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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

by

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## Approval Page

We hereby certify that this dissertation, submitted by Helen Hernandez, conforms to acceptable standards and is fully adequate in scope and quality to fulfill the dissertation requirements for the degree of Doctor of Philosophy.

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An Abstract of a Dissertation Submitted to Nova Southeastern University
in Partial Fulfillment of the Requirements for the Degree of Doctor of Philosophy

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

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Helen B. Hernandez
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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 teach patients how to 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. According to prior research, the characteristics of system behavior in a real life environment remain elusive. A suitable approach to acquire information about potential usability problems encountered by first-time users is to obtain this information from the health care professionals who train them.

The purpose of the study was to discover the lived experiences and shared impressions of insulin pump trainers during training sessions with first-time users. Interpretative Phenomenological Analysis (IPA) was used to uncover the phenomena associated with usability challenges that first-time users of insulin pumps face when learning to use the device. Six participants representing a homogeneous sample were recruited from a wide geographic area in the United States, and semi-structured interviews containing open-ended questions were conducted with the respondents.

The data from the lived experiences and shared impressions of the participants were used to develop the following five super-ordinate themes: *Emotion-charged Environment*, *Personalized Training*, *Safety Issues and Disaster Planning*, *Professional Dedication*, and *The Voice*. The essence of participants' experience was described around the pivotal moment when the training sessions are successfully completed and insulin pump therapy becomes alive.

The findings of this study have implications for information systems professionals who conduct research on the safe design and usability of safety critical medical devices. In addition, the findings from this study create opportunities for practice to improve the initiation of insulin pump therapy in patients with diabetes.

## Dedication

This dissertation is dedicated to the memory of my parents, Olga and Thilo Birkmann. They provided the necessary foundation for me to pursue my academic goals by breaking down social barriers and enrolling me in high school (Sigena Gymnasium, Nürnberg), when I was growing up in my native country of Germany.

## Acknowledgements

This study was developed out of compassion for individuals who are afflicted with the chronic disease of diabetes and whose suffering I have witnessed over the years. I have great admiration and respect for their health care team and their caregivers who stand by them during this difficult journey.

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Finally, I would like to thank the participants for taking the time to be interviewed for this study. This research was made possible because of their willingness to share their experiences. Their candid recollections allowed me to capture the essence of what it means to conduct insulin pump training sessions to help improve the lives of diabetes patients.

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# Chapter 1

# Introduction

## Background

Diabetes mellitus, commonly abbreviated *diabetes*, is a disease that impacts the function of the body to properly control blood glucose levels (Schaeffer, 2013). Continuous subcutaneous insulin infusion (CSII) with insulin pumps provides an opportunity for improved self-management by individual patients to treat their symptoms (Pickup, 2012). When used appropriately, CSII is more beneficial to patients than the administration of multiple daily injections (MDI) with insulin, because CSII therapy can reduce fluctuations in blood glucose levels (Heinemann, Fleming, Petrie, Holl, Bergenstal, & Peters, 2015).

Users play an important role in a positive outcome during insulin pump therapy. However, insulin pumps are 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, & Sulik, 2015). Users' actions during the operation of such systems could result in an outcome that can cause damage or harm to the individual (Masci, Ayoub, Curzon, Harrison, Lee, & Thimbleby, 2013). A user's health is entirely dependent on their ability to program the insulin pump correctly and to avoid adverse events.

According to Ross, Milburn, Reith, Wilshire and Wheeler (2015), adverse events frequently happen due to erroneous task execution or omissions. For example, "alarm fatigue" (Heinemann et al., 2015, p. 719) created by a pattern of repeated inappropriate warnings from the pump interface could lead a user to ignore warnings of an occlusion alarm. The user may be unaware that there is little or no insulin delivered to their body, which constitutes potential serious harm to the user (Heinemann, et al.).

*Design and Use*

According to Campos, Doherty, and Harrison (2014), the safe use of a medical device requires a design that is consistent with the intended use of the system. Interaction design issues should be addressed by presenting the "right information at the right time in support of activities" (p. 285). Constraints in the system may distract users to miss a task or even prevent users from completing a task.

In their case study of two similar infusion pumps (i.e., "device A" and "device B"), Campos et al. (2014) tested the infusion time command feature on both pump interfaces. They noted that "device A" possessed the necessary features to perform certain tasks, but that the indicators on the device were inconsistent. For example, the top line on "device A" was missing the display *VTBI/TIME*, preventing the user from recognizing that infusion time start can be entered (Campos, et al.). In addition, the interface on "device A" lacked a *CONFIRM* mode, making the user unaware that infusion would commence as soon as they enter the dosage amount. Such inconsistencies and resource constraints in the interface design of insulin pumps can potentially prevent the user from recovering from an input error at the time of programming, resulting in medication infusion with the wrong dosage.

Errors like these are problematic, because many interactive systems in health care are safety critical to the treatment of patients. "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.

Usability testing is performed in the medical device industry to provide information on how users interact with their tools and to locate usability problems or design flaws that may need to be addressed in redesign (Miller, Arnold, Capan, Campbell, Zern, Dressler, Duru, Ebbert, Jackson, Learish, Strauss, Wu, & Bennett, 2017). The study of these use-related [usability] problems in medical devices is of vital importance. Schaeffer et al. (2015) posited that an ambiguous design of medical devices can have an adverse impact on self-care situations.

*Insulin Pump Operation*

The successful implementation of insulin pump therapy differs among users and careful patient selection is a predictor for insulin pump therapy success (McAdams & Rizvi, 2016). The ideal insulin pump candidate should be motivated to comply with the programming and constant interaction between the user and the pump (Lawton, Kirkham, Rankin, White, Elliott, Jaap, Smithson, & Heller, 2016).

According to Schaeffer (2013), the safe engineering of medical devices needs to match what users need, what they are capable of, and what their limitations are. During 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 & Rizvi, 2016). In addition, users have to factor in their individual rate of insulin sensitivity, along with "premeal insulin boluses" (Zarkogianni, Litsa, Mitsis, Wu, Kaddi, Cheng, Wang, & Nikita, 2015, p. 2738). Realistic task executions by the user during the entering of dynamic information (e.g., carbohydrate intake; blood sugar reading) need to find support during initial design of the system (Campos et al., 2014).

*Training of Users*

Medical experts stress the need for education of beginning insulin pump users (Heinemann et al., 2015). Training sessions by health care professionals to teach first-time users the proper handling of the pump device is a requirement for insulin pump therapy.

The complexity of insulin pumps creates a steep learning curve for diabetes patients when switching to insulin pump therapy. An important factor for users to become comfortable in operating the device is usability, specifically, the usability attribute of learnability. From the usability standpoint, ease of learning or learnability is the attribute of usability that describes the "capability of the software product to enable the user to operate and control it" (Alonso-Ríos, Vázquez-García, Mosqueira-Rey, & Moret-Bonillo, 2009). Learnability is an important factor in the effort users need to make to learn to operate a system or device within a reasonable time frame. In system design, the time needed for learning and training to perform system functions has to undergo functional analysis to match user goals to ensure learnability (Zhang, Johnson, Patel, Paige, & Kubose, 2003).

**Statement of the Problem**

Insulin pumps are known for their complexity of use and medical device manufacturers engage insulin pump trainers to instruct first-time users on the operation of insulin pumps. When new insulin pumps are prescribed by a medical doctor and shipped to patients, these trainers conduct sessions to help them use the devices correctly and control the symptoms of their disease.

According to Campos et al. (2014), 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. The addressable problem of the study is a lack of insight into the experiences of insulin pump trainers during learning sessions with first-time users. 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.

Heuristic evaluation of insulin pumps usability from a user perspective has been conducted and reported in multiple studies. Usability research related to insulin pumps and other infusion pumps has centered on the relationship between user interface design and the effectiveness of task completion by a single evaluator perspective, namely first-time-users. Further study was needed to analyze these problems while assessing the interaction between the users and their health care professionals (Lyles, Sarkar, & Osborn, 2014; Zarkogianni et al., 2015). Heinemann et al. (2015) called for additional studies to "guide efforts to optimize the design of pumps according to the needs of different groups of users" (p. 719).

The focus of the study was to discover the lived experiences and shared impressions of insulin pump trainers during training sessions with first-time users. Their experiences and impressions were used to uncover the phenomena associated with usability challenges that first-time users of insulin pumps face when learning to use the device.

The study built on previous research by Campos et al. (2014) who posited that user actions should be considered “basic units” (p. 286) during the analysis of human-computer interaction. According to Campos et al., previous analytical methods that focused on tasks failed to observe if task performance would change over time. Furthermore, they stated that analysis based on a model of cognition provides a stronger support for assumptions, because it focuses on human performance. Campos et al. were concerned, however, that the exploration of detailed features in device design are complicated by cognitive models. Their research is an important contribution for the analysis of realistic user action which helps eliminate inconsistencies with what a designer had envisioned.

The investigative lens for this study consisted 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). A phenomenological study design approach using interpretative phenomenological analysis (IPA) provided 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).

The social reality of insulin pump trainers was constructed from the real-life setting of their training activities, because—at that point—users were 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 was the clinical therapeutic setting that took place between a trainer and a first-time user where tasks are carried out in real-life situations.

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 remained was the safe design of the interface on medical devices such as infusion pumps based on real-life situations. The study aimed to extend the efforts of Campos et al. by examining the lived experiences of trainers and to gain knowledge about a more precise specification about events that occur in a real-life setting, as trainers describe as their experiences during insulin pump training with first-time users.

**Goals and Research Questions**

Insulin pump trainers are situated at the convergence of the interaction between the user and their efforts to perform tasks that take place in a real-life setting. These trainers provided an excellent resource to assess the nature and extent of task difficulty exhibited by users as they learn to use insulin pump devices for self-management. In the study, the interviews conducted with the trainers were geared to enable the discovery of the lived experiences and shared impressions of insulin pump trainers about the usability challenges faced by first-time users of insulin pumps while being taught how to use the device.

The goal of the study was to uncover new insights about human interface issues on insulin pump interfaces in a real-life setting, through the lens of the trainers of first-time users. 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 remained elusive. A gap was discovered in the understanding what constitutes a realistic scenario. This gap generated 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.

The overarching research question for this study which served as the grand tour question guided 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 highlighted 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?

These research questions were addressed by analyzing the qualitative data obtained from interviews with insulin pump trainers that describe their lived experiences during the training of first-time insulin pump patients. The aim was to furnish the essence of the phenomena that can be discovered from a "structural description of the experiences" (Creswell, 2013, p. 81) and to “elucidate the taken-for-granted assumptions” (Ashworth, 2015, p. 13) by which trainers navigate through the process of teaching their patients how to use an insulin pump for the first time. Interview transcriptions were coded and organized into themes that emerged from the storytelling of the insulin pump trainers and from their descriptions of real-life situations that involve the training of first-time users on an insulin pump interface.

**Stance of the Researcher**

This researcher has been working in a diabetes clinic for the past eleven years and has witnessed the enormous struggle of patients while they deal with the debilitating chronic condition of diabetes. Left untreated or uncontrolled, an individual will suffer greatly and have poor quality of life (Pickup, 2014). There is currently no instant cure for diabetes. Instead, the objective of current therapy is to slow down the progression of the disease to counteract adverse effects and prevent premature death (McAdams & Rizvi, 2016; Polonski, 2012).

In order to keep symptoms in check, patients afflicted with diabetes have to be proactive and observe the medical advice issued by their health care professional. Everything they do—eat, work, sleep, exercise—evolves around the disease and determines the course of treatment and its success. Insulin therapy to treat diabetes by the way of an electromechanical, programmable device—the insulin pump—is an intriguing option this researcher felt compelled to explore.

While this researcher had no experience conducting pump training sessions, she had received medical training from the supervising physician to learn about the objectives of insulin pump therapy. This training enabled her to interact with insulin pump manufacturer's representatives and the clinic's patients when being initiated on pump therapy to ensure the successful completion of all steps required in the process. When discussing the feasibility of prescribing insulin pump therapy for a given individual, the final issue health care professionals at the clinic always needed to sort out was: *Will this patient be able to learn how to use the pump effectively to control their diabetes?* This observation had invoked a personal desire in the researcher to conduct a study that elicits and analyzes empirical data from insulin pump training sessions and to contribute to the understanding of usability, learnability and use-related problems in medical devices for the self-management of diabetes.

**Relevance and Significance**

The need for this work is demonstrated by the following research. Lawton et al. (2016) stated that identifying predictors of success is important in diabetes care because it allows health care professionals to verify what benefits a patient can gain from insulin pump therapy. According to Schaeffer (2013), the activities surrounding the process of human factors engineering are either not understood or not sufficiently utilized. Previous research emphasized that human factors engineering principles need to be applied during the research phase when products are developed for health care (Schaeffer et al., 2015).

The research is relevant to the study of human computer interaction (HCI) and information systems (IS) because of the synergy between user experience, interface design, and optimization of system performance (Bailly & Oulasvirta, 2014; Schaeffer et al., 2015). In the information systems domain, researchers have emphasized the need to understand the relationship between user success and perceived ease of use (Venkatesh & Davis, 1996).

Usability problems in medical devices have been mostly studied in isolation by performing user tests, often with vague criteria (Schraagen & Verhoeven, 2013). In a number of studies, the researchers applied the perspective of a simulated environment and conducted usability studies with health care professionals and with first-time users (Campos et al., 2014; Miller et al., 2017). According to Campos et al. (2014), there is a need for further research to "obtain a better understanding of how the system might operate in practice" (p. 295), because user behavior is "shaped … by available resources" (p. 296). Analysts are often uncertain about the activities carried out by users on a device, which prevents these professionals from properly supporting user tasks during the design phase.

The ability of diabetes patients to safely perform self-management of the disease by the use of an insulin pump is put into question in a number of research studies. Among the main concerns are usability issues related to the interface (Heinemann et al., 2015; Miller et al., 2017; Schaeffer, 2013; Schaeffer et al., 2015; Schraagen & Verhoeven, 2013). During development of the device, designers should follow the principles and design methods to enhance human well-being and for the optimization of system performance (Schaeffer et al., 2015). Previous studies did not capture a thorough analysis about actual usage of the systems when measuring if the device was safe to operate for intended use.

The analysis of interactions between users and the system's elements depends on an understanding of the behavior of users (Schaeffer et al., 2015). A more precise definition of what constitutes plausible behavior by a user than was provided by Campos et al. (2014) was addressed in this research. A gap was found in research with focus on usability studies about the precise specification of the way that the system is used in practice. According to Campos et al., usability testing alone is unlikely to uncover "all plausible user interactions with the system" (p. 284). Campos et al. hesitated to make assumptions about user behavior and its correlation to specific sequences in task representation: It would impede the analysis of interactive systems based on plausible task execution.

The study by Campos et al. (2014) resembles a holistic account where they presented a multi-faceted problem (Creswell, 2013). They identified interactive paths connecting task execution as factors that—if not properly addressed—may contribute to an unwanted variance between designer choices and the behavior exhibited by users while carrying out tasks. They based the nature of user activities on assumptions collected from "operation manuals and interviews with clinical staff" (Campos et al., 2014, p. 290). Campos et al. (2014) investigated hypothetical scenarios with the aim to illustrate how effective distinct user strategies are for achieving goals. The authors attempted to address the variance between developmental choices made by designers and the applicability of the design to the way the system is actually used in terms of behaviors. Although they recognized interaction design issues as a "keyhole problem" (p. 284), Campos et al. did not provide a qualitative assessment of the observed use of a device, because they were unable to conclusively determine the nature of real-life situations.

**Barriers and Issues**

Various barriers and issues were encountered during the study. These obstacles were overcome with advance planning and work-arounds.

Insulin pump trainers tend to be very busy professionals in the health care industry. They typically work in excess of 40 hours per week. Some prospective participants cancelled the commitment after having agreed to be interviewed. Some others remained unresponsive after receiving the Informed Consent form, requiring the researcher to continue her recruitment efforts. Data was collected from a pilot participant and five individuals, and sufficient time was spent with each participant to obtain a rich data set. According to Smith and Osborn (2015), a small sample size is acceptable in a qualitative study using an IPA approach, as long as a "sufficient in-depth engagement with each individual case" (p. 29) is conducted. This type of approach facilitates a "detailed examination of similarities and difference, convergence and divergence" (p. 29) necessary to allow a thorough analysis of the findings.

Another barrier that arose due to the busy schedule of participants was the need for flexibility to change appointments on a moment's notice. The pilot interview was rescheduled one time due to illness; one participant delayed the interview time several hours on a short notice; and another participant rescheduled her interview appointment three times during a two-week period. The flexible work schedule of the researcher ensured that opportunities to conduct the interviews were based on the needs of participants.

The variation of insulin pump models currently on the market was a potential issue that could have hindered an unbiased analysis of usability issues observed by trainers when they teach first-time users how to operate a pump. Most of the insulin pump models currently or recently sold in the United States feature selection buttons on the programming and display surface which labelled with chevrons and an "OK" or a "Home" button (Animas®, 2016; Insulet Corporation, 2017; Medtronic, 2017). In contrast, the insulin pump models by Tandem® Diabetes Care (2016) are designed with a color touchscreen interface.

In a self-reported study presented at a recent conference, representatives of Tandem® Diabetes Care posited that a touchscreen interface on their insulin pump t:slim X2™ model is easier to use than the Medtronic insulin pumps which feature a selection button programming interface (Mack, 2017). According to Gindrat, Chytiris, Balerna, Rouiller, and Ghosh (2015), however, a variation between touchscreen and tactile input presently exists in the cognitive activity executed with the respective task. No inference was made about the usability differences or the effort associated with each task.

In a recent study, Waldenmaier, Schöllkopf, Westhoff, Heinemann, and Freckmann (2018) presented empirical evidence that showed that the touchscreen interface of the Tandem® Diabetes Care model required considerable more user keystrokes to program certain values than any of the other pumps, except when entering a quick bolus for immediate delivery of insulin to the body. Until further studies are done that shed light on significant usability differences between touchscreen and selection button interfaces on insulin pumps, no further consideration will be given to identify the differences as a barrier to transferability of findings. The issue of potential bias was mitigated by engaging in sound practices of qualitative methods to ensure validity of results and is further discussed in Chapter 3.

An important issue was the researcher's personal assumptions about the obstacles encountered by diabetes patients as first time users on insulin pumps, based on her past training and experience during her eleven-year employment history at a Northcentral Florida diabetes clinic. According to Lawton et al. (2016), actual predictors of insulin pump therapy success occasionally diverge from health care professionals' experience with their patients.

An effort was made to put aside perceived biases and to remain objective by engaging in the process of bracketing—setting aside previous assumptions—to ensure rigor in research (Ahern, 1999). In addition, a reflexive journal was kept that lists "preparation, action and evaluation" (p. 408) to keep track about the effectiveness of the research process and to mitigate "possible areas of potential role conflict" (p. 409), such as previous business relationships with potential participants.

**Assumptions, Limitations and Delimitations**

This proposal rested on the assumption that selected participants were willing to meet with the researcher and take the appropriate time needed to gather information for further analysis and to provide potential answers to the research questions. In addition, it was assumed that participants were comfortable to freely discuss the experiences they encountered while teaching first-time users how to use an insulin pump. The data collection depended on a reasonably accurate recollection of participants of what they observed during these training sessions with first-time users of insulin pumps. Participant recruitment was conducted using responses to a demographic survey to ensure that the pool of potential participants was well-suited to provide the necessary data (Sekaran & Bougie, 2013).

The use of purposive sampling to obtain the information could have affected the validity of this study, because this type of sampling method could impact the generalizability of the study (Sekaran & Bougie, 2013). In IPA, however, purposive sampling is a preferred method because it ensures a relatively homogeneous sample (Smith, Flowers, & Larkin, 2012).

It is believed that homogeneity of sample was achieved by selecting health care professionals with a solid background in teaching diabetes patients how to self-manage their condition. Participants desirable for this study were institutional clinical staff, trainers employed by insulin pump manufacturers, or independent health care workers who have been certified in diabetes education, including the training of patients how to operate an insulin pump.

This approach ensured that the research questions posed to the participants for this study were meaningful in the context of their environment. The findings from the study could potentially be transferred to similar training environments involving patients and their health care providers. According to Guba and Lincoln (1982), transferability of findings of qualitative studies serves to demonstrate external validity. The study did not involve or address direct observation of users nor attempt to quantify measures of ease of use and learnability (e.g., efficiency ratings, user performance ratings, user preferences).

During the data collection process, observations from participants working with patients diagnosed with both types of diabetes (type 1 and type 2) were considered in order to improve the likelihood of achieving the desired sample size. Although the pathology of type 1 diabetes is clinically distinct from type 2 (Ismail-Beigi, 2012; Zarkogianni et al., 2015), the technique to treat uncontrolled blood sugar 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 (Animas®, 2016; Insulet Corporation, 2017; McAdams & Rizvi, 2016; Medtronic, 2017; Tandem® Diabetes Care, 2016). For the purpose of this study—which was to discover potential usability problems as observed by insulin pump trainers—a distinction between type 1 and type 2 diabetes patients was not relevant, since the analysis of the data obtained from the interviews did not lead to new discoveries in that respect.

The sample population was drawn from respondents all over the United States. The scope of the project was 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 was expected to enrich an understanding of phenomena uncovered in real-life situations. The users they observed were not part of the study.

Another delimitation to make the study more focused was to obtain information about the pump interface difficulties, while the trainers are teaching first-time insulin pump users how to program their personalized settings and situational data for the transmission of insulin dosage parameters to the pump. Mechanical difficulties observed by the trainers during these training sessions with first-time insulin pump users (e.g., changing the insulin reservoir or rotating the infusion site) are beyond the scope of this project.

This study aimed to generate insights about usability issues with insulin pump programming interfaces as experienced by the trainers during the instructional sessions. The focus of the study was to perform a qualitative analysis of the data obtained from the interview sessions to report the trainers' perceptions about ease of use and learnability.

**Definition of Terms**

The following section is a list of key terms and their associated definitions used throughout this research. Some of these definitions represent commonly accepted usage in the field of medicine. They are significant enough to mention or are not readily known beyond the research area of medicine. Other definitions cover terms used in the discipline of human computer interaction (HCI) studies to clarify these terms for information systems researchers whose focus may be in research streams distinct from HCI.

The designation user and patient are used interchangeably in the context of this study, depending if the discussion centers on HCI issues (user), informs about medical issues (patient), or presents quotes from transcribed interview data (patient). For the purpose of this study, the intended user of an insulin pump represents the patient who is receiving insulin pump therapy.

**Active Insulin:** The amount of insulin active in the patient's bloodstream. After injecting a bolus (see below), the active period lasts approximately four hours (Millstein, Becerra, & Shubrook, 2015).

**Auto Mode**: An insulin pump specific feature to facilitate optimal dosing for patients on intensive insulin therapy, a relatively new feature on certain insulin pump models. The pump's software algorithm automatically adjusts the basal rate, based on the information transmitted to the pump from a glucose sensor worn by the patient. (Medtronic, 2017)

**Basal Rate:** In an insulin pump, the delivery of fast-acting insulin to the body, according to preset rates via continuous drip action (Pickup, 2014).

**Bolus:** Dosage of fast-acting insulin that is calculated based on the patient's food intake or administered upon the discovery of hyperglycemic events (see *Insulin to Carb Ratio* below) and is unique to the individual patient (McAdams & Rizvi, 2016). A bolus is added via the programming interface of the pump as a booster shot, in addition to the continuous drip action of the basal insulin delivery.

**Bracketing:** This activity of the researcher entails a written journal to ensure rigor in qualitative research and serves to demonstrate the "validity of the data collection and analytical processes" (Ahern, 1999, p. 407).

**Carbohydrate Counting:** Abbreviated *carb-counting*: The measure of how many carbohydrates are in a food item or meal and adjust insulin dosing appropriately (Millstein et al., 2015).

**Continuous Subcutaneous Insulin Infusion (CSSI):** The delivery of insulin to the individual's body through an infusion device, such as an insulin pump (McAdams & Rizvi, 2016).

**Diabetes Mellitus Type 1:** Autoimmune-type disease characterized by loss of insulin-producing beta cells in the pancreas, which triggers hyperglycemia in the blood stream. Diabetes mellitus type 1 is often of genetic origin (Zarkogianni et al., 2015).

**Diabetes Mellitus Type 2:** Chronic metabolic disorder characterized by high blood sugar, insulin resistance, and relative lack of insulin. The prevalence of this disease is linked to dietary choices, reduced activity levels, and obesity (Ismail-Beigi, 2012).

**Diabetic Ketoacidosis:** Abbreviated *DKA*. Excessive ketone levels in the bloodstream, caused by insulin deficiency (Wolfsdorf, Glaser, & Sperling, 2006). DKA is an "important cause of morbidity and mortality among diabetic patients" (LeRoith, Taylor, & Olefsky, 2000, p. 336).

**Endocrinology:** The study of the chemical structures in the hormones of the human body (Nussey & Whitehead, 2001). An *endocrinologist* is a medical specialist who treats disorders linked to hormonal abnormalities.

**Finger-Sticks:** Self-monitoring of blood glucose using "finger-stick blood samples, test strips, and portable meters" to check blood glucose levels (Olansky & Kennedy, 2010, p. 948).

**Human Factors:** Principles of human factors research represent any behavior of a human that impacts technology (Schaeffer, 2012). These principles contribute to the optimization of an information system for its intended users and have net benefits for usability (Lewis, 2014; Schaeffer et al., 2015).

**Hyperglycemia (high blood glucose level):** The condition of having excess amounts of glucose in the bloodstream on a prolonged basis (American Diabetes Association, 2015).

**Hypoglycemia (low blood glucose level):** The condition of having dangerously low levels of glucose in the bloodstream (American Diabetes Association, 2015).

**Infusion Set:** A needle is inserted into the patient's skin and connected with flexible plastic tubing to the insulin pump (Heinemann & Krinelke, 2012).

**Insulin:** Is a “peptide hormone” secreted in the pancreas of mammals with the aim to maintain normal blood glucose levels. When insulin secretion is abnormal, a synthetic version is administered to the body in prescribed dosages (Wilcox, 2005).

**Insulin Pump:** A battery-powered mechanical device with a programmable software interface, attached on the body with a subcutaneous plastic tube to deliver insulin to the body in preset quantities (Heinemann et al., 2015).

**Insulin Sensitivity:** The degree of sensitivity of an individual’s metabolism towards insulin in the blood stream. Low sensitivity describes a condition where the administration of higher amounts of insulin area is required to lower blood glucose levels. High sensitivity requires less amounts of insulin to be administered to balance the metabolism (LeRoith et al, 2000).

**Insulin to Carb Ratio:** **“**The amount of insulin that should be taken per amount of carbohydrate” (Millstein et al., 2015, p. 838).

**Interpretative Phenomenological Analysis (IPA):** A qualitative research approach “committed to the examination of how people make sense of their…experiences” (Smith et al., 2012, p. 1).

**Ketones:** Chemical compounds known as β-hydroxybutyric acid (Wolfsdorf et al., 2006). Linked to dehydration, an overabundance of ketones in the blood or urine affects the mental state of the patient and can induce coma or death (LeRoith et al., 2000).

**Learnability:** Is an attribute of usability and describes the capability of a technology to allow a human to learn how to use it (Alonso-Ríos et al., 2009).

**Multiple Daily Injections (MDI):** In diabetes care, it is the practice of performing multiple daily injections of insulin subcutaneously (Pickup, 2012).

**Occlusion:** In the context of insulin pump therapy, an obstruction in the tube between the pump and the catheter placed in the skin, or the catheter itself (Heinemann et al., 2015).

**Pathology:** The characteristics of a disease expressed in medical terms (Bantam Books, 1990).

**Reflexivity:** To put aside "personal feelings and preconceptions" (Ahern, 1999, p. 408).

**Stacking:** Administering an additional bolus, while the previous bolus is still active in the circulatory system of the body (Grunberger, Abelseth, Bailey, Bode, Handelsman, Hellman, Jovanovič, Lane, Raskin, Tamborlane, & Rothermel, 2014).

**Subcutaneous:** Property of the tissue situated under the outer layer of the skin. A subcutaneous injection means that a liquid substance is pushed into the tissue under the skin with a hypodermic needle (Bantam Books, 1990).

**Usability:** It considers the effective use of technology by implementing functionality centered on users' behavior (Alonso-Ríos et al., 2009; Norman, 1983).

## Summary

The background of the study was presented to clarify the relationship between the medical condition of diabetes and user actions required to administer treatment through continuous subcutaneous insulin infusion (CSII), also known as insulin pump therapy. Insulin pumps are a distinct class of medical devices: They require user intervention to self-manage the chronic symptoms of diabetes. The safe design of medical devices such as insulin pumps hinges upon recognizing the intended use of the system. Heuristic evaluation and usability testing of insulin pumps are the frequent focus of research studies, but the nature of a real-life situation of insulin pump usage remains elusive.

The statement of the problem was presented next, followed by the statement of goals and the research questions for the study. After a discussion to express the stance of the researcher, the relevance and the significance of the study were presented to justify the research. The study extended the research by Campos et al. (2014) with the aim to uncover phenomena represented in real-life situations as encountered by insulin pump trainers while they instruct first-time users how to use a pump. Barriers and issues, along with assumptions, limitations and delimitations which could impact the goals of study, were presented for evaluation. The *Definition of Terms* section focuses on medical terminology and also defines the topics identified that relate to human-computer interaction (HCI) studies. These topics were presented in the literature review that follows this chapter.

The phenomena were evaluated using interpretative phenomenology analysis (IPA) to discover the essence of the lived experiences of insulin pump trainers. The methodology used to obtain the data through semi-structured interviews with six participants is described in Chapter 3. Data analysis and findings are presented in Chapter 4. The findings include comments by participants about their experiences when conducting insulin pump training. A description of the tools used to perform the analysis and the methods to ensure quality control is also presented in Chapter 4. Chapter 5 provides answers to the research questions about the problems being observed by trainers when users navigate through the learning process, and presents conclusions which of these problems are related to the interface of the device. Chapter 5 includes a presentation of the implications of the study and recommendations for future research. A summary of the entire study concludes the dissertation report.

# Chapter 2

# Review of the Literature

## Introduction

The following is a review of the current literature covering a number of related topic areas, including: Metabolic disease with particular focus on diabetes, usability aspects of medical devices, user interface design, the safety critical aspect of medical devices, learnability, and training. The findings from these multidisciplinary topic areas are presented to support the relevance of the research area. The peer-reviewed findings reported in this study were a basis for the problem space, goals, and questions this researcher was looking to answer.

The complex nature of insulin dependence in individuals requires the inclusion of medical journals that examine the application of various therapeutic approaches, including continuous subcutaneous insulin infusion (CSII) therapy through an insulin pump. Due to the rapid pace of advancements in health care technology, insulin pump therapy has received particular attention in recently published studies. A variety of multidisciplinary factors that could contribute to its successful application are being discussed in those studies. The subsections in this chapter explore the literature related to interactive medical devices, use-related errors, safety risks, usability and user centered design, usability assessment, diabetes management with insulin pump therapy, insulin pump training, and learnability.

**User Interface Design and Medical Device Safety**

Actual usage of the system should be explored in detail to provide an understanding how humans interact with the elements of a system (Schaeffer et al., 2015). Such an examination helps to identify design flaws so that they can be eliminated to make medical devices safe and effective for users.

The ontology of human factors engineering research provides the taxonomy for the user interface design decision-making process and allows researchers to construct assumptions about clinical outcomes on different models of insulin pumps. Human factors engineering research aims at the optimization "how people use and interact with technology" (Heinemann et al., 2015, p. 719). The study by Schaeffer et al. (2015) about usability and training differences between two personal insulin pumps provides an example to demonstrate the relationship between human factors engineering design principles with user interface design issues. Schaeffer et al. associated error categories with programming errors reported showed mistakes made by their study participants during the data entry of basal rates, blood glucose levels, or carbohydrate counts. They were able to demonstrate that such errors in a real-time environment—when left unchecked—will cause the pump to deliver inappropriate doses of insulin. Their research brings attention to the ontological assumption that a pump that does not perform well under a usability evaluation can adversely impact human well-being and safety.

According to Cauchi, Oladimeji, Niezen, and Thimbleby (2014), safety can be impacted by software errors and inconsistent user interface features. 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 a wrong number [wrong dosage] of insulin delivered to the body can create harm to the user (Heinemann et al., 2015).

Zhang, Jetley, Jones, and Ray (2011) also linked poor interface design decisions in insulin pumps to the potential for "unintended and harmful consequences" (p. 1), which affects patient safety. Medical devices that require regular and systematic interaction between users and device interfaces are considered safety critical in the sense that a user's action could compromise safety by causing damage or harm (Masci et al., 2013). According to Miller et al., (2017), user interface problems in interactive medical devices are a primary cause of drug dosing errors. They found that an overreliance on automation could lead to wrong dosage delivery where systems perform in unexpected ways. Events of this kind can have "significant implications for patient safety" (p. 142).

Schaeffer et al. (2015) were able to demonstrate the need for continued evaluation of medical devices for their safety and effectiveness and uncover interface design issues that will impact usability. Waldenmaier et al. (2018) reported a potential relationship between the occurrence of errors and the handling efforts required for the initial set-up and the daily life use of the insulin pump. They were not able to determine conclusively, however, if this condition applies to all pump usage scenarios and stated that—although less convenient to the user—more steps could actually improve safety. According to Waldenmaier et al., usability of insulin pump systems is an important factor that affects the safety of insulin pump therapy and, therefore, the success in the management of the chronic condition of diabetes.

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 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 et al., 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.

According to Heinemann (2017), training outcomes determine the success of glycemic control in diabetes patients when they become familiarized with the functionality of technology such as insulin pumps. Research on insulin pump safety issues, however, may become impacted by a decline in academic research opportunities for diabetes technology (Heinemann, 2017). It was important in this study to present the perceptions of trainers to provide feedback about the usability of the insulin pumps. As trained experts in insulin pump therapy, their perceptions contributed to valuable insights about predictors of success for insulin pump therapy—an important issue in diabetes care (Lawton et al., 2016).

## Usability, Learnability, and Training

### *Usability*

An accurate term of usability remains mostly elusive, because experts are not in agreement about the precise meaning of its term and its attributes (Alonso-Ríos et al., 2009). Usability is often used to describe information systems designed to be “simple to use by untrained users” (p. 53). System designers who focus on usability follow the principles of “user centered system design” because they consider “how people make use of computer systems” (Norman, 1983, p. 3). Alonso-Ríos et al. (2009) presented other, alternate definitions of usability. For example, usability can also be defined as the “ease with which a user can learn to operate, prepare inputs for and interpret outputs of a system or component" (p. 54).

Usability is a term that invokes the consideration of attributes thought to contribute to the functionality of a system in a positive sense. The insulin pump programming interface is the mechanism where critical interaction between the user and the insulin pump system takes place. The usability of this programming interface affects the success of the application for which each model insulin pump is designed: The ability to regulate insulin delivery to the human body based on user input.

Usability is a condition that expresses that a system is "adaptable to different contexts of use" (Alonso-Ríos et al., 2009, p. 56). With insulin pump therapy, the distinction in the context of use is the regulatory aspect of administering or stopping insulin delivery to the body at the right time, based on variable factors (e.g., insulin sensitivity, blood glucose level, or lifestyle habits). These parameters differ greatly among patients. It is of paramount importance that the system is adaptable to facilitate prompt and continuous adjustments of these parameters without barriers to usability.

According to Wobbrock, Kane, Gajos, Harada, and Froehlich (2011), usability of a system consists of the principles of "ability and accountability" (p. 9:5). A system needs to be designed to fit the "abilities of whoever uses it" (p. 9:2) to the "widest range of people possible" (p. 9:5). To ensure the effectiveness of usability on the system, it is important to verify that users are able to accomplish tasks that allow them to reach their goals (Campos, Fayollas, Martinie, Navarre, Palanque, & Pinto, 2016).

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, programming a standard bolus into the pump to deliver insulin in anticipation of an impending consumption of carbohydrates through food intake should consist of a task sequence that can easily be learned and remembered. In insulin pump therapy, it is a task that precedes several daily events that require a user to calculate the amount of carbohydrates to be consumed. The amount then needs to be entered into the programming interface to prompt the system to deliver additional insulin to equalize blood glucose to a preset normal level. Any system constraint during such a common procedure can lead to use-related errors that affect the accuracy of insulin therapy for a patient (Schaeffer, et al.).

When assessing usability, it is important to “distinguish between the goals and practices of summative and formative usability” (Lewis, 2014, p. 663). Summative usability provides metrics of “global task and product goals” (p. 664). In their presentation of a method where they analyzed interactive systems by using constraints occurring in information resources, Campos et al. (2014) applied the practice of summative usability. Their aim was to assess both user goals and system design based on the tasks that needed to be carried out by the users to program the insulin pumps. In contrast, MacDonald and Atwood (2014) looked at usability evaluation methods in human computer interaction (HCI) studies that are restrictive to “task-centered user performance rather than a system’s fit to context” (p. 892). They posited that these evaluation methods will not be able to fully capture issues related to usability and the associated perceived usefulness of the system.

According to Hartson, Andre, and Williges (2003), formative evaluation methods are used to uncover usability issues during design stage, a summative evaluation is typically performed to assess usability of a system during actual usage. Their study features interviews with participants about their experiences−a characteristic of a summative evaluation to add to the "accumulated knowledge within the field of HCI" (p. 149).

*Learnability and Training*

Several classifications of usability were presented in the taxonomy by Alonso-Ríos et al. (2009), including the attributes of knowability, learnability, or ease of learning. The researchers defined knowability as a feature that allows a user to" understand, learn, and remember how to use the system" (p. 56). Empirical studies like the one conducted by Schaeffer et al. (2015) show significant differences in learnability and training on medical device interfaces and these differences were attributed to design flaws. If a device does not behave in a way that it is intended, problems during the training of users will become evident. According to Harrison, Campos, Masci, and Curzon (2015), user errors appear when the effect of an action is not visible or not being noticed by the user.

Schaeffer et al. (2015) posited that appropriate training on systems that are "intuitive, highly usable, safe, and optimized" (p. 228) will help make health care education more efficient. These factors will influence health care professionals as well as individuals to choose a system with "high level of comprehension" (p. 228) when selecting a brand and system type for insulin pump therapy. Bergman (2012) determined that a system that is difficult to learn will likely have an impact on user preference during selection of a suitable insulin pump.

When users have trouble learning and remembering information presented on the screen, they tend to get frustrated and lose interest in acquiring the skills to master the software. Saadé and Otrakji (2007) found that this condition could be attributed to the characteristics of the user interface. They stated that complexity of use in interactive systems, such as programmable medical devices, could lead to disorientation when users learn to operate or work with a device. User disorientation can often lead to reduced use and reduced effectiveness of the device. According to Harrison, Campos, Rukšėnas, and Curzon, failures in interactive systems occur if a user is confused by a misleading display. There is no benefit in the deployment of insulin pump therapy, if the training of patients has not been sufficiently addressed (Heinemann, 2017).

Learning and training differences start to appear where new technology is insufficiently optimized (Schaeffer et al., 2015). Such potential complications imply that a complexity of the device interface exists that negatively affects the memorability of the system, preventing the user from memorizing system elements and device functionality (Alonso-Ríos et al., 2009). 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, Keith-Hynes, Koops, & DeVries, 2016).

Training helps the user understand and organize knowledge about a physical system (Santhaman, Sasidharan, Yi, & Park, 2013). However, knowability [learnability] for an insulin pump is complex, because there is no prescribed universal regimen for the management of chronic diabetes (Queale, Seidler, & Brancati, 1997). Clinical and molecular profiles differ among patients, requiring personalized treatment by the attending physician (Zarkogianni et al., 2015). Therapeutic measures are based on the glycemic control history in the patient’s medical chart. These measures are calculated by licensed medical professions based on the patient’s medical profile in form of a unique sliding scale. Such a sliding scale cannot be generalized to another individual, although similar symptoms of the disease may be prevalent. Insulin pump trainers have to observe these prescribed settings and explain them to the users when training them how to use the pump.

Participants in the McAdams and Rizvi (2016) study reported that health care professionals apply a selection bias when recommending patients for insulin pump therapy. These professionals expressed a fear that a population with challenged intellectual capacity may not be able to grasp the complexity of the devices in its entirety. To add to the problem, the condition of diabetes is associated with comorbidities that could impact vision and also carry a "wide range of cognitive impairments" (Kravitz, Schmeidler, & Schnaider Beeri, 2013, p. 489). These potential complications imply that a diabetes patient population exists that is not suitable to be considered for training on an insulin pump. HCI studies have shown consistently that training outcomes are affected by a user's age, their computer experience, and their individual degree of computer self-efficacy (Santhanam et al., 2013).

In contrast, the qualitative study by Lawton et al. (2016) revealed that psychosocial criteria as predictors for the success of pump therapy represent a limited value. The health care professionals interviewed in that study disclosed that intentionally preselected individuals for pump therapy based on subjective assumptions about their suitability. When reading the results from a recent clinical trial (*REPOSE)* that contrasted the value of quality training with conjectures about intellectual capability of the user, the health care professionals admitted that this new knowledge challenged their previous assumptions. The argument to ground learning and training difficulties on the characteristics of the user population at hand distracts from a more plausible cause of learnability problems on a device interface. When users are trained on a system with reduced error rates, it also reduces their training time and contributes to the effectiveness of the insulin pump therapy (Schaeffer et al., 2015). There is a need to evaluate and document outcomes of training programs so that health care professionals can achieve relevant improvement in patient outcomes for the treatment of diabetes (Heinemann, 2017).

**Summary**

The multidisciplinary nature of the topic areas required a broad scope of literature to be reviewed. The focus of literature searches was to learn about findings that discuss actual usage of a system—in a general context and in a health care application context. The emphasis was on locating material about medical devices, such as infusion pumps. Examples were provided that position the usage of insulin pumps within the concept of the safety critical nature of medical devices in a health care environment, where users are required to self-manage their medical condition effectively to stay alive.

The foundational concept of usability was explored and further presented in the context of health care applications, providing examples how usability could affect the effectiveness of diabetes management. When a patient is new to insulin pump therapy, obstacles encountered during training require that their root cause is put under examination for potential usability problems. The role of learnability and training is inextricably connected with the approach used to match task execution sequences during the design stage to real-life conditions. Based on the review of literature, the exploration of the lived experiences of trainers in a real-life setting when teaching first-time users how to use an insulin pump proved to be a worthy research project.

# Chapter 3

# Methodology

## Introduction

This chapter contains the framework of the methodological research approach used for the study. After providing the explanation for the aim of the study, a list of the interview questions that were posed to the participants and their relationship to the research question is presented. This list is followed by a discussion of the rationale for selecting a qualitative methodology using interpretative phenomenological analysis (IPA).

The general steps that summarize the course of research are presented next, followed by a more detailed description of the method for participant selection and the instrumentation used for the study. An outline of the processes used to transcribe the interviews, analyze the data and report the findings is presented. Next, the analytical procedures used to code and analyze the data are described in summary form, with detailed description of the steps performed to follow in Chapter 4. An overview is given in this chapter how the results will be reported in Chapter 4. A system of quality control used to address internal and external validity (transferability) is presented next. The research process was conducted according to rigorous standards described for IPA methodology, which includes the need for reflexive bracketing and journaling. Ethical considerations are also discussed. Finally, the resources for the study and its feasibility are presented. At the conclusion of this chapter, a summary of the methodology that characterizes IPA is provided.

**Aim**

This study extended previous work done by Campos et al. (2014) by exploring the lived experiences of insulin pump trainers while they carry out the task of teaching an individual how to manage the chronic condition of diabetes with an insulin pump for the first time. The aim of the study was to gain insight into what constitutes a real-life situation and to provide an analysis of the phenomena the trainers report during the interaction with the patients in the aforementioned training sessions. In addition to the aforementioned study by Campos et al. that contains an analysis of two interactive infusion systems in a health care environment, the observation-based usability study by Schaeffer et al. (2015) was used to provide the ontology to classify phenomena.

Schaeffer et al. (2015) demonstrated the need to address “dangerous use-related errors” (p. 222) arising from design flaws which impact clinical outcomes. Daily interaction of the user with the pump to program settings is a continuous process to manage diabetes and the exposure to use-related errors is a prevailing risk factor. Through their research, Schaeffer et al. produced the ontology of a safety critical design and its role in patient-self-care situations. Their ontology reflects the characteristics of a training environment where they measured criteria involving the handling of the pump interface. For example, the nature of ease of training and the potential for user input errors were described in detail in their simulated scenarios. The findings by Schaeffer et al. are relevant to this study, and their ontology was used to organize themes during the coding and analysis phase.

The phenomena encountered by insulin pump trainers during those training sessions were analyzed, after interviewing a pilot participant and five additional participants to help frame answers for the stated main research question which served as the grand tour question:

What is the essence of the experiences of insulin pump trainers while they teach first-time users how to use the device?

In addition, several structural sub-questions highlighted 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?

These sub-questions were addressed in the IRB-approved interview guide (see Appendix D; see Table 1) and helped formulate questions that capture "subjective experiences and perspectives" of participants (Bhattacherjee, 2012, p. 109). This guide supported the task to help to "fully understand the deep structures that drive the conscious thinking, feeling, and behavior of the studied participants" (p. 109). Using the aforementioned interview questions helped to elicit responses about the types of problems trainers observe when users navigate through the learning process, about potential problems related to the insulin pump interface characteristics, about the learnability and ease of use of the interface, and about any errors observed by trainers during task execution by users.

Table 1
*Interview Guide Questions and the Research Question to Address*

| |
|---|
| 1. Please tell me about your experiences when you teach patients how to use an insulin pump for the first time. (Grand tour question) |
| 2. Please tell me about any problems in general you observe during the sessions with your users. (Sub-question 1) |
| 3. What type of feedback are users giving you about problems they encounter? (Sub-question 1 and 3) |
| 4. Please provide some detail about the tasks you assign to the patients to program the pump with their own individual settings. (Sub-question 2, 3 and 4) |
| 5. Please describe what issues you may have noticed with the programming of the pump. (Sub-question 2 and 3) |
| 6. What are your impressions about the patients acquiring the necessary skills to safely manage their diabetes with this new tool? (Sub-question 1, 2 and 4) |
| 7. What are your impressions about the process of learning insulin pump self-care management? (Sub-question 4) |

**Rationale for Choosing the Method**

In simple terms, one can expect that insulin pump training sessions occur in a setting that can easily be staged with the necessary criteria to reach the training goal. The desired outcome is the successful initiation of a diabetes patient on the pump, allowing the individual to resume the self-management of their medical condition with this newly acquired tool. If this research was to be conducted using quantitative methodology, data collection would focus on metrics of already known phenomena associated with insulin pump, such as measures of user preferences or a statistical evaluation of use-related errors. The goal of this study, however, was to discover *new* phenomena that arise from the descriptions how the training environment is experienced from a distinct point of view (Carel, 2011). This called for a qualitative method to allow the researcher to perform content analysis of phenomena to discover the essence of the trainers' experience with users new to insulin pump therapy.

A qualitative method using interpretative phenomenological analysis (IPA) was applied, because it allowed the capture and analysis of what trainers are "seeing, remembering and experiencing" (Smith et al., 2012, p. 13). It was important to examine the trainers' point of view, because previous studies were not able to fully capture the dynamics of a realistic user environment. This study provided an insight into a research area that previously appeared to offer an inadequate understanding (Morse & Richards, 2002), because it captured the events of a realistic user environment when patients learn how to program the pump according to their personal settings based on the distinct symptomology of their disease.

According to Guba and Lincoln (1982), use of an appropriate qualitative method facilitates extensive understanding about the behavior of humans when using the meanings and intentions they attach to their activities. Ashworth (2015) stated that a phenomenological approach is suitable in studies that aim to "elucidate the taken-for-granted assumptions" (p. 13), because it can provide necessary clarity to the observed phenomena. This study used an approach based on the teachings of Edmund Husserl (1859-1938)—the founder of phenomenology. Husserl proposed that researchers should begin their investigation with what is being experienced by the participants. A phenomenological approach allows a researcher to obtain a "system of interrelated meanings" (p. 12). For the purpose of this study, the focus is on the interaction between trainers and first-time insulin pump users during instructional sessions, as seen with the eyes of the trainers.

According to Smith and Osborn (2015), the IPA approach provides the necessary methodology to perform a “detailed exploration” (p. 25) of the personal meaning that trainers attach to their lived experiences. It also permits the examination of the phenomena within the social world of the participants. This study is situated in the context of the expanding prevalence in diabetes worldwide (Popkin, 2015), and is characterized by these health care professionals’ objective to succeed in the improvement of their patients’ lives. The examination of the trainers’ experiences within this context helped to understand their frame of reference. This goal was achieved using IPA to permit sense-making of their experiences and to “see things as they present themselves” (Smith & Osborn, 2015, p. 25).

**General Steps**

The general steps carried out during this study were as follows. The hardware and software resources to conduct the study were acquired and tested for functionality. This included the equipment needed to record and process the data obtained through the interviews with participants, along with the funds for expenditures (see Table 8).

The study was approved by the Institutional Review Board (IRB) representative of the College of Computing and Engineering at Nova Southeastern University, Ft. Lauderdale, Florida on September 25, 2018 (see Appendix E). The approval of the dissertation proposal was granted by the dissertation committee on October 3, 2018. Permission to proceed with the study was granted by the dissertation committee on October 17, 2018, after the dissertation proposal had been successfully defended. Recruitment was initiated on October 29, 2018 after thoroughly preparing the materials needed for the interview, creating a test day interaction template, staging the interview, rehearsing the presentation style, and testing the Skype connection. The overall recruitment strategy for the pilot and the five participants is described further below in the section titled *Participant Recruitment*.

The initial contact with prospective participants was facilitated by the distribution of the Recruitment Flyer (see Appendix A) that was approved during the IRB process. It directed interested individuals to a web link to complete an online demographics questionnaire (see Appendix B) that was also approved during the IRB process. This online demographics questionnaire was used to determine if a prospective participant would meet the requirements for the study and to provide a method of contact. The General Informed Consent Form for Participation in the Research Study (Informed Consent; see Appendix C) approved during the IRB process was provided to the pilot and each prospective participant, after they indicated verbal or written agreement to participate in the study. The Informed Consent form served to familiarize the participants with the goals of the study and data collection methods. Each participant was given the choice to return the form with their signature via Email or take a snapshot of their signature and send it via text message through their smartphone at the time of the interview.

The interviews were scheduled for a time based on each participant's preference, during which participants had the opportunity to ask questions about the Informed Consent form. The transcription of the interviews was performed by Sunrise Transcriptions in St. Petersburg, Florida, a medical transcription service the researcher had previously used through her employer. After each interview was transcribed, the transcription was sent back to the participant for further comments and clarification.

After completing the interview, each participant, including the pilot participant, received a $100.00 VISA gift certificate as stated in the Recruitment Flyer and approved during the IRB process.

The analytical process followed the methodology of IPA as outlined in Smith (2011), Smith et al. (2012), and Smith and Osborn (2015). A comprehensive report of the analytical procedures is provided in Chapter 4 of this study.

## Participant Selection

### *Sampling*

Health care professionals who conduct insulin pump training have the unique experience which is the focus of this study. This aspect made 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 & Bougie, 2013). This sampling design enabled a “fairly homogeneous sample” (Smith & Osborn, 2015, p. 28), which means that the individuals in the group carry out similar duties and, therefore, share similar experiences. The respondents’ professional designations included Certified Diabetes Educator (CDE), Registered Dietician (RD), Clinical Diabetes Specialist, Clinical Business Manager, Registered Nurse (RN) and Family Nurse Practitioner (FNP). The interview questions were significant to participants and were designed 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 was performed to provide answers to the stated research questions.

*Pilot Participant*

The pilot participant was recruited by personal invitation on October 27, 2018. She was recruited among the researcher's business professional contacts. The pilot responded on October 30, 2018 via Email and was asked to start the evaluation by completing the Demographic Questionnaire on *Survey Monkey*. Her response was received on October 31, 2018, and she was sent a reply Email with the Informed Consent form attached. The text of the Email briefly explained the role of a pilot participant and prompted the pilot to call the researcher's cell phone for further questions and to schedule the interview. The Informed Consent form was returned by the pilot via Email on November 6, 2018 and the interview was scheduled for November 12, 2018, to be conducted by phone. Due to illness, the pilot rescheduled the interview for November 20, 2018.

At the time of the interview with the pilot, the researcher went through every step of the process. She explained the reasons for having an Informed Consent form, the purpose of recording the interview and that it will be transcribed, and the purpose for using a backup recorder, in case the first recording device fails. The researcher explained how confidentiality and privacy would be handled, and stated the fact that the pilot will have an opportunity to review the transcription before it was used for the data collection process. The entire interview process with the pilot took approximately 50 minutes. The recorded portion of the interview was 38:32 minutes long.

The pilot had the following comments regarding the recruiting and interview process. She indicated that the demographics questionnaire on *Survey Monkey* was not clear about *Question 8*: *Please let us know how you would like to be contacted*.

Therefore, a further directive was appended to *Question 8* on the Survey Monkey page: *(please type an Email address or a phone number into the text box below).*

Next, the pilot was invited to comment on the way the interview was conducted. She stated that she felt comfortable about the process and that the directives and explanation given prior to the interview start were satisfactory. When asked about the interview questions, she stated that they seemed repetitive or redundant, but could not offer an explanation which questions were similar. The researcher explained to her that there was some overlap between questions, and that this was done intentionally to allow information to flow freely and to give the participant an opportunity to expand on certain issues. The pilot was satisfied with this explanation.

The researcher took note and expanded her test day interaction template to include a thorough explanation to future participants about the fact that the questions may sound redundant and are simply place holders to jog the participant's memory: *If you feel that you have already answered a question in a different section or: If you don't have anything to add to a specific question, please let me know. I will then make a note and move on to the next question.*

The researcher felt that the interview process with the pilot participant was a success. No significant problems were encountered during the recruitment of the pilot and the completion of the interview process. A $100.00 VISA gift certificate was sent to the participant later that day in a sealed envelope that also contained a *Thank you* note.

*Recruitment of Participants and Obtaining Consent*

Participant recruitment began on November 21, 2018, after the changes recommended by the pilot participant were incorporated. The abstract of the dissertation proposal, the Recruitment Flyer and the Informed Consent form were uploaded to the researcher's personal website at https://www.helenbirkmann.com/research.htm. A public posting inviting health care professionals with insulin pump training experience, linking to the Recruitment Flyer and Informed Consent form was made on the researcher's LinkedIn, Facebook and Twitter accounts on said date. On November 23, 2018, a personal invitation was sent to 36 contacts via Email, containing an overview of the study procedures and with the Recruitment Flyer as an attachment. These leads were obtained from contact information on LinkedIn profiles and from prior business relationships with pharmaceutical sales representatives who work for manufacturers of insulin (e.g., Novo Nordisk; Eli Lilly. The researcher had obtained these from the diabetes clinic where she works. Another phase of personal invitations was sent to a total of 26 leads on November 27, 2018. A third phase soliciting from among 42 contacts followed on December 7, 2018. These mailings were timed with additional public postings on social media (LinkedIn and Twitter).

The goal was to arrive at a sample of six to eight participants who had trained first-time insulin pump users in the past. This number is a typical sample range applied in IPA research (Smith & Osborn, 2015). A total of ten individuals responded during the duration of the recruitment campaign. The home states of the respondents included Alabama, Arkansas, California, Florida, Illinois, Nebraska, North Carolina, and Tennessee. Unless interested individuals had replied via Email or phoned the researcher after receiving a personal Email invitation, they were contacted according to the preference indicated on the *Survey Monkey* response. All respondents were eventually asked to complete the online demographics questionnaire on *Survey Monkey* to allow prescreening.

Individuals who left their Email address received an invitation to schedule an appointment, explaining the next steps and with the Informed Consent form attached to the Email. Others who left a phone number only were contacted by phone. If the individual wanted to proceed, their Email address was collected to receive further instructions and a copy of the Informed Consent form. Respondents who did not return the Informed Consent form received a reminder one week later, inviting them to ask questions. If no response to the reminder was received, the respondent was marked inactive in the researcher's recruitment contact list, and no further attempts to contact were made.

Table 2 below summarizes the recruitment responses received on *Survey Monkey* and through initial contact by phone or Email. Respondent #9 heard about the research from another individual who saw the posting on LinkedIn, but did not complete the online demographics questionnaire. Table 2 also lists the outcome of the recruitment efforts.

The individuals' responses on *Survey Monkey* regarding *Organization Name on the Certification* and part of the responses regarding *Current or Recent Occupation* were intentionally left out of the dissertation report as they may contain personal identifiable information (PII). For the same reason, descriptive information about each participant's State of residence was omitted to protect their identity.

Table 2
*Recruitment Responses*

| # | Interview Date | Qualification | Certified | # First-time Users Trained | Referral Type | Interviewed |
|---|---|---|---|---|---|---|
| 1 | 10/31/18 | RN | Yes | 150 | Personal | Yes: Pilot |
| 2 | 11/22/18 | Clinical Diabetes Specialist | Yes | 300 | Email | No |
| 3 | 11/23/18 | CDE; FNP | Yes | 50 plus | Email | No |
| 4 | 11/24/18 | RD; CDE | Yes | 50+ | Social Media | Yes |
| 5 | 11/27/18 | RD; CDE | Yes | 500 | Email | Yes |
| 6 | 12/8/18 | Clinical Business Manager | Yes | 100's | Email | Yes |
| 7 | 12/8/18 | Clinical Manager | Yes | 1000+ | Personal | Yes |
| 8 | 12/8/18 | Clinical Diabetes Specialist | Yes | 100+ | Email | No |
| 9 | 12/8/18 | Diabetes Educator | Yes | 200+ | Snowball | No |
| 10 | 12/9/18 | CDE | Yes | 50 | Email | Yes |
| 11 | 12/28/18 | RD; CDE | Yes | 5 | Email | No |

If the aforementioned method were to fail to deliver the desired number of study participants, additional recruitment would have been attempted via referral through personal contacts within the Northcentral Florida area pharmaceutical sales force. To generate more interest for participation in the study, the Recruitment Flyer would have been sent to diabetes education and treatment centers, and to endocrinology specialty clinics within a wide geographical area in the United States, obtained through business contacts available at the researcher's place of employment. Further recruitment of participants would have been attempted by searching for individuals who have insulin pump trainer experience via resume posting sites (e.g., *Indeed*).

The basic requirements to participate in the study were listed as follows:

1. The participants needed to be qualified to conduct insulin pump training sessions. This requirement was verified by querying potential participants if they are certified now or have been in the past through one or more insulin pump manufacturers (e.g., Medtronic; Tandem® Diabetes Care). Alternatively, a participant may have been trained through a national society such as the National Certification Board for Diabetes Educators.

2. The participants must have conducted at least one pump training session in the recent past (e.g., within one to two years prior to the interview).

3. At least one of the pump trainings the participant conducted must be for a patient new to insulin pump training.

4. Respondents, when selecting *Yes* on the online survey form (IRB-approved Online Demographics Questionnaire, see Appendix B), indicating that they are available for the research study, were instructed to leave their contact information.

## Interview Process, Setting and Instrumentation

### *Interview Process*

Insulin pump trainers tend to be health care professionals with busy work schedules. Semi-structured interviews were conducted by telephone on a schedule convenient for the participant. All respondents expressing an interest to participate in the study were given the choice to be interviewed via Skype or by telephone. All study participants chose to be interviewed by telephone. The duration of the interview had been estimated in the dissertation proposal to last from 60 to 75 minutes. This included the time for introduction, to allow for answering of questions about the Informed Consent form, for the taping of the recording itself, and for wrap up questions to take place after the recording had stopped. Part of the wrap-up included obtaining the participant's address to send a *Thank you* note and the honorarium for the interview—a $100.00 VISA gift certificate.

The actual time spent for each interview was below the initial estimates of 60 to 75 minutes. The shortest interaction (duration of entire call) was just shy of 37 minutes. The longest interaction with a participant was close to 1 hour and 7 minutes long. The average time of an interview was approximately 53 minutes. Table 3 contains the list of participants with the date they were interviewed at, along with the length of the actual recording and the duration of the entire call. The participants were assigned random two-digit identification numbers and in a random sequence to conceal their identity.

Table 3
*Interview Table*

| Participant | Interview Date | Duration of Recording* | Duration of Entire Call* |
|---|---|---|---|
| #28 (Pilot) | 11/20/18 | 38:32 | 48:00 |
| #12 | 11/30/18 | 53:49 | 59:55 |
| #47 | 12/4/18 | 48:24 | 53:50 |
| #50 | 12/13/18 | 59:04 | 66:57 |
| #73 | 12/19/18 | 30:36 | 36:50 |
| #40 | 1/4/19 | 34:30 | 39:54 |

*In minutes and seconds

The researcher had prepared two documents in advance to guide her during the interview process. The Interview Preparation and Interview Day Guide (see Appendix F) outlined the steps to prepare the participant for the interview and set them at ease by use of some or all of the warm-up questions (see Appendix D; see Table 4). This enabled the researcher to stay on course during the interview process from start to finish (e.g., when to start or stop recording). The Interview Day Interaction Template (see Appendix G) gave specific details to follow to help explain to the participant what to expect during the interview. It was designed to take the researcher and the participant to the point where they both would be comfortable with each other, so that the recording of the interview could commence. According to Smith et al. (2012), it is important to make the participant comfortable to talk and to avoid "jumping in too quickly" (p. 64).

Table 4
*Warm-up Questions*

| | |
|---|---|
| 1. | How has your day been so far? |
| 2. | You work as an [ABC] in the healthcare sector? |
| 3. | Diabetes care is your main focus then? |
| 4. | For which pump models have you trained in the past? |
| 5. | Can you explain what you think might be a trend that patients increasingly want to get a handle on managing their diabetes? |

The IRB-approved Interview Guide (see Appendix D) was followed to pose the questions to the participant, while keeping in mind that a certain amount of flexibility during the interview process would allow the information to flow. Throughout the interview process, the researcher used the interview guide to stay on track for the topic areas to be covered. An attempt was made to elicit a response to the each of the interview questions outlined from the Interview Guide to obtain the trainers' perspective of the events that take place while training the patient. The researcher anticipated that the trainers wanted to discuss usability issues that are not directly related to the focus of this study, such as user difficulties observed with mechanical functions of the insulin pump (.e.g., trouble changing insulin cartridges or swapping batteries). Such deviations from focus were welcomed, because they could reveal additional use-related errors, such as alert fatigue discussed in the *Background* section in Chapter 1.

If a reply failed to embody the desired depth required to understand the phenomena, the researcher made an attempt to "go deeper" (Smith et al., 2012, p. 68) by posing probing questions (e.g., *Can you be more specific?).* When the researcher was satisfied with the depth of the information received, wrap-up questions (e.g., *Is there anything else you would like to add?*) served to cue the participant in that they had the option to either provide more insight or to decline and wait for the next question.

*Setting*

From a methodological perspective, the research was conducted with minimal interference by the researcher in a non-contrived setting (Sekaran & Bougie, 2013). The demographics questionnaire (see Appendix B) was placed online where interested individuals could respond from virtually anywhere on the Internet. The interviews were being conducted in the researcher's home office where all the resources necessary to conduct the study were assembled. The room could be locked from the inside to prevent accidental disruptions by family members, and to ensure total privacy during the contact with the participant.

*Instrumentation*

Two IRB-approved instruments were used to conduct the interviews. During the recruitment phase, interested individuals were directed to go to *Survey Monkey* and complete the above mentioned online demographics questionnaire. Once the interview took place, the aforementioned IRB-approved Interview Guide was used to collect the data. It contained seven broad, open-ended questions which were designed to make the data collection instrument flexible towards the participants' responses. This method allows a researcher to "probe interesting and important areas" (Smith & Osborn, 2015, p.

29) that might arise to permit the researcher to uncover yet unknown phenomena. The researcher hoped that this method would contribute to "ultimately provide an understanding of the common experiences of the participants" (Creswell, 2013, p. 81).

A flexibility towards participants' responses helps to guide along the interview process, because interviews may not necessarily follow the sequence envisioned by the researcher (Smith et al., 2012), especially, when the participant may have already provided an answer on the topic as part of another interview question. Exercising too much control over the desired sequence of the interview and moving on too quickly may run the risk of failing to obtain more extensive and complete answers (Smith, et al.).

**Transcribing**

The transcription of the audio recordings was produced by Sunrise Transcription Inc., a medical transcription service with a good track record based on the researcher's previous experience when using this vendor. They are a HIPAA-compliant medical service company in St. Petersburg, Florida. Turnaround time on all transcriptions was anywhere from one to three days. A total of $357.00 was spent on the transcriptions.

The transcribed interviews had been formatted by the transcription company in large paragraphs to distinguish between the researcher's questions or comments throughout the interview and the participant's responses to the questions. The researcher listened to the audio recordings and proof-read the transcriptions to make corrections or fill in blanks. When responding to a given question from the interview guide, some participants would speak anywhere from 9 to 13 minutes continuously and their responses needed to be broken up into smaller paragraphs to make the transcription more legible.

Once the transcriptions were organized into smaller paragraphs, each transcription document was separated into seven sections corresponding with the seven questions in the Interview Guide, and headers were added to the document to make these sections stand out. This enabled the researcher to correlate data to the aforementioned research questions during the analysis. The continuous rereading of the transcribed interviews allowed the researcher to get familiar with the data collected.

**Data Organization and Analysis**

The data analysis performed required coding, memoing and thematic analysis of the transcribed interview data. The process of coding followed the analytical methods for IPA as described by Smith et al. (2012), and Smith and Osborn (2015). IPA methodology outlines the process how 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). Each individual narrative was analyzed which required immersion into the data, making preliminary notes, and adding descriptive, linguistic and conceptual comments (Smith, et al.). To guide the researcher to a deeper level of interpretation after initial coding, the researcher applied an analytical framework approach adapted from Bonello and Meehan (2019, Table 1, p. 486), and from Chong (2019). This framework approach was separated into three distinct phases and encapsulated IPA methods as recommended by Smith et al. (2012), and by Smith and Osborn (2015). The approach enabled the researcher to identify common threads that would lead to a thematic analysis of the data and the formulation of emergent themes (DeSantis & Ugarizza, 2000).

By permitting a broad definition of a theme to be a "category, domain, unit of analysis, phase process, consequence and strategy" (DeSantis & Ugarizza, 2000, p. 358), the researcher successfully performed the activity of "extracting or inferring themes embedded in the data" (p. 363). In addition, the framework approach clarified the "systematic and visible stages to the analysis process" and allowed for the triangulation between the emergent themes and the conceptual underpinnings (Sechelski & Onwuegbuzie, 2019, p. 796). The analytical phases and steps involved to perform the analysis are outlined in Tables 5, 6 and 7 below, and described in detail in Chapter 4 in the *Data Analysis* section.

Table 5
*Phase 1: Data Coding According to IPA Methods*

| Stage | Analytical Process | Strategy | Task Performed | Items Captured | Objective |
|---|---|---|---|---|---|
| 1 | | Descriptive Coding | Reading: Initial marking and memoing | Things that matter to the participant | To understand preferences/routine/ beliefs |
| 2 | Exploration and Familiarization | Linguistic Coding | Reread & highlight specific use of language | Colloquialism; repetitions; emotional expressions | To extract a distinct perspective from a participant's use of language |
| 3 | | Conceptual Coding | Reread; using concepts introduced in C2 | Draw from the researcher's "experiential or professional knowledge" (Smith et al., 2012, p. 89) | To generate awareness of the social meaning within a health care context. |
| 4 | Categorization | Deconstruction | Reread: Organize all participant statements into themes | Reading *between the lines*; initial themes | What is the meaning to the participant? What is the participant actually saying? |

Source: Adapted from Bonello and Meehan (2019); Chong (2019); Smith et al., (2012); Smith and Osborn (2015).

Table 6
*Phase 2: Preliminary Data Analysis—Creating a Hierarchical Thematic Framework*

| Stage | Analytical Process | Strategy | Task Performed | Items Captured | Objective |
|---|---|---|---|---|---|
| 1 | Create a thematic framework | Compare content among initial themes | Organizing and condensing themes | 9 Emergent Themes | Define themes and make them more manageable |
| 2 | Quality Control | Enrich data by review of all texts and notes documents | Reading again to capture more data for emergent themes | New items that overlap from other initial themes | Mitigation; provide more richness and focus of data |
| 3 | Looking for Patterns | Triangulation and final map data to themes | Establish conceptual links for each theme | Patterns | To help drive the analysis to a more theoretical level |

Source: Adapted from Bonello and Meehan (2019); Chong (2019); Smith et al., (2012); Smith and Osborn (2015).

The tools for data analysis consisted of Microsoft Word 2010, Microsoft Excel 2010, Microsoft Visio 2003, and NVivo 12 Plus. Manual coding and memoing was performed in Microsoft Word 2010 by marking and commenting text in the transcribed interview; then the marked and commented text was consolidated in a Microsoft Excel 2010 worksheet for organization. A master table of emerging themes (see Table 9 presented in Chapter 4) was created using a process of iterative analytical steps that included a cyclical cross-comparison of themes (Bonello & Meehan, 2019). The researcher considered both the individual narratives and the group of participants as a whole by "fragmenting and reorganizing the data" (Smith et al., 2012, p. 91). After completing this step, the contents of the worksheet were imported into the qualitative data analysis software NVivo 12 Plus to prepare for the abstraction of data.

The creative process of identifying patterns within the imported data by focusing on conceptual links between themes helped drive the analysis to a more theoretical level.

The mapping of the conceptual basis was performed and the previously defined emergent themes enabled the creative process of defining super-ordinate themes. By applying a "careful mental process of logical content analysis," the super-ordinate themes were developed during the creative process of bringing meaning to the manifestation of participants' experiences (DeSantis & Ugarizza, 2000, p. 355).

Table 7
*Phase 3: Conceptual Data Analysis*

| Stage | Analytical Process | Strategy | Task Performed | Items Captured | Objective |
|---|---|---|---|---|---|
| 1 | Deeper level of interpretation | Assert conceptual basis | Focusing on conceptual links between themes | Items that can be linked to a conceptual basis | Draft of super-ordinate themes |
| 2 | Mapping | Abstraction of data | Finalize super-ordinate themes | Connections between emergent and super-ordinate themes | Systematic review |
| 3 | Find connections between super-ordinate themes | Interpret super-ordinate themes | Link super-ordinate themes to research questions | Connections between super-ordinate themes | Draft summary statements and provide the basis for the essence |
| Transition to Write-up of Analysis | | | | | |

Source: Adapted from Bonello and Meehan (2019); Chong (2019); Smith et al., (2012); Smith and Osborn (2015).

A discussion of the mapping between super-ordinate themes and the stated research questions will follow in Chapter 4 in the *Results* section.

**Format for Presenting Results**

The results of the data and thematic analysis described in the *Data Organization and Analysis* section above are detailed in Chapter 4 in the *Results* section. The results contain a description of the conceptual basis and the connections between the super-ordinate themes and illustrate the creative process used to define the super-ordinate themes as such.

The presentation of the results includes sense-making of the thematic analysis in accordance with the methods recommended for IPA (Smith et al., 2012). The write-up of the results outlines the "meanings inherent in the participant's experience" and the super-ordinate themes were translated into a narrative account (Smith & Osborn, 2015, p. 48). Tables were included in the presentation of the results and accompanied by graphs generated in NVivo 12 Plus qualitative data analysis software. They illustrate the logical sequence how themes were formulated to be "congruent to the people being studied" (DeSantis & Ugarizza, 2000, p. 357). Direct quotes from the transcribed interviews provide support for the discussion of the connections among patterns, and illuminate connections among super-ordinate themes.

## Quality Control

### *Internal and External Validity*

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).

During the data coding and memoing stages described in the outline of the analytical procedures defined in Phases 1 and 2 (see Tables 5 and 6), a diligent process to ensure quality of data was established by the researcher. After the coding process was considered complete, all initial themes thus created were examined to ensure that data was assigned to the appropriate theme. When it was discovered that some initial themes were underrepresented, a rigorous activity ensued to extract more data from the transcribed interview and to enrich the respective initial themes.

The researcher made every attempt to stay close to the formal methods of IPA. During the final stages of the data analysis—at a critical point when super-ordinate themes were being defined—the researcher engaged in a micro-analysis of the super-ordinate themes and it appeared that two of the super-ordinate themes were too closely related. This problem became more evident when the researcher attempted to link participant statements to each of these two super-ordinate themes while preparing for the write-up of the findings. By making the decision to merge these two themes into one, the researcher avoided "producing an analysis that was too descriptive" (Smith et al., 2012, p. 103) and succeeded engaging in multi-level interpretation when presenting the findings.

The researcher performed quality control by carrying out the activity to read and reread the transcriptions, before engaging in the analytical process and composing the final report (Smith et al., 2012). The voice recordings were examined by the researcher as many as three times in order to audit the transcribed interview documents, to complete sections left blank and verify transcribed statements that appeared inconsistent with the rest of the text. The raw files of the transcribed interviews were read by the researcher a minimum of three times and formatted to make them more legible. The formatted transcribed interview files were read a minimum of five times during Phase 1 of the aforementioned analysis. The files generated during Phase 2 containing the initial themes table were read and reread about four times, before entering Phase 3 and received additional examination by rereading during the completion of Phase 3.

The researcher hoped to attain quality in data collection to ensure the "trustworthiness" (Guba & Lincoln, 1982, p. 246) of the findings by carefully selecting participants who had the ability to make the time for the interview. The interview process was diligently organized, thoroughly staged, rehearsed, and then tested during a pilot interview, before actual data collection commenced. Furthermore, the researcher engaged in journaling before, during, between, and after interviews which enabled her to recognize her own biases and potential misconceptions.

The researcher aimed to set aside these personal assumptions to retain an objective lens when she was examining the subjective accounts of each participant. Keeping the journal also helped the researcher to continuously improve the research process while conducting the study. This system is called reflexive bracketing (Ahern, 1999) which means that the researcher took steps to eliminate bias and subjective assumptions. More details about the process of reflexive bracketing and journaling applied will follow in the next section.

A selection bias effect—the types of participants selected for the study—can pose a threat to external validity when there is a concern that results cannot be generalized (Sekaran & Bougie, 2013). In IPA, however, the emphasis is on finding a "fairly homogeneous sample" (Smith & Osborn, 2015, p. 28) and on committing to a "detailed interpretative account of the cases" (p. 29) as described in Chapter 4 of this report.

According to Guba and Lincoln (1982), external validity is expressed by "transferability" (p. 246) when study participants consist of a sample representative of the population. In addition, enough "thick description" made available using the recommended process of the IPA was designed to achieve a "reasoned judgment" about the possibility of transferability (p. 247).

*Reflexive Bracketing and Journaling*

The choice of a phenomenological approach demands that the researcher makes every attempt "to eliminate any prior assumptions and personal biases" (Bhattacherjee, 2012, p. 109) during interaction with participants of a study. For IPA studies, it is preferred that the researcher temporarily set aside any bias that consists of pre-existing concerns or assumptions. This can be achieved by engaging in "attentive listening" to the participant during the interview sessions (Smith et al., 2012, p. 64). During each interview session, the researcher made every attempt to listen to the participant's responses with an open mind, and to refrain from drawing premature conclusions. Journaling is a suitable activity to accomplish this goal and to help deflect ideas containing bias so they could be sorted out later. These journal entries served to clarify the researcher's personal value systems and be aware of areas that have the potential of being subjective. The researcher continuously referred to the journal after each interview and after reading each transcript as a method to promote internal validity (Ahern, 1999). Furthermore, the journal entries continued through the coding and analysis phase to deliver a sound methodology reflected in the thought processes involved during the creative process.

Eliminating all previous assumptions and knowledge, however, may not be practical during the analysis phase. According to Ahern (1999), subjective awareness of the researcher is a desired component that can contribute to the sense-making of the data. At a point during the analysis while engaging in the quest for patterns, the researcher's professional experience with insulin pump patients was a valuable starting point that helped her to conceive new ideas and interpret "concealed meaning" (Morse & Richards, 2002, p. 148).

Keeping the journal helped with reflexivity to retain a certain amount of transparency in the process (Ortlipp, 2008). Journaling of the researcher's own thoughts and impressions promoted critical self-reflection of actions taken during the interview process. The journal entries were used to justify researcher opinions and thoughts and became an acceptable part of the design, the data generation, the subsequent analysis and the interpretation of the data (Ortlipp).

*Data Saturation*

The researcher had stipulated in the dissertation proposal that she was looking to collect data from six to eight participants. When conducting the study, a pilot participant and five other participants were interviewed in rapid succession and provided a wealth of information. Expert recommended guidelines for sample size in phenomenological studies vary (Creswell, 2013; Morse & Richards, 2002), and the researcher considered the following additional criteria to make a decision about data saturation as follows. According to recommendations by IPA methodology (Clarke, Braun, & Hayfield, 2015), a "homogeneous focused sample can help in identifying meaningful themes" (p. 229) and is a good fit for rich data. The researcher engaged in the process of self-examination to evaluate if data saturation had been met, after she had completed the coding and analysis of the interviews of five participants and the pilot.

According to Fusch and Ness (2015), data saturation is reached when attaining additional new information and further coding is no longer feasible. The researcher viewed the data set she had collected to be "rich in quality" and "thick in quantity" (p. 1409). She also believed that she would not able to provide additional themes beyond the ones established during Phase 2 of the analytical process. The master list of emergent themes (see Table 9) shows the distribution of the final nine themes among participants—including the pilot—to be ranging between 78 and 100 percent. The researcher concluded that she would not be in a position to "shed any further light on the issue under investigation" (Mason, 2010) with additional interview data. The researcher felt confident she would no longer be able to collect new data from additional participants that would lead to substantial new findings, and she decided to halt recruitment efforts for further participation.

## Ethical Considerations and Compliance

The researcher had taken the Collaborative Institutional Training Initiative (CITI) basic coursework for the Human Research curriculum group on May 7, 2016, and renewed the coursework on March 30, 2019. She was competent to initiate all required documents for the study and perform the investigative process according to the IRB protocol. No invitations to participate were generated and no participant was recruited until permission to proceed with the study was granted by the dissertation committee on October 17, 2018.

The rights to privacy of the individuals and their rights during the interview process were explained to them during the initial contact by phone or Email, and before they signed the Informed Consent form. The researcher went over the terms of the Informed

Consent form with each participant again just before the recording of the interview commenced. During this occasion, the researcher emphasized that the participant could take a pause or could request to terminate the interview at any time. The Interview Day Interaction Template (see Appendix G) was used by the researcher to accomplish the objective of setting the participant at ease.

This strategy reduced any chance of misunderstanding on the part of the participant that could have resulted in an alleged misrepresentation of the study objectives (Sekaran & Bougie, 2013). It also served to ensure that the participant felt comfortable to be interviewed.

The participants' privacy was protected by recording the interviews without mention of their names and identity. Instead, participants were assigned random two-digit ID numbers as part of the audio recording, and were referenced as such during the reporting phase of the study. The recorded voice files were uploaded to Sunrise Transcriptions via their secure Exavault FTP portal, labelled with the participant's two-digit ID. The transcribed interviews were downloaded from the Exavault portal to be stored on the researcher's computer in her home office. The files were subsequently deleted from the portal. The files are stored on the researcher's computer at her home office with password protection. Backup of the files containing personal identifiable information of the participants was made on an encrypted Western Digital external hard drive with password protection and is kept under lock at the researcher's home office.

The information provided by the participants was treated as strictly confidential within the scope of research reporting. Prior to including any information in the research report, participants had an opportunity to review the transcription of the recorded interviews, to make changes, and to request omission of statements. This also gave them the opportunity to desensitize data that could potentially lead to their identification.

Additional steps to preserve participants' privacy and ensure confidentiality were taken by the researcher by disguising the names of insulin pump manufacturers within the context of the interview data. There was a chance that readers might be able to deduce a participant's identity, if they were aware of their employment status. Instead of citing participants' responses verbatim when presenting results, the company names the participants referred to in their statements reported in Chapter 4 were arbitrarily labelled Company A; Company B; Company C; etc. and do not correlate to any specific insulin pump manufacturer.

**Resources and Feasibility**

Specific resources required for the study consisted of hardware and software resources, transcription assistance, funding for gift certificates and transcription expense, and a central location for the planning, analysis and completion of the study. The researcher successfully secured all required resources to conduct the study (see Table 8). The computer and voice recording equipment, and other hardware and software resources had been available to the researcher at her home office where she conducts all her study assignments and research activities. A license of NVivo 12.0 Plus was purchased before the study commenced. The transcription service was hired based on the fact that they had a proven track record of trustworthiness and quality performance with the researcher through her employment. The budget to acquire the gift certificates, pay the transcription service, and acquire the qualitative data analysis software was self-funded.

Table 8

*Resource List*

| Hardware | Quantity | Source |
|---|---|---|
| Computer w/ camera and microphone | 1 | Researcher |
| Laptop | 1 | Researcher |
| Digital voice recorder | 1 | Researcher |
| Samsung tablet to act as a backup to voice recorder | 1 | Researcher |
| Laser printer | 1 | Researcher |
| **Software & Subscriptions** | **Quantity** | **Source** |
| Microsoft Office Suite | 1 | Researcher |
| Skype account | 1 | Online |
| Email account | 1 | Researcher's university Microsoft Outlook account |
| Survey Monkey account | 1 | Online |
| Exavault account | 1 | (part of file exchange platform) |
| NVivo 12 Plus software | 1 | QSR International |
| Various social media accounts | N/A | Online |
| Transcription service | 1 | Hired by Researcher |
| **Facilities** | | **Location** |
| Office space to perform study | | Researcher's Home Office |
| **Budget** | **Amount** | **Source** |
| Gift certificates for five participants and pilot | $ 635.70 | Self-funded |
| NVivo 12 Plus software license | $ 114.00 | Self-funded |
| Transcription service for six cases | $ 357.00 | Self-funded |
| Skype fee to allow incoming calls | $ 9.98 | Self-funded |

**Summary**

In this chapter, the aim for the study was sufficiently explained to substantiate the conclusion that an approach using interpretative phenomenological analysis (IPA) was a suitable method to conduct the research. The preparation of all official documents required to perform the research according to Institutional Review Board (IRB) guidelines had been completed prior to commencing with the recruitment. The study was approved by the center representative of the IRB on September 25, 2018 and determined to be exempt from further IRB review. The acquisition of required resources was in place before the study commenced. The funds to activate software subscriptions, to hire the transcription service and to purchase the gift certificates for the participants were subject to self-funding and had been appropriated.

Permission to proceed with the study was granted by the dissertation committee on October 17, 2018, after the dissertation proposal had been successfully defended. The steps of the research process were described in detail in this chapter. The description included details about the recruitment of participants, about the instrumentation used, and how the interview and data collection processes were conducted. An overview was presented how the coding and the analysis of the data were conducted. A detailed description of the analysis and the presentation of the findings are presented in Chapter 4 of this report.

# Chapter 4

# Results

## Introduction

This chapter first provides a detailed description of the analytical framework approach for qualitative studies adapted from Bonello and Meehan (2019), and from Chong (2019) that guided the researcher through the analysis. This framework approach consisted of three distinct phases and encapsulated IPA methods as recommended by Smith et al. (2012), and by Smith and Osborn (2015). The approach enabled the researcher to identify common threads that would lead to a thematic analysis of the data and the formulation of emergent themes (DeSantis & Ugarizza, 2000).

A system of coding and memoing was applied to the data according the methods of interpretative phenomenological analysis (IPA) and is being presented in this chapter (Smith & Osborn, 2015; Smith et al., 2012). An overview of three phases of coding, memoing, and interpretation had previously been presented in Chapter 3. In this chapter, an in-depth description of the activities that occurred during these three phases is presented. Phase 2 of the data analysis resulted in the definition of nine emergent themes that represent how the data were organized. Next, twelve patterns (see Table 11) were discovered and linked to a conceptual basis that characterized the emergent themes.

The last phase of the data analysis resulted in the creation of the five super-ordinate themes that encompass the essence of the participants’ experiences. The patterns that connect each super-ordinate theme also connect each theme to the nine emergent themes initially developed (see Table 12). The steps taken during the entire analytical process are laid out by a thick description of the decisions made by the researcher, and supported by references from qualitative methodological literature, when appropriate.

In the *Findings* section of this chapter, the participants' quotes from the interviews are presented for each of the five super-ordinate themes, using the aforementioned twelve patterns (see Table 12) to organize the discussion. Following this section is a discussion about the tools used for the analysis. The tools represent a mix of methods, using word processing and spreadsheet software by Microsoft, and triangulating the results with qualitative data analysis software by QSR International, supported by data visualization. Finally, a report is presented that describes the researcher's effort to sort out biases and preconceptions by engaging in journaling and bracketing during the interviews with the participants and during the subsequent data analysis and interpretation.

**Data Coding and Analysis**

After the completed review of the transcribed interview data, the researcher worked out a coding strategy according to IPA principles, designed to "learn something about the participant's lived experience" (Smith & Osborn, 2015). The researcher created a separate document for each transcribed interview to outline analytical methods recommended in IPA adapted from Smith et al. (2012), and from Smith and Osborn (2015). Each transcribed interview was matched with a distinct version of this document, labelled *Participant Coding* and appended by the participant's random 2-digit identifier. To organize the steps throughout the process of analysis, the researcher adapted a framework approach from Bonello and Meehan (2019, Table 1, p. 486), and from Chong (2019) to stay on task throughout the entire analytical process. The adapted framework consisted of three consecutive phases (see Appendix H, Outline of Analytical Procedures) with the aim to prepare the data for the presentation of results.

As a method to stay focused, the researcher applied the recommendations by Chenail (1997) how to keep "things plumb in research" (p. 2). While engaging in a given coding or analytical stage, the researcher defined the "area of curiosity" (p. 5) as: *Discover the lived experiences and shared impressions of pump trainers*. The "mission question" (p. 5) stated that the researcher intended to *uncover the phenomena associated with usability challenges*.

*Phase 1: Data Coding According to IPA Methods*

Phase 1 encompassed an iterative approach of reading and rereading the transcribed interviews during four defined stages of coding and memoing as described below. As an aide to guide the researcher through the task of coding and commenting on passages within the transcribed interview text, the researcher followed the recommendations by Saldaña (2016) by engaging in a "brain dump" (p. 44) to trigger ideas that would enable her to dig deeper into the participant's responses later.

The objective of Stage 1 of Phase 1 was to capture "descriptive comments" (Smith et al., 2012, p. 84) and to engage in the process of "initial memoing" (p. 83). To accomplish this, the following steps were undertaken. First, the transcribed document was modified to invoke the Microsoft Word 2010 *Line Numbering* feature, to start over on each page. The *Comments* feature in Microsoft Word 2010 under the user initial *HBH* was used to mark and comment any text that stood out as things "which matter to the participant" (p. 84). The selection process included anything having to do with the participant's preferences, their routine, or their beliefs. The result was a descriptive and preliminary data set that served to familiarize the researcher with the text. During this stage, the researcher was trying to obtain information about “what is going on here” (Saldaña, 2016, p. 102). Getting to “the heart of the narrative of the participant’s concerns” (p. 77) as suggested by Saldaña was an activity the researcher engaged in at a later stage.

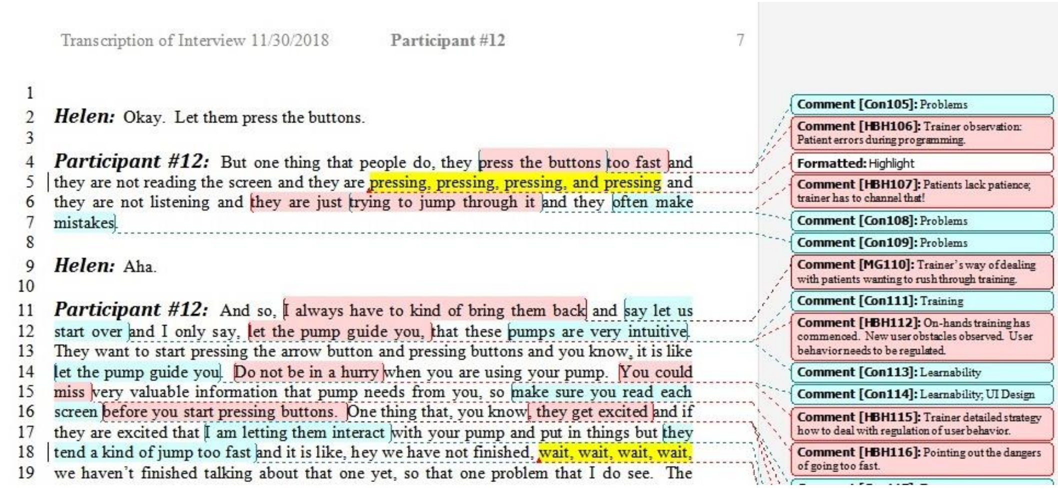
Stage 2 of Phase 1 involved rereading the document and the capture of “linguistic comments” (Smith et al., 2012, p. 88) that stood out as a specific use of language (e.g., colloquialism), because language use could reveal a distinct perspective of meaning expressed by the participant. These linguistic comments were highlighted in the document in yellow, copied and organized in table format in the separate document titled *Participant Coding* and reported “in vivo” (Saldaña, 2016, p. 77), because they originated from the participants’ expressions, verbatim. The researcher made additional comments in the linguistic comments table to try to capture the participant’s thought process regarding the specific use of language.

During Stage 3, the researcher engaged in another rereading of the document to label conceptual comments. Using Microsoft’s *Comment* feature, the objective was to mark all text that was related to concepts introduced in the literature review of this study (e.g., *safety critical*). This time, the initial *CON* was used; this triggered the software to mark comments and text with a color distinct from Stage 1. The purpose of this coding task was to annotate “conceptual comments” (Smith et al., 2012, p. 88) to draw on the researcher’s “own experiential and/or professional knowledge” (p. 89).

The definition of the conceptual codes were 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. According to Todorova (2011), social meanings are connected with personal meanings. In this study, the aim was to generate an awareness of the social meaning surrounding the specific health care context of the self-management of diabetes to elucidate people's sense-making about health and illness.

The coding method applied in Stage 3 aimed to identify conceptual comments and resulted in some additional concepts that came to mind during this creative process. All concepts used in a given document were copied and organized in the accompanying *Participant Coding* file, and annotated with additional comments, using a creative process to reflect on the data.

During Stage 4, the objective was to engage in the process of "deconstruction" to "get closer to what the participant is actually saying," to emphasize the "importance of context," and to capture interrelationships between experiences (Smith et al., 2012, p. 90). The creative process involved annotations using the Microsoft Word *Comments* feature with the initial *MG* to arrive at yet another distinct coloring scheme triggered by the software. Following the explicit instructions by Saldaña (2016) described in his section *Examples of Analytical Memos* (pp. 45-53), the researcher jotted information about passages to be used for later reflection during the conceptual data analysis. The coding task during Stage 4 presented the researcher with an opportunity to organize the data into preliminary themes. Figure 1 shows a snapshot what a coded interview document looked like after Stage 4 was completed.



Transcription of Interview 11/30/2018 **Participant #12** 7

***Helen:*** Okay. Let them press the buttons.

***Participant #12:*** But one thing that people do, they press the buttons too fast and they are not reading the screen and they are pressing, pressing, pressing, and pressing and they are not listening and they are just trying to jump through it and they often make mistakes.

***Helen:*** Aha.

***Participant #12:*** And so, I always have to kind of bring them back and say let us start over and I only say, let the pump guide you, that these pumps are very intuitive. They want to start pressing the arrow button and pressing buttons and you know, it is like let the pump guide you. Do not be in a hurry when you are using your pump. You could miss very valuable information that pump needs from you, so make sure you read each screen before you start pressing buttons. One thing that, you know, they get excited and if they are excited that I am letting them interact with your pump and put in things but they tend a kind of jump too fast and it is like, hey we have not finished, wait, wait, wait, wait, we haven't finished talking about that one yet, so that one problem that I do see. The

**Comment [Con105]:** Problems
**Comment [HBH106]:** Trainer observation: Patient errors during programming.
**Formatted:** Highlight
**Comment [HBH107]:** Patients lack patience; trainer has to channel that!
**Comment [Con108]:** Problems
**Comment [Con109]:** Problems
**Comment [MG110]:** Trainer's way of dealing with patients wanting to rush through training.
**Comment [Con111]:** Training
**Comment [HBH112]:** On-hands training has commenced. New user obstacles observed. User behavior needs to be regulated.
**Comment [Con113]:** Learnability
**Comment [Con114]:** Learnability; UI Design
**Comment [HBH115]:** Trainer detailed strategy how to deal with regulation of user behavior.
**Comment [HBH116]:** Pointing out the dangers of going too fast.

*Figure 1.* Example of a coded document during analysis Phase 1, Stage 4

Data captured during Stage 4 was copied and organized in table form in the accompanying *Participant Coding* file, annotated with the page and line number where the data were located within the document. By the time the researcher had reached Stage 4, the creative process of rereading the transcribed interview and envisioning the participant as she tells the story helped the researcher develop a preliminary list of emergent themes. The Stage 4 data were subsequently rearranged in table format, using the ontology created during Stage 3. Other themes that appeared striking were added. Figure 2 shows a snapshot of the Stage 4 portion of the *Participant Coding* file. At this stage, participant statements were frequently coded several times: Descriptive coding and commenting would also overlap with conceptual coding; items coded during process of deconstruction would overlap with both descriptive and conceptual coding. The intent was to capture data in depth and in a meticulous fashion to prevent omission of important concepts and themes.

Participant 12 – Coding/Memoing Notes 2/1/19 to 2/9/2019 4

Fourth Reading

SFL, step 2, p. 90: Deconstruction

**To get closer to what the participant is actually saying**
**Emphasize the importance of context**
**See interrelationships between one experience and another**
**What is the meaning of this to the participant?**

Items related to Participant meaning are commented in pink!

As per Smith & Osborn, 2015, page 42, Initial List of Themes

| IMPORTANT FOR SUCCESS | | |
|---|---|---|
| User prior knowledge | 1:8 | Getting the user profile down |
| User motivation | 1:10 | |
| User preparation prior to training | 1:14 | |
| Knowing user fears | 1:11; 1:39; 2:1-7 | |
| Watching user reactions throughout the training | | Determines the next step |
| Must understand certain principles (insulin on board) and before the user is allowed to do the programming | 5:38 | Regardless what time it takes |

*Figure 2.* Example of annotations in a *Participant Coding* file

After the coding of a transcribed interview was completed for a given participant, an attempt was made to capture the essence of the participant's experience by designating a preliminary theme labelled *Take Away*. The information in this category was used later to facilitate the creation of super-ordinate themes. In the *Take Away* theme worksheet, the researcher made notes on what she learned about the participants' experiences during their story-telling. If appropriate, statements made by the participant when prompted at the end of the interview if they had anything else to add, were included in this theme. These statements were deemed important because they represented the v*oice* of the participant with the hope to provide a basis for formulating the essence of the participants' lived experience (Smith & Osborn, 2015).

*Phase 2: Preliminary Data Analysis*

The objective of Phase 2 was to consolidate the data and create a "hierarchical thematic framework" (Bonello & Meehan, 2019). The activities consisted of identifying the initial themes, condensing the list, finalizing the emergent themes, and creating the master list of emergent themes (see Table 9). The researcher succeeded in condensing the data into a format where the characteristics of emergent themes could be closer examined. This process helped drive the analysis to a more theoretical level by looking for patterns (Smith & Osborn, 2015), while using an iterative approach of creative thinking and evaluation. The researcher adapted the analytical guiding frame (AGF) and overall guiding frame (OGF) approach from Chong (2019) to establish an audit trail for the analytical process used in this study. It also helped the researcher to stay focused through the complex process of trying to make "critically reflexive connections" (p. 298).

Phase 2 consisted of three stages. During Stage 1 of Phase 2, a Microsoft Excel workbook format was chosen to work up an *Initial Themes Table* by assigning a separate worksheet for each of 15 themes extracted from the *Participant Coding* files that accompanied each transcribed interview. The outline of the initial themes followed the examples provided by Smith et al. (2012, Box 5.6, p. 101), and by Smith and Osborn (2015, Box 3.8, p. 47). To organize the data, the researcher adapted a method to "synthesize and interpret data" from Bonello and Meehan (2019, p. 484) by stipulating the main themes and subdividing them into related subtopics, if they appeared unmanageable as a whole. The researcher inserted each respondent's statement(s) into the worksheet, along with the researcher's additional comments, identified all statements by participant ID number, and inserted a column with page and line numbers that allowed navigation back to the transcribed interview for each participant. The organization of these worksheets enabled the researcher to further "examine the data for patterns…both by participant and by theme" (p. 484).

After examining each initial theme and using creative thinking to decide if a particular theme was redundant or may serve to enhance another theme, it was decided to merge seven of the initial themes into the other themes. The researcher followed a creative process adapted from Bonello and Meehan (2019) to classify and organize the entire data set by grouping participant statements according to "key themes, concepts and emergent categories" (p. 484). The result was the master list of emergent themes (Table 9) that contained eight emergent themes derived from the original 15, and a new theme labelled *Interaction*.

Table 9
*Emergent Themes Master List*

| Final | All Initial Themes | Emergent Themes | Participant | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | #12 | #28 | #40 | #47 | #50 | #73 |
| 1 | | Interaction | ✓ | | ✓ | ✓ | ✓ | |
| 2 | Learnability | Learnability | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 3 | Reactions | Reactions | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 4 | Responsibility | Sense of Responsibility | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 5 | Safety Critical | Safety Critical | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 6 | Success Criteria | Success Criteria | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 7 | Training Strategy | Training Strategy | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 8 | Usability | Usability | ✓ | ✓ | ✓ | ✓ | ✓ | |
| 9 | User Issues | User Issues | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| | Compliance | (Success Criteria) | | | ✓ | | | |
| | Feedback | (User Issues) | | ✓ | | ✓ | | |
| | Love & Hate | (Reactions) | | ✓ | ✓ | ✓ | ✓ | ✓ |
| | Medical | (Safety Critical) | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| | Tech Support | (Safety Critical) | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| | User Interface Design | (Usability) | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| | Wishes | (Reactions) | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| | Prevalence of Themes in % | | 89 | 89 | 100 | 100 | 100 | 78 |

During Stage 2, the researcher examined the data within the worksheets for each of the initial themes and found that several themes were underrepresented in the data (e.g., less than five participant direct quotes attributed to a given theme). It became apparent to the researcher that she had in fact not been "keeping things plumb" (Chenail, 1997, p. 2) as required to ensure quality in qualitative research. There had been very little data extracted from the coded transcribed interviews to fulfill the stated objective to *uncover phenomena associated with usability challenges*. In addition, many of the participant statements about usability challenges were relevant to other emergent themes and had been assigned to those.

To address the lack of rich data about usability challenges, the researcher engaged in another concentrated reading of each transcribed interview. The aim was to identify specific comments that reflected participant statements regarding usability, user errors, user interface design, user feedback and user problems. This time, the researcher engaged in the process of "structural coding" (Saldaña, 2016, p. 98) that would later help to align findings with the research questions as stated in Chapter 1 of this report.

Structural coding involves coding a larger segment of data to facilitate an in-depth analysis of a topic (Saldaña, 2016). As an example, the following situation is presented. Research sub-question 3 presented on page 8 of this report states: *What type of usability errors are encountered when trainers teach first-time users how to program their insulin pump?* Several segments of text on page 9, lines 33-44 and page 10, lines 1-2, in the transcribed interview for Participant #47 were explored by the researcher:

> "On the [Company A] pump, everything you are doing, it makes you confirm it and then you have to save it. There are multiple steps. But, you just have to be careful and not be in a hurry to be hitting *Confirm* and moving through it...but I do see where people come in and they feel like their pump is not working right and we look

at it and their A.M. and P.M. are off."

The structural code applied in the text of the interview transcription for participant #47 was labelled *Usability Errors* and appended with the comment *Trainer needs to make sure the users double checks the input before hitting CONFIRM.*

During the process of addressing the aforementioned deficiencies, the researcher created an additional theme and labelled it *Interaction.* The purpose of this theme was to align the data coding and analysis process with the stated goals in Chapter 1: To obtain knowledge from insulin pump trainers who are situated at the convergence of the interaction between the user and their efforts to perform tasks that take place in a real-life setting.

As a result of this activity, a satisfactory amount of additional data was added into the *Initial Themes Table* workbook; some of the comments and data pieces discovered in this process had a good fit for several themes. In addition, themes that contained large data sets were divided into sub-categories to make them more manageable and to enable a multi-faceted description for the presentation of results.

Stage 3: The process of making these adjustments and finding data that could enrich several themes paved the way to proceed to Stage 3 of Phase 2, because it enabled the researcher to discover patterns across cases to help drive the analysis "to a more theoretical level" (Smith & Osborn, 2015, p. 101). The researcher began with creating a table (see Table 10) to list each of the nine emergent themes with sub-categories, if appropriate.

Table 10

*Definition of Emergent Themes and Sub-Categories*

| Emergent Theme Label | Description and Thought Process |
|---|---|
| Interaction | Engagement between the trainer and the user during the process of learning: What the trainer does to enable the user to learn how to manage the device. |
| Learnability | Describes the processes surrounding the learning of the software product (Alonso-Ríos et al., 2009). Subdivided into: Preparation; Tricks of the Trade; Going by the Patient's Pace; Age-related Issues; Complexity Issues; Selection/Suitability. |
| Reactions | Response by the participant to an event or condition. Subdivided into: Motivation and Confidence; Fear/Concern; Resentment and Frustrations; Trust Issues; Compassion; Wishes and Desires (*The Voice*); Loves; Hates. |
| Sense of Responsibility | Items that describe a feeling of obligation evidenced in the participants' statements; a feeling of obligation towards a positive outcome of the training. |
| Safety Critical | User action or omission that could cause damage or harm (Masci et al., 2013). Subdivided into: Medical Issues/Terminology; Mechanical Issues; Programming and Alerts; Troubleshooting/Plan B; Safety Features. |
| Success Criteria | Things the trainer needs that either must be in place or must happen—something she is not willing to compromise on. |
| Training Strategy | The trainer's approach of teaching the user how to manage the pump. Subdivided into: Assessment and Foundation; Highlighting Benefits; Empowerment/ Making it seem Easy; Style and Manipulation; Sequence; Duration. |
| Usability and UI Design | Any statement that refers directly to usability and any statement that explicitly describes the user interface design; any statement that discusses the menus on the insulin pump. |
| User Issues | Includes: User Feedback, User Errors and User Problems. Anything where the trainer either observed a specific issue while the user was handling the pump, or statements made by users to the trainer reported back to the researcher. |

The task performed during Stage 3 was to engage in "deeper thinking, synthesis, and revisiting the data with new perspectives" (Bonello & Meehan, 2019, p. 495) and to find conceptual links for each emergent theme. The researcher reexamined each worksheet of the nine items on the master list of emergent themes (see Table 9) by using a creative process to categorize segments among the nine emergent themes in abstract terms. A new table (see Table 11) was created to map patterns across cases (Bonello & Meehan, 2019; Smith & Osborn, 2015) by marking data segments in the *Initial Themes Table* workbook and linking them to specific concepts.

The researcher proceeded to define the patterns by focusing on "smaller units of behavior, observations or verbal expressions" (DeSantis & Ugarizza, 2000, p. 359). This helped the researcher to locate "intellectual and affective content that depended on intrinsic form" (p. 361) and to label these in a "more general and abstract" form. To provide such meaningful and affective content, the researcher relied on her professional expertise in a healthcare environment and used a creative process to create patterns that included these criteria. According to Ahern (1999), the researchers' subjective awareness of the context can help identify issues, because it enables them to "be alert to themes in common with the broader human experience" (p. 408).

The researcher engaged in rereading the data pieces and comments collected in the *Initial Themes Table* workbook and used a creative process to develop conceptual patterns. These patterns were assigned to sections of participant or researcher comments and linked to a specific data piece. Several striking patterns were defined initially, such as *Learning Curve* and *Unrealistic Expectations*, and others were added when ideas were invoked by rereading the data.

For example, the abstract term *Reassurance* was applied to data that contained statements describing how the trainer was able to overcome fear and apprehension exhibited by a patient. This abstract pattern was located in several emergent themes: Interaction; learnability; reactions; training strategy. All participant statements pertaining to *Reassurance* were highlighted in green. The intention was to repeat this process until a complete list of patterns was established that could easily be traced back to any of the emergent themes by looking for statements and data pieces highlighted in distinct colors.

At this point, the workbook representing the final list of emergent themes (see Table 10) contained huge data sets, along with comments extracted from the transcribed interview of each participant, including the pilot. The strategy of using yet another workbook to work on the patterns with a large volume of data became unpractical. The researcher felt that it was time to test the powers of NVivo 12 Plus to determine if it would help to take the task of qualitative data analysis to a higher level.

Collective data import into NVivo from the *Initial Themes Table* workbook was not successful at the first attempt. The NVivo file import command only pulled in the first worksheet in the set, which was *Interactions*. Another test to import the entire workbook resulted in another random worksheet being extracted. The NVivo software classified the Excel file contents as a survey and treated each row in the worksheet it imported as a case. The file import command in NVivo resulted in a data compilation that was contrary to the organization of data inside the Excel workbook: Significant statements by participants had been grouped together within a theme or sub-section of theme, but in separate rows in the worksheet.

After reading online support notes for NVivo file import strategies, the researcher decided to convert each worksheet of the *Initial Themes Table* workbook into a Microsoft Word format. If a theme was divided into subcategories, a distinct Microsoft Word document was created for each subcategory and imported. A total of 35 documents were created and imported into NVivo.

Due to an undefined software error, some comments captured when the researcher manually converted the *Initial Themes Table* worksheets into individual Word documents did not transfer to NVivo. Specifically, it omitted additional comments added during the mitigation period in Phase 2, Stage 2, when the transcribed interviews were reread to capture additional data for themes that lacked focus or richness of data. The researcher reformatted each Word file again from within the Excel workbook and, this time, all of the researcher's comments captured as part of the transcribed interview appeared in the NVivo data files. The researcher was able to complete the task of developing patterns that connected emergent themes in NVivo.

*Phase 3: Conceptual Data Analysis*

The development of patterns is a result of the researcher's activity to create "mental images" by being very attentive to what emerged from the data (Morse & Richards, 2002, p. 133). After mapping the patterns to the underlying data within the emergent themes data set in Stage 3 of Phase 2, the researcher moved to Phase 3, Stage 1 by linking the patterns to a conceptual basis. This was accomplished by engaging in a creative thinking process to obtain a "deeper level of interpretation than participants' spoken discourses" (Bonello & Meehan, 2019, p. 492). The researcher performed a literature search to locate adequate definitions and labelled each pattern with a conceptual base with the aim to rise above the "noise of the data" (p. 492). Table 11 lists the conceptual basis for each of the patterns identified.

Table 11
*Patterns and their Definitions*

| Pattern | Definition |
|---|---|
| Behavior Modification | During operant conditioning to reinforce target behavior, stimuli are applied to control the desired behavior (Delprato & Midgley, 1992). |
| Compassion | Compassion is the "sensitivity to suffering in self and others with a commitment to try to alleviate and prevent it" (Fotaki, 2015, p. 199). Compassion is number 1 on the list of ethical requirements for a health practitioner, according to the American Medical Association (Dougherty & Purtilo, 1995). |
| Complexity | The condition of an "innovation perceived as relatively difficult to understand and use" (Venkatesh, Morris, Davis, & Davis, 2003, p. 430). |
| Expectations | Patients have unrealistic expectations about the effectiveness of their treatment, which is common in health care and complicates the process of treatment (Woolf, 2012). |
| Honesty | Honesty in health care delivery is the underlying foundation of caring (Borhani, Alhani, Mohammadi, & Abbaszadeh, 2010). To be direct and straightforward has been found to be more effective in health care than the practice of *sugar-coating* (Quirk, Mazor, Haley, Philbin, Fischer, Sullivan, & Hatem, 2008). |
| Learning Curve | The effort a user needs to expend to learn a system (Davis, 1989). We learn faster when a task is "focused, familiar and consistent" (Johnson, 2014, p. 159). A "continuous series of improved user performance" (Nielsen, 1993, p. 29) |
| Learning Outcome | The user masters the system to achieve "efficiency of use" (Nielsen, 1993, p. 30) and acquires a "high level of productivity" (p. 26). |
| Reassurance | "Indicating that there is no cause for anxiety" (Teasdale, 1989, p. 444). It is a "purposeful attempt to restore confidence" (p. 447). |
| Satisfaction | Goal commitment and expectancy in the individual leads to positive performance (Locke & Latham, 1990). Individuals who are goal-committed exhibit "ability, adaptability, creativity and capacity to perform in the situational context they are in" (p. 241). Goal success leads to satisfaction. |
| Trust-building | Interaction between health care providers and patients that is perceived by the patients as "honest, collaborative, and supportive" reinforces trust (Becker & Roblin, 2008, p. 801). Health care providers must exhibit behaviors that build this trust to be effective in patient care. |
| UI Problem | Problems associated with the interface of a device (Sauro & Lewis, 2012). |
| Voice for Improvement | Trainers' suggestions for improvements should be heard, because they can lead to "better patient outcomes and better system performance" (Batalden & Davidoff, 2007, p. 2). Change making should be encouraged in "all parts of the system" and that includes the training environment (p. 2). |

To develop the super-ordinate themes, the researcher used the *Visualize/Chart Node Coding* feature in NVivo to inspect each pattern and made note how the software projected multiple links to some or all of the emergent themes previously defined in the master list of emergent themes (see Table 9). During this activity, the researcher engaged in a deep thinking process regarding what had been learned from the process of insulin pump training of new users, as observed through the eyes of the trainers. The researcher applied a creative process to perform the task of synthesizing the patterns and assigning a higher order theme to each cluster of patterns (Bonello & Meehan, 2019). The result was an abstraction of six clusters to represent striking aspects of the trainers' experiences and a preliminary labelling of super-ordinate themes:

1. Emotion-charged Environment
2. Tricks of the Trade
3. Safety Issues
4. Responsibility
5. A Calling
6. This Needs to Change

During the thought process of selecting these labels, the researcher was attempting to facilitate a structural description of the insulin pump trainers' experiences and put her attention on ideas that were "strikingly apparent" in the text (Saldaña, 2016, p. 184), rather than focusing on a "multiplicity of events" (Bonello & Meehan, 2019, p. 492).

Stage 2 of the conceptual data analysis consisted of a systematic review of the super-ordinate themes to provide labels that would provide a better fit with the conceptual basis of the patterns located. During this review, the researcher applied a process of creative thinking and engaged in a critical analysis of the six identified clusters. At this point it was determined that the preliminary super-ordinate themes 4 and 5 were closely related, if not redundant. Both themes attempted to capture the sense of responsibility insulin pump evident in the participants' statements about the needs of the users, and both themes supported the researcher's striking discovery that insulin pump trainers often work beyond the requirements of their training activities. The two themes 4 and 5 were merged together under the label *Professional Dedication*.

The researcher then proceeded to map the patterns with the emergent themes to establish links between emergent themes and super-ordinate themes. This activity was performed to provide a basis for the "coherent abstraction of the findings" (Bonello & Meehan, 2019, p. 495) needed to present the conceptual basis for defining these super-ordinate themes. The activity was supported by using the *Visualize/Chart Node Coding* graphical display function in NVivo.

Stage 3 of the conceptual analysis phase involved creating a framework for the interpretation of the super-ordinate themes and establishing a method to recognize the connections between them (Smith & Osborn, 2015). While engaging in the activity to define patterns that connect each super-ordinate theme to the emergent themes, patterns that were shared among super-ordinate themes became apparent during the process. The patterns were developed from the NVivo imported files containing all participants' coded statements in relation to emergent themes and subcategories. The patterns can be traced back to a given participant and their actual statement to a precise location within each transcribed interview. A narrative account of super-ordinate themes and their connections among participants' experiences will be presented in the *Findings* section of this report.

The five super-ordinate themes developed were labelled *Emotion-charged Environment; Personalized Training*; *Safety Issues and Disaster Planning*; *Professional Dedication;* and *The Voice* (see Table 12, themes 1 to 5). The completion of the super-ordinate theme development enabled the researcher to examine each phenomenon as it manifested itself and "emerges into the light," and to make sense of its connection to its "deeper latent form" (Smith et al., 2012, p. 24). A description of the conceptual basis as it relates to the patterns that make up each super-ordinate theme is provided in Chapter 5 in the *Conclusions* section of this report.

Table 12
*Super-ordinate Theme Development – Themes 1 to 5*

| | Super-Ordinate Theme | Pattern | Emergent Theme |
|---|---|---|---|
| 1 | Emotion-Charged Environment<br><br>The users suffer from a life-threatening, scary disease. The trainer has to put them at ease to build an environment where users can feel comfortable to be conducive to learning. In addition, patients have unrealistic expectations. Trainers emphasize that optimized insulin pump therapy may not be easier than injecting, but is certainly better than! | Behavior Modification<br>Compassion<br>Complexity<br>Expectations<br>Honesty<br>Learning Curve<br>Reassurance<br>Trust-Building | Interaction<br>Learnability<br>Reactions<br>Safety Critical<br>Sense of Responsibility<br>Success Criteria<br>Training Strategy<br>Usability & UI Design<br>User Feedback |
| 2 | Personalized Training<br><br>There is no set pace to teach patients how to use the pump; it depends on their ability, which is something the trainer has to spot in advance. The pace and style of training depends on how prepared the users are and how much background they have about the self-management of diabetes. | Learning Curve<br>Learning Outcome<br>Reassurance<br>Trust-building<br>UI Problems | Interaction<br>Learnability<br>Reactions<br>Safety Critical<br>Sense of Responsibility<br>Success Criteria<br>Training Strategy<br>Usability & UI Design<br>User Feedback |

Table 12, continued

| | Super-Ordinate Theme | Pattern | Emergent Theme |
|---|---|---|---|
| 3 | Safety Issues and Disaster Planning<br><br>Being able to troubleshoot is the key to safety in pump therapy; this is emphasized during training when users are taught problem-solving skills. The trainer's commitment to facilitative the learning process is bound by the reality that there is no room for failure. | Behavior Modification<br>Complexity<br>Expectations<br>Honesty<br>Learning Curve<br>Learning Outcome<br>Reassurance<br>Trust-building<br>UI Problems | Interaction<br>Learnability<br>Reactions<br>Safety Critical<br>Sense of Responsibility<br>Success Criteria<br>Training Strategy<br>Usability & UI Design<br>User Feedback |
| 4 | Professional Dedication<br><br>Training a patient how to use an insulin pump is only one part of the overall task to start a diabetes patient on pump therapy. Trainers are motivated by their compassion for their patients and the positive feedback they receive from successful pump patients. | Compassion<br>Complexity<br>Expectations<br>Learning Outcome<br>Reassurance<br>Satisfaction | Interaction<br>Learnability<br>Reactions<br>Safety Critical<br>Sense of Responsibility<br>Success Criteria<br>Training Strategy<br>Usability & UI Design<br>User Feedback |
| 5 | The Voice<br><br>Trainers want to participate in health care quality improvement. They suggest improvements, or: Elimination of features that they do not consider practical for the course of treatment. The trainers object to new technology being pushed on patients that does not work as promised. | Behavior Modification<br>Complexity<br>Expectations<br>Learning Curve<br>Learning Outcome<br>UI Problems<br>Voice for Improvement | Learnability<br>Reactions<br>Safety Critical<br>Sense of Responsibility<br>Success Criteria<br>Training Strategy<br>Usability & UI Design |

## Findings

Data from six semi-structured interview transcriptions were analyzed, using an analytical framework approach adapted from Bonello and Meehan (2019, Table 1, p. 486), and from Chong (2019). This framework approach encapsulated IPA methods as recommended by Smith et al. (2012), and by Smith and Osborn (2015). The major findings that emerged from this study are as follows.

1. *Emotion-Charged Environment* – Users' fears, frustration and distrust are met by the trainers with compassion, honesty and reassurance. Trainers work hard to counteract these negative sentiments to facilitate the learning process, using encouragement and strategies of behavior modification to reduce the learning curve.
2. *Personalized Training* – Pump manufacturers provide trainers with a checklist that outlines all the steps to be taken. The reality is, however, that users arrive at the training sessions with unpredictable levels of basic knowledge about diabetes care or with little or no advance preparation. Therefore, the training is conducted around the individual's needs. Trainers will do whatever it takes to achieve a favorable learning outcome.
3. *Safety Issues and Disaster Planning* – Training users to troubleshoot is the key to safety in insulin pump therapy. Furthermore, insulin pumps can fail unexpectedly and there has to be a *Plan B* that involves preparations to continue insulin therapy with other means on a moment's notice.
4. *Professional Dedication* – In addition to the training sessions, trainers perform diabetes education, teach carbohydrate counting, ensure that the user has a support system, and perform post-training technical support. These activities are usually beyond the scope of the training sessions. Trainers will interface with suppliers and other members of the user's health care team on behalf of the user. The trainer assumes responsibility for the learning outcome where other members of the user's healthcare team fail. The pivotal moment occurs when a user reports back to the trainer that they feel so much better since they have

started using the insulin pump. The user's positive feedback fills the trainer with pride and joy.

5. *The Voice* – Successfully initiating a patient on an insulin pump for the first time is where the therapy becomes alive. The participants' feedback can make valuable contributions to stakeholders to ensure continued success of this type of therapy.

**Super-Ordinate Themes**

The super-ordinate themes were developed from the analysis of the data, and were the result of systematic data coding, data analysis, and creative thinking to capture significant attributes of the participant experiences. The super-ordinate themes were generated from a "descriptive core of comments [by participants] which have a clear phenomenological focus" while staying "close to the participants' explicit meaning" (Smith et al., 2012, p. 85).

When presenting the quotes of the participants, the designation *user* [of the insulin pump device] is interchangeable with the designation *patient*—the individual receiving insulin pump therapy. The participants are identified only by two-digit random numbers to protect their identity. Text within the participants' quotes indicating a dialog between the trainer and the user are italicized. Occasionally, a segment of a participant statement is underlined for emphasis.

*Emotion-Charged Environment*

The interaction between trainer and user during the training sessions is characterized by the specialized health care context in which this training takes place: An individual diagnosed with diabetes is learning how to operate a device that helps them stay alive.

The situation is marked with emotional responses from users that are a clear reflection of the fact that they suffer from illness. Display of emotions by patients is typical in a health care environment (Fotaki, 2015). In this context, the patients' sentiments reflect the fact that diabetes is a progressive disease with potential long-term complications (Ismail-Beigi, 2012). Diabetes ranks in fifth place for cause-specific mortality among people (Fritzen, Heinemann, & Schnell, 2018). The candid statement by #28 offers a glimpse into the world of an individual having to deal with diabetes, when she did not hesitate to call the chronic condition of diabetes by a colorful name:

> "I understand where they are coming from with their frustration, maybe sometimes there is denial, because they are just angry, because they have been diagnosed with this <u>horrible disease</u>…imagine having to check your blood sugar all the time…"

The Oxford English Dictionary (Oxford University Press, 2019) defines *emotion-charged* as an "event, situation, etc., filled with strong feelings and tension." Trainers report a wide range of negative sentiments observed in users: Fear, frustration, anger, shame, embarrassment, panic, apprehension, nervousness, confusion, impatience, denial, and indifference. When presenting findings regarding the emotion-charged environment in which training sessions take place, it is of great interest to elucidate how trainers deal with the negative sentiments observed in users. A selection of remarkable quotes from each participant is presented in Table 13:

Table 13
*Participant Quotes for Theme Emotion-Charged Environment*

| Quote | Participant |
| --- | --- |
| *Can I hide it in my bra?* | #12 |
| *I do not want you to panic!* | #28 |
| …that scary piece of equipment… | #40 |
| *How much more button pushing is it?* | #47 |
| *Take a deep breath!* | #50 |
| …so they do not freak out in those times! | #73 |

#12 reported that she witnessed fear, shame, and nervousness in users:

> "It is like a nervous energy that they are excited and also nervous and scared at the same time… I think it is more the fear of the unknown…in so far as their fears and barriers, they are afraid they are not going to be able to understand the technology and use their insulin properly… Women are like: *Where I am going to put it, how can I hide it*? Men are concerned about: *Am I going to be able to wear down my belt and I am going to be able to hide it*? Or: *I do not know where to put it, I sleep naked*."

Some individuals are hesitant about adapting insulin pump therapy, because it "identifies them to others as having an illness" (Millstein et al., 2015, p. 837).

When users perceive a system as complex, they fear that their memory capacity may not suffice to learn the required activities (Norman, 1983). Complexity in a system exists when the system is "perceived as relatively difficult to understand and use" (Venkatesh et al., 2003, p. 430). Fear of not being able to grasp the technology is evident in negative sentiments observed in the users. Participants know that this fear impacts the users' learning curve, defined as the effort they need to expend to learn the system: When users perceive a system as being difficult to use, it inflates their learning curve (Davis, 1989). #28 suggested that the trainers should adapt to a user's learning style, because using an insulin pump is "not something that you learn overnight." According to her observations, it "can be very, very confusing to patients because they want to get something that is simple:"

> "You just have to make sure that, whoever is doing the training, has to be very flexible to train that particular individual according to what they feel comfortable with, and either simplify it or make it a little bit more techy, it just depends on… you know, the trainer is the key. I truly think it is an important component to a positive training because if they leave there, feeling: *Okay, I can do this. I feel comfortable!* …then they are going to succeed."

#28 asserted that advance preparation by users reduces the learning curve and, therefore, reduces training time:

> "If the patient is prepared, and actually, there are some trainings that have lasted about 45 minutes, if not less. − When I am training a patient for the first time, a lot has to do with their learning curve. I have to first assess: Are they going to be technical, are they techies, or do I have to simplify things. I always begin training where I tell the patient: *I do not want to you to get your doctorate in the pump, I want you to get an associate's degree…*because it just basic training."

> "I make sure that the patient is first and foremost prepared. I give them time to review the material and, if I meet with them ahead of time—where I have met with them at a doctor's office and they have brought the material—I will generally flag the important things."

Found in the description of the methods used by participants to put users at ease during the training sessions, compassion is a striking pattern that characterizes the interaction between trainer and user in this emotion-charged environment. Compassion is the underpinning of ethics of care for health care professionals, it is on the top of the list of the American Medical Association's ethical requirements for health care practitioners, and it is the basis for high quality care (Dougherty & Purtilo, 1995; Fotaki, 2015). Reassurance is also a pattern that connects several super-ordinate themes and characterizes a strategy used by trainers to deal with users' fears. Reassurance is a "purposeful attempt to restore confidence" (Teasdale, 1989, p. 447) through "indicating that there is no cause for anxiety" (p. 444), and it can be achieved by making a "deliberate intervention" (p. 445).

#12 uses phrases such as *Let us get you on the pump!* to signal to the user that this will be an effort of teamwork; reassuring the patient that they are not alone in this undertaking. #12 reported that she emphasizes the benefits of the pump during the learning process, and demonstrates to users how much easier it will be to determine insulin dosing, once they are on the pump:

> "*The doctor wants you to have your blood glucose target range, let us just say between 100 and 120.* − I told them the pump uses that as a guideline to calculate out the amount of correction insulin that you need when you give the pump of blood glucose. So when you check the glucose levels [and put that into the pump], the pump will automatically calculate out what your dose of insulin will be, and so you do not have to do anymore math and−believe me−when the people hear they do not have to do more math, <u>they love it</u>."

> "You tell them that all you do is what you are required to do: *You are required to enter your blood glucose, and estimate your carbohydrate grams as best as you can, and then enter that into the pump, and the pump does the math*."

#28 cited encouragement as vital to counterbalance users' fears:

> "You got to make them feel comfortable, you want them to succeed, and if you do not give them that encouragement, so that they can be confident−exactly, because they are already scared enough as it is."

Furthermore, #28 impresses upon users that wearing an insulin pump is "doable" and shares with them that she has worn one in the past:

> "I will begin the session by telling the patients: *I do not have diabetes—knock on wood—yet because you never know what you are going to be dealt with*. However, I tell them that I have worn the pump and I have counted my carbs, I have checked my blood sugar and I have done <u>everything</u> that I am asking them to do, so that they can understand that it is something that is doable, even for somebody who does not have it [diabetes]."

All trainers reported that they apply some type of behavior modification strategy to channel the user's emotions toward the desired learning outcome. The pattern identified as *Behavior Modification* ties in with the super-ordinate theme of *Personalized Training* described below. Based on the fundamental characteristics of behaviorism first published by B.F. Skinner, behavior modification is the activity that embodies the control of others to achieve a predictable result (Delprato & Midgley, 1992). Trainers are experienced in determining the best method of control for a particular situation, and apply a strategy that will benefit a particular user.

#28 rejected the notion of "talking down to patients" and reported that she always makes an attempt to slow down impatient users who are "very anxious to get started." She uses verbiage such as that it is "in their best interest" to follow her advice, step by step. This approach by #28 is considered "flexible interaction" and represents a style of interaction where the patient participates in the "goals and actions to be taken" (Franklin, Lewis, Willis, Rogers, Venville, & Smith, 2018, p. 563). A strategy of collaboration between trainer and user helps the user to master self-management of the pump, because the user and the trainer work together to define and "negotiate goals," rather than "being told what their goals should be" (Franklin et al., 2018, p. 568).

The behavior modification strategy applied by #28 is an example where operant conditioning can achieve a desired behavior. She uses "consequential causality" to incite a response from the patient that forces them to accept change (Delprato & Midgley, 1992, p. 1511). To provide a stimulus, she reminds patients what life was like before switching to insulin pump therapy:

> "*When you are on MDI* (multiple daily injections), *you are set at a specific time and date for the shots. You have no flexibility; you have no quality of life. This is when you got to do it*… Some people will go into the bathroom; some people will do without it because they are embarrassed. *With the pump, you have the flexibility that, if you check your blood sugar and it is elevate… Guess what? You can treat that number. Exactly, if you are at work*…so they have lots of flexibility."

Occasionally, a trainer's attempt for successful behavior modification leads to nowhere, and the trainer will be proactive about rejecting a user as a good insulin pump candidate. #40 expressed that users, who refuse to comply with certain requirements to receive insulin pump therapy, show little or no promise to benefit from insulin pump therapy. Her choice of language to express users' disregard for compliance emphasizes the futility of prescribing insulin pump therapy to the individual in question:

> "There are certain behaviors that are required of the patient utilizing an insulin pump and, if they are not willing to perform those behaviors, then <u>there really is no sense in wasting our time</u>. If someone sits with me…*I never test my blood sugar*!... how they got their pump in the first place, I do not know and: *I do not plan on testing my blood sugar!* …then I will have a conversation with their physician and say: *That probably is inappropriate!* …and we will act accordingly."

Insulin pump trainers use empowerment as a trigger to promote reassurance and as a strategy to dampen negative sentiments. #12 reported that she tells patients that they "command and control the pump." She also reported that she is "very hands-on" during the training and lets the patients program the pump to learn how to change the settings. #40 believes that users will feel empowered and that their fears will subside once they hold their pump for the first time:

> "It is not just that scary piece of equipment, but [when] they have it in their hand: *Oh, that isn't so bad*! − like I hear it lot -- *Oh my gosh, I thought it was so much worse than it is!* …and that is always a good thing when the lights come on and they say: *Oh yeah, I can do both*! …because there is a lot of fear in the beginning."

#50 uses a similar strategy. She believes in hands-on training right from the start: "I do not hold the insulin pump. I give them the insulin pump and I instruct them and usually I am sitting right beside them." #50 added that it also helps to make sure that she is in a "private room with a closed door" to try to "block out all possible noise." This allows the user to better concentrate on the learning material during the training session.

#47 emphasized that—after conducting training session covering many vital details—it helps to simplify things to the patient: "I focus on *All you have to do on a Daily Basis*: You are just putting your blood sugars in and you are just putting your carbs in!" Her statements during her interview are reflective of her use of language when she interacts with users during the training sessions. When talking to users, she gives them the impression that insulin pump management will eventually become a simple task: "*This is all you are doing; you are just putting…; it [the pump] will do whatever you tell it to do!"*

#50 also stated that "you have to relate the fact that the pump is that is something simple" and she applies a similar strategy: "I try to simplify everything that I teach. We are going by the educational level of the patient." She is very cognizant of the varying needs of her users during the process of acquiring pump management skills. She described her amazing repertoire of teaching props:

> "There is a difference in teaching adults and teaching children. Those are based usually on the parents, but you always want to include your children … I like to use animals with children, to have them play with that; they play therapy with the insulin pump. So, I have a pink pony: *We are going to give pink pony a shot; you want me to give the pink pony a shot?"*
>
> "I always have different things for children. For children, I have stuffed toys; for adults, I have like a pad that is soft and pliable. In nursing school, I was taught with an orange. So if I need to, I could bring out an orange, but we don't use oranges any more. I always try to use something spongy, so it's just like the skin."

The use of figurative language to drive a point home is another skill set used by #50 extensively when she talks to the user:

> *"Do you know what the word occlusion means*?" And my example for occlusions is a straw: Let's think about a straw. If a straw was open and you are going to put in the drink, right? Well, if the straw is a little bit bent, then what happens is you can still get some out of the straw, but you are not getting as much. So, that is kind of like your insulin."

The statements made by #50 during her interview are filled with metaphors that reflect her sentiments during the interaction with users. To signal to users that there are certain skills they need to achieve during the training sessions, she tells them that she is "not going home with them." When she engages in behavior modification by teaching safety, she tells users to "stay away" from certain behavior or situations, because "this [the insulin pump] is not a toy." To induce users to be proactive about alerting other health care professionals about potential problems when she is not available, she tells them that the technical support line is their "lifeline."

An important pattern that characterizes the training environment is reflected in the unrealistic expectations users have about insulin pump therapy. Unrealistic expectations by those afflicted with an illness often include misconceptions about the effectiveness of treatment and lack of knowledge about the risks and benefits (Woolf, 2012). Participants reported that users are not being adequately informed about insulin pump therapy. To address these unrealistic expectations, insulin pump trainers are cognizant that they need to avoid the practice of *sugar-coating* and, instead, provide users with a "direct and straightforward" overview (Quirk et al., 2008, p. 362).

Honesty in a health care environment is interpreted by patients as "caring behavior" (Quirk et al., 2008, p. 359). Caring behavior contributes to a patient's belief that the health care professional will "act in the patient's best interest" (Becker & Roblin, 2008, p. 795). This behavior fosters trust-building between the trainer and the user. Health care providers must exhibit behaviors—such as honesty—that build trust to be effective in patient care (Becker & Roblin). Trust-building also helps the users to trust their own abilities. #12 reported that she coaches users to trust the pump's functions by telling them to "let the pump guide" them. She also reported how she deals with users who are frustrated when "they are not getting the type of control" they envisioned:

> "That would typically be the biggest problem that I have is: They are not getting the type of control they had before, and they are a little frustrated. So, trying to get them a little more time, I say: *Give it another day or two*…and I can make minor adjustments to their settings so I often will do that, just to kinda give them something and I say: *Well, let us just turn up your basal rate a little bit, let me show you how to do that…*we walk through it and then, they at least know that I am with them trying to actively help them get better control."

#73 believes that "things [can] go wrong because of human error." She commented that problems are linked to [wrong] expectations:

> "You just put the pump on and that is going to address all your issues and manage your diabetes for you and that is not a simple easy thing. In fact, I think it becomes more involved and requires a lot more attention and monitoring because when you really definitely have to explain it, checking blood sugars more frequently is going to be huge."

A "hesitation to use technology" was observed by #47 in some users and she has a solution for them:

> "One problem, sometimes more in older people, is the hesitation to use technology and being afraid to touch buttons and press screens versus, when you get a younger person, they are just zipping through those screens and they are so used to button pressing, so I really have to point out with the older people: *If you are in a screen and you are not sure what to do, just that there is an ESCAPE button, just escape back out to the home screen rather than keeping on pushing buttons*."

#40 reported that some of her users are "very concerned about the time factor" involved with insulin pump therapy. She stated that it is important to be up front and honest with users about time and effort required for pump therapy:

> "…and suddenly: *Now here is this device on my belt, I have to test my blood sugar, I have to count my carbohydrates* … So until they become very comfortable with that, then that can be an issue that: *It takes me more time to manage my diabetes than it ever has before!"*

> "I am very clear to point that out that it feels like: *It is going to take a little bit more effort in the beginning, but once you get there, it is going to be very beneficial, because you can manage it, you can move your A1C* (average blood glucose target)*, you can have success with diabetes management, not always feel like a failure, with just a little bit of effort.*"

#73 made similar statements about the need for users to put forth an effort:

> "Managing your blood sugar in any form, no matter what device you use, insulin [therapy] requires some effort and, clearly, the knowledge of being able to make corrections, being able to extend your insulin delivery…"

> "I have seen situations where we have got patients who are on an insulin pump and not maximizing the benefits of it. They are <u>not</u> making adjustments for exercise or know how to suspend it when … after they are having a low or extending the boluses over time, there are just so many features and benefits..."

In the emotion-charged environment during the training sessions, trainers deal with negative sentiments of their own. A prevailing fear is that users forget steps, make incorrect adjustments, or override the pump settings. Such mistakes can cause life-threatening episodes of hyperglycemia or hypoglycemia, by "jumping too fast," as #12 aptly puts it:

> "What I typically hear on the 24-hour follow-up, problems that I run into is [when patients report]: *I forgot to hit DELIVER BOLUS!...* and usually it is that they are jumping so fast, they think they are done and they are not done."

If a user fails to administer a bolus, there may not be enough insulin in the blood stream to keep blood glucose levels in a prescribed range. #12 reported:

> "That's usually the biggest concern I have is that [when patients report]: *My blood sugars were really high today;* and what I say is: *Well, the settings that we are giving you, we have calculated out but it is going to take a little time to get the accurate settings, so that your numbers are going to start coming down*."

#47 expressed concern that users override the pump settings and administer too much insulin, because they fail to understand that pump therapy works different from injection therapy. She stated that it is important for her to spend some time explaining "how the pump works and what is different about a pump versus injections":

> "It is different from injections and I usually have to really go through how, what they have done in the past as far as doses and, especially, if they were wanting to kind of manipulate doses of how they need to trust what the pump has given them and go with that and <u>not override</u> things, because sometimes patients override the pump estimate."

#50 elaborated on the same subject:

> "You do not need to override the insulin pump. You can override it and you can decide: *I am going to go ahead and take 2 units of insulin1…*but when you do that, what you are setting yourself up for, you are setting yourself up for a low [hypoglycemia]!"

The phenomena observed around the theme *Emotion-charged Environment* reflect the fact that users switching to insulin pump therapy suffer from a life-threatening disease and that the trainers are making every effort to put them at ease and build an environment conducive to learning. This theme shows connections to the four other themes on various levels (see can make valuable contributions to stakeholders to ensure continued success of this type of therapy.).

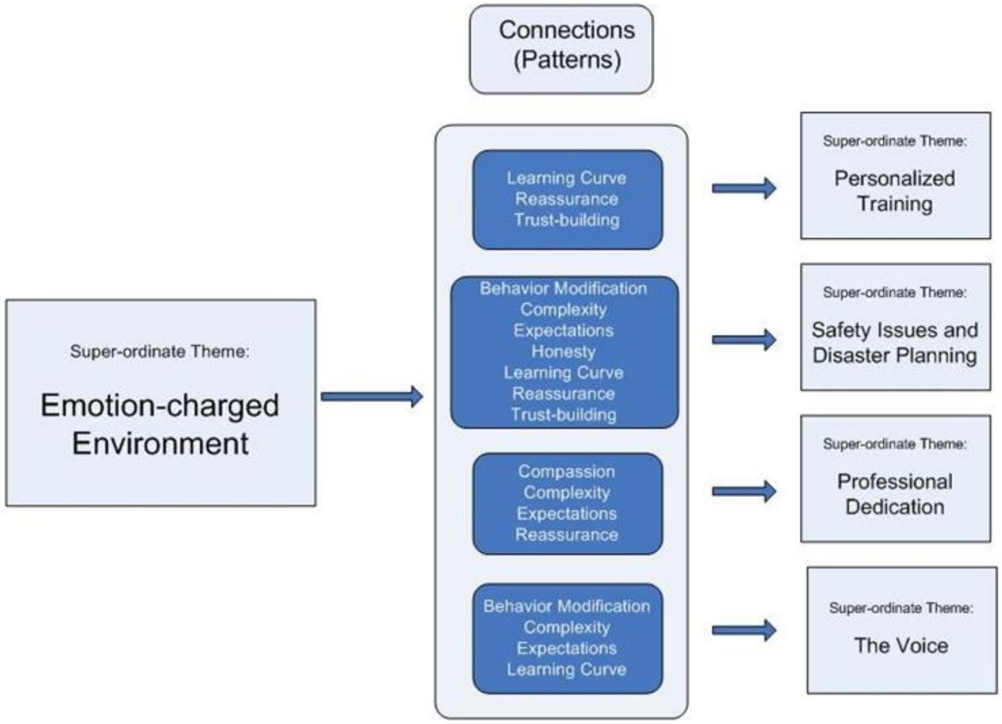



*Figure 3.* Theme *Emotion-charged Environment* and its connections to other themes

During the training sessions, trainers modify style and pace of the sessions by doing an assessment of their knowledge level. They observe non-verbal cues from the user and counterbalance fears and apprehension with compassion and reassurance to help deflate the learning curve. Multiple patterns connect *Emotion-charged Environment* to the theme *Safety Issues and Disaster Planning* and indicate a strong relationship. When dealing with the critical issues of teaching users safe handling of the insulin pump and preparing an alternate plan during pump malfunctions, participants report a variety of behavior modification strategies to reinforce target behavior in the users. The participants' commitment is expressed in the connection to the theme *Professional Dedication*, when participants made statements that exemplify the satisfaction they gain from their job. The connection of this theme to the theme *The Voice* is reflected in the feedback from participants about contributions to make these training sessions less stressful for users.

Once the trainers are able to exercise control over the users' emotions and succeed in making a user "feel comfortable," as #73 and other participants frequently expressed, they proceed with the task of training the users.

*Personalized Training*

Training of an insulin pump user has to be performed according the guidelines by pump manufacturers. Participants reported that they are provided with universal checklists that outline the topics to be covered during the sessions. When submitting their report to the insulin pump company at the end of the training sessions, they have to certify that the patient has successfully completed the training. According to #73, the checklist serves to "make sure that I cover all the points."

The Oxford English Dictionary defines *personalized* as "designed…to meet someone's individual requirements" and as *training* as "the action of teaching a person…a particular skill or type of behavior" (Oxford University Press, 2019). It was discovered that—while the manufacturer's checklist is the guiding frame about what needs to be covered during the training—it is entirely up to the trainers to find ways to ensure that the tasks are successfully completed. The following findings represent quotes from the participants' interviews, when the participants described their repertoire of skills used to accomplish the learning goals for a positive learning outcome. A selection of remarkable quotes by the participants is presented in Table 14.

Table 14
*Participant Quotes for Theme Personalized Training*

| Quote | Participant |
|---|---|
| Just get a feel for where they are coming into this session. | #12 |
| If they have questions, I always stop. | #28 |
| That is where the magic happens—give them enough insulin and they do well! | #40 |
| …then you get to other people that do not know anything about diabetes. | #47 |
| I see that lightbulb come on! | #50 |
| It's just like setting your alarm clock! | #73 |

Pump manufacturers have certain guidelines for the time spent during insulin pump training sessions. It is the basis for reimbursement to their contracted trainers. When asked about the time commitment to perform the training, #40 reported:

> "The training schedule very much depends on the patient. I spend about 90 minutes with a patient who has been on a pump before and then I just call to check in. If the patient is new to pump therapy, I will spend up to two hours the first time and provide additional visits as needed… I was recently training an older patient and I met with her three times with a fourth visit scheduled, so it really is situational."

#28 reported that she allows 2 hours, but is willing to be flexible and extend it to 2 ½ hours "just to make sure" that the user "feels comfortable" to go home with the device.

Another factor that shapes the insulin pump management learning curve is the question if users followed instructions for advance preparation by reading the study materials before showing up to the training. Participants correlated user preparation efforts to the learning outcome. *Learning Outcome* is a critical pattern describing that the desirable outcome for the training session should be for the user to master the insulin pump and achieve "efficiency of use" (Nielsen, 1993, p. 30). #12 provided the following information in this regard:

> "Just to get a feel for where they are coming into this session, I also asked them if they have done any of the recommended homework that the pump

> manufacturer has submitted to them for pre-pump education in regards to the videos that are available and the brochures and the manuals that have been given."

> "From my experience, I would probably guestimate that [only] about 30% of patients actually have read or watched videos, the other 70%−honestly−really have not or maybe not had the time or they just wanted to do it all during the training session. So in regards to that, it is a little disappointing, as I would hope that more patients would actually engage in the pre-pump education prior to the session but, nonetheless, I move forward."

#40 believes that the better prepared a user is, "the more success they will have sooner."

She makes every attempt to ensure that users prepare for the training session:

> "Prior to them coming to meet with me, I will send them an e-mail which tells them exactly what they have to do in order to be prepared for class so that I set them up for the most success. If they come to me with the tape still on the box and they've never opened a thing, then they are not going to be very successful until they get to the hands-on piece, so that they can get an increased comfort level and they can feel like they are invested in this."

A similar statement was made by #73: "When I see someone who has already taken the pump out of the box, I think that is going to be someone who is a little bit easier to train…they may have actually read the instructions ahead of time!"

When a user ignores instructions by trainers to study the learning material before the come to the session, #28 believes that it has a negative impact on the learning process and that users will have a hard time to grasp the subject matter:

> "If they really did the research, if they reviewed the books, if they went on and watched the videos like they are instructed to do, before you contact them and they are really prepared and they really into it; yes!− If they kind of procrastinate which some people do, they figure they will learn it on the fly, as they would say, so they will learn it right there and then, they see that it is not that easy."

#40 expressed similar views regarding the consequences of not preparing for the training session and pondered about reasons why patients do not come prepared:

> "They get books upon books, right? Minimum of three books for everybody... There are online videos, hundreds of online videos. They [the videos] go

> through all of the tasks that a patient needs to acquire to use that pump safely, but it is whether or not that patient is willing to access that resource material in order to acquire that skill, that is the question."

She begins her training sessions by interviewing users so she can assess their knowledge; she seizes the opportunity to dampen their fears, providing reassurance about the user's ability to grasp the task:

> "So, at first, we'll kind of interview them to find out their knowledge level: Have they discussed this with a doctor before? Have they a relative or a friend that uses an insulin pump? Do they have any preconceived notions? − I had a new patient who thought that we were going to go to surgery to get that pump installed. And, so having that kind of information ahead of time is always helpful, because they are able to relay their fears when they know."

#50 described the organization of her training sessions in a similar way. She first assesses the user's knowledge level; then she provides the user with an overview of everything that needs to be covered; finally, she focuses on the specifics of the therapy as prescribed by the physician. This is an opportunity to establish trust between the trainer and the user, because the trainer takes the time to get familiar with the user's knowledge level and she describes to the user what is expected of them. The pace of training is decided by #50 on the fly, as she looks for non-verbal cues from the user:

> "I think it is very vital that I observe our patients and their reactions, so I can tell whether or not they understand what I am saying, or whether they are confused. I think that, as an educator, it is important for me that <u>I see that light bulb come on</u> in my patients' face, when they understand what I am saying to them. − When they are looking <u>like a deer in the headlights,</u> I can tell right quick they do not understand it."

#73 also adjusts her pace based on the "patient's ability to really grasp this" and rationalized that users should be "very comfortable" with discussions about insulin to carb ratios, because "this is not new to insulin, just new to insulin pumps." To keep the pace going, #50 looks for additional cues, such as lack of attention:

> "If I find that they are kind of drifting, then I say: *Would you like to get up to take a break, maybe go to the bathroom, get something to drink*? …So that we can bring them back to what it is. I also found that having them do hands-on…I try to keep their attention by having them do things…I find that it keeps them more engaged. Otherwise, if I'm doing it, they are going to get bored. They are also not going to learn."

Distraction is another issue that insulin pump trainers try to avoid. #73 usually goes to users' homes to train them and finds it helpful when there is another person with the user. She welcomes the fact that users are able to "rely on someone else to help them through," as long as that "someone" does not represent a distraction.

#47 described a detailed list of steps that she performs while familiarizing the patient with the pump which includes: Going through carb counting, providing an "overview how a pump works," teaching terminology "what is called bolus," explaining the infusion set, reservoir and battery, and going through "what else is in the [shipping] box." She then brings out the workbooks and explains the buttons, screen icons and overall functionality of the pump interface. #47 prefers to be the one doing the initial setup on the pump as far as basal rate, time and date, etc. Finally, she goes into the actual management of diabetes through the insulin pump. #47 believes in having the users practice repeatedly on the task of everyday pump programming:

> "I will have them practice. I generally have them put in just kind of like a blood sugar of may be 150 and put 45 carbs or something in, and have them actually give a bolus and then, depending on their level, I may have them do that several times."

> "I find, like the older patients need to practice like lots of times and then I have find it in the books, there are pictures of each screen and so we have to point out: *These are your screens, you just follow this part; you will have to really practice and practice…*"

Knowing the "terminology of an insulin pump" is important, and #50 ensures that users know what words like *active insulin* mean:

> "When the doctor asks them: *Did you make a change to your basal rate? − What is that?* − They don't even know where do it, they don't even know where in the insulin pump to do what the doctor asks you to do: *If you do not know how to do it and you are totally blank, you write down everything or you have the nurse write down the changes that need to be made and you can pick up the telephone and you call the customer support department so they can walk you through*."

Participants provided information about user interface problems they frequently observe when users initially manage the pump. User interface problems (pattern: *UI Problems*) are defined as problems experienced by users when interacting with the interface of a device (Sauro & Lewis, 2012). Issues frequently reported by participants reflect confusion by users over the hierarchical menu structure in pump interface software. User interface designers often struggle with optimization of hierarchical menu design when it comes to "maximizing user's selection performance" (Bailly & Oulasvirta, 2014, p. 42). When users are "distracted from achieving their primary goals" on hierarchical menus, task execution is affected because they can only view a small portion of the information needed (Campos et al., 2014, p. 284).

Examples for user interface problems observed by #47 include resetting the time after a battery change, but not setting it correctly for AM and PM. Furthermore, #50 mentioned that the insulin pump software interface may be using a different jargon from what the patient is used to, and that it is important to teach the terminology appropriate for the context of this health care setting. #12 reported that Company A is actively engaged in usability research and provided this useful insight:

> "Because of their studies, they put the backwards arrow button instead, because they learned from these users that were touching and interacting with the pump that it was confusing people."

Other examples involve the sequencing of tasks. According to Johnson (2014), the order in which a user performs tasks "often matters" (p. 213). Campos et al. (2016)

cautioned that task execution will not be successful, if there is an "incompatibility between the task and the state of the interactive application" (p. 144). #40 reported that the pump software among each of the Company A models currently on the market exhibit some differences in the sequence of task execution and also have "different bolusing areas." #47, who trains on all major insulin pump models currently on the market, reported differences in the sequence of entering a carb ratio in the pump model of Company A versus Company B, and she has be cognizant of this fact, when she is showing users to program their corrections factors and carb count.

#47 added that, therefore, certain things must be covered in training. Another concern mentioned by #47 involves being on top of blood glucose levels, because it is critical to avoid diabetic ketoacidosis (DKA), which can lead to sudden death (LeRoith et al., 2000):

> "In order to be on the pump, they either need to be wearing a sensor where you are seeing your trends in your blood sugars or: You need to be checking your blood sugar four to six times a day. You cannot be only checking your blood sugar once a day. Because if something were to fail, your infusion site gets kinked or comes out, you do not realize it!"

#73 wants users to make an effort to check blood glucose levels during the night as well "to see if they might have a possible low [hypoglycemia]" so it can be addressed. Her statements are similar to those by other participants who reported that they follow new users "for the next 24 to 48 hours quite closely to make sure that we set the basal rate appropriately" to avoid dangerous hypoglycemic events.

#50 reminds users to always have a blood glucose monitor with them. When she shows users how program their individual settings, the input values differ, depending on the time of day. It is expected that an individual who has a regular day job is asleep between midnight and 6 AM, and that needs to be factored in to determine the variable basal rates throughout a 24 hour period. This means that the night time blood glucose target determined by the prescribing physician differs from the rate appropriate when the user is awake and expected to consume food that contains carbohydrates. The medical term is called *personal profile*. If a user with a varying personal profile mistakenly reverses AM and PM on their pump, they will be receiving an inappropriate insulin regimen throughout a 24 hour period.

User problems that center on dexterity on the pump surface are reported by all trainers, as revealed by #50:

> "We were kind of having a little issue with just touching…So, I was like: *Let's try it again*...and he was feeling a bit frustrated, I said: *Okay, let us do this. I want you to just take a deep breath and let's try to relax and I want you just to try not to be frustrated because sometimes it is just that your fingers and my fingers are big, OK? So, therefore, let's try touching above the name!*" –

#12 believes in the superiority of the touch screen-type pump interface of the Company A model over the chevron-style selection key interface on other manufacturers' pump models. On a pump that has chevron-style navigation buttons, a user makes a selection by clicking down on a button with pressure. Repeated clicks of a button are required to navigate up and down nested menus in order to make a selection (see Figure 4). For numeric input, such as administering a bolus, the user has to press the *UP ARROW* navigation button enough times until the desired number appears on the screen. On a pump with a touchscreen interface (see Figure 5), users still have to navigate through nested menus accessible through the *MENU HOME* button by applying simple touchscreen finger pressure as they would on a smartphone, but they are able to use a built-in numeric key pad to input the desired value.

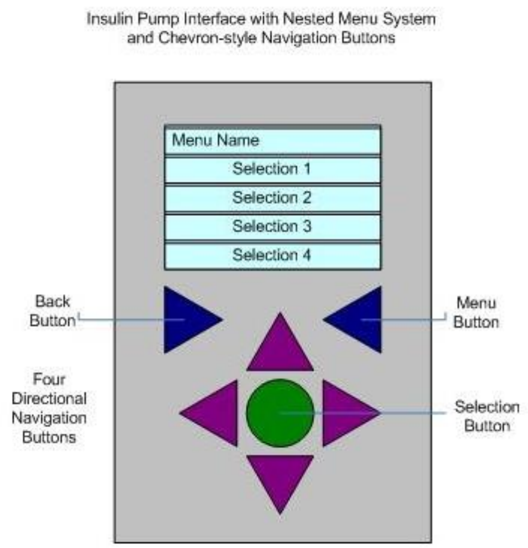



*Figure 4.* Insulin pump interface featuring chevron-style selection buttons

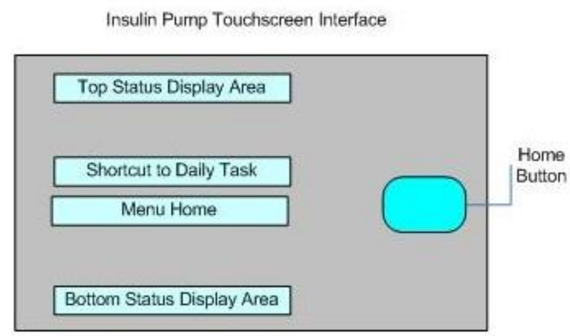



*Figure 5.* Touchscreen insulin pump interface

When conducting research on the optimization of insulin pump therapy, however, medical professionals have conducted independent studies and question the superiority of pumps with "increased handling efforts" (Waldenmaier et al., 2018, p. 401). As demonstrated in the recent study by Waldenmaier et al. (2018), having to perform more steps for some daily vital functions on a touchscreen pump, compared with a pump that has a chevron-style button interface, cannot be considered an advantage

It is noteworthy that #50, who has extensive experience trains on all pump models on the market, reported user problems on the touchscreen pump in users with little or no experience on smartphone touchscreen interfaces. She described how she coaches her users to overcome obstacles with dexterity, observed occasionally in "older patients":

> "What I am seeing is *hitting hard* and so I am like: *No* or *stop; touch gently, touch. Touch like maybe if you were going to touch your wife, you will gently touch her, you need to gently touch this. Or if you are going to gently rub your animal, then we are going to just gently touch this*."

Participants provided a lot of data about users' individual settings and personal profiles. Each individual who is on insulin pump therapy will have unique instructions from their health care provider that contains measurements of the insulin dosage that is appropriate for their disease profile. #28 confirmed that these instructions are "different and personal for each individual patient" and that "no particular patient is the same." The insulin to carbohydrate ratio which determines the amount of carbohydrate intake to be counter-acted by 1 unit of insulin can vary greatly among individuals. #12 reported that she cannot complete the training process without this information:

> "…when I have the orders from the physician regarding their insulin pump settings... so, then I can work [from] there, where I show them how the order was converted from their previous insulin regimen into their pump regimen and put the orders with that. This is also an opportunity for me to know whether or not they know how to carb count."

To verify the effectiveness of these prescribed measurements, #28 advises users to schedule a two-week follow up with their prescribing physician, and a health care professional is supposed to perform any adjustments during that visit. When nighttime blood glucose levels dip low, there is the danger that the user does not become aware of it while they are asleep. #28 who has extensive experience in performing insulin pump [dosage] adjustments reported:

> "These equations are wonderful, but reality is: The human body can be very complicated, so theoretically they should work, provided that the patient is doing what they are doing or maybe we might have to tweak them, and that is why they generally come to the providers every certain amount of time, because may be we might have to adjust their basal rate. Because, at nighttime, we notice that they get up in the middle of the night and they check their blood sugar, <u>they tend to be really low</u>, but then we have to … adjust the basal… and we have to give them less basal at nighttime while sleeping."

The basal rate—the rate at which insulin is delivered continuously in drip action— is programmed into the pump at start-up based on the prescribing physician's orders and depends on their insulin sensitivity. According to #73, most patients do not know what their insulin sensitivity is, and policies on making changes to these settings differ greatly. #28 reported that "9 out of 10 times," the prescribing physician wants the user to return to the office for the adjustments. This use of language is a way to express that there are very few exceptions to what she was about to reveal:

> "There were some doctors who want them to change the basal rate, change the carb ratio, change the sensitivity: *Good, you know, what you are doing!* --They will do it. But there are other doctors say: *No, this needs to be done in the office*, or some doctors will say: *You call me, and we will talk you through it*. Every doctor is different, but generally, on the whole, the first initial setting is done by the provider."

Participants reported that they are skilled at calculating settings and making the adjustments, but pump manufacturers policies vary. #50 reported that, for the companies she had for worked in the past, she used to do all the calculations. Company F, however, where she is under contract at the present, has a policy that greatly differs from the others:

> "All the other insulin pumps I have done—Company A, Company B and I have done Company C, and I have done Company D, so with all of the other companies that I have worked for in the past and with Company E, I have calculated all of these out. So, I take their total daily dose and I have formula that I work with and I determine what the settings will be. − It has been different working for Company F as a consultant. It is really made my job easier, but then I do not have to take that responsibility."

#40 uses a demo pump for users to practice before she allows them to perform input and change settings on their personal pump. She believes that it is important for users to "practice with that pump." For the interview, she went through the steps of the day-to-day operation of the insulin pump.

In addition to adapting their training styles to the needs of users, trainers need to be cognizant of the difference in features and input sequences on the various pump models.

#47 pointed out that the some of the steps involved in training differ among insulin pump models, regardless of manufacturer: "On the Company A pump, everything you are doing, it makes you *CONFIRM* and then you have to save it." #40 stated she needs stay focused during training on the specifications of the various Company A models a user is prescribed with, because the latest model no longer has a *MENU* button on the right.

An additional critical item that needs to be taken into consideration during the training of individuals is the user's lifestyle habits. #40 considers daily habits in regards to work schedule, off days, exercise routine and their meal schedule, when discussing pump settings with the users. The nature of user activities throughout a 24 hour period requires careful calculation of the basal rate setting and the user's individual insulin sensitivity. #28 shared the same concern:

> "Basal rate is what you are getting every hour on the hour or the drip action. So, what happens is, let us say in the morning, they are kind of sedentary, they really not doing much, they kind of just, you know, reading the paper or whatever, they are just getting too much of a basal rate, their blood sugar may start to drop."
>
> "Let us say in the afternoon, they are walking the dog, they are doing laundry, they are doing housework, they are all over the place, and their basal rate is set at a certain percentage where they are getting too much. So, you have to back off from the basal rate. You have to kind of see how they are active, after two weeks being on that, and then you can make the adjustments."

To achieve training goals, participants believe in immersing the user into the task, sometimes right from the start; other times, as they see practical. #28 had her own theory about how users learn best, and applies the following strategy:

> "9 out of 10 times, the patients are visual learners. So what I like to do is, I have the pump and I have the book in front of them, and I will refer back and forth with the book and the pump; and I usually like for them to handle the pump on their own. If I push the buttons for them, they are not going to feel comfortable, so I usually tell them: *I want you to hold on to it like back in the day when you would play videogames if you ever played any videogames*… and I explain to

> them about the face of the pump for example home screen the different buttons, what they do."

#28 considers apps "wonderful resources nowadays" and stated that she directs users to download apps to their smartphones or tablets to make day to day programming of the insulin pump simple:

> "All you have to do is ask them [the apps] how many carbohydrates to a *Wendy's* salad and it will give it to you, so that is another good resource. I mean, there are different resources that you can go that will help you with the carbohydrate counting."

The system of training used by #40 covers a comprehensive overview of all pump features. She quickly immerses the patient into the tasks that are required of them on a regular basis. She may, however, decide during the conclusion of the training session and before she sends the user home, to push the pump with saline, instead of insulin. The user would then continue their manual insulin therapy via syringe (MDI) until the trainer clears him/her for full therapy:

> "We go through all of the screens and all of the functions and every benefit that the pump has, very briefly and then we kind of drill in and practice those tasks that are required of them multiple times every day. And by that I mean: Using the bolus feature, bolus wizard, bolus calculator, or if they are going to just manually bolus…"

> *"Then, that is what we practice about, because I tell them: When you leave me, I have to have a comfort level knowing that you know how to bolus number one*, and number two: *You can change your infusion site if something happens and that it comes out beforehand*. …and so then, after we practiced, we put insulin in a reservoir or normal saline, depending on how well they did with all those previous tasks."

Mechanical problems observed by the trainers during the process of teaching the users how to use the insulin pump are beyond the scope of the investigation. Training on the mechanical operation of the pump, however, is an important component during preparation for insulin pump therapy, because mechanical failures are tied into the alert system of the insulin pump interface. In order to overcome fear of insulin pump therapy, users must overcome their fear of attaching a mechanical device to their body, using a catheter. It is an integral step of succeeding in learning outcome, as #12 describes:

> "You know if they have not seen a video or if they have not seen it done and sometimes when I have like severe apprehension I actually bring IPad with me and I will pull up the *YouTube* video of inserting their infusion set and we will just sit and watch someone do it, it is like see they did it, they are fine: *So now let's have* <u>*you*</u> *do it*!"

> "So I think it is such an important concept. It is 23 inches of tubing and this reservoir is locked into the pump and there is this weird looking infusion set with this long needle and you know they are uncomfortable with it. Who wouldn't be? Fear of the unknown… and then once they do it, you actually see their faces are just flush: *Oh, that was not so bad*."

Insulin pump software interfaces are designed to report mechanical failures back to the user so that they can be acted upon. The medical community, however, is skeptical about the effectiveness of occlusion alarms (Heinemann et al., 2015). Insulin pump trainers have experienced such issues and #12 shared her expertise in this regard:

> "I always review infusion sets or cannular kinking and the new pumps now, fortunately, I believe, they have a safety feature in them that is a menu prompt that says *INFUSION BLOCK*… but sometimes that is not entirely the case, but the person may have a cannula inserted in their abdomen or wherever that is kinked and they are not getting the actual boluses that are required, that they are commanding."

> "−So what I always do is−I was trained on a rule that if you give yourself a bolus and you recheck your blood sugar in two hours, and your blood sugar has increased by at least 30 to 40 points or more: *Give yourself an injection and remove the infusion set and insert a new infusion set that you may have a blocked cannula*."

The advice given by #50 in this regard is right to the point: "When in doubt, change it out!"

As discussed in the section for the super-ordinate theme *Emotion-charged Environment*, successful learning outcome is not always achieved during insulin pump training. Recommending against insulin pump therapy appears to be the exception to the rule. In such situations, it is based on a trainer's conviction that learning how to manage the insulin pump is not within reach of a user's capabilities. #12 reports an instance where she had to be proactive and notify the prescribing health care professional that the patient needs to go back on injections:

> "I only had one instance in all my years of teaching pump patients that I actually called the endocrinologist and said that this patient is not capable of operating the pump. Most people, they embrace it and I do not see any problems. I rarely have that much concern about someone's ability to stay on the pump and I think that with proper training and making sure you answer all the questions and being there as a resource for them."

Likewise, #40 will not hesitate to communicate to a prescribing physician that pump therapy is "not appropriate," when she considers the user's ability to master the training as highly improbable: "It is patient assessment at the time of training, as well, for their appropriateness to the therapy." If she can be sure, however, that there is a "pretty good support system," she will make every effort to provide a user with the opportunity to benefit from pump therapy:

> "…she lives with her daughter, who is a nurse and a pretty good support system, but she works 12-hour shifts four days a week, so she is not always there to help her. So I said: *Let us just have it on in your pocket with saline, so that it is no-harm no-foul if you mess it up. And then, when your daughter is there, she can help you and when she is not, then it is up to you to learn how to do those things on your own and you always have me, and you always have the helpline*."

The theme *Personalized Training* has multiple connections to *Safety Issues and Disaster Planning*, indicating a strong relationship (see Figure 6). A smooth learning curve and a positive learning outcome contribute to the user's ability to master insulin pump management. Reassurance by trainers builds trust for the user to learn how to troubleshoot and become familiar with the user interface to manage the pump.

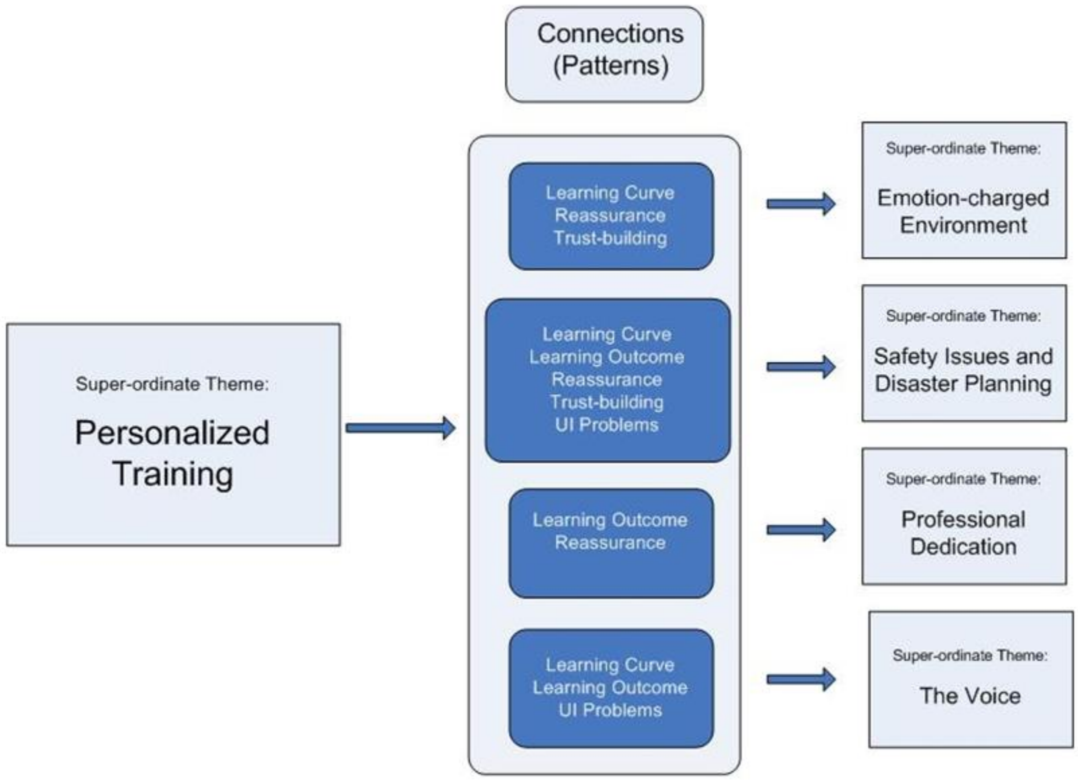



*Figure 6*. Theme *Personalized Training* and its connections to other themes

The connections to the theme *Professional Dedication* consist of the willingness by trainers rise to any challenge, if necessary, to ensure a positive learning outcome, although reimbursement for extra time and effort spent is not guaranteed by the insulin pump manufacturers. The connections to the theme *The Voice* are exemplified by statements from the participants that suggest improvements to reduce user interface problems.

From the above quotes of the participants, it is evident that trainers−while closely following the insulin pump training checklists−draw from their experience what would be the most efficient and appropriate approach for a given user to prepare them for self-management of the insulin pump. An important task during the personalized training is to coach users about safe handling and to prepare them for events, when the pump failure occurs. These issues are described in the next section of the findings.

*Safety Issues and Disaster Planning*

According to the literature review conducted in Chapter 2, insulin pumps are considered safety critical devices in healthcare, because user's action could compromise safety by causing damage or harm (Masci et al., 2013). The findings showed that discussing safety issues with users is a top priority among insulin pump trainers, and the participants provided a thick description how these are being addressed. They emphasized that instructing users on how to troubleshoot was a vital component of the learning curriculum.

Furthermore, pump failure is to be anticipated at any given time, and participants gave examples how users are instructed to plan for alternate insulin delivery methods—the so called *Plan B*. The Oxford English Dictionary defines *disaster* as "an event that has unfortunate consequences" and the verb *plan* as "decide on and make arrangements for in advance" (Oxford University Press, 2019). Table 15 below provides some remarkable quotes by participants on the subject of safety issues and disaster planning.

Table 15
*Participant Quotes for Theme Safety Issues and Disaster Planning*

| Quote | Participant |
|---|---|
| *Don't be in a hurry; you could miss very valuable information!* | #12 |
| …if too much [insulin] is given, it could kill them! | #28 |
| [Teaching safety is] number 1 on my list! | #40 |
| Take double what you need [when going out of town]! | #47 |
| When in doubt, change it out! | #50 |
| You never know if there will be a malfunction! | #73 |

It is important that trainers stress the danger of malfunctions of the pump. Participants explained that users need to be prepared to continue to manage their blood glucose without it. #73 reported: "Highs can also result in them going into DKA and we do not want that!" Her advice to users is as follows:

> "You already know the process of insulin and how important it is, like to have it, so, this is a device that provides the insulin and, if in any event that you think that your device is not working properly, you know you have a backup plan with a pen or syringe, for backup insulin, just to make sure that you do not miss your dose."

#47 makes this clear to the patients right from the start: "I always tell them, if they go out of town, to take double what they need, because you cannot just get them somewhere." #12 also expressed the importance of planning how to "get insulin when the pump cannot provide it to you", because the user cannot "have a situation where they are without insulin":

> "It is part of our training process and this is mandatory training for every patient on the insulin pump as well as anyone that I need to upgrade, we call it a Plan B. So always having a Plan B where, you know, you need to make sure that you are bringing an insulin syringe with you at all times so that you have an alternate means of providing yourself insulin."

> "I also always recommend that they bring an additional infusion set with them, so that if it dislodges or comes out, they have an opportunity to reinsert a new infusion set and be able to reconnect their pump to the new infusion set."

A prevailing concern among participants was the issue of overcorrecting (stacking) which puts users in danger of delivering too much insulin to the body, causing hypoglycemic events. Stacking is when a correction bolus is still active in the body, and the patient tries to override the pump and issue another correction bolus (insulin booster shot) prematurely. This is a frequently observed behavior by diabetes patients switching to insulin pump therapy and is counterbalanced by trainers with behavior modification strategy. #73 cited as her main goal to avoid "a situation where they are stacking insulin." #12 explains the instructions she gives to the users:

> "…the understanding of what insulin on-board or active insulin is. This is a really important piece of information that we put into the pump, because it helps people *not* overcorrect and nobody understands active insulin until I explain it to them which is basically saying that: When you give yourself a bolus, the pump documents that amount of insulin given at that time and then the pump has a timer of 3 to 4 hours—depending on how we set it up—where it will start lowering the amount of insulin from that bolus through the four hour period until it gets to zero."

To discourage the patients from acting out on their propensity to add a correction bolus prematurely, #12 provides this explanation:

> "And I always recommend, when you are initially on the pump, you always check your blood glucose two hours after you initially give yourself a bolus to make sure that you properly corrected, that your blood glucose level is getting into an appropriate range, because after two hours you may have to give yourself additional insulin through a correction, but the pump takes into account the amount of active insulin you still have left at that time and will minus it out from any correction that you would be giving yourself."

#47 uses scenario-based instruction to drive this point home:

> "Then I talk through what the active insulin is, where it is tracking all the insulin that they are using for a bolus and so if they are, you know, we kind of say: *If you are 300 and you give a bolus and then you come back an hour later and it is 200, the pump is not going to give you extra insulin because it knows you already get insulin*."

The pump software is designed to alert users of potential mechanical failures, but trainers coach the users to be vigilant for obscure problems and use common sense to address issues. Anticipating such problems adds to the learning curve of acquiring the skills to manage the pump, and #12 emphasized that users need to be proactive:

> "This is the number one concern and this is something I reinforce to people, because this is the only means for you to get insulin. You have to ensure that your infusion set and your cannula is properly functioning, and so I usually say at the first day of inserting an infusion set: *This is when you are going to find out*

> *if you have a malfunctioning cannula… just put a new one in*… so that would be my one concern is that for safety, is the cannula getting blocked?!"

When there are infusion site problems, insulin can leak and clog the infusion set, and if the patient is unaware, this malfunction can trigger diabetic ketoacidosis (DKA) in just a few hours (Millstein et al., 2015).

To teach insulin pump troubleshooting skills, #47 uses the following scenarios:

> "I just usually will have them practice doing a bolus with a high blood sugar over 250, because the pumps trigger this message where it says: *High Blood Sugar, Check for Occlusions* and all that, and I want them make sure they see that screen and they will know how to deal with that. And then, I will usually have them, I kind of talk through a scenario of: *If your blood sugar is low, you are not going to be entering your carbs that you eat for that, because those carbs are what brings your blood sugar back up*."

As an important task for insulin pump therapy to be successful, users need to keep tabs of their blood sugar levels and administer a bolus, if necessary. #47 emphasized that users need to apply common sense and she cautions users to "be on top of their blood sugar":

> "Do not ever keep putting a high blood sugar in over and over and over; thinking that the insulin in your blood is going up; so obviously, you are not getting any insulin and your blood sugar just keeps going up."

#50 elaborated on scenarios to prevent users from being careless:

> "You do not need to be leaving home and you are going be gone till tonight and you only have 20 units, you have to be prepared! Number one, you need a safety… you need a little kit, you need to always have extra infusion sets, you need to have insulin, and you need to have a way to infuse the insulin, and you need to have another cartridge, because you never know what is going to end up happening."

> "…and you can get stuck on the interstate, you go shopping and pull out your infusion set and then you do not have another one, and you cannot just say, *Okay, just forget it. I will go ahead and continue shopping*! Because if you do, you are setting your own self up for failure and you are taking your life in your hands because <u>this is not a toy</u>."

#28, however, believes that the user is generally the catalyst for problems that render the pump not operating correctly, when users have the wrong expectations about their role in managing the insulin pump:

> "You cannot go wrong with the pump. If it is used properly, it really does work. … The only way it can go wrong is−let us say−the person just relies on a constant basal rate, they check their blood sugar, but they do not put it in the pump…"

When asked to clarify if she is indicating that users' non-compliance is an issue, #28 replied:

> "That is a huge factor for their being any problems with the insulin pump, it is really most of the problems with the pump, it is actually a behavioral problem with the patient. It has nothing to do with it, it is really not the pump."

#28 further clarified the scope of her statement and indicated that she was referring to problems that patients experience with the navigation keys on the face of the pump and with the programming interface, e.g., perceived cognition problems or dexterity issues:

> "Sometimes if the patient is older, depending on dexterity, they may say, well, with the older pump, model X and model Y, they might say that the buttons are a little hard to press and I explained to him: *All the buttons, they do not want it to be that easy to press because God forbid, you brush up against it, and you hit something*."

#28 then elaborated on the solution she provides to users how to activate the backlight on the pump.

> "Sometimes, the older people have problems with a little bit of dexterity…The screen, I know with the older pumps, model X and model Y, they used to say the screen … is not big enough or it is a little bit dark and a lot of times the patients did not realize that there is a little backlight that you can press."

She added that it was very important that the patient is proactive about the life cycle of the insulin pump.  Any suspicion that the pump is damaged calls for an immediate replacement:

> “Now, you may come across a problem with the pump. Let us say…it has been dropped or there are any cracks in it, I mean, there could be an issue with insulin delivery, and that is one of the things that …it is very-very important with patients. If there is any type of cracks, any damage to the pump, I tell the patients:
>
> *You do not want to take any chance, you contact the manufacturer, you contact Company A. You let them know what is going on, do some diagnostic testing over the phone*! And then 9 out of 10 times…they will overnight them an insulin pump within 24 hours.”

It is essential that users understand the mechanics of the insulin pump and how it interfaces with the body, because the pump does not have a sensor that can detect if insulin is reaching the blood stream or not. This situation adds to the complexity for the self-management of an insulin pump, and trainers have to address such potential safety issues during the training. Doing a site change—rotating the injection site on their abdomen according to prescribed intervals—is a critical task. #40 described her ritual to impress the urgency of performing a scheduled site change upon users and ensure that the pump is properly connected to the body:

> “The most critical task is changing their insertion site, in my opinion. Our verbiage on that site change sequence says on every single screen: *Do not connect to body until you are ready!* -- So I make them put their hand on their heart, another hand in the air, and swear, that they will not connect this pump to themselves until that reservoir tubing change sequence tells them to insert the infusion set into their body and they look at me like I am a little paranoid!”

In addition, an inadequate insertion site prevents insulin from being delivered to the body, and the pump software may not issue an adequate alarm. #50 described the obstacles associated with selecting a proper insertion site:

> “*I do need you to move it every three days and stay away from these places right here. − You gotta stay away from these scars*! …And so if a woman had a baby and she has got all these stretch marks, you gotta stay away from those. If they have had surgery of some sort, they have to stay away from scars!”

Reassurance that a critical event can be handled is part of the task to teach users about safety issues. #47 instructs users to "always be prepared for highs" and also have an extra infusion set with them outside the home. When ordering food at a restaurant, it is important that users plan for delays and do not add a meal bolus dose [in preparation for carb intake] until the food is available: "Do not ever give a bolus and walk into a restaurant and start ordering food…it could be an hour to wait…"

No one would hesitate to agree that children are picky eaters, and #47 recommended that they should be given a bolus *after* they eat, because chances are that they will not finish the entire meal. When a bolus is given, but the planned amount of carbohydrates is not being consumed, there is the danger of receiving too much insulin which induces critically low blood glucose levels (hypoglycemia) in the patient.

Several participants expressed concern about the safety of users who acquire a pump, do their own setup, and forego the insulin pump training. Although #50 reiterated that the Company A pump is "the easiest program pump today on the market," she tries to reach out:

> "We have to really watch people who are younger, who are coming from one pump to another pump because they are likely to go on there and set it up themselves. Even if I have a patient who I am putting on a pump, they say: *Oh, I have already done all that.* - Well I feel like: *It may be because I need to make sure that what you put inside your pump is correct. I do not care may be it will take us to 30 minutes, but I still may have to review everything that you've done*."

Another valuable tip came from #50 regarding diagnostic testing: "If you are having an X-ray, if you are having an MRI, or any type of radiation, you cannot wear these devices during that or else you could damage the pump."

Intended as a safety feature, the *Automatic Suspend* feature on insulin pumps is referred to by #50 as a "very good feature, especially for people who live alone." The feature works as follows: If no button is touched on an insulin pump for 12 hours, insulin delivery will be automatically halted by the pump software, accompanied by an audible alarm. This setting is to prevent dangerous low hypoglycemia, and the screeching alarm sound is intended to get somebody's attention, if not the user's. This automatic suspend feature can be disabled.

The connections of this theme to *Emotion-charged Environment* and *Personalized Training* have already been covered in the previous sections. The connections to the theme *Professional Dedication* reflect the trainer's commitment that there is no room for failure during the instructional process with the users (see Figure 7). The trainers have to work through the complexity of insulin pump management interfaces with the users, and the training is further complicated by the fact that a user's metabolism is dynamic and that therapy needs can change over time.

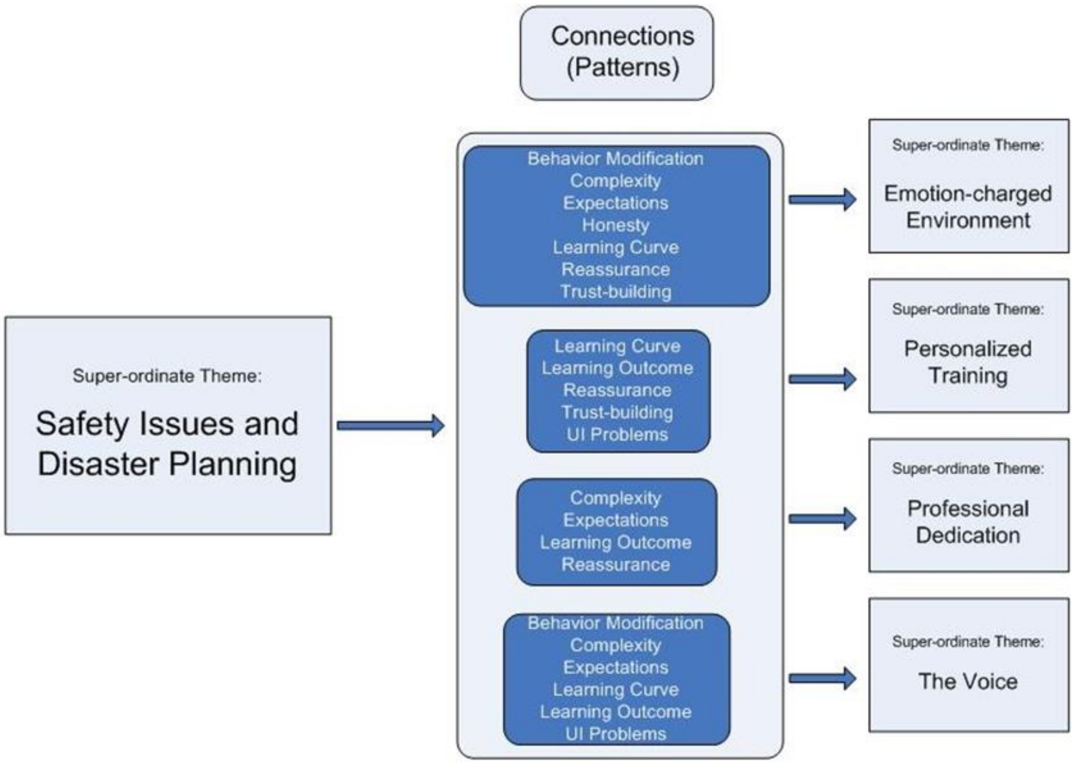



*Figure 7*. Theme *Safety Issues and Disaster Planning* and its connections to other themes

The aforementioned safety tips and precautionary advice by trainers how to coach users so that they can safely manage the insulin pump on their own are an important part of the training material. To assure safety in handling and to prepare for a potential pump outage is vital to the success of insulin pump therapy. Users need to be confident that they are capable of managing any situation. The participants' responses to the interview questions speak of their dedication to their assignment as trainers. As #28 aptly put it: "The trainer is the key" to successful insulin pump self-management by users.

*Professional Dedication*

The Oxford English Dictionary defines dedication as "the quality of being dedicated or committed to a task or purpose" and professional as "worthy or appropriate to a professional person" (Oxford University Press, 2019). On the basis of definition alone, this description may fall short of the level of depth required to explain the findings under this super-ordinate theme.

When adding attentive interpretation based on the participants' interview data to the findings for this theme, however, a much deeper level of what it means to a trainer to have professional dedication was discovered. Participants reported that they elect to take control of situations where the user is left without adequate pre-training or post-training support, although there is little opportunity to receive remuneration for the additional services provided. This finding became particularly "resonant" in meaning after engaging in a "deeper reading" of the participants' statements (Smith et al., 2012, p. 104). The participants' motivation to assume responsibility for the failures and neglect by other members of the health care and support teams is expressed in their statements, when they attest to the love for their profession. Table 16 below represents some remarkable statements made by participants that comprise this super-ordinate theme:

Table 16
*Participant Quotes for Theme Professional Dedication*

| Quote | Participant |
|---|---|
| I would never refuse patients' call or text. | #12 |
| I spent a whole week calling him [virtually] every hour on the hour. | #28 |
| I will work with whatever I am faced with, with very few exceptions. | #40 |
| I always have extra options for [infusion] sets with me. | #47 |
| Some trainers just put them on the pump, say: Good-bye!...and then collect their money, but that is not what it is really all about! | #50 |
| [Give every diabetes patient] that opportunity to have the benefits of using a pump! | #73 |

Pump manufacturers have guidelines how much time they allow their hired trainers to spend on training and how they reimburse their contracted trainers for the duration of training. Participants invariably reported that they will allow extra time if needed to achieve training goals. #50 acknowledged that learning how to use an insulin pump is a complex task and "can become overwhelming." She reported that she will not hesitate to stop the session and meet with the user again at a later time:

> "I do have patients who, like I said, some of my older patients do a lot of times require more time and a lot of times they require a return visit. If we have just spent three hours, then I think that the idea of learning has probably been stopped."

> "We may detach the patient like: *Why do not we just take a break for the day and then we can come back and we can meet again tomorrow morning, so you are fresh and let just try what you are doing tonight*. And I try not to overwhelm them about what we are going to be doing tonight!"

#47 is willing to go out of her way to accommodate the needs of the user and will make time to meet with them in person, if necessary:

> "So, on Day 3, when they are changing it out [the infusion set]: *Do you want me to do over the phone?* and are they able to do by them themselves or do I need to have them call me and we will do them over the phone step by step or do I actually need to meet them in person? It is like a safety factor with that because I think that probably one of the biggest problems is making sure they know how to change it out themselves."

#47 will do what it takes to help users succeed in the self-management of the insulin pump and would never leave a "patient on their own." Her compassion for her users is representative of all participants interviewed; most reported that they will take calls weeks, if not months later from a user in need. #47 always invites users to call her if "they are having trouble" with their settings.

> "There are a lot of primary care offices where the doctors are not even sure how pumps operate and so for those, that is where I am having to do a lot of phone calls and stuff with them or meet them back up at the doctor. − So kind of depending on the doctors, that is where I have to kind of meet back up with them in a week and we start some education on how to manage their pump settings safely."

In addition, #47 will make sure that users have appropriate supplies to start with. If the infusion set is not suitable for the user's physical characteristics, there is the danger of "site kinking" and that condition may induce dangerously high blood glucose levels:

> "If they are real thin and lean, especially with the pediatric population, and I am looking at: What do they send them for infusion sets? Is this an appropriate set or not? …and I always have extra options for sets with me and that we can see if they are going immediately get problems with kinking with a straight-in site, then I will just say: We really need to the start out with these angled sets and you need to call the company and get your stuff swapped out."

When the trainer considers the sessions completed, the feedback they receive from users received has a wide range of sentiments. Participants consider it their responsibility to ensure that the pump therapy meets the users' expectations. #28 had the following comment, expressing her sense of responsibility towards a successful outcome:

> "Some are very positive, some are not so positive, some are, you know, *It is ok, I'll eventually get it*. It is just different answers, different answers all around…I've gotten a lot where patients will tell me: *I love this pump. It is the best change I've ever done!* and then I've gotten people who tell me, you know, *I think I made a mistake* or *I'm not getting this*!" and <u>then it is my job</u> if I truly think that it is going to benefit them to say them [and I say]: *Let us give it another chance. Let's try it this way.* And try a different mode that maybe they are willing to look it in a different way."

Deriving satisfaction from doing their jobs is a pattern striking for this super-ordinate theme. According to Locke and Latham (1990), individuals who are goal-committed exhibit an "ability, adaptability, creativity and capacity to perform in the situational context they are in" (p. 241). Goal success leads to satisfaction. #73 derives great satisfaction from her observation that insulin pump therapy "works wonders in patients with type 2 [Diabetes]." Her frequent statements about users being able "to maximize the benefits of the pump" are a testimonial to this observation. #40 repeatedly expressed that helping patients to reap the benefits from insulin pump therapy is what gives meaning to her life:

> "That is where the magic happens—give them enough insulin and they do well, then they feel good. They want to exercise. Oh my God, it is awesome."
>
> "So, if I can impact a patient's life by helping them had success with this, I absolutely want to do that and I want to help them know that it is not this difficult. …and if you can drop that A1C [target blood glucose average reading] and you feel good, you have got energy and you want to exercise, you do not need to treat hypoglycemia so often and you are not gaining weight− I can go on and on and on with that− then folks are going to have success and <u>here is a technology in its finest hour</u> to help them have success."

When a positive learning outcome is successfully achieved, #47 is proud to be part of a user's adoption of insulin pump therapy. She referred to it as a "life-changing" event:

> "It is a very rewarding job to do. I think that it is life-changing to the patients, especially, when they are someone who has had diabetes for years and they have been against being on a pump and then they are started on a pump hesitantly, because they do not think it is going to work for them and they are not going to like it. And then they come back and tell you <u>how much better they feel</u> and how much easier it was and: *I should have done this years ago.* There are a lot of those kinds of people."

#50 believes that insulin pump therapy enables individuals with diabetes seize control of their condition:

> "The whole thing is that what we wanted to do is to… we want them [the pumps] to give you better control in your life. And my theory on that is that I want you to live a normal healthy life and live it safely."

When reflecting on #47's description of the tasks she is willing to perform—in addition to the instructional portion of the insulin pump training—it is evident that there is so much more to training than observed on the surface. All participants described a variety of additional tasks for which they voluntarily assume responsibility. The trainers will try to preselect a suitable pump for users if given the opportunity, they will make the training pace and style fit the user's needs, they assure that the user gets appropriate supplies and substitute at their own cost, they make up for lack of tech support for which other members of the user's health care team are responsible, and they take the initiative to protect patients from harm.  According to #40, "a salesperson will prefer to sell an insulin pump than not," but she will step in and alert the prescribing physician that he/she needs to reevaluate the appropriateness of insulin pump therapy.

The theme *Professional* Dedication is used to explain that user training is only part of the overall task of starting an individual with diabetes on the pump (see Figure 8). Trainers are willing to go the extra mile to accommodate the varying needs of their patients.  From the statements by participants it is evident that they have confidence in their abilities and that they are committed to their goals.  Participants also made frequent comments about how much they enjoy helping other people and how fulfilling it is.

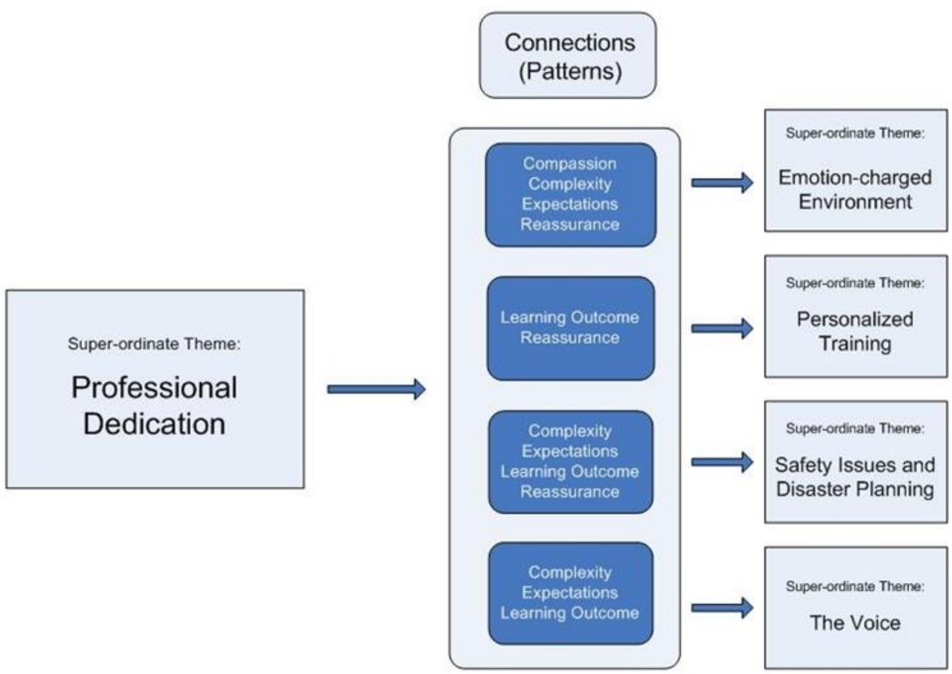



*Figure 8*.  Theme *Professional Dedication* and its connections to other themes

The professional dedication of these trainers is extraordinary, as evident in the rich description by the participants how they carry out their duties as insulin pump trainers. In addition, participants were motivated to provide input for potential improvements in insulin pump therapy to benefit the users, as discussed in the following section.

*The Voice*

The participants' voice presented within this super-ordinate theme contains suggestions about improvements and feedback about problems that deserve attention. From the interview data of the participants, it is evident that the critical task of switching a patient from daily injection therapy (MDI) to pump therapy (CSII) rests on the shoulders of trainers. These trainers are the primary facilitator of insulin pump therapy and they make every attempt to control the circumstances they are faced with to induce a positive learning outcome.

Insulin pump trainers deserve attention from the medical community, from those involved in designing and evaluating safety critical medical devices in the information systems community, and from the health care professionals involved in caring for individuals who about to receive insulin pump therapy or have just been initiated on a pump. Table 17 provides a selection of comments by participants about things that they would like to bring to attention.

Table 17
*Participant Quotes for Theme The Voice*

| Quote | Participant |
|---|---|
| The other manufacturer it is very problematic …people waiting 50 to 60 minutes on hold. | #12 |
| Some new pump designs are overkill as far as features go. | #28 |
| …and here's a technology in its finest hour! | #40 |
| Those doctors [primary care physicians in rural areas] do not have any idea how to manage a pump. | #47 |
| An advanced insulin pump class is always a good idea. | #50 |
| That could be a coverage issue [supplies not covered by insurance companies]. | #73 |

#28 expressed serious concerns shared among other participants that complexity is an issue, affecting users' learning curve, and that could be helped by users being better prepared. She believes that there should be more emphasis to ensure that diabetes patients are prepared to go on insulin pump therapy:

> "I think that before a patient is given an insulin pump or is prescribed an insulin pump, they have to, I think they need to go to different classes. Let me be specific: They <u>need</u> to go to carb counting classes. They <u>need</u> to understand that they are being giving a device that has medication, but if too much is given, it could kill them, OK? If too little is given, they could end up in the hospital. So, it is either/or. They have to understand that this is −It is serious, it is a serious thing."

Using figurative language, #73 referred to it as "coming out of the gate early" when a user studied the material beforehand. According to #73, an "excited" user is a motivated user, and there is less chance that a user will "freak out" when experiencing an obstacle during the training. #40 was also concerned about the critical skill of carbohydrate counting that users must acquire:

> "I will also ask if they know how to carbohydrate count, because the most successful patient on an insulin pump will also be utilizing carb counting for the dosing so that they do the appropriate amount of insulin for the food rather than just taking a set dose like mostly they did before. That is <u>why</u> they are on a

pump, so that the settings and everything can be most appropriate for them."

#28 regrets that users may not realize the responsibility that is required to handle the device correctly and her choice of language leaves nothing up to speculation:

> "You take too much [insulin], you could die. The same thing is with the insulin [injections]: This is a device. It has a medication in there. … It is a drug that you have to handle appropriately and you have to be responsible. If you just wear it, just to get through and not put forth an effort on your part, you are not going to get the results that you want."

Sorting out if an individual is a good pump candidate is important to #28 and she believes that interested users need to be "proactive":

> "They have to be emotionally ready. They have to be engaged in their own health care because it is important. Because if they just do not care or they are just like: *I just do not want to give myself any more shots. I just do not feel like dealing with this*. Okay, that is the wrong person to give an insulin pump to… If they come in and just say, *Okay, I guess*…and not really very interested, that to me is a red flag, and that is when I say: *You know what, let us try this, may be go home and practice on this by yourself, and let us go there,* but it is all, you have to really be, almost like analyzing the person."

> "If a person tells you: *I just want to get healthy! I will live longer! I want to be around for my family*! −That is the person who sounds to me like they really want to take it. They want to know what is going on. If they come into a class prepared, knowing the information, and we have a conversation, or they are engaged in the conversation with they asking really good valid questions, I know that person is going to be successful with what they are doing."

To ensure that users attain a good fit for insulin pump therapy, the trainers rely on behavior modification, a pattern connecting to the super-ordinate themes *Emotion-charged Environment* and *Safety Issues and Disaster Planning*. The definition of a "good insulin pump candidate" is of importance to #73, as well:

> "They have got be comfortable with insulin and understand exactly what insulin does and then feel comfortable in being able to manage a high blood sugar or low blood sugar, they should be very savvy in that area before they would use a device. …they [the pumps] may malfunction and so you will have to use your backup skills, your expertise in managing your blood sugar in a way that really signals to your provider that you are a good insulin pump candidate."

Several statements made by #40 stood out as a calculated use of language to direct attention to where situations or decisions made by others regarding insulin pump therapy are "inappropriate." While all participants made favorable statements about making insulin pump therapy available to as many individuals as possible, the statements made by #40 revealed her deep desire to be proactive about questionable situations or decisions. She stated that users should not expect that trainers will "spoon-feed all that information," which means that users need to be aware of the expectations for the training to be successful. When adverse situations occur as a result of users' failure to "listen with both ears," #40 expressed her frustration with the comment "live and learn." A deep insight is revealed about #40s commitment to "this awesome job [she has]," and she calls the pivotal moment when insulin pump therapy is starting to show success a "magical" moment.

Participants would like to see more technical breakthroughs that allow diabetes patients to lead a normal lifestyle. #28 favors a tubeless pump model, similar to the one on the market by Company A: The user wears the insulin reservoir attached to their upper arm, which would be great for "swimmers and surfers," and controls the dosage with a hand-held device.

#40 questioned a safety feature on the pump called *UNLOCK* that prevents accidental input on the pump interface through pressure points. She was concerned that users with certain disabilities are at a disadvantage, generating unwanted user interface problems:

> "…and the only reason being that because there are people that do not have vision because of diabetes that also use pump. It is not recommended, but if they have a great support system and they cannot see that pump to unlock it, they may

> have got a bit of a hurdle there, so as with anything, we would like that *UNLOCK* feature to not be there, but unfortunately it is still."

At the conclusion of the interview, #40 revealed that she is concerned about the lack of compassion exhibited by some prescribing physicians. Her wish is that "the insulin pumps would be marketed better to [individuals who have diabetes] type 2, because they could be helped a lot better." #40 reported that some physicians leave the [diabetes type 2] patient wondering if their condition can ever be managed successfully:

> "That defeatist attitude at the start of the encounter for that patient, when they sit with a physician who is <u>not</u> motivated to help them do better…so they may think: *Oh! That is not for me, it is so hard! –* Or: *[It is designed] for people with type 1 diabetes, so that means that I have bad diabetes [type 2 diabetes] and I am going to die! If they want me to go on a pump that means I might as well just plan my funeral*."

#40, who is a certified diabetes educator, reported that that she encounters resistance from some prescribing physicians who refuse advice from other seasoned diabetes healthcare professionals, including her:

> "They really think they know everything, some of them, that they do not want learn something and they certainly do not want to learn it from the diabetes educator."

#12 reported her concerns about users' difficulties to reach a technical support person at Company A, after being on hold for "50 to 60 minutes." #47 had the same concerns about the accessibility of Company A's technical support line. She stated that "a lot of complaints about customer service" have been reported by users recently:

> "Since some of the newer pumps have come out, they have been much more popular and they are getting more patients on the pumps, I get a lot of problems with people saying: *I tried to call the helpline and I am waiting for an hour before someone gets to me…* and then they feel like the customer service team is not very understanding and not very helpful, where−before−I never got that."

#47 wanted to provide input about a new generation insulin pump made by Company A that mimics a body system where an add-on sensor reports blood glucose levels to the pump software wirelessly. An algorithm determines basal settings and the pump is launched in auto-mode, which requires a "lot of training and meetings" and "a whole hour of training on the sensor." The combination technology with sensor and a pump that auto-adjusts basal rates based on an algorithm is ground-breaking, but she considers it too much of a learning curve for some people.

"For older people," #47 reported, the previous generation [pump without the sensor] would be much more "appropriate" and she considers that model a "very easy-to-use pump." #47 also believes in arranging a so called p*re-pump*: A meeting with the user to go over different pumps and their features before the order by the physician is placed. The intent is to identify the "ease of training compared to the individual and offering the best option for them to decide."

#50 articulated that there are several specific features she would like to have included in any insulin pump. She spoke about a *MISSED MEAL BOLUS* alarm:

> "So if you find that you ever missed taking your bolus, and that is the question you would ask them. I am really kind of busy at lunch and I am not going to eat at the same time, well, would you like to set a reminder and in that way if you push the button and you give your bolus, it will not go off at all. But if you eat anywhere from 11 to 1, then, at 1:01 if you have not pushed that button, then you are going to get an alert that you have *MISSED MEAL BOLUS*, which gives you the opportunity to go back in and give yourself a bolus. That is a pretty good idea."

Another good tip by #50 was *SITE CHANGE REMINDER* which she suggested should be on all the pumps:

> "They have one that is a *SITE CHANGE REMINDER*, so once they do a site change then it comes up and then they can change the time and day or they can change if they want to change it down to every two days, and what it is going to do is that an

> alert is going to come up and say, it is time to change your site. So that is another thing we do not really want them going over ever three days; you know although we know that people do that, we really like them to change them every three day."

Furthermore, #50 would like to encourage "people to continue the process of learning" and suggested that "an advanced insulin pump class is always a good idea." She also believes that "continued education is really the key" and, therefore, trainers should continue to learn about "additional advanced features on the insulin pump" and use the resources of the American Association of Diabetes Educators (AADE) at https://www.diabeteseducator.org.

#50 wanted to share some additional comments about technological advances she finds useful. Referring to the new glucose sensor by Dexcom that replaces the need for users to prick their finger [do finger-sticks] several times a day to obtain a small blood sample read by a glucose meter, she had this to say:

> "They do not even have to have finger-sticks anymore with the G6. So, the FDA (U.S. Food and Drug Administration) has approved with no finger-sticks, so that is why we are moving more and more <u>in the future of diabetes</u> where people can be on a continuous sensor and not have continue to stick [a needle into] their fingers."

> "It is really changed over the last 18 years and I have been doing this for 18 years, so I have seen a lot of changes, and it's one of the best that come out. Parents, they can put their child on the Dexcom and they can do *SHARE PROGRAM*, they can be in their bedroom and the child can be in their bedroom and if that blood sugar starts going down, that parent is going to be woke up."

The first and foremost concern expressed by #12 was that she was not spending enough time with users. As independent contractor with Company A, she indicated that the time spent with users is inadequate: "Probably the one thing that I wish sometimes I have more an opportunity for is more follow-up with patients…you know, we're kind of dictated."

In addition, #12 provided input about user interface design issues on pumps with chevron-style selection buttons because of the tedious way that numbers are being entered:

> "The one pump that I teach, if I had any feedback is the way that you enter the information, you have to use the up arrow key and scroll up to the number that you are getting and people talk about: *I did not realize it was going to take so long for me to get myself a bolus* and: *This is a lot [of steps]…* because they have to enter in the command and then they have to scroll up to a whole number sequence to get through their programs or to get to their blood glucose value to give themselves a bolus."

#12 shared that users would not have this problem on a pump with touchscreen interface:

> "I find it much more user friendly, because when they go into the bolus screen, they have a number pad that they just enter the number in and hit *NEXT*. So, <u>you do not have to do this scrolling up and down</u>, you know, that would be something I would say if there is any thought of one of the pumps that would be flaw is the scrolling and I know patients have commented on that: *I wish there was a way I didn't have to scroll through with this*."

All pump manufacturers should invest in research in human factors engineering–an important request issued by #12: "It would be nice if there were more people that did this human factor studying when it comes to insulin pumps, because they could make them better, they could make them more user-friendly."

This final theme touches on many remarkable statements made by participants that relate to their wish to participate in the improvement in the health care delivery of insulin pump therapy, because they are in the unique position as observers when insulin pump therapy becomes alive (see Figure 9).

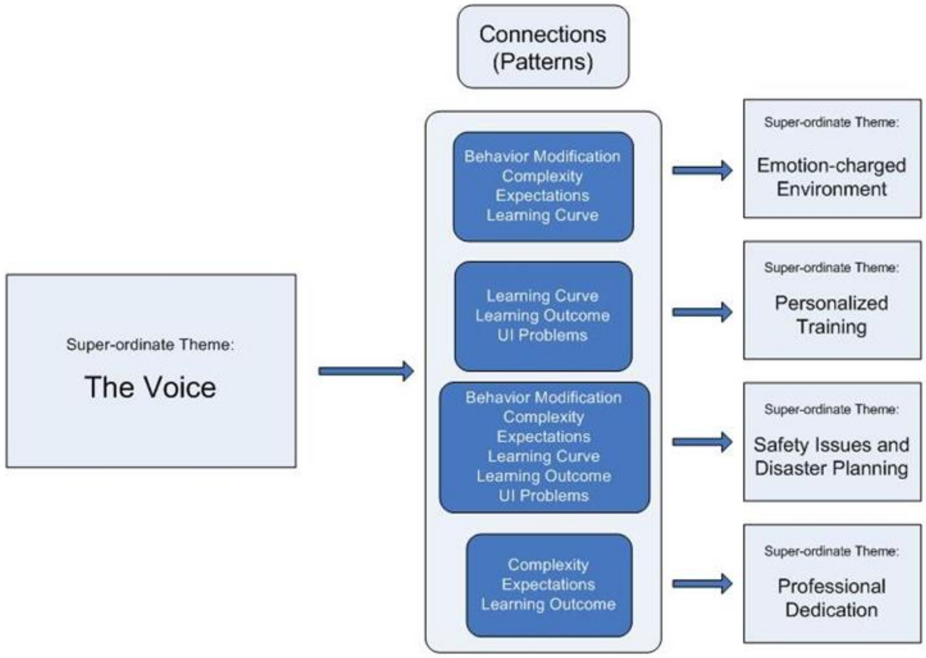



*Figure 9*. Theme *The Voice* and its connections to other themes

The theme *The Voice* has multiple connections to each of the other four super-ordinate themes. In its relationship to *Emotion-charged Environment*, the participants' voice is questioning new pump features that add unneeded complexity, that frustrate users, and are considered unnecessary. Another concern frequently mentioned was that users rarely come prepared to the training sessions, requiring the trainer to impromptu adjust their training pace. All participants expressed frustration about the fact that users being prescribed insulin pump therapy often lack basic diabetes management skills and carb counting skills, and that they are not checking their blood glucose level often enough. A positive learning outcome is expected from trainers, regardless of the obstacles to learning they encounter.

Participants believe that users are largely unaware of the responsibility required to handle the insulin pump correctly, and that safe use of the device is affected when certain behaviors are not met. Furthermore, participants would like to provide input when they believe that a user's learning curve is too steep to attain a positive learning outcome, no matter how creative the strategy during personalized training.

To summarize *The Voice*, participants emphasized that they derive a deep satisfaction from their profession. They would like to see users master all of the technological advances that insulin pumps have to offer to improve their condition, because they want them—as #50 expressed—to "live a normal healthy life and live it safely."

**Tools for Analysis and Data Visualization**

The software visualization tools in NVivo 12 Plus and Microsoft Visio 2003 were used for two purposes: As a supplement to the description of the analysis and the findings; and as a method to aid the researcher during the analysis when attempting to detect patterns and connections. The visualization tools and their output are presented below in the sub-section *Data Visualization*.

The intended tool of choice to perform data coding and analysis was NVivo 12 Plus. The participants' interview files were imported into the software, and initial data coding commenced based on the steps recommended for IPA by Smith et al. (2012), and Smith and Osborn (2015). The method of creating nodes and categories in NVivo was not effective in allowing the researcher to become more familiar with the data, because of the inability of the software to allow a word search within the imported documents while in EDIT mode. In addition, NVivo did not permit viewing of files side by side. Due to the NVivo learning curve involved, in addition with being a novice qualitative researcher, the researcher believed that she could not have coded the data effectively due to the limitations of the NVivo program.

The coding was performed in Microsoft Word 2010, instead. Word provides the ability for coding, highlighting, and commenting in multiple color schemes, and the researcher was able to view and edit multiple documents simultaneously, limited only by the number of computer screens connected to the researcher's computer. Some of the data organization was supported using Microsoft Excel 2010 spreadsheet functions. The researcher's home computer features three side-by-side monitors and documents could be viewed and edited on different screens and within different software programs, with ease. The ability of to view multiple data sets simultaneously greatly facilitated the iterative process of moving back and forth between individual interviews to perform the in depth coding and data analysis critical for IPA. The researcher's familiarity with Word enabled her to use it as an efficient and productive tool for achieving the objectives of the IPA method.

After becoming thoroughly familiar with the data from the interviews and succeeding in creating the emergent themes, the researcher imported the coded data along with the researcher's comments in the interview files into NVivo. This enabled the researcher to focus on identifying patterns within the data set by running data queries and visualize the output, as described above. NVivo was also used to organize the conceptual basis and the definitions for each of the twelve patterns. By using a creative thinking process and by being very attentive to what emerged from the data (Morse & Richards, 2002), the researcher succeeded in defining the five super-ordinate themes described in the *Finding*s section above.

The researcher used the data visualization tools in NVivo 12 Plus and in Microsoft Visio 2003. The *Visualize/Chart Node Coding* visualization tool in NVivo (see Figure 10) was used during the analysis to locate patterns within emergent themes and to inspect multiple links to some or all of the emergent themes previously defined in the Emergent Themes Master List (see Table 9). This visualization tool was applied each of the nine emergent themes to record which patterns are represented in each theme and the resulting column charts were used during data analysis to synthesize the patterns and, eventually, define higher order themes. Figure 10 is an example to show that the pattern *Behavior Modification* was situated in five of the nine emergent themes.

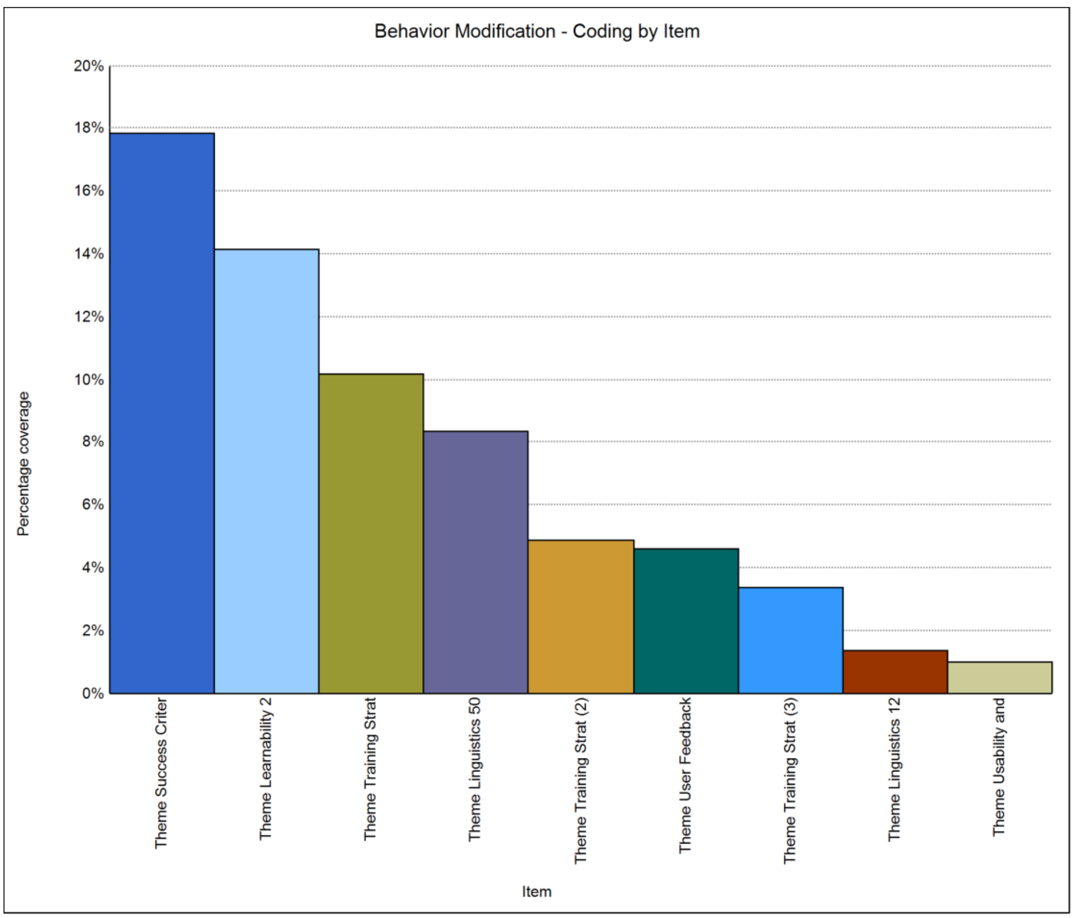



*Figure 10.* Example for output obtained through *Chart Node Coding* visualization tool

To create a *Word Cloud* to visualize word frequency, the coded interview files were imported into NVivo to explore words most frequently used by participants. The researcher determined that the word frequency returned by the software during this first attempt of creating the *Word Cloud* was predictable and, therefore, inconclusive: After excluding commonly used words that are an integral part of English grammar (e.g., *you*; *and*), the result for the top ten frequent words (e.g., *pump*; *patient*; *blood*; *sugar*) were obvious results, because they are part of the study context and, therefore, frequently mentioned by participants during the interviews. The data used for creating this instance of *Word Cloud* did not produce any insightful results.

The files of the *Initial Themes Table* workbook where the participants' significant statements all commentary by the researcher were collected, seemed more appropriate, because these contained the core of the data to be analyzed. Commonly used terms related to the context of the study (e.g., *insulin*; *pump*; *patient*; *trainer; user*) were excluded from the query for the same reason, because their rank in the query results could be predicted through the study context. The resulting *Word Cloud* (see Figure 11) was a better fit to the core of the data obtained through the participants' interviews and a more fitting representation for the focus of the study, which was to investigate insulin pump trainers while the teach patients how to use the pump for the first time.


*Figure 11*. *Word Cloud* based on data organized in *Initial Themes Table*

Microsoft Visio 2003 was used to visualize the patterns that connect each super-ordinate theme to the other themes in the sequence. Using Visio gave the researcher flexibility to create a schematic illustration for each super-ordinate theme that depicts how the description of the findings was organized. The illustrations also served to provide a concise overview of the connections between each theme. These illustrations were presented in the *Findings* section above (see Figure 3; see Figures 6 through 9).

**Journaling and Bracketing**

A reflexive journal titled *Field Notes* was kept by the researcher in Microsoft Word 2010 format in accordance with recommended qualitative research procedures. Keeping a reflexive journal enabled the researcher to promote internal validity of the results, to uphold transparency in the process, and to justify the decision-making process throughout the study (Ahern, 1999; Ortlipp, 2008). The task of journaling and bracketing is an integral part of IPA methodology and serves to prevent a researcher from taking their perceptions for granted (Smith et al., 2012).

This reflexive journal included the "researcher's private, personal thoughts, ideas, and queries regarding her research observations and interviews" (Phillippi & Lauderdale, 2018, p. 381) to alert the researcher to "possible areas of potential role conflict" (Ahern, 1999, p. 409). It was organized in chronological order of events and tasks, starting on November 10, 2018 at the point of first contact with a prospective participant. The entries continued throughout the interview process with each participant, throughout the entire analysis phase, and concluded at the point when super-ordinate themes had been defined.

For each interview, the researcher made notes about her own performance as interviewer for the purpose of improvement for the next interview. For example, on December 4, 2018, the researcher wrote into the journal after interviewing #47: "I think I interrupted Participant #47 quite a lot and should have shown a little more restraint. Have the feeling that I took over the conversation at times, rather than allowing her to finish speaking." On December 19, 2018, after the interview with #73, the researcher made the following entry:

> "I tried to remember *not* to interrupt the participant's response so many times as I may have done in other interviews. However, for this one, I would pose a question and she stopped responding after 2 minutes or so. I had to improvise with probing questions to obtain more information."

During the interviews with the participants, the researcher reflected on her personal impressions of the participant's statements and recorded ideas that appeared striking. For example, during the interview with #12 on November 30, 2018, the researcher recorded the following ideas:

> "Sometimes, patients forget where things are while pushing buttons. A pump with chevron keys: Have to use up arrows to keep scrolling. So, if you need to enter 15 carbs, you have to push the up arrow 15 times…The success of pump

> training is the [sole] responsibility of the trainer. They have to be a resource for the patient until they can be sure that they get it and beyond. More follow-up is always needed. The trainers are the main support system for the patients."

After the first interview, the researcher decided to pen initial notes on a scrap pad rather than typing notes directly into the *Field Notes* journal on the computer to reduce background noise. The following thoughts were recorded in the journal about #50 who was interviewed on December 13, 2018:

> "Participant had a few questions when I went through the *Interview Preparation and Introduction*, explaining what is expected. She wanted to know more about how I am going to ask these questions. I explained to her that they are all very similar and intended to jog her memory. So, if she gives me a lot of information already in one question, we may be able to skip the next question or two. And I emphasized that she does not have to answer the question directly, just say what comes to mind."

At the end of the interview, the following entry was made:

> "Had trouble with participant's phonology; had to pay close attention to make sure that I understood what she was talking about. This participant was very detailed and that is a blessing. I would pose a question and she would talk for at least 5, if not 10 minutes. This was the longest recorded interview so far: 53 minutes."

Once the interviews were concluded, the researcher made notes about the process of proof-reading the voice recordings against the transcribed interviews and used these notes in Chapter 3 to describe the quality measures applied during data collection.

During the analysis phase, the researcher used the *Field Notes* as a guide to "provide rich context for analysis" (Phillippi & Lauderdale, 2018, p. 381) and recorded the methodology and decision-making process throughout the interpretation and analysis. The notations became the basis for the write-up of the *Data Coding and Analysis* section in Chapter 4. The researcher performed a literature review and used the *Field Notes* guide to select, define, and apply the steps used for data coding, analysis and interpretation. Various sources dealing with qualitative methodology in general, with phenomenological approaches and with interpretative phenomenological analysis were consulted and findings were organized to justify the conceptual basis for the methodology used. For example, the entry that became the basis for Phase 1, Stage 4 of the analysis read as follows:

> "Stage 4 represents the fourth analytical review of each transcribed interview. Following the recommendations by Smith et al. (2012), I was engaging in the process of "deconstruction" (p. 90). During this stage, I was attempting to:
>
> - Get closer to what the participant is actually saying;
> - Emphasize the importance of context of each respective statement reviewed;
> - View the interrelationships between one experience and another, and;
> - What the meaning of it was to the participant (on a conceptual level).
>
> I marked text and provided comments to the transcribed document for each participant with a third distinct set of initials and comment color. By reading the document, I tried to project myself into the trainer's position while engaging in the process of training the individual. I tried to visualize what it was that they were experiencing at a particular moment during the training."

While reviewing DeSantis and Ugarizza (2000), the following entries reflected some of the ideas used by the researcher to interpret the data. A theme can be a "category, a domain, unit of analysis, phase process, consequence and strategy" (p. 358). − Themes are "embedded in the data and must be extracted or inferred from the data by the researcher" (p. 363).

The issue that the researcher considered most critical during the effort of engaging in reflexive bracketing was her personal experience as an administrator in a diabetes clinic in Northcentral Florida. The long history of her interaction with insulin pump trainers, pump manufacturer representatives, and patients using insulin pump therapy proved very difficult to eliminate when moving to coding, analysis, and interpretation. Instead, the researcher applied a method of “reduction” and considered different ways of “thinking and reasoning about the phenomena at hand” (Smith et al., 2012, p. 14). This enabled her to consider alternate views and perspectives of the participants’ experiences, before she selected what she deemed an appropriate “particularity of a given phenomenon” (p. 14).

During the analysis, the researcher made an ongoing effort to avoid using her own experience as the “single lens to view and understand participants’ experience” (Deggs & Hernandez, 2018, p. 2553). Eventually, her experience at the diabetes clinic became an asset that the researcher embraced as an advantage, because it enabled her to correctly define and categorize phenomena for this study within this complex scientific context.

**Summary of Results**

Chapter 4 provided a detailed overview of data coding, analysis, and interpretation and described the methodological framework that supported this activity. Five super-ordinate themes were the result of data analysis: *Emotion-charged Environment*; *Personalized Training*; *Safety Issues and Disaster Planning*; *Professional Dedication*; and *The Voice*—a collective of feedback by participants to establish their desire to participate in the improvement of health care delivery. The participants’ quotes that related to their statements within each of the five super-ordinate themes were presented in the Findings section. Following was a discussion of the software tools used to process the data and the attempts to extract meaning from data visualization efforts. Finally, a detailed description is presented for researcher’s efforts to sort out biases and preconceptions. This was accomplished by engaging in journaling and bracketing during the interviews with the participants and during the subsequent data analysis and interpretation.

# Chapter 5

# Conclusions, Implications, Recommendations, and Summary

## Introduction

This chapter provides answers to the research questions using the findings described in Chapter 4. The essence of the phenomena discovered by analyzing and interpreting the data collected from the participants is presented. The strengths, weaknesses, and limitations of the study are also discussed. Additional information is provided to explain the implications of the study, recommendations for practice, and recommendations for future research. At the end of this chapter, a summary of this study is presented.

## Conclusions

The findings presented in Chapter 4 are positioned to answer the overarching research question and the four sub-questions that guided this study. The conclusions to the findings are presented here to "reflect phenomenologically on the living meaning" of the trainer's lived experience (van Manen, 2017, p. 813). According to Smith et al. (2012), and Smith and Osborn (2015), IPA methodology is an appropriate tool to elucidate the participants' experience in a meaningful way. The sensemaking of the participants' experience for the purpose of answering the research questions was performed by the researcher through the attempt to grasp "what is essential in the sense of the original-unique" (van Manen, 2017, p. 823).

Grand Tour Question: What is the essence of the experiences of insulin pump trainers while they teach first-time users how to use the device?

The very nature of the trainers' experience occurs during the pivotal moment when the training is completed successfully and insulin pump therapy becomes alive. This fills the trainers with great joy and satisfaction, and provides meaning to their experience. During the training sessions, trainers navigate through users' unrealistic expectations, users' negative sentiments in the form of fear, frustration, anger, embarrassment, panic, confusion, denial, and shame. Trainers find that users are often ill-equipped to deal with insulin therapy in general, but trainers are poised to apply a huge effort to deliver to users what #40 called "a technology in its finest hour." They reach this goal, because of their amazing skill set and because they are able to project themselves into the lives of people suffering from a "horrible disease," as #28 candidly described it. Despite the unfavorable conditions they are faced with while conducting the training sessions, trainers have great resolve to deliver all that insulin pump therapy has to offer to individuals suffering from diabetes. Trainers are motivated to reach this goal by positive feedback from the users, and they want the users—as #50 befittingly expressed it—to "live a normal healthy life and live it safely."

These conclusions were reached by thoroughly analyzing and interpreting the data collected during the interviews with the participants. The essence of the trainers' experience during the insulin pump training sessions was obtained using interpretative phenomenological analysis (IPA) which required the researcher to carefully observe the manifestation of the phenomena as they "appear on the surface" and use a creative process to find the connection with their "deeper and latent form" (Smith et al., 2012, p. 24). On the surface, the researcher gathered and categorized the phenomena obtained from descriptions by the participants about what happens during the training sessions. By carefully listening to the participants as they reflected on the significance of their experiences, the researcher was able to extract meaning from their narrative (Smith, et al.).

Insulin pump trainers set a conscious goal to succeed in the difficult task of teaching individuals how to manage a chronic disease with the use of a complex medical device, such as the insulin pump. With a high goal commitment, trainers associate value with attaining those goals, because they equate their reward with the benefits that users receive from the trainers' efforts (Locke & Latham, 1990): Better control of blood glucose levels means that individuals feel better. Positive feedback from users provides the satisfaction the trainers derive from their role in alleviating the suffering of others (Fotaki, 2015; Locke & Latham, 1990).

Sub-question 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?

Four among the five super-ordinate themes provided answers to this question (see Figure 12). For the theme *Emotion-charged Environment*, participants reported that users' negative sentiments presented a distraction to the learning process and that these sentiments needed to be overcome. According to Tanenbaum, Adams, Iturralde, Hanes, Barley, Naranjo, and Hood (2018), individuals with diabetes have coping issues, and the mental burden to deal with their chronic condition is excessive.

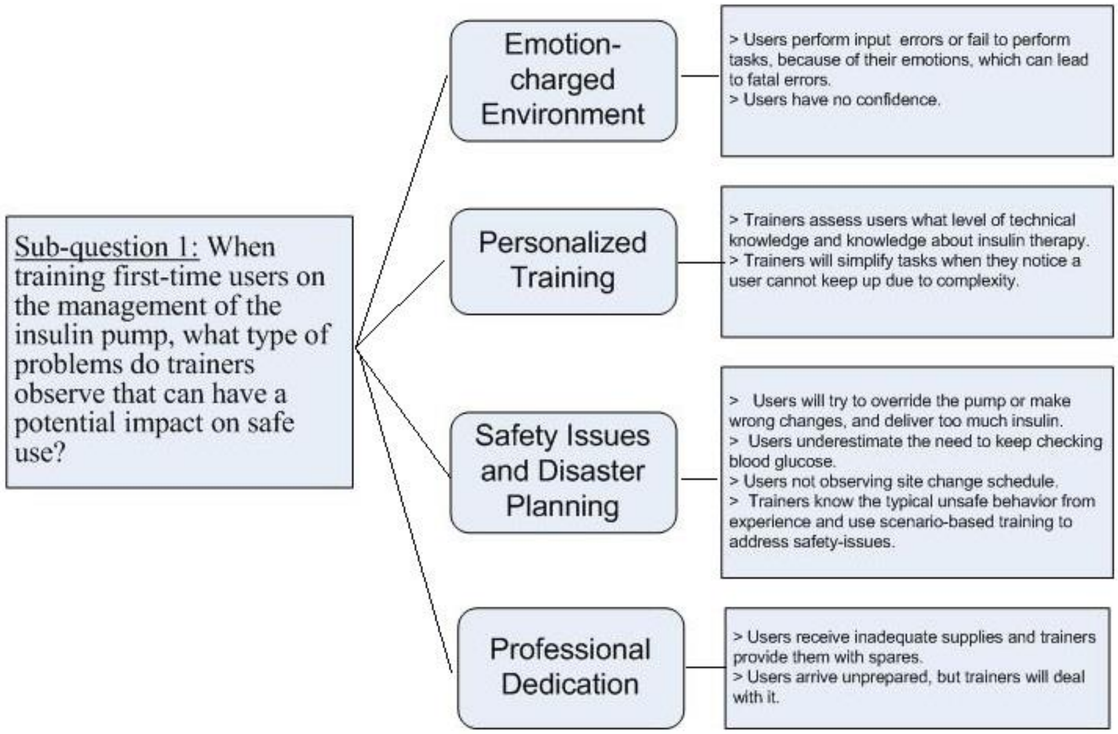



*Figure 12*. Sub-question 1 themes and findings

Trainers intervene in the form of reassurance or certain behavior modification strategies to help users who are scared, nervous, confused, or apprehensive and lack confidence in their ability to grasp the technology to manage the pump. The participants' strategy follows the observation by Tanenbaum et al. (2018) that users "have different psychosocial needs to overcome barriers to adoption" (p. 1102). The participants reported that—under such conditions—a user will make errors or fail to perform tasks, which can lead to fatal errors. According to Khan and Choudhary (2018), distress impacts a user's ability to manage the pump and is linked to poorer self-management.

For the theme *Personalized Training*, the participants reported that they first assess a user and focus on his/her level of knowledge and make use of the time available to the best of their abilities. The trainers go through the required steps, but will simplify tasks when they notice that the user is not quite as "techie" as #28 and #73 described it, because complexity can prevent certain users from reaching the desirable skill level to manage the pump. Consistent with the findings by Santhaman et al. (2013), and Venkatesh et al. (2003), the complexity of a device becomes a hurdle when it is perceived by users with low computer self-efficacy as difficult to understand.

Participants reported that safe handling of the insulin pump is priority during the training sessions. The theme *Safety Issues and Disaster Planning* provides a thick description of problems observed by trainers that impact safe use. The trainers are using scenario-based instruction to address safety issues to prevent users from overriding pump settings, from relying too much on pump alerts, and from failing to address site change routines. In addition, they stress the importance of checking blood glucose levels regularly. These observations concur with the findings by Ross et al. (2015) who attributed adverse events due to omissions. In addition, the safety issues observed by participants are congruent with the findings by Heinemann et al. (2015) who questioned the effectiveness of pump warnings, which might lead a user to ignore an occlusion. The analysis of the participants' statements is also consistent with the findings by Campos et al., (2014), Campos et al., (2016), and Harrison et al. (2016) who cautioned that the design of a system has to allow users safe interaction with the system, but prevent them from making a wrong choice.

The participants' dedication to their job as discussed in the findings of the super-ordinate theme *Professional Dedication* contributes to successful insulin pump initiation of a user. For example, trainers will deal patiently with users arriving unprepared for the lessons, despite the tireless reminders by trainers when setting up the appointment for training. Consistent with the findings by Becker and Roblin (2008), Borhani et al., (2010), Dougherty and Purtilo (1995), Fotaki (2015), and Locke and Latham (1990), insulin pump trainers as healthcare professionals have high ethical standards, and the participants reported that they obtain personal satisfaction from their commitment to serve these users. Compassion for the users is deeply rooted in the participants as the "sensitivity to suffering in self and others with a commitment to try to alleviate and prevent it" (Fotaki, 2015, p. 199). It represents the norms and values inherent in health care professionals who observe ethics of care (van der Cingel, 2008) and allows them to "provide high quality responsive care" (Fotaki, 2015, p. 199).

The participants exhibit a thorough understanding how to sort out the negative sentiments of the users and how to work around the problems users encounter during the training sessions. Individuals with diabetes struggle with physical discomfort associated with wearing the pump, with unexpected technological demands, and with loss of self-esteem due to the visibility of the pump to others (Hayes, Frearson, Keller, Cartmale, & Lewis-Hayes, 2011; Reidy, Bracher, Foster, Vassilev, & Rogers, 2018; Ritholz, Smaldone, Lee, Castillo, Wolpert, & Weinger, 2007; Tanenbaum et al., 2018). Trainers are mindful of the demands that diabetes management imposes upon a user, and exhibit a strong commitment to help users overcome these issues, because the successful management of diabetes will result in better control of blood glucose levels to benefit these users (Heinemann, 2017; Jayasekara, Munn, & Lockwood, 2011; Shah, 2018). Insulin pump therapy shows great promise to deliver this goal, as long as users are exhibiting a reasonable level of engagement in the therapy (REPOSE Study Group, 2017).

Sub-question 2. Which of these problems observed relate to the interface characteristics of the device? Two among the five super-ordinate themes provided answers to this question (see Figure 13).

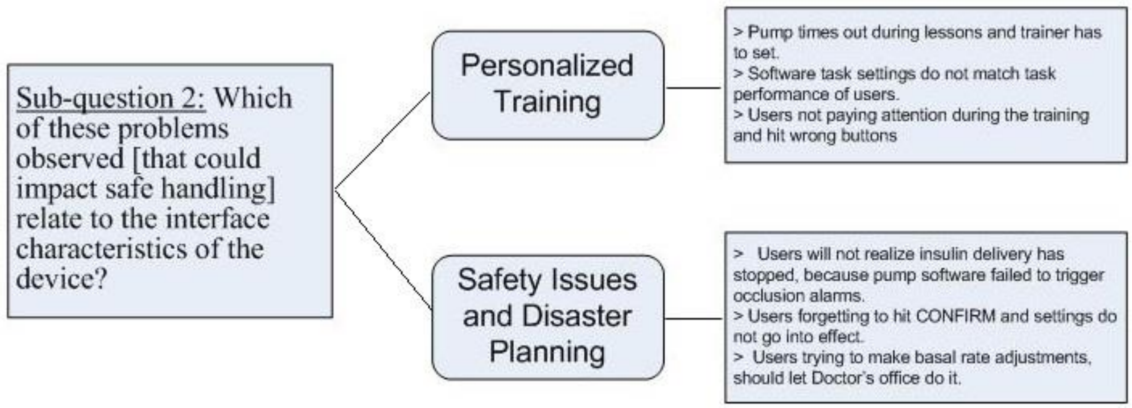



*Figure 13.* Sub-question 2 themes and findings

Within the context of the super-ordinate theme *Personalized Training*, participants described a number of issues with user interface problems that need to be overcome to ensure safety. Participants reported that—during the initial setup—the pump software will time out and the trainer has to rush the user to learn how to reset time, date, basal rate and target glucose range. In addition, a hesitation to use technology was observed by several participants, when users appeared apprehensive to press buttons. According to Jayasekara et al. (2011), technical factors associated with managing the insulin pump are obstacles to pump adoption, and the appropriate size and closeness of physical or digital buttons affect effectiveness of task execution (Preece, Rogers, & Sharp, 2015).

Other participants observed that users would continue to push buttons randomly in frustration without reaching the intended goal. To help users recover from this type of error, the participants instruct the users to find the *ESCAPE* button, in order to safely exit back to the home screen. Another striking statement by participants was when they observed that users learning a touchscreen pump would try to push buttons too hard. Users new to touchscreen interfaces are not familiar with the finger action required to control the device, because the sensory activity in a human differs between touchscreen and tactile devices such as the chevron-style insulin pump interface (Gindrat et al., 2014; Preece et al., 2015). In contrast, other users learning how to use a chevron-style insulin pump would complain that the buttons are too hard to push.

Several participants provided detailed description how the software task settings do not match the task performance of the users. To add to the confusion, the task sequence programmed into the software on insulin pump models varies even among models from the same manufacturer. In addition, participants reported that users' attention span diminishes over the course of the training session, and they forget steps. This is consistent with the findings by Heinemann et al. (2015), Masci et al. (2013), Ross et al. (2015), and Schaeffer et al. (2015) who posited that adverse events frequently happen due to erroneous task execution or omissions, and can result in an outcome that can cause damage or harm.

The theme *Personalized Training* focuses on the phenomena that underlie the trainer-user interaction. When learning how to program settings into a system interface, the "order in which tasks are done often matters" (Johnson, 2014, p. 213), but that is not always the case with insulin pump software (Ross et al., 2015). In a system like the insulin pump that is not "self-regulating," repeated "loops of interaction" are required (Dubberly, Pangaro, & Haque, 2009, p. 71) to meet the goal of safe handling. The user has to be confident that they can make changes on their own. The analysis of the participants' observations is consistent with the findings by Campos et al. (2014), Miller et al. (2017), Schaeffer et al. (2015), and Zhang et al. (2011) who posited that inconsistencies and resource constraints can cause fatal errors. This discovery ties in with the interview questions about the safe handling of the pump. Statements by the participants made regarding pump programming issues observed in users often converged with the safety critical aspect of insulin pump management.

The theme *Safety Issues and Disaster Planning* contains a multitude of comments by participants about interface problems that could affect safe handling of the device. One of these issues is the situation where insulin delivery has slowed down or stopped, but the software fails to issue and alarm. The other extreme is that too many alarms are prompted through the software interface and the user fails to respond, a condition called alarm fatigue. This is consistent with the findings by the medical researchers who expressed skepticism about the effectiveness of occlusion alarms (Blauw et al., 2016; Grunberger et al., 2014; Heinemann et al., 2015).

When participants reported about the software differences among the insulin pump models currently on the market, the discussion centered on the requirements to activate task execution. In some software interfaces, no command will be activated unless the user hits the *CONFIRM* button. This is important for users to learn and, as #47 reported, users cannot be "in a hurry" while moving through the task sequence. When entering values or changing settings on other insulin pump models, these go into effect once the value is entered, leaving the user without an opportunity to make corrections. Participants reported that they consider this an obstacle and that it increases the learning curve for users. This is consistent with findings by Campos et al. (2014) who posited that a device lacking a *CONFIRM* mode poses a danger, because the user might be unaware that infusion commences as soon as they enter a value. In addition, Harrison et al. (2015) determined that user errors occur, when the effect of an action is not visible or not being noticed by the user.

Another observation shared by participants was the fact that users are eager to make adjustments on their insulin pump basal rate—the continuous rate of drip action where insulin gets delivered in varying rates over a 24-hour period. Basal rate changes are a critical issue, and therapy is impacted, when users perform incorrect changes, or simply transpose AM and PM when resetting the pump or making changes. This confusion frequently happens after battery changes, when users have to reset the time. Therefore, many physicians require that the users make an appointment at their office, and the health care team will make the modifications. This is consistent with the finding by Ritholz et al. (2007) who posited that health care providers need to evaluate a user to decide if the user is suitable for an active approach to self-care. According to Schaeffer et al. (2015), entering incorrect basal rates was among the most common errors observed in users. Reduction of errors is vital, because number errors are a common task in a health care environment (Cauchi et al., 2014).

Sub-question 3. What type of usability errors are encountered when trainers teach first-time users how to program their insulin pump?

To find answers for sub-question 3, the focus was on presenting findings when participants reported that user exhibited certain behaviors where functionality of the insulin pump software impacted the effective use of technology ((Alonso-Ríos et al., 2009; Norman, 1983). The findings supporting answers to sub-question 3 are found in all five themes (see Figure 14), but have some overlap with the findings that support answers for sub-question 2, as a number of usability errors have already been discussed in the aforementioned section. This overlap is evident in the context of interview questions 4 and 5, which were both formulated to collect data for sub-questions 2 and 3.

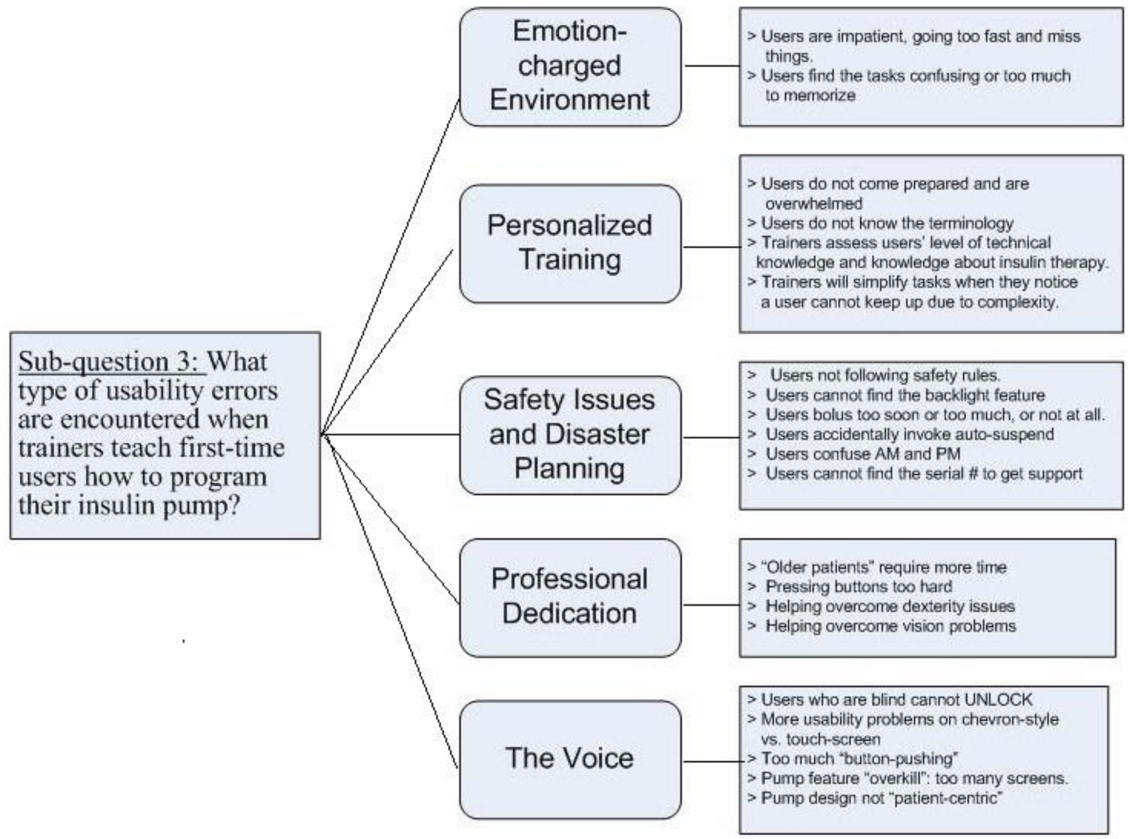



*Figure 14.* Sub-question 3 themes and findings.

During their interviews, participants were asked to provide details about tasks they assign to users and then describe the problems they may have noticed with pump programming. The data obtained from at least four of the participants show that answers were rather brief for either one of the interview questions 4 and 5, because the participant felt that they had already provided a sufficiently detailed response for another question.

To provide answers to sub-question 3, the theme *Emotion-charged Environment* had some relevant information from participants, when it was described by #12 that users "are jumping too fast" and miss important things. As mentioned in the answers provided for sub-question 2 above, #12 reported that users new to insulin pump therapy "typically forget to hit *DELIVER BOLUS*." This means that users believe that they have executed the task and added insulin to bring down their blood glucose levels into a normal range, but the task sequence was never completed in the system. In addition, users may find the tasks confusing or too much to memorize. This condition occurs when a user has a limited attention span and is not able to retain information in short-term memory for a sufficient time to execute the next step (Johnson, 2014). Participants frequently spoke about keeping things simple for users and keeping the training environment free of distractions.

Rich information was provided by participants in conjunction with the theme *Personalized Training*. Participants reported that the users who do not come prepared to the training sessions are, not surprisingly, overwhelmed by a steep learning curve. In addition, some users do not know the terminology associated with diabetes therapy or do not know how to carb count. The users' lack of knowledge and unpreparedness is prompting trainers to take additional time to bring users up to speed, before they can commence the insulin pump training sessions. According to Johnson (2014), we learn faster and achieve the learning outcome when the vocabulary is "task focused, familiar and consistent" (p. 159). Some of this behavior by users reflects their inability to integrate diabetes management into their day to day living (Barnard & Breton, 2018).

Technological demands play a huge role in reluctance to insulin adoptions, and the users' unpreparedness, and their lack of knowledge of terminology or carb counting greatly affects learnability (Jayasekara et al., 2011; Johnson, 2014; Miller, 2009; Sweller

& Chandler, 1994; Waldenmaier, Zschornack, Kalt, Buhr, Pleus, Haug, & Freckmann, 2019). The research by Campos et al. (2014) addressed the effects of constraints in the system on a user's activity goal. A user' lack of required knowledge can represent an additional constraint for achieving goals, when they do not understand the status feedback from the pump or available actions on the menu, because they failed to get familiar with the required vocabulary. Participants reported that they try to simplify tasks to overcome perceived complexity on insulin pump software interfaces.

The theme *Safety Issues and Disaster Planning* contains a thick description by participants about the need for users to acquire trouble-shooting skills and to have a backup plan, when—not if—the insulin pump fails. This analysis is consistent with the findings by Hayes et al. (2011), Heinemann et al. (2015), and Wheeler, Donaghue, Heels, and Ambler (2014) who reported that problems with the pump should be anticipated. When users are not able to rely on the pump, they have to be ready to switch back to manual injections and invoke their so called *Plan B*. Usability errors from which users are not able to recover to resume normal pump operation fall under the *Plan B*.

All participants reported a number of usability issues with the pump, when questioned about safe use of the device. For example, #28 reported that some users are not able to find the backlight feature, and she addresses that issue as part of the training. In addition, users may accidentally invoke auto-suspend, when they are not touching a button on the pump for more than 12 hours. This problem was mentioned by #50 when discussing the auto-suspend safety feature, which is intended to alert the user or a family member that the user may be experiencing hypoglycemia, and is not able to respond. #47 reported about the confusion with AM and PM that was already discussed in the section for sub-question 2, something that could occur after battery reset.

Participant #50 spoke extensively about the task of finding the serial number of the pump. Having the serial number available authenticates the pump user when calling for factory technical support. #50 emphasized that the serial number on pumps may not easily be located. Depending on the pump model, the serial number could be located on a tape on the back of the pump; it could be etched into the pump underneath the battery, which requires removal of same; or it could be viewed in the pump menu and needs to be recalled by searching in the settings.

In the context of the theme *Professional Dedication*, participants observed additional usability problems, many of which have already been presented in the aforementioned section for sub-question 2. Participants reported dexterity problems with users pressing buttons too hard on touchscreen pump interfaces, or complaining that the buttons are too rigid on other pump interfaces. They also reported feedback from users who complained that entering information requires tedious finger activity; many users expressed their frustration about excessive "button pushing" to complete a task, as reported by #28 and #47. A user's perception of usability is affected when the frequency in which buttons have to be pressed to reach the goal is considered excessive (Johnson, 2014). This analysis is also congruent with the findings by Chamberlain and Gilgen (2017), and by Waldenmaier et al. (2018) in their research on insulin pump usability.

All participants were willing to spend more time with users to help "older people" overcome these problems, as was extensively described by #28 when she discussed the observations she made during pump training. The analysis of their statements is consistent with the findings by Tanenbaum et al. (2018) who posited that a "one-size-fits-all approach" (p. 1102) does not work for all insulin patients, and with Heinemann et al. (2015), and Norman (1983) who posited that the needs of users differ which requires consideration. For example, #40 reported that people with vision problems have trouble with unlocking the pump, and should have a good support system to help them manage the pump. The analysis of her statement is consistent with the findings by Heinemann et al. (2015), Reidy et al. (2018), and by Saarinen, Fernström, Brorsson, and Olinder (2014) who emphasized that involvement of others is vital as a support system for insulin pump users.

The themes *Personalized Training* and *Safety Issues and Disaster Planning* represent overlap with the theme *The Voice*, when participants reported about the aforementioned usability problems and simultaneously provided recommendations how to solve some of these problems. Some participants directed attention to the need for insulin pump manufacturers to design pumps more "patient-centric," as expressed by #28. Additional discussion about the participants' experiences and their recommendations for improvement is presented within the answers for research sub-question 4.

Sub-question 4. What can trainers tell us about the learnability and ease of use of the insulin pump programming interface?

Answers to this research questions were found in all five of the super-ordinate themes (see Figure 15). The participants' voice represents their input about potential improvements for the delivery of insulin pump therapy. It is important that they should be heard, because their suggestions for quality improvement come directly from the "context awareness" of insulin pump therapy (Batalden & Davidoff, 2007, p. 3).

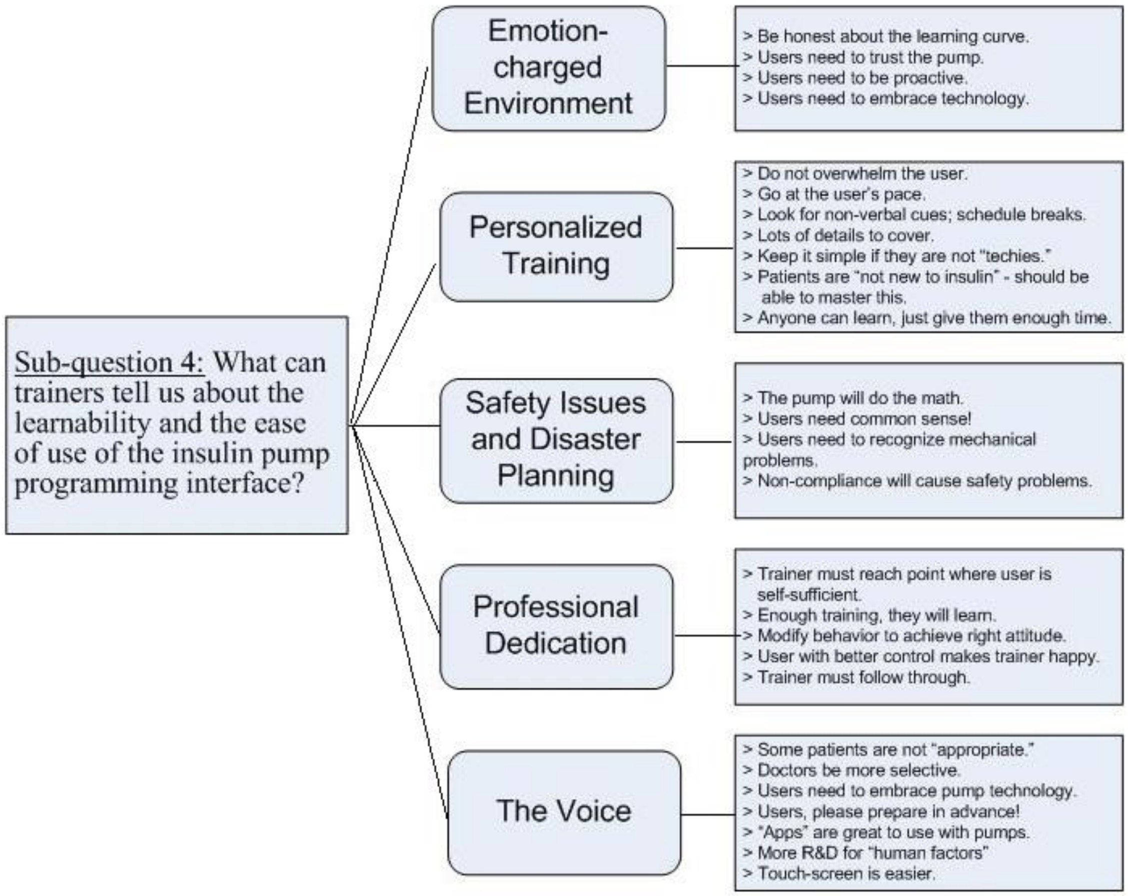



*Figure 15.* Sub-question 4 themes and findings

A number of participant statements reflected on how to best meet users' unrealistic expectations. For example, users often hold the expectation that diabetes treatment will become easier with the use of an insulin pump, versus the traditional treatment by manually injecting multiple doses of insulin daily. This phenomenon was discovered in the theme *Emotion-charged Environment*. #40 replied how she deals with this type of situation: "I am very clear to the point that it feels like it is going to take a little bit more effort in the beginning…" The strategy used by #12 is more subtle. She starts her training by listing all the benefits that users will receive from switching to insulin pump therapy. Regardless of presentation style, the essence is that trainers are consistently honest to users about the extra effort required which they use to build trust with the users.

This is consistent with findings by Becker & Roblin (2008), Borhani et al. (2010), and Quirk et al. (2008) who posited that honesty is an effective way in health care delivery to appear supportive and caring. It also helps users to trust the effectiveness of the insulin pump, itself. According to Teasdale (1989), being honest about the learning curve involved and presenting it in a tactful way puts users at ease and restores confidence in the user's ability to learn the system.

When accompanied by compassion−a prerequisite for those successful in health care delivery (Dougherty & Purtilo, 1995; Fotaki, 2015), it is also consistent with the findings by Delprato & Midgley (1992) who based their research on B. F. Skinner's behaviorism, asserting that suitable stimuli will achieve the desired behavior in others. These activities contribute to the learnability of the insulin pump software interface.

In addition, a lot of discussion by participants focused on their views about the type of criteria that represent a suitable insulin pump candidate. Participants stipulated that users need to be proactive about the switch to insulin pump therapy, to have a handle on their diabetes regimen, to be able to carb count, to be willing to check their blood glucose regularly, and to embrace technology. This includes the advance preparation by users to get ready for the training; however, it was reported by most participants that this is a particular directive users seem to ignore frequently.

The reality of the participants' experiences differs from their assertion that a user must meet all these requirements to be trained successfully. In the context of the theme *Personalized Training*, a number of interesting phenomena were observed in the narration of the trainers. For example, at the beginning of the interview, #73 was very clear about what she expects from user getting ready to enter insulin pump therapy. She stated that a user has to be technically oriented, that an “appropriate pump patient” needs to be familiar with “how much insulin they may need to cover the carbohydrates they consume,” and that the user has to “monitor blood sugars regularly.” Her demands are consistent with the prerequisites for insulin pump therapy stipulated by medical professions. The essential steps to lead to initiation of pump therapy include regular self-monitoring of blood glucose, completion of diabetes education, and completion of carbohydrate-counting training (Millstein et al., 2015). In essence, participants would list the desirable criteria required for a user to be successful on the insulin pump, but then go into extensive discussions how they work through obstacles when the user they train represents a poor fit to their expectations. This situation was reported as a recurring experience by all participants.

The participants’ experience includes a number of user encounters where they moved forward with the training, regardless. They reported that they used their training experience and their judgment to compensate for many shortcomings on the part of the user. Trainers understand the crucial role they play to overcome complexity and to eliminate unrealistic expectations by users. Participants often cautioned not to overwhelm the user, because there are a lot of details to cover.

The trainers interviewed possess a repertoire of creative strategies how to reduce the complexity of insulin pump management. To monitor the users’ progress, trainers look at non-verbal cues and encourage users to take a break to refresh the user to regain their attention and focus on the task. In addition, trainers are willing to assume responsibilities that go beyond the training requirements to be sure that their patients are comfortable with the new device. They will adjust their training pace, go over carb counting, revisit basic diabetes treatment regimen, make extra time if a participant is slow or has issues with adapting to technology—not very "techie," as #73 expressed it, reschedule for another day, if necessary, and apply every effort to allow the training experience to have a positive outcome.

In other words, participants expressed that [most] everyone can learn how to use an insulin pump, but the findings show that it is up to the trainers to be mindful and creative to make it happen. #28 stated that the "trainer is the key." The analysis of the participants' strategy is consistent with the findings by Barnard and Breton (2018), Becker and Roblin (2008), Locke and Latham (1990), Reidy et al., (2018), and Teasdale (1989) who reported about various methods of positive reinforcement used in patient care.

Within the context of the theme *Safety Issues and Disaster Planning*, participants made statements that provided additional information about the learnability and ease of use of the insulin pump programming interface. Once a user has been introduced to data entry tasks, and understands that failure to regularly monitor their blood glucose levels and failure to keep track of carbohydrate count consumed would put them in danger, trainers will convey the pleasant surprise that the pump will automatically calculate the user's dose of insulin. When users hear that they no longer have to do "the math," as several participants denoted, participants report that users are excited and have reached the point where insulin pump therapy becomes much simpler to understand.

In addition, participants emphasized that the troubleshooting scenarios they engage in during insulin training are designed to help users recognize mechanical problems. According to the findings by Jayasekara et al. (2011), and Reece and Williams (2014), extensive training ensures users' expertise to deal with potential problems. Participants cautioned that users should not hesitate to pursue an alarm issued by the software interface, which are consistent and easy to understand. They also stated that users should use common sense to sort out if a repeated alarm is an indicator of a mechanical problem that needs their attention. The analysis of their statements is consistent with the findings by Heinemann et al. (2015), Masci et al. (2013), Ross et al. (2015), and Schaeffer et al. (2015) who posited that improper handling, erroneous user action, or omission of critical steps can cause damage or harm to the individual.

Within the context of the theme *Professional Dedication*, participants made statements that reflected on their role regarding the learnability and perceived ease of use of the insulin pump programming interface. From their statements, it is evident that they are committed to following through and reaching a point where a user becomes self-sufficient. The pivotal moment when a user reports that they are feeling better since they have been on the insulin pump is met by trainers with enthusiasm. The trainers' positive performance is linked to their goal commitment (Locke & Latham, 1990). Consistent with the findings by Reece and Williams (2014), participants believe that users are able to learn with enough training, but wish that they had more opportunity to spend with users. The analysis of their statements is confirmed by research studies recommending the implementation of structured diabetes management program into every physician office to optimize insulin pump therapy (Lange, Ziegler, Neu, Reinehr, Daab, Walz, Maraun, Schnell, Kulzer, Reichel, Heinemann, Parking, & Haak, 2015; Peters, Ahmann, Battelino, Evert, Hirsch, Murad, Winter, and Wolpert, 2016). The trainers' strategy of behavior modification and encouragement to achieve that users meet the challenge of learning the insulin pump interface with the right attitude reduces a user's learning curve.

For the last of the seven interview questions, participants were provided with the opportunity to make additional statements about things that were important to the trainer. Within the context of the super-ordinate theme *The Voice*, these statements provided a wealth of answers for sub-question 4. Question 7—*What are your impressions about the process of learning insulin pump self-care management?*—was designed to elicit additional responses from participants to enhance the data.

All participants shared information about experiences that made their job more difficult, and the most striking comment by participants was the question about a user's unwillingness to learn the steps and comply with the requirements. Individuals who are not willing to learn will ignore information input and prevent information processing (Schneider & Shiffrin, 1977), because they refuse to aim their attention to the learning material. This is consistent with the findings by Jayasekara et al. (2011), Lawton et al. (2016), McAdams and Rizvi (2016), Ritholz et al. (2007), and Tanenbaum et al. (2018) who posited that an individual needs to be motivated and must be able to embrace pump technology. As an exception to the participants' willingness to engage in remedial efforts to bring a user up to speed is when they face users who—despite well-meant intervention by these trainers—exhibit behavior that indicates non-compliance.

In addition, participants commented that prescribing physicians need to be more "selective" about potential insulin pump users. For this reason, #40, who has extensive experience in training users on insulin pumps, is proactive about making the prescribing physician aware about an unwillingness of a user to engage in the learning process and comply with basic requirements in the handling of the pump. According to Peters et al. (2016), a user's mental and psychological abilities need to be evaluated before deciding on a selection. This is their recommendation in the internationally co-sponsored medical practice guideline for insulin pump therapy used as a reference for treatment decision made by many physicians. According to the findings by Lawton et al. (2016), however, psychosocial criteria as predictors for the success of insulin pump therapy are of limited value, because health care professionals occasionally make subjective assumptions individual's suitability for insulin pump therapy. In their study about barriers to insulin pump adoption, Barnard and Breton (2018) reported that their participants' assumptions about personal and psychological suitability had been challenged by "observing individuals make effective use of CSII who they would not have recommended for this type of therapy in routine clinical practice" (p. 3).

Most participants pointed out the wealth of information that is available to learn more about insulin pump therapy: Supplemental software applications ("Apps"); YouTube videos; books; user guides received with the pump; forums; diabetes support societies; etc. Even if a user failed to prepare in advance for the insulin pump training sessions and is exposed to a steep learning curve as a result, participants urged that users are able to catch up and should engage in a continuous learning process, regardless. The analysis of their statements is consistent with the findings by Heinemann et al. (20150, Reece and Williams (2014), the REPOSE Study Group (2017), and Wheeler et al. (2014) that insulin pump therapy needs to include ongoing training of the user.

Some participants provided uplifting input to improve learnability and ease of use of the insulin pump programming interface. Participant #12 engaged in a detailed discussion how one pump manufacturers engages in research and development activities to promote the “human factor” and she stated that their effort is making it easier to learn and manage the insulin pump software. Other participants also touched on the topic of improvements she has seen in other models. The analysis of their feedback is consistent with the studies by Heinemann et al. (2015), Schaeffer (2013), and Schaeffer et al. (2015), who posited that learnability and ease of use can be improved by adhering to human factors engineering principles.

Several participants who train on multiple pumps unanimously declared that a touchscreen pump is easier to use. These participants stated that it takes them less time to train the user. This is in contrast to statements by other participants who believed that insulin pumps with touchscreen interfaces are more suitable for individuals with smartphone experience. Their assumptions are not consistent with a recent study by Waldenmaier et al. (2018), who discovered that, for a number of critical tasks, the touchscreen pump required more key strokes by the user to complete the task. Nested menus are characteristic for both the touchscreen pump models and the pump models with chevron-style navigation buttons, and menu design on both pump interfaces is bound by the task sequences that need to be executed. Gindrat et al. (2015) found that cognitive activity differs between input types, but made no inferences that one input type was superior to the other in regards to learnability and ease of use. The participants’ subjective statements regarding the learnability and ease of use of touchscreen type interfaces warrants further investigation.

**Strengths, Weaknesses, and Limitations**

The strengths of this study lie in its novel context and in the researcher's ability to understand the medical jargon used by participants to describe their experiences. No known published study on infusion pump usability exists that presents findings obtained from the health care professionals who train users. In addition, the researcher's knowledge of insulin therapy for individuals suffering from diabetes allowed her to easily grasp the significance of the participants' statements about the obstacles they presented regarding disease management. The researcher was able to find useful patterns, identify connections, and present the super-ordinate themes in a plausible manner.

While the researcher's connection to the study was considered a strength, it could also be considered a weakness, because the researcher had an eleven-year employment history at a Northcentral Florida diabetes clinic which included training of disease management for individuals suffering from diabetes. Her assumptions about insulin pump management could have easily introduced bias into the study. Every attempt was made to deflect previous assumptions and to listen to participant's responses with an open mind. The researcher used journaling to help deflect ideas containing bias, and performed a meticulous review of medical journals on the subject of insulin pump therapy, which enabled her to address this weakness.

The small sample size of six participants, including the pilot, was not considered a weakness of the study. In phenomenological studies, a sample size of five or more is generally acceptable if attaining additional new information is no longer feasible (Clark et al., 2015; Creswell, 2013; Morse & Richards, 2002). The interview process resulted in data "rich in quality" and "thick in quantity" (Fusch & Ness, 2015, p. 1409), and the researcher felt confident that she had conducted "sufficient in-depth engagement with each individual case" (Smith & Osborn, 2015, p. 29).

Another weakness was that the researcher was the only individual who conducted the analysis and interpretation of the data collected. Triangulation of the research data to obtain "corroborating evidence" (Creswell, 2013, p. 251) from another investigator was not an option for this study. According to Smith et al. (2012), applying rigor to ensure "thoroughness" (p. 181) is a factor that contributes to validity of the results, which the researcher demonstrated by performing a detailed description of the analytical process and interpretation of the data.

A limitation was that the study participants were recruited within the United States. This limits the findings to the cultural context of the participants' country of origin. A further limitation was that the study was focused on training sessions with users new to insulin pump therapy. The participants were instructed to provide information exclusively about users new to insulin pump therapy, *not* about users switching to another model of insulin pump.

**Implications**

No known published qualitative research exists that presents findings about insulin pump trainer experiences during their training sessions with patients who are new to insulin pump therapy. This study has implications for information systems professionals, who conduct research on the safe design and usability of safety critical medical devices. According to Campos et al. (2014), continued research is necessary to better understand how an infusion pump is operating in practice. The research also has implications for health care professionals involved in the treatment of diabetes who are concerned with identifying predictors of success in insulin pump therapy (Lawton et al., 2016). Individuals who have an interest to approach the self-management of diabetes with insulin pump therapy can benefit from the findings of this study, as well.

In addition, the findings create opportunities for health care professionals to improve the initiation of insulin pump therapy in patients with diabetes, and for information systems researchers focusing on usability studies to extend or replicate the study in future research.

**Recommendations for Practice**

The following recommendations are designed for practice to improve health care delivery for insulin pump patients. As a matter of priority, insulin pump trainers deserve attention from other members of the user's health care team, including the health care providers, when they attempt to provide input about the prerequisites for the insulin pump training sessions and about the expectations for adopting insulin pump therapy. Users should be more encouraged by their health care team to be diligent in the compliance of their treatment regimen, because it is the principal means to receive more benefits from insulin pump therapy, when compared with multiple daily injections (Jayasekara et al., 2011; Reece & Williams, 2014; Shah, 2018). In addition, the users' health care team should ensure that users understand medical terminology, diabetes management, and carbohydrate counting prior to the training sessions. Diabetes education sessions are usually available at local hospitals where users can learn from certified diabetes educators who will encourage them to be proactive about managing their diabetes.

Furthermore, insulin pump trainers should be allotted more time with their users while initiating pump therapy, particularly, when they have to first teach a user the basics about insulin therapy in general, such as carbohydrate counting, before they can even commence with the training to teach users how to use the device.  Post-training support for users new to insulin pump therapy needs improvement and requires increase of the number of technical support specialists for those situations, when users have an after-hour emergency and cannot get through to a support agent on the manufacturer's support hotline.

More opportunities for training should be provided for health care providers who prescribe insulin pumps and for health care professionals who make pump adjustments, because the feedback from the participants about their perceived lack of expertise is alarming.  This recommendation should also extend to health care providers who are familiar with insulin pump therapy, but do not have a complete grasp on who could benefit from insulin pump therapy within their patient population.

Ongoing training sessions with users who are receiving insulin pump therapy is needed to ensure that users stay in compliance and receive optimal benefits from this therapy (REPOSE Study Group, 2017; Wheeler, 2014).  This can be done in form of group sessions and voluntary support sessions where insulin pump users are encouraged to engage in learning from presentations and from the interaction with one another.  A waiver can be signed by each session participant to ensure compliance with the disclosure of private information according to the Health Insurance Portability and Accountability Act (HIPAA).

Users should be familiarized with the different models of insulin pump therapy and be allowed to make informed decisions which pump model and interface type they would be most comfortable with.  For example, premature judgements about a user's ability to manage a certain model and interface type based merely on their age are inconclusive. Young adults who may be familiar with smartphone technology may not show a positive attitude towards adopting diabetes technology, regardless of the pump interface type (Tanenbaum et al., 2018).

Insulin pump trainers should receive recognition for the important role they play in the initiation of insulin pump therapy for users, because they can make valuable contributions to other stakeholders to ensure continued success of this type of therapy.

## Future Research

This study was limited to the experiences of insulin pump trainers during training sessions with users who are new to insulin pump therapy. Recommendations for future research should include studies to research insulin pump trainer experiences during sessions with users who are switching to another model pump. This would facilitate discoveries to determine the antecedents for adopting another insulin pump model.

Another area of research could consist of a survey of users who initiated pump therapy on their own without any formal instruction from trainers or members of the user's health care team. Their experiences could provide insight about usability and learnability problems experienced in a self-guided learning environment. Such findings can be compared with findings from this study which is important for information systems professionals concerned with the improvement of the design of an insulin pump interface and software. In addition, a structured survey of this group of users with a suitable instrument to assess usability issues could enable researchers to evaluate the results statistically. Their conclusions can provide further insight for information systems professionals involved in the design of insulin pump interfaces and software, and for instructional designers to improve learning material for insulin pumps and enhance insulin pump training strategies.

The conditions that insulin pump trainers are subjected to during training sessions should be further explored. Trainers are faced with multiple obstacles during the insulin pump training sessions with users for which they assume responsibility to ensure a positive outcome. Questions also remain about the role ambiguity trainers are subjected to and how that shapes their actions and attitudes. Assessing insulin pump trainers' coping mechanisms could provide other health care professionals with insight about what is required in practice to bring a patient's skill level up to a point where they can safely manage the insulin pump on their own. The findings from a future study that examines participants' training strategy contributing to insulin pump therapy success more closely could also provide other health care professionals with insight.

A further area of research that deserves attention is to identify the antecedents that prompt users to become better prepared for insulin pump therapy initiation, and to comply with self-management tasks to receive optimized benefit from the therapy (Reidy et al., 2018; Shah et al., 2018). Further research is needed to quantify the benefits obtained from insulin pump therapy in comparison with multiple daily injection therapy. This can be done by assessing users' overall well-being with a suitable survey instrument. Information can also be collected from users' health information records and lab results, if appropriately obtained within legal guidelines, and further evaluated.

Furthermore, useful information can be obtained from investigating the antecedents that prompt some users to drop insulin pump therapy and return to multiple daily injection therapy, as noted by Grose, O'Brien, and Castle (2017). Participants provided detailed statements on what they believe constitutes a suitable insulin pump patient. The analysis of the findings based on these data are grounded in medical research studies, but further research is needed to establish a valid measure that can be used during the selection process for insulin pump therapy.

This study was limited to participants' experiences while performing training sessions for insulin pump therapy. Further research is recommended to determine if insulin pump adoption is impacted by a user's choice to self-monitor blood glucose with a continuous glucose monitoring device (also worn as a bodily attached sensor), instead of performing multiple fingersticks per day. Previous studies that research this area have been limited to evaluation or observation of users in a controlled environment. Further studies are needed to enhance the understanding from the perspective of insulin pump trainers, who are simultaneously hired or contracted to train users on continuous glucose monitoring systems when initiating insulin pump therapy.

Furthermore, it would be helpful to assess the knowledge of health care providers who prescribe insulin pumps and the knowledge of health care professionals to whom users turn when experiencing issues with managing the pump. The findings from this type of study can be used to determine the extent of their abilities, and use the conclusions obtained to improve practice.

## Summary

Diabetes mellitus 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). Insulin pump therapy is more beneficial to patients than the administration of multiple daily injections with insulin, because it is more efficient in the reduction of fluctuations in blood glucose levels when properly used (Heinemann et al., 2015).

The safety critical nature of medical devices such as insulin pumps to control a potentially fatal medical condition is widely discussed in the literature. Previous studies about usability issues with insulin pumps were conducted on the basis of behavior observation with users during simulated task execution. Furthermore, evaluations of the safety critical aspect of insulin pumps that aimed to identify design flaws and to eliminate task execution errors due to inconsistent user interface features were conducted in controlled environments (Campos et al., 2014). The reduction of errors is critical, because a wrong dosage of insulin delivered to the body can create harm to the user (Heinemann et al., 2015). The characteristics of system behavior during operation and proper analysis of the system based on realistic problems remain elusive. A gap was discovered in the understanding of what constitutes a realistic scenario.

The goal of the study was to uncover new insights about usability issues on insulin pump interfaces as observed by health care professionals when they train first-time users how to manage their chronic condition of diabetes with the device. The study aimed to extend the efforts of Campos et al. (2014) by examining the lived experiences and shared impressions of insulin pump trainers, and to gain knowledge about a more precise specification about events that occur in a real-life setting, as trainers describe as their experiences during insulin pump training with first-time users. The observation-based usability study by Schaeffer et al. (2015) was used to provide the ontology to classify phenomena.

The overarching research question for this study which served as the grand tour question guided 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 highlighted 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?

A phenomenological research design using interpretative phenomenological analysis (IPA) provided the basis to reveal the personal meaning that the trainers attach to their lived experiences (Smith & Osborn, 2015). To organize the steps throughout the process of analysis and interpretation, the researcher applied an analytical framework approach adapted from Bonello and Meehan (2019), and from Chong (2019) that encapsulated IPA methods as recommended by Smith et al. (2012), and by Smith and Osborn (2015).

Six participants representing a homogeneous sample were recruited from a wide geographic area in the United States, and semi-structured interviews containing open-ended questions were conducted with the respondents. The participants either worked for one of three major insulin pump manufacturers in the United States, or worked as independent contractors who regularly perform insulin pump training. Their business designations included Registered Nurse, Registered Dietician, Certified Diabetes Educator, Clinical Manager, and Clinical Business Manager. All participants were insulin pump certified by one or several manufacturers. To compensate the participants for their valuable professional time, each of them received a $100 VISA gift certificate after completing the interview.

The transcription of the interviews was performed by a certified medical transcription service. The transcribed interviews were analyzed by the researcher, following a process of thorough coding, analysis, organization, triangulation, and interpretation of the data. The researcher used journaling to track her progress and to help deflect ideas and assumptions containing bias stemming from her work experience in a Northcentral Florida diabetes clinic. A systematic review and interpretation of the lived experiences of the participants resulted in the development of five super-ordinate themes:

1. *Emotion-Charged Environment* – Users' fears, frustration and distrust are met by the trainers with compassion, honesty and reassurance. Trainers work hard to counteract these negative sentiments to facilitate the learning process, using encouragement and other strategies of behavior modification to reduce the learning curve.
2. *Personalized Training* – Pump manufacturers provide trainers with a checklist that outlines all the steps to be taken. The reality is, however, that users arrive at the training sessions with unpredictable levels of basic knowledge about

diabetes care or with little or no advance preparation. Therefore, the training is conducted around the individual's needs, and trainers will do whatever it takes to achieve a positive learning outcome.

3. *Safety Issues and Disaster Planning* – Training users to troubleshoot is the key to safety in insulin pump therapy. Furthermore, insulin pumps can fail unexpectedly and there has to be a *Plan B* that involves preparations to resume insulin therapy with other means.
4. *Professional Dedication* – In addition to the training sessions, trainers perform diabetes education, teach carbohydrate counting, ensure that the user has a support system, and perform post-training technical support. These activities are usually beyond the scope of the training sessions. The trainer assumes responsibility for the learning outcome where other members of the user's healthcare team fail. The pivotal moment occurs when a user reports back to the trainer that they feel so much better since they have started using the insulin pump. The user's positive feedback becomes a meaningful experience for the trainer.
5. *The Voice* – Successfully initiating a patient on an insulin pump for the first time is where the therapy becomes alive. The participants' feedback can make valuable contributions to stakeholders to ensure continued success of this type of therapy.

The results of the study revealed that the trainers' lived experiences were indeed shared among the six participants to a large degree. The connections between the five super-ordinate themes center on the obstacles encountered when trainers first meet with users and have to deal with their negative sentiments in order to exercise control over the learning environment. The trainers' strategy is supported by their personal skill set to reduce the learning curve. They use reassurance, compassion, honesty, and trust-building in order to facilitate a positive learning outcome.

Overcoming the negative sentiments and meeting the users' concerns by setting them at ease connects the training to the issue of safe handling of the insulin pump. Troubleshooting and a *Plan B*—disaster planning during pump malfunctions—is part of a targeted approach to help users master the learning process. The trainers' professional dedication is reflected in their description about the extra effort they apply to complete the training sessions, and in their statements about the joy the feel during the "magical" moment when insulin pump therapy is successfully initiated.

The insulin pump trainers are the primary facilitator of insulin pump therapy, and their feedback and recommendations are important to other stakeholders. Participants made statements that they are concerned when faced with users' failure to prepare for the sessions in advance, and with their lack of knowledge about insulin therapy, in general. The trainers believe that users are largely unaware of the responsibility required to handle the pump correctly, and are hoping that their recommendations would stimulate positive change.

The following conclusions were reached that provided insights and answers to the overarching research question and the four sub-questions:

**Grand Tour Question. What is the essence of the experiences of insulin pump trainers while they teach first-time users how to use the device?** The very nature of the trainers' experience occurs during the pivotal moment when the training is completed successfully and insulin pump therapy becomes alive. This fills the trainers with great joy and satisfaction, and provides meaning to their experience. Trainers navigate through a number of challenges of their own associated with user negative sentiments, with their unpreparedness, and their reluctance or ignorance to comply with basic diabetes management skills. Trainers are motivated to reach a positive learning outcome because of their commitment to their profession and because they equate their reward with the benefits that users receive from the trainers' efforts (Locke & Latham, 1990).

**Sub-question 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?** Individuals with diabetes have coping issues, and the mental burden to deal with their chronic condition is excessive (Tanenbaum et al., 2018). Under these conditions, safe use is impacted because of the distraction that the distress experienced by the users represents (Khan & Choudhary, 2018). Trainers use their enormous skills set of setting users at ease to overcome the users' negative sentiments. It was also discovered that users frequently ignore pump warnings about occlusions in the line—insulin delivery is blocked—due to a condition called alarm fatigue (Heinemann et al., 2015). Users also may overlook occlusions and fail to act when their blood sugar rises abnormally and the pump software does not sense the issue and fails to trigger an alarm.

**Sub-question 2. Which of these problems observed relate to the interface characteristics of the device?** During initial setup, the pump may time out due to input delay, and the settings have to be reentered. In addition, users appear to either be apprehensive to push buttons on the device, or push buttons randomly in frustration to recover from an error. Furthermore, task sequences in the pump software may not match the order in which the user normally performs tasks, and this causes confusion. Users may forget steps, when they are in a hurry or if their attention span diminishes. Users may fail to hit the *CONFIRM* button included in certain pump software interfaces. In models that do not feature a *CONFIRM* button, users may not realize that the command is executed and that the task has commenced. Users occasionally confuse AM and PM when resetting the pump after a battery change or when making changes to their basal rate.

**Sub-question 3. What type of usability errors are encountered when trainers teach first-time users how to program their insulin pump?** Answers and insights for this research question resulted in a large overlap with answers and insights provided for sub-question 2. Additional insights gained from the statements of the participants revealed that users often forget to hit *DELIVER BOLUS* in the software menu to start a meal or after an abnormal glucose reading. Frequent observations by participants were the unpreparedness of users, the users' unfamiliarity with terminology, and their lack of knowledge of carb counting. The inability of users to integrate diabetes management into their day to day living is eventually manifested as usability errors, because it represents additional constraints in the system and prevents users in achieving their goals. Examples of findings regarding usability errors include problems finding the pump serial number in the right place, or activating auto-suspend, but failing to reset the 12 hour alarm threshold. Many participants reported that they observe frequent usability errors in distinct patient populations; some related to perceived cognitive decline, such as the elderly, or related to disabilities, such as the vision impaired.

**Sub-question 4. What can trainers tell us about the learnability and ease of use of the insulin pump programming interface?** Participants asked for collaboration between trainers and other members of the user's health care team to help prepare users for insulin pump therapy. They recommend that other members of the health care team invest in the training preparations by better clarifying expectations and reinforcing requirements for insulin pump therapy. These requirements were most often cited as knowledge of terminology, carb counting skills, and frequent blood glucose monitoring. Participants believe that learnability and ease of use is affected by these factors. Participants also stipulated that users should be proactive about acquiring these skills and be ready to embrace the technology, including advance preparation to get ready for training.

Trainers understand the crucial role they play to overcome complexity and to eliminate unrealistic expectations by users and possess a repertoire of creative strategies to overcome these obstacles and reduce the complexity of insulin pump management. Participants expressed that [most] everyone can learn how to use an insulin pump, but the findings show that it is up to the trainers to be mindful and creative to make it happen. When trainers convey to users the advantages an insulin pump has to offer, such as the automatic calculation of bolus dosage based on their input, it positively affects the perceived ease of use of the insulin pump software. Once users acquire troubleshooting skills and understand the mechanical function of the pump, it helps to subdue their concerns about the complexity of the insulin pump software, and this improves learnability. Participants believe that—with enough training—anyone can learn, and wish they could have more time with their patients.

This study has implications for information systems professionals, who conduct research on the safe design and usability of safety critical medical devices. The research also has implications for health care professionals involved in the treatment of diabetes who are concerned with identifying predictors of success in insulin pump therapy (Lawton et al., 2016). Individuals diagnosed with diabetes and who have an interest to approach the self-management of the disease with insulin pump therapy can benefit from the findings of this study, as well.

The following recommendations are designed for practice to improve health care delivery for insulin pump patients. Feedback from insulin pump trainers can make valuable contributions to stakeholders to ensure continued success of this type of therapy. Other members of the patient's health care team should collaborate with insulin pump trainers to ensure that the users are prepared. Insulin pump trainers should be allowed more time with patients and be compensated for the extra effort. Post-training support issues at the manufacturer level need to be addressed. All members of the patient's health care team need to be adequately trained in the delivery of insulin therapy, including the providers who prescribe insulin pumps. Patients should be allowed input as to the type of insulin pump they are most comfortable with. Ongoing training sessions for insulin pump users should be arranged throughout the duration of therapy.

Recommendations for future research include the identification of antecedents that prompt patients to switch to another insulin pump model. Usability challenges encountered by users when self-starting on the pump could provide further insights for information systems professionals testing interface design. The antecedents that would induce users to come better prepared to the training sessions could be useful, because that ties in with the issue about the suitability of a given individual to be recommended for pump therapy. The insulin pump device is a vital component for insulin pump therapy, but there are other technological advances such as continuous glucose sensors, wireless glucose meters, and smart phone apps that could further be examined to determine their impact on the learning process for insulin pump therapy. Further research on the improvement of diabetes control through insulin pump therapy, compared with multiple daily injections, is of vital interest to the medical community.

Assessing insulin pump trainers' coping mechanisms could provide other health care professionals with insight about what is required in practice to bring a patient's skill level up to a point where they can safely manage the insulin pump on their own. The findings from a future study that further examines insulin pump trainers' instructional strategy for successful insulin pump therapy initiation could provide other health care professionals with insight. For future research, it would also be helpful to assess the knowledge level of health care providers who prescribe insulin pumps and the skill level of health care professionals to whom users turn when experiencing issues with managing the pump.

# Appendices

# Appendix A

## Recruitment Flyer for Participation in the Research Study

This flyer was distributed to prospective participants via Email, via Social Media postings (e.g., LinkedIn), and in person to pharmaceutical and medical device representatives who are engaged in the treatment of diabetes mellitus.

**Recruitment Flyer for Participation in the RESEARCH STUDY Entitled**
*Usability Challenges with Insulin Pump Devices in Diabetes Care:*
*What Trainers Observe with First-Time Pump Users*

**Document Date**: September 22, 2018

**Principal Investigator and Contact:** Helen B. Hernandez, MISM, BA, 921 Aspen Drive, South Daytona, FL 32119. Telephone: 386-872-0483 Email: hh436@mynsu.nova.edu

Dear Health Care Professional,

We are reaching out to you with an invitation to participate in a research study that designed to analyze the experiences of health care professionals who have experience training patients for insulin pumps therapy. The focus of the study is to obtain the narrated experiences of insulin pump trainers during their training sessions with first-time users of insulin pumps.

To participate in this research, we are looking for individuals who have performed at least one training session within the last year. We require that you are currently (or have been recently) insulin-pump training certified through a medical device manufacturer or through a national accredited institution, such as the National Certification Board for Diabetes Educators (NCBDE).

You will be asked to participate in a one-time scheduled teleconference via Skype or by telephone for a recorded interview session (45-60 minutes) to answer research questions. There will be an opportunity for you to review the content transcribed from the recorded session. Total time commitment for all activities is approximately 2.5 hours, maximum: 3 hours. The information provided will be used only for this research study and will be de-identified to protect your privacy.

To compensate for the time to get input from busy health care professionals such as you, we will compensate you in the form of a VISA Gift card in the amount of $100.00, once you have approved the transcribed interview session material.

If you are willing to participate, please visit the following link to the prescreening questionnaire to answer four simple questions that will allow us to determine if you meet the prerequisites to participate in this research study: http://www.surveymonkey.com/[Link]

If you have any further questions or concerns about the nature of this research study, please do not hesitate to contact me immediately.

Respectfully,

Helen B. Hernandez, Ph.D. Candidate
Email: hh436@mynsu.nova.edu
Doctoral Program / Ph.D. in Information Systems
College of Engineering and Computing
Nova Southeastern University

# Appendix B

## Online Demographics Questionnaire

This questionnaire served as an initial screening questionnaire and was created and published using SurveyMonkey (https://www.surveymonkey.com). Prospective participants were being directed to the URL of demographics questionnaire from the context of the Recruitment Flyer (see Appendix A). The URL was not made available until permission was received by the dissertation committee to commence with the research.

NOVA SOUTHEASTERN UNIVERSITY
College of Engineering and Computing

**Demographics Questionnaire for the RESEARCH STUDY Entitled**
*Usability Challenges with Insulin Pump Devices in Diabetes Care:*
*What Trainers Observe with First-Time Pump Users*

**Document Date**: September 20, 2018

**Principal Investigator and Contact:** Helen B. Hernandez, MISM, BA, 921 Aspen Drive, South Daytona, FL 32119. Telephone: 386-872-0483 Email: hh436@mynsu.nova.edu

**Demographics Questionnaire to be answered online as a screening activity to identify suitable participants:**

1. What is your current or recent occupation that includes (included) training of patients on insulin pumps? [TEXT BOX]
2. Do you have insulin pump certification status? [Yes/No radio buttons]
3. If not, have you had certification status in the recent past? [TEXT BOX]
4. What is the organization name on your certification? [TEXT BOX]
5. Have you ever trained a patient using an insulin pump for the first time? [Yes/No radio buttons]
6. If yes, how many patients who are using a pump for the first time have you trained? [TEXT BOX]
7. Are you available for a research study to answer questions about your experiences during the training? [Yes/No radio buttons]
8. Please let us know how you would like to be contacted. [TEXT BOX]

# Appendix C

## General Informed Consent Form for Participation in the Research Study

This informed consent form was sent to selected participants for review and approval at the onset of the scheduled interview sessions and prior to the commencement of the interview. It was also provided upon request to any prospective participant making inquiries or seeking more information about their participation in the study.

NOVA SOUTHEASTERN UNIVERSITY
College of Engineering and Computing

**General Informed Consent Form for Participation in the Research Study Entitled**
*Usability Challenges with Insulin Pump Devices in Diabetes Care:*
*What Trainers Observe with First-Time Pump Users*

**Document Date** September 22, 2018

**Who is doing this research study?**

**College:** College of Engineering and Computing
Nova Southeastern University
3301 College Avenue
Ft. Lauderdale, FL 33314-7796

**Principal Investigator:**
Helen B. Hernandez, MISM, BA
921 Aspen Drive
South Daytona, FL 32119
386-872-0483
hh436@mynsu.nova.edu

**Faculty Advisor/Dissertation Chair:**
Laurie P. Dringus, Ph.D.
Professor, College of Engineering and Computing
Nova Southeastern University
3301 College Avenue
Ft. Lauderdale, FL 33314-7796
954-262-2073
laurie@nova.edu

**Site Information:**
Principal Investigator's home via teleconferencing
921 Aspen Drive
South Daytona FL 32119

**Funding:** Unfunded

**What is this study about?**

This is a research study, designed to analyze the experiences of health care professionals and create new ideas that other people can use. The study is being conducted by Helen B. Hernandez (doctoral candidate). The purpose of this research study is to

- Obtain the narrated experiences of insulin pump trainers during their training sessions with first-time users of insulin pumps;
- Obtain examples of interaction with users [patients] while they are programming the pump interface;
- Obtain information about safety critical aspects in diabetes self-care management with the use of insulin pumps.

This study is being done to obtain new insights about the interaction between the user and the insulin pump interface in a real-life setting, also known in research as a Human Computer Interface (HCI) study. This may help to gain a better understanding for medical device software designers about user actions performed in real-life scenarios in a safety critical environment.

**Why are you asking me to be in this research study?**

You are invited to participate in this research study because you as an insulin pump trainer have first-hand insight of the interaction between the user [patient] and their efforts to perform tasks in a real-life setting. We are looking to highlight the human perspective of patients who are engaged in the self-management of a chronic illness like diabetes.

There will be a one participant for an initial pilot study and six additional participants for the primary study.

**What will I be doing if I agree to be in this research study?**

While you are taking part in this research study, you will be asked to participate in a one-time scheduled teleconference via Skype or by telephone for an interview session to provide feedback to approximately seven (7) questions for a total duration of no more than 60 minutes. Immediately preceding this interview session will be about a 15 minute session to go over the informed consent and answer any questions that you have regarding the interview procedures and how your data is being used.

The interview session itself will be recorded and transcribed by a certified medical transcriptionist in a secure environment. The completed transcription will be Emailed or mailed to you, asking for your review and input, potential clarification of items, and your feedback about the discussion. This may take approximately 30 minutes.

**Research Study Procedures**

As a participant, this is what you will be doing:

> The study procedure consists of a list of open-ended questions according to an interview guide. This means that you will be asked one question at a time that pertains to certain aspects of the material we hope to obtain from the study. Open-ended questions are standard procedures used to collect and analyze data for a study of this scope.

**Example Question**:

> *Please tell me about your experiences when you teach patients how to use an insulin pump for the first time.*

You will be replying by providing us with a narrative of your choosing about anything that comes to mind after the question is posed.

**Screening Procedures**

To participate in this research, we are looking for insulin pump trainers who have performed at least one training session with a first-time insulin pump user within the last year. To verify that you have conducted insulin pump training in the past on a professional level, we require that you are currently insulin-pump training certified through a medical device manufacturer or through a national accredited institution, such as the National Certification Board for Diabetes Educators (NCBDE), or have been in the recent past.

**Are there possible risks and discomforts to me?**

This research study involves minimal risk to you from a physical perspective. However, there is a risk of disclosure of non-compliance information and confidential data. All measure will be taken to ensure the confidentiality and privacy of the data recorded, transcribed and stored regarding this study according to the provisions outlined by the Institutional Review Board (IRB). Please see their website at https://www.nova.edu/irb/manual/policies.html **Standard Operating Procedures (SOPs) & Policy** 1-3. Investigator Responsibilities.

Any questions regarding the research itself, your rights or if you believe that you have a research-related injury, please contact Helen Hernandez and Dr. Laurie Dringus. You may also contact the Institutional Review Board (IRB) at 954-262-5369 or Email irb@nova.edu.

Loss of time is a minimal risk to participate in this study. The total time involved for each participant including all activities that include evaluating the potential to participate, completing the inclusion survey, any communication with the research prior or after the teleconference, the teleconference consisting of informed consent clarification and interview session, and the time spent to review the transcription is maximum 3 hours.

**What happens if I do not want to be in this research study?**

You have the right to leave this research study at any time, or not be in it. If you do decide to leave or you decide not to be in the study anymore, you will not get any penalty or lose any services you have a right to get. If you choose to stop being in the study, any information collected about you **before** the date you leave the study will be kept in the research records for 36 months from the end of the study but you may request that it not be used.

**What if there is new information learned during the study that may affect my decision to remain in the study?**

If significant new information relating to the study becomes available, which may relate to whether you want to remain in this study, this information will be given to you by the investigators. You may be asked to sign a new Informed Consent Form, if the information is given to you after you have joined the study.

**Are there any benefits for taking part in this research study?**

There are no direct benefits from being in this research study. We hope the information learned from this study will provide new insights for health care professionals and those involved in the design of medical device software interfaces.

**Will I be paid or be given compensation for being in the study?**

You will be given the following compensation for being in the study:

- VISA Gift Card in the face amount of $100.00 to compensate for your time.
- This will be paid upon return of the transcribed interview with confirmation of the authenticity of the transcription or indicating any revisions you would like to make.
- The compensation will not be prorated

**Will it cost me anything?**

There are no costs to you for being in this research study.

**How will you keep my information private?**

Information we learn about you in this research study will be handled in a confidential manner, within the limits of the law and will be limited to people who have a need to review this information.

We will be using random two-digit identifiers for participants during the recording of the interview and subsequent transcription. This data will be available to the researcher, the Institutional Review Board (IRB) and other representatives of Nova Southeastern University, and any regulatory and granting agencies (if applicable). If we publish the results of the study in a scientific journal or book, we will not identify you. All confidential data will be kept securely stored on a single desktop computer at 921 Aspen Drive, South Daytona FL 32119, with password protection only known to the principal investigator.

The original signed consent to participate will be scanned and an image kept on the same desktop computer, password protected. The original hardcopy will then be shredded. A backup of the data will be kept on an external Western Digital backup drive with encryption and with password protection and only be accessible to the principal investigator. All data will be kept for 36 months from the end of the study and destroyed after that time by erasing the data files, removing them from the computer's and external backup drive's 'Recycle bin' and running a utility such as CCleaner to verify that all deleted files have been removed from the computer's and the external backup drive's file storage partitions.

**Will there be any Audio or Video Recording?**

This research study involves audio and/or video recording. The recording will be transcribed by a private, professional certified medical transcriptionist. This recording will be available to the researcher, the Institutional Review Board, and the named dissertation chair, the named coinvestigators of the study and the professional transcriptionist. The medical transcriptionist will be asked to certify that she has destroyed the recording and the transcribed information from her hard drive after completion of transcription.

The exchange of recordings and transcriptions between the principal investigator and the transcriptionist will be done via a secure, encrypted file transfer service, such as Exavault. The recording will be kept, stored, and destroyed as stated in the section above. Because what is in the recording could be used to find out that it is you, it is not possible to be sure that the recording will always be kept confidential. The researcher will try to keep anyone not working on the research from listening to or viewing the recording.

**Whom can I contact if I have questions, concerns, comments, or complaints?**

If you have questions now, feel free to ask us. If you have more questions about the research, your research rights, or have a research-related injury, please contact:

Primary contact:
Helen B. Hernandez, MISM, BA can be reached at (386) 872-0483 or via Email: hh436@mynsu.nova.edu

If primary is not available, contact:
Laurie P. Dringus, Ph.D. can be reached at 954-262-2073 or via Email: laurie@nova.edu

**Research Participants Rights**
For questions/concerns regarding your research rights, please contact:

Institutional Review Board
Nova Southeastern University
(954) 262-5369 / Toll Free: 1-866-499-0790
IRB@nova.edu

You may also visit the NSU IRB website at www.nova.edu/irb/information-for-research-participants for further information regarding your rights as a research participant.

**Research Consent & Authorization Signature Section**

Voluntary Participation - You are **not** required to participate in this study. In the event you do participate, you may leave this research study at any time. If you leave this research study before it is completed, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

If you agree to participate in this research study, sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

**SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:**

- You have read the above information.
- Your questions have been answered to your satisfaction about the research.

**Adult Signature Section**

I have voluntarily decided to take part in this research study.

| | | |
|---|---|---|
| Printed Name of Participant | Signature of Participant | Date |
| Helen B. Hernandez | Signature of Person Obtaining Consent & Authorization | Date |

# Appendix D

## Interview Guide for the Research Study

This document contains warm-up questions that were used to facilitate the interview process and make the participant comfortable with the interaction. The subsequent interview questions were used to elicit information from the participants during the scheduled interview.

NOVA SOUTHEASTERN UNIVERSITY
College of Engineering and Computing

**Interview Guide for the RESEARCH STUDY Entitled**
*Usability Challenges with Insulin Pump Devices in Diabetes Care:*
*What Trainers Observe with First-Time Pump Users*

**Document Date**: September 20, 2018

**Principal Investigator and Contact:** Helen B. Hernandez, MISM, BA, 921 Aspen Drive, South Daytona, FL 32119. Telephone: 386-872-0483 Email: hh436@mynsu.nova.edu

**Warm-up Questions immediately preceding the Interview:**

1. How has your day been so far?
2. You work as an [ABC] in the healthcare sector?
3. Diabetes care is your main focus then?
4. For which pump models have you trained in the past?
5. Can you explain what you think might be a trend that patients increasingly want to get a handle on managing their diabetes?

**Interview Guide Questions:**

1. Please tell me about your experiences when you teach patients how to use an insulin pump for the first time.
2. Please tell me about any problems in general you observe during the sessions with your users.
3. What type of feedback are users giving you about problems they encounter?
4. Please provide some detail about the tasks you assign to the patients to program the pump with their own individual settings.
5. Please describe what issues you may have noticed with the programming of the pump.
6. What are your impressions about the patients acquiring the necessary skills to safely manage their diabetes with this new tool?
7. What are your impressions about the process of learning insulin pump self-care management?

# Appendix E

## Memorandum from Center Representative of the Institutional Review Board

The memorandum documents the determination of exemption from further IRB review under 45 CFR 46.101(b).

**MEMORANDUM**

To: **Helen Hernandez**

From: **Ling Wang, Ph.D.,**
**Center Representative, Institutional Review Board**

Date: **September 25, 2018**

Re: **IRB #: 2018-477; Title, "Usability Challenges with Insulin Pump Devices in Diabetes Care: What Trainers Observe with First-Time Pump Users"**

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I have reviewed the above-referenced research protocol at the center level. Based on the information provided, I have determined that this study is exempt from further IRB review under **45 CFR 46.101(b) ( Exempt 2: Interviews, surveys, focus groups, observations of public behavior, and other similar methodologies)**. You may proceed with your study as described to the IRB. As principal investigator, you must adhere to the following requirements:

1) CONSENT: If recruitment procedures include consent forms, they must be obtained in such a manner that they are clearly understood by the subjects and the process affords subjects the opportunity to ask questions, obtain detailed answers from those directly involved in the research, and have sufficient time to consider their participation after they have been provided this information. The subjects must be given a copy of the signed consent document, and a copy must be placed in a secure file separate from de-identified participant information. Record of informed consent must be retained for a minimum of three years from the conclusion of the study.

2) ADVERSE EVENTS/UNANTICIPATED PROBLEMS: The principal investigator is required to notify the IRB chair and me (954-262-5369 and Ling Wang, Ph.D., respectively) of any adverse reactions or unanticipated events that may develop as a result of this study. Reactions or events may include, but are not limited to, injury, depression as a result of participation in the study, life-threatening situation, death, or loss of confidentiality/anonymity of subject. Approval may be withdrawn if the problem is serious.

3) AMENDMENTS: Any changes in the study (e.g., procedures, number or types of subjects, consent forms, investigators, etc.) must be approved by the IRB prior to implementation. Please be advised that changes in a study may require further review depending on the nature of the change. Please contact me with any questions regarding amendments or changes to your study.

The NSU IRB is in compliance with the requirements for the protection of human subjects prescribed in Part 46 of Title 45 of the Code of Federal Regulations (45 CFR 46) revised June 18, 1991.

Cc: Laurie Dringus, Ph.D.
Ling Wang, Ph.D.

# Appendix F

## Interview Preparation and Interview Day Guide

This document contains step-by-step instructions and was used to guide the researcher through the entire interview process.

# Interview Preparation and Interview Day Guide

## Preparation

1) **Test the Skype Connection** - Sit down at your computer with Joe in the other room to view the connection.

2) **Practice the Interview** – Perform a test session with Joe in the other room obtain feedback and also time the interaction.

3) **Supply Checklist** - make sure you have everything you need to conduct each interview.

- Waiver
- Olympus Recording Device
- Journal for notes
- Pen(s)
- Cup of Water

## Interview Day

- **Welcome and Warm-up Questions → learn by heart and intersperse during the orientation**

  How has your day been so far?

  You work as an [ABC] in the healthcare sector?

  Diabetes care is your main focus then?

  For which pump models have you trained in the past?

  (Can you explain what you think might be a trend that patients increasingly want to get a handle on managing their diabetes?)

- **Explain Agenda**

  First, I will take a few minutes to explain how the interview is conducted.

  Then, I will have you sign a waiver that indicates your willingness to participate in this study and lets you know that I will be recording the interview and be taking notes of your comments, but will keep all your personal information private.

  Finally, I will start the recording and proceed with the interview.

- **Grab the Interaction Template**
- **Verify receipt of the waiver on the phone (if necessary).**
- **Start the recording on the Skype.**
- **Start the recording on the Digital Voice Recorder**

- **Proceed with the questions (make sure you don't mention their name)**

**Question 1;**

Please tell me about your experiences when you teach patients how to use an insulin pump for the first time.

**Question 2:**

Please tell me about any problems in general you observe during the sessions with your users.

**Question 3:**

What type of feedback are users giving you about problems they encounter?

**Question 4:**

Please provide some detail about the tasks you assign to the patients to program the pump with their own individual settings.

**Question 5:**

Please describe what issues you may have noticed with the programming of the pump.

**Question 6:**

What are your impressions about the patients acquiring the necessary skills to safely manage their diabetes with this new tool?

**Question 7:**

What are your impressions about the process of learning insulin pump self-care management?

**Is there anything you would like to add?**

---

- **Stop Recording.**
- **Wrap up and reminder that they will be receiving the transcription for approval.**
- **Gift certificate in the mail – verify address.**
- **Thank you for your cooperation, the interesting information your provided and for your patience while we go through these questions.**

# Appendix G

## Interview Day Interaction Template

This document contains a guide that helped the researcher stay focused when setting the stage and preparing the participant for the recording portion of the interview about to take place.

## Interview Day Interaction Template

Welcome and Purpose

Thank you for agreeing to participate in this interview. Today I am asking you to describe your personal experience when you train patients for insulin pump therapy who are first-time users and new to insulin pumps. My overall goal is to use the description of your experiences to provide an analysis later. My ultimate goal is to use your observations to share with the medical community and with the computer science community what constitutes a real-life, actual scenario of pump usage.

And also: To raise awareness what it is like to train a patient on a medical device for the self-management of their condition.

I have very little assumptions about the nature of the training experience, and I have never trained a patient on pump therapy. Since this is a study about human computer interaction, I will be asking questions about problems encountered, but I also want to hear about successes that describe the training session experience. -- I will be happy to answer more questions about the study either right now or after the interview.

Just to let you know, I will make small notes from time to time if something comes to mind that I either need to ask you later, or something that corresponds to a journal that I reviewed; so, I may ask you to clarify statements that you make from time to time.

Test Participant's Role

I will ask you a total of seven questions to guide your narrative around certain topics that I am researching. Do not hesitate to use medical or technical terms such as 'postprandial' or 'premeal bolus'. I would like you to give me specifics what happens during the training scenarios with a patient new to pump therapy.

Things to Keep in Mind

Here are some things that you should know about your participation:

- There are no right or wrong answers. If you have any questions, comments or areas of confusion while you are working, please let me know.
- If you feel that you have already answered a question in a different section or: if you don't have anything to add to a specific question, please let me know. I will then make a note and move on to the next question.
- Your name or identity will not be associated or reported with data or findings from this evaluation. If you have not already done so, let's complete the Informed Consent form now and you can take a snapshot of your signature and text it to me at 386-872-0483.
- Finally, the audio portion of the interview will be transcribed and you will have an opportunity to review your narrative, in case you want to add something before the interview data is used in the study.

Do you have any questions before we begin?

# Appendix H

## Outline of Analytical Procedures

This diagram illustrates the three phases of analytical procedures mentioned in Chapter 3, and further described in detail in Chapter 4 of the dissertation. These procedures were applied to code and analyze the transcribed interview data in preparation for presenting the results in Chapter 4.

# Outline of Analytical Procedures

"Area of Curiosity" (Chenail, 1997, p. 5): **Discover the lived experiences and shared impressions | of insulin pump trainers.**

"Mission Question" (p. 5): **Uncover the phenomena associated with usability challenges.**

## Phase 1: Data Coding according to IPA Methods

**(Smith et al., 2012; Smith & Osborn, 2015)**

Stage 1: Descriptive Comments – Things that matter to the participant
Stage 2: Linguistic Comments – Specific use of language and colloquialism
Stage 3: Conceptual Comments – Looking beyond what was being said and draw from my own experiential and professional knowledge.
Stage 4: Deconstruction – what is the meaning of this to the participant (during this stage, I organized the data into preliminary themes)

## Phase 2: Preliminary Data Analysis -- Create a Hierarchical Thematic Framework

**(Bonello & Meehan, 2019; Chong, 2019)**

Stage 1: Refine and condense emergent themes to eliminate redundancy and organize into a master table according to IPA methods; reorder data if deemed appropriate (Bonello & Meehan, 2019)
Stage 2: Review and mitigate any areas within the themes that lacked focus or richness of data. Create subcategories within themes that had large sets of data to facilitate later reporting in the DR.
Stage 3: Prepare for conceptual data analysis by looking for patterns across cases to help drive the analysis to a more theoretical level (Smith & Osborn, 2015, p. 101)

## Phase 3: Conceptual Data Analysis

**Clarke et al., 2015; Chong, 2019; Morse & Richards, 2002; Saldaña, 2016; Smith & Osborn, 2015;**

Stage 1: Deeper level(s) of interpretation by focusing on patterns identified across cases
Stage 2: Identify recurrent themes and applying a conceptual basis to define super-ordinate themes
Stage 3: Finding connections among super-ordinate themes to provide the basis to describe the essence of the insulin pump trainer experience
Stage 4: Move to write-up and presentation of results

# References


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