A socio-technical approach to assist the selection of medical devices in hospital settings:

Process improvement in an anesthesiology context

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Abstract

The continuous innovation in health technologies demands their evaluation to guarantee their ability to deliver the upmost care, quality, safety and value for money. However, few medical devices are evaluated in hospitals within structured formats integrating the views and perspectives of hospital stakeholders, especially in the anesthesiology context. Multicriteria Decision Analysis (MCDA) has been increasingly explored within Health Technology Assessment, but few studies have been developed in hospital settings. This study aims to develop a socio-technical approach to improve the process of evaluating anesthesia kits currently applied at Hospital Santa Maria through inclusion of relevant experts, to promote consensus, and use of technological tools to bring innovation and support to a more transparent and structured evaluation process. A MCDA socio-technical approach for process improvement in the evaluation of anesthesia kits, named MD – Evaluation tool, was designed. Therefore, exploratory interviews were made with anesthesiologists to understand their views and concerns on anesthesia kits. Then, the MACBETH approach was applied to build individual quantitative evaluation models with anesthesiologists, capturing each perspective, and then to build a compromise group model through qualitative protocols of questioning, using web-based platforms and a decision-conference. The aftermath of this study is the improvement of the evaluation process through a decision-support tool, composed by an Excel tool and the MACBETH software, suitable to guide the DM during the evaluation and selection process of anesthesia kits. The validation of this tool in the anesthesiology context indicates that it could be adapted and implemented to improve evaluation processes for other medical specialties.

Keywords: MCDA; Decision Support Model; Anesthesiology; MACBETH; Procurement; Hospital-based HTA; Medical Devices

1. Introduction

Nowadays, the research and innovation in healthcare technology as well as its broad adoption are majorly driven by the need to guarantee a continuous improvement in healthcare quality and safety. However, healthcare technology acquisition faces some challenges, such as, a significant increase in health expenditure. To promote the introduction and diffusion of health technology whereas maintaining financial sustainability, government institutions have increased the implementation of Health Technology Assessment (HTA) and procurement practices. [1] Within their application, a major consideration is the fact that hospitals are complex social systems that embrace structural and technological aspects and the impact of individual entities as well as the cost-effectiveness trade-off. [2]

The healthcare related decisions are usually carried out by decision-makers (DM), which must consider the conflicting trade-offs between options as well as balance the multiple objectives. [3] This amount of information usually is quite overwhelming, therefore proving difficult to process and systematically evaluate. Since this task may include several DM, the difficulty increases due to the individuals' different priorities and perspectives. To overcome these adversities and increase the consistency and legitimacy of decisions, one must introduce a structured approach to provide support in decision-making, known as multiple criteria decision analysis (MCDA). The MCDA approach encompasses several methods which appraise alternatives according to multiple criteria to reach a decision with multiple goals.[3]

The MCDA approach can be combined with HTA to aid in the assessment of medical devices. HTA can act as a bridge between clinical research and effective prioritization during decision-making. Thus, it involves a thorough assessment of evidence that can help the DM understand the relative value of heath technologies, such as medical devices.[4]

The present study addresses the process of evaluation and, subsequently, acquisition of medical devices in hospital settings. More precisely, the development of a new socio-technical approach that improves the evaluation process of anesthesia kits currently applied at Hospital Santa Maria, through the inclusion of more experts and use of technological tools to bring innovation and support to a more transparent decision-making organizational structure. The multi-dimensional complexity of this assessment, going from budget constraints to diversity of perspective and clinical experience regarding a certain medical device, will be explored. Furthermore, a decision-support tool will be built to aid in this process.

2. Literature Review

The neuraxial anesthesia and analgesia techniques comprise spinal, epidural and combined spinal-epidural blockade. [5] The administration of local anesthetics in the neuroaxis can either trigger a loco-regional blockade in surgical procedures or provide pain management after surgery via epidural infusions, through a catheter.[6] [7] Thus, the injection site of local anesthetics can be made in the spinal cord or the epidural space. [5]

The medical procedures performed using either spinal, epidural or combined spinal-epidural blockade can be associated with possible complications and morbidities. For instance, a morbidity which extends transversely to all the mentioned blockades is the postdural puncture headache. This is caused by the needle accidentally puncturing the dura membrane, which odds of happening may increase according to the specifications of the medical device. [8] [9]

To build an approach capable of capturing all the decisive factors as well as the multiple goals to consider during the evaluation of anesthesia kits, the implementation of a MCDA framework is the right course. MCDA have been successfully implemented to support decision-making in a wide variety of areas, from sustainable energy to budgeting. The increasing appliance of MCDA is due to its potential for improving the quality of the decision process by leading a more explicit, rational and efficient path than deliberative processes. [10] In addition, MCDA approaches are often described as a set of methodologies that allow to simultaneously explore the multiple and conflicting decision-making criteria as well as try to measure the reliability and credibility of the possible alternative solutions. Thus, MCDA methods appraise multiple clinical endpoints and structure complex decision problems in healthcare decision making. The main goal is to produce an optimal and transparent clinical decision process to, consequently, produce a consistent choice and increase the legitimacy of decisions, minimizing the responsibility of the final decision-maker. [11] [12]

The MACBETH is a qualitative swing weighting approach, known as a cognitively friendly approach in empirical settings since it's based on an interactive pairwise comparison solely through qualitative judgements. [13] [14] This process has been reported to have a positive impact since asking the stakeholders to express themselves qualitatively rather than numerically it leads to a reduction in the cognitive load which turns into a more natural evaluation process.[13] [14]

The business process reengineering (BPR) concept has been successfully applied not only in healthcare but also in other industries. Even if, at a first glance, industry may not be the first impression about healthcare, this huge sector involves a significant amount of logistical operations. When necessary, business process reengineering can be applied, for example, on purchasing and material management to produce a sustainable healthcare design. [15]

Despite the willingness to apply the MCDA techniques in healthcare, there is a deficit of guidelines and standards of which technique to employ in a specific context. This is relevant especially to avoid deducing inaccurate evidence and misleading the DM. [12]

3. Methodology

Throughout the whole process several stakeholders intervene and add-value and expertise. Thus, the types of stakeholders involved are the DM, the anesthesiologist that previously was solely responsible to select the anesthesia kits and gives the final approval throughout the several steps of the new process; and the experts, representing the group of anesthesiologists that belong to different subspecialties and will provide their input.

The developed socio-technical approach, named MD-Evaluation tool, it will be explicitly presented (Figure 1).

3.1. Modelling the current evaluation system

The fundamental concepts of business process reengineering (BPR) as well as screening criteria were used as inspirational guidelines. For instance, one of the BPR principle states that for rethinking and redesigning the business process, firstly it's necessary to understand the current situation and, only then, build a thorough reengineered process. In addition, suggests that this assessment is documented using, for example, flowcharts. Thus, semi-structured exploratory interviews were conducted to gain an insight from the stakeholders on which aspects need to be enhanced. As a result, the collected data allowed to identify the challenges in the current evaluation process:

- The lack of a technological tool as a mean to support and ease the evaluation process;

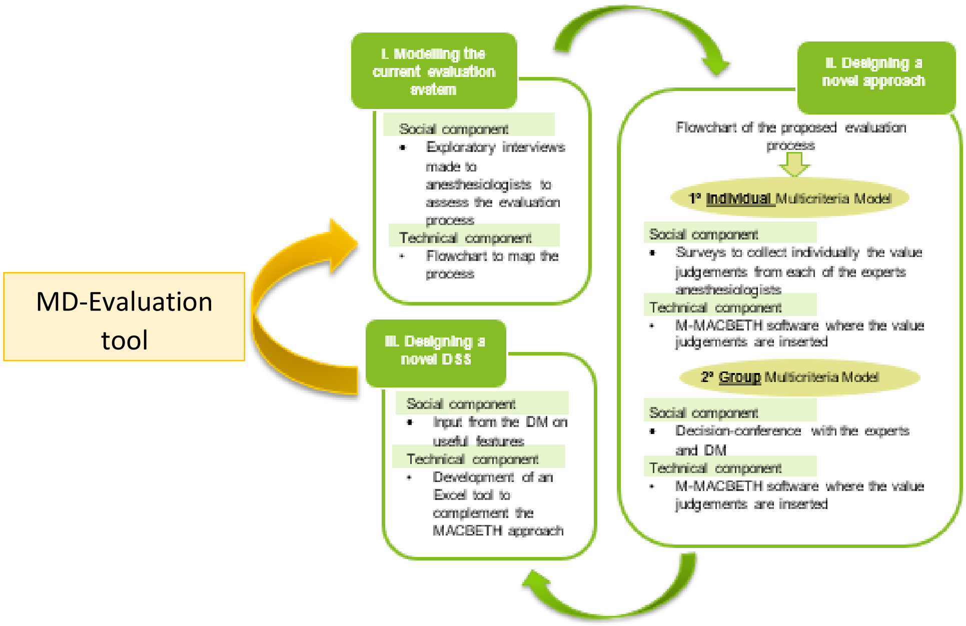

Figure 1 - General overview of the whole methodology of the proposed socio-technical approach, the MD-Evaluation tool.

- Limited exchange of perspectives and values between stakeholders;
- Lack of registered documentation to corroborate DM's final decision;
- Discontent of some stakeholders with the final decision.

In addition, the input regarding the financial aspect indicated that, usually, the received proposals, for each type of anesthesia kit, do not have a significant difference in price between the medical companies. In addition, the criterion of adjudication expressed in article 139º of the Public Contract Code states that the chosen proposal should be the most economical advantageous, if properly justified that the best proposal is other somewhat more expensive, usually the suggestion is accepted. Therefore, price is not a crucial criterion for the DM when contemplating the available options.

3.2. Designing a novel approach

As mentioned, exploratory interviews were conducted to assess the current state of the evaluation process to understand how to redesign it and then document the proposed evaluation process in a flowchart. Then, a web-based platform, the SurveyMonkey, is used to perceive and structure the multiple factors to evaluate the anesthesia kits. After, another survey is implemented to collect the value judgements of each expert to build individual multicriteria models in MACBETH. Then, a decision-conference with the experts and DM allowed to build a group multicriteria model in MACBETH.

3.2.1. MACEBTH approach

The MACBETH approach has been defined as "an interactive approach that uses semantic judgements about differences of attractiveness of several stimuli to help a decision maker quantify the relative attractiveness of each". Thus, the main upside is to not require direct numerical representation but rather express a qualitative judgement. [16]

An elicitation of key aspects is made to determine the evaluation criteria Ei that will define the value tree in MACBETH. The descriptors of performance Pi are defined as a set of impact levels for each criterion i. The set of performance levels is ranked on order of attractiveness with anchors, both a "neutral" and "good" level, which will be assigned the 0 and 100 scores, respectively. [16] A pairwise comparison between each pair of impact levels Lx and Ly, with $x > y$, is made to determine the relative difference of attractiveness between Lx and Ly. The experts answer according to the MACBETH scale with a "no", "very weak", "weak", "moderate", "strong", "very strong" or "extreme" rating. These value judgments will be inserted in the MACBETH software and originate a numerical value scale per criterion and help to determine the weights of criteria.

Afterwards, by considering the value scale score of each alternative A in each criterion i as well as the weights for n criteria it's, thereby, possible to obtain an overall performance score $V(a)$ for each alternative, accordingly to the additive aggregation model:

$$V(A) = \sum_{i=1}^{n} w_i v_i(A) \text{ with } \sum_{i=1}^{n} w_i = 1 \text{ and } w_i > 0$$

$$\begin{cases} v_i(Good_i) = 100 \\ v_i(Neutral_i) = 0 \end{cases} \text{for } i = 1, \dots, n \qquad (1)$$

where w_i represents the weight of a criterion i and v_i the value of local performance of an alternative in that criterion. Also, by convention, the sum of weights must be equal to 1 and the weight of each criterion must be positive. [17]

3.2.2. Structuring the multicriteria models

To define the criteria and descriptors of performance a web-based platform, designated SurveyMonkey, is applied to elicit the key aspects and concerns when evaluating anesthesia kits. The questioning protocol enquired about the characteristics that would exclude the selection of a certain anesthesia kit, the main concerns directly related to the anesthesia device or what are the essential outcome goals to consider that the treatment performed with the anesthesia kit was successful, among other topics. Upon receiving the answers from the experts, the information was gathered and clustered with the aid of the DM to define the criteria and respective performance levels. Five criteria were defined, namely the medical device's handling, the technique efficiency, the functional recovery, the patient satisfaction and morbidity.

3.2.3. Individual multicriteria model

To model the value judgements of each participant and avoid any influence or group bias, the web-based survey platform, SurveyMonkey, is once more applied. The purpose is to allow a free expression of each expert and make them familiar with the process. The individual value judgements are collected and, based on them, build the value scales for criteria and, subsequently, obtain the criteria weights. Therefore, for each expert, it is asked to specify the difference of attractiveness between performance levels, according to the MACBETH scale. According to good practices and to reduce eventual inconsistencies within the multicriteria decision-making model, the pairwise comparison of performance levels was made using the two anchors already stipulated, the "good" and "neutral" reference levels. Thus, for each criterion, it was asked how each anesthesiologist classified the improvement necessary for the performance levels below the "neutral" level to achieve that same "neutral" level. Simultaneously, considering the performance levels between the "good" and "neutral" reference level, a likewise procedure was employed to ask the difference the attractiveness regarding the "good" level. In addition, it was also asked the difference of attractiveness between each consecutive level. The first part of this web-based survey platform allowed to obtain the value scales by asking importance of improvements within criterion. Meaning that, for each criterion and considering their experience using anesthesia devices in their daily clinical practice, what would be the difference of attractiveness between two performance levels, according to the MACBETH scale. Afterwards, in the second part of the web-based survey platform, the elicitation of difference of attractiveness occurs to determine the criteria weights. Considering that all the levels were on the neutral level, it was asked to rank the improvements (overall attractiveness) to the good level, according to the MACBETH scale. Based on the survey results, for each expert, the qualitative judgements were introduced in the matrixes of judgements in the M-MACBETH software.

3.2.4. Group multicriteria model

After the assessment of each of the individual value judgements, now a compromise between the group of experts will be obtained. As before, the objective is to collect the value judgments to insert in the M-MACBETH software and, therefore, build the value scales for criteria as well as obtain the criteria weights. To that effect, a decision conference was held in the department of anesthesiology at Hospital Santa Maria, in Lisbon. The decision conference has a very similar structure to the individual multicriteria modeling since the same questions made on the web-based survey platform were repeated during the decision conference. Therefore, the questioning process in terms of difference of attractiveness between performance levels for each criterion to determine value scales and criteria weights is the same underpinning individual multicriteria models. However, in group, the problems were discussed, possible inconsistencies were solved and validated by the experts and, in the end, possible adjustments were made. Therefore, an instant validation and creation of the multicriteria group model.

The purpose of repeating the questions is to promote a debate of the perspectives and clinical experience from which each person answered a certain question. From there, potential ambiguity on interpretation can be exposed and clarified as well as present different clinical points of view to the group. Only then, the group can reach a general agreement and, subsequently, obtain the compromise group model to build the tool for medical device's selection.

3.3. Designing a novel Decision Support System (DSS)

The DSS developed to potentially be used in future acquisition processes composed by a decision-support tool in Excel complementing the M-MACBETH software. The evaluation process involving the M-MACBETH in future acquisitions will basically be a replica of the group multicriteria model. To design the decision-support Excel tool, once again the social and technical components were considered. More precisely, the DM was probed and asked to indicate any useful features. The input received was to create a tool that embraced the process from the very first moment to the last. Therefore, on the technical side, a decision was made to design an Excel tool that starts with worksheets containing the data submitted by the medical companies during the public applications process. At the end, graphics, tables and other data types would be available to use as evidence of the decision analysis in the report to deliver to the Sales department.

4. Results

The main outcomes of the developed socio-technical approach will be presented. Firstly, a real application case based on the acquisition process of anesthesiology medical devices, more precisely anesthesia kits, at Hospital Santa Maria. Secondly, it will be displayed a decision support tool combining the tool built in Excel, which purpose is to aid in the selection of medical devices, alongside the MACBETH software and, therefore, be applied by the DM in future acquisition processes.

4.1. Socio-technical approach for selection of anesthesia kits

This socio-technical approach was developed to, in the end, suggest the alternative that presents itself as the highest value proposition. In this case, the public application process is organized through numbered positions, each one representing a type of anesthesia kit, and for each position only the best possible medical company proposal of anesthesia kit will be selected (Table 1). Since this socio-technical approach was formulated at Hospital Santa Maria, the data source used to implement this tool is based on their last acquisition process of medical devices for anesthesiology. Contains, among other files, the companies' catalogues of anesthesia kits, which can help to understand the differences in their characteristics, and the obligation's notebook, which defines the guidelines for a company to fulfil to be eligible for the public applications.

Inclusion requisites are imposed in this evaluation process not only by Hospital Santa Maria but also by government legislation. For instance, maximum unit price is established and submission of catalogues with detailed technical specifications. The implementation of inclusion requisites was based on the screening criteria concept. Therefore, the inclusion requisites determine a list of items necessary to comply, without any exception, other medical company's proposal is automatically rejected. In this case, all of the anesthesia kits proposed by the medical companies accomplished the inclusion requisites. However, as visible in table 1, the anesthesia kit in position 7 did not have any proposal. Since the position number 12 only had a single proposal and all the inclusion requites are verified, then the proposal will likely be accepted.

Table 1 - Matching between the four medical companies (Brand A, Brand B, Brand C and Brand D) and the positions to which they submitted a proposal (G – Gauge).

		Medical companies			
Position	**Designation**	**Brand A**	**Brand B**	**Brand C**	**Brand D**
7	Continue epidural anesthesia kit 17G				
10	Sequential anesthesia kit pencil-point		X	X	
11	Epidural anesthesia kit 18G		X	X	
12	Epidural anesthesia kit 20G			X	

For position number 10 and 11, the same two medical companies, Brand B and C, competed for the positions without infringing inclusion requisite. Therefore, position number 10 and 11 are plausible candidates to continue the evaluation process.

Proceeding with the M-MACBETH software, for each anesthesia kit, it was defined its impact on the criteria and then its performance was evaluated using the group multicriteria model. The impact level on each criterion for each medical device was determined according to the data in the acquisition process mentioned above, which was then completed and validated by the DM.

Afterwards, the global performance score (Figure 2 and 3) is obtained, being displayed in the yellow column whereas the partial performance score, regarding each criterion, is showed in the remaining columns. Looking at Figure 2, for position 10, the medical device option with the higher global performance score is the Brand C, equal to the 'Good' reference level. In the case of Figure 3, for position 11, the medical device option with the higher global performance score is the Brand B, equal to the 'Good' reference level. In both cases, the

Table of scores

Options	Overall	Handling	Efficiency	Recovery	Satisfaction	Morbidity
Brand C	100.00	100.00	100.00	100.00	100.00	100.00
Good	100.00	100.00	100.00	100.00	100.00	100.00
Brand B	48.95	55.56	0.00	100.00	100.00	0.00
Neutral	0.00	0.00	0.00	0.00	0.00	0.00
Weights :		0.1195	0.2094	0.2637	0.1594	0.2480

Figure 2 - Results of the group multicriteria model for the position 10. The overall and partial performance scores as well as the criteria weights are presented.

Table of scores

Options	Overall	Handling	Efficiency	Recovery	Satisfaction	Morbidity
Brand B	100,00	100,00	100,00	100,00	100,00	100,00
Good	100,00	100,00	100,00	100,00	100,00	100,00
Brand C	94,69	55,56	100,00	100,00	100,00	100,00
Neutral	0,00	0,00	0,00	0,00	0,00	0,00
Weights :		0,1195	0,2094	0,2637	0,1594	0,2480

Figure 3 - Results of the group multicriteria model for the position 11. The overall and partial performance scores as well as the criteria weights are presented.

criterion that was decisive was the 'Medical Device's Handling.

4.2. Decision-support tool

The development of this socio-technical approach had always a key outcome: formulate a decision-support tool for the evaluation and, subsequently, selection of anesthesiology medical devices. More precisely, a tool combining the MACBETH software and a clinical decision-support Excel tool. The MACBETH software purpose would be exactly the same as the role played throughout the formulation of this socio-technical approach, meaning to build a quantitative model based on the pairwise comparison of judgments. Meanwhile, the tool in Excel will not only complement the MACBETH proceedings but also assist the onset and the aftermath of the whole decision-making process at the hospital.

Furthermore, the main focuses of this tool are to bring innovation and improve the evaluation process of anesthesia devices currently applied. Hence, the Excel tool was formulated as an interface complementing the MACBETH process, which will require the exchange of information. On one hand, the decision-conference can be guided using the Excel tool, either in face-to-face or online meetings, which in turn, can facilitate reaching an informed agreement to introduce in the MACBETH software. On the other hand, the Excel tool can be fulfilled with data from MACBETH and, for example, help to delineate the final report. As a last resort, the clinical decision-support excel tool can also be used as a simplified analysis of the performance scores in case of not being able to handle MACBETH.

However, for more detailed and customized graphics, MACBETH already defined features can be explored. The implementation of this tool will allow to structure the decision-making process in a way that assures the many adversities that could jeopardize its credibility and reliability are tackled. For instance, this tool establishes a structure where certain evaluation steps promote clinical critical thinking in group. In addition, since the physicians have distinct clinical experiences or even different academic backgrounds, all of this will influence the rationale behind the thinking and decision-process. Therefore, this tool promotes communication and tries to reduce the tendency to automatically fall back on pre-defined concepts without giving it a second thought.

The framework of the Excel tool is presented below through the outline with a concise explain of each section content or features (Figure 4).

5. Discussion and Conclusion

Underpinning this socio-technical approach, there was a MCDA approach coupled with hospital-based HTA, which was tailored to the anesthesiology context at Hospital Santa Maria. HTA involved an assessment of evidence concerning the safety, quality, efficacy and application of the anesthesia kits. Therefore, gathering both the most scientific evidence and the social value evidence, it is not only crucial as well as necessary to a proper HTA.

In a nutshell, it was acknowledged that the current decision-making process concerning the acquisition of anesthesia kits in place at Hospital Santa Maria had room for improvement. Therefore, after reviewing the process, another approach, MD-Evaluation tool, was proposed and tested according to the hospital settings. Thereby, it ultimately led to the resulting decision-support tool combing the MACBETH software and an Excel tool.

The MD-Evaluation tool has a potential to contribute since its implementation based on MCDA principles and methodologies resulted in an evidence-based, transparent and technological support tool to aid in decision analysis of medical devices in a medical specialty so crucial but, somewhat, neglected in

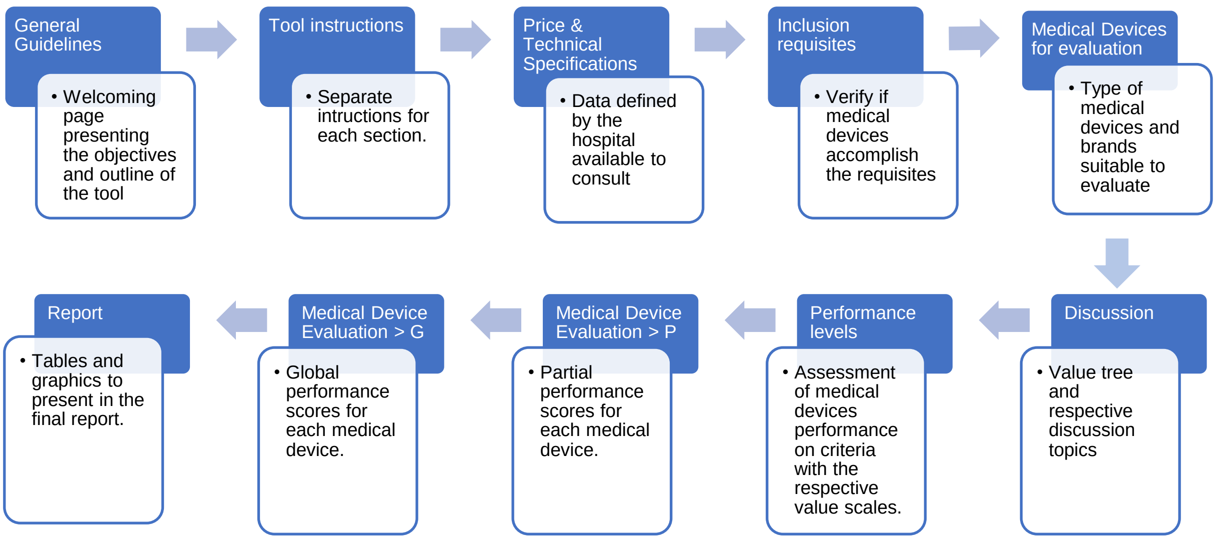

Figure 4 - Outline of the Excel tool with the 10 sections described briefly.

terms of research when compared to other medical specialties. More precisely, it stands out for addressing decision-support when evaluating medical devices in neuraxial anesthesia whereas, up-to-date, the focus of the studies is on anesthesia treatment options. In fact, the proposed tool increases the span of validated implementations of MCDA and its ability to answer to much needed topics of investigation. In Hospital Santa Maria, this sounded approach allowed to improve the evaluation process of anesthesia kits and its validation make them aware of the possibility of adapting it for other medical specialties' evaluation processes in hospital settings.

To conclude, future investigations could be comparing the results obtained in Hospital Santa Maria, considered a central hospital, and a district hospital, with possibly less anesthesia subspecialties. Another possibility could also be comparing this socio-technical approach in the Hospital Santa Maria, a university hospital, and in a non-university hospital. Therefore, performing this type of external benchmarking (comparison with other hospitals) would allow to explore if different hospital settings would have very disparate necessities or priorities**.**

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