%)
No	15 (94%)
Duration of the unit's existence (single possible response):	
< 1 year	2 (13%)
< 5 years	4 (25%)
Between 6 and 10 years	4 (25%)
> 10 years	6 (38%)

Abbreviations: HB-HTA, hospital-based health technology assessment; MD: medical device.

the MD in 42 percent (49/59) of hospitals, to medical specialists only in 27 percent (32/59) of hospitals, and to the entire hospital staff in 30 percent (36/59) of hospitals. However, manufacturers are informed of the decision in only 61 percent (37/61) of hospitals. Manufacturers are more aware of decisions in large hospitals (notification in hospitals <500 inpatient beds = 4/15 [27 percent], notification in hospitals >500 inpatient beds = 33/52 [63 percent], $p = 0.0474$) (Table 1).

Data used for the HB-HTA report

The collection of data for the report may be performed by the medical professional who requested the MD (24 /61 hospitals, 39 percent), by the professional who evaluates the request (20/61, 33 percent), or by both (17/61, 28 percent). For 16 hospitals (26 percent), the manufacturer is required to submit a report on the therapeutic interest of its product. Sixty hospitals performing HB-HTA activities out of 61 (98 percent) reported more specifically the type of data considered for evaluation. These data include both specific clinical and economic data (59/60, 98 percent), organizational impact data (54/60, 90 percent), strategic data (41/60, 68 percent), post-marketing vigilance data (31/60, 52 percent), and nonspecific clinical data (30/60, 50 percent). Patient opinion data are only considered in 40 percent of cases (24/60). Other data can also be provided and used for evaluation, such as impact on patient attractiveness and on ethical aspects (3/60, 5 percent) (Figure 1). Even when a MD has already undergone national evaluation by the HAS and received a favorable opinion for national reimbursement, 61 percent (37 out of 61) of hospitals with HB-HTA processes still conduct their own internal evaluations at the hospital level.

After the HTA process decision, hospital commissions can also request follow-up of patients treated with the MD; a reevaluation process exists in 62 percent (38/61) of hospitals.

Collaborations and partnership for HB-HTA activities

Sixteen out of 57 (28 percent) centers (four missing answers) collaborate with other hospitals in sharing their HB-HTA results; the results are shared between hospitals that are geographically close to each other or that belong to the same territorial hospital

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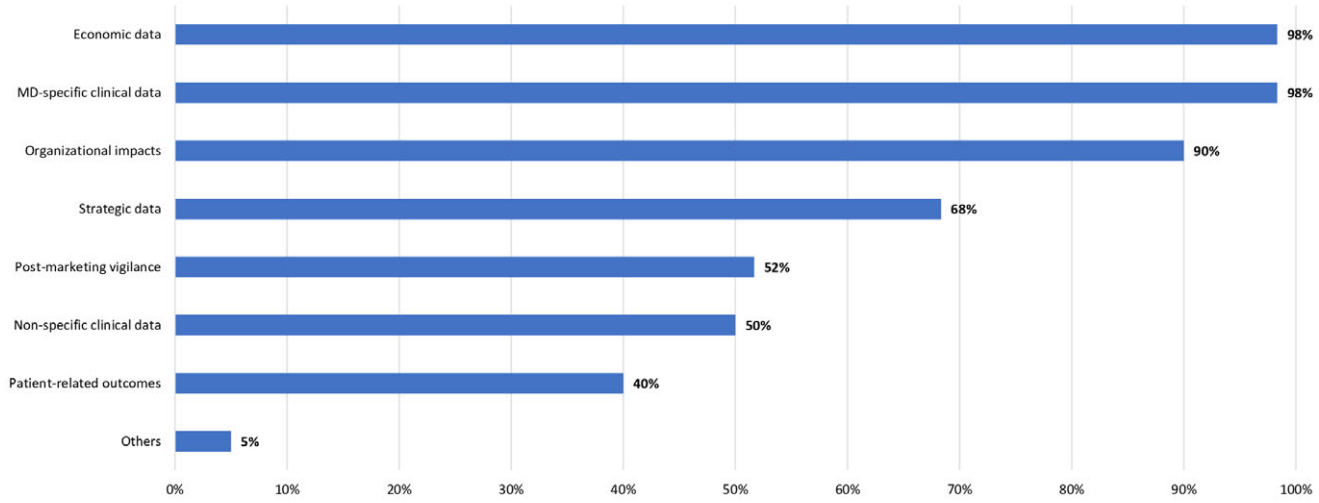

Figure 1. Type and frequency of data consideration for the assessment process.
Abbreviations: MD-specific clinical data: Medical devices specific clinical data

group. Finally, no hospital reported any collaboration with the national HTA agency, HAS (0/61, 0 percent).

Discussion

This quantitative survey highlights, for the first time to our knowledge, the major trends in HB-HTA activities regarding MDs that occur in France and provides an overview of the processes involved in the acquisition of innovative MDs for individual use.

The findings indicate that a majority of French hospitals recognize the significance of the HB-HTA process in informing decisions regarding the adoption of innovative MDs. In fact, almost all the surveyed hospitals reported having an evaluation process for assessing innovative MDs. Indeed, as described in the international literature, HB-HTA can be used a cost-containment tool in the MDs selection process (17) but also as a way to collect more reliable evidence by including local data when there is insufficient peer-reviewed evidence (18).

The study also confirms some results highlighted in a previous qualitative survey in France, including that formalized HB-HTA activities are mainly found in UHs (9). The benefits of having a highly structured HTA unit in a HB-HTA process have been previously described: The upsides are the depth, high-quality, and scientific rigor of the HTA process and the fact that the HTA unit works in partnership with all stakeholders interested in the technology and is relatively independent from clinicians and/or hospital management (5;19). The GRETAH survey suggests that HB-HTA is not however limited to UHs, with some private nonprofit hospitals having also set up structured scientific committees performing HB-HTA, including skilled evaluators for health economics assessment.

However, the HTA units found in this survey do not have all the features described in the AdHopHTA project and by Gałazka-Sobotka *et al.* (12–14). According to the 2018 AdHopHTA classification, the 16 structured units identified in our study can be categorized as "stand-alone units". This means they have a formalized and specialized level of structure but limited collaboration with national institutions, such as the French national health authority (HAS) demonstrated in our study. On the other hand, the remaining 45 processes identified in our survey, which have a much less developed level of structure, would be classified as "independent-informal groups" (13). In addition, none of the "stand-alone units" surveyed met the five criteria described by Gałazka-Sobotka *et al.* Indeed, only one unit has a full-time HTA expert dedicated to this activity (specialization) and as mentioned before, no unit is currently collaborating with centralized HTA agencies (integration). The current situation is probably related to the lack of formal recognition of HB-HTA in French regulatory texts, as well as to the absence of official funding for this activity.

To date, there has been no collaboration between the national and local levels of HTA in France. However, the existence of a formal collaboration between the local and national levels is a key point in the development of a quality HTA process according to the AdHopHTA Handbook (12). At an international level, in November 2013 the pan-Canadian Collaborative hosted a symposium about hospital and regional HTA. The conclusions were that local HTA in Canada complements HTAs conducted at the provincial and federal levels to improve the efficiency and effectiveness of health service delivery in institutions or regions faced with limited resources (20). Based on the same observation, in 2015 the AdHopHTA project was funded by the European Union to foster the application of high-quality HTA within hospitals and to develop tools for improving collaboration among national and regional HTA agencies (11). In 2017, a French expert panel also discussed and compared some topics related to HB-HTA in France and highlighted that the development of collaboration between national and local levels should be promoted to reach a better quality of assessment and higher levels of coordination (6).

Our study also provides information on the degree to which local/hospital-based HTA results are currently shared among hospitals. The GRETAH survey shows that, at present, few hospitals in France share data from their HTA assessments. The French expert panels of 2017 also outlined this point and recommended that hospitals share their HTA data analysis, to prevent other hospitals from replicating analyses on the same topic (6). The available evidence suggests that the recommendations made by an HB-HTA unit may be of interest to other hospitals, even if they are not necessarily directly usable because of local conditions in a

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given hospital. Also, the results of systematic reviews conducted by one HTA unit could be used by other units as a starting point for their own HTA reports. A "community of practice" has thus been created in the province of Quebec among a network of hospitals performing HTA. It allows the exchange of experience, knowledge, and content of assessments (5;21).

Our study also underlined certain deficiencies in the evaluation. For instance, the incorporation of patient impact data in HB-HTA assessments in France remains limited (40 percent). Although the quantitative study does not extensively investigate the underlying reasons for this gap, possible explanations exist regarding the underutilization of patient data. Some sources highlight the absence of clear methodologies and regulatory mechanisms guiding the integration of patient data in HTA processes (22). In response to this challenge, a French working group convened in 2021 to address the role of Patient-Reported Outcome & Experiences Measurements (PROMs/PREMs) in the evaluation and pricing of health technologies in France (23). This working group provided recommendations aimed at improving the collection and utilization of PROMs/PREMs data, in HTA and HB-HTA French processes.

Limitations of the survey

This study has several limitations, related to its methodology and its survey approach, as mentioned in the scientific literature (16). The first limitation concerns the categories of hospitals included and the representativeness of the French healthcare system; for-profit hospitals were not included in this research because the SF-ETS board could not identify the relevant professional or contact practicing the HB-HTA in this hospital category. In addition, participants were not required to answer every question, resulting in discrepancies in the response rate. Finally, it is important to acknowledge that certain questions in the survey may not have provided enough detail to precisely capture all the different variations or aspects of HTA processes. For example, the survey did not provide a comprehensive understanding of the level of structuration of the different pathways and of the stakeholders involved in relation to various categories of innovative MD within the HTA units. Also, the survey did not precisely specify the methodologies used for analyzing the data in the HB-HTA reports by each HTA unit. These aspects would require a complementary qualitative approach to increase the accuracy of the mapping of HB-HTA practices in France.

The study also focuses on innovative MDs for individual use and thus covers only part of the possible fields of activity for HB-HTA that could potentially include other health products and equipment. However, given that many hospitals in France have a MD commission due to French legislation, this MD selection made it easier to target the right interlocutors for our study.

Conclusion

Despite some limitations, this survey is, to our knowledge, the first to describe HB-HTA processes for MDs for individual use in France with a quantitative approach. The GRETAH survey allowed us to collect meaningful data on the current organizations in French hospitals and will therefore help to implement previous recommendations and to improve HB-HTA in general. This effort is necessary to enhancing the HB-HTA system for a potential direct consequence on the quality of MDs purchased in the context of hospital budgetary control and a likely beneficial impact on patient care. However, the results underlined the diversity of HB-HTA organizations in France; different levels of structures within HTA organizations exist that link to the category of healthcare facilities (UHs/non-UHs). Our study highlights the need for financing and recognition of HB-HTA activities at the regulatory level to allow the formalization of already existing units and the development of this activity in other hospitals within the French territory. It also promotes the need for better coordination between HTA activities performed at the local and national levels to improve the efficiency and effectiveness of the health service.

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