

Health Technology Assessment Tools for Biomedical Equipment Acquisition

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Abstract — Health Technologies Assessment is a practice that enables the evaluation of the consequences of the use of a technology. However, the lack of standardization and methodologies to guide the process remains a challenge. This paper presents the development and validation of a Health Technology Assessment tool which process was carried out in three stages. First, the tool was developed to assess the acquisition process of medical equipment, after which a discussion group was formed to obtain different perceptions regarding the tool. Finally, was the implementation through case studies, evaluating its real use and applying an evaluation survey to measure its usefulness in the processes of acquisition of medical equipment. The importance of each type of technology assessment was weighed and modules for technical, clinical, financial, ethical, social and organizational evaluation were developed. In addition, validation with experts demonstrated the usefulness of the tool in the selection and acquisition processes of medical equipment in a way that will reduce costs and enable better investments.

Keywords — Medical equipment acquisition, Health Technologies Assessment, Health Technologies.

HERRAMIENTA DE EVALUACIÓN DE TECNOLOGÍAS PARA LA ADQUISICIÓN DE EQUIPOS BIOMÉDICOS

Resumen — La Evaluación de Tecnologías en Salud es una práctica que permite a las instituciones de salud valorar de forma integral las consecuencias del uso de una tecnología, sin embargo, la falta de estandarización y de metodologías que guíen el proceso sigue siendo un reto por superar. Este trabajo presenta el desarrollo y la validación de una herramienta de evaluación de tecnologías en salud la cual se realizó en tres fases: primero se desarrolló la herramienta que permite valorar el proceso de adquisición de equipos biomédicos, después se conformó un grupo de discusión para obtener diferentes percepciones frente a la metodología empleada, el diseño y desarrollo de la herramienta para finalmente implementarla mediante casos de estudio evaluando su uso real y aplicando una encuesta que permitió valorar su utilidad en los procesos de adquisición de equipos biomédicos. Se ponderó la importancia de cada tipo de evaluación de tecnologías seleccionada y se desarrollaron los módulos para las evaluaciones técnica, clínica, económica y ética, social y organizacional. Por su parte, la validación con expertos demostró la utilidad de la herramienta en los procesos de selección y adquisición de equipos biomédicos de manera que se disminuyan costos y se realicen mejores inversiones.

Palabras clave — Adquisición de equipos biomédicos, Evaluación de Tecnologías en Salud, tecnologías en salud.

FERRAMENTA DE AVALIAÇÃO DE TECNOLOGIAS PARA A AQUISIÇÃO DE EQUIPAMENTOS BIOMÉDICOS

Resumo— A Avaliação de Tecnologias em Saúde é uma prática que permite às Instituições de Saúde valorizar de forma integral as consequências do uso de uma tecnologia, no entanto, a falta de standardização e de metodologias que guiem o processo segue sendo um desafio por superar. Este trabalho apresenta o desenvolvimento e a validação de uma ferramenta de Avaliação de Tecnologias em Saúde a qual se realizou em três fases: primeiro desenvolveu-se a ferramenta que permite valorizar o processo de aquisição de equipamentos biomédicos, depois se conformou um grupo de discussão para obter diferentes percepções em frente à metodologia empregada, o desenho e desenvolvimento da ferramenta para finalmente implementá-la mediante casos de estudo avaliando seu uso real e aplicando uma pesquisa que permitiu valorizar sua utilidade nos processos de aquisição de equipamentos biomédicos. Ponderou-se a importância de cada tipo de avaliação de tecnologias selecionadas e desenvolveram-se os módulos para as avaliações técnica, clínica, económica, ética, social e organizacional. Por sua vez, a validação com experientes demonstrou a utilidade da ferramenta nos processos de seleção e aquisição de equipamentos biomédicos de maneira que se diminuam custos e se realizem melhores investimentos.

Palavras-chaves—Aquisição de equipamentos biomédicos, Avaliação de Tecnologias em Saúde, Tecnologias em Saúde.

I. INTRODUCTION

Healthcare Technologies (HCTs) are all equipment and biomedical and surgical devices used in medical attention. These include medication, organizational support systems, such as information, along with medical and surgical procedures [1]. Biomedical equipment has become a powerful tool to solve different problems in human healthcare, improving diagnoses and treatment of more illnesses. However, the incorporation of these technologies implies a great responsibility from healthcare providers (HCPs) due to the different risks which impact patients and users, situation which elevates adverse event indexes. The process of Health Technology Assessment (HTA) is a practice which allows the HCPs to wholly assess the technical, clinical, social, financial and ethical consequences derived from the use of one technology [2]. The acquisition of biomedical equipment is a stage in the process of HTAs where purchasing plans and programs are found according to needs, priorities and availability of resources [3]. The adequate implementation of biomedical technology for the provision of healthcare services guarantees the quality in the service and the safety of patients by means of positive relationship costs, cost-benefit, effectivity, thus reaching convenient healthcare results [4]. However, despite the importance of this process, most technology acquisition decisions are made by management without multidisciplinary participation from medical, technology or engineering areas. This is reflected in the investments in acquisitions which, in short term, do not respond to the real needs of the community, and in a worst case scenario, are incompatible with hospital infrastructure, and generate high maintenance costs, as well as, technological accidents for misuse due to the lack of training and poor functional impact among

users [5]. This study aimed to develop and validate a Health Technology Assessment Tool (HTAT) for the acquisition of biomedical equipment by HCPs. The tool was developed and submitted to validation by a discussion and expert group using case studies.

II. METHODOLOGY

The study was carried out in three stages: the first was the development of an HTAT enabling the valuation of the acquisition process of biomedical equipment in an HCP. During the second stage, a discussion group was set up to obtain different perceptions of the HTAT method employed, as well as, the design and development of the tool. In the third stage, a tool was implemented by means of case studies to evaluate the real use of the tool and a survey was applied to value the use of the HTATs developed in the acquisitions process of biomedical equipment.

A) Development of a software tool for HTAT in the acquisition process of biomedical equipment. In this part of the project, an HTAT prototype was developed based on the proposed methodologies of the OMS [6], CENETEC [7] and a survey was applied to a group of experts in HTATs. Functional requirements of the tool were developed for the software development, as well as, the design of an objective tree, the establishment of duties and detailed design.

Likewise, for this stage, an online survey was applied aiming to evaluate the pertinence and importance of the variables and of the types of evaluations chosen for the HTAT methodologies of the OMS and CENETEC. The results of the surveys were statistically analyzed in order to assign a percent value to each one of the chosen evaluations indicating the importance of this type of evaluation in the acquisition process. Moreover, each

parameter in the evaluation types was assigned a percentage value to visualize its importance level in the HTA process. Finally, the HTATs output a quantitative value for each of the biomedical technologies the HCP is considering for acquisition. This value enables purchasing decision making based on the carrying out of a standard process.

B) Validation of the designed tool and perception of future users. A discussion group was set up through an evaluation of experts. An initial valuation of HTAT experts was proposed by means of a qualitative focus and a collaborative research model, and the needs, strengths and improvement opportunities were identified for the prototype.

C) Validation of functionality and usefulness of HTATs. A case study was applied to five (5) experts in clinical engineering of the chosen HCPs in Medellín. This enabled the assessment of functionality and the definition of other guidelines and requirements to consider in the design. For the selection of experts, we took into account their degree of interest and commitment, along with the level of experience in processes of evaluation and acquisition of biomedical equipment. Likewise, we applied a survey aiming to evaluate the usefulness of the tools in the areas of clinical engineering of the healthcare providers of the city of Medellín.

III. RESULTS

A. Development of a software tool for the HTAT in the acquisition of biomedical equipment process. For the definition of the most relevant activities in the HTAT procedure in the acquisition phase, it was necessary to go through the bibliography, highlighting types of evaluations that are made and the subcategories of these types, simultaneously analyzing how the activities change, as well as, the change in the HTATs along time. Four (4) large types of HTATs were suggested by the bibliography: clinical evaluation, technical evaluation, economic evaluation and ethical, social and organizational evaluation. At the same time, we identified evaluation criteria for each type. In order to define the evaluation types and subcategories of the HTAT process, we designed and applied an online survey using MonkeySurvey. The survey was taken by twenty-two (22) HTAT experts in Colombia and Mexico. The survey enabled the scoring of the importance of each of the types of HTATs in a quantitative manner from 1 to 4, being 1 the “not important” option, 2 the “somewhat important” option, 3 the “important” option and 4 the “very important” opinion. This is how the results in Table 1 were obtained.

Table 1. Average score of each type of evaluation

TYPE OF EVALUATION	AVERAGE SCORE
Clinical Evaluation	3,68
Technical Evaluation	3,82
Financial Evaluation	3,59
Ethics, Social and Corporate Evaluation	2,95

Upon converting each score to a percentage, we get a weighted percentage for each one of the types of chosen evaluations, as shown in Table 2.

Table 2. Percentage of importance of each type of evaluation

TYPE OF EVALUATION	PERCENTAGE OF IMPORTANCE
Clinical Evaluation	26%
Technical Evaluation	27%
Financial Evaluation	26%
Ethics, Social and Corporate Evaluation	21%

The data on Table 2 were compared to those obtained with acquisition procedures of other organizations and differences were found in percentages. However, the order of importance remained the same, technical evaluation being the first, followed by clinical evaluation, then economic and lastly, ethical, social and organization [8].

The technical evaluation is a very important aspect and should have the greatest weight at the moment of making a technological acquisition, since it evaluates conditions related to the functional and technical areas of the equipment [9]. For the development of the HTAT software in the acquisition process of biomedical equipment, the Wavemaker framework was employed, as well as JAVA and a MySQL database. Modules were programmed for each one of the stages of the process for the technological evaluation types selected. The HTAT begins to work when the user inputs the different technologies (or equipment options) to evaluate, beginning with the technical evaluation. Later, the system allows for the valuation and comparison of each technology starting from the financial, clinical, ethical, social and organizational evaluations. Lastly, the software is in charge of weighing each one of the responses in order to give a recommendation.

Technical Evaluation

Technical evaluation begins when the user inputs technical specifications considered important for the technology he is evaluating. After that, he should value them with a score of 1 to 5 in the cell named “score” on the form in Fig. 1 (where 5 is VERY HIGH for the

equipment in said specification, 4 is a score of HIGH, 3 is MODERATE, 2 is BAD and 1 is DEFICIENT). The system will finally calculate and present a value for the technical evaluation of each of the machines.

Financial Evaluation

The financial evaluation contemplates not only the value of the equipment to purchase but also its depreciation, value increase, maintenance and other accounting movements [10]. The need for a financial evaluation stems from the condition of managing the limited resources in most healthcare provider institutions in our country. It's important to note that the results of this evaluation must be contrasted to the technological evaluation in terms of safety, efficiency and effectiveness outputs [11]. The financial evaluation seeks to offer guidelines that will allow for the objective and systematic choice of the best option from a group of solutions to a certain need (opportunity) from the monetary point of view [11]. For the financial analysis for acquisition of new technology, we propose an investment evaluation that will consider profitability, risk level and liquidity. An investment is characterized by three parameters: initial investment (K), equipment life (n) and cash flow (R) [12].

Using (1) we calculate the cash flow as a result of income derived from the use of the equipment minus payments.

$$Flow\ chart\ (R) = Income\ (I) - Payments\ (P) \quad (1)$$

The cash flow for the lifetime of the equipment in successive years was calculated using (2).

$$Future\ value = \frac{n}{Current\ value \times (1 + i)} \quad (2)$$

i is inflation, *n* is the number of years for which the analysis is made. By means of (3), we calculate the profitability of the new technology CNV (Current Net Value), for which we subtract the equipment investment (K) from the cash flow year after year [12].

$$CNV = - Investment + \frac{FC1}{(1+i)} + \frac{FC2}{(1+i)^2} + \dots + \frac{FCn}{(1+i)^n} \quad (3)$$

For the CNV calculation, we have a few options represented in Table 3 and enable the financial scoring of the acquisition of the new biomedical equipment.

Fig. 1. Form for the technical evaluation of biomedical equipment

Table 3. Recommendations according to CNV

RESULT CNV	RECOMMENDATION
Positive CNV	Acquisition of technology recommended
CNV = 0	Not many benefits are perceived with the acquisition of the new technology
Negative CNV	Acquisition of technology not recommended

The system easily calculates the CNV and does so taking as constant, the numerator of (3) to calculate the accrued CNV for n = 5 according to what is shown in Fig. 2.

AÑOS	VAN acumulado
0	-K
1	-K + FC1 / (1+i)
2	-k + FC1 / (1+i) + FC2 / (1+i)^2
n	-k + sum_{j=1}^n FC_j / (1+i)^j

Fig. 2. Accrued CNV for n years. Taken from [12].

In order to make a financial analysis of the different biomedical equipment proposals, the user must complete the form shown in Fig. 3. As shown in Fig. 3, the user inputs the initial investment value, estimated value of procedures he expects the new equipment to undergo in a year, annual maintenance and metrology costs, insurance cost, if applicable and the average price of the procedure for each of the different biomedical equipment pieces being evaluated (three allowed). The user needs to calculate the CVN for each year, thus determining what year the return on investment begins to earn a positive CVN.

Fig. 3. Financial analysis form for the acquisition of biomedical equipment

Fig. 4. Financial evaluation form for cost minimization in the acquisition of biomedical equipment

At the end of the financial evaluation, the user has to score each equipment piece between 1 and 5, according to investment, turnover time or according to the lesser cost of the two (where 5 is VERY HIGH for the equipment in said specification, 4 is a score of HIGH, 3 is MODERATE, 2

is BAD and 1 is DEFICIENT). In the case of renovation of technology or when it is impossible to establish the procedure number to apply nor is there an established price for any, the system proposes a financial evaluation for the minimization of costs, as shown in Fig. 4. The financial evaluation for cost minimization for each piece of equipment being considered is the initial cost and maintenance and metrology annual costs to finally present a 5-year projection.

Clinical Evaluation

The clinical evaluation is the stage in which clinical personnel are called to evaluate the technology in their activities and so value its characteristics, quality, relevance, experience and satisfaction [5]. For the clinical evaluation, many healthcare providers opt for technology demonstration processes aiming to familiarize users or potential future users with the biomedical equipment. Before beginning the clinical evaluation, these steps must be followed [5]:

- Define the number of machines to be evaluated.
- Define the beginning and end of each evaluation. (Establish a schedule for each machine and supplier).
- Define a potential clinical crew to be trained by supplier.
- Define specific criteria to be taken into account depending on the technology.

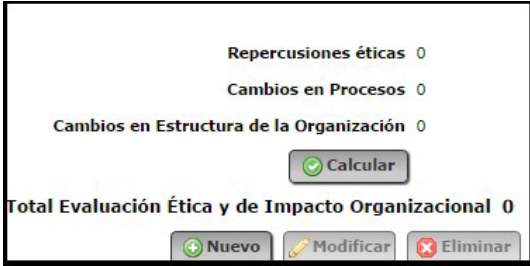
For the development of the HTATs, the clinical evaluation criteria proposed in [5] were considered and the user should score them from 1 to 5, where 1 is DEFICIENT compliment of the technology criteria and 5 is VERY HIGH compliment of the criteria for the technology evaluated. This will be done using the form shown in Fig. 5.

Fig. 5. Clinical evaluation form for the acquisition of biomedical equipment

Ethical, social and organizational evaluation

The ethical, social, and organizational evaluation aims to learn the general manner in which the implementation and use of technology affects society and to pose ethical questions that are most important at the time of making a decision on whether or not to incorporate these new technologies in the organization [8].

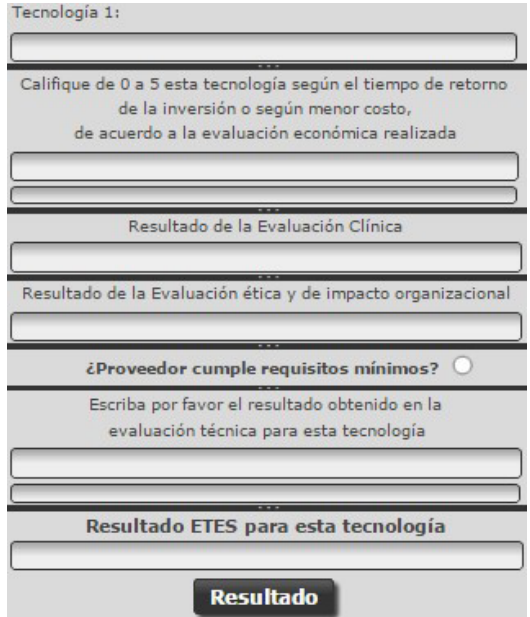
For the ethical, social, and organizational impact evaluation, the user has to assign a score from 1 to 5 to each one of the criteria shown in Fig. 6 (where 1 means many repercussions or changes when implementing technology and 5 means few repercussions or changes).



The screenshot shows a web form with the following elements:

- Three input fields with labels: "Repercusiones éticas 0", "Cambios en Procesos 0", and "Cambios en Estructura de la Organización 0".
- A "Calcular" button with a green checkmark icon.
- A "Total Evaluación Ética y de Impacto Organizacional 0" label.
- Three buttons at the bottom: "Nuevo" (with a green plus icon), "Modificar" (with a yellow pencil icon), and "Eliminar" (with a red X icon).

Fig. 6. Ethical repercussions, process and organizational structure changes evaluation form



The screenshot shows a web form for HTAT results with the following elements:

- A header "Tecnología 1:" followed by an input field.
- Instructional text: "Califique de 0 a 5 esta tecnología según el tiempo de retorno de la inversión o según menor costo, de acuerdo a la evaluación económica realizada".
- Two input fields for ratings.
- Section "Resultado de la Evaluación Clínica" with an input field.
- Section "Resultado de la Evaluación ética y de impacto organizacional" with an input field.
- Section "¿Proveedor cumple requisitos mínimos?" with a radio button.
- Text: "Escriba por favor el resultado obtenido en la evaluación técnica para esta tecnología".
- Two input fields for technical evaluation results.
- Section "Resultado ETES para esta tecnología" with an input field.
- A "Resultado" button at the bottom.

Fig. 7. Results form for the HTAT for each machine

Recommendation

Finally, the user will be able to calculate the total result for the quantitative evaluation made, which will enable the decision for purchasing (or not). The system weighs the

result of each evaluation according to Table 2 and presents a general result for the HTAT. Choosing the technology whose result is the greatest is recommended. Fig. 7 shows the form which summarizes the process of technology acquisition for biomedical equipment.

IV. DISCUSSION

When going over the bibliography for equipment evaluation at the stage of acquisition, we find that, although it is not a recent topic, there is a need for standardization and building of tools to support the process. In the identification of relevant HTAT activities for the process of acquisition of biomedical equipment, we find that, throughout time, the financial evaluation of technology in healthcare has been and is still valid and widely used, showing the need to be included in the evaluation process, because of its importance and relevance at the time of making decisions on whether or not to acquire biomedical equipment at an HCP. When comparing the new tool to the theory framework for biomedical equipment, we find that this software is an integral solution, since it enables process standardization, an integral financial evaluation, and incorporates new criteria for technical and financial evaluations. Criteria such as ethical, social, and organization evaluation were not taken into account in many of the HTAT procedures reviewed. However, there was always a direct or indirect organizational analysis, thereby demonstrating its importance. The clinical analysis of sanitation technologies was always present in the HTAT process, although, in certain cases, the institutions do not use this specific term. The evaluation of technical parameters has been in existence since the middle of the 21st century and remains constant today, showing this parameter was created out of the need a more complete HTAT process based on evidence in order to ease decision making. By assigning percentage values to the types of evaluation, we find it isn't enough to only have value output from surveys, but that it is necessary to complete the information with evaluation processes of biomedical equipment on the acquisition stage already defined and used by HCPs in the city of Medellín. In the validation of HTATs, the importance of having standard processes of HTAT in the acquisition of biomedical equipment is confirmed, as well as the usefulness in the medical realm.

V. CONCLUSION

It is important for the HPCs to have a standard process of HTAT in the stage of biomedical equipment acquisition and the development of this tool eases decision making,

which will reduce costs on a long term basis and will enable making better investments in the HCP. For future development, we recommend adding a series of templates that include specifications that are unique to each technology and allow for these to be weighed according to their importance in the healthcare service to be provided by the biomedical equipment in question.

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