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Perception of users with visual impairments regarding adverse events in the use of technologies for diabetes

Ribeiro Brandão M., Institute of Biomedical Engineering, Federal University of Santa Catarina, Brazil, ORCID 0000-0002-3642-0723, marianaribeirobrandao@gmail.com

Vitor Fogaça J., Institute of Biomedical Engineering, Federal University of Santa Catarina, Brazil, ORCID 0009-0007-7625-9130. jvsf2003@gmail.com

Brum Marques J. L., Institute of Biomedical Engineering, Federal University of Santa Catarina, Brazil, ORCID 0000-0001-8910-4735, jefferson.marques@ufsc.br

Garcia Ojeda R., Institute of Biomedical Engineering, Federal University of Santa Catarina, Brazil, ORCID 0009-0007-7625-9130, renato.garcia.ojeda@ufsc.br

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Abstract: The lack of usability in diabetes technologies can lead to adverse user events. Currently, the literature provides limited insight into the perceptions of individuals with diabetes and visual impairments who use blood glucose monitors. The objective of this research is to analyze the experiences of people with visual impairments in using diabetes technologies, to identify the occurrence of adverse events, and to propose strategies to mitigate risks. This exploratory study consisted of interviews with 10 visually impaired individuals with diabetes living in Brazil. The data were categorized according to adverse events, accessibility problems with the devices were identified, and strategies were proposed to improve usability. All participants consistently reported not using blood glucose monitors due to usability and accessibility challenges. Instead, they required support from another person to perform measurements or had to rely on health services, as they did not have access to technologies with audio features or tactile indicators for glucose monitoring. Involving users in comprehending technology-related problems is essential to generate evidence of challenges with real world data and establish strategies for technological improvements. The adverse events reported by participants were categorized as difficulties in use, inefficient design, and problems with the reliability of measurement results. Suggested improvements included audible feedback, higher display contrast, and tactile indicators on the device to enhance accessibility. Considering accessibility from the beginning of the project, developing technologies that consider inclusive design, involving users in a collaborative environment, and working in an interdisciplinary team in the Living Lab ecosystem aim to develop safer and more inclusive technologies for all people.

Keywords: Diabetes, Blood Glucose Monitoring, Accessibility, Usability, Medical Devices.

1. Introduction

Diabetes is a chronic disease that occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces. People with diabetes have an increasing risk of health problems, including heart attack, stroke, neurological conditions and kidney failure, and can lead to permanent vision loss by damaging the blood vessels in the eyes (World Health Organization, 2024). In 2020, 1.07 million (95% UI: 0.76, 1.51) people became blind due to diabetic retinopathy, and approximately 3.28 million (95% UI: 2.41, 4.34) had moderate or severe visual impairment (Curran, 2024). Visual impairment occurs when an eye condition affects the visual system and its functions (World Health Organization, 2023). It can be classified into different categories, including mild, moderate, severe visual impairment, and blindness (Dandona, 2006; Pan American Health Organization).

Technologies are used in health care delivery to improve quality of life for populations. However, it is necessary to understand accessibility and safety barriers in medical devices used for all types of exams and procedures by populations to reduce disparities in providing health services to people with disabilities (Story, 2009; Yee, 2010).

Several medical devices are used for diabetes management: blood glucose monitors (BGM) and continuous glucose monitoring (CGM) or therapeutic systems for insulin administration, such as pens and insulin infusion pumps. In these technologies, all users must be able to adjust settings and operate independently, thus characterizing them as accessible devices (Burton, 2012). However, visually impaired patients with diabetes often encounter barriers that prevent access to available health care (Heinemann, 2016).

A study conducted by Burton et al. presented some criteria that characterize a BGM as accessible, including audible data output, a high contrast screen with larger fonts, control buttons that can be identified by touch and are distinct in color contrast, accessible test strip calibration (e.g., automatic), an operating manual in an electronic format readable by screen reader software, and accessible software (Burton, 2012).

Another study evaluated the accessibility of five glucose monitoring systems (Heinemann, 2016). The following features were considered: backlight on the monitor screen, test strip light, different audible features such as beeps or reading, tactile markings, and Bluetooth capability. None of the monitoring systems analyzed were fully accessible (Heinemann, 2016). A study conducted by Burton et al. showed that all of the BGMs analyzed had low-contrast displays that are difficult to see for people with impaired vision. Furthermore, none of the devices with audible resources are the most popular today or among the best-selling technology (Burton, 2012). Another study conducted by Uslan et al. analyzed 17 BGMs, but none were fully accessible (Uslan, 2003). Thus, individuals may use the devices inappropriately, leading to adverse events and even the development of other health conditions (Nguyen, 2024).

The use of diabetes technologies aims to improve the management of diabetes; however, its use can be challenging for visually impaired patients with diabetes and can cause serious health consequences. Insulin delivery and monitoring devices, such as pens, pumps, and BGMs, are often not designed with the needs of this population in mind (Akturk, 2020).

The availability of accessible medical devices for visually impaired patients is scarce. Some of the issues faced with BGM include low-contrast displays that are difficult for people with low vision to see (Burton, 2012), testing equipment lacking colour contrast (Macdonald, 2017), lack of speech output, small visual displays, and high levels of reflection (Blubaugh, 2012). Current literature on this topic is scarce and provides little insight into the perceptions of patients with both diabetes and visual impairment who rely on these technologies. Without a clear understanding of these barriers, it becomes difficult to propose effective strategies to improve usability and accessibility, and consequently the quality of care, for this population.

The lack of accessibility to medical devices is a major concern. Due to barriers, individuals with disabilities are less likely to obtain routine preventive health care than people without disabilities (Ada, 2022). More accessible health solutions are essential to promote equity and achieve health promotion, prevention, and safety. Consequently, it can help reduce disparity, increase inclusion, and make health spaces more equitable (Brandao, 2024).

The objective of this study is to explore the main difficulties and perceptions of people with visual impairment in using currently available diabetes technologies, with a particular focus on BGMs. By doing so, it seeks to support the development of technological solutions that make device use safer and more reliable. In addition, strategies to enhance the accessibility of medical devices and mitigate adverse events will be discussed.

2. Methodology

This study is exploratory and applied, as it aims to provide more information on the subject to be investigated and generate practical knowledge for solving specific problems on the use of medical devices by people with diabetes and visual impairment. It consists of a qualitative approach, as it seeks to explore and understand the problems of a group of users based on an inductive process. So, the researcher generates results from the data collected (Creswell, 2010; Malhotra, 2001).

The research was realized using the PDCA (Planning, Execution, Control and Action) quality tool. In the first stage, the population and the usability technique to be applied were determined, the protocol for the application of the technique was developed, and the mapping and recruitment of participants were realized. The exploratory research consisted of the application of the usability technique interview with 10 visually impaired people who have diabetes, realized in the city of Florianópolis, Brazil, during the year 2024.

Of the total participants, one person had partial vision loss, and the others were blind, with total vision loss. The inclusion criteria were people over 18 years of age who have diabetes. The recruitment of participants was carried out through contact with an association for the blind. It was conducted in the form of an interview so that the visually impaired participants would not have difficulty filling out the form with the questions. The responses were transcribed, and the problems reported resulting from the use of the glucose monitor were categorized.

After the analysis, a graphic representation was created summarizing the adverse events reported by users involving the glucose monitor. The research to understand the problems in diabetes technologies was approved by the ethics committee for research involving humans of the Federal University of Santa Catarina with project number 74674323.3.0000.0121 and the participants agreed to participate in the research as presented in the consent form. The guide of the questions asked is explained in Table 1.

Table 1. Interview Guide with visually impaired and diabetic users

Research Guide with visually impaired and diabetic users
1. Initial presentation: Welcome, introduction 2. Which technology(ies) do you use (or have you used) in diabetes care? 3. How were you instructed to use this equipment? How do you use the device? 4. Have you ever experienced any problems while using it? Which ones? 5. Do you consider the results generated by the equipment reliable? 6. If you were to change something about the glucometer to make it easier to use, what would you change? 7. Final presentation

The variables analyzed during the interview were: which medical devices users use (or have had contact with) to monitor diabetes; how they were instructed to use the technology; whether they use the technology, and if so, how; problems they have faced using the technology; accessibility barriers and recommendations for improvements to the device interface. Participants were residents of Florianópolis, Santa Catarina, Brazil, over 60 years old.

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3. Results and discussion

A total of 10 visually impaired and diabetic participants agreed to participate in the study. Of the total, three people reported that diabetes had caused their vision loss. One of the participants claimed that in addition to being blind, he also had one of his legs amputated due to diabetes. Of the total of 10 participants, one reported having severe visual impairment, and the others were blind. All participants reported at least one adverse event associated with the use of the glucose monitor. These adverse events are explained in Table 2.

Table 2 - Adverse events reported by users with visually impaired and diabetic

Adverse Event	Description of the report
Unable to perform the measurement, dependence on another person to perform the measurement	"Currently, I do not monitor myself very often. Before, when I had help, I was able to record the results. However, now I do not have anyone to help me, so I end up not doing it." "I have a visual impairment and cannot see the results on the device." "When I feel something is wrong, I go to the health centre." "When I could see, I used regular devices. I could see the results by myself. Nevertheless, after I lost my vision, I always needed someone's help to take the measurements." Since I live alone and cannot see, it is impossible. Unfortunately, the technologies are not accessible at this point."
Health consequences due to lack of measurement	"I have had serious crises and needed medical attention." "I try to guide myself by symptoms, such as dizziness or weakness. However, the ideal would be to have accurate records for the endocrinologist to evaluate." "I have devices, but I only use them when I notice that something is very out of the ordinary. Sometimes I am at 35, sometimes at 290 mg/dL."
Discomfort during measurement	"I find it uncomfortable to prick my finger every day." "They need something more modern that does not prick my finger. I do not have enough blood to prick so many times!" "I find it uncomfortable to prick my finger every day."
Lack of glucose value trend alert	"For example, if it is at 70, I get desperate thinking it is going to go down further, but sometimes it is going up, and I do not even need to worry. This causes much confusion." "It should indicate the trend, whether glucose is going to go up or down, and not just the momentary value."
Dirt on the hands interferes with the result	"Especially when hands were not clean before measuring. This situation can alter the results."
Battery problem	"The batteries ran out quickly, and sometimes the devices did not work properly."

Regarding diabetes monitoring and control, all blind participants reported that they were unable to monitor their blood sugar alone, needed other people or needed to go to a health service to take the measurement. The need to go to a health service to take the measurement also raises awareness regarding accessibility in health spaces to ensure mobility. In addition to the lack of continuous monitoring due to the absence of accessible technology, other adverse events were reported: worsening of clinical health conditions (such as hypoglycemia and hyperglycemia) due to lack of measurement, discomfort during use, discrepancies in measurement results due to incorrect use because of the lack of visualization and tactile indications, dirt on the hands interfering with the results, and battery problems.

The lack of diabetes monitoring can lead to serious health problems. Participants use the BGM only when they detect a problem, which implies potential health damage to the patient, as explained in Table 2.

Regarding the perception of people with visual impairments about the BGM, they claimed that the lack of accessibility makes it impossible to use it. All participants reported that the devices should have audible resources. In addition to the problems highlighted by the lack of auditory feedback, participants reported the absence of tactile indicators and lack of contrast in the devices. These technology accessibility problems are presented in Table 3. One of the research participants had severe visual impairment but did not have total loss of vision. She claimed to use a magnifying glass to view the results and recommended that the devices have a more contrasting interface.

Table 3 - Accessibility Problems reported by users with visually impaired and diabetic

Accessibility Problems	Description of the report
Lack of audible resource that impacts the lack of use of technology	“It would be essential to have a voice program that would inform the results. That way, I could have the autonomy to monitor my glucose levels.” “It would be great if there was a device that would prick your finger and tell you the glucose level. For example, “It is 120” or “It is 200 mg/dL and a bit”. That would make things much easier for people who cannot see.” In the case of a blind person, how would they interpret the information? I think it would be essential to have something with auditory feedback.”
Lack of indicative resources in the device impacts non-performance of measurement or incorrect use of measurement	“When you can see, it is easy to know where to put the drop of blood, where the light comes on. However, without sight, you have to depend on someone to guide you, and that does not always work. I have already gotten the wrong place to put the blood, and the measurement did not work.” “But the device can give an error if there is not enough blood. This is a problem for it since it cannot see if it is working correctly.” “The device would sometimes fail, especially if there was not enough blood. It was also common for the health centre to run out of test strips, so we ended up having to buy them ourselves.” “I have a visual impairment, and I cannot see the result on the device.”
Lack of contrast on the display to view the results	“I use insulin pens and a glucose meter. I need to use a magnifying glass to see the numbers.” “Because in the confusion of hypoglycemia, it is impossible to distinguish things. I have taken too much insulin by mistake. That is very dangerous.” “I remember one time when I took the same dose three times. I felt really sick and only realized it later.” “They could be more contrasting and even emit audible warnings.”

Participants highlighted that they are familiar with technologies that continuously CGM through the use of a subcutaneous sensor and that have built-in voice capabilities. However, they claim that the cost is high. Due to financial conditions, they cannot afford to purchase the technology. Another advantage of CGM is related to monitoring glucose trends. When using a BGM, the result is available at the time of measurement, but there is no progress. Another technology mentioned by participants was the insulin pen. They see it as an alternative to using syringes, allowing for greater autonomy in administering insulin. “It is the best method ever invented. Very practical.

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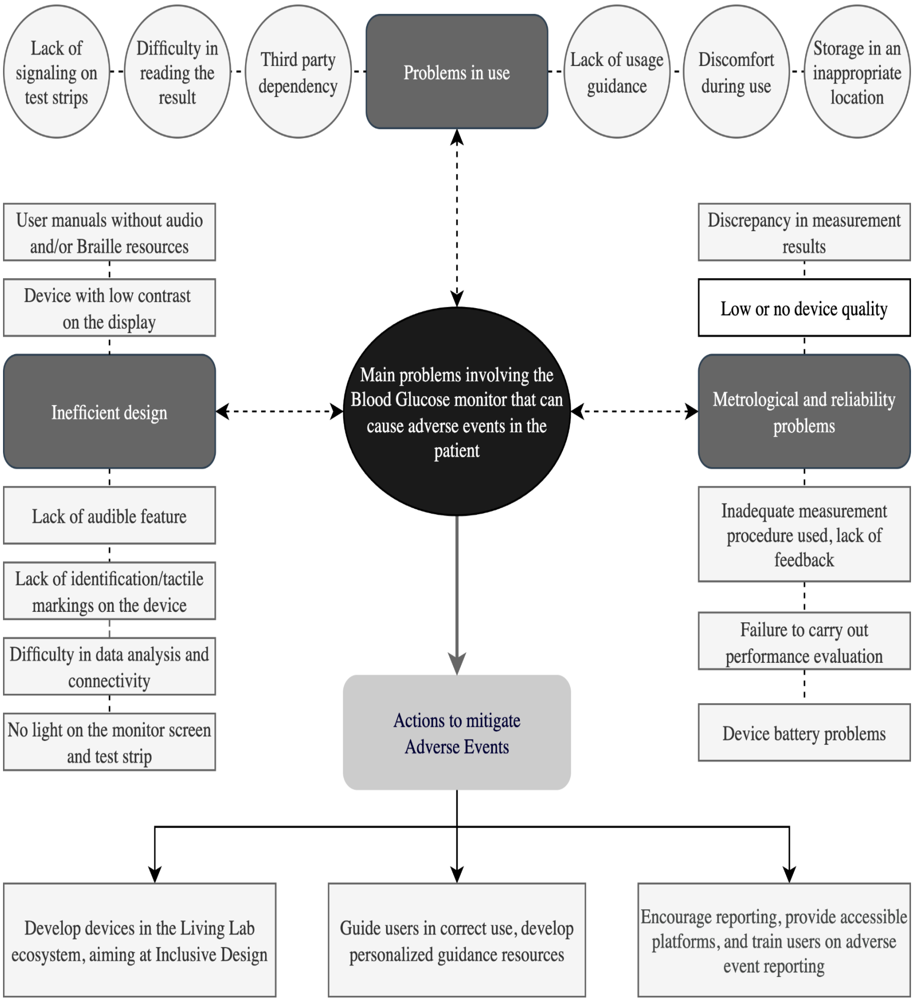
Before, syringes were very complicated for people who cannot see", reported one of the participants.

Participants also reported the reliability of the measurement results. They mention that the value of the measurement result often differs from clinical conditions or when comparing measurements taken by a relative at home and the health service. Inadequate use can also interfere with measurement results. A participant presented this topic when her hands were not properly cleaned before measuring, reporting that dirt can alter the results.

The adverse events reported were categorized as problems in use, inefficient design, and metrological and reliability problems. A diagram with a visual presentation is presented in Figure 1.

Figure 1. Main Causes of Adverse Events involving the Blood Glucose Monitor.



Note that this diagram illustrates the issues with using blood glucose monitors and actions to mitigate adverse events. The diagram highlights several usage issues, such as lack of labeling on test strips, difficulty reading results, and reliance on third parties. The diagram organizes these issues and their consequences, such as discomfort during use, discrepancies in measurement results, and poor device quality. Actions to mitigate these issues include developing devices within the Living Lab ecosystem, guiding users on correct use, and providing personalized guidance resources. The diagram also highlights the importance of reporting adverse events, including accessible platforms and user training.

One of the actions to mitigate the occurrence of adverse events consists of developing medical devices inserted in a Living Lab ecosystem with a focus on Inclusive Design. This environment aims to integrate industry, health professionals, academia, government, and final users to identify the problems and develop user-centred technologies. In addition, providing users with accessible and personalized guidance on correct device use, as well as encouraging the reporting of adverse events, are key strategies to reduce risks associated with medical devices.

The lack of accessible medical devices leads to disparities in the healthcare services available to people with disabilities. This study highlights the challenges faced by individuals with visual impairments in using diabetes-related medical devices and underscores the importance of advancing technological development within an interdisciplinary and collaborative Living Lab ecosystem.

Considering patients with visual impairments in the development of BGM is essential. As highlighted in the user survey and as discussed by Heinemann et al., it is necessary to implement strategies to ensure that the patient can remove the test strip from the box, identify the drops of blood that should be applied to the correct location on the test strip and in sufficient quantity so that the measurement can be initiated. In addition, it must ensure that the patient does not contaminate himself or the surrounding environment with blood. Another factor of concern is the reading of the result generated by the equipment (Nguyen, 2024).

Visually impaired patients with diabetes need to know how to interpret the results to aid in decision-making. However, as shown in this study, none of the participants performed the glucose measurement alone, and this can lead to serious adverse events. In line with what was discussed by Heinemann et al. and Nguyen et al., patients cannot perform their daily diabetes care autonomously and are totally dependent on external assistance. This is not only associated with substantial additional costs for the health system but also leads to massive restrictions on patients' independence (Heinemann, 2016; Nguyen, 2024; Uslan, 2003).

The lack of autonomy in diabetes management by visually impaired people was found in this study since users depend on others to perform the measurement. This data converges with the study by Heydarian et al., which found that, compared to non-visually impaired people, visually impaired people were less likely to report high self-efficacy in diabetes management (Heydarian, 2021).

Having voice resources available, having tactile indicators on the devices, having backlighting on the monitor screen and on the test strip, and having connectivity with external applications for cell phones or notebooks are some recommendations to improve the accessibility of monitoring systems.

In addition to improving the device, the importance of metrology is highlighted to ensure the metrological reliability of measurements and provide adequate guidance on the correct use of technology to avoid adverse events. Having usage instructions in Braille and other alternative formats, such as audio recordings and electronic text of information, is a recommendation to improve the usability of devices.

This research demonstrated the relevance of involving users in the perception of usage problems within a living lab healthcare ecosystem, which consists of an interdisciplinary and collaborative healthcare ecosystem. A living lab is defined as a user-centred research methodology for developing, testing, and implementing complex healthcare innovations in a real-life context based on the following pillars: user-centeredness, co-creation, real-life context, test innovation, and open innovation (Zipfel, 2022; Santonen, 2022).

In line with Brandão et al., further research is needed that incorporates the diversity of user profiles into the development process, thereby making technology management more inclusive and accessible to the population (Brandao, 2024).

Continuing training with the entire team, including accessibility parameters in the adoption of the medical devices and developing standard operating procedures,represents additional strategies that clinical engineering and other stakeholders can implement to foster a more accessible healthcare environment. At the pre-market stage of medical device development, excluding diverse user profiles from the design and validation processes can lead to performance issues for certain populations, thereby perpetuating structural inequalities in healthcare. Existing evidence emphasizes the need to include diverse patient populations in device design and validation, as biased data used during technology development is a common root cause of performance variation across different population groups.

A key issue reported by all survey participants was the cost of more accessible technologies. Access to affordable medical devices often does not extend to the entire population that requires these resources. Beyond accessibility barriers, financial costs further prevent a large portion of the population from using many technologies. Given the significant health impact associated with the lack of affordable medical devices, it is recommended to establish a collaborative Living Lab ecosystem involving stakeholders such as government agencies, manufacturers, end users, healthcare professionals, and universities.

4. Conclusions

This study highlighted accessibility issues involving medical devices used by people with visual impairments and diabetes. Main adverse events reported included difficulties in operation, inefficient design, and problems with the reliability of measurement results. To analyze the perception of users with visual impairment and diabetes, interviews were conducted and accessibility barriers were identified in medical devices that make it impossible for blind people to use medical devices for diabetes monitoring. Through user research, it was shown that none of the participants performed continuous glucose monitoring due to the lack of accessibility in the technologies, requiring an external person or a visit to the health service to monitor glucose. The research converges with other studies that show a lack of accessibility in medical devices.

The application of usability techniques inserted in a Living Lab ecosystem, such as the interviews conducted in this study, has the potential to serve as a hub for integrating various stakeholders in healthcare, integrating academia, industry, government, and society. Involving people with visual impairments in the development of devices is essential to guarantee accessibility. In addition, it is important to have public policies that encourage equality in technological access for all people. Making medical devices accessible enhances healthcare quality, reduces the occurrence of adverse events, and increases patient safety.

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During the writing of this article, the authors used AI tool to improve the language and grammar of the manuscript. After using this tool, the authors reviewed and edited the content as needed and assume full responsibility for the publication's content.

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