Practical considerations for sensitive studies during medical device usability assessments

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SUMMARY

Usability assessments on medical devices where participants are required to simulate the use of the device and share information about sensitive topics, such as intermittent catheter, ostomy bag or pelvic floor trainer use, can be challenging. This paper explores some of these challenges and how to address them.

KEYWORDS

Usability Assessments, Sensitive Topics, Simulated Use

Introduction

The application of usability engineering allows for the identification and mitigation of potential risks, and one such application is medical devices. This process also supports the development of devices that are intuitive, easy to learn and easy to use (BS EN, 2015; ISO/IEC, 2015). The application of usability engineering is important, since medical devices are becoming increasingly complex while at the same time, are being used by less skilled users in a home environment (AAMI, 2009). At the core of this process is the ability to test a medical device with study participants that are representative of the intended users while they interact with the user interfaces (AAMI, 2009).

However, some usability assessments involve medical devices where device interactions and subject matter discussions can be viewed as personal (or sensitive) and potentially necessitate recruitment from vulnerable user groups. In these cases, research may elicit emotions from participants, the topic itself could be viewed as sensitive (Dempsey, Dowling, Larkin, & Murphy, 2016), and the study could present a range of complex issues (Marsh, Browne, Taylor, & Davis, 2017). Potential examples of these types of studies include those testing medical devices such as intermittent catheters, ostomy bags, or pelvic floor trainers.

The practical, emotional, and ethical concerns related to these studies require careful consideration and planning (Marsh, et al., 2017; Dempsey, et al., 2016). This paper serves to open a discussion around key considerations, when planning medical device assessments of a sensitive nature, by outlining the high-level themes identified by a team of Human Factors consultants during two collaborative sessions.

Method

High level themes were identified during two 30-minute remote collaborative sessions (via Microsoft Teams). The sessions where structured to address the following questions: 'What challenges did you face?', 'Why was this a challenge?', and 'How were these challenges addressed?'.

Six consultants with a range of experience in conducting assessments of medical devices of this nature took part. Notes were taken during the discussions and short descriptions added to a virtual white board (via a Miro board). Additionally, unstructured contributions to the Miro board were also encouraged. The facilitator recorded notes during discussions to offer additional context for analysis. Towards the end of each session the facilitator asked the consultants to review the notes to ensure that these were a true reflection of their contributions. At the end of each session, the notes were grouped together based on the main concepts these addressed. Where notes addressed more than one discussion point, these were structured under more than one concept. After the final discussion, the notes were integrated and grouped together into themes.

The themes were checked against the findings of a second analysis by one of the consultants and found to be mostly consistent. Differences tended to be where the author focused on actionable insights. For instance, the notes grouped under 'comorbidities and accessibility' by the second analyst, were separated and grouped under 'information' and 'venue' by the first analyst. **Findings**

Below are the high-level themes that the consultants felt needed greater consideration due to their potential impact on participants. They emphasised the importance of addressing these themes during the planning process to prioritise the needs of the participants in study preparation. Where assessments are of a sensitive nature, consider:

Terminology

Identifying and using terminology that are both clinically accurate and commonly used by device users, both in documentation and during sessions - One consultant mentioned that during a study they became aware of discrepancies between clinically accurate terminology and the language used by participants. As a result, they had to clarify the terminology being used to ensure clear communication. Several consultants mentioned the need to become familiar with both clinical and lay terms used to describe concepts. Consultants suggested that it is useful to research and become familiar with these terms to support understanding between the researcher and participant. Another suggestion was to listen to the terminology used by the participants and identify where a difference in understanding could impact the safe use of the device. This could also have an impact on access to recruitment, where the complexity of information discourages potential participants from applying or completing the recruitment process. ***Anatomical mannequins***

Clearly stating in the informed consent form that, if relevant, an anatomical mannequin is used during the study and that the participant will be asked to simulate the use of the device on it - Consultants mentioned that interacting with an anatomical mannequin could potentially be a source of embarrassment for participants. To mitigate against this, the discussion explored the need to be clear in the informed consent form that this will be part of the study. One consultant suggested that an image of the mannequin could be included in the documentation for clarity. Several consultants also mentioned that they found that participants wanted to contribute to products that would improve their lives and this, combined with the professionalism of researchers, tend to reduce any initial embarrassment.

Mannequins may not be representative of the differences in user anatomies - Several consultants mentioned differences between the anatomical representation of mannequins and that of real people.

A concern was raised that this could cause participants distress and that there is a need to consider what wording is used in the discussion guide used in study sessions to pre-emptively address this. One suggestion was to clearly state that the mannequin is a representation and may not be representative of all the differences in human anatomy.

Ensuring that the device and mannequin combination have been tested for variations of the device in study - One consultant mentioned that if a study mannequin-device combination does not work, then it could impact the study. Some test devices come in a range of sizes that may not all work as intended on an anatomical mannequin. At the same time, conducting pre-tests on all device sizes could pose challenges, particularly if there are only a limited number of high-value devices available for the study. Consider planning on how to conduct pre-tests of devices to enhance the realism of study outcomes.

Accessibility

Identifying the co-morbidities and preferences of different device user groups to inform the accessibility of the information provided to participants - For instance, some user groups may have reduced vision or difficulty to concentrate. Several consultants raised concerns about the accessibility and length of wording in documentation. An example mentioned was that of informed consent forms that need to be accessible for participants while also contain information required by regulatory bodies. Consider if the information should also be presented in an audio or video format in addition to the written documentation.

How accessible the venue is for different user groups in terms of potential co-morbidities - To support the recruitment of representative user groups, consider additional accessibility issues. For instance, when it comes to mobility, does the venue provide parking? Is the study room big enough to support the use/temporary storage of mobility equipment? If the use of a lift is required, can it accommodate mobility equipment? How convenient is the location of the venue for potential participants? Could noise outside the room impact the ability of participants with hearing loss to contribute to the study? Due to the sensitive nature of the research ensure that the room is quiet, and that the session will not be interrupted, unless the participant needs a break. Consider if a home environment may facilitate more natural behaviour.

Self -Reflection

Reflecting on own concerns/attitudes/barriers that could impact on the study - The consultant's knowledge of, and exposure to, the subject material could support clear and effective conversations, reducing the time spent on clarifying terms. Often, participants want to contribute to the improvement of devices that they are dependent on and therefore view the session as a collaboration. One consultant mentioned that they focus on an attitude of, 'we are in this together', and 'we are learning from you', when doing research of a sensitive nature. Consider getting comfortable with the terminology and subject material, and consciously reflect on own attitudes and approaches before each session.

Building Rapport

Taking time to build rapport - Consultants felt it was important to build in time at the beginning of a session to provide time for the participant to acclimatise to the study environment. Generally, it was felt that researchers could facilitate a trusting, relaxed, friendly, and open attitude to support this

process. Examples of this include starting with more general questions before moving onto questions of a more personal nature, and phrasing more personal questions in an open way to allow the participant to control the narrative, for example use, ‘tell me more about your condition’.

Discussion

Themes provided outline considerations to support the planning and conducting phases of sensitive research studies. Building on already established principles (Beauchamp & Childress, 2019; Emanuel, Wendler, & Grady, 2000; World Medical Association, 2013), the themes address some of the complexities inherent in these types of studies. Studies of this nature require careful planning and consideration on the selection of an appropriate research design and data collection methods (Ashton, 2014; Dempsey, et al., 2016; Dickson-Swift, James, Kippen, & Liamputtong, 2008).

The significance of building rapport to facilitate the flow of information during sessions were mentioned. Suggestions included creating a friendly and open atmosphere, allowing time at the outset of the session, and using questioning techniques to help participants adjust to the research environment. These strategies can be seen to support trust between the participant and researcher, which Marsh, et al., (2017) assert is the cornerstone of the research process. Marsh, et al., (2017) also highlighted the challenges researchers encounter when investigating sensitive aspects of participants’ lives. Researchers may be affected by research and should prepare to disengage both physically and psychologically on completion of the research (Lee, 1993).

One critical area for consideration is that of the use of terminology. While the use of plain language and avoidance of jargon in instructions and interview questions are widely acknowledged principles (Medicine, n.d.; World Medical Association, 2013), implementing them effectively in practice remains a challenge. One approach to overcoming this challenge is ensuring a high level of familiarity with the subject material and the language commonly used by both device users and the clinical team. However, it is important to recognise that clarity on terminology and comprehension may only emerge through direct interaction between the researcher and the participant. Therefore, researchers should be flexible and ready to adapt during the study session.

The importance of identifying the impact of co-morbidities and preferences of device user groups for accessibility was also highlighted. Concerns were raised about the accessibility of wording in documentation. The consultants’ suggestion aligns with the statement by the World Medical Association (2013), emphasising that the informed consent process should include straightforward, clear-language materials that participants can grasp. However, these often need to meet regulatory standards, resulting in lengthy and complex information. The recommendation to utilise audiovisual formats alongside written documentation resonates with the guidance provided by the World Medical Association (2013), which underscores the effectiveness of additional means to enhance communication, where relevant. Participants should also be given the opportunity to raise questions and receive explanations for any uncertainties, with a clear explanation of the study’s objectives and anticipated results given to cultivate a collaborative atmosphere (National Cancer Institute, n.d.).

To effectively address the usability needs of a representative sample of the population, prioritising the removal of practical barriers to research access is important. Venue accessibility was emphasised and included considerations such as parking, step-free entrance, lift, room size, and

noise level. Ensuring an interruption-free session in a quiet environment is essential due to the sensitive nature of the research.

While practical measures at removing barriers to access are crucial, consultants also highlighted another challenge: ensuring participant comfort. This underlines the importance to create a setting in which participants feel at ease to express their thoughts and concerns freely, without any sense of obligation to take part in the study (Emanuel, Wendler, & Grady, 2000). Factors contributing to discomfort may include discussions that involve personal or intimate information (Lee, 1993), the use of anatomical terminology or interacting with medical mannequins. Despite the potential for discomfort, consultants noted that they found that participants often expressed a desire to contribute to studies involving the design of medical devices relevant to their health conditions. This sentiment is supported by the findings of Alexander, Pillay and Bronwyn (2018), which indicated that participants, even when experiencing discomfort, remain willing to engage in future research and often derive benefit from the experience. In light of these considerations, it is essential to explore how access to recruitment for medical device users can be facilitated.

When using anatomical mannequins, consultants felt that it was important to acknowledge the potential for participant embarrassment. Informing the participant that they may interact with a mannequin to simulate device use, and potentially incorporating an image of the mannequin in presession documentation could manage concerns. Consultants highlighted that mannequins may not accurately represent human anatomical differences, potentially causing distress, and propose that pre-emptive wording could be added in the discussion guide. Planning pre-testing of the devicemannequin combinations could enhance study realism despite challenges in availability of prototypes. Additionally, the U.S. Food and Drug Administration (n.d.) suggests that participant well-being should be continuously monitored and that study procedures adjusted as needed.

An integration of these themes and principles provided guidelines for a checklist to ensure that these considerations are incorporated in the early stages of study design so that the practical, emotional, and ethical impact on the participant is fully realised.

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