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Usability Challenges with Insulin Pump Devices in Diabetes Care: What Trainers Observe with First-time Pump Users

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USABILITY CHALLENGES WITH INSULIN PUMP DEVICES IN DIABETES CARE: WHAT TRAINERS OBSERVE WITH FIRST-TIME PUMP USERS

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ABSTRACT

Insulin pumps are designed for the self-management of diabetes mellitus in patients and are known for their complexity of use. Pump manufacturers engage trainers to help patients use the devices correctly to control the symptoms of their disease. Usability research related to insulin pumps and other infusion pumps with first-time users as participants has centered on the relationship between user interface design and the effectiveness of task completion. Another suitable approach to acquire information about potential usability issues encountered by first-time users is to obtain this information from the health care professionals who train them. However, there is a lack of insight into the experiences of insulin pump trainers during learning sessions with patients new to insulin pumps. The focus of the study is to present the lived experiences and shared impressions of the insulin pump trainers and to provide the essence of their lived experiences.

Keywords

Insulin pump, interface, usability, safety critical, training, phenomenology

INTRODUCTION

Diabetes is a complex disease that prevents the body's metabolism from regulating blood glucose through its normal ability to produce adequate amounts of insulin (Ismail-Beigi, 2012). The health care practitioner's goal is to minimize potential complications from diabetes by teaching patients how to control fluctuating glucose levels with the administration of insulin injections, dosed to keep blood glucose levels within a prescribed range. Continuous subcutaneous insulin infusion (CSII) through insulin pumps provides an opportunity for improved self-management by individual patients to treat symptoms of diabetes (Pickup, 2012). When used appropriately, CSII is more beneficial to patients than the administration of multiple daily injections (MDI) with insulin, because CSII therapy is more efficient in the reduction of fluctuations in blood glucose levels than MDI (Heinemann, Fleming, Petrie, Holl, Bergenstal and Peters, 2015).

Patients who adopt insulin pump therapy after being approved by a physician play an important role to achieve a positive outcome, but the successful implementation of insulin pump therapy differs among users. Careful patient selection is a known predictor for insulin pump therapy success (McAdams and Rizvi, 2016). The ideal insulin pump candidate should be motivated to comply with the programming and need for constant interaction with the pump (Heinemann et al., 2015).

With insulin pump therapy, users are required to determine and act upon multiple variables, such as blood glucose levels, exercise duration and intensity, potential stress factors, and the carbohydrate count of the meal they intend to consume (McAdams and Rizvi, 2016). Insulin pumps are deemed to be complex interactive medical devices, and improper handling of the pump puts the patient at risk (Heinemann et al., 2015; Schaeffer, Parks, Verhoef, Bailey, Schorr, Davis, Halford and Sulik, 2015). Pump manufacturers employ certified pump trainers to start patients on CSII. Although it is not mandatory, patients are expected to undergo training sessions with certified health care professionals. It is important to the safety of the patient that the patient receives this training to properly learn the functionality of pump management (Heinemann et al.).

Many interactive systems in health care are safety critical to the treatment of patients in the sense that any malfunction or inappropriate use can lead to "severe health damage" in a patient (Blauw, Keith-Hynes, Koops and DeVries, 2016, p. 3159). The safe engineering of medical devices needs to match what users need, what they are capable of, and what their limitations are (Schaeffer, 2013). This requirement needs to be aligned with the intended use of the system. The system interface should present the "right information at the right time in support of activities" (Campos, Doherty and Harrison, 2014, p. 285).

Constraints in the system may distract users to miss a task or even prevent users from completing a task. "Error-prone activities" (Campos et al., 2014, p. 288) in interactive systems and resource limits affecting system functional states must be avoided, because they adversely affect the safe operation of the device. According to Campos et al. (2014), realistic task executions by the user during the entering of dynamic information need to find support during initial design of the system.

There is little discussion about the nature of realistic user scenarios obtained through knowledge of real-life situations in the context of insulin pump usability (Campos et al., 2014). One way to obtain this information is through a health care professional involved in training a user to manage their own insulin pump. A suitable approach to acquire information about actual pump usage by patients new to insulin therapy is to view the challenges faced by first-time users of insulin pump through the eyes of their trainer. However, there are few studies involving health care professionals engaged in pump training. The addressable problem of the study is a lack of insight into the experiences of insulin pump trainers during learning sessions with patients new to insulin pumps. In addition, there is a lack of understanding of the dynamics that trainers experience and observe with patients during first-time user interaction with this type of safety critical device in a health care environment.

The overarching research question for this study which serves as the grand tour question will guide the discovery of understanding the experiences of the insulin pump trainers: *What is the essence of the experiences of insulin pump trainers while they teach first-time users how to use the device?*

The following sub-questions will highlight specific areas of interest how insulin pump trainers perceive their interaction with first-time users during the instructional process:

1. When training first-time users on the management of the insulin pump, what type of problems do trainers observe that can have a potential impact on safe use? 2. Which of these problems observed relate to the interface characteristics of the device? 3. What type of usability errors are encountered when trainers teach first-time users how to program their insulin pump? 4. What can trainers tell us about the learnability and ease of use of the insulin pump programming interface?

LITERATURE REVIEW

A literature review was conducted by examining health care and information systems publications. In the case of usability studies, there is frequent collaboration among health care and information systems professionals who embrace common goals. This literature review reflects research on metabolic disease with particular focus on diabetes, on usability aspects of medical devices and user interface design, on the safety critical aspect of medical devices, and on learnability and training. The peer-reviewed findings reported in this study are the basis for the problem space, goals, and questions this researcher seeks to answer.

User Interface Design and Medical Device Safety

Insulin pumps require systematic interaction between users and device interface, because a user has to make "treatment decisions multiple times a day" which may affect their health (Blauw et al., 2016, p. 3158). Schaeffer (2013) specified risk assessment as a high priority in the medical device arena due to the "life-saving nature of the devices used by humans" (p. 846). The study by Schaeffer et al. (2015) about usability and training differences between two personal insulin pumps is an example to demonstrate user interface design issues on medical devices such as these**.** The researchers associated error categories with programming errors reported and cited mistakes made by their study participants during data entry of basal rates, blood glucose levels, or carbohydrate counts.

According to Schaeffer et al. (2015), actual usage of the system should be explored in detail to provide an understanding how humans interact with the elements of a system. The examination of this interaction can help to identify design flaws so that they can be eliminated to make medical devices safe and effective for users. In addition, safety can be impacted by software errors and inconsistent user interface features (Cauchi, Oladimeji, Niezen and Thimbleby, 2014). For example, reduction of errors during number entry on medical devices is vital because it is a common task in a health care environment. This finding is of grave concern in the case of insulin pump programming, because wrong dosage of insulin delivered to the body can create harm to the user (Heinemann et al., 2015). Schaeffer et al. (2015) were able to demonstrate that errors in a real-time environment—when left unchecked—will cause the pump to deliver inappropriate doses of insulin.

The safety critical nature of medical devices is a neglected topic in research of health care systems. With considerable differences in design among insulin pump models (Waldenmaier, Schöllkopf, Westhoff, Heinemann and Freckmann, 2018), patients need assurance that a given device has been undergoing rigorous testing for its safety and that it has been rated as user- and training friendly.

Usability, Learnability and Training

Usability is a characteristic that expresses that a system is "adaptable to different contexts of use" (Alonso-Ríos, Vázquez-García, Mosqueira-Rey and Moret-Bonillo, 2009, p. 56). With insulin pump therapy, the system design must provide for administering or stopping insulin delivery to the body at the right time, based on fluctuating variables (e.g., insulin sensitivity, blood glucose level, or lifestyle habits). It is of paramount importance that the system is adaptable to facilitate immediate and continuous adjustments of these parameters without barriers to usability.

According to Waldenmaier et al. (2018), usability of insulin pump systems is an important factor that affects the success in the management of the chronic condition of diabetes. A system that stresses a user's visual and cognitive abilities can generate use-related errors which have a negative impact on usability (Schaeffer et al., 2015). For example, when the patient prepares to consume a meal containing a calculated number of carbohydrates, it requires the programming of a standard bolus [one-time dose] into the user interface to deliver insulin. This activity is a repetitive task to equalize blood glucose levels within a safe range and it should consist of a task sequence that can easily be learned and remembered.

The training of an individual on the use of an insulin pump is an important factor that contributes to the safe use of the device (Blauw et al., 2016). Training helps the user understand and organize knowledge about a physical system (Santhaman, Sasidharan, Yi and Park, 2013). According to Pickup (2012), initiation of pump therapy on a patient needs to be conducted by a health care professional "trained in pump procedures" (p. 1620). It is important to study the training experiences of insulin pump trainers, because few studies exist that give a voice to the trainer. Uncovering and analyzing the phenomena experienced by trainers can contribute to an understanding of the dynamics of training a patient to self-manage a safety critical medical device.

METHODOLOGY

The investigative lens for this study consists of interpretive inquiry with the aim to reveal multiple views of the trainers' experiences during insulin pump training with first-time users. According to Bhattacherjee (2012), interpretive methods serve to investigate and learn about a "phenomenon of interest from the observed data" (p. 35) and by allowing constructs of interest to "emerge from the data as the research progresses" (p. 93). This calls for a qualitative method that enables the content analysis of new phenomena and the formulation of the essence of the trainers' experience with users new to insulin pump therapy.

Rationale for Choosing the Research Procedures

The goal of the study is to discover new phenomena from the lived experiences and shared impressions of insulin pump trainers during training sessions with patients new to insulin pumps. Their experiences and impressions will be used to uncover the phenomena associated with potential usability challenges that first-time users of insulin pumps face when learning how to use the device. An interpretive examination of the phenomena will provide the essence of their lived experiences in the hope to reveal the nature and significance of usability issues discovered from the trainers' experience in a new way (van Manen, 2016).

A phenomenological study design approach using interpretative phenomenological analysis (IPA) as experienced from a distinct point of view (Carel, 2011) will provide the basis to "learn about the problem or issue from participants" (Creswell, 2013, p. 47) and to describe the "common meaning [i.e., essence]...of their lived experiences" (p. 76). IPA allows the capture and analysis of what trainers are "seeing, remembering and experiencing" (Smith, Flowers and Larkin, 2012, p. 13). The trainers' point of view is examined, because previous studies were not able to fully capture the dynamics of a realistic user environment. This study will capture events during which patients learn how to program the pump according to their personal settings and the distinct symptomology of their disease. The research procedures of IPA will provide an insight into a research area that previously appeared to offer an inadequate understanding (Morse and Richards, 2002),

In addition, the social reality of insulin pump trainers can be constructed from the real-life setting of their training activities, because—at that point—users are being trained how to operate a fully functional insulin pump as a replacement to MDI therapy. The insulin pump trainers' observations of difficulties encountered by the users are shaped by their experiences within the social context (Bhattacherjee, 2012). For the purpose of this study, the social context is the clinical therapeutic setting that takes place between a trainer and a first-time user where tasks are carried out, using real-life situations.

Participant Selection

Health care professionals who conduct insulin pump training have a unique experience which is the focus of this study. This situation makes judgment sampling a suitable method to identify potential participants, because it involves selecting only those individuals who can be expected to provide the required information (Sekaran and Bougie, 2013). This sampling design will provide the basis to achieve a "fairly homogeneous sample" (Smith and Osborn, 2015, p. 28), which means that the

individuals in the group carry out similar duties and, therefore, share similar experiences. The intent is to collect data from about six to eight individuals, spending sufficient time with each participant to obtain a rich data set. An IPA approach allows for a small sample size as little as three as long as "sufficient in-depth engagement with each individual case is conducted" (Smith and Osborn, 2015, p. 29).

Study participation will require that respondents are certified or have been certified in the past through one or more insulin pump manufacturers (e.g., Medtronic; Tandem® Diabetes Care). Alternatively, a participant may have been trained through an official society such as the *National Certification Board for Diabetes Educators*. A participant should have conducted a minimum of one pump training in the recent past with a patient new to insulin pumps. The sample population will be drawn from a wide geographic area in the United States with leads obtained from social networking platforms, such as *LinkedIn*, by news posting and by personal invitation. Participants responding to the invitation will be asked to complete a demographic survey to list their qualifications as an insulin pump trainer and to provide their contact information.

Interview Process

Semi-structured interviews will be conducted via Skype or by telephone on a schedule convenient for the participant. The duration of the interview will be approximately 45-60 minutes, allowing for time to familiarize the participant with the interview process and go over the Informed Consent form, if necessary. The interview instrument is an IRB-approved interview guide. It contains seven broad, open-ended questions which are designed to make the data collection instrument flexible towards the participants' responses. This method allows the researcher to "probe interesting and important areas" (Smith & Osborn, 2015, p. 29) that might arise to permit the researcher to uncover yet unknown phenomena. Using this method will contribute to "ultimately provide an understanding of the common experiences of the participants" (Creswell, 2013, p. 81).

The interview questions will be significant to participants, because the questions are aimed to elicit each participant's individual perceptions of their experiences while training users new to insulin pump therapy. From each participant's narrative, a detailed analysis following the principles of the IPA approach will be performed to provide answers to the stated research questions.

An experienced insulin pump trainer at a diabetes clinic in North Central Florida was asked to participate in a pilot interview to verify that the interview instrument was understandable and relevant to the intended participants. The pilot recommended no changes and participant recruitment commenced. After the rest of the study participants are selected, an interview schedule will be created based on the participants' time preference. Transcription of the audio recordings will be generated by a third party medical transcription service. The participants' privacy will be observed and they will be identified in the text and the subsequent report through unique random two-digit numbers.

Quality Control

Smith et al. (2012) presented a rationale on how to achieve validity and quality using the IPA. To achieve internal validity, researchers are expected to show that they are sensitive to the process at an early stage. Examples are: The ability to apply empathy and be able to "put the participants at ease" (p. 180); sufficient "idiographic engagement"; "thoroughness" in data collection; "quality of the interview" process; and "completeness of the analysis" (p. 181). To ensure the "trustworthiness" (Guba and Lincoln, 1982, p. 246) of the findings, this researcher hopes to attain quality in data collection by carefully selecting suitable participants. The interview process has been diligently organized, thoroughly staged, and was tested during the pilot interview, before actual data collection commenced. The quality of data obtained from each interview will be reassessed to ensure that they align with the research questions (Belotto, 2018).

Furthermore, the researcher is using the process of bracketing and will keep a journal with the intent to set aside personal assumptions and to retain an objective lens when examining the subjective accounts of each participant (Deggs and Hernandez, 2018). This journal will also help the researcher to engage in purposeful reflection during the analysis phase of the study. Notes made at the conclusion of each interview will help the researcher sort out any misconceptions or biases about the information shared by the participant, which will help to "increase rigor and trustworthiness" regarding the observations (Phillippi and Lauderdale, 2018, p. 382). In addition, disclosing the researcher's background delivers an awareness of factors that might influence the research and provides an insight how the data is interpreted (Deggs and Hernandez, 2018). The researcher will clarify the interpretation of data during the analysis "as a means to connect [it] with theory and pre-understandings" (Deggs and Hernandez, 2018, p. 2556).

Assumptions, Limitations and Delimitations

This study relies on the assumption that selected participants are willing to take the appropriate time needed to provide information for further analysis and to provide potential answers to the research questions. In addition, it is assumed that

participants will be comfortable to freely discuss the experiences they encountered while teaching patients how to use an insulin pump. The data collection depends on a reasonably accurate recollection by participants of what they observed during the training sessions. Participant selection will be made using responses to the aforementioned demographic survey to ensure that the pool of potential participants is well-suited to provide the necessary data (Sekaran and Bougie, 2013).

The scope of the project is limited to the investigation of the lived experiences of insulin pump trainers while working in training sessions with diabetes patients for the first-time use of an insulin pump. The trainers' worldview of the difficulties first-time users face when learning how to use and self-manage their medical condition with an insulin pump can enrich an understanding of phenomena uncovered in real-life situations. The users they observed will not be part of the study.

During the data collection process, observations from participants working with patients diagnosed with both types of diabetes (type 1 and type 2) will be considered to increase the likelihood of achieving the desired sample size. Although the pathology of type 1 diabetes is clinically distinct from type 2 (Ismail-Beigi, 2012), the technique to treat uncontrolled blood glucose levels with insulin through continuous subcutaneous insulin infusion—the insulin pump—is universal for the treatment of diabetes. Devices are generally rated for both types, unless there is regulatory limitation related to the approval process at the U.S. Food and Drug Administration (McAdams and Rizvi, 2016). For the purpose of this study, a distinction between type 1 and type 2 diabetes patients is not relevant at this time, unless the analysis of the data obtained from the interviews leads to new discoveries.

ANALYSIS

The identification of themes will be based the ontology used by Schaeffer et al. (2015) in their study about usability and training differences on two insulin pump models in a simulated use environment. IPA methodology will provide the necessary steps to move from the descriptive narratives of the trainers' experiences to the interpretive task to provide sense-making of these experiences (Smith et al., 2012).

Analysis of data collected from the interviews will be performed with the methods recommended in IPA, starting by identifying an initial list of themes through manual coding and followed by a clustering of themes (Smith and Osborn, 2015), These themes will later be analyzed in NVivo 12 software, after analyzing each individual narrative, adding the codes established through reading and rereading the transcripts, and also adding relevant notations from the reflective journal. The coding scheme will be further refined by immersion into the data, by making preliminary notes, and by adding descriptive, linguistic and conceptual comments, etc. (Smith, et al., 2012). The result will be the creation of a master table of emerging themes that considers individual narratives and the group of participants as a whole by "fragmenting and re-organizing" (p. 91) the data.

A cross-analysis will follow by finding connections across the emergent themes which will facilitate the development of needed super-ordinate themes that define the aforementioned connections (Smith et al., 2012). Once the interpretation of data classified during the analytical step is complete, a write-up will be performed to formulate the essence of the participants' lived experience (Smith and Osborn, 2015). The presentation of the analysis and results will follow, along with conclusions and recommendations for further research.

CONTRIBUTION OF THE STUDY

Previous studies were conducted on the basis of behavior observation with users during simulated task execution. Assumptions about user actions should include realistic scenarios (Campos et al., 2014) formulated from real-life situations, but proper analysis of system behavior based on realistic problems remains elusive. There is a gap in understanding what constitutes a realistic scenario. This gap generates a need to understand the experiences observed by trainers in a real-life setting with first-time users. In addition, this study may be used to correct assumptions of a realistic sequence of users' interactions with devices to inform designers of proper paths taken by user actions.

When Campos et al. (2014) uncovered inconsistencies with the objective to develop systems where performance objectives are matched with user tasks, they based it on information obtained from clinical staff knowledgeable in insulin pump management and from operation manuals. The important issue that still remains is the design issues of medical device interfaces such as inherent in infusion pumps, based on real-life situations. This study aims to extend the efforts of Campos et al. (2014) by examining the lived experiences of trainers and to gain knowledge about a more precise specification of events that occur in a real-life setting, as trainers describe as their experiences during insulin pump training with first-time users.

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