

HB-HTA focus in a tertiary hospitals' network in Northern Italy: a three-years experience analysis

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Abstract. *Background and aim:* Health Technology Assessment (HTA) is a multidisciplinary process to determine the value of health technology in health sector articulated through the of Hospital Based HTA (HB-HTA). This study aims to investigate the diffusion of the HTA culture in hospitals (HB-HTA) and to analyze the thinking of healthcare professionals regarding the HTA. *Methods:* The study was performed through the administration of two questionnaires respectively to hospitals' HealthCare Workers (HCW) to assess the HTA's knowledge and to hospitals' HCW that have submitted a new technologies or devices' request to Direction between 2017 and 2019. *Results:* Considering 988 questionnaires send to HCW only 416 (42.1%) answer were collected, with a higher attention towards HTA made by physicians (148; 35,6%). It's fundamental to observe that despite a mean response rate, 286 HCW (68.7%) shows interest expressed as 4 or 5 scoring on a Likert Scale for the HB-HTA concept as an instrument to help the hospital management. Considering 23 questionnaires to HCW that have made new technologies requests 15 (71.4%) of them show a higher attention and knowledge to HTA voiced as 4 or 5 scoring on a Likert Scale. *Conclusions:* In conclusion, this study shows a high interest in HTA among the HCW and underlines the adoption of HB-HTA method will represent a strategic lever to support clinical and organizational decision-making processes in the current welfare landscape and for the future developments. At the same time the HCW directly involved into technologies evaluation will be able to steer the HTA culture in hospital setting. (www.actabiomedica.it)

Key words: Health Technology Assessment, Hospital-Based Health Technology Assessment, Health Technology Assessment Knowledge, Health Technology Assessment Evaluation

Introduction

Hospital facilities are ever-increasing springboards for innovative health technologies, by employing a large amount of resources for their acquisition and deployment.

The Organisation for Economic Co-operation and Development (OECD) in a 2017 report highlights how the diffusion of technologies has concretely contributed to the improvement of human health, however representing a considerable item of expenditure (1).

Therefore, a pragmatic tool is needed to guide innovative processes within healthcare companies. This tool must simultaneously ensure the provision of effective, high-quality and appropriate services and prioritize interventions in terms of sustainability of the entire system (2).

The growing focus on HB-HTA processes is due to the increased awareness of the need to analyze the value of healthcare technologies weighted according to the specific organizational context in which they are implemented (MESO level the MACRO level refers to activities characterized by a more planning-oriented

imprint and with a broader focus, at national or regional level). The phenomenon of diffusion of the HTA culture within hospital companies can be analyzed as an instrument of response to several phenomena on the part of company management (3). The first consists of the exponentially growing 'pressure' from the health-care system on healthcare facilities to increase their levels of effectiveness and efficiency aimed at systemic improvement at an overall (regional and national) level. This has led to a need for de-centralization of decision-making processes, thus ensuring greater autonomy and accountability in their governance, as opposed to the adoption of binding budget obligations. A second phenomenon concerns the gradual affirmation of the weight of contextual elements, from which arise opportunities to be grasped by companies that may in turn translate into advantages also of a competitive nature linked to the value of the technologies introduced, these contextual factors change about the specific skills and resources linked to the organizational-company dimension. Given this, it is appropriate that elements and evidence contributing to the decision-making process be examined within the organizational context. A final factor can be traced back to the popularization of the doctrine of Evidence-Based Medicine (EBM), which has led to the need to readily transfer evidence into clinical practice.

Clinical governance finds a worthy ally in the hospital-based health technology assessment (HB-HTA) approach both for the introduction of technological innovations and for evaluating the disposal of obsolete technologies, which do not comply with the standards of value and quality aimed at protecting public health. HB-HTA is a tool for performing HTA activities tailored to the hospital context for managerial decisions. It includes the processes and methods used to produce HTA reports "in" and "for" hospitals.

Health technology assessment (HTA) is a multidisciplinary process that uses explicit methods to determine the value of health technology at different points in its lifecycle. The purpose is to inform decision-making to promote an equitable, efficient, and high-quality health system (4).

Consequently, HTA can be defined as a "clinical practice-oriented" scientific research activity or evaluation process to support managerial decisions and

their implementation regarding the adoption and use of health technologies (5). The evaluation process is based on the detection of indirect and direct consequences in terms of the dimensions of safety, clinical efficacy (efficacy and effectiveness), costs and economic effects, and ethical, social, organizational, cultural, and legal implications linked to the technology evaluated at comparison with possible alternatives.

It consists of a multidimensional decision analysis structured in several consecutive phases.

The initial phase is the priority setting. In this phase, the technologies or clinical needs that require an evaluation are identified.

Once the report has been commissioned, the assessment phase begins. In this step, technologies are evaluated on a technical, clinical and economic level.

It is necessary to define the policy question, which consists in clearly identifying the question which decision-makers must answer.

The HTA protocol, on the other hand, establishes which problems will be managed by the new technology, its time horizon for adoption, and the existence of available data on it.

It is important to recognize the relationship between new technologies and existing ones, to evaluate their real need and strategic importance.

During the HTA process it is necessary to study the background information, that are the information available on the technology considered.

At the same time, the research question will be defined. This question is preliminarily evaluated by searching the scientific literature.

In the central phase of the study, the dimensions are evaluated. For this evaluation it is mainly used the PICO (Problem, Patient or Population; Intervention; Comparison/Control; Outcome(s)) or PICOT (Timeframe/Technology) methodology (6).

This type of research conduct is very widespread and used as it is aimed at identifying the patient, the type of intervention that has been taken into consideration, the existence of any alternatives, the type of data and the published outcome.

Once the evaluation process is complete, the discussion of the data and the drafting of the report containing the conclusions and the recommendations reached at the end of the study begins.

The latter consists of advice and suggestions that emerge from the analysis of the results and which can subsequently be translated into operational strategies, organizational or clinical guidelines, and health directives.

The process is moving towards its conclusion with the dissemination and publication of the results. Their implementation is then necessary through the transfer of scientific results in an operational and practical key (7).

The creation of a structure within hospitals assigned to HTA activities can give rise to organizational contexts inclined to translate empirical evidence into clinical practice and decision-making processes.

HB-HTA plays a pivotal position in guaranteeing Health Technology Management (HTM) through the efficient and effective management of health technologies during their entire life cycle within the hospital.

The purpose of the HB-HTA is therefore to adopt the HTA method by contextualizing and arranging the evaluation processes at the level of the single organization in which decisions are made regarding the adoption of health technologies (8). This translates into the structuring of tailor-made evaluation processes and methods aimed at producing hospital reports.

The aim of this study is to carry out a methodological research structured in quantitative and qualitative analysis through:

- the investigation of the current state of the art and of the diffusion of the HTA culture in hospitals (HB-HTA);
- the analysis of the thinking of healthcare professionals regarding the usefulness of HTA as a tool to support clinical governance and technological innovation in healthcare.

The research question can be structured according to the following three premises:

- the degree of diffusion of the HB-HTA culture in healthcare facilities;
- the ability to arouse interest in professionals and their perception of the strategic role that HB-HTA can play in technological innovation;
- the degree of productivity and effectiveness of the processes carried out by the ASST Rhodense Technology Evaluation Commission.

These objectives will be obtained through the administration of two questionnaires. The purpose of the first one is to investigate the current state of the art regarding the dissemination of the HTA discipline at the hospital level. This survey aims to investigate whether there is knowledge and culture in healthcare facilities of the HTA tool used to evaluate healthcare technologies, their implementation or decommissioning, and as an accelerator of innovation. At the same time, the second one will be aimed to investigate the organization and functioning of the hospital HTA structure based on previous experiences in the hospital. Specifically, the questionnaire aims at identifying the possible limits and strengths of the technology assessment process conducted at the level of the single structure. It was decided to administer the questionnaire to a restricted pull of professionals directly involved in the assessment process, following their request during the period of the Commission's activity.

Patients and methods

A survey was performed between October 2022 and November 2022 in the Garbagnate Milanese and Rho Hospitals (PO), two tertiary hospitals part of a Hospital network called ASST Rhodense. It adopts quantitative and qualitative operational research methodologies (mixed methods) through the administration of two questionnaires

In these structures, there has been an internal commission in charge of the assessment of health technologies since 2017. The pandemic period has significantly influenced its work. It was therefore necessary to reevaluate the HTA process. Secondly, ASST Rhodense serves one of the most urbanized and industrialized territories in the hinterland of Milan, with a total resident population of 485,634. In addition, the complexity of the case-mix treated and the heterogeneity of services provided favored the choice of these two structures for the study.

As part of the methodological analysis, two distinct paths of analysis were undertaken; the first takes the form of a "generic" questionnaire administered to investigate the actual spread of the culture and pragmatic utility of HB-HTA practice within the hospital.

The second path of analysis is aimed at investigating a more operational aspect by processing and analyzing historical data about the technology assessment process and the work done by the Commission thus translating into a “specific” questionnaire, administered only to those who have requested a technology assessment in the past, thus participating in the process and the assessment process.

The questionnaires administered in the course of the survey were structured by a research team of public health and health management areas.

The questionnaires were structured using a special digital platform (Google Forms) to be then sent informatically with a link through the medical and nursing services to the professionals, as for the administrative staff, the Administrative Management was involved in sending and administering the questionnaire.

The questions were asked clearly and concisely, precisely framing the topic being surveyed so as not to confuse the participants, thus obtaining accurate and reliable answers. The questions were phrased through assertions that depicted a positive attitude toward the topic under study.

The response options of both questionnaires were determined by means of a five-point bipolar Likert scale, where 1 represents the lowest degree of agreement with the statement of the question, while 5 represents the highest degree of agreement with the statement under study. The qualitative of the scale varies according to the questionnaire (poor/high for the generic questionnaire, strongly disagree/fully agree for the specific questionnaire), for both questionnaires we also chose to formulate open-ended questions to investigate further opinions of professionals inherent to the research object.

Results

From October to November 2022 two questionnaires were performed through a tertiary Italian hospitals’ network, the ASST Rhodense, in order to assess the presence and knowledge of the HTA instrument among the ASST’s healthcare workers (HCWs). A first generical questionnaire was sent to a selected pool of 851 medical workers to assess the hospital population

directly and indirectly involved in clinical assistance. This generical questionnaire has been designed to inquire about and assess their knowledge of HTA and its utility. Answers to the questionnaire were collected by 416 (48,9%) HCWs.

Table 1 shows a brief description of the professional composition of the HCWs and their opinion on HTA and its implementation into healthcare structures. As we can note the main responder population was physicians, followed by nurses and administrative staff, in this pool constituting the hospital-based population. It’s interesting to notice as most answerers considered HTA as an opportunity to increase healthcare structures’ effectiveness and functioning, while adverse considerations such as danger or unconcern have been posted by few HCWs.

Questionnaire also enquired about the effect of HTA introduction on the quality and transparency of hospital tertiary network. In Figure 1 there is a description of answers given by sampled pool about these two areas. It could be noticing a certain homogeneity between the two issues assessed with most answers ranging from 4 and 5, suggestive of great attention and consideration about these topics.

Table 1. Occupation and consideration of HTA based on a HealthCare Workers responder to questionnaire (N=416).

Health Technology Assessment Hospital-Based	N (%)
Occupation	
Physician	148 (35,6%)
Nurse	118 (28,4%)
Administrative	77 (18,5%)
Technician	26 (6,2%)
Auxillary staff	22 (5,3%)
Professions of Rehabilitation Sciences	13 (3,2%)
Pharmacist	7 (1,7%)
Obstetric	3 (0,6%)
Other	2 (0,5%)
HTA to healthcare structures provides	
Opportunity	393 (94,5%)
Other	11 (2,6%)
Danger	5 (1,2%)
Unconcern	3 (0,7%)
Challenge	2 (0,5%)
Innovation	2 (0,5%)

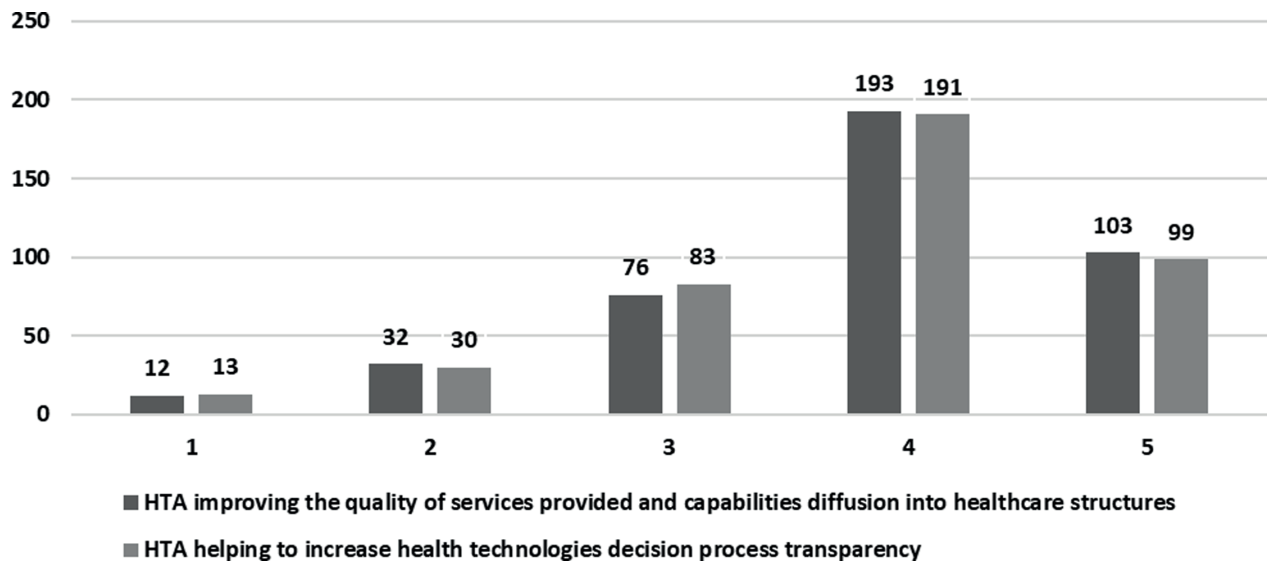


Figure 1. HTA impairment on quality and transparency of hospital network (N=416).

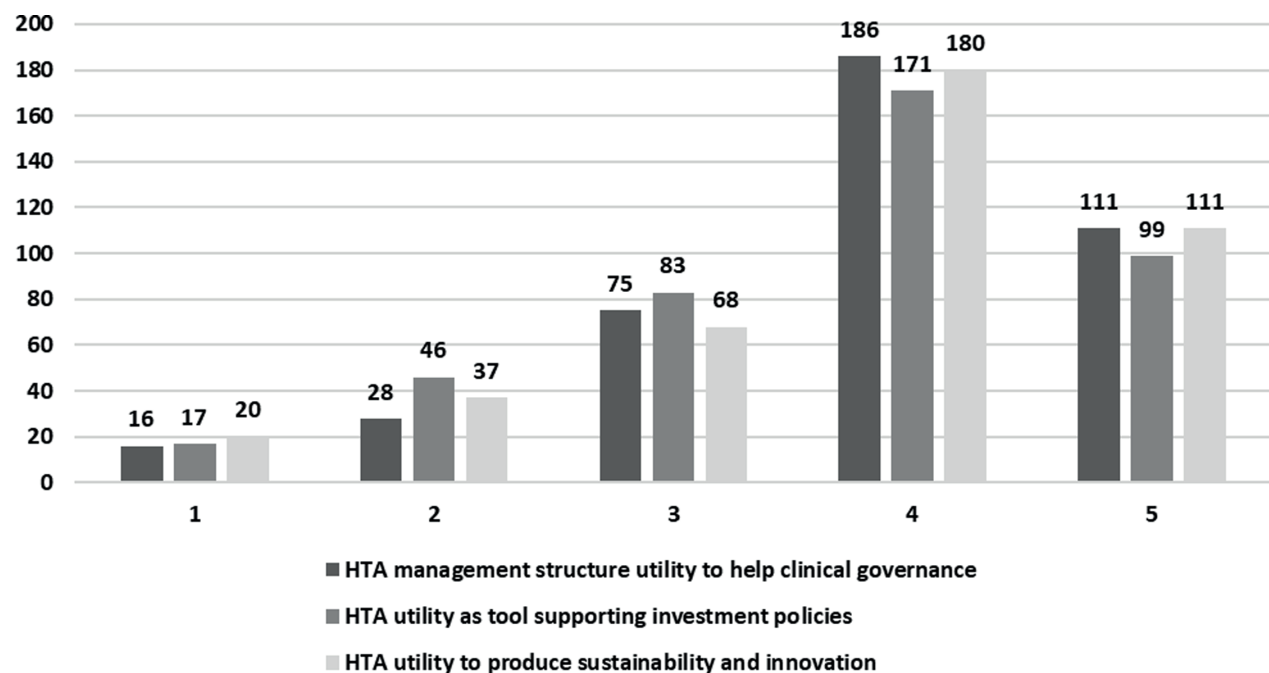


Figure 2. HTA effect on hospital management (N=416).

In Figure 2 we have reported the evaluation of the HTA influence on hospital and linked structures' management. While most of the sampled workers clearly considered HTA a useful instrument to help clinical governance with a 4-5 points rate close to 70% for the

utility of HTA as a clinical governance support tool or for the HTA possibility to generate sustainability, e.g. by reducing and waste and inefficiency, and innovation; no more than 65% of survey respondents show equal attention to HTA as a tool to support investment policies.

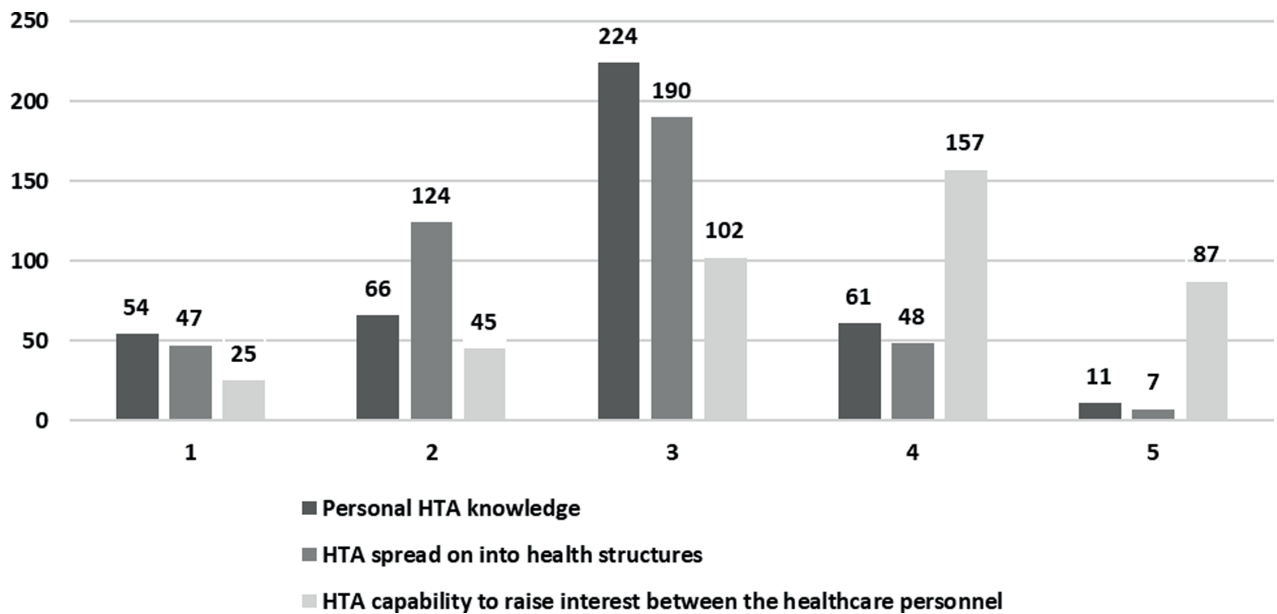


Figure 3. HTA knowledge and perception between Healthcare Workers (N=416).

Table 2. HTA evaluation process overview (N=21).

Health Technology Assessment Hospital-Based	N (%)
HTA evaluation process Key points	
Method in collecting evidence	17 (80,9%)
Transparence	15 (71,4%)
Fairness	14 (66,7%)
Consistency and rigour	12 (57,1%)
Multidisciplinarity	9 (42,9%)
Efficiency of the processes	7 (33,3%)
Absence of conflict of interests	4 (19%)
Dissemination and development of knowledge	4 (19%)
HTA evaluation process weakness	
Process complexity	14 (66,7%)
Complexity of the required documentation	13 (61,9%)
Expansion of the evaluation time	10 (47,6%)
Applicants in evaluation phase limited involvement (ex ante)	9 (42,9%)
Applicants in development and dissemination phase limited involvement (ex post)	8 (38,1%)
Expansion of the implementation time	6 (28,6%)
Lack of support during documentation compiling	4 (19%)

In Figure 3 the personal HCWs knowledge about HTA as well as their perception of the spread of HTA into hospitals or other healthcare structures and the capability of HTA to prompt interest among the healthcare workers. It might be noticed as most of the answers show a middle HTA knowledge or a middle attitude towards HTA spreading in the healthcare

structure. At the same time, the HTA perception as a driven to raise interest in technical devices is higher with a peak on a high or excellent perception.

In table 2 strength and weakness of the HTA evaluation process were reported due to the HTA hospital's inner commission questionnaire. As it could be noticed the main key points referred to the field of

clarity and methodological accuracy; at the same time the leading weakness could be addressed to the difficulty of HTA evaluation and the fact that this is a highly time-consuming process, with repercussions on the hospitals' management effectiveness.

Through the commission precision questionnaire, we have also assessed the influence of an HTA commission presence in a healthcare structure; Figure 4 highlights as almost any specialist agreed with the vision of a high-utility tool in new technology introduction in a hospital. The questionnaire was submitted to the pool of clinicians who interacted with the Technology Assessment Committee during its three-year activity (2017-2019). The questionnaire was administered to 23 of the 35 clinicians who made an enquiry, as 12 of them retired or moved to another hospital. a total of 21 responses were recorded, with a response rate of 91%. This response rate reflects the strong interest in the instrument on the part of those who used it to introduce technological innovations in the hospital. As far as the time period is concerned, the questionnaire was administered in October and November 2022, as for the previously mentioned questionnaire. In the three years 2017-2019, the Commission considered a total of fifty applications, of which 15 were not assessed (because they did not meet the minimum requirements to be

eligible for assessment), 5 were assessed without reaching the cut-off required for introduction, and 30 were assessed positively (with an average score of 49.81). Compared to the generic questionnaire, the specific questionnaire offers the possibility of appreciating the opinions of professionals with more structured knowledge of the subject and who can express more operational considerations regarding the process, the data that emerged from the analysis of the first question confirms this, 71.4% believe they have adequate knowledge of the discipline.

In Figure 5 we have reported the insight about the hospital HTA commission on new technologies and devices implementation process, considering the application process itself and at the same time the procedure facilitation for hospital employees.

The last questionnaire's key points were the items that could increase the effectiveness of new technologies and devices' introduction process. In Figure 6 it's interesting to notice that a large part of the commission considers periodical manufacturing companies' meetings fundamental as appropriate employees' training to increase their HTA knowledge.

Lastly in questionnaires, we also looked into the opinion of the HTA hospital commission and sampled healthcare workers' own HTA knowledge, and in

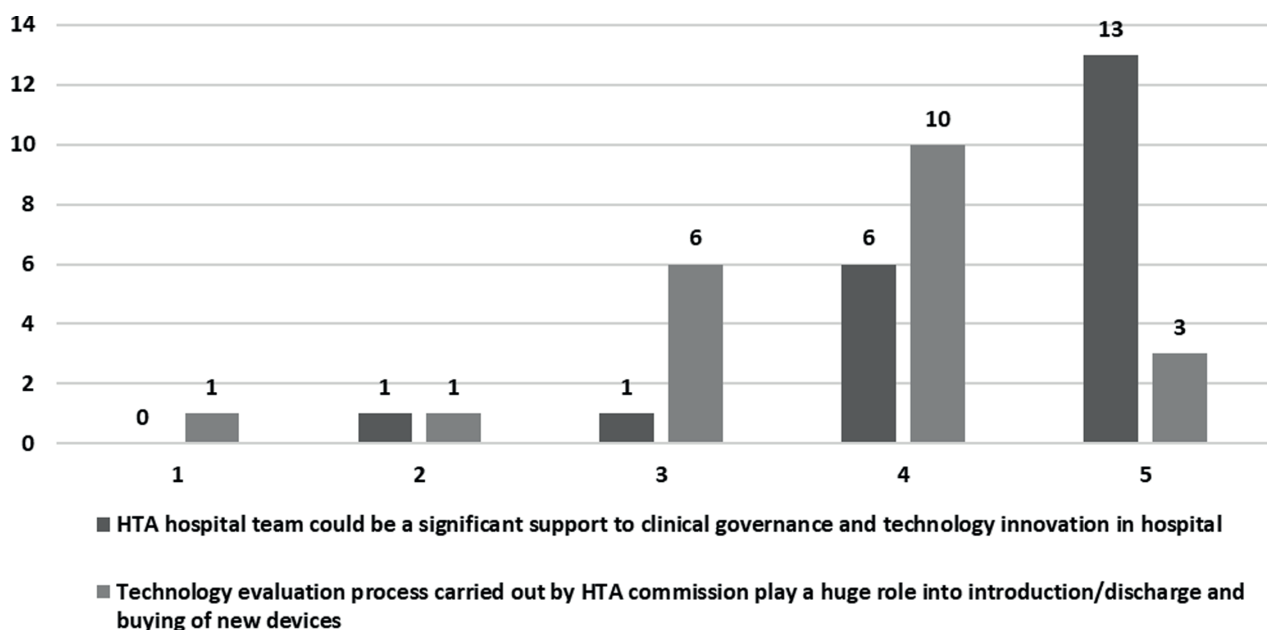


Figure 4. Evaluation of the influence of the HTA commission on technology and devices innovation management (N=21).

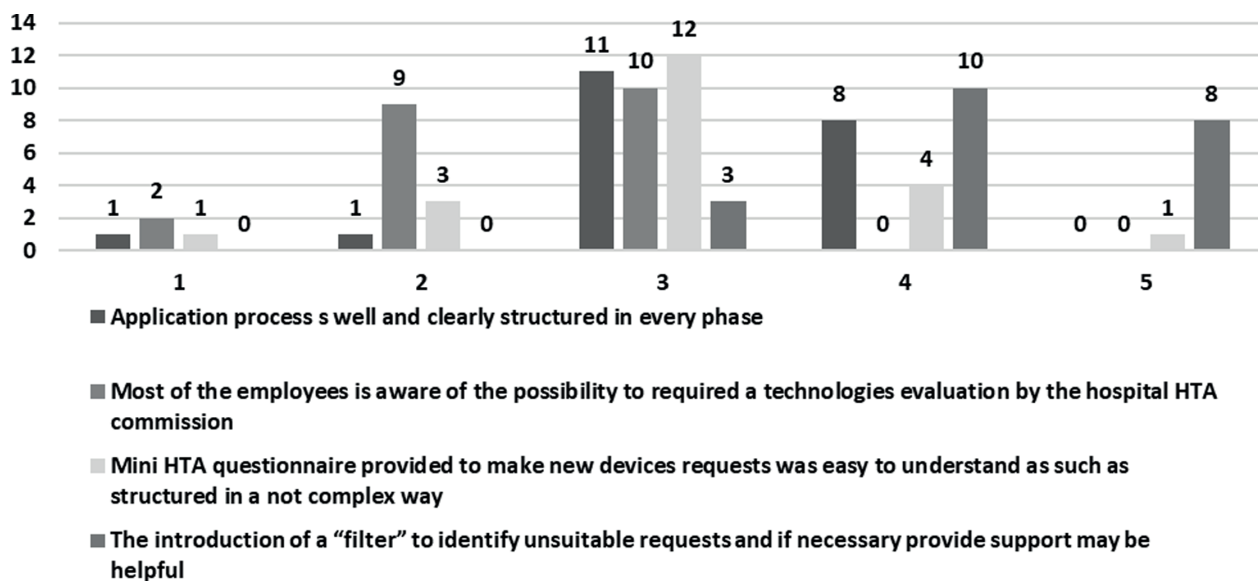


Figure 5. Evaluation New technologies requirement iter (N=21).

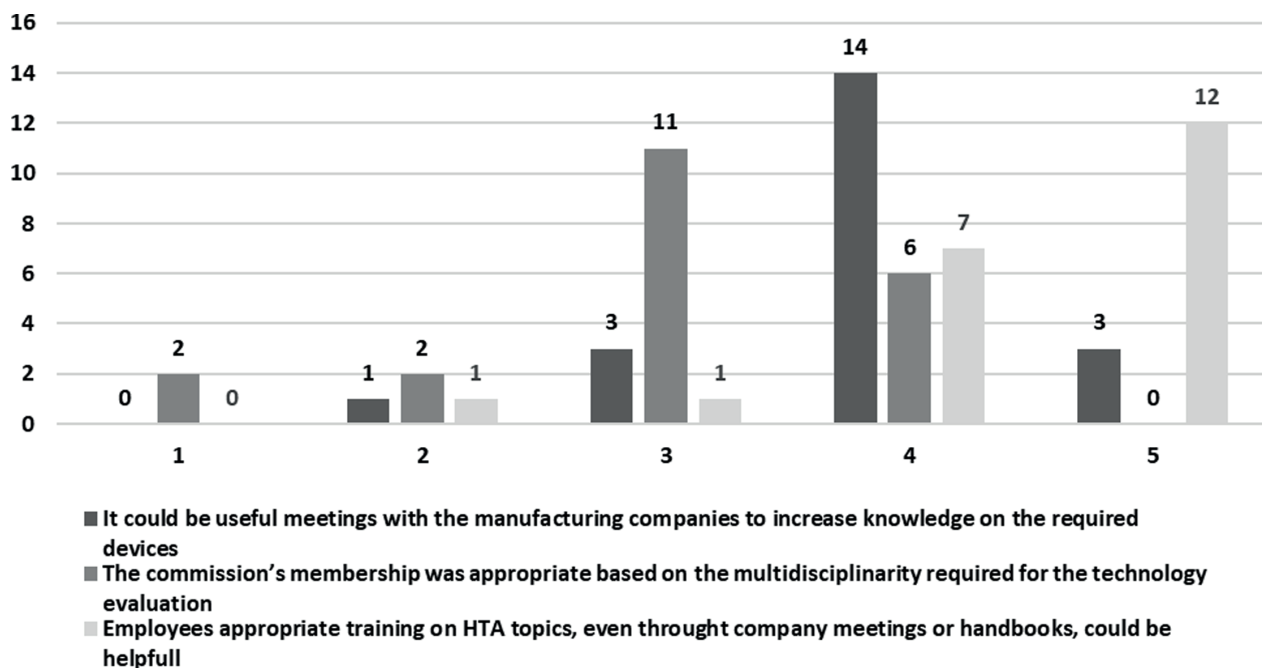


Figure 6. Evaluation of increasing HTA process items (N=21).

Figure 7 we have reported the results. It could be seen as more than 70% of interviewed commission’s components deemed their knowledge high or very high by assigning a 4 or 5 score while between sampled health-care workers this amount is slightly above 16% and more than 50% say they have middle knowledge.

Conclusions

The HB-HTA represents one of the most important future topics in terms of hospital management increasing the hospitals’ efficiency to increase care quality providing an economic-time reduction. (9,10) Since

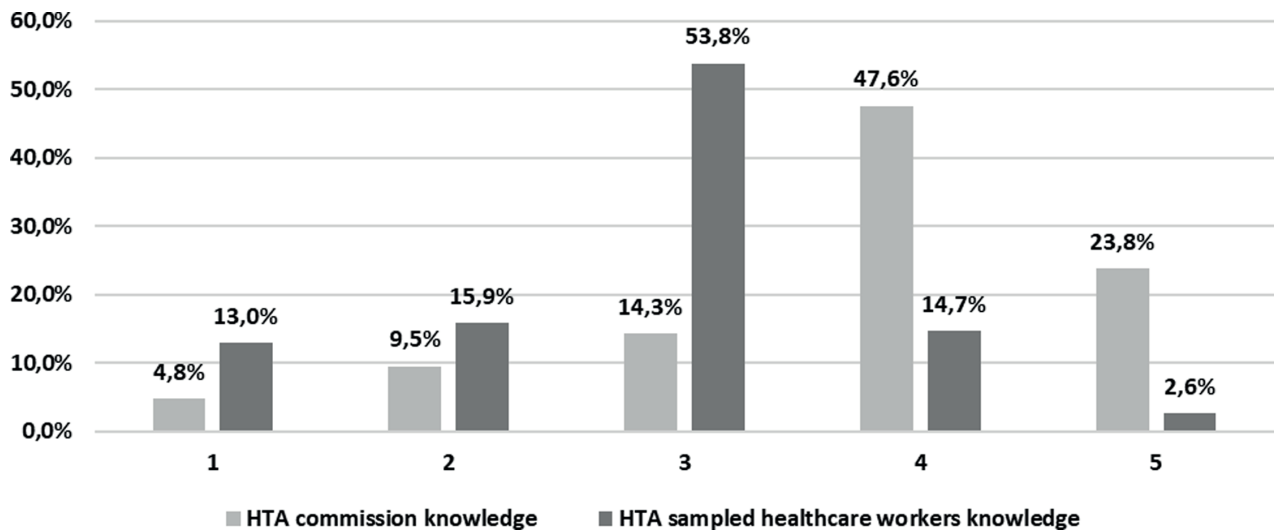


Figure 7. Analysis of own HTA knowledge into HTA hospital commission (N=21) and sampled Healthcare Workers (N=416).

the introduction of the U.S. Office of Technology Assessment (OTA) in 1976 (11), this new approach to technology device evaluation spread through North America and Europe during '80 (12). The subsequent evolution of the HTA hospital commission was the creation of the first HB-HTA during '90.

Through the XXI century, the introduction of new technologies such as robotic surgery devices or telemedicine platforms has increased the necessity of HB-HTA in order to a more accurate and precise clinical approach or to diminish the economic effect on Healthcare Systems (HS) (13,14). Nowadays HTA influences all the technologies in an HB-HTA model, not only the newest ones, involving for example imaging devices and clinical reports or diagnostic softwares. This has increased the effectiveness of the tacking-in-care process in healthcare structures. Indeed, HB-HTA proves to be an effective tool in managing vital knowledge for decision-making policy development by systematically synthesizing and evaluating research evidence all over the HS (15). So, in addition to supporting managerial decision-making processes, the adoption of an HTA perspective is an effective tool to support the organization of clinical governance of the entire healthcare network. Considering the Healthcare Network in its entirety HTA could affect public health intervention campaigns deeply, considering screening campaigns wherein economic costs management poses

a challenge that can be faced with HTA, for example through the introduction of new markers or tests. (16)

Another key point that highlights that HTA and HB-HTA should be an integral part of the health system agenda, is the introduction of digitalization and the rise of hospital technology into the expenditure items of the new National Recovery and Resilience Plan (NRRP) (17). This economic recovery plan was developed by the Italian government to obtain part of assets from Next Generation EU, an economic recovery project dedicated to member states. A total investment cost of approximately 4 billion Euro has been allocated to upgrade hospital technological facilities, changing more than 3000 devices for medical imaging, raising the digitalization level of 280 level 1 and 2 healthcare facilities in the headquarters of the Emergency and Acceptance Departments (DEA) (18). This has a double value to renew imaging device stock but also to increase HTA's influence in hospital structure boosting the transition to an HB-HTA HS.

Linked to the importance of this transition, our study has highlighted how the introduction of HB-HTA is perceived by healthcare professionals as an element for improving quality and transparency in the network of healthcare facilities. This highlights the perception of HTA as a cornerstone of future healthcare networks by several professional figures, involved in hospital management, in both the administrative

and clinical areas. At the same time with the great re-deployment of financial resources into hospitals, HTA is perceived by most healthcare professionals as a tool to support clinical governance, generating sustainability and innovation among other things. On the contrary, the method's ability to support investment policies is not sufficiently recognized.

The survey shows, compared to the other items investigated, that workers have an average perception of knowledge of HTA and perception of its diffusion in hospitals and other healthcare facilities. Furthermore, despite the continuing necessity to compare with technologies' innovations which implies pre-existing attention to this topic, HTA can generate a high level of interest in technological devices.

Some interesting considerations also emerge from the study of the results of the specific questionnaire. The subjects questioned acknowledge the methodology, transparency, and correctness of the evaluation method. The main weaknesses found are the complexity of the process and the required documentation, as well as the length of the evaluation time. Almost everyone agreed that the presence of the HTA commission in healthcare facilities is a very useful tool for introducing new technologies in these environments.

It is also important to notice that despite this the questionnaire was carried out to 851 HCWs only 416 of them performed it; this low involvement, close to 50% might be explained on a double-layer view: the main reason might be the narrow timeframe to answer the questionnaire because some HCWs don't answer due to holidays or not having accessed the e-mail box; the second one might be that several HCWs might consider themselves not well-prepared to answer the questions sent. In this regard the survey also shows that for the majority of individuals, it is possible to improve their knowledge of HTA through meetings with manufacturing companies and adequate training of employees on the subject, suggesting maybe the need to organize meetings and training moments. An interesting observation is the engagement of different professionals; indeed, despite sending more questionnaires to nurses (451/988; 45.6%) compared to doctors (310/988; 31.4%) and administrates (80/988; 8.1%), we lower observed response rate in this category

(118/416; 28.4%) probably due to less engagement in new devices evaluation and request processes.

At the same time, specific questionnaires were sent to all the HCWs that from 2017 to 2019 sent to HTA hospital commission requests to purchase new technologies or devices. Starting population involved was 35 HCWs but 14 (40%) were lost at follow-up due to their retirement or change of place of work. All the leftover 21 HCWs (100%) replied to the questionnaire sent.

Finally, linked to the previous analysis of self-reported HTA knowledge, it should be noted that the level of knowledge on HTA stands at a high level for the workers directly involved in the process of new technologies and devices' introduction through new technologies' applications, unlike the other professional figures involved for which it stands at a medium level. This could be simply explicated considering that workers directly involved are frequently the most engaged in the technologies assessment in a clinical ward, resulting in higher expertise due to the practice in this topic.

The assumptions behind the creation of the two questionnaires concern the possibility of interpolating the data that result from the two analyses, the specific questionnaire lays the groundwork (by analyzing historical data) to investigate whether or not against the positive opinion of those who have benefited from a corporate HTA function, the generalized data (extended to the corporate generality) is aligned or not. Thus, the two questionnaires, although marked by different traits in terms of the degree of complexity and technicality/specificity of the questions, are characterized by some common points concerning the analysis of the usefulness of an HB-HTA unit.

Despite the fundamental importance and innovation of this study, involving two different hospitals and different professional categories, there are several limitations to this study. First of all, the small number of healthcare providers involved; secondly in this study we have considered exclusively self-reported HTA knowledge but a small amount of questions was not foreseen to assess the HCWs actual knowledge about it, therefore missing an element of comparison.

In conclusion, in the current healthcare and welfare landscape and for the future developments that

will ensue from it, especially in the Italian context due to the increase of healthcare funds provided by the NRRP, the adoption of the HB-HTA method will represent a strategic lever for healthcare facilities to support clinical governance and the governance of organizational decision-making processes. For patients, it will also be a guarantee in terms of safety, delivered and perceived quality and effectiveness of healthcare services.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement, etc.) that might pose a conflict of interest in connection with the submitted article.

Ethic Committee: not applicable

Authors Contribution: Conceptualization, M.G.C and S.C.; methodology, P.M.P and S.C.; validation, P.M.P., S.C., M.G.C. and S.S; formal analysis, P.M.P., S.S. and M.G.C.; investigation, M.G.C; resources, M.G.C.; data curation, M.G.C. and P.M.P; writing—original draft preparation, P.M.P., M.G.C and S.S.; writing—review and editing, P.M.P., M.G.C. and S.S.; visualization, P.M.P; supervision, S.C.; project administration, P.M.P. and S.C. All authors have read and agreed to the published version of the manuscript.

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