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Review

Application of Usability Techniques in Medical Devices in Health Technology Management: A Rapid Review

Mariana Brandão^{†,*} and Renato Garcia[†]

Institute of Biomedical Engineering (IEB-UFSC), Federal University of Santa Catarina, Florianópolis, Santa Catarina, Brazil.

[†] These authors contributed equally to this work.

* Corresponding Author Email: marianaribeirobrandao@gmail.com

ABSTRACT

The role of clinical engineering in health technology management (HTM), incorporating human factors engineering tools, such as usability techniques, allow for improvements in the development of safer, more effective, and quality use of technological solutions. This work resulted in a rapid review of the application of usability techniques to contribute to the development and use of technological solutions for health, so that the occurrence of adverse events can be mitigated. As a consequence, information can be provided for improvements in health technology processes, in order to stimulate and highlight the importance of human factors in health. In order to understand the application of usability techniques in clinical engineering throughout the life cycle of HTM, an exploratory study was done on the literature involving medical devices. This work reinforces the importance of applying techniques to identify the problems faced in the use of technologies and thereby contribute to the activities of clinical engineering so as to reduce errors and failures. The integration and consideration of human factors in the life cycle of HTM is essential for the further advancement of clinical engineering in technology management throughout the healthcare ecosystem, and also in the discussion, construction, and validation of strategies that will help in preventing adverse events.

Keywords—*Clinical engineering, Human factors engineering, Usability techniques, Health technology management, Health technology assessment.*

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INTRODUCTION

Technological advances have enabled a rapid increase in the use of medical equipment in healthcare facilities.¹ As a result of this growth in the frequency of use of health technologies, it has become necessary to incorporate processes that help with technological management throughout the life cycle, from the development and manufacturing stages to incorporation and use in health services. Health technology management (HTM), in order to make patient care more effective and with greater safety and quality, must encompass and consider the entire context in which the technology is incorporated, and is essential to make its use more appropriate and reliable. The Institute of Biomedical Engineering at the Federal University of Santa Catarina (IEB-UFSC) has a management model based on three main pillars: infrastructure, human resources, and technology, thus providing a systemic assessment of the technological resource².

Health technologies are essential for monitoring, therapy, and diagnosis of diseases, but their use can cause adverse events for users. The main problems that could lead to adverse events are differences in functionality between technologies from different manufacturers; lack of standardization³; inefficient maintenance services; inadequate planning for incorporation; inefficient technology design; problems arising from hidden flaws; inadequate use; failure to take human factors and user ergonomics principles into account when developing technological solutions⁴; unsatisfactory instructions or training; improper storage and/or improper use; inadequately structured management procedures^{5,6}; incorrectly used accessories; displays showing results that are difficult to read; and incorrectly changed alarm settings.⁷

Studies that address technology–user interaction often neglect the human factors' perspective, but because of an increase in technological complexity in healthcare, the need to implement research in this area has also grown proportionally.⁸ Usability and user experience is essential in healthcare⁸, and can solve usage problems, increase safety, reduce incidents that cause harm to patients, and provide greater reliability in the use of technology in healthcare environments.^{7,9} Applying usability techniques at different stages of the life cycle makes it possible to contribute to

technological development more safely. In addition, they can be applied to different types of technology and help to improve use and mitigate likely risks to users in HTM.¹⁰

One of the requirements to be considered in the process of evaluating and developing new technological solutions in healthcare is usability, which establishes a relationship between the characteristics of human factors with ease of use, efficiency, and user satisfaction during the use of technology.^{8,11,12} When considering human factors in clinical engineering, the ability of users to use technological resources in a safer and more effective way is considered, according to the real contexts of healthcare environments.¹³ The area of study of human interaction with other elements of a system to achieve adequate usability is called human factors engineering (HFE), which is fundamental for analyzing human behavior in the face of new technologies and establishing improvements in protocols for use in health services.^{7,11,14} Investigating human behavior, considering their limitations, abilities, and interactions with the environment, helps to improve safety, efficacy, and quality in HTM.^{9,15}

HFE

The area responsible for applying knowledge about the characteristics and limitations of people with technologies, processes, and environments is called HFE.^{7,9} The focus of HFE is to understand how people interact with technology and to study how design affects the interactions that people have with technology.⁹ It is therefore a strategic tool to be incorporated into the activities of clinical engineering in HTM. The tool used to evaluate human interaction with a product is usability, and its consideration in healthcare is fundamental.⁸ Most researchers agree that usability is a useful tool for evaluating the user experience,⁸ which consists of an approach that goes beyond the design of the interface, and encompasses the system, the user and their characteristics, and the context of use of the technologies or system.¹⁶

Usability, as defined by the NBR ISO 9241-11:2011 and NBR IEC 62366:2016 standards, is a metric used to measure how well a product can be used by certain users and achieve specific objectives, by considering parameters such as effectiveness, efficiency, and satisfaction in a given context of use.^{11,12} The interaction between the

components involved in establishing a usability metric describes the integration between the user, task, and equipment to achieve a common goal, by measuring the metrics of effectiveness, efficiency, and satisfaction.¹² There are five attributes that are involved: learnability, efficiency of use, ease of memorization, low error rate, and user satisfaction.¹⁷ Usability is attributed to effectiveness, efficiency, satisfaction, usefulness, learnability, and accessibility.¹⁸ The different usability attributes are described on Table 1.

There are several international standards and regulations, presented in Table 2, which can be used to initiate a usability approach in HTM,^{5,8,9} and are important for demonstrating compliance with safety requirements.⁵ HFE has a series of techniques that aim to study the interactions between devices and their users, facilitating identification of problems and dangers related to use.^{9,10} By incorporating usability evaluation methods into cyclical human-centered design processes in an iterative way, it is possible to develop designs that involve users, making products, systems, and/or services more usable.¹⁷ In this way, usability techniques enable users to understand the problems they face and thus contribute to the development of technological solutions.

Usability Techniques

In order to assess usability, qualitative and/or quantitative techniques can be applied,⁸ in the pre-commercialization stages, in the processes of innovation, exploration, experimentation, and evaluation of prototypes,²⁰ as well as in post-commercialization, when technologies are already incorporated in their environment of use. Therefore, taking usability into account beyond development and use is essential for safety and reliability,²¹ which is why the methods can be applied throughout the life cycle.²² Usability techniques aim to assist in testing and evaluation with users,⁷ enabling the construction of a collaborative and interdisciplinary ecosystem, in which the actors involved with technological health resources interact with each other, enhancing the implementation of solutions and user-centered technological incorporation.²³

The application of usability techniques is an additional tool for analyzing human factors in HTM.¹⁰ There are various ways of obtaining information regarding technology–user interaction: information and opinions related to usability can be collected with the aim of understanding users and the environment of use; observing people performing certain tasks associated with the product; discussing aspects of the project in user groups with the aim of obtaining new ideas; conducting structured studies with users using the technology in their own real environment or in simulated locations; including in a risk management plan for hazard identification; as well as using tools to model interfaces at different levels of reliability in the course of developing healthcare solutions.^{7,11}

TABLE 1. Description of usability attributes.

Usability attributes	Description
Effectiveness	Accuracy with which users have achieved certain established objectives, ¹² and thus consists of an important metric for measuring the risk of error during use and ensuring patient safety. ¹⁹
Efficiency	Accuracy in relation to the resources spent by users to achieve a given objective. ¹² The system must be efficient and have the lowest possible error rate. ¹⁷
Satisfaction	Absence of discomfort and positive attitudes toward the use of a product ¹² refer to perceptions, feelings, and opinions. ¹⁷ The system must be pleasant from the user's perspective. ¹⁹
Usefulness	Checks whether the product or service achieves its use objectives. ¹⁷
Learning	Learning measures the ability of users to recall the system after a period of training or time without performing a particular task. ¹⁷ The system must be easy to use from the user's perspective. ¹⁹
Accessibility	Easy access to the products needed to complete the objective by people with the widest range of abilities. ^{12,17} Considering accessibility enables clarity and simplicity in design for people who may temporarily have some limitation or those who have it permanently. ¹⁷

TABLE 2. Standards involving in the usability of medical devices.

Standard	Title	Main objective
ABNT NBR IEC 62366:2016	Healthcare products—Application of usability engineering to healthcare products.	To specify the process for analysis, specification, development, verification, and validation of the safety-related usability of healthcare products.
ABNT NBR ISO 14971:2020	Medical devices—Application of risk management to medical devices.	To specify the principles of the process for risk management of health products, including aspects of usability.
ABNT ISO/TR 16982:2014	Ergonomics of human-system interaction—Usability methods that support user-centered design.	To provide information about usability methods, advantages, disadvantages, and other factors relevant to the use of each usability method.
ABNT NBR IEC 60601-1-6:2020	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability	To specify the minimum usability requirements for medical electrical equipment.
ABNT NBR IEC 60601-1-11:2012	Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance. Requirements for medical electrical equipment and medical electrical systems used in domestic health care environments.	Specifies requirements for electromedical equipment used in domestic environments, including usability aspects.
ABNT NBR ISO 13485:2016	Health products Quality management systems Requirements for regulatory purposes	Specifies minimum requirements for quality management systems in healthcare products, considers usability aspects.
ABNT NBR ISO 9241-210:2011	Ergonomics of human–system interaction Part 210: Human-centered design for interactive systems.	Specifying requirements and recommendations for human-centered design for the entire life cycle.
ABNT NBR ISO 9241-11:2011	Ergonomic requirements for working with visual interaction devices. Part 11: Usability guidelines	Specifies minimum requirements to identify the necessary information to be considered in the specification or evaluation of usability.
AAMI/ANSI HE75	Human factors engineering—Design of medical devices.	Reference covering general principles, managing the risk of use errors, design elements.

Each technique has specific principles and characteristics that need to be known to ensure that the analysis of medical technologies is objective and with valid results.^{7,10} No technique is best in all situations.^{11,24} Usability techniques can be divided according to the type of data to be extracted from the research: quantitative, when the evaluation of parameters has a numerical perspective; qualitative, to extract choices and feelings from the user's point of view⁸; as well as mixed methods, containing qualitative and quantitative data.

There are various techniques specified in regulations,^{11,24} international guidelines and guidance materials,^{5,9} and books and scientific publications, some of the main ones being, but not limited to, observational analysis, interviews, focus groups, task analysis, questionnaires, the Delphi method, heuristic evaluation, usability testing, and user error analysis. Figure 1 shows a comparative illustrative proposal for usability techniques, based on the classification between qualitative, quantitative, and mixed-method analysis, whether the application of the technique depends on direct contact with the technology,

and whether the user's perspective on the product or the researcher's view when observing the technology-user interaction is considered predominantly.

Usability techniques have been used at various stages of the life cycle of health technologies, from pre-commercialization to post-commercialization processes,¹⁰ and are strategic HFE tools to support HTM. The choice of the usability technique depends on the information you want to extract.⁸ In addition, its results are only reliable when the participants are people who are representative of the population and who perform a certain task of interest.¹¹ Primary knowledge of usability techniques, including an understanding of the differences and basic principles of application, is essential to choose the one that best meets the needs.²⁴

for synthesizing knowledge. This approach is used when steps in the process of a systematic review are simplified, or omitted, to produce information from the selection of research that is available in the literature, and that is of relevance to a topic of study.²⁵ The rapid review was developed to ensure that decisions influencing the application of usability techniques in medical equipment can be informed by an up-to-date and reliable account of the scientific evidence that is relevant in the context of the research.

This rapid review research was based on the Ministry of Health's Methodological Guideline for the preparation of systematic reviews²⁶ as well as the University of Oxford's PRISMA methodology, which consists of a set of evidence-based items that aim to assist in the presentation of research results.²⁷ The guiding question of the rapid review research proposed for this case study was:

"What are the usability techniques that are applied to medical equipment over the course of the technological life cycle?"

To determine the choice of articles, inclusion and exclusion criteria were established, which included population parameters of the desired technology, the type of intervention used, the availability of the work, the date of publication, and the type of evaluation of the results, as presented in Table 3. To answer this question, a search strategy used was to define keywords to identify publications that respond to this theme: Usability; Human Factor; Medical Device; and Medical Equipment. The search was carried out in the following electronic databases: IEEE, Pubmed, and Scielo, which were used systematically, and Scopus, Scielo, Lilacs, Sage, and JMIR, in which searches were carried out independently. In order to determine the choice of articles, inclusion and exclusion criteria were established, which included the population parameters of the intended technology, the type of intervention used, the availability of the work, the date of publication, and the type of evaluation of the results. The use of the logical operators "AND" and "OR" helped in the literature search. The databases were searched using a combination of keywords: (Usability OR "human factor*") AND ("Medical Equipment*" OR "Medical device*").

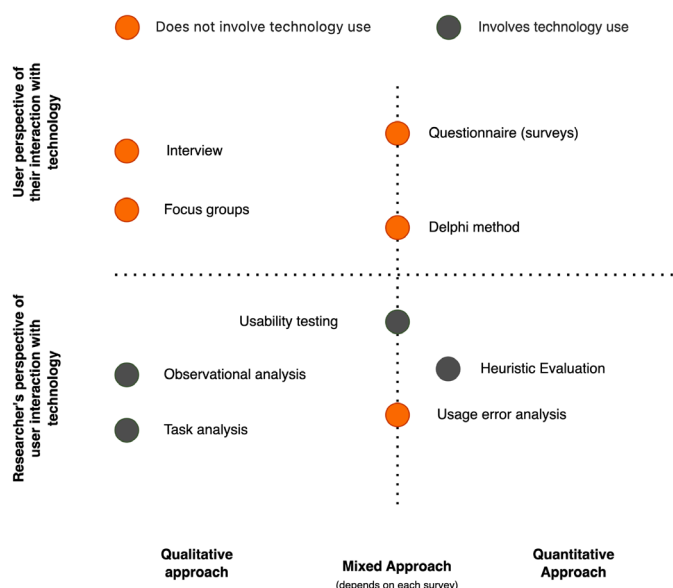


FIGURE 1. Comparison of the usability technique.

In order to understand the application of usability techniques in clinical engineering throughout the life cycle of HTM, an exploratory study was done on the literature involving medical devices.

MATERIALS AND METHODS

This research was conducted through a rapid review, which consists of a reliable and systematized methodology

TABLE 3. Rapid review inclusion and exclusion criteria.

Parameters	1. Exclusion Criteria	2. Inclusion Criteria
Population	1.1 Equipment/devices other than medical devices. Accessories and isolated parts will not be considered. Screening applications, medical records, and medical software will also not be considered. Studies that do not specify the technology will be disregarded.	2.1 Medical equipment used for diagnosis, monitoring, and/or therapy of diseases.
Intervention	1.2 Does not apply usability engineering techniques and/or does not describe the technique.	2.2 Studies that show results of the application of usability engineering techniques.
Availability of the work	1.3 Incomplete and/or unavailable texts.	2.3 Full texts available
Publication date	1.4 Works more than 10 years old from the date of publication.	2.4 Works up to 10 years old from the date of publication.
Assessment	1.5 They do not present results of the application of usability techniques in medical equipment. They do not show the assessment of usability and the interference of human factors with technology.	2.5 They present results of the application of usability techniques in medical equipment to evaluate the usability of technology and the interference of human factors.
Type of work	1.6 Nonprimary studies (such as reviews, meta-analyses) and/or works from the same research project.	2.6 Primary studies and works not part of the same research project.

After the initial search, a publication date filter was applied, excluding articles with a publication date greater than 10 years ago. The titles and abstracts were read, and a total of 189 publications were selected. Reading these studies in full resulted in the exclusion of 124 articles that did not meet the established inclusion criteria. Thus, 65 articles were eligible to compose the rapid review, which present the application of usability techniques in medical equipment. The studies were classified according to the techniques used, the type of medical equipment in which the evaluation was carried out, the stage of the technology life cycle in which the methods were applied, and whether or not there was a conflict of interest in the research. The usability techniques presented in the articles were applied by the researchers to observe user interaction with the medical equipment or to identify problems by observing and transcribing the opinions of the users of the technologies.

RESULTS

The results of the review showed a variety of possibilities for applying usability techniques to medical equipment, from higher risk class devices, such as computed tomography,²⁸ to even less complex equipment for home use.²⁹ Of the 65 studies, the medical equipment with the most research was the infusion pump, with sixteen in total,³⁰⁻³⁵ followed by pulmonary ventilator with five,^{36,37} defibrillator with five,^{38,39} and vital signs monitor, referenced in five studies.⁴⁰⁻⁴³ In addition to those already mentioned, usability techniques have also been applied to: glucometer,⁴⁴⁻⁴⁶ pulse oximeter,²⁹ anesthesia machine,^{47,48} electrosurgical unit,⁴⁹ endoscope,⁵⁰ insulin infusion pump,⁵¹ operating table,⁵² ultrasound,⁵³ among others, demonstrating the diversity in the application of usability techniques. In some selected studies, human factors methods were applied to more than one piece of

equipment, who applied the methodology to blood pressure monitors and pulse oximeters.³⁸

The results show that usability techniques are being used for a variety of purposes, from design validation in the early stages of product development, to assisting in the processes of incorporating technology into a facility; to assessing the ergonomics of medical equipment; to analyzing usability problems through adverse event analysis; investigating product design problems; analyzing the instructions for use of a piece of equipment; and assisting in identifying hazards and minimizing risks to the patient, even at the level of comparing usability between different types of make/model of a technology.

An analysis of the selected papers showed that usability techniques are being applied at different stages of the technology life cycle, from pre-commercialization to post-commercialization. Usability techniques were applied both individually and integrated with one or more other methods, with the integration of techniques being the most widely used methodology in the selected studies. The studies that applied more than one technique reinforce the importance of integrating different methods to extract information from different perspectives, as each technique has its advantages and limitations. An example of the presence of integrating techniques is the usability test, which was the method with the highest number of applications among the selected works, and which was generally accompanied by the implementation of questionnaires in the pre-test, to analyze the profile of the participants, and in the post-test, to quantify user satisfaction regarding the usability of the technology. In the post-test questionnaire, most of the time, the SUS Scale, a tool used to extract relevant information about how satisfied the user feels when interacting with the technology, was applied.

A complementary tool, also applied in some of the selected studies, was the use of eye tracking used to analyze the user's eye movement when interacting with the product interface, to help assess the usability of users when using technologies.^{47,54} Another validated tool used

in the selected studies was the NASA-TLX Scale, used to measure people's mental workload. This scale was applied in all the studies in which this usability technique was used, and was applied through integration with other methods.^{28,36,37} Reducing the physical and mental workload is one of the recommendations, in which the authors cite the importance of manufacturers considering these scenarios for users and providing customizable options to meet the needs of the end operator.²⁸

DISCUSSION

Human factors in health must be involved throughout the entire life cycle of the technology in the technology management processes of clinical engineering activities, from the pre-commercialization stages, based on a user-oriented development of health technologies, to the post-commercialization stages, involving the clinical staff in the processes of technological incorporation, investigation of problems in the use of technology to minimize harm to the patient, among many other activities that involve clinical engineering.^{7,10,13}

Interdisciplinary interaction in health technology processes is essential for identifying potential problems in the use of medical equipment in establishments, and thus establishing and implementing improvement actions. The implementation of a collaborative and interdisciplinary living lab ecosystem has the potential to contribute to HTM, through the application of usability techniques with different actors involved with medical devices, including clinical engineering, end users, health professionals, industry, and government, among others. Usability techniques can be applied at different stages of the life cycle of health technologies, helping to identify user needs in order to develop and/or improve technological solutions. A program proposal was developed to cover the main activities considering human factors, as shown in Table 3. The objective to apply usability techniques for the consideration of the human factor in each life cycle stage is presented in Table 4.

TABLE 4. Objective to apply usability techniques for the consideration of the human factor in each life cycle stage.

Life Cycle Stage	Main Activities	Objective to Apply Usability Techniques for The Consideration of The Human Factor
Design and development	<ul style="list-style-type: none"> - Innovation ideation. - Design, prototyping, and development. - Compliance with regulations. - Regulations, good manufacturing practices, and certification. - Production, distribution, storage, and marketing. 	<ul style="list-style-type: none"> - Establishing project goals and requirements based on the problems identified by users when using the technologies. - Collecting data on user needs. - Developing solutions centered on user needs. - Testing solutions with the user for validation, risk, usability analysis, and project adjustments.
Planning and selection	<ul style="list-style-type: none"> - Market analysis - Health technology assessment (HTA) - Sizing up the establishment's profile by analyzing the technologies, infrastructure, and human resources to understand the need for incorporation. - Checking that the technology has been regularized with the health agency and complies with regulations, ordinances... - Carrying out economic analyses of the total cost of ownership. - Specifying and selecting the technology. - Purchasing process (bidding if necessary) 	<ul style="list-style-type: none"> - Meeting user needs, combining clinical interest with the technologies available on the market. - Consider usability aspects when specifying technology, check that technological development is user-centered and based on standards. - Consider usability in technology selection. - Consider human factors engineering principles and usability techniques to incorporate into HTA.
Receipt, verification, and acceptance	<ul style="list-style-type: none"> - Ensure that all equipment incorporated complies with what has been requested. - Ensure that they are evaluated before first use through acceptance tests that attest the safety and performance of the technology. - Document and implement criteria for supplier qualification. 	<ul style="list-style-type: none"> - Test the incorporated technologies with users for final acceptability, checking that they meet the need.
Inventory	<ul style="list-style-type: none"> - Carry out the inventory (survey, registration, and identification) of the entire technology park with all the necessary information to ensure the accuracy and traceability of the data. - The entire inventory process must be documented and conducted periodically. 	<ul style="list-style-type: none"> - Involve the user who operates the technology in the inventory of the technology park, to understand the importance of identification and traceability for management. - Identify possible flaws in the processes of incorrect and/or incomplete identification of the inventory, thereby hindering traceability.
Installation	<ul style="list-style-type: none"> - Install the equipment in compliance with the manufacturer's regulations and recommendations. 	<ul style="list-style-type: none"> - Show users the impact of the infrastructure on performance and security with the technology. - Evaluate the infrastructure to check the implications for users' use of the technologies. - Understand the difficulties faced by users when interacting with the infrastructure.
Training	<ul style="list-style-type: none"> - Ongoing and periodic training program to ensure that operators are able to carry out their activities. - Drawing up and implementing good practice guidelines for the proper use of health technologies. 	<ul style="list-style-type: none"> - Train users to operate the technology properly. Carry this out immediately after installation and inventory and periodically on an ongoing basis with the entire team. - Develop training focused on solving problems faced by users. - Develop good practice materials for proper use.

Life Cycle Stage	Main Activities	Objective to Apply Usability Techniques for The Consideration of The Human Factor
Use	<ul style="list-style-type: none"> - Risk management - Draw up and implement standardized procedures and protocols for the use of technologies. - Develop methodologies to ensure technological traceability. - Analyze the history of failures and analyze the probable causes. - Investigate the adverse events involved. 	<ul style="list-style-type: none"> - Understand the problems of using the technology and understand the impact of human factors on the occurrence of failures and adverse events. - Analyze the cause of failures incorporated into risk management in order to establish improvement strategies. - Analyze usability problems in order to establish specific strategies and improvements in new technological solutions.
Technical interventions	<ul style="list-style-type: none"> - Define and implement procedures to ensure the metrological traceability and safety of technologies. - Develop and implement procedures for inspection, testing, calibration, preventive and corrective maintenance, electrical safety tests, and qualification. 	<ul style="list-style-type: none"> - Involve the user in the importance of carrying out calibration, maintenance, and other technical interventions for the safety and performance of the technologies. - Analyze the impact of human factors on technical interventions in technologies.
Obsolescence, decommissioning, and final disposal	<ul style="list-style-type: none"> - Developing and implementing procedures describing the criteria for decommissioning technology, taking into account the technical, operational, financial, or strategic aspects of the establishment. - Execution of the activity by issuing a decommissioning report. 	<ul style="list-style-type: none"> - Analyze the effectiveness of using the technology. - Evaluate the needs of the clinical staff to ascertain the need for technological replacement. - Researching technological advances that consider human-centered aspects for technologies with better usability.

Analysis of the Application of Usability Techniques in Pre-Commercialization

In processes involving the development of technological solutions, it is essential to include the user in the gathering of data on the need and validation of the product, enabling the prior identification of usability problems that the technology may pose.¹⁰ Therefore, user-centered design encompasses the active involvement of people during technological development, with a clear understanding between user requirements and tasks, providing solutions through continuous interactions with users in an interdisciplinary team.¹⁵

The pre-commercialization stage is the time when the technology is under development, and it is essential to include the user in gathering data on the need and validating the idea or product. This stage makes it possible to reduce future complications by anticipating possible usability problems that the technology may pose.

The studies in which usability techniques were applied in the pre-commercialization stages demonstrate the need to include users throughout the technological development process to ensure better usability results and

greater patient safety,^{55,56} as well as making it possible to reduce costs.⁵⁷ The application of usability techniques in the technological development process reduces the need for design modifications and more costly upgrades post-market introduction, which becomes a competitive advantage. In addition, there are considerable improvements in safety, which minimize the likelihood of medical device recalls. When HFE approaches are used during the technology–user interface development process, especially taking into account the user’s perspective, there are considerable improvements in ease of use.⁹

Analysis of the Application of Post-Marketing Usability Techniques

Usability techniques applied in post-marketing demonstrate the relevance of studies considering human factors during the use of technologies, and thus assist manufacturers, researchers, among other actors, who wish to explore ergonomic studies after incorporation of technology into the market.⁵⁸

The application of usability techniques in the process of incorporation in health establishments can obtain

satisfactory results, as the use of technologies in environments directly impacts the experience of staff and patients, and the selected equipment will normally be used for several years.⁵⁹ Inadequate incorporation that does not meet local and operator needs can lead to disuse of the technology, as well as operating errors, resulting in problems for patient safety. In addition to the impacts on the establishment, considering usability in the process of incorporation also provides manufacturers with information on users' needs, and thus helps with feedback for the development of new products.⁵⁹ Liu et al. also presented a usability evaluation methodology through the integration of techniques that can provide evidence to support the selection of more appropriate equipment, by considering the context of use of the technology.⁶⁰

By applying usability methods, it is possible to recommend improvements to the technology-user interface and increase safety⁶¹; identify how the context of use can affect the usability of technology⁵⁵; as well as understand educational needs⁶⁰ and improve training strategies³⁹ and instructions for use.¹⁹

Studies have shown that the application of usability techniques through the analysis of adverse events makes it possible to identify sources of hazards and investigate the causes of these incidents associated with the use of medical devices,⁶² and thus assist in both the pre-marketing and post-marketing of technologies. Through the evaluation and analysis of adverse events in databases, it is possible to optimize risk control solutions in the use of medical equipment and achieve satisfactory results in usability to contribute to the development of public health and better user experiences.³²

Another approach, little explored in other studies, is the use of technology by individuals with physical/sensory disabilities, demonstrating in their research that medical devices are often not designed to meet the needs of specific users.⁶³ Clinical engineering needs to work toward managing health technologies that are more accessible to everyone.

Usability techniques can also be applied in the design and implementation of training programs, which are a stage in the technology's life cycle, and should be carried out periodically and continuously. Training should

include the difficulties faced by users in order to mitigate the occurrence of user errors. Therefore, a continuing education program should consider the problems faced by users in their day-to-day use of the technology, both when it is first introduced and throughout its life cycle. Usability techniques can be applied to analyze the impact of training to investigate its effectiveness and thus establish actions that can improve the use of the technology.

Throughout the use of technology in healthcare environments, usability techniques can be applied continuously to analyze the users' perspective on interaction with the technological resource. In this way, it is a strategy for identifying possible problems and planning preventative actions. Drawing up and monitoring indicators involving technologies is a clinical engineering activity that must also take human factors into account when critically analyzing the results of the metrics. Incorporating user evaluations of user satisfaction, error rate, effectiveness, and efficiency in performing certain tasks are important usability metrics to be considered in clinical engineering.

Clinical engineering must incorporate the monitoring and analysis of adverse events in its activities. Analysis of failures and adverse events also requires attention to probable human errors, and applying usability techniques can help to investigate the probable causes, and thus establish strategies more assertively. Clinical engineering should also stimulate the environment for reporting adverse events, by implementing actions that minimize the main barriers that influence the deficiency in the reporting process by operators, which are fear of guilt, lack of time, nonperception of effectiveness when reporting, lack of knowledge of the reporting system, lack of feedback, and a complicated and time-consuming platform for reporting. Metrology in health is a strategic tool for identifying adverse events and hidden failures involving health technologies. Metrological problems can be associated with inaccurate diagnoses and inadequate treatment, as these factors are directly related to the prevalence of adverse events.

When assessing obsolescence, applying usability techniques can provide data to help clinical engineering make decisions on whether or not to discard technology, by understanding the problems faced and clinical needs,

as well as assessing the availability of new technologies on the market. Human factors must also be taken into account in the stages of technological substitution, so that the transition and incorporation of a new technology has minimal impact on the healthcare environment.

CONCLUSION

This work demonstrated that the application of usability techniques can assist clinical engineering in the development and use of technological solutions that integrate the user in the processes throughout the life cycle, and that provide data with a more systemic view of the problem. Some of the actions of clinical engineering highlighted and discussed in these usability techniques consist of: development of technologies with better usability for users; process of incorporation of new technologies in establishments that meet clinical needs; preparation and implementation of training and qualifications in technologies; development of good practice materials for appropriate use; identification and monitoring of the occurrence of failures and adverse events to propose improvement actions; and performance evaluation as a metrological tool to preventively identify adverse events and hidden failures, as well as in the evaluation of technological obsolescence considering the users in these processes. Therefore, human factors must be considered throughout the life cycle, integrating a feedback system of information for continuous improvements.

The integration and consideration of human factors must be encouraged for the further advancement of clinical engineering throughout the healthcare ecosystem, in the discussion, construction, and validation of strategies that may assist in the prevention of adverse events. Incorporating usability techniques must be a tool applied throughout the life cycle of technologies as a strategic methodology to ensure safety, regulatory compliance, and cost reduction in healthcare environments. With these integrated and collaborative actions, the aim is to achieve an increasingly humanized, inclusive, collaborative, sustainable management of health technologies, focused on the best user experience and focused on quality and safety for all people involved in the technological processes in health.

AUTHOR CONTRIBUTIONS

Conceptualization, M.B. and R.G.; Methodology, M.B. and R.G.; Formal Analysis, M.B.; Writing–Original Draft Preparation, M.B.; Writing–Review & Editing, M.B. and R.G.; Supervision, R.G.

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The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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