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RESEARCH ARTICLE

The influence of hospital-based HTA on technology acquisition decision

[L'influence des unités d'évaluation des technologies en milieu hospitalier sur les décisions d'acquisition]

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Abstract: This study aimed to describe the configuration and operation mode of a Hospital-Based Health Technology Assessment (HB-HTA) unit to enhance understanding of its effects on hospital resources and, to a lesser extent, to note the weaknesses and strengths of such practice. The study used a tracer case, which focused on a specific HTA project in connection with medical equipment acquisition. From June to August 2015, we conducted a single case study with embedded units of analysis at the HTA Unit of a large university hospital centre in the province of Quebec (Canada). We used semi-structured interviews with key informants representing three groups: 1) members of the HTA unit; 2) decision-makers; and 3) hospital stakeholders with an interest in the tracer case. We interviewed thirteen people involved in various stages of the tracer case. Overall, respondents were confident about HTA unit practices that use a standardized, rigorous and evidence-based approach to carry out HTA projects. In addition, the evaluation process was perceived as comprehensive given that it included the participation of both stakeholders and decision-makers. This was seen as a way to ensure implementation of the recommendations and follow-up. The configuration of this HTA unit has a decisive influence on decision-making. It also contributes to the implementation and follow-up of recommendations through the promotion of a culture of evaluation in the hospital. A better understanding of the HTA unit impact on hospital resources would require knowledge of the various technology regulation pathways.

Keywords: Hospital-Based Health Technology Assessment, HTA unit configuration, decision-making process, perceptions**.**

Résumé : Cette étude vise à décrire la configuration et le fonctionnement d'une unité d'évaluation des technologies de santé (ÉTS) en milieu hospitalier afin d'éclairer ses effets sur l'organisation hospitalière et, dans une moindre mesure, de déceler les forces et les faiblesses d'une telle pratique. Une étude de cas unique avec différents niveaux d'analyse imbriqués a été menée sur la période de juin à août 2015 dans une unité d'ÉTS d'un Centre Hospitalier Universitaire (CHU) de la province de Québec (Canada). Cette dernière, à travers l'utilisation d'un cas traceur, s'intéresse à la gestion d'un projet d'ÉTS questionnant l'introduction d'une technologie médicale. Cette analyse repose sur la conduite d'entretiens semi-dirigés auprès de : 1) membres de l'unité d'ÉTS ; 2) décisionnaires ; 3) personnes ayant un intérêt direct vis-à-vis du cas traceur. Treize personnes impliquées à différentes étapes dans le cas traceur ont été interrogées. Dans l'ensemble, les méthodes de travail de l'unité d'ÉTS sont reconnues par les participants de l'étude. Il ressort également que l'intégration des décideurs et des parties prenantes dans la conduite des projets d'évaluation favoriserait la mise en application et le suivi des recommandations. De par sa configuration, l'unité d'ÉTS exerce une influence décisive sur les décisions concernant la gestion des ressources hospitalières. Elle joue également un rôle dans la mise en place et le suivi des recommandations par la promotion d'une culture d'évaluation en milieu hospitalier. Cependant, la connaissance des différents moyens de régulation des technologies de santé présents à l'hôpital permettrait une meilleure compréhension de l'impact de l'unité d'ÉTS sur les ressources hospitalières.

Mots clés : Évaluation des technologies de santé en milieu hospitalier, configuration d'une unité d'ÉTS, processus de prise de décision, perceptions.

Introduction

The Health Technology Assessment international (HTAi) Interest Group (IG) on hospital-based health technology assessment (HB-HTA) identified the HTA unit as one of the possible approaches to HB-HTA. According to the results of a survey conducted in 2008 by this IG, an HTA unit is the most widely used entity among respondent organizations [1]. Also called integrated-specialised HB-HTA unit, it is considered, from an organizational perspective, as the most comprehensive HB-HTA model to date [2]. This model, which is characterized by a multidisciplinary team fully dedicated to HTA activities, is commonly spread among teaching hospitals where most emerging health technologies are implemented before their global introduction and deployment [1,3].

Objective

Our study, conducted in the context of an HB-HTA unit in the province of Quebec (Canada), aims to explore the links between the configuration of an HTA unit and its effects on hospital resources by using a specific HTA project regarding medical equipment acquisition as a tracer case. Many studies currently question the impact of HTA recommendations [4-11] without necessarily considering the way HTA is conducted and the context in which it is done [12-13]. Analysing the configuration of this HB-HTA unit through a tracer case should shed light on the following questions: How have recommendations been derived from the HTA process? What is the role of a HTA unit regarding recommendation implementation? What are the strengths and weaknesses of this HTA unit?

Context

In Canada, HTAs can be undertaken at different levels. The Canadian Agency for Drugs and Technologies in Health (CADTH) is in charge of producing HTAs of national interest [14]. At a provincial level, HTAs are conducted by agencies in the provinces of Alberta, Ontario and Quebec [15]. However, Quebec is the only province where hospital HTAs are mandated by law [6].

The university hospital centre where this study was conducted set up an HTA unit in 2006 in order to provide health managers and clinicians with the best available evidence to support decision-making and to foster the emergence of a culture of evaluation within the hospital. The HTA unit includes two administrators and six full-time research officers entirely dedicated to evaluation activities. Moreover, to ensure rigor and transparency, the unit relies on two committees, the orientation committee and the scientific council, having decisional authority within the HTA process. The orientation committee is in charge of proposing annual orientations on evaluation projects and prioritizing HTA activities. Concerning the scientific council, its role is to validate HTA products and recommendations. Finally, the HTA unit relies on stakeholders (organizational/medical staff), who initiate and/or have interests in a specific HTA project. They are a part of the HTA process through their involvement in a working group.

Methods

We adopted a single case study method with embedded levels of analysis, based on an exploratory and descriptive approach. We conducted semi-structured interviews with key informants, completed by documents and observations related to the tracer case, and an analysis of the scientific literature. Documents included HTA unit methodological guidelines, HTA unit PowerPoint presentations regarding the tracer case, and email correspondence between the HTA unit and stakeholders during the scoping phase. Observations were also made during a meeting where members of the HTA unit presented the HTA results to stakeholders. Data triangulation enabled data convergence [16]. The tracer case consisted of an ongoing evaluation project questioning the introduction of a specific technology within the hospital.

Due to time constraints, this field study took place during a three-month period.

Thus it is important to state that the study does not cover the full HTA process, and consequently some issues regarding the tracer case could only be addressed in terms of assumptions. However, the consultation of the final HTA report published in January 2016 provided an opportunity to confirm these assumptions retrospectively.

Study setting and participants

This study was conducted in a large university hospital centre in Quebec from June to August 2015. Eligible participants were those involved at different levels in the tracer case. Interviews were first conducted with key informants from the HTA unit involved in the project defined as the tracer case. Then, using the snowball method, we contacted stakeholders from other departments and management units whose names were provided by previous key informants. As suggested by Guest et al. [17], we initially planned twelve interviews, with the possibility of adjusting this number according to data saturation [18].

Interviews and analyses

We developed a semi-structured interview guide that covered two main topics: 1) configuration of the HTA unit and its ways of functioning; and 2) interactions between members of the HTA unit and stakeholders involved in the tracer case. After participants' consent was obtained, interviews were digitally recorded, transcribed, and codified using the NVivo[19] software. We used an inductive approach [20], highlighting key messages and classifying them by emerging codes. The interviewer was external to the hospital organization but knowledgeable of HTA and hospital technologies. The interviewer was also in charge of developing the interview guide and responsible for transcribing, codifying and analysing the collected data.

Ethical considerations

The study received approval from the research ethics committee of the institution where the project was conducted (FWA00000329 and FWA00004683). For confidentiality purposes, any technical elements related to the tracer case, which could reveal the identification of participants, were suppressed.

Results

Out of a total of 14 individuals who were contacted, 13 agreed to participate. One person declined due to unavailability. Interviews were conducted during the month of July 2015. Informants represented three stakeholder groups: the HTA unit group, the decision-maker group, and a stakeholder group with specific interests in the tracer case.

Configuration of the HB-HTA unit

The analysis of the HB-HTA unit configuration, including the composition of the groups involved in the tracer case, shows the interactions between the different people involved in the HTA process and their associated effects.

The HB-HTA unit group was made up of the two research officers in charge of conducting the project defined as the tracer case, and the two HTA unit managers. Research officers who were part of this HTA unit come from various disciplines (sociology, biology, pharmacy) but share a background in research related to the medical sphere. Regarding managerial staff, one staff member mainly carries out administrative tasks, but is also involved, to a lesser extent, in scientific activities. The other manager holds the position of scientific manager and has a medical background as a physician, which ensures a better understanding of the clinical aspects of evaluation projects. The two managers participate in the scientific council and in orientation committee meetings, but they have no prescriptive authority.

The decision-maker group was composed of two members of the orientation committee and three members of the scientific council. They were seen as the most appropriate persons to complete interviews for the study case. As per our request, they were identified by managers from the HTA unit. These two entities are composed of approximately twelve mem-

bers who serve as representatives or directors from various departments within the hospital.

The stakeholders group comprised four people directly concerned by a specific HTA project, represented here by the tracer case. This group was composed of three members of the working group (out of four): one manager and two clinicians. Another clinician was added to the stakeholder group. He was the instigator of the evaluation project that constitutes the tracer case.

Finally, it is worth mentioning that in the interest of neutrality, the working group does not interact with the orientation committee or the scientific council to avoid biases in the decision-making process.

Organization of work

The purpose of any HTA project is to reduce uncertainty for decision-makers to ensure their ability to make the most appropriate decisions in relation to a given context:

"HTA has to be seen as a tool to support the decision-making process for managers and clinicians in bridging research and decision-making in the hospital […]. In fact, it's about reducing the degree of uncertainty for decision-makers by bringing in knowledge from research and outside experience." (Manager, HTA unit group)

For this to happen, the unit has developed standardized practices to avoid biases as much as possible in the realization of assessments. As a result, every evaluation project follows the same process presented in Table 1.

Exploring HB-HTA through the tracer case

The tracer case refers to a HTA questioning the introduction of new diagnostic equipment intended to measure specific patient parameters within a specialized medical unit to improve prognosis quality for a particular population. This decision-making question relies on three evaluative questions: What is the diagnostic performance of the existing technologies? What is the clinical performance? What are the associated-risks for the patient?

1. Initiation phase

1.1. Call for projects

Following the launch of the annual call for HTA projects in the hospital, the manager of the concerned department mobilized his staff to present projects to the HTA unit. Then the Head of one of the medical units met with his working team to explore their needs:

"*What I'm expressing here is the typical opinion of people from my unit […]. I'm not neutral but I try to rally to the opinion of the majority and to me this majority wants to go forward with the evaluation to see if there are benefits."* (Project instigator, stakeholder group)

1.2. Project analysis and selection by the orientation committee

Due to the multiplicity of projects presented and the length of the selection process, the orientation committee members interviewed were unable to recall which criteria were determinant in the selection of the tracer case. However, they reported that they bring both a comprehensive and a strategic point of view on hospital resources and that they question clinical relevance. They can also bring their opinion and assert their interests from the hospital board perspective to which they belong.

1.3. Setting up of HTA projects

After the selection of the tracer case, the HTA unit managers started setting up the HTA project by designating two officers to carry out the evaluation:

"*HTA projects are conducted by two independent evaluators. Two HTA unit officers perform each step individually, followed by a pooling of data leading to consensus. It's a way to ensure that we don't introduce any bias; that's part of our standards.*" (Research officer, HTA unit group)

With respect to the constitution of the working group for this tracer case, the project instigator was asked to identify people interested in taking part in the HTA

Table 1: Approach for conducting HTA projects at the HB-HTA Unit

1. Initiation phase	2. Evaluation process	3. Dissemination
1.1. Call for projects 1.1.1. Launch by the HTA unit to management committees in the hospital (once a year to plan projects for the following year). 1.1.2. Identification of needs by stakeholders (managers, clinicians, health care providers). 1.1.3. Submission of evaluation questions from stakeholders to the HTA unit management body. 1.1.4. Project pre-study by a HTA unit officer. 1.2. Project analysis and selection by the orientation committee Presence of the HTA unit management body during the selection process. 1.3. Setting up of HTA projects 1.3.1. Selection of two HTA unit officers to carry out the evaluation process by the HTA unit management body. 1.3.2. Constitution of the stakeholders working group. In general, HTA project inquirers are asked by the HTA unit management body to identify the members of the working group.	The HTA unit working team can rely on the scientific manager's advice, clinical point of view, and attendance at meetings with stakeholders during the whole evaluation process. Status reports are sent to decision-makers on a regular basis. 2.1 Guidance 2.1.1. Preliminary documentary search protocol development. 2.1.2. Scoping meeting between HTA unit working team and stakeholders working group: - Project clarification; - Goal setting and timelines; - Protocol validation. 2.2 Results 2.2.1. Documentary research (document identification, document selection, eligibility evaluation, quality evaluation, data extraction). 2.2.2. Knowledge synthesis. 2.2.3. Preliminary results: Presentation by the HTA unit working team to the stakeholders working group. This meeting is followed by an open discussion and must ultimately lead to a consensus. 2.2.4. Final report (HTA product) drafting by the HTA unit: This report leads to recommendations. 2.2.5. HTA product review by HTA unit management body. 2.2.6. HTA product presentation by the HTA unit working team to the working group. This meeting is also followed by an open discussion and must lead to a consensus. 2.3 HTA product approval 2.3.1. HTA report submission to the scientific council by the HTA unit management body: - Individual review of the HTA report by the scientific council; - Scientific council meeting to discuss the report and to offer comments. Presence of the HTA unit management body. 2.3.2. HTA report comments review by the HTA unit working team. 2.3.3. Scientific council final approval.	HTA product submission at first to inquirers and the hospital management board. Active dissemination: Results presentation by the HTA unit working team to other interested groups. To a larger extent: Passive dissemination: Release of the HTA product online on the HTA unit website.

project. The working group was made up of three clinicians, selected for their clinical expertise, and the department manager, previously involved in the call for projects, to keep an eye on projects related to the department. One of the selected clinicians was particularly interested in the introduction of this kind of diagnostic equipment within the unit due to previous experiences from a fellowship in Europe where such technology was used to measure specific patient parameters.

2. Evaluation process

2.1 Guidance

At the earliest stage of the project, the evaluation questions appeared to be very broad and vague, leading to difficulties for the HTA unit in defining the scope of the project. To have an overview of all the potential options, the initial intent was to compare the performance of various diagnostic devices, which corresponded to different techniques. Thus it became clear that there was more than one evaluation question regarding diagnostic performance, and the HTA unit did not have sufficient resources to address all of them. In addition, when exploring the scientific literature, research officers realized that devices were too different to be compared, and that data on the subject were scarce and associated with poor quality. Those difficulties led to an important realignment of the HTA scope while conducting the evaluation, which is uncommon situation for this HTA unit. After consultation, the working group agreed with the HTA unit's proposal to focus the project on a single device, identified as the most relevant. As a matter of fact, it is the device that one of the clinicians from the working group used during his fellowship.

"*The topic was made complex by its technological aspects, the differences in the devices and the techniques to assess them, the weakness of the standard, and also the comparison of the clinical standard with studies that were not particularly encouraging. The evaluation approach evolved over time in relation to the original request.*" (Manager, HTA unit group)

In this project, the scoping stage was longer than planned but the evaluation process was not called into question by the interviewees. A member of the HTA unit also appreciated the reactivity of the working group and its openness to dialogue. According to pre-established HTA unit standards, research officers were then able to conduct scientific documentary research and make the synthesis of their findings.

2.2 Results

Preliminary evidence-based results were presented to the working group by the HTA unit during a meeting. Based on our observations, the presence of the scientific manager of the HTA unit was valuable in bringing a clinical point of view to the results presented by the research agents. Moreover, the working group was dynamic and everyone took part in the discussion. During interviews, a member of the scientific council highlighted that the presence of the working group was a real added value and enhanced the HTA product by bringing a practical point of view to the scientific evidence provided by the HTA unit. However, respondents also noted some weaknesses in the current practice. Although the HTA process has been shown to rely on the use of high quality scientific data, the use of economic data seems to be given less importance:

"*Cost analysis is not systematic, if the HTA unit concludes there is no efficacy, no added value [refers to the assessed technology or medical practice], it is not worth doing it […]. Basic cost analysis can be done but at the moment, we cannot assess the economic aspect, these skills have to be developed within the team or be found through collaborators.*" (Research officer, HTA unit group)

One of the scientific council members also recognised this absence of economic data:

"The objective is rather scientific than economic. Although the economic aspect

may not always be highlighted when concluding an HTA, the subject is not eluded during decision makers' meeting". (Scientific council member, decision-maker group)

The case study ended at this point of the HTA project (Table 1: part 2.2.3). According to the HTA unit approach, an additional meeting between the HTA unit and the working group should be planned to present the final report and discuss the recommendations before sending the HTA report to the scientific council for approval.

According to the preliminary results of the tracer case, it is not possible to form a judgment on the diagnostic performance of the studied equipment at this stage, given the questionable quality of the evidence base. Consequently, its potential introduction within the hospital remains uncertain. The final HTA report, which was released in January 2016, confirms the preliminary results going toward the non-introduction of the technology in routine clinical practice within the hospital. However, the HTA unit has encouraged clinicians interested in the assessed medical device to set up a field project to demonstrate technology safety, efficacy and organizational benefits. The field project suggests a potential close collaboration with other university hospital centres in Quebec having similar interests regarding the acquisition of the assessed technology.

2.3 HTA product approval

The scientific council is in charge to give an opinion on the HTA final report. As the tracer case was not submitted to the scientific council at the time of the conduct of the case study, the following comments from both HTA unit decisional committees members relate to difficulties with respect to HTA approval in general. A member of the scientific council reported that it is sometimes difficult to decide on report approval because evaluative questions push the limits of current knowledge:

"*Most HTA projects, which are requested by clinicians, experts in their fields, go beyond the limits of science and current studies. It's sometimes difficult to interpret, deduce and draw conclusions on a small number of studies or studies with limited transferability*." (Scientific council member, decision-maker group)

Also, a member of the orientation committee confessed to sometimes being skeptical when recommendations are approved without a high level of data evidence:

"*The difficulty is bringing recommendations to clinicians that are based on limited data with a weak level of evidence. Generally, these recommendations are tied to cost reduction without necessarily being relevant […]. People are skeptical. As a consequence, they will not use the HTA product in their practice*." (Orientation committee member, decision-maker group)

This opinion should be taken into consideration because members of the orientation committee represent various boards within the hospital and have a role to play in the implementation and follow-up of recommendations.

3. Dissemination

Finally, once approved, the HTA product should follow the dissemination process described in Table 1. It is important to note that impact assessment is not part of the mandate of this HTA unit, and no specific action is currently planned to assess how the recommendations regarding this HTA project are being implemented, or their impact on clinical practices and hospital resources. Impact assessment might be implemented within this hospital in the coming years.

Discussion

Ultimately, the critical role of a HB-HTA unit is to provide hospital decision-makers with the best options. Therefore, a comprehensive understanding of the HTA process is necessary to assess the consistency of the issued recommendations. Finally, although the HTA unit does not take part in the decision-making process, it has a role to

play regarding the implementation and follow-up of recommendations.

HTA process appraisal

As the hospital decision-making process should rely on recommendations based on the best available scientific evidence [21], the HTA approach requires a high level of understanding when reviewing scientific literature. Consequently, this justifies the presence of dedicated full-time research officers with a high degree of training in research in different medical related fields. Besides, HTAs can be highly dependent on the availability and nature of the evidence [15]. The research officers encountered evidence-related problems when managing the tracer case, leading to a high degree of uncertainty regarding the results. Collecting data in the field, as done in some HTA units in the province of Quebec, is a way to fill the gaps in the literature [15]. Moreover, it is also important to mention the lack of expertise in health economics within this HTA unit. Although economic analysis has been recognized as an integral part of the HTA process [22], this component remains absent, or at least partial, within the studied HTA unit. A HB-HTA unit, such as the one studied, does not usually have sufficient resources to carry out field studies and economic evaluations. According to one of the HTA unit managers, this could be developed in the future. In addition, the local context should also be considered when conducting a HTA [4]. Stakeholders and HTA unit managers have a role to play regarding this matter. Involving stakeholders adds a practical dimension to the HB-HTA process. Furthermore, the medical background of one of the HTA unit managers brings a clinical perspective to the conducted HTA giving more consistency to the recommendations.

HTA unit role in the implementation of recommendations

Translating recommendations into clinical practices is one of the major challenges in HTA activities [23]. As a matter of fact, the configuration of this HTA unit can be considered as a facilitator by integrating both stakeholders and decision-makers in the HTA process. On the one hand, it implies a willingness on the part of stakeholders to change their practices if necessary. On the other hand, the integration of evaluation at the high decision-making level ensures implementation of recommendations [3]. Moreover, the multidisciplinarity of the decision-makers involved makes possible for various interests within hospital to converge. Besides, this HTA unit also plays a pivotal role by providing a neutral link between stakeholders and decision-makers. Neutral position associated with a transparent HTA process has to be seen as a way to set up good practices and to foster human relationships.

HTA evaluation

It is not the mandate of HTA units to assess the impact of the projects they carry out. HTA self-evaluation could affect the impartiality of the results and raise questions regarding the role of the HTA unit in such evaluation. Besides, it is important to note that impact assessment of HTAs can be difficult to implement [4]. Benefits from HTA products could be noticed only after several years [24]. Given that this HTA unit has been established since 2006, some HTA products could be subject to impact evaluation. However, with regard to the tracer case this kind of assessment seems to be still premature. Furthermore, due to the variety of players involved, influential factors, and potential impacts, it is sometimes unclear whether the effects observed are really due to HTA reports [24]. A comprehensive understanding of all pathways through which technology can enter the hospital is also necessary.

Limitations

We used a single case study in order to gain in-depth knowledge of this unique situation [16]. Single case use may have some limitations. Firstly, given the small sample of participants and the fact that the study involved only one assessment project, it is delicate to generalize the results to other HTA projects conducted by this HTA unit.

For example, a good cooperation between the HTA unit and the working group was observed, leading to high expectations regarding the implementation of the recommendation, but it is unlikely that this is always the case. It might be of interest to extend this exercise to other evaluations conducted by the studied HTA unit. Secondly, the last interviews were not entirely redundant given the interviews conducted previously, leading to partial data saturation [18]. For example, the lack of details from orientation committee members regarding the selection of the tracer case appears as a limitation. However, standardized processes suggest that every assessment follows the same path. Moreover, interviews provided the study with a large diversity of points of view thanks to all the key categories of players represented. Thirdly, as the final HTA report from the tracer case has been released some time after the completion of the study, some findings presented were provisional rather than demonstrated facts. A follow-up study would be necessary to confirm or refute the results on the long run. Still, the recommendations presented in the final HTA report are convergent with the perceptions of interviewees.

Finally, the use of data triangulation made possible to bring together information collected from different sources and increased the robustness of our results [16]. In addition, an individual from outside the hospital looked after data collection, which brought more neutrality to the study and prevented biases from emerging.

Conclusion

This case study highlights how the configuration and processes of a HB-HTA unit can impact hospital resources. On the one hand, this HTA unit configuration could be seen as a way to have decisive influence on decision-making without having prescriptive authority. On the other hand, it would also contribute to the implementation and follow-up of recommendations. In this case study, the HTA unit is one way to regulate technology introduction in the hospital.

However, a better understanding of the HTA unit's influence on hospital resources would require accurate knowledge of all regulation technology pathways within the hospital and the integration of impact evaluation in the HTA project management process.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

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