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Health Technology Assessment to Improve the Medical Equipment Life Cycle Management*

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***Abstract*— Health technology assessment (HTA) is a tool to support decision making that is intended to assist healthcare managers in their strategic decisions. The use of HTA as a tool for clinical engineering is especially relevant in the domain of the medical equipment once it could improve the performance of the medical equipment. It would be done by their systematically evaluation in several aspects, in their life cycle. In Brazil, the Institute of Biomedical Engineering (IEB-UFSC) through the clinical engineering area has been working on the development of methodologies and improvements on HTA for medical equipment. Therefore, this paper presents the effort to create specific methodologies that will improve the dissemination of HTA, focusing on incorporation and utilization phase of the medical equipment life cycle. This will give a better support to the decision makers in the management of the health care system.**

Keywords: **Clinical Engineering, Medical Equipment, HTA.**

I. INTRODUCTION

The continuous development and growth of health technologies, from drugs to medical equipment, has led to the development of the need for Health Technology Assessment (HTA) over the last two decades. The suboptimal usage of health technologies not only affects patient care, but also the efficiency of the healthcare system [1].

HTA is a research-oriented use, based on an assessment of available and relevant knowledge, rooted in science and scientific methodology. The HTA essential properties are orientation to decision making, multidisciplinary nature and scope [2], [3]. However, HTA is becoming a tool for decision support, as a systematic interdisciplinary process based on scientific evidence. HTA-related activities can be used in any stage of the life cycle of health technology: from technology research and development to disinvestment [1].

Over the last few years, the clinical engineering area at IEB-UFSC has made great effort in the formation and consolidation of a HTA team. The clinical engineering is a branch of biomedical engineering that goes beyond the boundaries of research and enters in the domain of hospitals and other environments that use medical equipment. The clinical engineer performs an essential role in the management of medical technology aimed at rational and appropriate use of resources, available in the healthcare system.

To optimize the HTA usage, it is relevant that clinical engineer takes into account the stage of the life cycle in which the equipment is located. The life cycle can be divided into several phases: innovation, regulation, diffusion, incorporation, utilization and abandonment [3]. According to the stage considered, different approaches for assessment are designed for each equipment.

In this sense, the research is aimed at addressing the challenges of adaptation, development and improvement methods that are able to provide an effective contribution to the healthcare technology management, specifically medical equipment.

Some initiatives were implemented to adapt HTA to specific medical equipment . The systematization and rationalization of HTA is widely used in drug evaluation, however, barriers and limitations have arisen in the medical equipment. Thus, from the perspective of clinical engineering, methodological advances are necessary in order to implement this new perspective of HTA.

This article exposes how HTA can be allocated in the medical equipment life cycle, through the latest methodologies developed at IEB-UFSC. Different models of HTA will be presented, focusing on incorporation and utilization phase of medical equipment.

II. METHODOLOGY

Initially, evidence from the literature was collected in order to allow the identification of the key parameters that must be evaluated during each phase of the medical equipment life cycle, such as clinical, technical and operational criteria and costs, as well. It is also important the identification of specific criteria to each phase of the life cycle to ensure the review of relevant parameters. As an example, it is expected emphasis on the efficacy criterion in development and incorporation phases, and the effectiveness criterion in the medical equipment utilization phase. The criteria should be evaluated according to evidence and information.

Besides, the use of HTA in clinical engineering actions is according to the priorities established by the World Health Organization (WHO) issues, associated with the assessment, regulation and management of medical equipment [4].

III. RESULTS

This article presents selected models and another one in development. These models allow an interaction between the

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management actions of technologies undertaken by clinical engineering in medical equipment life cycle and the decision makers.

Subsequently, in this scenario the role of clinical engineering should be emphasized. As the clinical engineer is identified as the appropriate professional to facilitate the evaluation process, considering the type of health technology assessed, medical equipment and also the fact that their constant actions in equipment management produce clear results to the decision-makers.

A. Methodology for medical equipment incorporation in hospitals

This is a hospital-based HTA model which considers a multidisciplinary group, working on an internal HTA committee facilitated by clinical engineering. The committee has the task of analyzing the requests about medical equipment incorporation. It also encourages and supports methodological actions on the theme, aimed at expansion of HTA activities inside the hospital.

The HTA committee classifies the requests according to some criteria: the context of the incorporation, cost, relevance to the institution, and then decides how to proceed to complete the form of MINI-HTA proposed. Depending on the equipment under consideration, a task force will be formed to aggregate other multidisciplinary professionals to the HTA committee.

The form specifically developed to assess medical equipment has questions regarding clinical, technological, human resources, patient, economic and institutional aspects. For each of these domains there are questions already defined as the method of MINI-HTA [5]. For example, Figure 1 approaches the technology and patient domain with some predefined questions.

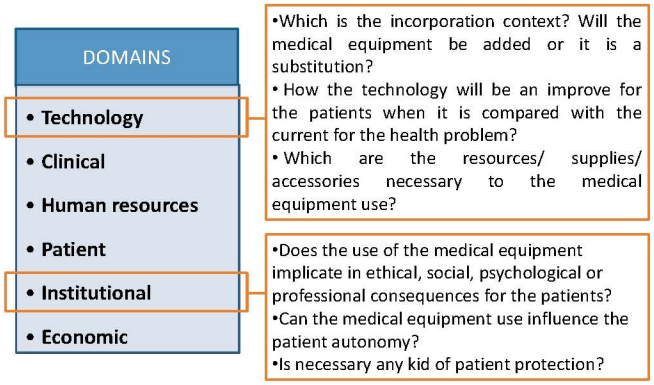

Fig. 1. MINI-HTA for medical equipment: sample questions for technology and patient domains.

The committee generates its recommendation about the medical equipment incorporation for each domain analyzed, and forwards it to the managers, the final decision-makers. The recommendation may be classified as high, medium or low, according to the weight of evidence and information collected through the HTA methodology.

For this methodology, two examples of the application were done relating to an incorporation request for a high-frequency ventilator (Case 1), exemplifying how the MINI-HTA for medical equipment could be used in hospitals. The final recommendation advises that the equipment should not be incorporated, due mainly to the clinical domain (the quality of the evidence is not adequate and it is similar to the conventional mechanical ventilation), human resources (equipment of high complexity that requires well qualified users) and economic (equipment with high purchase value).

The other request was about the incorporation of a phototherapy chamber (Case 2), whose final decision affects a network of hospitals. In this second case, the final recommendation indicates that one specific chamber should be incorporated. This equipment was aptly evaluated in the most domains of analysis. Table 1 presents a summary of recommendations for each domain, for both cases.

TABLE I
RECOMMENDATION TO INCORPORATE A HIGH-FREQUENCY VENTILATOR (CASE 1) AND A PHOTOTHERAPY CHAMBER (CASE 2).

Domain	Case 1	Case 2
Technology	Medium	High
Clinical	Low	Medium
Human Resources	Low	High
Patient	Medium	High
Institutional	High	High
Economic	Low	High

From the cases above was possible to infer that the MINI-HTA for medical equipment can support adequately the decision making process of medical equipment incorporation in hospitals.

This methodology aims at structuring the decision process of medical equipment incorporation in hospitals and intends to generate an improvement in the quality of hospital services, in order to improve the impact on patients.

B. HTA and Multi-Criteria Decision Aid (MCDA) in the medical equipment incorporation process

The model is supported by three levels: strategic, tactical and operational. A conceptual approach is used in the strategic level which is formed by the decision making domains, technology assessment and medical equipment incorporation [6]. A detailed proposol presenting the criteria and the relationship between the domains of strategic level is carried out in tactical leval.

In the operational level a structure was created to allow documenting and assessing the medical equipment that could be incorporated. That covers five phases: health problem, eligibility assessment, life cycle, health technology assessment, and priority indicator of incorporation. Each phase has its particularity and impacts in the incorporation process. The Figure 2 shows the operational level.

The operational level model is strengthened by the adaptation of the HTA focused on medical equipment, using scientific evidence and information. The originality of the

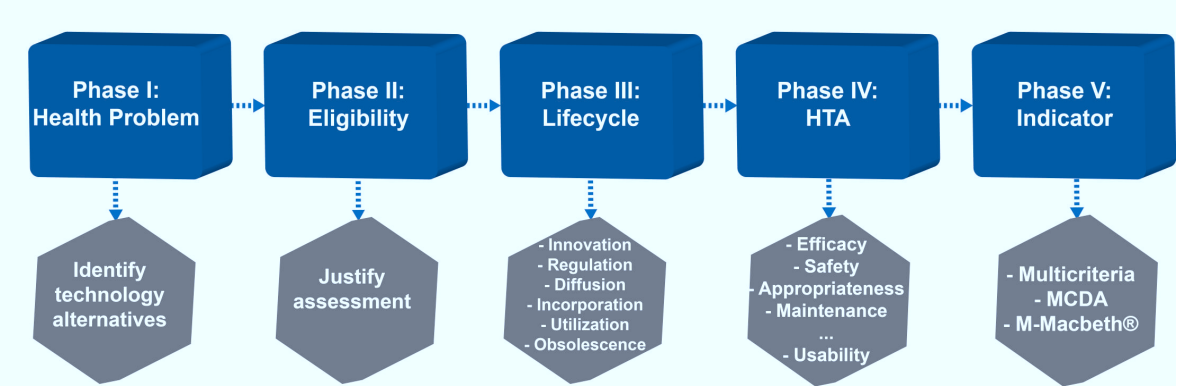

Fig. 2. Operational level. The model considers phases, alternatives, assessment, criteria and tools.

model considers the hybrid process, comprising the HTA and MCDA. In the fourth phase, through the HTA application for medical equipment it is possible to retrieve scientific evidence, regarding the safety and efficacy/effectiveness of the technologies. The evaluation of these criteria is essential to the incorporation process since clinical pre-market studies usually have a limited number of participants and short duration, and it cannot detect rare but serious adverse events or long-term failures [9]. Added to this, developing countries may have a regulatory system with many flaws. Brazil, for example, has recently begun to require safety and efficacy/effectiveness evidences, in regulation phase [10].

Also in the fourth phase, there is the recovery of additional information from the literature, which allows the identification about some performances related to infrastructure, human and technical resources. These criteria are represented by: learning curve, installation ease, maintenance ease, usability and total cost of ownership (TCO). Thus, it is possible to formulate recommendations regarding the criteria considered in the process of medical equipment incorporation.

In the last phase such recommendations are transferred to the performance level in a MCDA model, in particular the method Macbeth (Measuring attractiveness by a category based evaluation technique). From this structure it is possible to obtain the priority indicators for incorporation. In this case, technological alternatives, justification of the assessment, technological horizon, evidence and information inherent in the evaluated criteria were considered [7].

A sample application example has been achieved, with two technologies: phototherapy equipment and robotic surgery system. For the phototherapy equipment we had 58.06%, on the priority incorporation indicator. And for the robotic surgery system the indicator was 39.16%. Table 2 presents the overall scores of the evaluated technologies and some criteria with their weights and scores. The values were obtained by applying the Macbeth method.

However, these technologies are not competing. In such cases the overall attractiveness can be useful in formulating recommendations when there is a need to incorporate several technologies, but with limited resources. Also, it is possible to investigate whether the technology has a minimum attractiveness according to the expectations and needs of the healthcare establishments.

TABLE II

GLOBAL SCORES FOR THE EVALUATED MEDICAL EQUIPMENT AND THE CONSIDERED MULTICRITERIA. THE SCORES ARE SUPPORTED BY EVIDENCE AND INFORMATION FROM LITERATURE.

Options	Overall	Safety	Efficacy	Maintenance ease
All higher	100.00	100.00	100.00	100.00
Robot assisted	**39.16**	42.86	42.86	50.00
Phototherapy equipment	**58.06**	0.00	42.86	100.00
All low	0.00	0.00	0.00	0.00
Weights		**0.2340**	**0.2127**	**0.1915**

In addition, a sensible analysis enabled the verification of a lower variation in overall scores. This low sensitivity shows that the model behaved robustly towards the face of changing its parameters.

C. Proposal of a methodology for medical equipment assessment in the utilization phase in hospital

Considering the HTA models for medical equipment incorporation that has already been developed, other studies about the subject for the utilization phase of these technologies has emerged. Therefore, a proposed model to use HTA in order to investigate the appropriateness of medical equipment considering multi-criteria is in development.

Researches in the complementary and scientific literature have revealed essential domains (criteria) in the management of medical equipment in use. Then, there was the need for synthesizing these domains, in order to obtain indicators of medical equipment appropriateness. HTA and MCDA may be considered on the assessment domains and on the indicators of generation, respectively.

The proposed methodology follows the steps of structuring, evaluation of the domains and recommendations. The structuring corresponds to a hierarchical tree formed by the goal of investigation, domains, and alternatives (levels). In

TABLE III
SUMMARIZATION OF HTA MODELS FOR MEDICAL EQUIPMENT.

Model	Objective	Domain	Type of HTA	Life cycle phase
Methodology for medical equipment incorporation in hospitals	Integrate HTA in medical equipment incorporation assessment within the Clinical Engineering field	Clinical Human Resources Patient Instituitional Economic	MINI-HTA	Incorporation
HTA and Multi-Criteria Decision Aid (MCDA) in the medical equipment incorporation process	Extend actions of health technologies management, by obtaining a priority indicator of incorporation	Safety Efficacy/Effectiveness Learning curve Installation Maintenance Usability Total Cost of Ownership	General HTA	Incorporation
Proposal of a methodology for medical equipment assessment in the utilization phase in hospital	Investigate medical equipment appropriateness in the utilization phase considering multi-criteria	Clinical Technical Operational Costs	MINI-HTA	Utilization

the assessment of the domains, HTA should be used as a tool to promote a thorough evaluation, based on evidence and information. The domains considered were: clinical, technical operational and costs, which have multi-criteria.

For example, the technical operational domain consists of risk criteria, learning curve, infrastructure and maintenance. By evaluating these domains aggregated by multi-criteria it is possible to classify the medical equipment appropriateness according to three levels: appropriate, inappropriate or uncertain. Then, recommendations are formulated according to the magnitude of the classification levels of the medical equipment appropriateness.

Table 3 presented the main characteristics of the models: their objectives, domains of assessment, scope and HTA type.

IV. CONCLUSION

Summarizing all the actions carried out by the IEB-UFSC, HTA research line confirms the HTA relevance as a tool to support the management of health technologies. And above all, it aimed at strengthening the use of HTA instruments, through the dissemination of methodologies and the technical reports produced.

The research conducted allowed the developing of a methodological guideline in partnership with the Brazilian Ministry of Health and the Pan American Health Organization (PAHO). The guideline is considered a new methodology in the field of HTA for medical equipment and it can support health managers in making decisions about medical equipment incorporation within the ministry of health. Its methodology recommends collecting evidence and information and assessing them on the following domains: clinical, admissibility, technical, operational, economic, and innovation [8].

Then, this guideline has been included among the actions to structure and disseminate methodologies about HTA in Brazil. It has been consistent with the clinical engineering actions, which encourages the use of the most appropriate technologies through a balance between human resources, technology specification and infrastructure, aiming effective health services.

Given the success of the models listed above as future work we intend to continue the development of the methodology for medical equipment assessment in its utilization phase. Through the investigations performed, it was possible to develop this proposed methodology that enables clinical engineers to contribute for the formulation of recommendations to mitigate the unfavorable aspects and maximize the benefits of using medical equipment.

The modeling process of medical equipment management at different phases of the life cycle deliveries indicators and recommendations, for clinical engineering structures, about the selection and use of safe, effective and appropriate cost-effect technologies.

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