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Methodology for the replacement of high-tech medical equipment, applying economic evaluation and business process analysis

Metodología para la sustitución de equipos médicos de alta tecnología, aplicando la evaluación económica y el análisis del proceso empresarial

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business process modeling notation, cost-effectiveness analysis, health economics, health technology assessments, health technology management, medical devices.

Palabras clave:
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Abstract

Introduction: decision-making about when MEs replacement should take place is a traditional hospital challenge due to its high cost for health institutions and the risk it could represent in any existing medical care practice or procedure. The Health Technology Assessment (HTA) for MEs allows prioritizing its replacement in a hospital. Most MEs replacement evaluations focus solely on cost analyses; however, these evaluations do not consider the full role that MEs play in the healthcare processes In this sense, the investment cost of the equipment and other critical factors to evaluate the process, costs and productivity must be considered either. **Objective:** this paper proposes a methodology to support the decision to replace or not MEs, based on economic evaluation and business process analysis. **Material and methods:** cost-effectiveness, intermediate effectiveness, and process workflow analysis are applied. The best MEs alternative is identified through a decision-tree and time indexes, productivity and performance indicators. This methodology was tested by evaluating, as a case study, whether it is necessary to replace the sterilizers/washing machine that are in the last stage of their lifecycle, operating in our Central Sterilization Units. **Results:** the methodology presented in this paper has a high potential to detect delays, measure efficiency, productivity and costs of the processes, and even, based on the workflow analysis, to be able to improve the processes where MEs are operating. **Conclusion:** furthermore, HTA-based MEs replacement methodology allows to generate cost-effective information for decision-making at the management level.

Resumen

Introducción: *la toma de decisiones sobre cuándo se debe reemplazar el equipo médico (EM) de alta tecnología es un desafío para los hospitales, debido especialmente a su alto costo para las instituciones de salud y al riesgo que podría representar en cualquier práctica o procedimiento médico asistencial. La evaluación de tecnologías sanitarias (ETS) de los EMs permite priorizar su sustitución en un hospital. La mayoría de las evaluaciones de reemplazo de EMs se enfocan únicamente en análisis de costos; sin embargo, estas evaluaciones no consideran el papel completo que juegan los EMs en los procesos de atención médica. En este sentido, también se debe considerar el costo de inversión del equipo y otros factores críticos para evaluar el proceso, los costos y la productividad.* ***Objetivo:*** *este artículo propone una metodología para apoyar en la decisión de reemplazar, o no los EMs, basada en evaluación económica y análisis de procesos de negocio.* ***Material y métodos:***

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se aplican análisis de costo-efectividad, eficacia intermedia y flujo de trabajo del proceso. La mejor alternativa de EMs se identifica a través de un árbol de decisión e índices de tiempo, productividad e indicadores de desempeño. Esta metodología fue probada evaluando, como caso de estudio, si era necesario reemplazar los esterilizadores/lavadoras, que se encuentran en la última etapa de su ciclo de vida, operando en las Unidades Centrales de Esterilización de nuestra institución. ***Resultados:*** *la metodología presentada en este trabajo tiene un alto potencial para detectar retrasos, medir la eficiencia, productividad y costos de los procesos, e incluso, con base en el análisis del flujo de trabajo, poder mejorar los procesos donde operan los EMs.* ***Conclusión:*** *la metodología de reemplazo de EMs basada en ETS, permite generar información costo-efectiva para la toma de decisiones a nivel gerencial directivo.*

INTRODUCTION

Health decision-makers are obliged to use their resources rationally and efficiently based on factors that avoid unnecessary investments that could be a significant economic burden for their organizations. In this sense, the Health Technology Assessment (HTA) supports the decision-making in order to promote an equitable, efficient, and high-quality health system. The HTA uses explicit methods to determine the value of a health technology at different points in its lifecycle. The dimensions of value for a health technology may be assessed by examining the intended and unintended consequences of using a health technology compared to existing alternatives. These dimensions often include clinical effectiveness, safety, costs and economic implications, ethical, social, cultural and legal issues, organizational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population.[1]

The HTA can be applied at different points in the lifecycle of health technology, i.e., pre-market, during market approval, post-market, through to the disinvestment of health technology.[1] In the final stage, it is important to determine when withdrawing health technology from any existing health care practices or procedures that are deemed to deliver little or no health gain because of unresolved performance issues or unresolved safety issues or continuous unreliability or history of serious failure or their high cost of repair making that the device no cost-effective, financially unviable, and therefore do not represent efficient health resource allocation.[2]

Health technology is an intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, medical devices (MDs), medicine, vaccine, procedure, program or system.[1] The MDs can be an article, instrument, apparatus or equipment that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.[3] The Medical Equipment (MEs) is recognized as a category of MDs and are defined as devices, accessories and instruments for specific use, intended for medical or surgical care or exploration procedures, diagnosis, treatment and rehabilitation of patients, as well as those to carry out biomedical research activities.[4]

There are particular characteristics of MDs, such as the device–user interaction, the incremental nature of innovation and the broader organizational impact that lead to additional challenges for HTA. In this sense, there are publications that provide key recommendations for assessment of MDs, as well as, regulatory processes that highlight the need for integrated evaluations,[5-9] and economic evaluation.[10,11] In these publications have been identified that the regionalization may had an influence in the methods of assessing and appraising medical technologies, likewise, economic evaluation is only used as background information in some instances. While many of the principles that guide the economic evaluation of MDs have themselves to those that guide the evaluation of other health technologies, such as pharmaceuticals. Performing an economic analysis of MDs is not straightforward. The cost and effectiveness of given MDs may depend on a number of factors.[12]

In recent years, there has been significant advances in MDs which crucially influence the cost of investment as well as sustainability costs which must be traceable and controllable. Also, is essential to consider initial the planning investment project, the operating cost of the new MD,[13] that should be both effective in improving patient outcomes as well as cost effective before it is implemented into clinical practice.[14]

The cost of repair and maintenance of MEs can be fairly more burdensome than considering its replacement. The decision-making on repair or replacement is a traditional problem in the hospitals. So that is very important consider a planning timely replacement of

MEs to overcome this issue.[15] In this sense, Fennigkoh, in 1992, developed a simple mathematical model to identify and prioritize medical equipment in need of replacement integrating factors as equipment service and support, equipment function, cost benefits, and clinical efficacy.[16] Taylor et al. in 2005, used the Medical Equipment Replacement Score (MERS) system to score the priority replacement for medical devices producing real-time results.[17] Mora, Piña & Ortiz in 2018 developed an indicator considering technical and economic aspects, that provides the functionality condition of the MEs and determines its replacement priority integrating factors as purchase cost at present, maintenance cost, consumables cost and depreciation.[18] Tobey proposed that the replacement should be accomplished through a systematic, evidence-based methodology to replace equipment in a prioritized fashion. Some key factors for replacement are evaluating and scoring these parameters, computerized maintenance, as well as, management system, standards, among others. Tobey mentioned that biomedical engineers have the tools, knowledge, and information to take on a leadership role in this area and be an invaluable resource for health care.[19]

In 2021, Hussien proposed a comprehensive framework for an optimized replacement planning for MDs based on the available budget. The proposed method uses the TFN-AHP model (Triangular Fuzzy Number-Analytic Hierarchy Process) to set up the assessment criteria and evaluate them by contemplating qualitative/quantitative replacement criteria and an optimization technique to generate a prioritized list of devices to be replaced. The proposed TFN-AHP model consists of three steps: identify goal/s (replacement of MEs prioritization in this case), perform device criteria evaluation (second level of the hierarchy structure) and the alternatives (third level of the hierarchy structure).[20] Likewise, in 2021 Liao et al. developed a Markov Chain model to optimize the decision-making process for replacement of MDs integrating technical factors as network problems, accessory problem, physical damage, random failure, tech support, among others.[15]

The studies mentioned provide information for prioritizing the replacement of MEs, but without considering additional elements such as workflow, distribution, usage requirements, human resources, and cost-effectiveness analysis (CEA). Currently, the replacement of MEs is subject to an analysis of benefit, usefulness and safety for the patient and the user, also its significant social impact for the allocation of the budget. The funding to replace MEs can be from the hospital unit's own budget, from institutional programs or even from organizations or foundations that support health investment projects. Whatever the origin of the funding, the purchase request must be supported by a study of the cost benefit of the investment in which reference is made, qualitatively and quantitatively, integrating: a) number of patients who will be treated with the MEs, b) the benefits that the patient and the institution will obtain, c) the estimated cost of the investment to be made, d) the cost of the studies, treatments or process, considering costs direct and indirect (personnel, supplies, services, equipment maintenance, etc.), e) what logistical problem to solves.[21,22]

Therefore, it is very important for the replacement of MEs considering additional elements like workflow, distribution, usage needs, human resources, and CEA. In this paper, we propose a methodology to assess HTA-based MEs replacement using economic analysis including intermediate effectiveness factors, decision-trees for the identification of MEs alternatives, Business Process Modeling (BPM), recommendations about HTA for MDs and implementation of management processes through the definition of time indexes, productivity indicators, and MEs performance. This strategic planning was applied in the last stage of the life cycle[20] of MEs, to objectively determine when to retire MEs from any existing health care practice or procedure.

The methodology was tested to evaluate the convenience of replacing the sterilization and washing machine installed in the Central Sterilization Units of our institution. The evaluation considers whether the technology is still effective or whether its replacement can improve process efficiency to reduce costs and increase productivity. From this information the manager can make decisions for the institution.

MATERIAL AND METHODS

The HTA-based MEs replacement strategic planning is a methodology based not only in key recommendations of HTA for MDs[5-9] and HTA[23] but also in economic evaluation of MDs [10,11], methods of economic evaluation[24] and methodology of Business Process Modeling,[25] as depicted in the flow chart in *Figure 1*.

This methodology consists of three phases integrated, as described below:

1. *HTA for MEs*
   a. Identifying the initial conditions:
      a.1. The actual problem, clinical applications, the human resources (medical staff - physicians, nurses, technicians, engineers), and

the material sources (infrastructure, equipment, and medical supplies) are identified.

- a.2. Identifying MEs alternatives.
- a.3. Identifying the process where the MEs are used and their timelines.

b. List the HTA questions.

- b.1. Comparative assessment, data extraction and analysis, it will be described in the corresponding section.

c. Synthesis: summary answers.

d. Status Question:

- d.1. First case, if the results obtained are not conclusive, it is possible to return to phase B to extract and analyze more information;
- d.2. Second case, the replacement of MEs is prioritized, and
- d.3. Third case, only improvements in the management processes are required.

e. The report is delivered and the board of directors analyzes the outcomes for decision-making.

2. *Comparative assessment, data extraction and analysis. The main elements for clinical application and workflow are identified for every MEs alternative.*

a. High-level Business Process Modeling is used to show a multi-level interrelationship of the workflow (patient-physician-nurse-MEs).

b. Economic evaluation. It will be described in the corresponding section.

c. Time index of the workflow involved in every MEs alternative is defined by measuring time-consuming staff (physician, nurses, and technicians) for each activity.

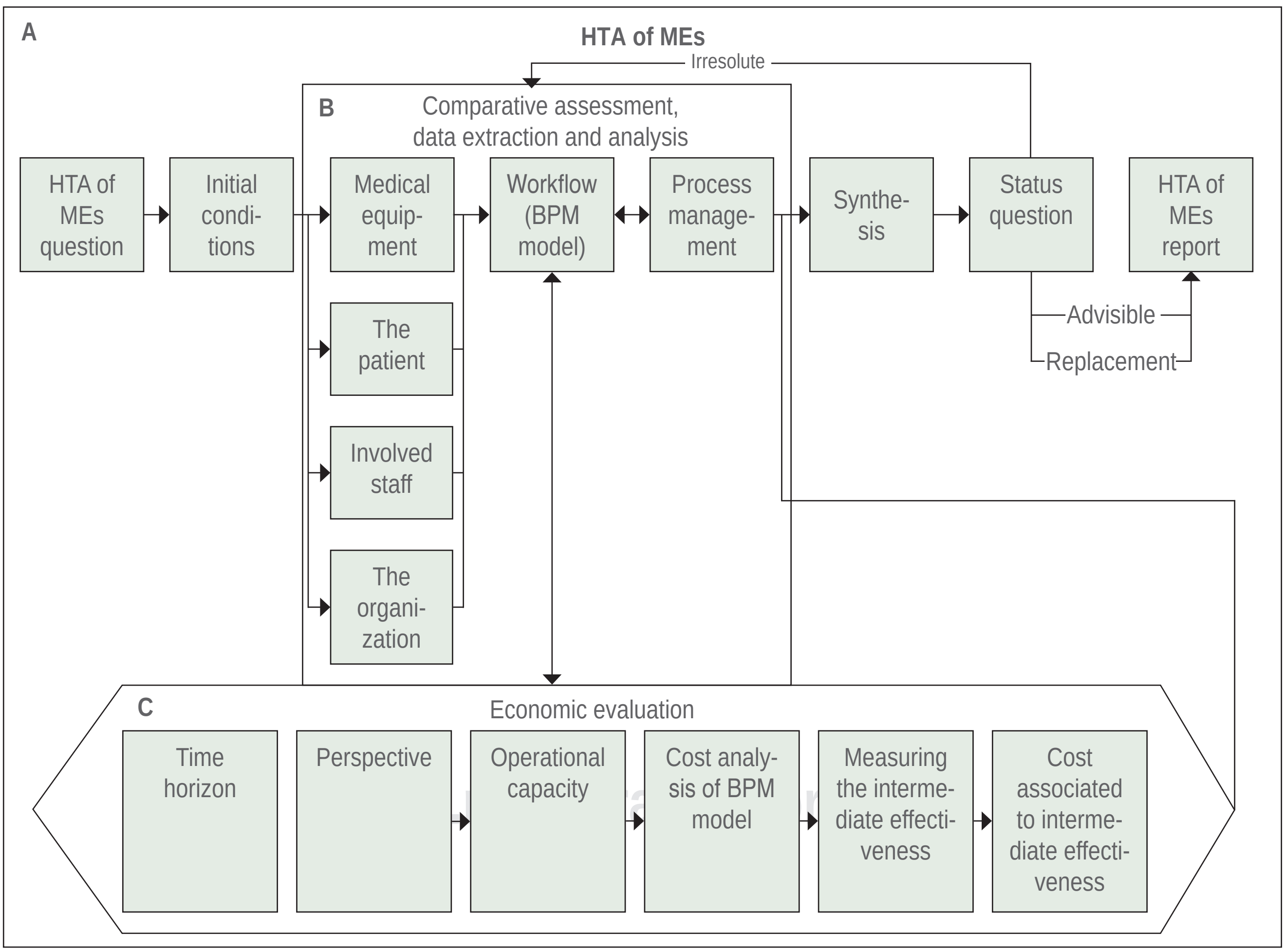

Figure 1: HTA-based MEs replacement methodology. **A)** HTA for medical equipment (MEs). **B)** Comparative assessment, data extraction and analysis. **C)** Economic evaluation.

   d. Process management indicators are established, such as performance, productivity, and efficiency factors, i.e., MEs time out of operation.
3. *Economic evaluation based on CEA, it compares MEs alternatives and considers both costs and consequences.*
   a. The time horizon is established over an analysis period.
   b. The institutional perspective based on the costs of relevant economic factors and operative capacity is defined.
   c. Identification of the economic factors relevant involved in the MEs and the cost analysis is carried out using BPM, as indicated in B1.
   d. Intermediate effectiveness is calculated based on the consequences of applying the MEs, i.e., repeated processes.
   e. The cost associated with intermediate effectiveness is calculated based on point C.3.
   f. The CEA is modeled using the decision tree for MEs alternatives.

It is essential to consider that the intermediate effectiveness is evaluated because this factor represents the impact of the improving process in patient care when using Mes.

RESULTS

Sterilization case study

The Instituto Nacional de Rehabilitación «Luis Guillermo Ibarra Ibarra» (INR-LGII, for acronym in Spanish) in Mexico City has two sterilization units, one in the Orthopedic Care area called the Orthopedic Sterilization Center (OSC) and another in the Burn Care area (CENIAQ, for acronym in Spanish) called CENIAQ Sterilization Center (CSC). In OSC, there are old, obsolete and discontinued MEs (steam sterilizers and washing machines), failing continually, resulting in long periods out of service, impacting the scheduling or even cancellation of surgeries and increasing maintenance costs.

Those facts have given rise to the following questions: Are the current sterilizers still cost-effective for the institution? Will the new equipment improve the process? Should the institution replace the sterilizers and washing devices? We proposed the HTA-based MEs replacement methodology to answer those questions?

First, we identified the MEs used in the process carried out in OSC and CSC. In both cases, the devices are of the same brand and has similar technical characteristics (automatic control cycles). Second, the user areas of the MEs are identified, such as, operating room, emergency room, intensive care and hospitalization. Third, the workflow for the sterilization process is identified, including operating procedures, formats, and fieldwork to morning, evening, and night shifts. The nurse's staff determined the workflow, productivity, and activities time. Likewise, washing, preparation, sterilization, sterile storage, and delivery activities are undertaken in both units. And fourth, the multi-level interrelationship of the workflow was developed through the BPM model using the open-source software BizAgi Process Modeler.[26] *Figure 2A* shows five complex activities or sub-processes and eleven simple activities in the OSC case where MEs is used. Likewise, *Figure 2B* shows five complex activities or sub-processes and five simple actions in the CSC case where MEs is used.

The BPM diagram allowed us to analyze the workflow where MEs are involved during the sterilization process. As a result, it is possible to identify not only the workflow but also the client (a surgical nurse who demands the material), the activities, and makers, that is to say, the nurse (who carries out the sterilization procedure), and the supplier (who transports material).

Finally, in *Figure 2A and 2B*, we can appreciate some differences in workflow between the OSC and the CSC. The main one is that CSC does not involve the reusable equipment process when the supplier delivers material/instrumental for sterilization. Instead, the process can be recorded directly, so the nurse does not wait as long to check the material provided by the supplier.

Workflow indexes and process management indicators

The workflow indexes involved in the steam sterilization processes are described in *Table 1*, for each activity recorded on site. These indexes are classified according to every stage of the steam sterilization process to include the elements involved (steam sterilizer, washing machine, human resources) and they are considered in both cases OSC and CSC. *Table 1* indicates the definition of annual workflow indexes and the results obtained.

Two process management indicators have been established to measure the profits and quality improvements, as shown in *Table 2*. The first indicator defines

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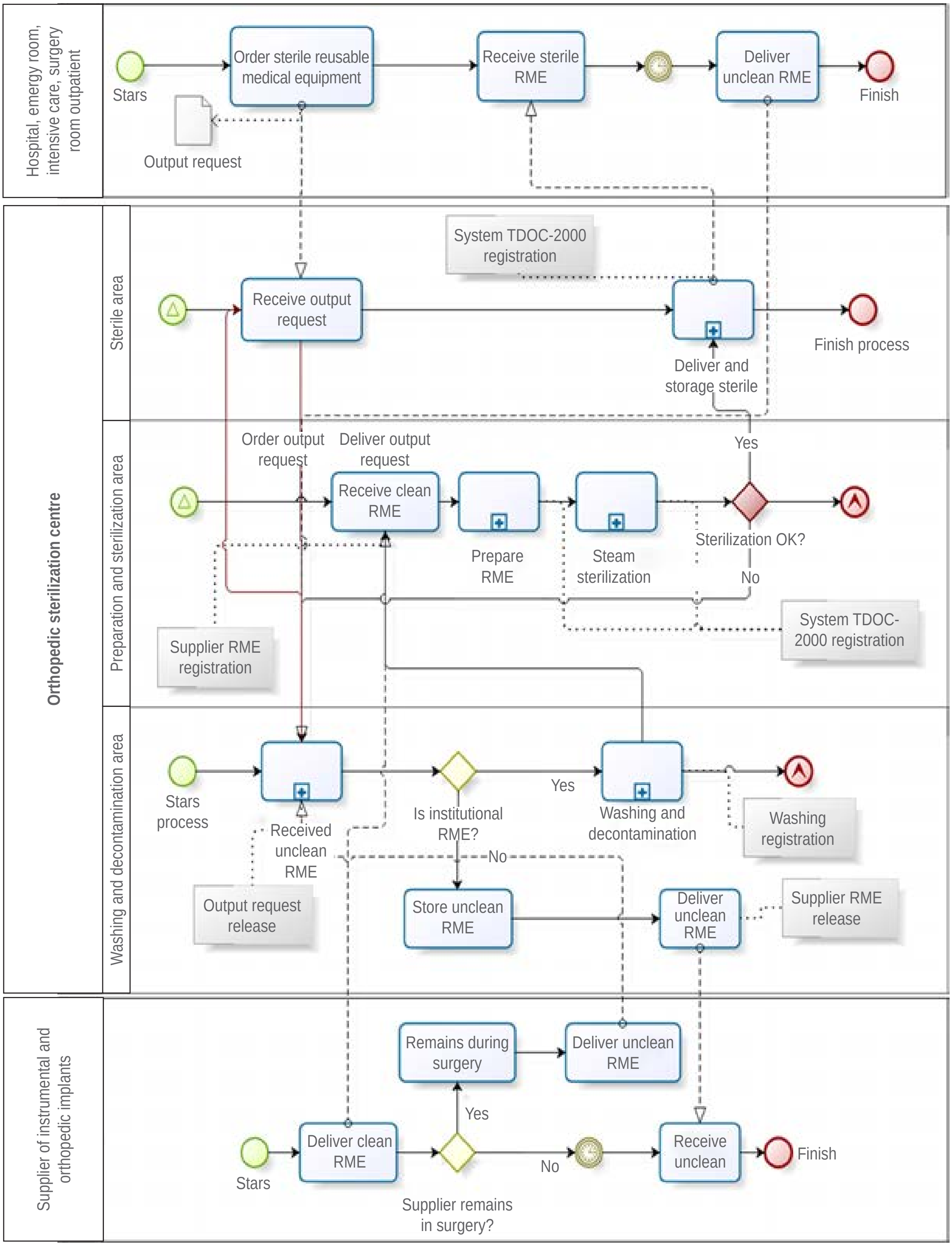
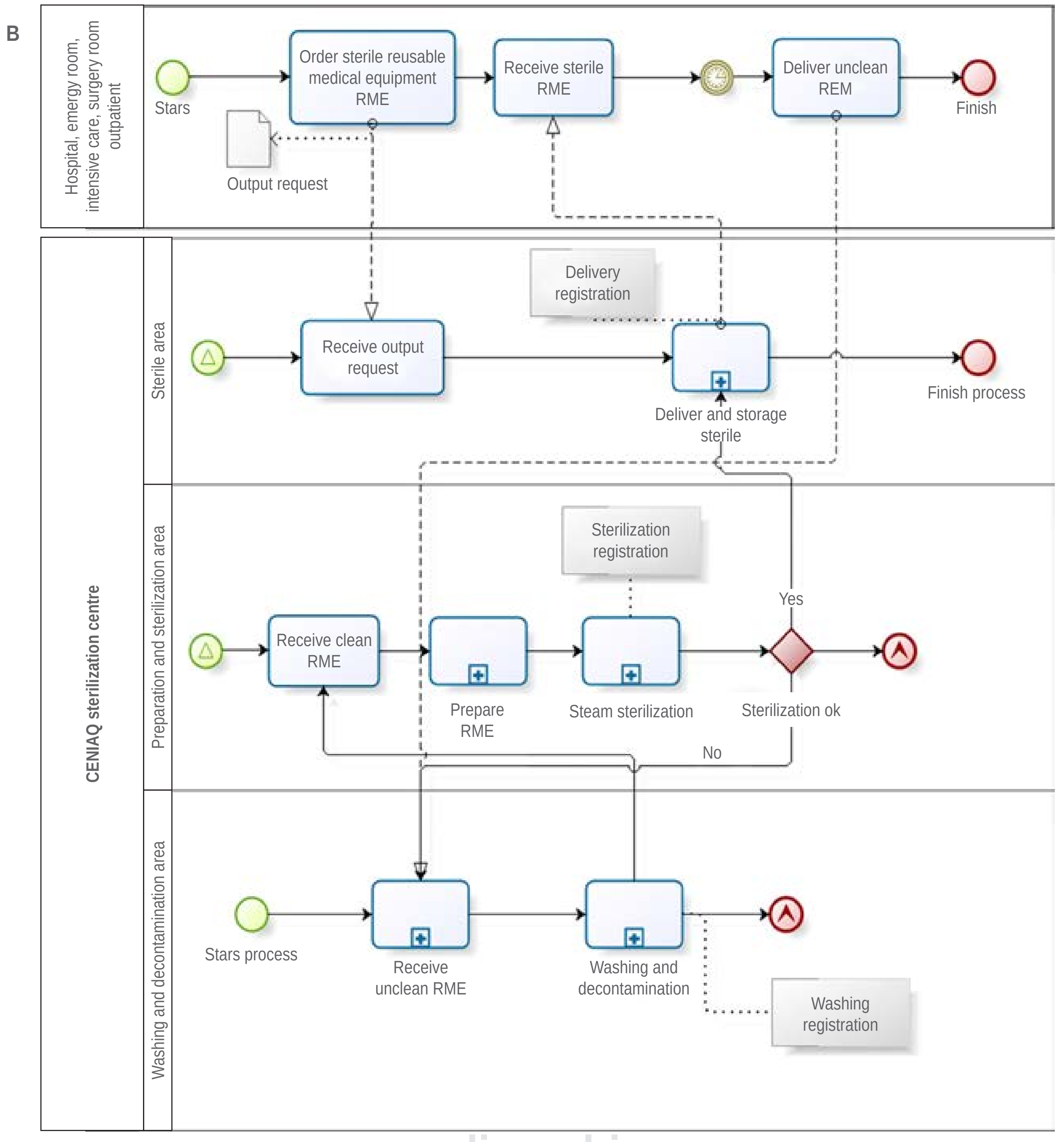


Figure 2: A) Flow chart of the orthopedic sterilization centre process. **B)** Flow chart of the CENIAQ sterilization centre process. RME = reusable medical equipment. CSC = CENIAQ sterilization centre. OSC = orthopedic sterilization centre.



Continue Figure 2: A) Flow chart of the orthopedic sterilization centre process. **B)** Flow chart of the CENIAQ sterilization centre process. RME = reusable medical equipment. CSC = CENIAQ sterilization centre. OSC = orthopedic sterilization centre.

the productivity (rate of sterilization process, RP). The second establishes the process's performance (rate of steam sterilizer, RS and rate of Washer, RW). These indicators are affected mainly by days of failures of the MEs and maintenance (efficiency factor, EF). *Table 2* shows the productivity (RP) and performance (RS and RW) indicators, as well as, annual EF for OSC and CSC cases.

Economic evaluation

The economic evaluation is performed from the workflow indexes and process management, as described below. The first step is to define the period for cost analysis; a period of one year was selected. Once the time horizon is set, the operative capacity of the both centrals is examined, including the number of sterilization cycles (SC) and the number of sterilized units (SU). In all cases, one SC was achieved by Sterilization Process (SP), i.e., the number of SC was the same for SP. *Table 3* shows the annual operative

Table 1: Definition of workflow indexes and annual workflow indexes.

Index	Definition	Formula	OSC	CSC
TTSS	**Total time of steam sterilization process** (h). Is the sum of times activities, from washing to delivery of sterile material	$TTSS = \sum_{m=1}^{m=j} t_m$	TTSS = 6.43	TTSS = 8.66
ATC	**Average time of chilled-of sterile bulk** (h). Is time that the material is removed from sterilizer (t_r), minus the time the sterilization cycle ended (t_f)	$ATC = t_r - t_f$	ATC = 0.46	ATC = 1.32
ATS	**Average time of sterilization cycle** (h). Is time the sterilization cycle ended (t_f) minus the start time of the sterilization cycle (ti)	$ATS = t_f - t_i$	ATS = 1.20	ATS = 0.80
ATW	**Average time of washing cycle** (h). Is the recording time when washing cycle ended (t_{fw}) minus recording time of washing cycle start (t_{iw})	$ATW = t_{fw} - t_{iw}$	$ATW_i = 0.78$ $ATW_u = 0.19$	$ATW_i = 0.62$ $ATW_u = 0.29$
ATD	**Average time to deliver sterile material** (h). Is the time when nurse deliver of sterile material (t_e) minus time when surgical nurse demand sterile material during surgery(t_s)	$ATD = t_e - t_s$	ATD = 0.03	ATD = 0.18

OSC = orthopedic sterilization center. CSC = CENIAQ sterilization center. h = hours. m = time of each activity. j = number of activities. t_r = material removal time. t_f = final-time of sterilization. t_i = initial-time of sterilization. t_{fw} = final-time of washing. t_{iw} = initial-time of washing. t_e = time for delivery sterile material. t_s = time for demand sterile material. ATW_i = average time of washing cycle of instrument washer. ATW_u = Average time of washing cycle of ultrasonic washer.

Table 2: Definition of process management indicators and annual result for orthopedic sterilization center and CENIAQ sterilization center processes.

Indicator	Name	Definition	Formula	OSC	CSC
Productivity	RP	Rate of Sterilization Process. Sterilization process in a day	$RP = \frac{24 * SN}{TTSS} * EF$	RP = 4.80	RP = 4.70
Performance	RS	Rate of Steam Sterilizer. Sterilizations cycles done in a day	$RS = \frac{24}{ATS} * EF$	RS = 13.6	RS = 29.30
	RW	Rate of Washer. Wash cycles done in a day	$RW = \frac{24}{ATW} * EF$	$RW_i = 9.80$ $RW_u = 36.54$	$RW_i = 24.10$ $RW_u = 77.01$
Efficiency Factor	EF	Equipment Efficiency. Probability that MEs is operating in a year	$EF = 1 - \left(\frac{OUT}{365}\right)$	$EF_{average*} = 0.43$ $EF_{Steam\ Sterilizer} = 0.68$ $EF_{Ultrasonic\ Washer} = 0.30$ $EF_{Instrument\ Washer} = 0.32$	$EF_{average*} = 0.84$ $EF_{Steam\ Sterilizer} = 0.98$ $EF_{Ultrasonic\ Washer} = 0.94$ $EF_{Instrument\ Washer} = 0.62$

OSC = orthopedic sterilization center. CSC = CENIAQ sterilization center. RP = rate of sterilization process. RS = rate of steam sterilizer. RW = rate of Washer. EF = efficiency factor. RW_i = Rate of Washer of instrument washer. RW_u = Rate of Washer of ultrasonic washer.
Where SN is the total of steam sterilizer realized. OUT represents the days out of service in a year.
* AVERAGE Efficiency represents the impact on productivity of both centrals.

capacity for OSC and CSC and their Rate Loading (RL, units/cycle).

The second step is to carry out the cost analysis for this process. We consider the Cost of Sterilization Process (CSP), defined as the sum of the annual costs of each relevant economic factor of the process by SP (C_i), as shown in Equation 1.

$$CSP = \frac{\sum_{i=1}^{n} C_i}{SP} \quad ...(1)$$

The C_i factors are identified and classified in fixed costs (FC) and variable costs (VC). Among FC, we can mention the physical area, MEs (steam sterilizer and washing machine), and medical instruments. We can remark medical supplies (cotton, clothing, envelopes, biological and chemical indicators, labels), electrical consumption of MEs, and human resources (nurses, engineers, and staff contracts) as VC. Macro-costing criteria were applied to calculate FC and VC. For example, the biomedical engineer performs and oversees maintenance; we calculate person-hour & salary-day. For the case of the nurse, it is considered the number of SP that they do per day as man-SP & salary-day.

The energy cost is calculated from the efficiency factor *(Table 3)*, the power consumption according to the electrical specifications of each piece of equipment, and the rate of the company that supplies electricity. CSP is computed for both centrals in the same temporality using the Consumer Price Index issued by the Bank of Mexico.[27] The CSP is calculated in Mexican pesos and converted to USD at the exchange rate of January 2022, as shown in *Table 3*.

As mentioned in HTA-based MEs replacement methodology, intermediate effectiveness (IE) represents the effect of using MEs on patient care. Therefore, the third step in this study is to determine IE, defined as performing sterilization processes without repetitions, as can be seen in Equation 2.

$$IE = 1 - \frac{RSP}{SP} \quad ...(2)$$

Repeated Sterilization Process (RSP) is defined as failure sterilization units (SUf) in relationship to Rate Loading (RL), as can be seen in Equation 3. In this order, SUf was identified at the end of cycle sterilization, this allowed us to perform a cost-effectiveness analysis of steam sterilizers and washing machines in OSC and CSC. The Annual Operative Capacity, including RSP for OSC and CSC, is shown in *Table 3*.

Table 3: Annual operative capacity, repeat sterilization process and cost of sterilization process.

Central	SC (cycles)	SU (units)	RL (units/cycle)	SUf (faulty units)	$RSP = \frac{SUf}{RL}$	CSP	RSP	IE	Cost/IE (USD)
OSC	4,598	82,764	18	28,980	1,610	$352.45	0.3502	0.6498	$542.39
CSC	2,211	54,169	24.50	245	10	$309.74	0.0045	0.9955	$311.14

SC = sterilization cycles. SU = sterilized units. RL = rate loading. SUf = faulty units. RSP = repeated sterilization process. CSP = cost of sterilization process. IE = intermediate effectiveness. SP = sterilization process. OSC = orthopedic sterilization center. CSC = CENIAQ sterilization center.

$$RSP = \frac{SUf}{RL} \quad ...(3)$$

The fourth step is to calculate the cost of RSP (CRSP) under the same criteria and formula used to calculate CSP *(Table 3)*. We identified that RSP workflow is performed similarly to SP workflow for this calculation. For example, when a SUf is detected, the nurse sends the material for washing and decontamination to begin an SP again. Now, we have all elements to make the CEA, as can be seen in *Table 3*. The next step is to make the decision tree model *(Figure 3A)* for each MEs alternative. This tree compares the CSP and CRSP for both OSC and CSC, this modeling includes the IE for CSP. The results are put on a cost-effectiveness plane, as shown in *Figure 3B*.

Interpretation

The results for OSC case are located in the upper-left position of this plane *(Figure 3B)*, which indicates low effectiveness and high costs, while for CSC case, the result is located in the lower-right position of the plane (see *Figure 3B)*, that is, high effectiveness and low costs. The interpretation is based on the cost-effectiveness decision matrix proposed by Drummond.[24] According to this guide, devices for OSC case cause poor efficiency, performance and low productivity and generate a more expensive process than the CSC case, this outcome falls on the element 7, introduce new technology of that matrix, which means that: steam sterilizers and washing devices located in OSC should be replaced.

Finally, a report is prepared and sent to the Director (decision-maker of the institution) to support his/her decision to replace, or not, the OSC devices.

DISCUSSION

HTA is a technique to provide reliable, pertinent, relevant and useful information to health professionals, so

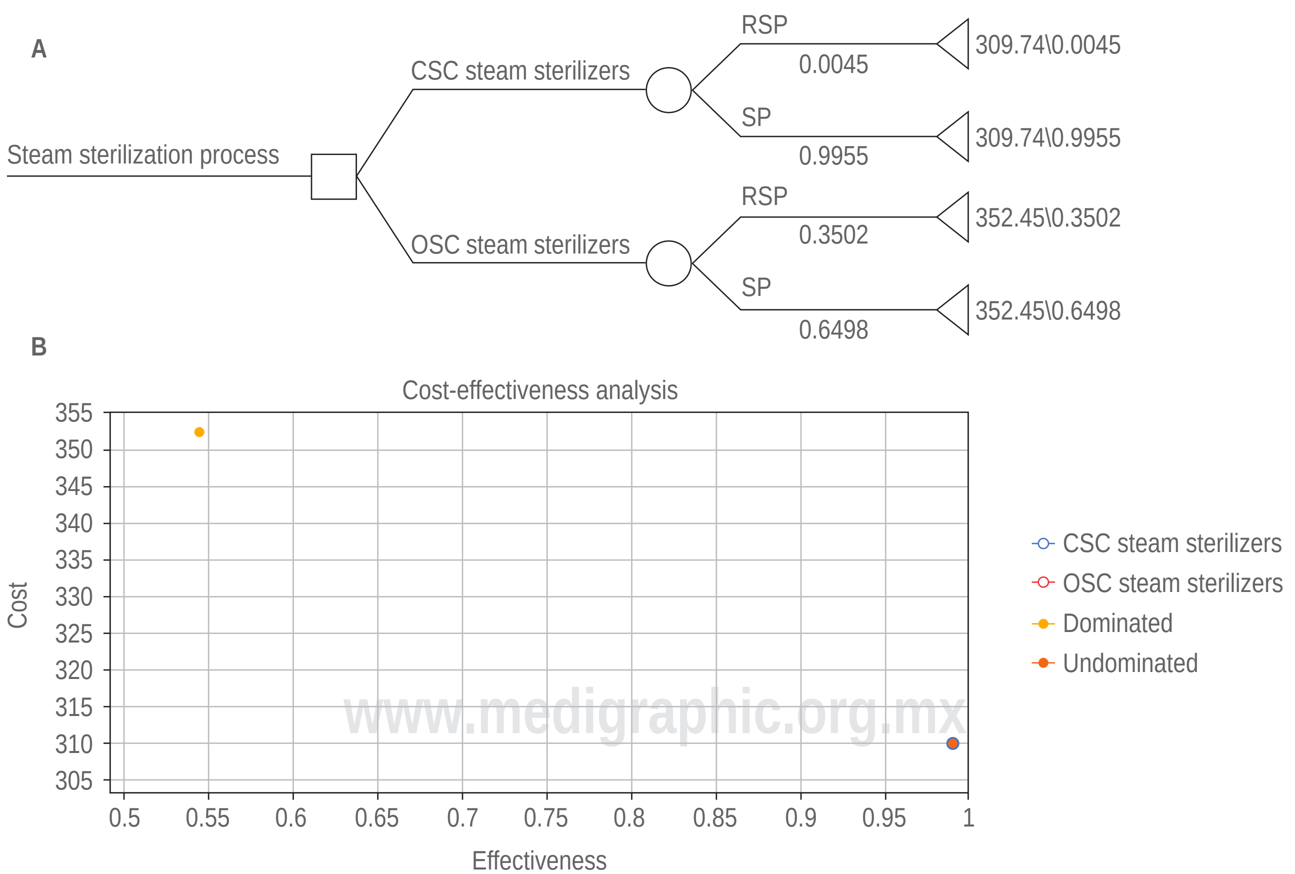


Figure 3: A) Cost-effectiveness analysis decision tree. **B)** Cost-effectiveness analysis plane.
CSC = CENIAQ sterilization center. OSC = orthopedic sterilization center.

that it serves to support decisions and health policies. The quality and efficiency of health care services depend not only on qualified personnel and very clear and precise procedures but also of high technology MEs, so their acquisition or replacement is a challenge due to the high costs that it represents for the health system.

There have been significant advances in high-tech MEs which crucially influence the cost of investment as well as maintenance costs which must be traceable and controllable. It has been mentioned in the literature that it is essential to consider initial the planning investment project, the operating cost of the new ME,[13] that should be both effective in improving patient outcomes as well as cost effective before it is implemented into clinical practice.[14]

However, very little has been published regarding when MEs should be replaced in clinical practice. For this purpose, some authors have developed mathematical models to prioritize the replacement based on device functional status,[15-20] others focus on cost-utility analysis and results are reported in terms of intermediate outcomes, such as success rate, complication rate, procedure duration, diagnostic performance, and level of measurement.[12]

Justifying the request for MEs replacement either with mathematical models, or based on a limited institutional budget, or even just a cost analysis, does not provide enough information for decision-making to replace medical devices, particularly high-tech ones.

To cover this gap, the HTA-based MEs replacement methodology proposed in this paper provides a quantitative and qualitative method considering economic analysis by applying CEA and supported by business process modeling, user requirements, functional status and maintenance of the MEs and expenses associated with their operation. Based on the indexes and indicators, the relevant economic factors were identified to measure:

1. The procedure where the MEs are involved;
2. MEs performance, and
3. The productivity of the medical services.

This method compares MEs alternatives and considers both costs and consequences. Through workflow analysis and process modeling, using BPM, the users and their interrelationships are identified. Intermediate effectiveness factors (#repeated studies/services) represents the impact for improving the process where MEs are used, they have an indirect effect on the patient's health.

From the cost-effectiveness analysis using intermediate measures (components for economic evaluation), we identify not only the actual cost of the process but also the number of studies/services, fixed cost and variable costs. The intermediate effectiveness factors have a positive impact on institutional management because they can be considered in real intra-hospital costs.

The decision tree graphically represents each MEs alternative, comparing it with its effectiveness. These results allow prioritizing the replacement of MEs, they are also useful to improve processes, reduce costs, and consequently, the quality of patient care is improved.

CONCLUSIONS

The strategic planning presented in this paper has a high potential for work in health technology management. It is possible to detect delays, measure efficiency, productivity and costs of processes where MEs are involved. HTA-based MEs replacement methodology opens a space of opportunity to generate interdisciplinary technology assessment groups to generate information for decision-making at the management level.

Likewise, it provides a reference base that allows identifying lines of action to follow to strengthen the institutional infrastructure when it is planned replacement or even incorporate large, complex or high-tech MEs that imply high investment in direct costs, infrastructure and specialized health staff.

Finally, this methodology can be applied in a systematic, quantitative, standardized and customized way for each hospital to obtain evidence to write a HTA report used in business decision-making by managers to justify or encourage replacement of health technology in the final stage of the MEs lifecycle

References

1. International Network Agencies for Health Technology Assessment. HTA Glossary.net. 2012. Available in: http://htaglossary.net/health+technology+assessment
2. Fiedler BA, David Y. Reframing product life cycle for medical devices. In: Managing medical devices with a regulatory framework. Amsterdam; Cambridge, MA: Elsevier 2017. pp. 3-16.
3. World Health Organization. Health Topics.2022. Available in: https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices
4. Ayala R, Arellanes EE, Moreno E. Gestión de equipo médico. Centro Nacional de Excelencia Tecnológica en Salud. 2020.

5. Ciani O, Wilcher B, Van Giessen A, Taylor RS. Linking the regulatory and reimbursement processes for medical devices: the need for integrated assessments. Health Economics. 2017; 26 (Suppl. 1): 13-29.
6. Polisena J, Castaldo R, Ciani O, Federici C, Borsci S, Ritrovato M et al. Health technology assessment methods guidelines for medical devices: how can we address the gaps? the International Federation of Medical and Biological Engineering Perspective. Int J Tech Assess Health Care. 2018; 34 (3): 276-289.
7. Tarricone R, Torbica A, Drummond M, MEDTECHTA Project Group. Key recommendations from the MedtecHTA project. Health Economics 2017; 26 (Suppl. 1):145-152.
8. Blüher M, Saunders SJ, Mittard V, Torrejon R, Davis JA, Saunders R. Critical review of European health-economic guidelines for the health technology assessment of medical devices. Front Med. 2019; (6): 278.
9. Drummond MF, Tarricone R, Torbica A. Economic evaluation of medical devices. In: Hamilton, J.H., (ed.) Oxford Research Encyclopedia of Economics and Finance. Oxford University Press, Oxford. 2018.
10. Tarricone R, Callea G, Ogorevc M, Prevolnik V. Improving the methods for the economic evaluation of medical devices. Health Economics. 2017; 26 (Suppl. 1): 70-92.
11. Tarricone R, Torbica A, Drummond M F. Challenges in the assessment of medical devices: the MedtecHTA project. Health Economics. 2017; 26 (Suppl. 1): 5-12.
12. Kingkaew P, Teerawattananon Y. The economic evaluation of medical devices: challenges. J Med Assoc Thai. 2014; 97 (Suppl 5): S102-107.
13. Bektemur G, Muzoglu N, Ali-Arici M, Kaya-Karaaslan M. Cost analysis of medical device spare parts. Pak J Med Sci. 2018; 34 (2): 472-477.
14. Sprague S, Quigley L, Adili A, Bhandari M. Understanding cost effectiveness: money matters? J Long Term Eff Med Implants. 2007; 17 (2): 145-152.
15. Liao HY, Cade W, Behdad S. Markov chain optimization of repair and replacement decisions of medical equipment. Resour, Conserv Recycling. 2021; 171: 105609.
16. Fennigkoh L. A medical equipment replacement model. J Clin Eng. 1992; 17 (1): 43-47.
17. Taylor K, Jackson S. A medical equipment replacement score system. J Clin Eng. 2005; 30 (1): 37-41.
18. Mora-García T, Piña-Quintero F, Ortiz-Posadas M. Medical Equipment Replacement Prioritization Indicator Using Multi-criteria Decision Analysis. In: Hernández HY, Milián NV, Ruiz SJ. Progress in Artificial Intelligence and Pattern Recognition. IWAIPR 2018.
19. Tobey J. Medical equipment replacement planning. In: Clinical Engineering Handbook, Florence Italy, Elsevier, 2020; pp. 227-235.
20. Hussien HW. Optimized medical equipment replacement planning. Addis Ababa University. Center of Biomedical Engineering, Etiopía, 2021.
21. Secretaría de Hacienda y Crédito Público. Acuerdo por el que se modifican los lineamientos para el registro en la cartera de programas y proyectos de inversión. Diario Oficial de la Federación. 2021.
22. Instituto Nacional de Rehabilitación. Políticas, bases y lineamientos generales para la recepción, aceptación, registro y control de las donaciones en especie que reciba el Instituto Nacional de Rehabilitación. 2009.
23. Kristensen F, Sigmund H. Health Technology Assessment Handbook. Danish Centre for Health Technology Assessment, Denmark, 2007.
24. Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. Methods for the economic evaluation of health care programmes, Oxford university press. 2015.
25. Tomaskova H, Maresova P, Penhaker M, Augustynek M, Klimova B, Fadeyi O, Kuca K. The business process model and notation of open innovation: the process of developing medical instrument. J Open Innov Tech Market Complexity. 2019; 5 (4): 101.
26. BizAgi, BizAgi Process Modeler Version 3.8.0.206. 2021. Available in: http://www.top4download.com/bizagi-process-modeler/crhbwqyd.html
27. Instituto Nacional de Estadística y Geografía (INEGI). Índice Nacional de Precios al Consumidor (INPC). Available in: http://www.inegi.org.mx.