Analysis of Accessibility in Medical Devices in Health Technology Management

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Abstract— **The availability of an affordable medical device is critical in the provision of healthcare to ensure that technology is not a barrier for users. It is essential to understand the accessibility issues present in medical devices to serve the diverse population of patients with varying limitations, abilities and disabilities. With the aim of promoting and discussing the impacts of accessibility in medical devices, this project aims to analyze accessibility problems in medical devices. A rapid review of the literature was prepared and a model for applying usability methods throughout the life cycle of health technologies was proposed to establish strategies to improve accessibility and mitigate risks. This work found a large number of accessibility problems involving different types of medical devices, as well as the lack of accessible technologies in healthcare environments. Different actions to provide a more inclusive and accessible health technology management throughout the life cycle were proposed, such as incorporating user-oriented development, training and development of standard operating procedures.**

Keywords-Accessibility; Medical Devices; Health Technology Management.

I. INTRODUCTION

The availability of an affordable medical device is critical in the provision of healthcare to ensure that technology is not a barrier to users [1]. To achieve the benefits for which the medical device was developed, it requires a safe and reliable technology-user interaction, so that errors in use by users do not cause harm, compromising the health of the population [2]. Therefore, a combination of human-centered project development, ergonomics, and accessibility tools, is necessary to ensure a high quality use of technological resources [3].

Considering accessibility aspects in the development of health technologies is essential to ensure inclusion and improve usability. Accessibility is defined in ABNT NBR 17060:2022 as follows: accessibility on mobile devices consists of the scope in which products, systems, services, environments and facilities can be used by people from a population with the widest variety of characteristics and capabilities, to achieve a specific objective in a specific context of use [4]. Incorporating usability into the projects aims to expand the target population, making technologies accessible to more people in different contexts of use [5]. In Brazil, the population with disabilities was estimated at 18.6 million (considering people aged 2 and over). The number corresponds to 8.9% of the population in this age group [6]. In the world, this number is estimated at 1.3 billion, representing 16% of the world's population [7]. According to law Nº. 13.146, of July 6, 2015, which establishes the Brazilian law on the inclusion of people with disabilities, every person with a disability has the right to equal opportunities with other people and will not suffer any type of discrimination. In addition, people with disabilities are being guaranteed comprehensive health care at all levels of complexity, with universal and equal access [8].

However, people with disabilities often do not have the opportunity to receive quality healthcare and sometimes have access to insufficient healthcare [9]. As technologies are increasingly present in healthcare, and are incorporated to assist users in their safer and more reliable use, consideration of accessibility aspects in technological development becomes a fundamental requirement to achieve the usability of a product [2]. Incorporating principles and methodologies considering usability and accessibility must be strategic business objectives, being essential to optimize performance, minimize undesirable consequences for human beings, maximize the well-being of the entire organization and improve relationships with customers [5].

The tool used to evaluate human interaction with a product is usability, and its consideration in health is fundamental and useful for evaluating the user experience [10]. Usability is a metric used to measure how much a product can be used by certain users and achieve specific objectives, when considering parameters such as effectiveness, efficiency and satisfaction in a context of use [11]. For a product or process to have good usability, it is necessary to consider different parameters and measure them with the intended users, such as effectiveness, efficiency, satisfaction, use, learning and accessibility. Accessibility is determined by the ease of access to the products necessary to complete the objective by people with the widest variety of capabilities [5][12]. When considering accessibility, it allows clarity and simplicity in design for people who may temporarily have some limitations or those who have them permanently [12].

The development of a product or service centered on the user's needs and perspective, integrated with their context and tasks, is called User-Centered Development [13]. It consists of an approach to developing usable and useful systems in an interactive way, with an emphasis on users when considering their needs, through the incorporation of ergonomic knowledge and techniques. There is a diversity

of usability methods that aim to support human-centered design, used to increase the usability of a product or system, which can be used in both design and evaluation. Some methods consist of: user observations; questionnaires; critical incident analysis; interviews; think out loud; document-based methods, among others [14]. Accessibility must be included as part of the human-centered project, so that it can expand the population that can use technologies effectively, efficiently and satisfactorily, and consequently, increase usability for all users [5].

Healthcare accessibility is essential in providing medical care to people with disabilities. Due to barriers, individuals with disabilities are less likely to receive routine preventative medical care than people without disabilities. Accessibility is not only required by law, but is also crucial for the inclusion of all people in the use of health technologies [1]. Work involving accessibility in medical equipment reinforces the problems surrounding technologies, as presented in the research conducted by Story et al., which showed harm to people with disabilities when using scales, examination tables and diagnostic imaging equipment [9]. Other equipment and description of accessibility problems will be presented in this article in section III.

Due to the importance of considering accessibility to ensure the inclusion of all people in the use of medical equipment, this work aims to carry out a rapid review of the literature in search of evidence as well as provide a model for incorporating in Health Technology Management.

The rest of the article is structured as follows. In Section II, we discuss the methodology used in the research. In Section III, the results are elucidated. In Section IV, we discuss the results found. Section V concludes the work with a summary and future research directions.

II. Materials and methods

This work was conducted in two stages. The first phase consists of the rapid literature review and the second phase consists of the proposal for a model that incorporates accessibility tools into the life cycle of a medical device in order to contribute to the safe management of health technologies. To explore accessibility in medical devices and discuss the contribution of Clinical Engineering to making healthcare environments more inclusive, a rapid review was carried out in the literature, which consists of a reliable and systematized methodology to synthesize knowledge. This approach is used when steps in the process of a systematic review are simplified to produce information from the selection of research that is available in the literature, and that is relevant to a study topic [15]. The constant increase in the amount of research carried out in the literature requires the implementation of an approach to evaluate published studies and contribute to decision-making, and thus provide an updated summary of the state of knowledge [16].

The conduct of this rapid review was based on the Methodological Guideline of the Ministry of Health for the preparation of systematic reviews [17], as well as on the PRISMA methodology of the University of Oxford, which consists of a set of evidence-based items that aim to assist in the presentation of research results [18]. The guiding question of the rapid review research proposed for this case study was: **"What is the evidence of accessibility issues in medical devices?"**

To answer this question, the search strategy used was through the definition of keywords to identify publications that respond to this theme. The use of the logical operators "AND" and "OR" helped in the literature search. The search in the databases was executed using the union of keywords: (*"medical device"* OR *"medical equipment"*) AND (*"accessibility"* OR *"disabled people"* OR *"disabled person"* OR *"disability"*) during the time period from January until February, 2024. The search was implemented in the following electronic databases: IEEE *Xplore* and Pubmed, which were used systematically. To determine the choice of articles, inclusion and exclusion criteria were established, which included 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. After the initial search, the date of publication, the titles and abstracts were read, selecting a total of 12 publications. Table 1 explains the number of articles found per database using keywords.

Table I. Number of articles found per database.

Database	*"medical device" OR "medical equipment")*	*("accessibility" OR "disabled people" OR "disabled person" OR "disability")*	*("medical device*" OR "medical equipment*") AN ("accessibility" OR "disable people" OR "disabled person" OR "disability")*
Pubmed	38.722	488.575	722
IEEE Xplore	11.512	20.788	139

The second stage of this work was to propose a model that incorporates accessibility during all activities of the life cycle, hence contributing to the Health Technology Management in pre-market and post-market.

III. Results

The results obtained through a quick literature review highlighted accessibility problems in different types of medical devices, such as examination tables [19]-[21], weight scales [22][23], nebulizers [24], glucometers [25], positive airway pressure device [26], neuromodulation devices [27], mammography [28]. The usability techniques applied to explore and investigate the problems were mainly: questionnaires, interviews, focus groups and usability testing.

In the studies analyzed, it was found that medical devices are often not accessible to the entire population. Story *et al* highlighted problems faced by patients with disabilities who have difficulties using different types of

medical equipment. The four main equipment with the biggest reported problems were: tables; radiology equipment; rehabilitation and exercise equipment and weight scales. Possible physical damage and incorrect reading of display values were the most recurrent problems, followed by physical positioning and transfer of patients on medical equipment [9].

The absence of accessible medical equipment was presented in some studies, such as the research conducted by Morris et al in outpatient clinics [19], which converges with Mudrick et al research that found the absence of adjustable exam tables and accessible weight scales in a large part of offices analyzed [20]. Iezzoni et al showed that doctors do not use accessible exam tables/chairs for patients, and that many doctors simply ask the weight of patients with mobility limitations [21]. Agaronnik et al presented in her study that medical diagnostic equipment, such as examination tables, scales and diagnostic imaging equipment are often inaccessible. Even if doctors have accessible equipment (e.g., examination tables), they do not always use them [23].

The mammography machine was also the target equipment for research. Yankaskas et al investigated women with visual, hearing, physical or multiple disabilities on reasons for not returning for regular mammograms. She found that women with multiple limitations were much more likely to report problems with transportation, parking, and accessibility to health services, as well as a lack of medical recommendation for screening [28].

Neuromodulation devices also had their accessibility assessed through the application of usability techniques. Glenn has found that most devices incorporate auditory cues, buttons with raised cutouts, speech commands, or other useful features to help people with visual impairments. However, no device has been found that is completely accessible to all users, regardless of visual, auditory and physical limitations [27]. In addition to medical devices present in hospitals, technologies present in the home environment also present accessibility problems, as presented by Blubaugh et al. In his study, the researcher showed that the vast majority of glucometers and blood pressure monitors available on the market have limitations for people with disabilities, especially people with reduced vision [25]. These studies discuss accessibility problems faced with medical devices that compromise the safety of using the technology. Ardehali et al also studied medical devices used at home, and found in his research that 71% of people with disabilities describe using medical devices as extremely difficult or somewhat difficult [29].

Another study that investigated problems with medical devices in the home was Constance, which explored in detail the types of difficulties experienced by patients with physical/sensory disabilities who use positive airway pressure devices. Problems were reported when performing manual tasks that were difficult for users, such as connecting accessories, changing filters, among others. These demands have contributed to patient frustration and reduced home medical device use [26].

In all studies analyzed in the rapid review, accessibility problems were found in medical devices. But there was no evidence of a proposal for a methodology to incorporate accessibility throughout the entire life cycle of technologies, from the development stages to use. Therefore, considering accessibility must be considered at all stages of the life cycle of health technologies, from pre-market to post-market phases, for that, a model was proposed as elucidated in Figure 1. When applying universal design as a strategy and including people from all ages and abilities throughout the technology lifecycle, from the ideation phase of digital health solutions to development, developers can design solutions with better accessibility. Universal design aims to design products in a safe and autonomous way, in a simple, intuitive way and with equal possibilities of use [4].

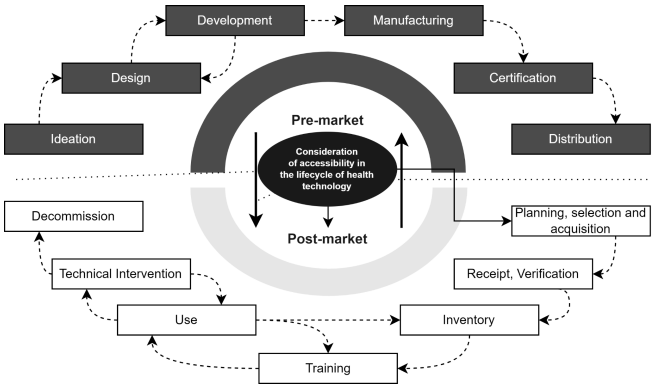

Figure 1. Consideration of accessibility in the lifecycle of technology.

The lack of accessible medical devices is among one of the factors that lead to the disparity in health services available to people with disabilities. It is essential to understand the accessibility and safety barriers present in medical devices used for all types of exams and procedures to meet the diverse population of patients with varying limitations, abilities and disabilities. The model shown in Figure 1 was developed with the application of usability techniques to investigate accessibility problems and improve the usability of medical devices.

The application of usability techniques with users at each stage of the life cycle considering population diversity is essential to develop more accessible technologies. The main steps consist of planning the project and defining the objective, studying the technology, choosing the usability techniques to be used, defining the population considering the diversity of users, developing a protocol for applying the technique, applying the protocol with users, analyzing the data, carry out an action plan with preventive strategies and continuously monitor to evaluate effectiveness and seek improvements. Considering current standards and regulations involving accessibility is a crucial part of the process. Some regulations and documents with accessibility standards for medical devices are listed in Table 2.

TABLE II. CURRENT REGULATIONS AND GUIDES WITH ACCESSIBILITY STANDARDS FOR MEDICAL DEVICES.

Name	Description
WCAG [31]	Web Content Accessibility Guidelines (WCAG)
ABNT NBR 17060:2022 [4]	Accessibility in mobile device applications - Requirements
ABNT NBR ISO 9241-171:2018 [32]	Ergonomics of Human-System Interaction Part 171: Software Accessibility Guidance
ABNT NBR IEC 60601-1-11:2012 [30]	Electrical medical equipment Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for electrical medical equipment and electrical medical systems used in domestic healthcare environments.
ABNT NBR 9050:2021 [37]	Accessibility to buildings, furniture, spaces and urban equipment
Law Nº 13.146/ 2015 [8]	Establishes the Brazilian law on the inclusion of people with disabilities.
Law Nº 10.098/2000 [33]	It establishes general standards and basic criteria for promoting accessibility for people with disabilities or reduced mobility, and provides other measures.
Regulatory Standard NR 17. Ministry of Labour [34]	Brazilian Ergonomics Regulatory Standard.
Guidance & Resources ADA [1]	Americans with Disabilities Act (ADA) regulations. Access to Medical Care for Individuals with Mobility Disabilities
Standards for Accessible Medical Diagnostic Equipment [35]	The Architectural and Transportation Barriers Compliance Board (Access Board or Board) is issuing accessibility standards for medical diagnostic equipment
Enforceable Accessible Medical Equipment Standards [36]	Developed by the National Council on Disability. Enforceable Accessible Medical Equipment Standards: A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities

IV. DISCUSSION

Architectural elements within healthcare facilities represent the most recognized accessibility barriers, but the problems go far beyond stairs and bathrooms. Lack of accessibility in medical equipment is a major concern. More accessible healthcare solutions are critical in promoting equity and achieving health promotion, prevention and security. Consequently, it can help reduce disparity, increase inclusion and make healthcare spaces more equitable.

According to the report of one of the users of the research conducted by Story et al.: *"it takes more than ramps to solve the health care crisis for people with disabilities"* [9]. It is necessary to develop technologies focused on population diversity through the involvement of users from the initial design process of medical equipment. Continuously carrying out training with the entire team and developing standard operating procedures are other strategies to be implemented by Clinical Engineering together with other actors in order to establish a more accessible healthcare environment.

With each innovation, new accessibility problems may arise. As such, it is critical to engage universal design principles from the earliest stages of the manufacturing process to ensure that inclusive devices are designed and accessible to all users, which can ultimately improve device usability, adherence and effectiveness [27]. Several emerging technologies are being increasingly used in healthcare, such as artificial intelligence, augmented and virtual reality, Internet of Things, blockchain, among others. Inserting accessibility aspects from the beginning of development is crucial to developing accessible solutions. The diffusion of medical devices into Homecare is another challenge. It is necessary to establish and implement measures that aim to assist in the safety and ergonomics of these technologies for the most varied types and profiles of patients, from those with greater technological skills to those with no aptitude at all [30]. It is necessary to establish strategies to guide patients in the use of these technologies and consider the diversity of users and context of use.

The limitations of this work consist of limited use of databases to search for evidence on accessibility in medical equipment, which may lead to the non-consideration of other work that addresses the topic; low number of works analyzing the accessibility of medical equipment considering the users' perspectives.

V. CONCLUSION AND FUTURE WORK

This work highlighted accessibility problems involving medical devices. Through a rapid review of the literature, it was found that most technologies are inaccessible and/or absent within healthcare environments. The fundamentals of

accessibility must be incorporated from the beginning of technological development, throughout the other stages of the life cycle of health technologies. This research reinforced the low number of publications involving accessibility assessment in medical devices, and highlights the need to conduct more research incorporating the diversity of user profiles in the development process to make technology management more inclusive and accessible for the entire population.

Due to the reality of the low amount of evidence and research conducted considering accessibility, for future work the Institute of Biomedical Engineering (IEB-UFSC) intends to carry out research carried out with users to highlight accessibility problems in medical equipment inserted in the Living Lab ecosystem, will feature integration with both patients and healthcare professionals, technology manufacturers, clinical engineering, architecture, and other areas and professionals involved. For that, usability techniques will be applied to explore more problems and establish strategies to improve the design of the medical equipment in health. To implement the Living Lab is essential to create an interdisciplinarity and collaborative Health Ecosystem, for the development of accessible and inclusive technologies for all people.

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