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1 **HOSPITAL-BASED HEALTH TECHNOLOGY ASSESSMENT OF INNOVATIVE MEDICAL**
2 **DEVICES: INSIGHTS FROM A NATIONWIDE SURVEY IN FRANCE**

3
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26 **ABSTRACT**

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

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

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

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

45
46 Key words : Medical devices, Hospital-based HTA, procurement, therapeutic innovations, France

47 **INTRODUCTION**

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

59 In France, the scientific evaluation of MDs undergoes a highly centralized process. The French national
60 health authority (Haute Autorité de Santé, HAS) was established in 2004 to manage all HTA activities
61 nationwide, and provides support on decisions concerning the eligibility for reimbursement of MDs for
62 individual use. However, the HAS manages to assess only a small proportion of the vast number of new
63 health technologies developed in the rapidly evolving field of MDs. In contrast, the procurement of MDs in
64 France is entirely decentralized and methods demonstrated in French hospitals, whether they are private or
65 public, are similar across all categories. Each hospital or hospital group assumes the responsibility for
66 acquiring healthcare technologies or drugs for their patients in accordance with the regulations outlined in
67 the French commercial code (7). As a result, individual hospitals or purchasing groups engage in direct price
68 negotiations with medical device manufacturers. Meanwhile, French hospitals are faced with ever-growing
69 demands for innovative and often costly medical devices that may not yet have been evaluated by the HAS at
70 the national level. As such, many hospitals, especially university hospitals (UHs), have been compelled to
71 develop their own HTA systems (8,9).

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

80 The European project AdopHTA, aimed at enhancing HB-HTA practices, provided recommendations for
81 good HB-HTA and proposed a description of the models observed in European countries. As a result, in
82 2018, an additional classification was suggested based on the combination of formalization and
83 specialization of HB-HTA with the level of integration at the national, regional, and provincial levels as a
84 criterion (11–13). Four distinct options have emerged from this classification: integrated specialized HTA
85 unit, stand-alone HTA unit, integrated-essential HTA, and independent group unit. In 2020, Galazka-
86 Sobotka *et al.* also proposed five criteria for defining the highest level of HB-HTA structuration. These five

87 criteria are as follows: 1) formalization with standard operating procedures; 2) specialization with full-time
88 employers and/or specific formal procedures; 3) integration between the work of the HB-HTA unit and that
89 of other healthcare stakeholders inside or outside of the hospital; 4) authority and centralization of power at a
90 high level in the unit (for example non-delegated decisions to lower organizational levels in the HB-HTA
91 unit e.g., to the person responsible for an HTA project); 5) professionalization with a high degree of
92 expertise available or training undertaken by the staff of the HB-HTA unit (14).

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

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

113 Very little is therefore known about HB-HTA processes for MDs in non-profit private and local hospitals in
114 France. In addition, some elements that could help describe the organization of HB-HTA processes more

115 specifically are currently unknown, such as the level of formalization of the HB-HTA units identified in the
116 2015 study, the type of data used for MD assessment, and the degree to which HB-HTA reports are shared
117 among hospitals and with the HAS.

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

122

123

124 **METHODS**

125 **Survey design**

126 A quantitative survey, based on those developed following good practice described in the literature (16),
127 appeared to be the most suitable solution for collecting original data on HB-HTA in French hospitals. The
128 one thus developed among professionals practicing HB-HTA in France for the procurement of innovative
129 MDs for individual use was named GRETAH (“orGanisation des Réseaux d’Evaluation des Technologies
130 de sAnté en milieu Hospitalier”). It was developed and validated by a scientific board composed of members
131 of the French-speaking society of hospital-based HTA (Société francophone pour l’évaluation des
132 technologies de santé – SF-ETS). A preliminary questionnaire was conceived and tested by two professionals
133 in order to refine its content. Open-ended questions and closed questions covering six topics were included in
134 the final questionnaire (available in supplementary file 1). The six topics were as follows: type of institution
135 (3 questions), organization (16 questions), communication (6 questions), evaluation (12 questions),
136 collaboration (3 questions), and funding (1 question). Some questions required a response, while others were
137 not mandatory. The survey was expected to take about 10 minutes to complete.

138 SF-ETS members’ second role was to define a list of healthcare centers to be contacted in which HB-HTA
139 activity for innovative MDs was plausible. As a result of this process, a first broadcast list was conceived
140 excluding centers in which innovative MDs were unlikely to be introduced, such as long-term care facilities.
141 At this point, the aim was to identify the professional likely in charge of or involved in the HB-HTA process
142 within each healthcare center. Subsequently, to widen the distribution of the survey, the 2020 yearbook of all
143 French hospital pharmacists was used to identify healthcare centers. In France, the hospital pharmacist is
144 legally responsible for the management and procurement of sterile MDs for individual use, so we assumed
145 that hospital pharmacists would be aware of the existence of a dedicated evaluation system for MDs.

146 The final survey targeted different categories of health facilities, such as local hospitals, teaching hospitals,
147 and non-profit private hospitals. Of note, in France, most cancer treatment institutions are non-profit private
148 hospitals. The survey was performed in Google Forms and an invitation was emailed to potential
149 professionals identified by the SF-ETS panelists as detailed above. The data collected in this survey were
150 kept anonymous, but respondents could leave their contact information, allowing us to contact them for
151 further details if needed. The survey was conducted between March and June 2022. The representativeness

152 of hospitals included in the study was estimated based on the number of hospital stays for acute care per year
153 per category of healthcare centers. These data were extracted from the “SCAN Santé” website of the French
154 hospital care information agency (Agence Technique de l'Information sur l'Hospitalisation, ATIH).

155

156 **Statistics**

157 Responses to each question were summarized using descriptive statistics. Continuous and categorical
158 variables were expressed as median and percentage when appropriate. Categorical variables were compared
159 using Chi-squared tests. For statistical comparisons, hospitals were categorized into two groups: UHs (for
160 university hospitals) and non-UHs (for non-profit private hospitals and local hospitals). The test for
161 differences in responses according to type and size of healthcare center was performed using Pearson's Chi-
162 squared test or Fisher's exact test when the sample sizes were too small. A standard significance level of 0.05
163 was used for the statistical tests. The questionnaire data were processed using Excel software (Microsoft
164 Office 2016). All analyses were performed through scripts developed in the R software (version 4.2.1, June
165 2022).

166

167 **RESULTS**

168 **Characteristics of the healthcare centers included in the survey**

169 We issued 131 invitations to take part in the survey, and 67 (51%) professionals responded from a diverse
170 range of 67 French hospitals: 29 UHs, 24 non-profit private hospitals, and 14 local hospitals. Of these, 52
171 (78%) were large hospitals with more than 500 inpatient beds. The 67 responders from 67 different hospitals
172 represented 42% of the healthcare supply in France in terms of bed numbers. Of all French hospitals, the
173 survey included 91% of UHs, 21% of non-profit private hospitals, and 12% of local hospitals.

174

175 **Technology assessment and decision-making processes**

176 A total of 61 centers out of the 67 (91%) responders reported the existence of a dedicated process for the
177 evaluation of innovative MDs, including at least the existence of a multidisciplinary committee involved in
178 the selection process for adopting new MDs for individual use. Of these 61 hospitals, 16 (24%) also declared
179 having an “HTA unit”, *i.e.*, a scientific committee in charge of summarizing evidence on MDs. This HTA

180 unit comprises at least five members for 44% of these hospitals and is multidisciplinary in all: 16 (100%)
181 units include a pharmacist, 14 (88%) a physician, 13 (81%) a surgeon, and 8 (50%) a health economist.
182 Among these 16 units, 11 (18%) are associated with an innovation committee and the other five are the
183 “scientific secretaries” of MD committees. In addition, the professionals in 38% of cases (six hospitals)
184 reported the existence of these units for over 10 years. However, out of the total number of units surveyed,
185 only one unit (6%, 1 out of 16) reported having dedicated full-time HTA experts within their team. All
186 reported HTA units were in larger hospitals (no unit in hospitals < 500 inpatient beds) ($p=0.0160$) and were
187 more frequent in UHs than in non-UHs ($p=0.0158$) (Table 1). Table 2 provides the descriptive variables
188 relating to the questionnaire responses of the 16 surveyed hospitals with HTA units.

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

197

198 **Characteristics of HB-HTA procedures**

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

207 A financial decision threshold exists in 17 plenary commissions (33%) for costly, innovative MDs. The
208 existence of this threshold makes the plenary commission's opinion conditional on external validation by a
209 hospital manager, such as a financial manager. The decision threshold varies widely among hospitals, from
210 €5K to €50K (median = €40k). The presence of this financial decision threshold was not associated with
211 either the size ($p=0.1525$) or the type of hospital ($p=0.2428$) (Table 1). One particular finding concerns the
212 existence of specific grants for costly innovative MDs, which encourages the acquisition of innovative and
213 costly MDs and is generally conditional on prior evaluation by a HTA unit or at least a multidisciplinary
214 committee. These grants were found in 26% (16/61) of the surveyed hospitals performing HB-HTA and
215 more frequently in UHs (grants in non-UHs = 2/38 [5%], grants in UHs = 15/29 [52%], $p=0.017$) (Table 1).
216 Regarding the communication of the final decision, access to the full HTA report is given to the medical
217 professionals who requested the MD in 42% (49/59) of hospitals, to medical specialists only in 27% (32/59)
218 of hospitals, and to the entire hospital staff in 30% (36/59) of hospitals. However, manufacturers are
219 informed of the decision in only 61% (37/61) of hospitals. Manufacturers are more aware of decisions in
220 large hospitals (notification in hospitals < 500 inpatient beds = 4/15 [27%], notification in hospitals > 500
221 inpatient beds = 33/52 [63%], $p=0.0474$) (Table 1).

222

223 **Data used for the HB-HTA report**

224 The collection of data for the report may be performed by the medical professional who requested the MD
225 (24 /61 hospitals, 39%), by the professional who evaluates the request (20/61, 33%), or by both (17/61,
226 28%). For 16 hospitals (26%), the manufacturer is required to submit a report on the therapeutic interest of
227 its product. Sixty hospitals performing HB-HTA activities out of 61 (98%) reported more specifically the
228 type of data considered for evaluation. These data include both specific clinical and economic data (59/60,
229 98%), organizational impact data (54/60, 90%), strategic data (41/60, 68%), post-marketing vigilance data
230 (31/60, 52%), and non-specific clinical data (30/60, 50%). Patient opinion data is only considered in 40% of
231 cases (24/60). Other data can also be provided and used for evaluation, such as impact on patient
232 attractiveness and on ethical aspects (3/60, 5%) (Figure 1). Even when a MD has already undergone national
233 evaluation by the HAS and received a favorable opinion for national reimbursement, 61% (37 out of 61) of
234 hospitals with HB-HTA processes still conduct their own internal evaluations at the hospital level.

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

237

238 **Collaborations and partnership for HB-HTA activities**

239 Sixteen out of 57 (28%) centers (four missing answers) collaborate with other hospitals in sharing their HB-
240 HTA results; the results are shared between hospitals that are geographically close to each other or that
241 belong to the same territorial hospital group. Finally, no hospital reported any collaboration with the national
242 HTA agency, HAS (0/61, 0%).

243

244 **DISCUSSION**

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

248 The findings indicate that a majority of French hospitals recognize the significance of the HB-HTA process
249 in informing decisions regarding the adoption of innovative MDs. In fact, almost all the surveyed hospitals
250 reported having an evaluation process for assessing innovative MDs. Indeed, as described in the international
251 literature, HB-HTA can be used a cost-containment tool in the MDs selection process (17) but also as a way
252 to collect more reliable evidence by including local data when there is insufficient peer-reviewed evidence
253 (18).

254

255 The study also confirms some results highlighted in a previous qualitative survey in France, including that
256 formalized HB-HTA activities are mainly found in UHs (9). The benefits of having a highly structured HTA
257 unit in a HB-HTA process have been previously described: the upsides are the depth, high quality, and
258 scientific rigor of the HTA process and the fact that the HTA unit works in partnership with all stakeholders
259 interested in the technology and is relatively independent from clinicians and/or hospital management (5,19).

260 The GRETAH survey suggests that HB-HTA is not however limited to UHs, with some private non-profit
261 hospitals having also set up structured scientific committees performing HB-HTA, including skilled
262 evaluators for health economics assessment.

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

274

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

287

288 Our study also provides information on the degree to which local/hospital-based HTA results are currently
289 shared among hospitals. The GRETAH survey shows that, at present, few hospitals in France share data from
290 their HTA assessments. The French expert panels of 2017 also outlined this point and recommended that

291 hospitals share their HTA data analysis, to prevent other hospitals from replicating analyses on the same
292 topic (6). The available evidence suggests that the recommendations made by an HB-HTA unit may be of
293 interest to other hospitals, even if they are not necessarily directly usable because of local conditions in a
294 given hospital. Also, the results of systematic reviews conducted by one HTA unit could be used by other
295 units as a starting point for their own HTA reports. A “community of practice” has thus been created in the
296 province of Quebec among a network of hospitals performing HTA. It allows the exchange of experience,
297 knowledge, and content of assessments (5,21).

298

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

308

309 **Limitations of the survey**

310 This study has several limitations, related to its methodology and its survey approach, as mentioned in the
311 scientific literature (16). The first limitation concerns the categories of hospitals included and the
312 representativeness of the French healthcare system; for-profit hospitals were not included in this research
313 because the SF-ETS board could not identify the relevant professional or contact practicing the HB-HTA in
314 this hospital category. In addition, participants were not required to answer every question, resulting in
315 discrepancies in the response rate. Finally, it is important to acknowledge that certain questions in the survey
316 may not have provided enough detail to precisely capture all the different variations or aspects of HTA
317 processes. For example, the survey did not provide a comprehensive understanding of the level of
318 structuration of the different pathways and of the stakeholders involved in relation to various categories of

319 innovative MD within the HTA units. Also, the survey did not precisely specify the methodologies used for
320 analyzing the data in the HB-HTA reports by each HTA unit. These aspects would require a complementary
321 qualitative approach to increase the accuracy of the mapping of HB-HTA practices in France.
322 The study also focuses on innovative MDs for individual use and thus covers only part of the possible fields
323 of activity for HB-HTA that could potentially include other health products and equipment. However, given
324 that many hospitals in France have a MD commission due to French legislation, this MD selection made it
325 easier to target the right interlocutors for our study.

326

327 **CONCLUSION**

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

340

341 **List of tables and figures**

- 342 - Figure 1: Type of data considered for the assessment process
- 343 - Table 1: Characteristics of HB-HTA processes according to the size of healthcare center
- 344 - Table 1: Characteristics of HB-HTA processes according to the type of healthcare center

345

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350

351

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