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Comprehending the Safety Paradox and Privacy Concerns with Medical Device Remote Patient Monitoring

Marc Doyle

Comprehending the Safety Paradox and Privacy Concerns with Medical Device Remote Patient Monitoring

by

Marc Doyle

A dissertation submitted in partial fulfillment of the requirements
for the degree of Doctor of Philosophy
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We hereby certify that this dissertation, submitted by Marc Doyle, 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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Medical literature identifies a number of technology-driven improvements in disease management such as implantable medical devices (IMDs) that are a standard treatment for candidates with specific diseases. Among patients using implantable cardiac defibrillators (ICD), for example, problems and issues are being discovered faster compared to patients without monitoring, improving safety. What is not known is why patients report not feeling safer, creating a safety paradox, and why patients identify privacy concerns in ICD monitoring.

There is a major gap in the literature regarding the factors that contribute to perceived safety and privacy in remote patient monitoring (RPM). To address this gap, the research goal of this study was to provide an interpretive account of the experience of RPM patients. This study investigated two research questions: 1) How did RPM recipients perceive safety concerns?, and 2) How did RPM recipients perceive privacy concerns? To address the research questions, in-depth, semi-structured interviews were conducted with six participants to explore individual perceptions in rich detail using interpretative phenomenological analysis (IPA). Four themes were identified and described based on the analysis of the interviews that include — *comfort with perceived risk, control over information, education, and security* — emerged from the iterative review and data analysis.

Participants expressed comfort with perceived risk, however being scared and anxious were recurrent subordinate themes. The majority of participants expressed negative feelings as a result of an initial traumatic event related to their devices and lived in fear of being shocked in inopportune moments. Most of these concerns stem from lack of information and inadequate education. Uncertainties concerning treatment tends to be common, due to lack of feedback from ICD RPM status. Those who knew others with ICD RPM became worrisome after hearing about incidences of sudden cardiac death (SCD) when the device either failed or did not work adequately to save their friend's life.

Participants also expressed cybersecurity concerns that their ICD might be hacked, maladjusted, manipulated with magnets, or turned off. They believed ICD RPM security was in place but inadequate as well as reported feeling a lack of control over information. Participants expressed wanting the right to be left alone and in most cases wanted to limit others' access to their information, which in turn, created conflict within families and loved ones. Geolocation was a contentious node in this study, with most of participants reporting they did not want to be tracked under any circumstances.

This research was needed because few researchers have explored how people live and interact with these newer and more advanced devices. These findings have implications for practice relating to RPM safety and privacy such as identifying a gap between device companies, practitioners, and participants and provided directions for future research to discover better ways to live with ICD RPM and ICD shock.

Acknowledgments

The path toward this dissertation has been a challenging journey. It would not be possible without the mentoring and guidance from several individuals. I would like to express my deepest appreciation to my committee and to my academic chair, Dr. Maxine Cohen. I am honored and grateful to have been a student of Dr. Cohen. I would not have completed this journey without her unwavering support from the infancy stages to this final report. From the classroom, idea paper, research proposal, Dr. Cohen motivated and challenged me to grow.

My committee members, Drs. Laurie Dringus and Marti Snyder provided priceless guidance. Dr. Dringus' knowledge and expertise in qualitative research with an idiographic focus was instrumental to my research. Dr. Snyder's phenomenological guidance, structure, thought provoking questions including interviews and data collection was extremely valuable. Dr. Deanne Samuel's editorial feedback was vital to completing the final report. The committee made this journey memorable.

Last and foremost, I acknowledge my daughter. She has been not only my motivation, she has given me more purpose, and reason to strive and be the best I can be as a role model, a positive influence, but most importantly, taught me what fatherhood is truly about. She has taught me patience, resilience, unconditional love that is inexplainable between a child and a parent. I hope that I motivate her to accomplish her dreams, because the sky is a limit, and I have no doubt she will be successful in anything she puts her mind to. I love you.

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Chapter 1

Introduction

Background

Despite having the most expensive health care system in the world, the United States ranks last overall among 11 industrialized countries on measures of health system quality, efficiency, access to care, equity, and healthy lives (Commonwealth, 2017). Due to years of alarmingly poor rankings, researchers are exploring various constructs to support improving care.

Historically, serious chronic illnesses or invasive procedures required an expensive hospital stay. The average expense per day for U.S. nonprofit hospitals was $2,039 (HKF, 2016); novel technology supports remote patient monitoring (RPM) with certain medical devices at a fraction of the cost (Figure 1). This technology may allow patients to have a shorter hospital length of stay. Broadband networks can support these devices to extend healthcare from facilities into the comfort of a patient's home. This continuum of care expansion is fueled by falling technology costs and skyrocketing healthcare costs, which, for many patients is measured by the Centers for Medicare & Medicaid Services (CMS) using the acute hospital inpatient prospective payment system (CMS, 2019).

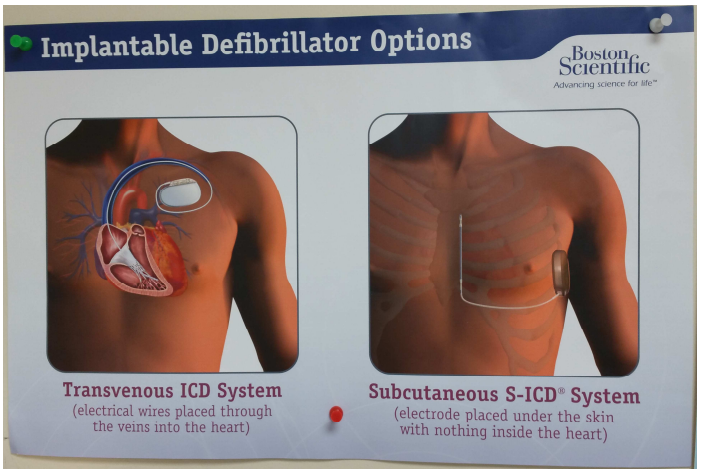

Figure 1. Implantable cardiac defibrillator options.

Considerable research has accumulated over the years on medicine and technology integration. Research has evolved from the basics of understanding cardiac anatomy, to addressing physiological issues and monitoring devices that address those issues remotely. Technology has transformed numerous medical artifacts to have RPM capabilities, for example, weight scales, glucometers, blood pressure monitors, pacemakers (PM), implantable cardiac defibrillators (ICD; Figure 2), left ventricular assist devices (LVAD), holter monitors, insulin pumps, and continuous positive airway pressure (CPAP) devices (Baig & GholamHosseini, 2013; Field & Grigsby, 2002; Serhani, El Menshawy, & Benharref, 2016). In a National Institutes of Health (NIH) study, mobile apps for monitoring the quality of perioperative patient care at home were found to be feasible and acceptable to patients and surgeons (Semple et al., 2015; Soh et al., 2019). However, there is relatively little research on the feasibility, or effectiveness, of apps or software for mobile phones (specifically smartphones) for RPM following surgery (Semple, Sharpe, Murnaghan, Theodoropoulos, & Metcalfe, 2015).

According to the American Telemedicine Association (ATA), "telemedicine is the use of medical information exchanged from one site to another via electronic

communications to improve a patient's clinical health status" (ATA, 2019, para. 1). Remote patient monitoring, including home telehealth, uses devices to remotely collect and send data to a home health agency or a remote diagnostic testing facility (RDTF) for interpretation (ATA, 2019). Varma et al. (2017) noted remote patient management is becoming the preferred method of post-implant follow-up of patients receiving cardiac implantable electronic devices (CIEDs).

Studies have explored safety and privacy issues surrounding RPM; the results generally show that patients using RPM are safer than those not using RPM (Freeman & Saxon, 2015; Parthiban et al., 2015; Varma et al., 2015; Varma et al., 2017). Other benefits of RPM include rapid clinical event detection and reduction in inappropriate shocks (Parthiban et al., 2015). Remote patient monitoring was also associated with improved survival with implantable medical devices (IMD) but demonstrated a graded relationship with the level of adherence (Varma et al., 2015).

Though there are important benefits in the use of RPM devices, experience suggests that despite good intentions, remote monitoring technology introduces several challenges that involve privacy concerns and lack of in-person contact (Huber et al., 2013). Researchers have found that because participants do not know how data are transmitted and when and how the data are analyzed and reviewed, privacy and surveillance concerns related to this lack of understanding have arisen (Skov, Johansen, Skov, & Lauberg, 2015).

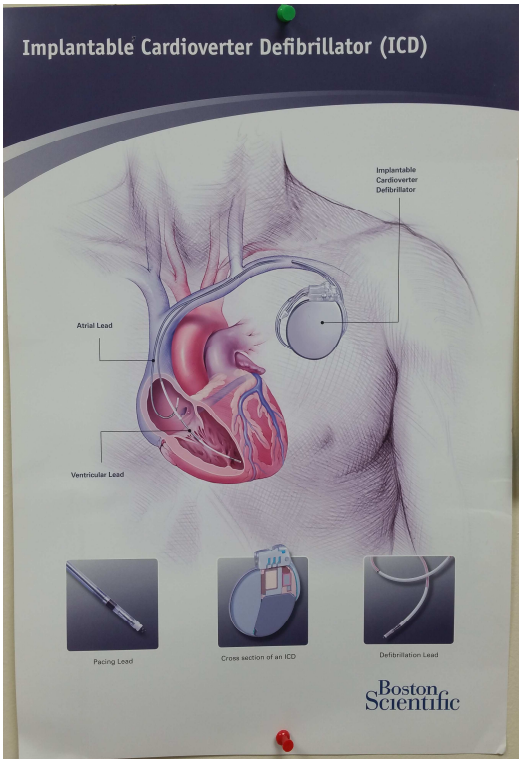

Figure 2. ICD components

Research has shown that patients do not feel safer even with the improved health benefits of RPM, creating a safety paradox (Skov et al., 2015). Boise and colleagues (2013) found that a high proportion (over 72%) of participants accepted in-home and computer monitoring and were willing to have data shared with their doctor or family members. However, a majority (60%) reported concerns related to privacy or security; many participants reported concerns about the potential risks of intrusion through sensor or computer monitoring and the potential that information could be given to the wrong people (Boise et al., 2013).

These concerns relate to the fact that human-computer interaction (HCI) has become an afterthought in medical device design, which poses a significant problem (Bannon, 2011). For example, Skov, Johansen, Skov, and Lauberg (2015) found that the physical design of RPM devices have caused problems, as participants were annoyed

with the green LED light and ended up covering up their devices. The bright LED lights kept patients awake at night and possibly interfered with natural melatonin hormone production that supports sleep. These findings support the need for additional research on HCI as well as on privacy and safety concerns.

Problem Statement

Skov, Johansen, Skov, and Lauberg (2015) described a safety paradox for remote monitoring that arises when participants perceive that their devices are less safe even though they are functioning properly and, in fact, improves the ability of patients to better monitor their health. In many cases, patients and their caregivers reported anxiety over lifesaving medical equipment potentially malfunctioning "due to the lack of feedback, which resulted in that most of them did not know if their monitor worked correctly" (Skov et al., 2015, p. 835). This issue may have arisen because RPM medical devices do not have standard feedback mechanisms that are accessible to patients (Skov et al., 2015). Information, such as on a display, through a wearable device, email, or by using a website to review personal RPM dashboards containing metrics such as battery life, device inventions, and device function, was not easily accessible to patients.

Sharing ICD data from RPM requires adequate context to support patient understanding of available information (Daley et al., 2017). Engaging patients with information that is useful and valuable to them through a personal health record (PHR) may require appropriate and individualized tailoring of information (Daley et al., 2017). Many of the issues with devices arise because even though certain medical devices have RPM capability, many products are designed in such a way that only the healthcare worker knows if the devices are functioning properly (Skov et al., 2015). This lack of

valuable information may have led to the perception issues with reliability and safety in the patient population.

RPM guidelines call for RPM to be active within two weeks of implantation (Slotwiner et al., 2015). Approximately 21% of RPM patients are noncompliant with RPM use and 38% do not have RPM activated within two weeks (Rosenfeld, Patel, Ajmani, Holbrook, & Brand, 2014; Mittal et al., 2016) even though Mittal et al.'s (2016) research showed an increase in survival rate for recipients that activate their RPM within two weeks. Rosenfeld et al. (2014) also found RPM underutilization among patients under age 40, small clinics, system characteristics (wand), and in rural areas. These challenges were investigated in this dissertation: investigation of safety and privacy issues as well as factors that may contribute to an improved perception of RPM devices.

Dissertation Goal

The research goal of this study was to provide an interpretive account of the experience of RPM patients, yielding implications for practice relating to RPM safety and privacy as well as suggestions for future research. This research obtained information on preferences, opinions, utility, and effectiveness of perceived safety and privacy information from participants on the factors that support an improved experience while living with RPM. The study was qualitative in nature, which allowed for the collection of rich personal details of participants' activities of daily living (ADL).

Research Questions

The purpose of this study was to increase understanding of how patients live and interact with RPM. The semi-structured interview process focused on two overarching questions to better understand how individuals live with RPM.

Specific research questions were:

1. How do RPM recipients perceive safety concerns?

2. How do RPM recipients perceive privacy concerns?

Stance of the Researcher

The researcher's personal experience in healthcare and HCI initiated an interest in better understanding implantable medical devices. For over a decade, the researcher worked with teams implanting numerous implants such as cardiac devices, vagus nerve stimulators (VNS), deep brain stimulators (DBS), and baclofen pumps. Vagus nerve stimulation (VNS) reduces seizures, DBS treats Parkinson's disease and improves tremors, and baclofen pumps reduce spasticity. With each of these IMDs, there are visible results. Cardiac devices differ slightly from the others in that they may be pacing a heart (or waiting for the heart to stop), however, there is no visible action for the patient to monitor. In cardiac RPM, healthcare workers monitor device performance, however, much remains to be understood about perceived safety and privacy.

Professional colleagues and cardiac surgeons, who implant medical devices several times per week, offered aid in gaining entry to this population. The researcher visited cardiac clinics several times; practitioners were eager to assist, placing the researcher in a position to establish rapport with this population. The researcher gathered qualitative data by using a semi-structured interview technique and utilized flexible open-ended questions with a stance that was curious and facilitative to better understand the aforementioned RPM population.

Relevance and Significance

The Centers of Disease Control and Prevention (CDC) and World Health Organization (WHO) have stated health is a human right. Moreover, healthcare disparities exist in certain minority populations and individuals living in rural areas that could be improved by RPM. With chronic disease rates on the rise, RPM provides patients greater ownership over their illness in a manner that may potentially reduce unnecessary visits for health care.

Heart disease is the leading cause of death in the U.S. (CDC, 2018). To date, limited research has been conducted to address the healthcare needs of cardiac patients who use RPM devices, creating a gap in the body of knowledge regarding perceived safety (Skov et al., 2015). Information is needed to support this medically needy population. From a public health perspective, this research may promote physical and mental health and support disease prevention by supporting academia, engineering, government, safety, privacy, and primary care with new knowledge. The rationale for addressing these issues, from the perspective of the information systems HCI field, was to promote improved RPM design and integration.

A phenomenological qualitative research study was conducted to obtain subjective knowledge of the cardiac RPM population's experience. This phenomenological study produced subjective knowledge that supported an understanding of the feelings, values, and perceptions that underlie and influenced RPM participants. New information from this study generated ideas for improvement that could support a future quantitative survey. Also, the new knowledge supported improving conceptual and

technical RPM product design. This study offers insights into how participants with RPM devices make sense of a given phenomenon.

Barriers and Issues

The safety paradox and privacy concerns were inherently difficult problems that needed to be better understood. One barrier to this research was that the patient population was elderly and ill with cardiac disease, the number one reason for death in the U.S. Obtaining qualitative information from the elderly was challenging for a number of reasons, such as hearing loss. Another barrier to this research was the lack of clarity in the definitions of RPM and telehealth. In the literature, similar terms were remote monitoring, home monitoring, and RPM. Telemedicine, telehealth, and video conferencing were also similar terms that covered similar concepts. For example, RPM does not require patients to make daily phone calls to report their data. RPM uses synchronous or asynchronous data transmission with a docking station, and should have required minimal effort because this patient population suffers from chronic illness, comorbidities, and some are geriatric. Asynchronous monitoring requires less effort on the user which is more effective and worth using (Figure 3).This was a barrier because several publications with unclear definitions have led to a lack of public understanding of RPM (Chaudry et al., 2010; Krumholz, 2010; Langreth, 2010).

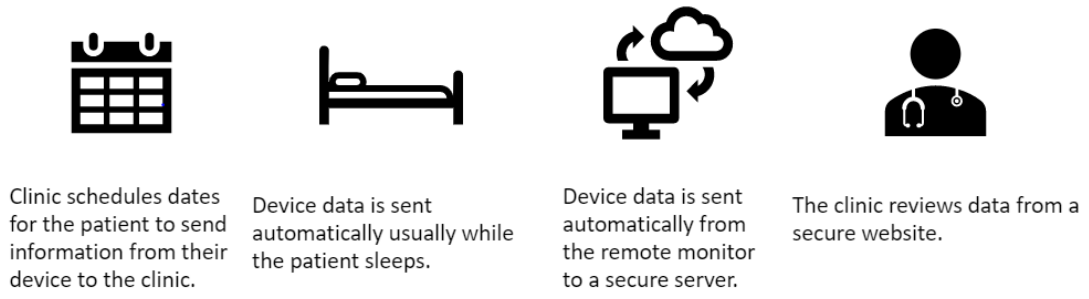

Figure 3. Example of asynchronous RPM

Patient demographics and culture were considered other barriers to this research. For example, language barriers made data collection somewhat difficult due to accents. Education, age, and cognitive function were not major barriers to this research. Patients with comorbid conditions may have suffered a stroke or had poor perfusion which could have affected cognition but this was not the case. Impaired cognition could have prevented participants from completing a survey or actively participating in the interview. As a result, delimitations included patients that were awake, alert, and oriented. Participants that did not meet those criteria were excluded from participating in this research.

Limitations and Delimitations

Limitations in qualitative research exist. There are a number of limitations that could have affected the validity of this study. One limitation of the study was generalizability. The semi-structured interviews produced a large amount of qualitative data, however, the lived experiences from a small purposeful sample (N = 6) cannot be generalized (Creswell, 2013). The researcher attempted to recruit a demographically diverse sample. The final sample was weighted with an equal number of females and males in varying age groups.

Qualitative interviews have been known for not being neutral tools (Bloomberg & Volpe, 2008, p. 82). The interactions between the interviewer and interviewee could have resulted in a change of perception by both parties. As a result, the researcher made an effort to withhold bias and opinion during the interviews. This was further aided by the researchers use of non-verbal communication while face-to-face with participants. Being in-person during the interviews supported less interruptions and background noise, and

promoted a fluid exchange of dialogue with the appropriate use of silence from the researcher to obtain as much rich and detailed information as possible. Participants were interested and able to express themselves but several participants were shy about discussing personal subjects. For example, some participants eventually were more comfortable than others discussing their anxiety of resuming exercise and being intimate, therefore some information might have been withheld, which affects the completeness of the report. English was a second language for two participants, and other participants had accents but they did not affect communication during the interview. However, a few accents made the transcription more challenging (e.g., Hispanic, Black, and Irish). With these possible limitations, the researcher is confident that the findings are valid to ICD RPM recipients.

Regarding delimitations related with this research, the researcher identified adult ICD RPM participants to be included. The researcher expected participants to fully share their lived experiences without filtering was a factor outside the researcher's control and the findings show a sufficient breadth and depth of data resulting from the interviews. Delimitations included any participants who were unable to sustain a conversation and patients who were not psychologically stable (e.g., suicidal, altered mental status).

The researcher was aware of his personal experiences and biases and did not lead participants. Reflexive journaling was used to manage, monitor, and control any potential bias. The researcher made the participants comfortable while maintaining the utmost level of ethics. The qualitative process produced copious amounts of data which was time consuming and labor intensive to analyze. Another limitation was being able to find

enough participants using RPM. None of the participants opted out of the study after participating in the in-person interview.

Definition of Terms

Agile – The agile method anticipates change and allows for much more flexibility than traditional methods. The process involves breaking down each project into prioritized requirements, and delivering each individually within an iterative cycle (PMI, 2018).

Asynchronous – Term describing store and forward transmission of medical images and/or data because the data transfer takes place over a period of time, and typically in separate time frames (Figure 3). The transmission typically does not take place simultaneously (ATA, 2019).

Bracketing – As defined by Husserl (Smith et al., 2009, p. 21), bracketing was the act of suspending personal judgment (about events and environments) in order to investigate with a fresh perspective (Creswell, 2013).

Human-computer interaction (HCI) – an interdisciplinary field with contributions from psychology, computer science, graphic design, anthropology, sociology, human factors, ergonomics, and information architecture. The field aims to design, evaluate, and implement technology for optimal human use (Shneiderman et al., 2017).

Network of Things – The Network of Things (NoT) model was based on four fundamentals at the heart of Internet of Things (IoT) which are sensing, computing, communication, and actuation. The model's five building blocks, called primitives, are core components of distributed systems and provided a vocabulary to compare different NoTs that are used to aid the understanding of IoTs (NIST, 2016). The five NoT

primitives are: 1) Sensor, 2) Aggregator, 3) Communication channel, 4) external utility (eUtility), and 5) Decision trigger.

Privacy – The claim of an individual to determine what information about himself or herself should be known to others (Westin, 1967). Privacy also involves when such information is obtained and what uses are made of it by others (Westin, 1967).

Protected Health Information (PHI) – Part of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule that protects all individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule names this information protected health information (PHI). Individually identifiable health information is information, including demographic data, that relates to the individual's past, present, or future physical or mental health or condition, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual. Examples of PHI include name, address, birth date, and social security number.

Remote Monitoring (RM) – Type of ambulatory healthcare where patients use mobile medical devices to perform a routine test and send the test data to a healthcare professional in real-time (ATA, 2019). Remote monitoring includes devices such as glucose meters for patients with diabetes and heart or blood pressure monitors for patients receiving cardiac care (ATA, 2019).

Store and Forward (S&F) – Type of telehealth encounter or consult that uses still digital images of patient data for rendering a medical opinion or diagnosis. Common

services include radiology, pathology, dermatology, ophthalmology, and wound care. Store and forward includes the asynchronous transmission of clinical data from one site to another (ATA, 2019).

Synchronous – Interactive video connections that transmit information in both directions during the same time period (ATA, 2019).

Telemonitoring – Process of using audio, video, and other telecommunications and electronic information processing technologies to monitor the health status of a patient from a distance (ATA, 2019).

List of Acronyms

- ALF – Assisted Living Facility
- CIED – Cardiac Implantable Electronic Device
- HH – Home Health
- ICD – Implantable Cardiac Defibrillator
- IMD – Implantable Medical Device
- IRF – Inpatient Rehabilitation Facility
- LTAC – Long-term Acute Care
- NoT – Network of Things
- PM – Pace Maker
- RM – Remote Monitoring
- RPM – Remote Patient Monitoring
- SNF – Skilled Nursing Facility

Summary

In this chapter, evidence was presented that technology has developed numerous medical devices that can now be monitored remotely (Baig & GholamHosseini, 2013; Field & Grigsby, 2002; Serhani, El Menshawy, & Benharref, 2016). These devices are becoming ubiquitous, and include exercising and weight monitoring devices, ADLs, wearables, non-contact technology, and invasive IMDs, creating privacy concerns. Evidence was presented that RPM improves safety monitoring, but patients do not feel safer, and in addition, they have privacy concerns (Huber et al., 2013; Varma et al., 2015). RPM technology introduces a number of challenges that involves privacy concerns and lack of in-person contact (Huber et al., 2013). For example, researchers note participants do not know how data are transmitted, and when and how the data are analyzed and reviewed, creating privacy concerns (Skov, Johansen, Skov, & Lauberg, 2015). This research investigated patients' safety and privacy concerns in order to enhance the provision of care for RPM patients.

As a result of this research, hospitals may be able to improve the effectiveness of communication among caregivers and improve the safety of clinical alarm systems, two 2019 national patient safety goals (The Joint Commission, 2019). For practitioners, the contribution of this study may be to better understand the needs to RPM patients. Future researchers may experiment with different types of technology, such as wearables and mobile devices, to investigate what human factors may further improve HCI in RPM.

Chapter 2

Review of the Literature

Introduction

This chapter presents a brief review of literature in the following areas: safety, privacy, security, and RPM to provide a better context for the current understanding of the subject matter for this study. The literature review and compilation of information advances knowledge in these subjects. The resulting scholarly findings served as a basis for developing the goals, research questions, and methodology of this study. The goal of this review and study is to contribute to the existing body of knowledge in this field.

Remote patient monitoring interactions may include two-way video consultations with a physician or healthcare provider, constant remote measurement of patient data, or automated or phone-based checkups of mental and physical wellbeing (Giger et al., 2015). Not only can care be provided less expensively in the home, evidence suggested that home care was a key step toward achieving optimal health outcomes for many patients (Barrett, Secic, Borowske, 2010; Dang et al., 2018; Leff et al., 2009; Mirro et al., 2018). Although RPM was considered to be intrusive for patients at home, little research has been conducted in the field of HCI on how people live and interact with such monitoring technologies (Skov, Johansen, Skov, & Lauberg, 2015). Andersen T, Andersen, P., Kornum, and Larsen (2017) found that patients that used a mobile application for cardiac monitoring reported generally negative feelings (uncertainty, anxiety, loss of hope) and that positive experiences (relief, reassurance, safety) arose

from getting feedback on symptoms and from continuous and comforting interaction with clinicians.

Health monitoring is a promising approach for improving access to care and improving health outcomes by making it possible to monitor patients remotely, allowing health care providers to intervene promptly if there is evidence of health status deterioration (Chaudhry et al., 2010; Dorsey & Topol, 2016; Wang et al., 2009). There was relatively little research on the feasibility, or effectiveness, of downloadable apps or software for mobile phones (specifically smartphones) for RPM following surgery, however, in the research that exists, mobile apps for monitoring the quality of recovery in postoperative patients at home were found to be feasible and acceptable to patients and practitioners (Semple, Sharpe, Murnaghan, Theodoropoulos, & Metcalfe, 2015; Yang et al., 2018). These findings, however, pointed to a gap in the research, since utilization of apps would potentially make the RPM process more accessible for patients.

Mobile phones have higher computing power, compared to previously, are increasingly a part of daily life, and have the potential to scale this technology. Using mobile devices, such as smart phones that include smart wearables, eliminated hardware needs and improved user convenience, which could potentially improve satisfaction (Jain & Tiwari, 2014; Edgerton, 2019). For example, smartphones can sense and model sleep and sleep quality without requiring the purchase of any new hardware or a significant change in people's behavior (Min, Doryab, Wiese, Amini, Zimmerman, & Hong, 2014). Non-contact technology is also being explored for monitoring certain vital signs from a distance. For example, received signal strength-based respiration rate monitoring is emerging as an alternative non-contact technology, with radio measurements of short-

range commodity wireless devices being used (Yiğitler, et al., 2019). This same concept could be applied to ICD RPM.

Good transitions between healthcare settings and provider to provider (warm hand-off) communication support the patient and family in understanding how to best manage his or her condition throughout the day (Coleman & Williams, 2007; Brown, 2018). Different settings require different levels of intervention. For example, in critical and intermediate care, interventions such as vital signs should be carried out every one to two hours. On the acute floor, the same intervention is conducted every four hours. In home health (HH), patients have vital signs ordered once per day or transmitted via RPM.

Post-acute care (PAC) is defined as care provided after an inpatient hospital stay. In PAC, there are several settings, such as inpatient rehabilitation facilities (IRF), outpatient rehabilitation, skilled nursing facilities (SNF), assisted living facilities (ALF), long term acute care (LTAC), HH and RPM, to which a patient may be discharged. In the IRF, patients receive 24 hour nursing care and are seen by a physician three times per week. The intervention frequency for HH has not been clearly established, but costs approximately $190 per day. Additionally, there are no guidelines for RPM clinicians that monitor data, such as qualifications and frequency of monitoring (e.g., hourly, daily, weekly). There appears to be a lack of standardization, which may lead to confusion among patients. This research focused on PAC participants using RPM. A byproduct of this research may bolster PAC levels of care by identifying a need for RPM feedback data. In addition, the researcher investigated how often patients believed their data was monitored and who they believed monitored their data.

Prescher, Deckwart, Winkler, Koehler, Honold, and Koehler (2013) found the RPM concept was perceived positively by patients and physicians. The devices were assessed as easy to use and robust. Through trial participation and daily measurements, most of the patients felt more confident in dealing with their disease than before. The perception of the nurses and physicians of the telemedical centers was professional and committed. Also, more than half of the patients noticed an improvement in contact with their primary physician; however, for 46.1% of patients, the level of contact between patient and provider did not change (Prescher et al., 2013). In another study, Agnisarman et al. (2017) found usability problems with installation and account creation led to high mental demand and task completion time, suggesting the participants preferred a system without such requirements. They found the majority of the usability issues were identified at the telemedicine initiation phase. The aforementioned studies suggest there are mixed feelings on the part of patients about these new technologies.

Safety

Within the field, there is conflicting research about whether RPM improves safety. As an example, Chaudry et al.'s (2010) research claimed that, among patients recently hospitalized for heart failure, telemonitoring did not improve outcomes. The process that Chaudry et al. (2010) used was distinctly different from traditional RPM devices because in this study they relied on the patient to telephone daily. The RPM group was instructed to call a designated number daily, and answer a series of questions about their symptoms using a keypad. Most RPM devices transmit via wifi and mobile networks daily. Despite this major difference, Forbes magazine published two (2010) articles arguing against RPM (Langreth, 2010; Krumholz, 2010).

Freeman and Saxon's (2015) research showed that RPM was associated with decreased morbidity and increased survival compared with periodic in-person device follow-up clinic appointments. Smaller randomized clinical trials have shown lower benefits or no significant survival difference (Freeman & Saxon, 2015). However, ICD RPM lowered the number of appropriate and inappropriate shocks delivered, and increased device battery life, compared to ICDs without RPM (Guédon-Moreau, 2012; Parthiban et al., 2015).

Varma, Piccini, Snell, Fischer, Dalal, and Mittal (2015) conducted a U.S. study with 269,471 patients implanted between 2008 and 2011 with pacemakers (PMs), implantable cardioverter defibrillators (ICDs), or cardiac resynchronization therapy (CRT) with pacing capability (CRT-P)/defibrillation capability (CRT-D) with wireless RPM. RPM was associated with improved survival, irrespective of device type (including PMs), but demonstrates a graded relationship with the level of adherence (Varma et al., 2015). Researchers were able to show that patients who used RPM were in fact safer, however, they did not study issues pertaining to patients' perceived safety and privacy.

Secondary benefits. Traditional ICD treatment plans have no monitoring between office visits; RPM closes this gap (Varma, 2013). The increased surveillance due to RPM has decreased in-person practitioner visits, which has secondary benefits such as not losing a work day, driving in traffic, paying tolls, or waiting in an office (Brugada, 2006). Care consistency has also improved with RPM (Varma, 2013; Varma et al., 2014). For patients with chronic disease, remote monitoring increased their disease-specific

knowledge, triggered earlier clinical assessment and treatment, improved self-management and shared decision-making (Walker, Tong, Howard, & Palmer, 2019). The research demonstrates that RPM patients are safer, but they do not feel safer.

In a qualitative study, telemonitoring was popular with chronic heart failure (CHF) patients because they felt reassurance arising from what was perceived as continuous practitioner surveillance (Fairbrother, 2014). However, professionals expressed concern regarding perceived patient dependence on practitioner support as well as additional workload for providers (Fairbrother, 2014). In another study, a mobile system that instructed patients (or family members) to transmit photos was able to improve the sense of security of patients and quality of postoperative follow up, avoiding unnecessary hospital visits and increasing patient satisfaction (Martínez-Ramos, Cerdán, & López, 2009). Šafaříková and Bulava (2018) found the method of device monitoring does not significantly affect quality of life (QoL) in patients with ICDs, nor does it affect levels of anxiety and depression. Generally, patients with ICDs using RPM were satisfied and would prefer not to lose RPM (Šafaříková & Bulava, 2018).

Age as a factor in acceptance. Technology was seen as the potential solution to safety and privacy concerns with medical devices. Lie, Lindsay, and Brittain (2015) found that for patients who did not see themselves as old or frail enough to require personal care provision and preferred to maintain their identity as autonomous and independent individuals, remote monitoring systems may be one method of supporting independence. In this scenario, cameras and sensors replace having someone physically present in the patient's home. The researchers found that acceptance of these changes involved careful negotiations with older individuals about their understanding of safety

and privacy, and their experiences and relationships with technology, their caregivers, and relevant service providers.

In two trials of a home monitoring system funded by the United Kingdom Technology Strategy Board, older individuals were interviewed pre-trial and post-trial about their perspectives on these safety and privacy issues (Lie, Lindsay, & Brittain, 2015). The researchers found that these individual's habits and norms did not need to be disrupted by the ambient system. IoT emerged as a disruptive and transformative technology that could potentially create innovative designs of RPM. The high degree of automation, interconnectivity and transfer of sensitive private data involved in such services raise ethical questions underpinning security and privacy concerns (Bhattacharya, Wainwright, & Whalley, 2017).

Privacy

Defining privacy has been notoriously difficult (Tsai et al., 2010) because of its multidimensionality (Culnan & Williams, 2009). At the organizational level, information privacy refers to the right to determine when, how, and to what extent information was communicated to others (Claerhout et al., 2005). For Greenaway and Chan (2005), organizational information privacy refers to how reputable companies treat their customers' personally identifiable information (PII). The U.S. government defines PII as information that can be used to trace an individual's identity, such as their name, social security number, and biometric records, alone, or when combined with other personal or identifying information which might be linked or linkable to a specific individual, such as date and place of birth, and mother's maiden name (GSA, 2019). The concept of information privacy is defined differently across industries. In addition, an increasing

number of media reports regarding government-backed surveillance programs has generated privacy concerns.

Privacy is defined as the claim of an individual to determine what information about himself or herself should be known to others (Westin, 1967). This definition also includes when such information was obtained and what uses was made of it by others (Westin, 1967). Westin (1991) used macro-level privacy questions in surveys to categorize individuals into privacy segments: privacy fundamentalists, pragmatists, and unconcerned. When asked directly, many people fall into the privacy fundamentalist group. They profess to care a lot about privacy and express particular concern over losing control of their personal information or others gaining unauthorized access to it (Culnan & Armstrong, 1999; Smith & Milberg, 1996). However, individuals reveal personal information for relatively small rewards, often for just drawing the attention of peers in an online social network (Kokolakis, 2015). This discrepancy between attitudes and behaviors has become known as the privacy paradox (Kokolakis, 2015).

The American Telemedicine Association (ATA) (2019) defined patient health information as part of the HIPAA privacy rule that protects all individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The privacy rule uses the term protected heath information (PHI) to describe this data. Protected health information is individually identifiable health information that relates to the individual's past, present or future physical or mental health or condition. Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number; ATA, 2019).

Privacy threats. To date, little research has been developed to explore safety perceptions of living with ICD RPM while identifying the intended and unintended consequences of perceived privacy with RPM. This study aimed to address the lack of research that focus on perceived privacy threats at the individual level.

Privacy threats are risks or harms that may be experienced by the data producer if his or her identity is associated with the data (Raij, Ghosh, Kumar, & Srivastava, 2011). Privacy issues and threats are better understood when they are bounded by a specific context, such as the healthcare industry (Bansal et al., 2008; Johns, 2006; Raji et al., 2011). Using an HCI lens therefore provides context-specific insight into information privacy.

In spite of the potential benefits of healthcare information technology (IT), major issues and barriers have been associated with the use of Electronic Health Records (EHRs), such as cost, technical issues, and privacy concerns (Hersh, 2004). Paradoxically, the identical practices that provided value to organizations and their customers also raise privacy concerns (Bloom et al. 1994). Developing robust privacy programs was a difficult and costly process (Culnan & Williams, 2009), but has been even more challenging in the healthcare sector. Healthcare organizations are expected to have safeguards in place against privacy threats (Liginlal et al., 2009). Despite advances in IMD technologies, the understanding of how device security and privacy interact with and affect medical safety and treatment efficacy, is still limited (Halperin, Kohno, Heydt-Benjamin, Fu, & Maisel, 2008). As a result, stakeholders are working towards carefully developing privacy programs and safeguards to mitigate privacy threats and protect sensitive information and avoid financial penalties.

Electronic health records that are integrated with RPM has the potential to improve the quality of healthcare and represents the primary mechanism through which interoperability of health information can take place (Agarwal et al., 2007). Understanding how individuals perceive information privacy threats, and how their responses affect their lives, is an important step towards addressing them. Mitigating privacy threats must take into consideration several drivers that influence actions and responses. It is important to distinguish between different types of responses while identifying mechanisms to apply the appropriate safeguards.

To date, RPM safety and privacy research has focused mainly on baby boomers aging in their home, with informal caregivers remotely monitoring activities of their relative (Birnholtz & Jones-Rounds, 2010; Huber et al., 2013; Vines et al., 2013). Experience from these studies show that despite good intentions, remote monitoring technology introduces a number of challenges that involve privacy concerns and lack of in-person contact (Huber et al., 2013). Researchers highlight the fact that participants do not know how data are transmitted, and when and how the data are analyzed and reviewed (Skov et al., 2015). Examples of issues with data privacy include a sophisticated cyberattack by hackers into Excellus Blue Cross and Blue Shield, a New York based insurer; the hackers gained access to over 10 million personal records (Rubenfire, 2015). On another front, Zetter (2015) published a YouTube video demonstrating how easy it was to hack a medical device. In this example, manipulating insulin administration could induce a life threatening condition.

Jain and Tiwari (2014), identify three types of threats that may potentially emerge when outsiders identify personal data: financial, psychological, and physical. Financial

threats can lead to loss of assets or property; related to this, the researchers include professional threats, such as the loss of a job or damage to one's business reputation. Psychological threats affect the data producer's emotions. Such threats include embarrassment due to demasking of white lies or demasking of emotional regulation, deterioration in social or family relationships, and development of pathological psychological conditions (Jain & Tiwari, 2014). Physical threats are threats to personal safety that may result in physical harm to the data producer (Jain & Tiwari, 2014). To reduce the probability of these threats when identity privacy cannot be maintained, behavior and context privacy must be maintained using restrictions (Jain & Tiwari, 2014).

According to Jain and Tiwari (2014), there are four types of contexts that are representative of the capabilities of today's personal RPM sensing systems: temporal, physical, psychological, and social. The researchers describe temporal contexts as characteristics related to the timing of a behavior, such as the exact start time of a behavioral episode. A temporal example would be timestamps of the start and end time of going to the gym, emotional states, and time of meeting with a friend. Physical contexts describe the physical environment where the behavior occurs, such as location and objects at a location (Jain & Tiwari, 2014). For example, the start and endpoint along with the route taken. Psychological contexts describe the psychological state of the user during the behavior. Psychological states may include being angry, stressed, and relaxed while driving or frightened during a car accident (Jain & Tiwari, 2014). There are several emotions a person may experience, all of which fall under this category (Lazarus, 2006). Social contexts describe the social environment in which a behavior occurs, and may

include who the user was with when the behavior occurred and whether the user was interacting with that person (Jain & Tiwari, 2014).

The notion of privacy issues and threats varies depending on several factors, such as industry sector, regulatory laws, and cultures (Malhotra et al., 2004; Milberg et al., 1995; Xu et al., 2008a). Organizations are facing challenges on how to respond appropriately to information privacy and security threats while not impeding healthcare workflow and delivery (Parks, 2012). Galliers and Land (1987) have proposed that information system research "methods must take account of the nature of the subject and the complexity of the real world" (p. 901).

Impact of privacy protections. Privacy regulations can be a burden on RPM healthcare workers. Bulgurcu et al. (2010) reported push back and resistance from users. According to Choi, Capitan, Krause, and Streeper (2006), before the Health Insurance Portability and Accountability Act (HIPAA), workflow was much smoother and more efficient than the newer workflow that involves locking doors and limiting computer access to avoid regulatory incompliance and penalties. Another example of how implementing privacy safeguards trigger workflow disruptions was documented by Coiera and Clarke (2004); in this case, managing patients' e-consent privacy preferences impeded clinicians' workflows.

Attitudes towards privacy. Privacy research has shown that what people say and do may be different. The privacy calculus attempted to discover at what monetary value an individual gave up their information (Carrascal, Riederer, Erramilli, Cherubini, & de Oliveira, 2013). The researchers found that Internet users valued their online browsing history at about seven dollars, which was the approximate price of a McDonald's fast

food meal. This phenomenon was also referred to as the imbalance challenge. Surveys of Internet users' attitudes showed that users were highly concerned about their privacy and the collection and use of their PII, but freely gave information away on social media, creating the privacy calculus (Carrascal, et al., 2013). A study has not been conducted to explore if patients who said they valued their medical information were willing to share.

Security

Security and privacy are inherently linked. Privacy regulations such as HIPAA directly influence how and what types of information may be shared and with which entities. On October 1, 2014, the U.S. Food and Drug Administration (FDA) finalized recommendations to manufacturers for managing cybersecurity risks to better protect patient health and information. The final guidance, titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," recommended that manufacturers consider cybersecurity risks as part of the design and development of a medical device, and submit documentation to the FDA about the risks identified and controls in place to mitigate those risks (FDA, 2014). The guidance also recommended that manufacturers submit their plans for providing patches and updates to operating systems and medical software.

As RPM increases, so does cybersecurity risks. Medical devices are transmitting data at times over unsecured connections. Device makers should plan to manage these information systems with software updates to reduce potential vulnerabilities. Vulnerabilities include: malware infections on network-connected medical devices or computers, smartphones, and tablets used to access patient data; unsecured or uncontrolled distribution of passwords; failure to provide timely security software

updates and patches to medical devices and networks; and security vulnerabilities in off-the-shelf software designed to prevent unauthorized access to the device or network (FDA, 2014).

Medical devices such as insulin pumps, continuous glucose monitors, pacemakers, and defibrillators (Figure 4) have become increasingly small and wearable in recent years (Clery, 2015). They often connect with a hand held controller over short distances using Bluetooth. Often, either the controller or the device itself is connected to the Internet by means of wifi, allowing data to be sent directly to clinicians (Clery, 2015). But security experts have demonstrated that with easily available hardware, a user manual, and the device's PIN number, they can take control of a device or monitor the data it sends (Clery, 2015). The goals of these developments are often positive, but threats to privacy, dangers of errors, and the need to preserve human control need careful consideration (Shneiderman et al., 2017).

Figure 4. Popular implantable cardiac defibrillators.

Attackers have used a modified programming device (Figure 5) with stronger antennae that allow them to communicate with a pacemaker from a longer distance (Sametinger, Rozenblit, Lysecky, & Ott, 2015). Examples of such attacks are a replay attack or denial of service (DoS) through man-in-the-middle techniques (MITM; Burg, Chattopadhyay, & Lam, 2018). Fear of such attacks exert such an important influence

that a former U.S. Vice President turned off communication to his IMD to avoid a potential terroristic attack (The New York Times, 2013). To increase the likelihood of success of eHealth interventions, Granja, Janssen, and Johansen, (2018) state future research must ensure a positive impact in the quality of care, with particular attention given to improved diagnosis, clinical management, and patient-centered care. Patients want to be provided with the means to manage their own health; privacy and security was the category they most often mentioned as leading to the failure of eHealth (Granja, Janssen, & Johansen, 2018).

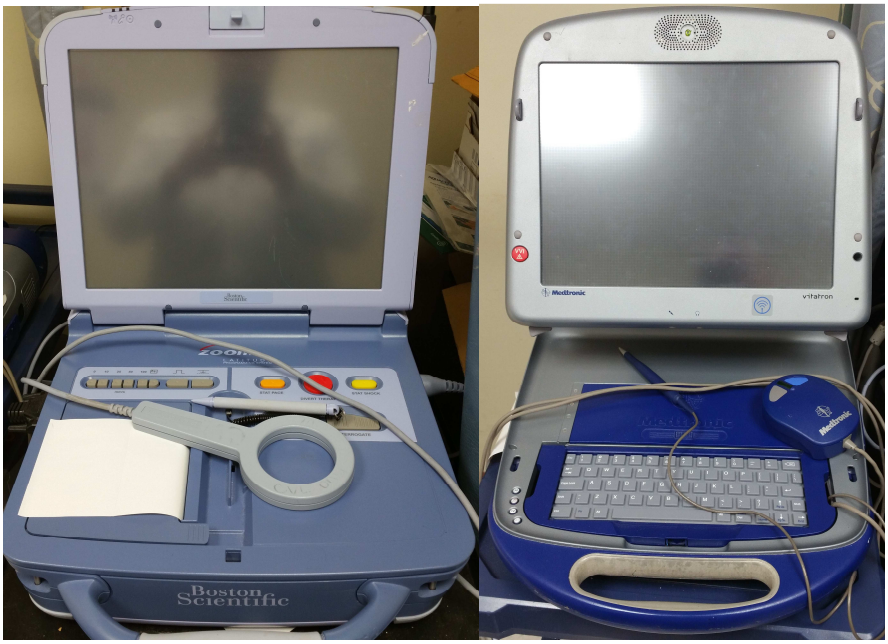

Figure 5. Wireless Boston Scientific and Medtronic ICD programmers.

Noncardiac RPM

In order to provide a thorough review of literature, this section reviews noncardiac RPM devices. RPM technology with the Internet of things (IoT) may fuel the evolution of the majority of healthcare devices, including IMD's. Although ICDs are main focus of this research, other medical devices are briefly discussed because of the

breadth of ubiquitous computing. In addition, sleep apnea is mentioned since it is a risk factor for developing cardiac disease.

According to the National Sleep Foundation (NSF), over 22 million American adults have sleep apnea (NSF, 2019). Sleep apnea occurs when an individual stops breathing while sleeping. The three types of sleep apnea were obstructive, central, and mixed. Obstructive sleep apnea may be caused by anatomical variations such as a large tongue, uvula, or small upper airway. Central sleep apnea is caused as a result of the brain failing to send signals to the breathing muscles. Continuous positive airway pressure machines (CPAP) was one method of treating these serious issues by using low air pressure to keep the airway open. Certain CPAP models display limited sleep reports focusing on use (Figure 6). These reports lack details such as the quantity or quality of events, the number of times a CPAP recipient stopped breathing, and the length of time. Untreated sleep apnea increases mortality and causes serious comorbidities such as diabetes, hypertension, heart disease, stroke, obesity, cancer, and trauma from falling asleep during driving.

Figure 6. CPAP device displaying sleep report.

Sleep apnea is a serious enough illness that more severe forms have been linked with premature death. It has been shown that CPAP adherence and leakage was improved with the use of a web-based telemedicine system at the initiation of treatment (Fox et al., 2012; Woehrle et al., 2018). This information is important to acknowledge because sleep disorder, left untreated, can damage the heart and brain and lead to obesity, which is a risk factor in developing certain cancers (Polednak, 2008).

The ResMed 10 model CPAP machine allows data transmission wirelessly to mobile devices. However, several insurance companies, such as Sunshine Health, are using these data for their benefit. For example, if a patient was not consistently (70% monthly compliance) using their CPAP, Sunshine ceased reimbursement and recovered the equipment. Comments on resmed.com from patients demonstrate patients' perception that access to their health data was intrusive and a violation of their privacy.

Min et al., (2014) developed sleep detectors as a result of a growing population that use smartphones as alarm clocks. The system classified a sleep state with 93.06% accuracy, daily sleep quality with 83.97% accuracy, and overall sleep quality with 81.48% accuracy. Interestingly, data collected from noise and movement were helpful in determining sleep quality (Min et al., 2014). The sleep detector technology can be used to monitor sleep quality with CPAP.

Blood pressure (BP), glucose, and vital sign RPM have shown improved outcomes in several studies. In the Logan et al., (2007) study, components included a Bluetooth enabled home BP monitor, a mobile phone to receive and transmit data, a central server for data processing, a fax back system to send physicians' reports, and a BP alerting system. In the Logan et al. (2007) pilot study, 24 hour ambulatory BP decreased

(both $P < .001$), and BP control improved significantly. Patients benefited from the technology and were able to view their data from their mobile phones. Information systems must be modular to accommodate various combinations of conditions, reinforce a routine, consolidate record keeping, as well as provide actionable feedback to the patients (Sultan, Kuluski, McIsaac, Cafazzo, & Seto, 2018). However, these studies did not measure perceived safety. The motivation of this study was to better comprehend the RPM safety paradox and privacy concerns in cardiac patients.

Summary

In this chapter, the evolution of healthcare and technology integration were discussed. The topics and links between safety, privacy, security, and RPM were reviewed in this chapter. A robust literature review was conducted along with an extensive forward and backward literature search. The literature used numerous terms for RPM, therefore, for the sake of clarity, in this chapter, RPM was defined as interactions that may include two-way video consultations with a physician or healthcare provider, constant remote measurement of patient data, or automated or phone-based checkups of mental and physical wellbeing (Giger et al., 2015).

RPM is less expensive than traditional in-person visits and improves patient outcomes. RPM was perceived to be invasive in the home environment, with patients reporting negative feelings (uncertainty, anxiety) about the technology; positive experiences (perceived safety) arose as the result of getting feedback from interaction with clinicians.

Research shows an increase in survival among recipients that activate their RPM within two weeks, however many RPM recipients appear not to understand that not

activating RPM within two weeks of implantation may be detrimental to their health. RPM non-compliance is quite high, with approximately 38% of recipients not activating their RPM promptly (Rosenfeld, Patel, Ajmani, Holbrook, & Brand, 2014; Mittal et al., 2016).

The literature review revealed numerous unknowns with regards to privacy, for example the fact that RPM recipients may not know who and how their data are being monitored. The review of literature supports the need for research questions on how RPM participants perceive safety and privacy.

Chapter 3

Methodology

Introduction

This chapters shows details on the approach of this research. The review of the literature highlighted a significant gap in the research examining the lived experiences of ICD recipients with RPM. In this chapter, the framework for achieving the study aims were established through the exploration of research methodologies, study processes and instrumentation, and resource requirements. The processes for collecting, authenticating, examining and presenting data are also outlined. At the conclusion of this chapter, the researcher summarizes the methodology utilized to conduct an interpretive phenomenological analysis (IPA) of ICD RPM recipients.

Table 1. Research Process Overview with Major and Sub Tasks

Major Task	Sub Tasks
1.0 Acquire Resources	1.1 Procure digital audio recorder 1.2 Procure Lenovo computer 1.3 Procure Microsoft Windows 10 1.4 Procure Nvivo software for Windows 1.5 Procure medical audio transcription services
2.0 Recruit Participants	2.1 Bracket and journal thoughts 2.2 Deliver invitation brochures to cardiac clinics and participants 2.3 Review prospective study participants 2.4 Ensure participants meet study criteria 2.5 Select and contact potential participants 2.6 Obtain statement of informed consent from participants
3.0 Conduct Semi-Structured Interviews	3.1 Schedule interviews 3.2 Conduct interviews with interview guide 3.3 Bracket and journal thoughts

4.0 Transcribe Interviews	4.1 Upload audio recordings of interviews to third party transcriptions service 4.2 Receive and review audio transcriptions 4.3 Send transcribed interviews to participants for review and clarification 4.4 Update transcriptions based upon feedback received from participants 4.5 Bracket and journal thoughts
5.0 Organize and Analyze Data	5.1 Import transcripts and data into Nvivo 5.2 Read and re-read transcripts 5.3 Analyze semantic content and language through initial noting 5.4 Develop emergent themes 5.5 Search for connections across emergent themes 5.5.1 Abstraction 5.5.2 Subsumption 5.5.3 Polarization 5.5.4 Contextualization 5.5.5 Numeration 5.5.6 Function 5.6 Move to the next case 5.7 Look for patterns across cases 5.8 Bracket and journal thoughts
6.0 Create Report	6.1 Write report and supporting narrative: 6.1.1 Create individual summaries 6.1.2 Describe themes 6.1.3 Create tables and figures 6.2 Bracket and journal thoughts 6.3 Finalize report

Research Method

This was a qualitative research study guided by IPA (Smith, Flowers, & Larkin, 2009). Recognition of qualitative research in the medical sciences, and specifically in disease process management, continues to increase (Dubose-Morris, 2014). Qualitative methods aim to better comprehend patients' experiences of health needs, accessing information, and keeping healthy.

Semi-structured phenomenological interviews were conducted to capture participants' lived experiences using RPM, in their own words (Marshall & Rossman, 2006). Interviews were analyzed using IPA. IPA is an approach to psychological qualitative research that has an idiographic focus, aims to offer insights into a given phenomenon, and has its theoretical origins in phenomenology and hermeneutics (Smith, 2007). This ideographic focus means that the researcher attempted to gain insight into how each individual, in his or her own context, made sense of the phenomenon under study. IPA guided the researcher in analyzing and understanding how physical and mental thoughts and symptoms were perceived. The researcher sought to understand in detail the lived experiences of a sample of RPM recipients in the context of their daily lives. Their perspectives were an important means of gathering information to better comprehend RPM through the lens of recipients.

The researcher took an inductive approach to data collection and used a semi-structured interview process to understand the lived experiences of ICD RPM participants. The open-ended design of these interviews allowed participants to relate what they found significant about their illness experience from their point of view (Ritchie, Lewis, Nichols, & Ormston, 2013).

General Research Process

IPA is one of several approaches to qualitative, phenomenological psychology. This analysis is distinct from other approaches, in part because of its combination of psychological, interpretative, and idiographic components (Gill, 2014). The goal of using IPA in this research was to understand patients' perspectives. The aim of this form of research inquiry was to focus on depth and breadth rather than representativeness. The

data gathering methods utilized a flexible approach that was open-ended, focusing on facilitating the sharing of information. When gathering the information, the researcher attempted to reflect on his own preconceived ideas of the phenomenon and tried to prevent them from interfering with the process of collecting and understanding the participants' experiences. The findings of this research may be used to re-examine previous understanding and theories that describe the phenomenon. Therefore, IPA research may lead to future studies and new research streams.

Guidance for the procedural steps for conducting phenomenological research utilized Creswell's (2013) approach. Strategies for the review, coding, and development of themes and analyses was based on Lacey and Luff's (2001) suggestions. These sources provided an organizing framework for the researcher to investigate, understand, and consolidate the findings from this research.

The general procedures of phenomenological research include being as non-directive as possible, while still trying to provide sufficient prompts to ensure that the participant responds to the content of the interview questions. Participants were encouraged to provide as full a description of their experience as possible, including thoughts, images, as well as full descriptions of the relevant situations they experienced. The researcher probed and asked for clarification as needed.

Sampling was purposive, which is common in IPA qualitative research. The literature recommends between three and six research participants. The sample size depends on the complexity of the inquiry and theoretical saturation, which is the point at which no new information emerge from the data (Lacey & Luff, 2001). Participants continuously expressed a need to control their information. Initially, all participants were

uncomfortable with their ICD RPM. The researcher journaled after each participant and recurrently noted that ICD RPM communication and feedback mechanisms were inadequate. Once the researcher repeatedly journaled similar thoughts and observations (in numerous nodes) saturation was achieved after six participant interviews.

The researcher contacted participants by phone and offered to meet at a local coffee shop or the participant's home. This process took time as some participants were not readily available and needed to make arrangements and/or obtain approval from a family member. The researcher explained that participation was voluntary. On several occasions, the researcher had to explain the study to potential participant family members. Older participants, were reluctant to participate because they were afraid of possibly being scammed. One potential participant was ready to be interviewed until his spouse informed the researcher at the last minute that he would not participate. His spouse abruptly ended the scheduling process and the researcher moved on to the next potential participant. On average, the scheduling process took about two weeks to find a suitable time period. Interviews were conducted in person so that participants could sign their consent to participate. After the interview was transcribed, participants had the opportunity to review and correct any inaccuracies in the transcription of the interview.

The interview was conducted in order to understand how experiences, perspectives, attitudes, and life circumstances affect perceived safety and privacy concerns. In-depth interviews were ideal for sensitive topics and also when focal topics do not fit into a structured survey instrument. The rapport established between researcher and participant through in-depth interviews supported open dialogue especially for sensitive heath topics or particular stigmas. In-depth interviews are an asset to qualitative

research, supported privacy, and may alleviate patient concerns regarding fear and reprisal. Interviews are the antithesis of surveys with forced choice options.

The research questions addressed how patients live and interact with RPM. The specific research questions were:

1. How do RPM recipients perceive safety concerns?

2. How do RPM recipients perceive privacy concerns?

Participant Selection

The researcher spoke with healthcare providers (e.g., surgeons implanting RPM cardiac devices, cardiologists, and nurse practitioners) supporting RPM at large volume ICD clinics to gain access to the phenomena under study (Smith et al., 2009). RPM recipients were identified through cardiology offices. The illnesses targeted were patients with chronic heart failure and arrhythmias requiring a defibrillator (e.g., heart attack, sudden cardiac arrest, ventricular arrhythmias). At the time of interview, participants had an ICD and their ICDs had RPM technology.

Institutional Review Board (IRB) approval was obtained through Nova Southeastern University (NSU) prior to data collection (Appendix A). The healthcare providers were provided an informational brochure (Appendix B) and were asked to speak with their RPM patients to get their permission for the researcher to contact them. The providers, with the patients' consent, forwarded their contact information to the researcher.

A homogenous group of participants enable deeper investigation via qualitative methods such as interviews to understand the participant lived experiences (Downey, 2015). Participants all had cardiac issues resulting in having a ICD with RPM. The

common cardiac issues were ischemic cardiomyopathy and dilated cardiomyopathy or hereditary heart disease. Participants with hereditary heart disease were unaware of their condition until it became an emergency. Creswell (2013, p. 155) recommends between 5 - 25 interviews for a phenomenological study. However, IPA involves detailed analysis of verbatim accounts of a small number of participants, usually through semi-structured interviews (Larkin et al., 2008; Smith, 2015). Regarding the sample that formed the basis of this study, Smith et al. (2009, p. 106) suggest that for most first "student projects, a sample size of up to six was sufficient for a good IPA study and indeed we would often advocate three as an optimum number for such work."

The unit of analysis was participants with ICD RPM who were willing to speak of their lived experiences. The goal of the interview process was to obtain a range of perspectives from participants with different ages and disease severity and to understand the extent of lived experiences.

Semi-structured Interviews

Before the interview, the researcher welcomed the participant, provided a brochure (Appendix B) and informed consent (Appendix C), reviewed the study materials, discussed the transcript review procedure, answered all questions and reminded the participant that he or she could stop participating at any time. After the participant signed the informed consent and was comfortable with the proposed interview process, the researcher provided time for any additional questions and then began the interview.

Demographic data were collected (Appendix D) on age, gender, race/ethnicity, relationship status, implant date, RPM activation date, insurance payor coverage, and

employment. The semi-structured interview (Appendix E) was developed based on a literature review to identify the issues that are important in the field of RPM and patient utilization and that researchers suggest require further investigation. The questions were based on themes found in the literature review related to RPM. The researcher attempted to have neutral questions that were not leading. Following are examples of interview questions from the perceived safety and privacy themes.

Safety.

- What notable experiences have you had with your ICD? How often do you (or your caregiver) believe your ICD is working properly?
    - How do you feel about this device monitoring your health? What data are monitored, how are data transmitted, who analyze your data, and how often does your doctor review?
- When not feeling well, have you or a caregiver ever questioned if the RPM device was working? If so, as the patient, what action did you take and what was the outcome?
- How much battery life is left in your ICD RPM device? Would you or a caregiver be interested in having the ability to find out on your own how much battery life was left in your RPM device at any time?
    - How do you feel about the frequency of communication between you and your healthcare provider regarding your device status?
- How do receiving emails, calls, or text messages regarding your device's performance make you feel?

- What is your experience accessing machines with ICD RPM? For example, how do airport security (metal detectors, scanners) and medical diagnostic tests such as an MRI make you feel?
- If applicable, please tell me about your experience before, during, and after an ICD shock?
    - Do you know when an ICD shock was imminent?

Privacy.

- Who do you believe has access to your ICD RPM data?
    - How do you feel your ICD RPM data are being used?
    - Tell me about your privacy with ICD RPM?
- How would you feel about your device disclosing your location on a map?
- Would you or a caregiver be interested in being able to see your data on a mobile device? Information could include location, operational status, and last time synched.
- What are your costs associated with ICD RPM information access?

Data Collection

All interviews were conducted face-to-face by the researcher, without the aid of an assistant. Data collection took place in a comfortable quiet area such as a local coffee shop or the participant's home, depending on what the participant chose. Interviews were conducted in a single visit for approximately one hour. The interview was recorded and the researcher took notes.

At the beginning of the interview, the researcher reviewed the interview process and gave participants the opportunity to ask questions. At this point, the researcher

explained the consent form in detail, and asked for the participant's signature. After the consent was obtained, the researcher reminded the participant that the interview was recorded, and thereafter, the recorder was switched on, and the interview process proceeded. For the duration of the interview, the participants had the opportunity to ask questions, or to stop the interview at any time, without consequence to the participant. At the end of the interview, the researcher again asked if the participant had any final questions. The researcher explained that his or her personal information was never shared, and that his or her name and other identifying information was modified to prevent identification. The researcher continued interviewing participants until no new research themes emerged for the population.

Transcription and Review of Data

Once the interviews were completed, a third party professional transcriber transcribed them with a standard non-disclosure agreement for participant confidentiality. Data were anonymized prior to being transcribed. After transcription, the researcher reviewed and compared the transcribed files with the audio file for accuracy. Participants also had the opportunity to review and correct their transcribed file (Appendix F). The demographic data complemented the interview data.

Data Coding, Organization, and Analysis

The in-depth interview was a guided conversation and was used to support data collection. To analyze the data, the recordings were transcribed. The researcher extracted the perspectives of the group of participants utilizing iterative interpretation. While taking a macro perspective, the data were analyzed with NVivo software by indexing themes into potential categories. To ensure trustworthiness, participants had 48 hours to review

and correct their data. A second individual cross-checked codes to maximize data accuracy. The data were anonymized prior to transfer and the individual signed a non-disclosure agreement.

Smith, Flowers, and Larkin (2009, pp. 82-101) recommended specific steps for coding and analysis:

1. Reading and re-reading: In this phase, after the participants have approved their own transcripts, the researcher read and re-read the initial and final transcripts, immersing himself in the data. During review and examination of the data, the researcher began to identify the structures that allowed for the analysis of the data. The transcripts were entered into NVivo in this stage.

2. Initial noting: This stage required time and great attention to detail. During this stage, based on information from the participant, including their relationships, experiences and environment, the researcher began to make initial notes about the meaning of the data. This information was examined from descriptive, linguistic, and conceptual perspectives. In this stage, the researcher annotated the transcript within NVivo with initial thoughts.

3. Developing emergent themes: During this stage, the researcher attempted to gain in-depth insight into the data by exploring the themes that emerged from the data and based on review of notes from the previous stage. Data were further organized, and themes were interpreted from the perspective of the participant, guided by the researcher's interpretation of the data. During this stage, nodes were constructed in NVivo based on emergent themes.

4. Searching for connections across emergent themes: During this stage, an effort was made to seek connections among themes by charting and mapping themes, in an effort to determine how they fit together. Specifically, the techniques included counting, contextualizing, and graphing data (if appropriate); connections were sought by examining words, phrases, and ideas. NVivo and analysis of the hard copy of transcription were used to expand upon the emergent themes.

5. Moving to next case: The above steps described the process for an individual case. After completing an examination of each case, the researcher ensured that the next participant's data were reviewed solely in light of the information from that individual. In other words, information from the previous case did not influence interpretation of following cases. This was one of the means by which the integrity of IPA was maintained. During this process, the researcher kept notes through journaling for each case, to ensure that thoughts about each case were bracketed.

6. Looking for patterns across cases: After determining emerging themes and connections for each case, the researcher collated and reviewed the themes across cases to determine whether there are any overarching themes allowed for the drawing of meaningful insights that pulled together findings across cases.

Lacey and Luff (2001) were used to supplement the procedures noted above. Their procedures on the analysis of healthcare data were somewhat parallel, yet offered additional details on anonymizing sensitive data, development and refinement of themes, coding and re-coding data. This process enhanced the review and analysis by suggesting

the researcher look back through the interviews to determine if any other references might have been missed.

The transcripts were analyzed line-by-line. Through this line-by-line analysis, initial codes were developed. Through the in-depth analysis of transcripts and codes, the researcher searched for emergent themes. Once these themes were discovered, the researcher then pursued connections among these themes. Cross-interpretative analysis of the themes emerged with the findings through IPA.

Reflexive Bracketing and Journaling

Bracketing is a term used to the describe the "attempt to place the common sense and scientific foreknowledge about the phenomena within parentheses in order to arrive at an unprejudiced description of the essence of the phenomena" (Kvale & Brinkmann, 2009, p. 27). The researcher had professional experiences with medical implants which was beneficial for this IPA study. These experiences allowed the researcher to both understand the context of the scientific terminology and approach of the study, and to interpret the scientific language into a form that was more understandable for the participants (Smith et al., 2009). Given the numerous RPM medical and technological terms, the researcher attempted to ensure that participants understood the terminology and that it was adequately explained to them. He also employed active listening techniques with participants. The researcher's orientation and beliefs towards safety and privacy concerns came from over a decade of experience working with teams and RPM recipients in the perioperative setting.

Format for Presenting Results

The last task of IPA was to create the report from the data analysis. This step included a detailed description of the findings related to RPM recipients' perceived safety and privacy. Findings were based on the recordings and emerging themes. Data visualization assisted in displaying the information in a meaningful format.

Samples of the codes and provisional categories derived from the transcribed interviews were presented in table format. The process of movement from provisional categories to refined themes and categories was described. Exploration of the relationships between these categories was presented, and descriptions provided of the process of refinement of the themes. Direct quotations from each of the participants was presented in the results to provide examples of the themes that have been derived from the interviews.

Resources and Instrumentation

The researcher needed resources to complete this study, such as access to NSU's Alvin Sherman Library to retrieve retrospective and current information to conduct a thorough literature review as a means of identifying the depth and breadth of the body of knowledge. The researcher contacted practitioners and cardiology offices that engaged in RPM. These offices had a high volume of RPM patients and provided an adequate sample as previously described. The researcher had a Lenovo Yoga work station with Windows 10 and Microsoft Office 2018 connected to a network.

Ethical Considerations and Compliance

As mentioned previously, the research was initiated after approval from NSU's IRB. After NSU IRB approval (Appendix A), the researcher applied for ethical review

and approval from the Jackson Health System Clinical Office of Research. He was informed that NSU's IRB approval sufficed and needed to be shared with clinical review board as well. A copy of the NSU IRB application was reviewed and accepted by the Jackson Clinical Research Review Board. After approval was obtained from all sites, research activities commenced. Research materials, including the questionnaires, consent form, and recruitment material were submitted to the NSU IRB. The researcher submitted and obtained IRB approvals per NSU's review protocol prior to interviewing participants who were recipients of RPM.

Immediately after conducting an interview, the researcher downloaded recordings onto a password-protected computer and deleted the recording. Consents were kept separate from questionnaires in a locked cabinet to which only the researcher had access. Questionnaires were given an identification code; participants' names were not used.

Limitations

Limitations in qualitative research exist. There are a number of limitations that could have affected the validity of this study. One limitation of the study was generalizability. The semi-structured interviews produced a large amount of qualitative data, however, the lived experiences from a small purposeful sample (N = 6) cannot be generalized (Creswell, 2013). The researcher attempted to recruit a demographically diverse sample. The final sample was weighted with an equal number of females and males in varying age groups.

Qualitative interviews have been known for not being neutral tools (Bloomberg & Volpe, 2008, p. 82). The interactions between the interviewer and interviewee could have resulted in a change of perception by both parties. As a result, the researcher made an

effort to withhold bias and opinion during the interviews. This was further aided by the researchers use of non-verbal communication while face-to-face with participants. Being in-person during the interviews supported less interruptions and background noise, and promoted a fluid exchange of dialogue with the appropriate use of silence from the researcher to obtain as much rich and detailed information as possible. Participants were interested and able to express themselves but several participants were shy about discussing personal subjects. For example, some participants eventually were more comfortable than others discussing their anxiety of resuming exercise and being intimate, therefore some information might have been withheld, which affects the completeness of the report. English was a second language for two participants, and other participants had accents but they did not affect communication during the interview. However, a few accents made the transcription more challenging (e.g., Hispanic, Black, and Irish). With these possible limitations, the researcher is confident that the findings are valid to ICD RPM recipients.

Regarding delimitations related with this research, the researcher identified adult ICD RPM participants to be included. The researcher expected participants to fully share their lived experiences without filtering was a factor outside the researcher's control and the findings show a sufficient breadth and depth of data resulting from the interviews. Delimitations included any participants who were unable to sustain a conversation and patients who were not psychologically stable (e.g., suicidal, altered mental status).

The researcher was aware of his personal experiences and biases and did not lead participants. Reflexive journaling was used to manage, monitor, and control any potential bias. The researcher made the participants comfortable while maintaining the utmost

level of ethics. The qualitative process produced copious amounts of data which was time consuming and labor intensive to analyze. Another limitation was being able to find enough participants using RPM. None of the participants opted out of the study after participating in the in-person interview.

Summary

In this chapter, the research design and IPA plan was discussed. The researcher detailed the identification of RPM participants who participated in semi-structured interviews; the data transcription and review procedures; the coding and annotation of data for emerging themes; the analysis of themes; and the development of a final report. The researcher maintained awareness of personal experiences and biases that could have affected this research. One action the researcher took was to engage in reflexive journaling to reduce potential bias. The research approach, sample, instrument, procedures, data analysis, format for presenting the results, and resource requirements were discussed. The phenomenological open-ended design allowed participants to freely discuss their lived experiences. The qualitative approach allowed the researcher and participants to gain in-depth knowledge of safety and privacy topics of interest and allowed for follow-up and probing questions, further adding to the breadth of information that was collected. The data were indexed and analyzed in search of common themes. The research provided an interpretative account of the experience of RPM patients, which resulted in implications for practice relating to RPM safety and privacy as well as provided suggestions for future research.

Chapter 4

Results

Introduction

The purpose of this interpretive phenomenological (IPA) was to explore the lived experiences of ICD RPM participants. By becoming familiar with participant experiences, the researcher anticipated gaining a better understanding how they lived with ICD RPM. Through a better understanding of how current participants have been implanted and supported, this researcher anticipates that future RPM can improve. This chapter describes research outputs and analysis, findings, and a summary. The purpose of this research study was to provide an interpretive account of the experience of RPM patients and provide an understanding of perceived safety and privacy concerns through participants own words.

There were two main research questions used to guide this study and understand how patients live and interact with RPM:

1. How do RPM recipients perceive safety concerns?

2. How do RPM recipients perceive privacy concerns?

In Chapter 3, the approach of this study was described and included the research method, participant selection, general research process, IRB considerations for human subjects, as well as resources and instrumentation. Chapter 4 contains a description of the lived experiences through the participants' lens with the results of the analysis. Smith et al. (2009) emphasized the importance of the results section of an IPA study because this

is where the researcher provides details of the extensive analysis of the participant's lived experiences. This is vital in IPA as it aids the reader of the research to better understand the participant's lived experiences. For example, Smith et al., described this as "…the only entrée the reader has to the lived experiences of the participant…" (p. 109). As recommended by Smith et al., a summary of the themes was created to offer a general overview of the analysis (Figure 7).

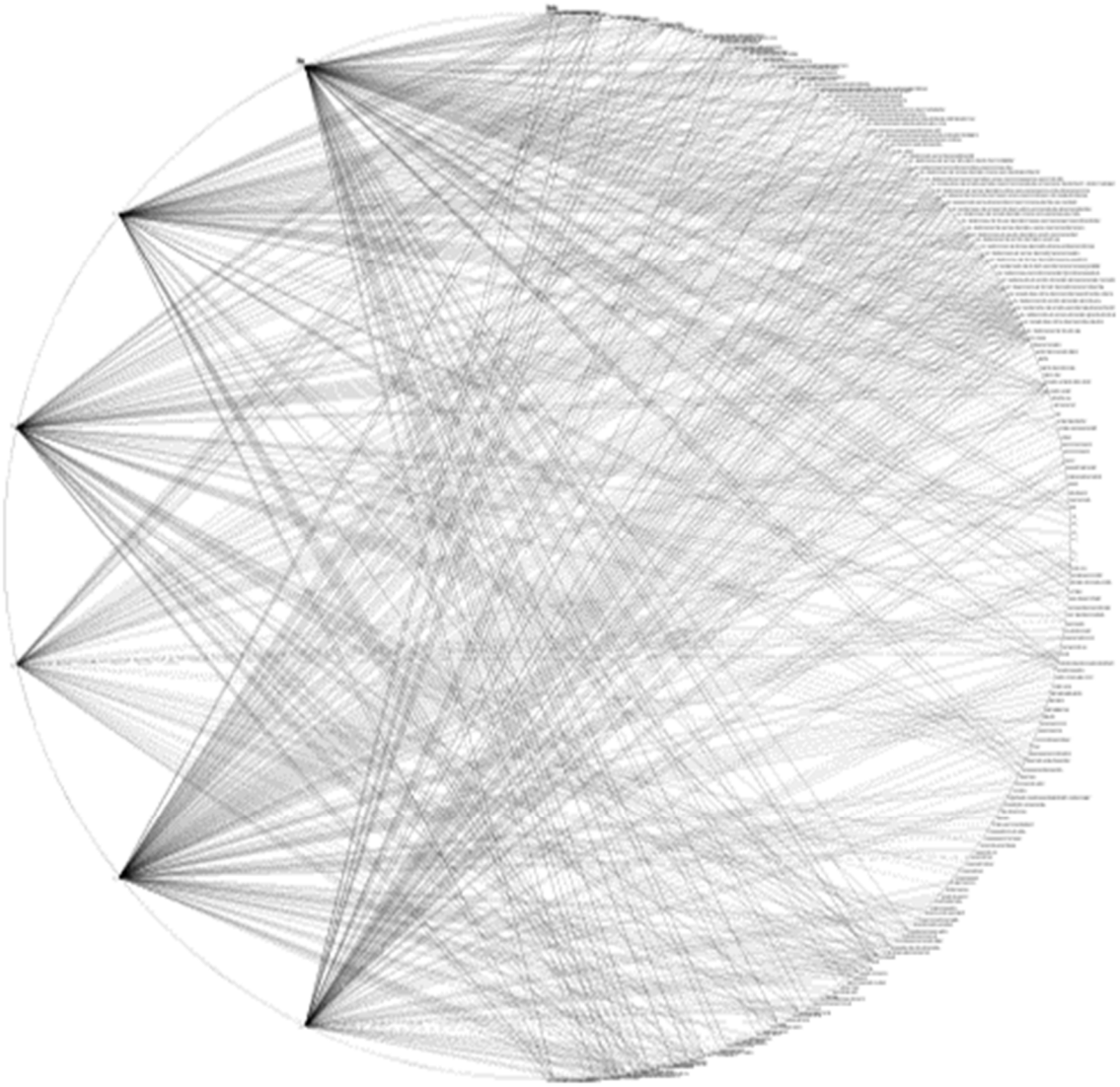

Figure 7. Aerial View of Mapping Participants with Nodes

A narrative review is presented with both general and specific participant responses from adults that are between the ages of 34 and 63. This chapter explains the data analysis, including the process for review, coding, and summary of findings.

Data Analysis

The Smith et al. (2009) methodological framework was used for this data analysis. The IPA included the following: Recruiting participants from a homogenous group and enough participants to understand their lived experiences with at least one participant that was hard of hearing and another that was not interested in interacting with computers; listening and transcribing of interviews with annotations; reviewing transcripts for needed changes consisted of reading and rereading, reviewing nodes in Nvivo, Word, and Excel; developing themes, probing for connections across developing themes; proceeding to the next interview, and connecting the dots or patterns across participant interviews. The researcher constantly recoded data that generated new nodes. This iterative process involved developing codes based on the interview data, coding the data by nodes, annotating the data as well as the coding, visualizing the data, and organizing the data nodes by overarching themes (Smith et al., 2009). The continuous fine-tuning of themes and concepts created an exploratory narrative of the lived experiences of ICD RPM participants.

Demographic Data

The participants used for this study represent a homogenous sample of patients who have ICD with RPM. Participant data was collected with a one-page paper demographic questionnaire (Appendix D) and then inserted into an Excel spreadsheet for calculation. A total of 40 participants were identified; six were interviewed for this study.

Several participants were not able to be reached due to incorrect contact information or changes in cardiac status. One participant no longer had an ICD due to a successful heart transplant. He was unable to participate but shared knowledge and notified the researcher of ICD Facebook support groups. Additional participants declined to participate due to family and work obligations. One participant's spouse would not allow the researcher to speak with the potential participant (her husband) and cited privacy concerns and mentioned being a prior victim of an elderly scam. Participant recruitment, broken down by clinics versus word of mouth recruitment, is shown in Table 2. One minor addition was made to the demographic questionnaire—participants were asked about their employment status. Participant demographic data are shown in Table 3.

Table 2. Participant Recruitment

	Invitations Sent	**Invitations Declined**	**Invitations Accepted**	**Interviews Conducted**
Clinics	34	29	5	5
Word of Mouth	6	3	3	1

All RPM participants were above the age of 30 (mean = 48.6); there was an almost even distribution of ages (31-40 = 2; 41-50 = 1; 51-60 = 2; 61-70 = 1). There were three females and three males in the study. Individuals with congenital cardiac conditions diagnosed during the newborn, pediatric, and adolescent stage were not interviewed since this study focused only on adults. Relationship status included two married, two divorced, and two single. Participant results for race/ethnicity were two Black, two White, and two Hispanic. Purposive sampling provided a balanced distribution with age and race/ethnicity.

Table 3. Demographic Data Content

Participant	Age Group	Gender	Ethnicity	Relationship Status	Employed
1	31-40	F	Hispanic	Single	Yes
2	51-60	M	White	Married	No
3	51-60	M	Black	Divorced	Yes
4	61-70	M	White	Divorced	Retired
5	31-40	F	Black	Married	No
6	41-50	F	Hispanic	Single	No

Interviews

Semi-structured interviews were conducted with six participants in person. The researcher met each participant at the location of their choosing such as coffee shops, the NSU Desantis building, and participant homes. The researcher used the glass conference room on the 4th floor of the Desantis building. At local coffee shops, interviews were conducted outside where the atmosphere was quieter even though the temperature was warm and humid. The participants chose the location and were comfortable even though the researcher was warm and sweaty at times. The estimated duration that was requested from the participants was one hour. Interviews spanned a length of time from 46 -72 minutes (Table 4). Some participants spoke faster than others and/or had heavy accents that made transcription a challenge. Participant accents ranged from Hispanic, Scottish, and English with and without colloquialisms. The accents made transcription challenging. The researcher learned the importance of reducing background noise while piloting the audio recorder and transcription process. For example, the background noise inside Starbucks made transcription more difficult and expensive because of additional human review needed as opposed to solely software transcription. Analyses of the interview times indicated shorter interview times for the younger participants.

Data Coding, Organization, and Analysis

The in-depth interview was a guided conversation and was used to support data collection. To analyze the data, the recordings were transcribed.

Table 4. Average Interview Length

Participant	Time
1	59
2	53
3	68
4	72
5	46
6	54
Average in Minutes	**58.6**

Transcription

Once the interviews were completed, a third party professional transcriber transcribed them with a standard non-disclosure agreement for participant confidentiality. Data were anonymized prior to being transcribed in Word. After transcription, the researcher reviewed and compared the transcribed files with the audio file for accuracy. Participants also had the opportunity to review and correct their transcribed file (Appendix F).

The demographic data complemented the interview data. The researcher discovered several transcription errors mainly pertaining to medical terminology and participants' accents. In this report, participant quotes are presented in their entirety where possible. In other areas, excerpts or parts of quotes were effectively drawn in to demonstrate a theme or the lived experience described or discovered.

Data Coding

Participants were given the opportunity (48 hours) to review their transcripts and provide additional thoughts or clarifications through a Google drive link (Appendix F).

Upon the complete review, the researcher uploaded data into NVivo (NVivo 12 Research Software for Analysis and Insight). Participant demographic data were also added for analyses of the demographic data set.

Transcripts were read multiple times before being finalized. Microsoft Word was initially used with the comments tool to group nodes before the researcher learned how to use Nvivo. Concepts eventually emerged that allowed the researcher to develop a coding structure (Appendix G). Transcripts were then coded and annotated multiple times. As additional transcripts were uploaded, the number of codes increased, were restructured, and subsequently united (Appendix H). The resulting nodes served as the foundation for coding data and the researcher's annotation.

The data coding and analyses was an extensive iterative process. As the themes emerged, additional concepts were explored. Before confirming the conclusions, the researcher iteratively reviewed the coded data. The iterative process resulted in a comprehensive understanding of the data and the IPA method. The researcher extracted the perspectives of the group of participants utilizing iterative interpretation. While taking a macro perspective, the data were analyzed with NVivo software by indexing themes into potential categories.

Journaling and Bracketing

As part of the IPA process, the researcher created a journal to support bracketing his thoughts and experiences. This process resulted in more than 10 journal entries totaling over 2,000 words tracking experiences and revelations throughout the research phases. Analyses of these entries demonstrated the researcher's growth from being

knowledgeable about ICD RPM, to better understanding of the lived experiences of the participants. An initial researcher journal entry read:

"I am interested in looking at the lived lives of ICD RPM participants because I believe healthcare professionals such as myself do not know what they are going through."

The next journal entry read:

"The first participant was interested in knowing more about the interview subject matter prior to making a decision if they would proceed and schedule an interview. It was challenging to inform them without going into actual interview questions. I will have to be aware of this moving forward when approaching new potential participants."

The next journal entry read:

"The first interview was much more personal than I thought. The time leading up to the interview and building rapport helped the participant and I be more comfortable. I was challenged again when going over the research aids such as the brochure without getting into any interview questions."

After making further adjustments to the semi-structured interviews, an entry read:

In other interviews topics and questions at times were not in sequence. For example, a question was answered in an earlier question or from probing. So, I caught myself asking a question and then realizing that the participant already answered while telling their story.

In several later journal entries, the researcher considered thoughts and recommendations after reflecting on interviews. An interesting theme that emerged early in the study read:

While coding the transcript for participant #1, I was surprised how emotional getting an ICD can be. Participant #1 thought she was dying during her initial emergency hospital stay.

A later journal entry by the researcher reflected a much more personal account of the IPA process:

> As I finalize the last interviews in this study, I am amazed how much more interested I am. I did not realize in the beginning of this project I would be face to face with participants that died and that were revived by their ICD on multiple occasions. It was invigorating to talk with people that want RPM to improve for themselves and future generations.

The passion demonstrated by the participants served as an inspiration for the researcher to understand their experiences and how their input could support improvement of RPM. The researcher continued journaling through the final report as part of the process of staying informed about the participants and including these thoughts as part of the emerging themes.

Findings

This chapter uses IPA to showcase thematic findings from six in-depth interviews with ICD RPM participants. Four major findings emerged from this study:

1. *Safety Comfort with Perceived Risk* – ICD RPM participants are most afraid during the first six weeks to three months of implantation. ICD RPM participants are traumatized by shocks and ICD alarms so much so that they consider having ICDs removed.

a. *Communication* – ICD RPM participants believe device communication needs improvement (e.g., battery life, device status). This is similar to prior research with poor feedback mechanisms (Skov et al., 2015). Participants would like to bypass using a docking station to transmit data and have data transmitted automatically through their mobile device.

2. *Control Over Information* – ICD RPM participants do not think about their devices much after one year unless there was a shock. However, their family members do. Participants expressed having family members having the ability to access their ICD RPM data. Some participants wanted an application to view their data while others were interested in a monthly summary. One older participant was not interested in using a computer. Overall, participants wanted to be able to manage the amount of information received and decide who else could have access.

    a. *Right to be Left Alone/ Geolocation/ Control over Information* – Most ICD RPM participants were not comfortable with geolocation services.

    b. *Geolocation* – A few ICD RPM participants were comfortable with geolocation for emergency services.

    c. *Privacy/Intimacy* – ICD RPM participants have lost jobs and feel a need to disclose information with new relationships because they believe that a part of human relationships included volunteering to self-disclose some information, but withholding

other information. The concept of privacy, part of the process by means of which humans establish relationships with each other, was important to these participants (Solove & Doris, 2010). Participants noted that ICD affected their sexual relationships.

3. *Education* – ICD RPM participants believe cardiology response protocol for post alarms are fast. However, they are unsure who actually reads the off hour transmissions to the cardiologist.
4. *Security* – ICD RPM participants believe security protocols are in place but do not think they are adequate. Participants believe their implants are vulnerable to hacking, magnets, and some electronic devices. Participants had negative experiences with diagnostic equipment (MRI), court and airport security.

Data Visualization

The researcher used several visualization techniques (e.g., word clouds, word trees, word queries, explore diagrams & hierarchy charts) to support exploring the words used most frequently by participants and to view source data by areas of coding similarities. In order to focus on common words the top 50 words were used that were four letters or greater. Several words, and similar words related to them, were counted 1334 times: words such as "changed," "change," and "changes" (Figure 8). This finding may be seen as noteworthy in a study on ICD RPM experiences because participants appear to have gone through significant life changing events. The second most common word, with 940 instances, was "think". The third most frequent word, with 624 instances, was "talk". This included generalizations, such as communicate, give, repeat, present, interview, and explain. The fourth most frequent word was "device". There were 278

instances of this word or generalizations, including:, implant, lead, pump, and brand. The fifth most frequent word, with 255 instances, was “information”.

Figure 8. Word cloud based on NVivo analyses of coded nodes.

Several other words were heavily weighted in the word cloud. These included “happened” with 132 instances, “expect,” “activated,” and “feel.” The word “changed” was used by all participants in discussing how their lives were affected as a result of the implantation. The term “communication” was used frequently in reference to participants feeling the need to have more feedback from their device system before and after something “happened.”

Super-ordinate Themes

During the semi-structured interviews, this researcher tried to make participants feel comfortable discussing their experiences with perceived safety and privacy. From

the interviews, to initial and iterative coding, to the analysis, the codes were revised, reallocated, and merged from micro nodes into broader macro themes. Explore diagrams were used to visualize the data(Figure 9). All themes were ultimately combined into four super-ordinate themes explored in this report. The following data visualization narrative captured the journey of both the sample of six ICD RPM participants and the researcher towards learning and understanding their lived experiences (see Appendix G).

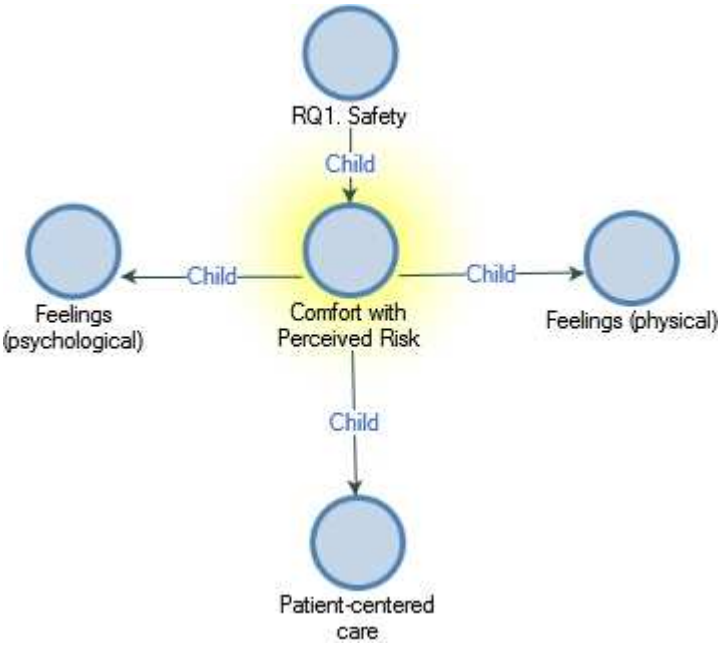

Figure 9. NVivo Macro Explore Diagram of the Term "Comfort with Perceived Risk".

Comfort with Perceived Risk

Comfort with perceived risk was referenced more than any other theme (Figure 10). There were three themes within the super-ordinate theme of comfort with perceived risk. There three sub-ordinate themes were patient-centered care, psychological feelings, and physical feelings. All participants referenced within this theme in all six interview transcripts.

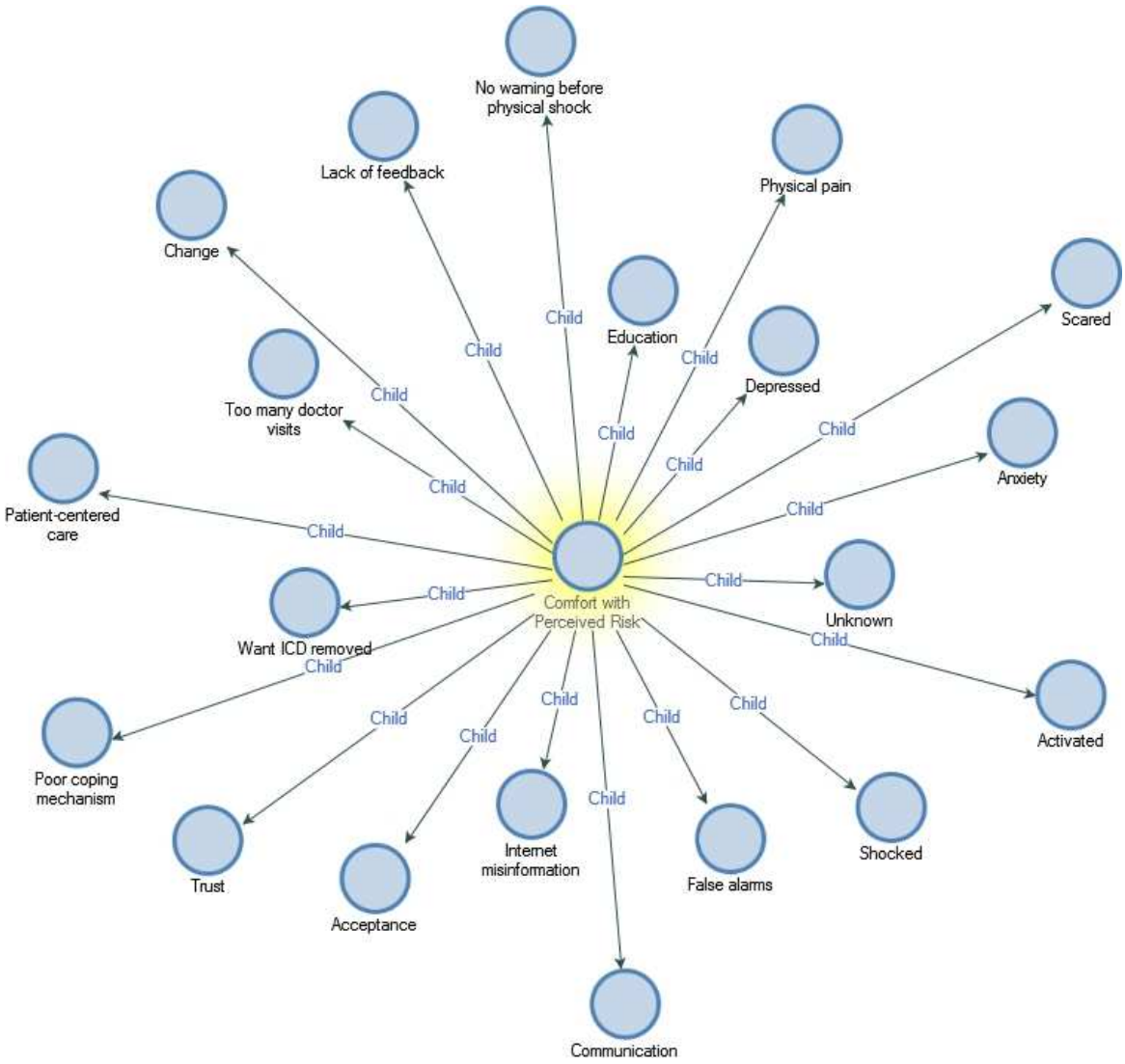

Figure 10. NVivo Micro Explore Diagram of the Term "Comfort with Perceived Risk".

Participants overwhelmingly discussed comfort with perceived risks. Participant #1's responses were commonly felt but uniquely framed in the context of patient-centered care, feelings, knowledge deficit, and experience with her first ICD RPM alarm:

> "To be honest, initially, when I had the implant on, I mean, it was-- I mean, I don't even know how to explain to you. But it was something scary at that point in time. I mean, nobody gave me any let's say-- I didn't get any courses, okay, this is a process that was missing. And this is going to be the effect or this and that, so. It was kind of scary the first few weeks. I was traumatized I could say because I didn't know what to expect, what not to expect. So any little thing I thought that I had to just go to the hospital or call my doctor physician. And to top it off, I mean, I had the defibrillator. The alarm went off probably the second

week that I had it on, the alarm went off. So I was freaking out. I called my physician. I'm like, I have never had this. I mean, it's an alarm. It sounded like a amber alert!"

Participant #1 further described her feelings experienced during the ICD alarm:

"It went on. I mean, it was probably on for a few seconds I could say. I was kind of panicky because I didn't know what to expect. I'm like, am I having a heart attack? I don't know what am I having at that point in time? I sent the transmission immediately to the doctor because I have the device at home. So automatically it transmitted whatever occurred to me at that point in time."

Participant #2 reinforced Participant #1 in the context of patient-centered care and not being central in the decision making process to have an ICD implanted:

"I initially had heart problems anyhow. I had a MI in November '97, and I was fine. Then, on January 11th, 2011, I had a cardiac arrest, and there was defibrillation. I was sent to the hospital and they decided to put in the ICD once we got to the hospital. They decided to put the ICD in".

Participant #4 reinforced participants #1 and #2 in the context of patient-centered care and impromptu medical events happening that led to an ICD device (Figure 11):

"I was in shock that something was being put inside my body to jumpstart my heart. I did not get to choose the device the doctor just told me what he recommended. He used Boston Scientific."

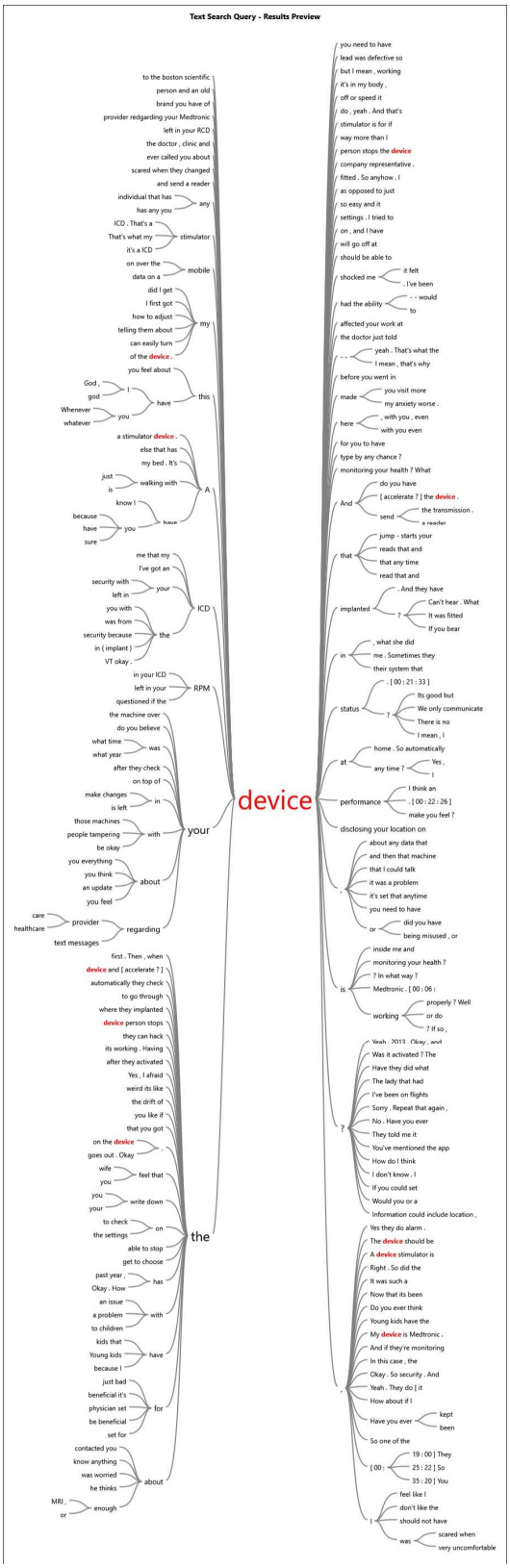

Figure 11. NVivo Word Tree of the Term "Device".

Participant #1 described thoughts that the event happened and having the ICD removed days after the device was implanted (Figure 12):

> "Well, I thought of it once I had the incision done and I had it in me. I felt like, not even two days of having it, I felt like going back to the hospital and saying, I want it out…because I was traumatized. I'm telling you from the whole thing. It was overwhelming. It was horrible, the experience. Now, I don't care but before, initially, I was like, oh my God, I want this out of me."

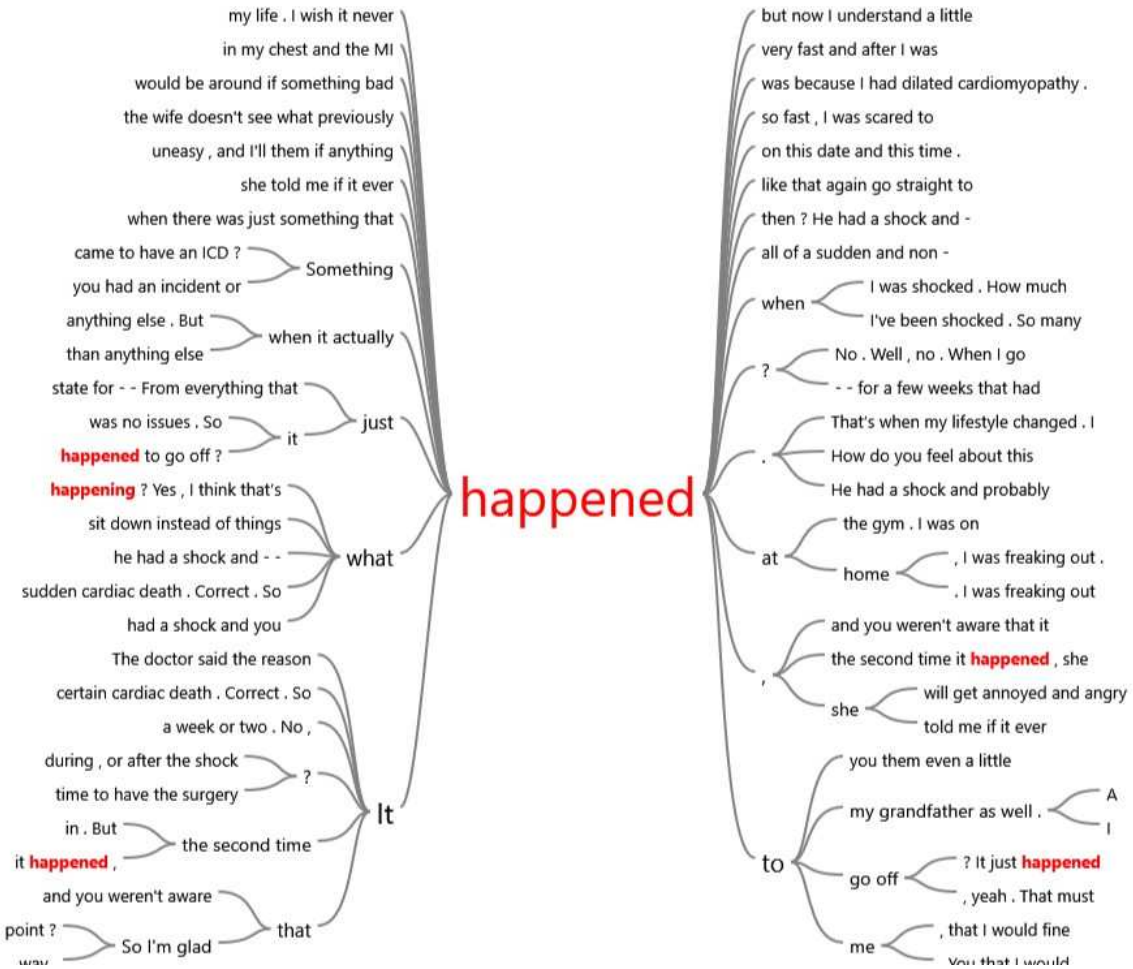

Figure 12. NVivo Word Tree of the Term "Happened".

Participant #6 described emotions from the lack of RPM feedback, and hearing information from others of instances of sudden cardiac death (SCD):

> "They say the machine works. I don't even know if the machine is going to work or not. When I go there, they tell me if the machine got batteries, if the battery is charged and everything, and I got enough charge in it. But this lady was in her kitchen and fell straight dead. It didn't jump her back up."

Participant #6 described her psychological traumatic memory with an ICD that malfunctioned supporting the other participant comments regarding patient-centered care and poor communication:

> "I was at the hospital visiting my sister that just had a baby and as I was waiting to go through security and I started getting shocked. It was the worst experience of my life. I got shocked over and over again for a long time on the floor. It took them way too long to get me to the emergency room even though I was already at the hospital. I was on the floor blocking the hallway to the elevator and several doctors stepped over me to get in elevator instead of helping me. After I was treated, the doctor told me that my ICD device lead was defective so they took me to surgery to replace it."

Participant #4 described a lack of communication between himself and his ICD with RPM (Figure 13):

> "Most of the time I think it's working but there is no easy way for me to verify on my own. It's weird, the device is inside me and I can't communicate with it and it can't communicate with me."

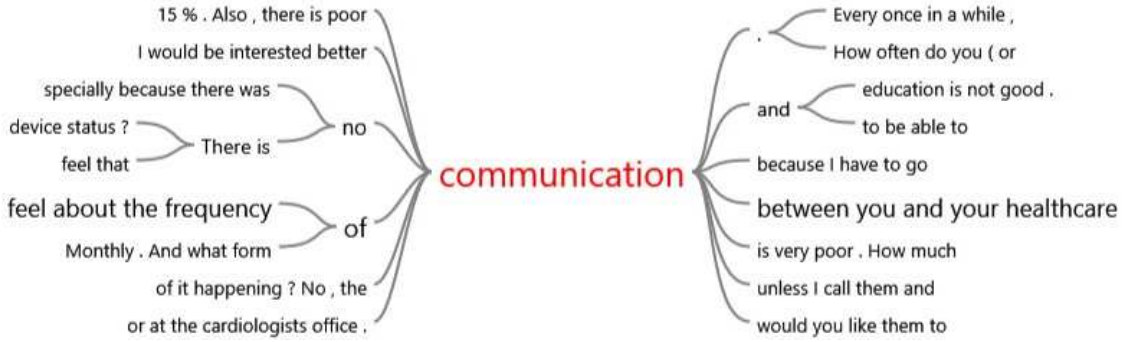

Figure 13. NVivo Word Tree of the Term "Communication".

Participant #2 described being anxious and not feeling safer even though practitioners said otherwise:

> "I was very uneasy, very agitated, unsure of what it was going to feel like or anything like that there. I was always on edge expecting to be shocked. Just the

> unknown and everybody else who I and even the cardiologists and cardiovascular the nurses often you're safer now than what you ever were. That, to me, doesn't wash. I don't agree with that. It'd still be them telling me. You haven't gotten one. So I was very anxious and very aware of being there".

Participant #2 described the difficulty obtaining his ICD battery status information:

> "Well, I've just been in hospital on Friday. I was actually internally defibrillated by the cardiology nurse. I was anesthetized. I was shocked because I was in VT. And the next day, they come up to do another interrogation, and I asked her-- I always ask her how long's left on the battery. And I don't know."

Participant #1 described anxiousness, fear of the unknown, self-doubt, and reading frightening information online:

> "Oh my God, I have this device. How about if I get an infection? How about if there is anything that goes wrong? Or how about 10 years from now, I mean I don't need it, or who knows? You start questioning yourself, so many things. Not only that, you start reading online so many things that sometimes you're like, you know what? Let me just shut down the computer. Let me not even look at it, because everybody has different experiences, and sometimes you can get even scared, the fact that you're reading all this online."

Participant #1 described the ICD alarm after-hours physician contact and thoughts on a data hub managing ICD RPM data:

> "Well, I'm sure the data goes to a hub, that there's people taking a look at it. Because I'm sure I'm not the only patient that has it. So once that data, the person that's analyzing that data, I'm sure it gives him a status of the patient, in this case, whatever my alarm was. They would say, okay, it was a false alarm, nothing occurred. The patient is fine. So he just reached out to me and said, Listen, the data that you transmitted, everything looks fine. I don't have any issues. However, I want you to come next day to my office. So there's a protocol, you go next day, he makes sure everything is fine."

Participant #2 described his change in employability and coping with job loss:

> "I'm more of a recluse now. I don't tend to go out. I've lost my licenses. I used to drive trains and coaches, and I can't do that no more. I've been lost jobs because of my health. I've also been refused jobs because of my health. Yeah, it is quite hard."

Participant #2 described physical feelings from being shocked:

> "Well, initially what I felt was dizzy, I felt my head grew, my eyesight grew quite blurry, and I guess my eyes sort of went when I'm cold. And from that, I knew that I was going to get a shock. And then I was shocked shortly after. And all the time since, that's the experience I've felt that I sort of go lightheaded, my vision goes blurry, then I'm shocked."

Participant #5 emphasized the intensity and severity of physical pain from the ICD shock:

> "The pain hurt so much…it felt like someone was punching my chest. Before I didn't know it was going to happen but during and after I felt scared and that I was dying because it shocked my heart so much."

Participant #3 described physical sensations and pain from an ICD shock:

> "Well, when it shock you, it feels like you stuck your hand in a socket. You know how you can go get your finger right now and stick it in an electric socket? That what it feel like. And it only did it to me two or three times, at the most. Two or three times, when I first got it put in."

Limited Access

Participant #1 described who she thinks has access to her protected health information (PHI) and to what extent (Figure 14):

"Well, I think at this point is a physician and Medtronic. That it's at the manufacturer because an agent of them has to be there. So I believe both of them have access to it. As of privacy, I don't know of to what extent. I mean, obviously, there's always a question if employees can extract that information and take it home. For let's say, research or anything. So, yeah, privacy is there. I mean, but there's up to a certain extent, you don't have full control of it.

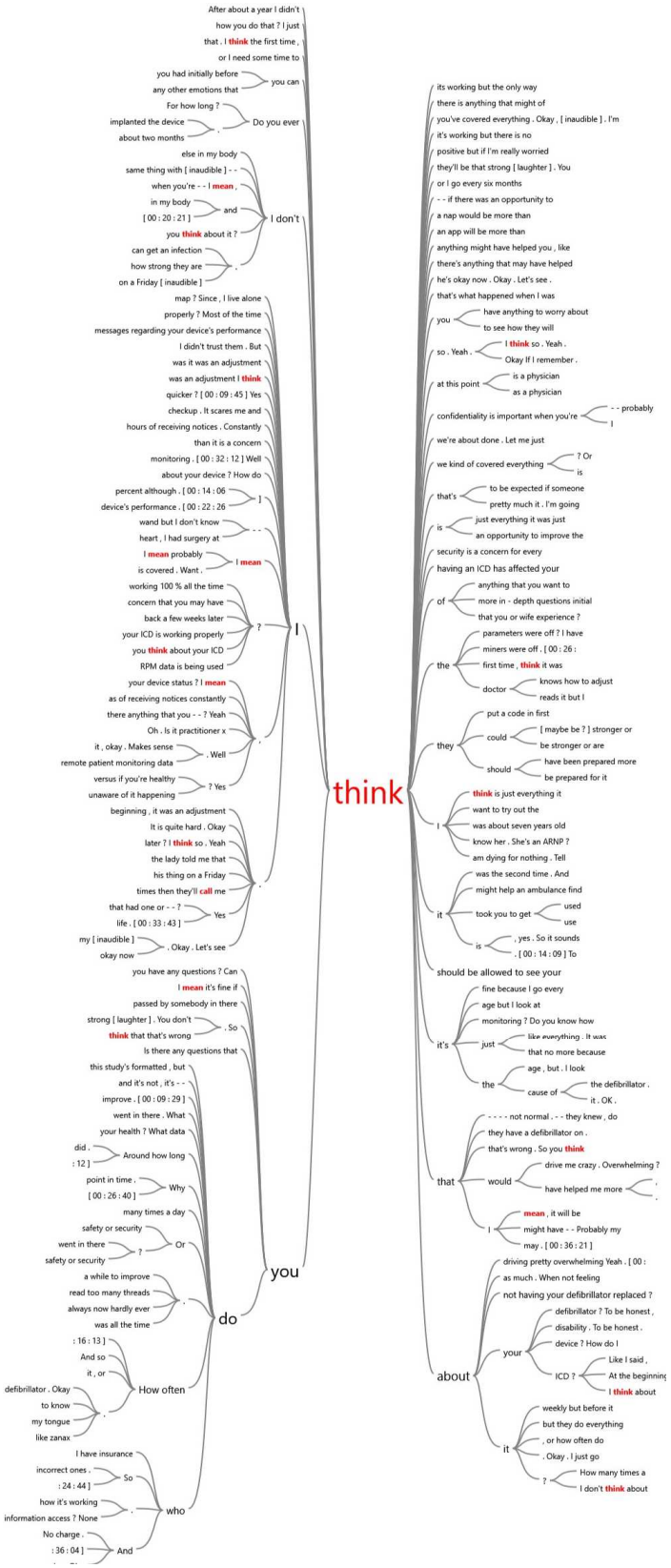

Figure 14. NVivo Word Tree of the Term "Think".

Participant #1 described who she thought should have access to her ICD RPM information:

> "Probably my kids. I could say, my kids, let's say. Yeah, to check up on mom.
> Yeah, could be."

Participant #5 commented that family members think about her ICD more than she does:

> "I talk to my husband because he thinks about the device way more than I do."

Participant #2 described who he thinks has access to his ICD RPM information:

> "As far as I'm aware, the technicians and the cardiology nurse as well as the cardiologist, himself. And if I'm admitted to hospital, let's see, the nurses and the doctors will have access to it."

Participant #4 discussed how living with a ICD RPM impacts his social life:

> "Yes, I feel that I need to disclose the ICD in my social life. Just in case it goes off and that has affected me making new friends and developing new relationships."

Participant #4 further discussed how living with an ICD impacted his professional life and the desire to limit access to employers, etc. (Figure 15):

> "I don't want employers and certain people to know I have one. I can't get a good job. I miss working full-time."

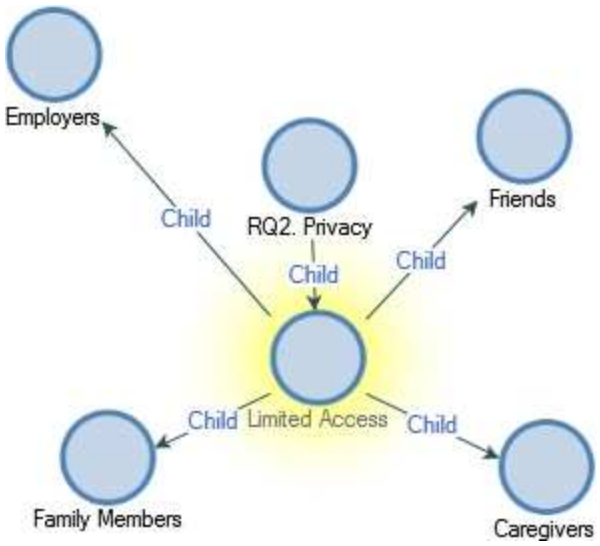

Figure 15. NVivo Explore Diagram of the Term "Limited Access".

Control Over Information

On the theme of control over information, participants were both for and against being geolocated. ICD RPM would be improved with tailored feedback from both information systems and clinicians. Participants wanted the ability to customize what information they need, what data is shared, and with whom it is shared (Figure 16). For example, participants wanted to have the option to decide if they would share their location with family, emergency responders, and friends. Some participants expressed the thought that they did not want anyone to know they had an ICD, unless they disclosed it themselves.

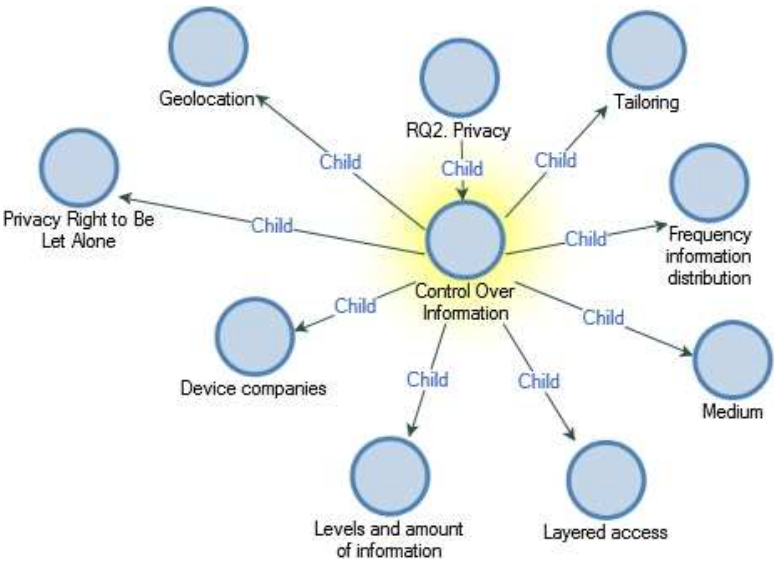

Figure 16. NVivo Explore Diagram of the Term "Control Over Information".

Participant #2 articulated his desire for emergency services to have geolocation information for access to his ICD location (Figure 17):

> "I would say it would be a good idea and especially in a city, where the paramedics don't always know the area, especially if it's in a building. Especially in a building, so they could locate you if they needed to. Sort of pinpoint you, that you were on second floor, eighth floor. For helping the paramedics sort of find where you are in a building."

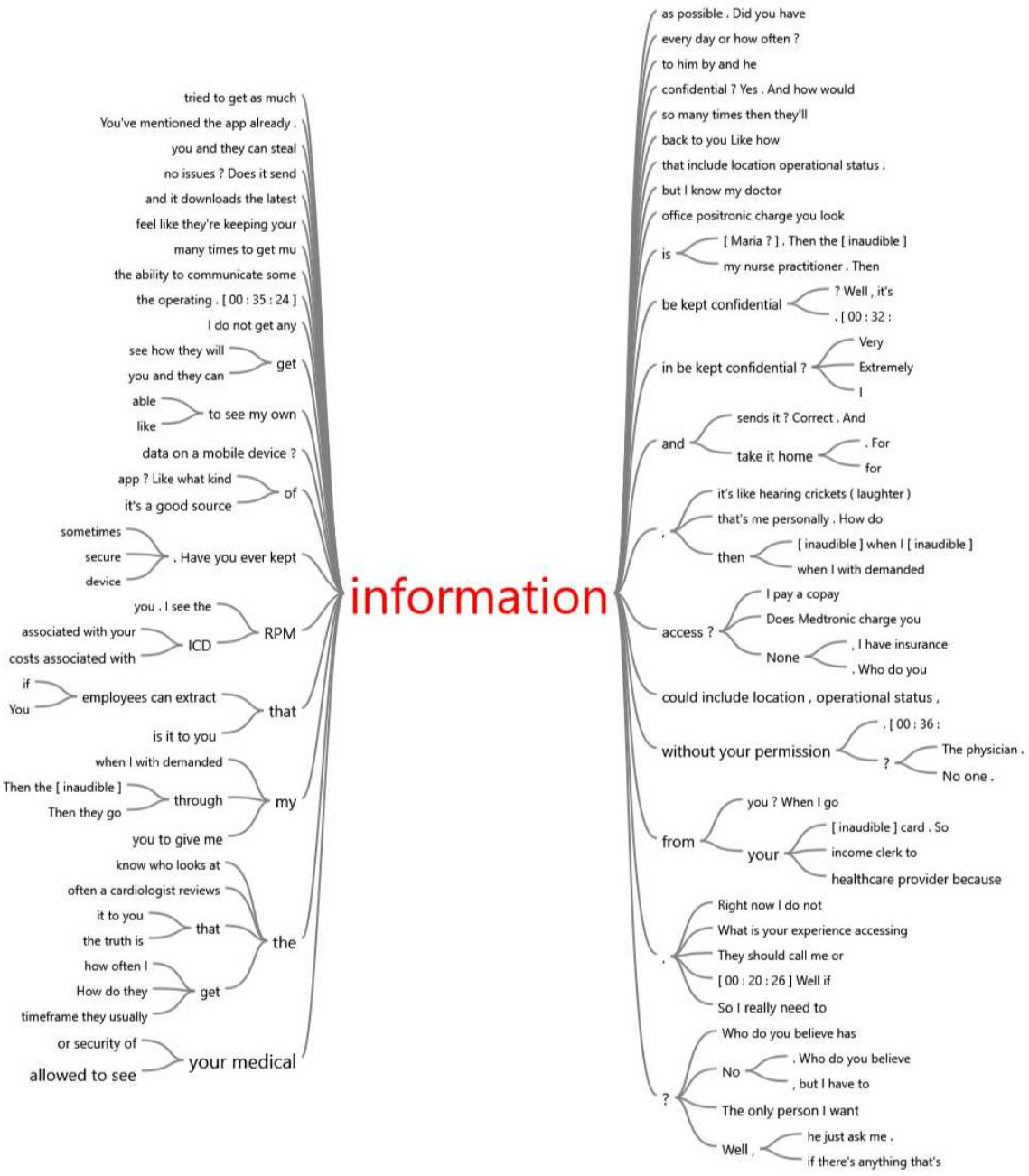

Figure 17. NVivo Word Tree of the Term "Information".

Participant #6 reinforced participant #2's desire for emergency services to have access to her ICD location due to living alone:

"Since, I live alone I think it might help an ambulance find me faster. So, yes."

Participant #1 was concerned with having ICD RPM geolocation service and compared it with social media location services:

> "Oh, no. I'm not happy with that. I don't want nobody to be tracking me like I'm a little icon. Where's participant #1 [laughter]? Even, I mean, I know Snap just came out with something which I was impressed. I have that now." You could share your location now. You can look and you can see all your friends, Oh, this one is at this pub. This one is at this restaurant. Oh, let's just go hang around with these fools. I was like, Wow, that just came out like two days ago. I was like, Whoa!"

Participant #5 shared the concern of participant #1 and felt that sharing her ICD location would be intrusive:

> "I feel that that would kind of be like tracking me."

Participant #4 was concerned regarding having ICD RPM geolocation but approved of ICD geolocation in an emergency:

> "I do not want to be tracked but I would be okay with it in an emergency."

Participant #3 shared the concern of participant #1 and #5, and did not approve of emergency services knowing his ICD RPM location:

> "I have a problem with that, but I may be sorry. But when you look at that that's like the police [laughter]. Yeah, that's like a privacy issue. That's what I mean by that."

Participant #2 mentioned loved ones regularly asked him if he was okay:

> "Well my wife keeps asking me three or four times a day, if not more, if I'm okay because she was there when I had the cardiac arrest. So she is very aware of it, very nervous of it."

Participant # 5 expressed the need to disclose the ICD in her social life:

> "Just in case it goes off and that has affected me in making new friends."

Privacy and Security

The salient security points that were identified were hacking, confidentiality, maladjustment, data breach, an ICD knowledge deficit with security staff, and subpar security on ICD RPM computer programmer (Figure 18).

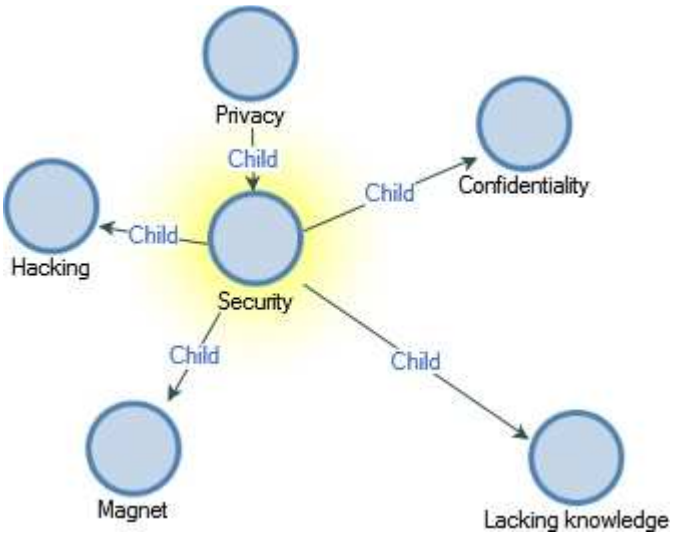

Figure 18. NVivo Explore Diagram of the Term "Security".

Participant #1 discussed the importance of privacy and confidentiality in relation to prospective employers and a potential data breach (Figure 19):

> "Yes, I think confidentiality is important when you're, probably when you're, I mean, I don't think it's the age, but. I look at it in the perspective as of let's say, as of employment wise. They're looking for somebody that's fit, somebody that doesn't have any issues. I mean, I'm not going to go out there in an interview and say, hey, I have a defibrillator on…and if there's a data breach. We know about this [laughter]."

Participant #1 discussed the importance of security in terms of hacking:

> "Yes, I think security is a concern for every individual that has any device in their system that they're able to control externally. That is a concern. The Medtronic representative was able to stop the device and accelerate the device. So one of the things that I always question myself is how about if I'm anywhere and somebody hacks in my system and controls it? I could die."

Participant #4 was concerned his ICD RPM could be manipulated:

"I'm afraid someone will adjust it wrong or turn it off sometimes."

Participant #2 mentioned that airport security staff are not familiar with ICD RPM:

> "…incidents where they have tried to ignore me, and tried to get me to go through the scanners and whatnot, and I've refused point-blank to go through."

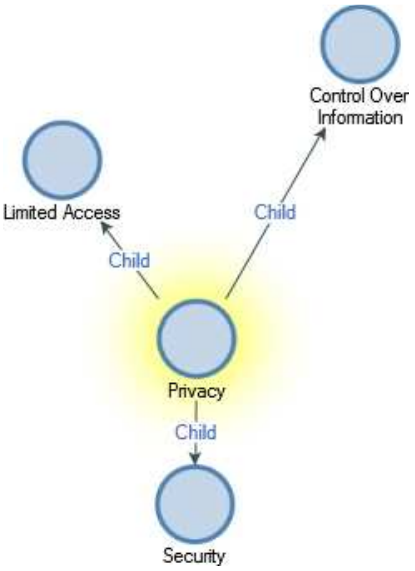

Figure 19. NVivo Explore Diagram of the Term "Privacy".

Education

There was a lack of ICD RPM education/information across all participants. Some wanted courses or the option of being part of a support group. Others did not know why three implants were implanted (e.g., battery, lead, defibrillator) (Figure 20). Patient education would be improved with courses, support groups, websites, handouts, experiencing a mock alarm, and having access to guidelines from their clinician for diagnostic tests (e.g., MRI). Research supported with education could help patients understand the best way to recover from an ICD shock; these shocks do not have to continue being a negative experience. The analyses revealed that the transition to living

with an ICD RPM could be improved vastly if input from patients were utilized effectively.

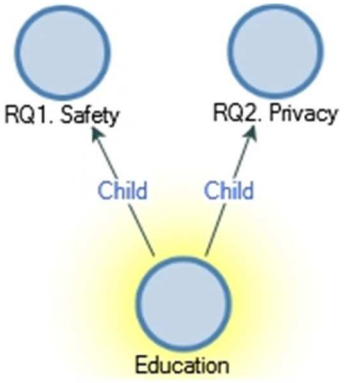

Figure 20. NVivo Explore Diagram of the Term "Education".

Participant #3 shared his physiological understanding (education) of cardiac disease and chronic heart failure (CHF) in the context of physical shock:

> "It's working all right for me because I ain't getting shocked. When I first began, well, they had to give me a certain medicine. They gave me that medicine first, for a couple of months because I would get arrhythmia. The arrhythmia meaning your heart speeds up and slows down, speeds up, slows down and then they rigged it so my heartbeat beating, if it beats too soon pace, I get fluid in my lungs because my heart don't pump good. My blood don't pump through my body good enough."

Participant #3 went on to express his education of how an ICD works:

> "I have a Medtronic ICD. That's a stimulator device. A stimulator device is for if your heart get to acting up, and it's going to fail, it jumps it off like a jump start. Like your battery dead in your car."

Participant #5's education statement reflected a common thread among the participants; not knowing the brand, quantity, or functionality of their ICD that was implanted:

> "I did not get to choose the device the doctor just told me what he recommended. He used Boston scientific."

Patterns Across Cases

The researcher identified the frequency of themes through the iterative coding and review of transcripts by each participant (Table 5).

The four identified themes were:

1. Comfort with perceived risk (T1)
2. Control over information (T2)
3. Education (T3)
4. Security (T4)

Table 5. Themes Summarized by Each Participant

	T1	T2	T3	T4	Total
Participant #1	91	14	13	15	133
Participant #2	87	19	3	12	121
Participant #3	58	14	6	5	83
Participant #4	41	3	2	5	51
Participant #5	55	9	3	5	72
Participant #6	75	16	7	5	103
Total	407	75	34	47	

Summary

This chapter provided a detailed overview of the analysis section, presented results from the demographics form, and IPA of the interview transcripts. IPA analysis resulted in over 100 significant statements and four themes related to the research questions, perceived safety and privacy concerns, as well as statements that provide evidence for each theme. The four themes included: comfort with perceived risk, control over information, education, and security.

Chapter 5

Conclusions, Implications, Recommendations, and Summary

Introduction

The review of the literature highlighted a significant gap in the research examining the lived experiences of ICD recipients with RPM. Chapter 4 laid the foundation for the findings presented in this chapter. In this chapter, the framework for achieving the study aims was established through: the interpretation of the thematic data; answers to the two overarching research questions; strengths, weakness, validity, and limitations of the study; and recommendations for advancing and improving the lives of people who currently have an ICD with RPM, as well as the experiences of future patients. This chapter also proposes recommendations for future research in the perceived safety and privacy concerns research streams.

Conclusions

The dissertation goal was to better understand the lived experiences of patients with ICD RPM. The aforementioned findings from this research answered the two questions regarding how patients live and interact with RPM and indicate the study goal was met.

1. How do RPM recipients perceive safety concerns?

2. How do RPM recipients perceive privacy concerns?

The findings and conclusions for each question are explored below. Themes are cross-referenced and demonstrate connectivity between the overarching study questions.

Research Questions

How do RPM recipients perceive safety concerns? Participants expressed their comfort with perceived risk for the most part. Within this theme, being scared, having anxiety, and acceptance were common subordinate themes. The majority of participants reported negative feelings from their initial traumatic event (e.g., MI, heart failure, etc.) and being scared of shocks. One participant was shocked 11 times over a four-month period. Most participants were dissatisfied with the level of ICD RPM education provided. They were unaware of or did not join support groups. They utilized online blogs for information, however, these scared them, rather than educated them, because of the nature of the horror stories they read. Those who did know others with ICD RPM were afraid as a result of hearing about occurrences of sudden cardiac death (SCD) where the device did not work or did not work adequately to save their friend's life. One participant became aware of her offspring having the same cardiac diagnosis, which created additional worry for the participant. Participants were afraid the alarm could go off at any time without warning.

Several participants expressed security concerns regarding the ICD being hacked, maladjusted, manipulated with magnets, or turned off. Participants believed ICD RPM security was in place but inadequate. One participant went as far as to express thoughts of the serious consequences if all ICDs were turned off in a populated area.

How do RPM recipients perceive privacy concerns? The most commonly expressed concerns by participants were their lack of control over information and lack of information about their devices. Privacy is the claim of an individual to determine what

information about himself or herself should be known to others (Westin, 1967). Privacy also involves when such information is obtained and what uses are made of it by others (Westin, 1967). Researchers have found that because participants do not know how data are transmitted and when and how the data are analyzed and reviewed, privacy and surveillance concerns related to this lack of understanding have arisen (Skov, Johansen, Skov, & Lauberg, 2015).

Limited access, privacy/intimacy, communication were popular subordinate themes. Under control over information, participants with children were interested in them having access to their ICD RPM information. Geolocation was one of the most controversial themes in this study, as most participants did not want to be tracked under any circumstances. They called the geolocation feature a lo-jack and displayed revealing and negative facial and body reactions during their interviews when discussing this topic. On the other hand, some participants noted they would like geolocation services. They claimed it might help emergency services locate them faster, especially if they were not familiar with the area or were located in a building (e.g., second versus eighth floor).

Limitations and Delimitations

Limitations in qualitative research exist. There are a number of limitations that could have affected the validity of this study. One limitation of the study was generalizability. The semi-structured interviews produced a large amount of qualitative data, however, the lived experiences from a small purposeful sample (N = 6) cannot be generalized (Creswell, 2013). The researcher attempted to recruit a demographically diverse sample. The final sample was weighted with an equal number of females and males in varying age groups.

Qualitative interviews have been known for not being neutral tools (Bloomberg & Volpe, 2008, p. 82). The interactions between the interviewer and interviewee could have resulted in a change of perception by both parties. As a result, the researcher made an effort to withhold bias and opinion during the interviews. This was further aided by the researcher's use of non-verbal communication while face-to-face with participants. Being in-person during the interviews supported less interruptions and background noise, and promoted a fluid exchange of dialogue with the appropriate use of silence from the researcher to obtain as much rich and detailed information as possible. Participants were interested and able to express themselves but several participants were shy about discussing personal subjects. For example, some participants eventually were more comfortable than others discussing their anxiety of resuming exercise and being intimate, therefore some information might have been withheld, which affects the completeness of the report. English was a second language for two participants, and other participants had accents but they did not affect communication during the interview. However, a few accents made the transcription more challenging (e.g., Hispanic, Black, and Irish). With these possible limitations, the researcher is confident that the findings are valid to ICD RPM recipients.

Regarding delimitations related with this research, the researcher identified adult ICD RPM participants to be included. The researcher expected participants to fully share their lived experiences without filtering was a factor outside the researcher's control and the findings show a sufficient breadth and depth of data resulting from the interviews. Delimitations included any participants who were unable to sustain a conversation and patients who were not psychologically stable (e.g., suicidal, altered mental status).

The researcher was aware of his personal experiences and biases and did not lead participants. Reflexive journaling was used to manage, monitor, and control any potential bias. The researcher made the participants comfortable while maintaining the utmost level of ethics. The qualitative process produced copious amounts of data which was time consuming and labor intensive to analyze. Another limitation was being able to find enough participants using RPM. None of the participants opted out of the study after participating in the in-person interview.

The sample was purposive and homogeneous, as is recommended in IPA, to understand the specific phenomenon from the perspective of ICD RPM participants. The experiences of each participant were unique and also similar in terms of having common ICD experiences. The researcher believes that the lived experiences of ICD RPM participants have been well represented by the interview data collected, coded, analyzed and presented, especially given that this was a mixed gender sample, and there were a range of age groups and different races and ethnicities. This study examined the ICD RPM individuals in a system with minimal standards, and for better or worse, standards appear to be mainly at the discretion of their practitioners.

Few researchers have explored the perceived safety and privacy concerns domain among patients who have ICD RPM. In the medical devices industry, competition to implement the latest smart implants should not overlook ICD RPM recipients as a key component in a healthy system that supports safe, secure, and private innovation.

Validity

Smith et al. (2009, pp 180-183) recommend four key points to judge validity and was built on previous research by Yardley (2000).

1. Throughout the study, the researcher applied *sensitivity to context*. The researcher considered the best methodology, format, interview techniques, with in-person synchronous communication. Participants were made as comfortable as possible prior to and throughout interviews and were well represented in the final report.
2. In order make a valid contribution to the body of knowledge, the researcher used the utmost *commitment and rigor* throughout this research. The sample size was purposive, homogeneous, diverse, and equal in gender. The research was replicable by other researchers because data were collected, reviewed, and investigated in a systematic method. Transcripts were available for any participants who chose to review them.
3. This research was conducted with the highest level of *transparency and coherence*. All aspects and details are included in the description of research, methodology, findings, and conclusions. Vast quantities of narrative and supporting analysis aid in framing the research findings and conclusions. The researcher aimed to present a first-person account of data analysis from the participants, where proper. The study methodology was carried out as originally proposed. One participant suggested the researcher update the interview guide to include ICD card information (e.g., serial and model numbers) but this was not necessary.
4. The last validity point *impact and importance,* was described by Yardley (2000). Research that is presented well allows the reader to distinguish themes and conclusions from this research. Few studies have focused on

RPM ICD and the lived experiences of users. IPA is a novel approach that was applied to this problem to gain a deeper understanding of this phenomenon. As a result, the ICD RPM experiences described in this research were educational and thought-provoking. Future qualitative and quantitative research should determine the significance of this contribution to the body of knowledge. It is hoped the findings help current and future ICD RPM patients.

Implications

The findings from this study have a number of implications for healthcare medical device companies, researchers, educators, practitioners, support groups, and patients. Prior to this study, there were few studies that have focused on RPM ICD and the lived experiences of users. IPA is a novel approach that was applied to this problem to gain a deeper understanding of this phenomenon published IPA. These research findings uncover several areas for future research and process development to better help patients navigate and prepare for this life changing journey. Overall, participants had traumatic experiences related to their initial cardiac event, continuing fear of being shocked at any moment, and overriding anxiety due to lack of information. However, participants adjusted to living with an ICD within about one year. The experiences shared by the participants are loaded with experiential data that show how they lived through both their day-to-day and their near-death experiences.

This study uses IPA to showcase thematic findings from six in-depth interviews with ICD RPM participants. Four major findings emerged from this study:

1. *Safety Comfort with Perceived Risk* – ICD RPM participants are most afraid during the first six weeks to three months of implantation. ICD RPM participants are traumatized by shocks and ICD alarms so much so that they consider having ICDs removed.
    a. *Communication* – ICD RPM participants believe device communication needs improvement (e.g., battery life, device status). This is similar to prior research with poor feedback mechanisms (Skov et al., 2015). Participants would like to bypass using a docking station to transmit data and have data transmitted automatically through their mobile device.
2. *Control Over Information* – ICD RPM participants do not think about their devices much after one year unless there was a shock. However, their family members do. Participants expressed having family members having the ability to access their ICD RPM data. Some participants wanted an application to view their data while others were interested in a monthly summary. One older participant was not interested in using a computer. Overall, participants wanted to be able to manage the amount of information received and decide who else could have access.
    a. *Right to be Left Alone/ Geolocation/ Control over Information* – Most ICD RPM participants in this sample were not comfortable with geolocation services.
    b. *Geolocation* – A few ICD RPM participants were comfortable with geolocation for emergency services.

c. *Privacy/Intimacy* – ICD RPM participants have lost jobs and feel a need to disclose information with new relationships because they believe that a part of human relationships included volunteering to self-disclose some information, but withholding other information. The concept of privacy, part of the process by means of which humans establish relationships with each other, was important to these participants (Solove & Doris, 2010). Participants noted that ICD affected their sexual relationships.

3. *Education* – ICD RPM participants believe cardiology response protocol for post alarms are fast. However, they are unsure who actually reads the off hour transmissions to the cardiologist.
4. *Security* – ICD RPM participants believe security protocols are in place but do not think they are adequate. Participants believe their implants are vulnerable to hacking, magnets, and some electronic devices. Participants had negative experiences with diagnostic equipment (MRI), court and airport security.

Recommendations

These findings can be used to improve the experiences of new ICD RPM recipients. First, medical device companies, researchers, educators, practitioners, and support groups should review these findings to develop and implement ways to close the identified gaps and improve overall HCI. A dedicated ICD RPM role could help reduce the gap between device companies, physicians, and patients. Education should not be an afterthought. Education protocols could be put in place to reduce participant uncertainty and the unknown. Sexual and physical education, associated with privacy/intimacy, is

recommended starting in the hospital and continuing post discharge (Hoseini, Afra, Asayesh, Goudarzi, & Afra, 2018). With regard to physical activity, participants were unsure of what limitations their ICD placed upon them (e.g., weight lifting, exercise, etc.). Further research would help address these knowledge gaps.

There is significant room for improvement in the delivery of care, as reported by these participants, which fits in with findings in previous studies (DuBose-Morris, 2014). According to Doyle (2006) healthcare has entered the information age, with the goal of attaining an entirely new cultural and healthcare delivery model that relies heavily on technology to enhance patient care and safety at a much higher level of efficiency. Agile methodology could be used as an efficient iterative approach to ICD design. In agile, small phases of work with frequent reassessment allow build and design work to quickly adapt to end-user requirements. The continuous feedback through retrospectives, sprints, and test first development, are all methods that would support improved ICD RPM iterative and incremental development. Also, using a third wave HCI approach, with wide ranging collection, would help to understand the design, methods, and applications of emerging forms of interaction with new technologies and human knowledge and experiences (Filimowicz & Tzankova, 2018).

Future Research

Future research areas have been discussed in the previous sections. Researchers have the opportunity to use these HCI shortfalls and further investigate ICD RPM perceived safety and privacy concerns.

The lack of education significantly affected participant perceived safety, fear, anxiety, and privacy concerns. Future research should address questions of whether

training preoperatively and postoperatively was adequate, how often trainings should have occurred for participants, and who should have been trained besides participants (e.g., practitioners, support groups, family members).

Other opportunities include future ICD RPM HCI design. Qualitative research is needed to compare and contrast what ICD RPM features currently have and how many of these features are utilized. If the IPA lived experiences reflected in this study were used as lessons learned, changes could be incorporated to improve living with an ICD RPM. Research is needed on better ways to manage ICD shock and alarm. Medical device companies need to place privacy first and redefine privacy as a meaningful word. If not, there could be more instances of epic single day stock losses in the U.S. where companies lose over $100 billion dollars over privacy issues or become bankrupt (e.g., Facebook in 2018 (Cambridge Analytics)). Participants need privacy with the ability to control their ICD RPM information.

Summary

This research study's goal was to understand the lived experiences of ICD RPM participants. Since RPM is becoming more widely used to provide care, and more devices (and sensors) are coming online with the internet of things (IoT), the human element should be placed first. In agile methodology, acceptance criteria would be developed before creating test scripts and the ICD RPM product. The human experience is currently missing from the ICD RPM acceptance criteria.

ICDs that administer electrical pulses or shocks are a standard treatment for candidates with specific conditions, such as life threatening arrhythmias and those at risk for sudden cardiac death. The medical literature identifies numerous technology-driven

improvements in disease management, for example, approximately 10,000 people receive an ICD each month in the U.S. (Medtronic, 2019). Moreover, the results of several studies demonstrate that ICD patients are safer when connected to remote monitoring, since problems and issues are discovered much faster, compared to patients without monitoring (Varma et al., 2017). However, what was not known, was why patients do not feel safer, creating a safety paradox, and why participants identify privacy concerns in the monitoring of ICD patients.

With regard to remote patient monitoring, there was a major gap in the literature explaining the factors that contribute to perceived safety and privacy. The research goal of this study was to provide an interpretive account of the experience of RPM patients. To close this gap, this study investigated two research questions: 1) How did RPM recipients perceive safety concerns?, and 2) How did RPM recipients perceive privacy concerns? Four themes—comfort with perceived risk, control over information, right to be left alone, education, and security—emerged from the iterative review and data analysis. In responding to the research questions, the lived ICD RPM experiences provided the following insights.

How do RPM recipients perceive safety concerns? Participants most often expressed their comfort with perceived risk in this study. Within this theme, being scared, having anxiety, and acceptance were common subordinate themes. The majority of participants had negative experiences with the initial traumatic event and were afraid of shocks. Most participants were dissatisfied with the level of ICD RPM education provided. They were unaware of, or had not joined support groups, and used online blogs that frightened them due to the nature of the horror stories they read. Those who knew

others with ICD RPM, were afraid because they had heard of occurrences of sudden cardiac death (SCD) due to device failure. Participants were afraid the alarm can go off anytime without warning and had instances of false alarm. Participants expressed fear and frustration with false alarms. False alarms made them feel as if they were dying and resulted in having a follow-up appointment the next day with their cardiologist.

Several participants expressed security concerns regarding the ICD being hacked, maladjusted, manipulated with magnets, or turned off. Participants believed ICD RPM security was in place but was inadequate.

How do RPM recipients perceive privacy concerns? The most frequently expressed concerns among participants was their lack of control over information and inability to tailor information for themselves or loved ones. Participants with children were interested in them having access to their ICD RPM information. Privacy/intimacy and right to be left alone were the second most common subordinate themes. In this study, most participants did not want to be tracked under any circumstances and stated they thought of the geolocation feature as something like a lo-jack. On the other hand, of participants reported they would like geolocation services as it might help emergency services locate them faster. The findings of this research are potentially important in the advancement of ICD RPM technology.

The researcher used scholarly methods to limit bias. Findings demonstrated validity based on Smith et al. (2009): sensitivity to context; commitment to rigor; transparency and coherence; and impact and importance.

This contribution to the field of information systems within human computer interaction literature was needed because few researchers have explored how people live

and interact with these newer and more advanced devices. Recommended areas of future research should include investigating ways to overcome ICD RPM frustration and improve communication that can be tailored to what recipients want. Education should also be examined as a means of reducing the uncertainty that was shared by ICD RPM participants. Additional research should examine changing the various ICD RPM issues into opportunities to provide a positive experience with this life-saving technology.

Appendix A: IRB Approval Letter

NSU NOVA SOUTHEASTERN UNIVERSITY
Institutional Review Board

MEMORANDUM

To: **Marc Doyle, RN, MBA**
College of Engineering and Computing

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

Date: **May 8, 2017**

Re: **IRB #: 2017-315; Title, "Comprehending the Safety Paradox and Privacy Concerns with Medical Device Remote Patient Monitoring"**

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 Category 2)**. 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: Maxine Cohen, Ph.D.
Ling Wang, Ph.D.

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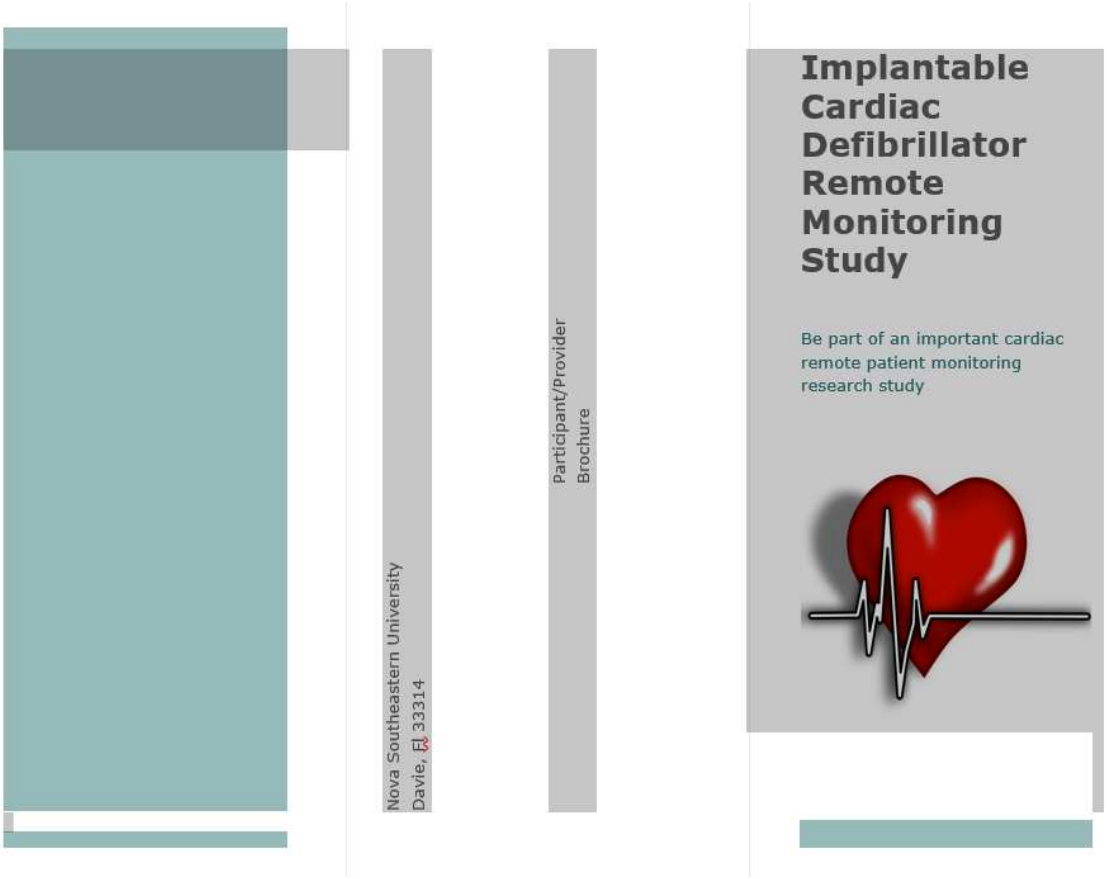
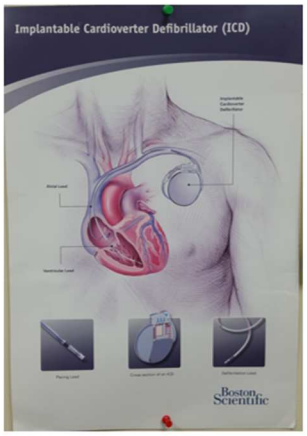
Appendix B: Recruitment Brochure





What topics will be discussed

This research will be conducted using an interview to investigate perceived safety and privacy. The open-ended design of qualitative research allows participants to relate what they find significant about their illness experience from their point of view (Ritchie, Lewis, Nichols, & Ormston, 2013). The researcher will use a semi-structured interview process to collect data on the lived experiences of ICD RPM participants. Institutional Review Board (IRB) approval has been obtained through Nova Southeastern University.

The research goal of this study is to provide an interpretative account of the experience of RPM patients which might result in implications for practice relating to RPM safety and privacy as well as providing suggestions for future research.

The purpose of this research study is to understand why RPM patients do not feel safer, creating a safety paradox, and why participants identify privacy concerns in the monitoring of ICD patients

Participation information:

You have the right to leave this study at any time or refuse to participate. If you make either choice, you will not experience any penalty or loss of services you have a right to receive. If you choose to withdraw, any information collected about you before the date you leave the study will be kept in the research records for 36 months after the study ends. This information may be used as a part of the research.

What will be needed

- Signed consent
- Demographic form
- One-hour interview

Contact Us

Nova Southeastern University
Davie, Fl 33314

Marc Doyle
Doctoral Student
954-687-2454
MD1322@nova.edu

http://cec.nova.edu/

Appendix C: Informed Consent Form

Consent Form for Participation in the Research Study Titled Comprehending the Safety Paradox and Privacy Concerns with Medical Device Remote Patient Monitoring

Funding Source: None.

IRB protocol # 2017-315

Principal investigator:
Marc Doyle
7265 N.W. 42 CT.
Davie, FL 33314
954-687-2454

Co-investigator: Dr. Maxine Cohen
Site info: local coffee shop or participant's home

For questions/concerns about your research rights, contact:
Human Research Oversight Board (Institutional Review Board or IRB)
Nova Southeastern University
(954) 262-5369/Toll Free: 866-499-0790
IRB@nsu.nova.edu

What is the study about?
You are invited to participate in a research study being conducted at a local coffee shop or in the comfort of your home. The research goal of this study is to provide an interpretative account of the experience of RPM patients which might result in implications for practice relating to RPM safety and privacy as well as provide suggestions for future research.

Why are you asking me?
You are invited to participate because you currently have an implanted cardiac defibrillator. There will be between three and six participants in this research study.

What will I be doing if I agree to be in the study?
First, you will answer a short background survey. Next, the researcher will interview you about your lived experiences regarding perceived safety and privacy related to your implanted cardiac defibrillator with remote patient monitoring. Total time is about one hour.

Is there any audio or video recording?
The researcher will record the interviews to help with analysis. These recordings will be available to be heard by the researcher, Mr. Marc Doyle, personnel from the IRB, and a third-party transcriptionist. Once the data are collected from the participants, data will be transcribed by a third party professional transcriber with a standard non-disclosure agreement for participant confidentiality. Data will be anonymized prior to being transcribed. After transcription, the researcher will review and compare the transcribed files with the audio file for accuracy.

The recordings will be kept securely in Mr. Doyle's possession. The recordings will be kept for 36 months from the end of the study. The recordings will be destroyed after that time by erasing

the audio files from the secure and protected computer. Because your voice could be identified by anyone who hears the tapes, the confidentiality of your recorded words cannot be guaranteed. However, the researcher will limit access to the tapes as described here.

What are the dangers to me?
Risks to you are minimal. This means they are not thought to be greater than other risks you experience every day. Being recorded means that confidentiality cannot be promised. No harm is anticipated as a result of providing comments. If you have questions about the research, your research rights, or if you experience an injury because of the research please contact Mr. Doyle at 954-687-2454. You may also contact the IRB at the numbers indicated above with questions about your research rights.

Are there any benefits to me for taking part in this research study?
There are no benefits to you for participating other than the possibility that your information may help researchers better understand perceived safety and privacy with cardiac remote patient monitoring.

Will I get paid for being in the study? Will it cost me anything?
You will not be paid for participating in the study. There are no costs to you.

How will you keep my information private?
The surveys will not ask you for any information that could be linked to you. The transcripts will not have any information that could be linked to you. The research materials will not contain your name, only a participant number. This form will contain your signature and the recordings will contain your voice. That is the only identifying information being collected. All information obtained in this study is strictly confidential unless disclosure is required by law. The IRB, Mr. Marc Doyle, and a third-party transcriptionist, may review research records.

What if I do not want to participate or I want to leave the study?
You have the right to leave this study at any time or refuse to participate. If you make either choice, you will not experience any penalty or loss of services you have a right to receive. If you choose to withdraw, any information collected about you before the date you leave the study will be kept in the research records for 36 months after the study ends. This information may be used as a part of the research.

Other Considerations:
If the researcher learns anything which might change your mind about being involved, you will be told of this information.

Voluntary Consent by Participant:
By signing below, you indicate that:
- this study has been explained to you
- you have read this document or it has been read to you
- your questions about this research study have been answered
- you have been told that you may ask the researchers any study questions in the future or contact them in the event of a research-related injury
- you have been told that you may ask IRB personnel questions about your study rights
- you are entitled to a copy of this form after you have read and signed it

• you voluntarily agree to participate in the study entitled *Comprehending the Safety Paradox and Privacy Concerns with Medical Device Remote Patient Monitoring.*

Participant's Signature: _____ Date: _____
Participant's Name: _____ Date: _____
Signature of Person Obtaining Consent: _____ Date: _____

Appendix D: Demographic Form

COMPREHENDING THE SAFETY PARADOX AND PRIVACY CONCERNS WITH MEDICAL DEVICE REMOTE PATIENT MONITORING

Demographic form

Age_____

Height_____

Weight_____

Gender_____

Ethnicity _____

Relationship Status_____

Date device implanted_____

Date RPM activated_____

Number of times in the past year, you visited a cardiologist_____

Number of times in the past year, that device issue made you visit hospital or doctor_____

Number of times in the past year, Remote Monitoring staff have contacted you_____

If applicable, insurance coverage_____

If applicable, number of battery changes_____

If applicable, number of shocks_____

Appendix E: Interview Guide

Interview guide
Can you to tell me the story of how you came to have an ICD?
What notable experiences have you had with your ICD?
Safety
Can you tell me about living with an ICD?
Did you have an abnormal heart rhythm or was it put in just in case?
Can you tell me what it was like when you went home?
What were some of the physical sensations, if any, you experience related to your ICD?
Can you remember how you were feeling (emotionally) at that time?
How often do you (or your caregiver) believe your ICD is working properly?
Many people experience a range of different emotions when they have a defibrillator. Can you tell me about the feelings you experienced?
How do you feel about this device monitoring your health? What data was monitored, how was it transmitted, who analyzes your data, and how often does your doctor review?
Do you feel differently about yourself? Has that stayed the same or changed over a number of years? If it changes, what do you attribute those changes to?
When not feeling well, have you or a caregiver ever questioned if the RPM device was working? If so, as the patient what was your response.
If the reply was "you just deal with it," Can you tell me how you do that?
How often do you think about your ICD?
Do you think having an ICD has affected your life, if so how?
How has it affected your family relationships?
How has it affected you professional relationships?
How has it affected your social relationships?
Have you ever experienced a shock? Can you tell me about the experience(s)?
Where did it happen? Were others present?
What was the physical sensation?
How did you feel emotionally before, during, or after the shock?
Did you feel differently about your ICD? How did it affect your life? Does it change with each event?
Can you tell me about having your ICD checked/interrogated?
Do you have any physical sensations during the procedure?
How do you experience any emotions before, during, or after the check?
Have you ever been told your ICD stopped a fast heartbeat (arrhythmia) and were unaware of it happening?
How much battery life was left in your ICD RPM device? Would you or a caregiver be interested in having the ability to find out on your own how much battery life was left in your RPM device at any time?
How do you feel about the frequency of communication between you and your healthcare provider regarding your device status?
Tell me about your second ICD (and each successive ICD if applicable).
How would receiving emails, calls, or text messages regarding your device's performance make you feel?

What was your experience accessing machines with ICD RPM? For example, how do airport security (metal detectors, scanners) and medical diagnostic tests such as an MRI make you feel?
If applicable, please tell me about your experience before, during, and after an ICD shock?
Do you know when an ICD shock was imminent?
What were your thoughts and feelings when you knew it was almost time to have the surgery?
Did you have your ICD replacements (if >1) at the same hospital(s)?
Tell me your thoughts and impressions of your day(s) of surgery.
Was the experience different from your other implant(s)? If so, how?
Did you feel any discomfort during the procedure? After? For how long?
Do you ever think about not having your defibrillator replaced?
What if anything, changes (has changed) with your new implant(s)? (e.g., physical, emotional, or social variations)
Did you talk to anyone about your thoughts and concerns?
Privacy
Tell me about your privacy with ICD RPM?
Tell me about the security with ICD RPM?
Have you ever kept information from your healthcare provider because you were concerned about the privacy or security of your medical information?
Who do you believe has access to your ICD RPM data?
How do you feel your ICD RPM data was being used?
How important was it to you that information in be kept confidential?
How would you feel about your device disclosing your location on a map?
Would you or a caregiver be interested in being able to see your data on a mobile device? Information could include location, operational status, and last time synched.
What are your costs associated with ICD RPM information access?
Who do you think should be allowed to see your medical information without your permission?

Appendix F: Transcript Review Letter

Dear participant,

Thank you again for participating in the study titled, "Comprehending the Safety Paradox and Privacy Concerns with Medical Device Remote Patient Monitoring." I sincerely appreciate your willingness to share your experiences related to cardiac monitoring.

As previously mentioned, your interview was recorded and has now been transcribed by a professional transcriptionist. Please follow this link, participant link to review your completed transcription through Google Drive. Besides me as the researcher, you are the only person who has access to this file.

At this point in the study, your assistance is requested to review the transcription and make any additions or changes at the bottom of the document under the section, "Participant Review & Feedback." I invite you to elaborate on the transcribed conversation or share any additional thoughts that might have arisen since our interview. Please provide your comments directly onto the Google Drive file and save your changes by _____(date). After you complete your changes, I will receive a notification from Google Drive. The file will then be saved offline.

If you have any questions about this process, the transcript or the future steps for this study, please me at md1322@nova.edu or by phone at 954-687-2454.

Thank you,

Marc Doyle, RN, MBA, PMP

Appendix G: Node Data Dictionary

Name	Description
RQ1. Safety	
Comfort with Perceived Risk	
Feelings (physical)	
Physical pain	When something hurts on the body.
Physical Shock	A sudden jolt or thump on the chest from electrical ICD impulses (e.g., feeling like getting punched in the chest).
Feelings (psychological)	
Acceptance	Willingness to tolerate a difficult or unpleasant situation.
Anxiety	Intense, excessive, and persistent worry.
Coping mechanism	Having difficulty with constructive coping mechanisms to reduce stress.
Depressed	A state of general unhappiness.
Employability	
Scared	Fear, afraid, scared, etc.
Trust	Firm belief in the reliability, truth, ability, or strength of someone or something.
Want ICD removed	Participant statements regarding having their ICD removed.
Patient-centered care	When patients are not included in their decision-making care. It includes listening to, informing and involving patients in their care. The IOM (Institute of Medicine) defines patient-centered care as: Providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions.
Communication	The act of transferring information from one place, person or group to another.
Change	To make or become different.
Smart implant	Smart implant.

Name	Description
False alarms	Redundant alarms.
Internet misinformation	Information from discussion groups and unofficial sites.
Lack of feedback	When participants do not get feedback.
Battery life	Battery life.
No warning before physical shock	When participants are not forewarned of shock
Poor knowledge transfer between KMS and or practitioners	Poor knowledge transfer between KMS and or practitioners.
Too many doctor visits	Participant comments regarding having to many office visits.
Unknown	
Education	Knowledge or lack of knowledge.
RPM Utilization	
Spontaneity	Sudden event.
RQ2. Privacy	
Control Over Information	Controlling one's own information.
Device companies	Device companies.
Frequency information distribution	Frequency of ICD RPM information distribution.
Geolocation	Geolocation is the identification or estimation of the real-world geographic location of an object or Internet-connected implant.
Lo-Jack	

Name	Description
Tracked like a little SnapChat Icon	
Layered access	Layered access of which groups of people have access to what data.
Levels and amount of information	Levels and amount of information.
Medium	Medium discussed in interview.
Application	
Email	
Text message	
Website	
Privacy Right to Be Left Alone	The right to privacy includes the right to be left alone.
Privacy Intimacy	
Tailoring	Be able to customize ICD RPM information.
Limited Access	
Caregivers	
Employers	
Family Members	
Children	
Loved ones	
Friends	
Security	Prevention of unauthorized access to any written information that is transmitted or transferred.
Confidentiality	Keeping a patient's personal health information private.
Data breach	Data loss.

Name	Description
Hacking	Gaining unauthorized access to an information system.
Lacking knowledge	
Magnet	Holding a magnet right over an ICD will temporarily disable it and keep it from delivering multiple shocks.
Maladjustment	
Poor security. Too easy to access	
Security staff ICD knowledge	

Appendix H: Coded and Auto Coded Nodes

Nodes
Nodes\\RQ1. Safety
Nodes\\RQ1. Safety\Comfort with Perceived Risk
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Feelings (physical)
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Feelings (physical)\Physical pain
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Feelings (physical)\Physical Shock
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Feelings (psychological)
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Feelings (psychological)\Acceptance
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Feelings (psychological)\Anxiety
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Feelings (psychological)\Coping mechanism
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Feelings (psychological)\Depressed
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Feelings (psychological)\Employability
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Feelings (psychological)\Scared
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Feelings (psychological)\Trust
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Feelings (psychological)\Want ICD removed
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care\Communication
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care\Communication\Change
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care\Communication\Change\Smart implant
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care\Communication\False alarms
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care\Communication\Internet misinformation
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care\Communication\Lack of feedback
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care\Communication\Lack of feedback\Battery life
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care\Communication\No warning before physical shock
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care\Communication\Poor knowledge transfer between KMS and or practitioners
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care\Communication\Too many doctor visits
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care\Communication\Unknown
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care\Education

Nodes\\RQ1. Safety\Comfort with Perceived Risk\Patient-centered care\RPM Utilization
Nodes\\RQ1. Safety\Comfort with Perceived Risk\Spontaneity
Nodes\\RQ2. Privacy
Nodes\\RQ2. Privacy\Control Over Information
Nodes\\RQ2. Privacy\Control Over Information\Device companies
Nodes\\RQ2. Privacy\Control Over Information\Frequency information distribution
Nodes\\RQ2. Privacy\Control Over Information\Geolocation
Nodes\\RQ2. Privacy\Control Over Information\Geolocation\Lo-Jack
Nodes\\RQ2. Privacy\Control Over Information\Geolocation\Tracked like a little SnapChat Icon
Nodes\\RQ2. Privacy\Control Over Information\Layered access
Nodes\\RQ2. Privacy\Control Over Information\Levels and amount of information
Nodes\\RQ2. Privacy\Control Over Information\Medium
Nodes\\RQ2. Privacy\Control Over Information\Medium\Application
Nodes\\RQ2. Privacy\Control Over Information\Medium\Email
Nodes\\RQ2. Privacy\Control Over Information\Medium\Text message
Nodes\\RQ2. Privacy\Control Over Information\Medium\Website
Nodes\\RQ2. Privacy\Control Over Information\Privacy Right to Be Let Alone
Nodes\\RQ2. Privacy\Control Over Information\Privacy Right to Be Let Alone\Privacy Intimacy
Nodes\\RQ2. Privacy\Control Over Information\Tailoring
Nodes\\RQ2. Privacy\Limited Access
Nodes\\RQ2. Privacy\Limited Access\Caregivers
Nodes\\RQ2. Privacy\Limited Access\Employers
Nodes\\RQ2. Privacy\Limited Access\Family Members
Nodes\\RQ2. Privacy\Limited Access\Family Members\Children
Nodes\\RQ2. Privacy\Limited Access\Family Members\Loved ones
Nodes\\RQ2. Privacy\Limited Access\Friends
Nodes\\RQ2. Privacy\Security
Nodes\\RQ2. Privacy\Security\Confidentiality
Nodes\\RQ2. Privacy\Security\Data breach
Nodes\\RQ2. Privacy\Security\Hacking
Nodes\\RQ2. Privacy\Security\Lacking knowledge
Nodes\\RQ2. Privacy\Security\Magnet
Nodes\\RQ2. Privacy\Security\Maladjustment
Nodes\\RQ2. Privacy\Security\Poor security. Too easy to access
Nodes\\RQ2. Privacy\Security\Security staff ICD knowledge
Nodes\\Autocoded Themes\\airport security
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Nodes\\Autocoded Themes\\alarm\defibrillator alarm
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Nodes\\Autocoded Themes\\battery\cell phone battery

Nodes\\Autocoded Themes\\battery\much battery
Nodes\\Autocoded Themes\\battery\much battery life
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Nodes\\Autocoded Themes\\call\phone call
Nodes\\Autocoded Themes\\call\receiving emails calls
Nodes\\Autocoded Themes\\defibrillator
Nodes\\Autocoded Themes\\defibrillator\cardiac defibrillator
Nodes\\Autocoded Themes\\defibrillator\defibrillator alarm
Nodes\\Autocoded Themes\\defibrillator\defibrillators lots
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Nodes\\Autocoded Themes\\device\device person
Nodes\\Autocoded Themes\\device\device status
Nodes\\Autocoded Themes\\device\device stimulator
Nodes\\Autocoded Themes\\device\device type
Nodes\\Autocoded Themes\\device\icd device
Nodes\\Autocoded Themes\\device\rcd device
Nodes\\Autocoded Themes\\device\rpm device
Nodes\\Autocoded Themes\\device\scientific device
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Nodes\\Autocoded Themes\\heart rhythm
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Nodes\\Autocoded Themes\\heart rhythm\abnormal heart rhythm
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Nodes\\Autocoded Themes\\information\medical information
Nodes\\Autocoded Themes\\information\much information
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Nodes\\Autocoded Themes\\issue\heart issues
Nodes\\Autocoded Themes\\issue\privacy issue
Nodes\\Autocoded Themes\\life
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Nodes\\Autocoded Themes\\life\regular life
Nodes\\Autocoded Themes\\little thing
Nodes\\Autocoded Themes\\little thing\little thing
Nodes\\Autocoded Themes\\medical information
Nodes\\Autocoded Themes\\medical information\medical information
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Nodes\\Autocoded Themes\\month\month fee
Nodes\\Autocoded Themes\\month\monthly email
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