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Living with an Implantable Cardioverter Defibrillator (ICD): Older Adults Tell Their Story

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Living with an Implantable Cardioverter Defibrillator (ICD)

Older Adults Tell Their Story

by

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DISSERTATION

Submitted in partial satisfaction of the requirements for the degree of

DOCTOR OF PHILOSOPY

in

Nursing

in the

GRADUATE DIVISION

of the

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[redacted]

DEDICATION AND ACKNOWLEDGEMENTS

This work is dedicated to my father, John James Bileschi (1928-1979),
my maternal grandmother, Louise N. Berry (1913-1992),
And my very much alive and vibrant Mom, Dixie Lee Bileschi

My father filed for bankruptcy when I was a senior in high school. No one in my family had ever gone to college or even a trade school. Yet, in 1972 my parents helped me go to college. My grandmother offered to help with the state tuition because she wanted me to be a nurse. Thirty-four years later, when entered a Ph.D. in nursing, I asked my mother how it was that I went away to college when family resources were scant and I, as the oldest of five children, was needed at home. She told me there had never been any discussion that I wouldn't go to college.

Likewise, pursuing a doctorate degree appeared to be a natural next step for an insatiable learner. I was preparing to retire from the Veterans Administration after 33 years caring for veterans in a variety of clinical and administrative roles. Although, it was much more than just a natural next step - it was a courageous undertaking - the magnitude of which I could never have anticipated. If not for the expertise and encouragement that I received from my advisor and dissertation chair, Meg Wallhagen, I would never have completed this dissertation study.

Meg is an insightful and patient mentor who taught me how to stay focused on the research process. The breadth and depth of her knowledge and experience was invaluable as I moved through the design and implementation phases of a research study. Meg always encouraged me to set realistic deadlines especially during the difficult months that followed a painful surgery. I appreciated how Meg also graciously overlooked my inability to ever meet the *unrealistic* goals that I continually set.

Pat Fox is a brilliant scholar and passionate expert on the elderly. As a member of my dissertation committee, I was fortunate to discuss the unfolding of my findings with Pat while at the same time, absorbing his energy and benefiting from his expansive view of the world. Meetings with Pat always left me energized and feeling that my research was revealing something very interesting and very significant.

I was also fortunate to be a student of Janet Shim, a medical sociologist. Janet guided me towards shifting the lens through which I view health care and explore the lens of different theoretical frameworks. Janet's comprehensive critiques of my writing provided insights and tools with which I was able to expand my thinking. I especially appreciated meeting with Janet and talking about work, line by line. Janet encouraged me never to compromise depth with breath.

When I met Paul Varosy at the San Francisco VA, I had more ideas than actual knowledge about the topic I had chosen for dissertation study. Thank goodness Paul was willing to support my steep learning curve. Paul has since introduced me to a network of researchers with similar interests for future collaboration. I will always remember the honor of being Paul's first Ph.D. nursing student mentee and his philosophy of giving back to the profession that is dedicated to providing research based care.

I wish to acknowledge Michele Pato for her overwhelming confidence that I could attain a Ph.D. I also want to acknowledge the University of California San Francisco School of Nursing faculty and administrators because they generously enriched my experience of pursing a doctoral degree. As a transplant from a small upstate N.Y. community, I have had the privilege to learn from, and with, an incredibly brilliant and generous group of colleagues during the past five years, some of which I now cherish as lifelong friends. Thus, the list of individuals significantly impacted on the completion of this dissertation is extensive.

Most importantly, I would like to thank my husband, my grown children, my mother, brother, three sisters, and my husband’s elderly aunts, for hanging in there with me as I worked very hard to realize my lifelong dream. It was hard for all of us to preserve through the sacrifices of being separated by 3,000 miles for weeks and sometimes months at a time. And now, as I am finally crossing the finish line, it has become increasingly clear that I’m not alone - my entire family is crossing it with me and we are all so proud that a member of our family has received her Ph.D.

LIVING WITH AN IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)

OLDER ADULTS TELL THEIR STORY

Cindy A. Wojtecki

ABSTRACT

Sudden cardiac death is an unanticipated event, resulting from a cardiac rhythm disturbance. The best option for reducing risk and improving survival in high risk populations is the implantable cardioverter defibrillator (ICD). More individuals are receiving and living with ICDs at advanced ages and for longer periods. Yet, scant research has studied the perspective of individuals who are dealing with the implanted technology while also managing aspects of advancing age in a community setting.

Using qualitative grounded theory methodology, the question of how an ICD affects the daily life of persons living with an ICD was explored. Human subjects' approval was obtained from the sponsoring university's human subjects committee and approval from the recruitment site was received before the study was started. Twenty-four older adults (≥65) who had lived with an ICD from two to 19 years were recruited from the device clinic of a tertiary care hospital. Data collection consisted of interviews that lasted 30-90 minutes and were conducted with a semi-structured interview guide. Data collection and analysis occurred in alternating sequences as initially described by Glaser and Strauss (1967) and further informed by Charmaz (2006) and Clarke (2005). The researcher transcribed verbatim and then checked transcriptions with audio recordings. Initial open coding examined minute sections of text followed by axial and selective coding in order to determine salient themes and properties that emerged from the data. Data was also collected in the form of analytic and self-reflective memos and positional maps. Theoretical and methodological notes were maintained regarding decisions made during the process. Study data revealed, the core process of “Living in Partnership” that can be characterized by three phases: *Entering into a Partnership, Managing the Partnership,* and *Contemplating or Not Contemplating Dissolving the Partnership.* The findings provided insights into the ways older adults come to understand the ICD in the context of their daily lives and serve to inform practitioners involved in their care. Further research focusing on personal meaning and impact is needed to plan for situations along the continuum of living with an ICD and dealing with advancing age.

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CHAPTER ONE

Introduction

Preface – *Getting to the Heart of the Matter*

Dr. Ernie (pseudonym) was 65 years of age when his implantable cardioverter defibrillator (ICD) was implanted. Eight years later, at age 73, he continues to practice internal medicine part time, to enjoy fishing and his family, yet he rarely talks about his ICD.

An ICD is an example of a life sustaining cardiovascular implantable electronic device (CIED) that can terminate a life threatening ventricular arrhythmia and dramatically reduce the risk for sudden cardiac death (SCD). Other examples of CIEDs include pacemakers and cardiac resynchronization therapy. The pacemaker is indicated for bradyarrhythmias, and cardiac resynchronization therapy has been shown to improve symptoms and survival in individuals with advanced chronic heart failure. Patients may have more than one CIED. Dr. Ernie only has an ICD.

As a nursing PhD student, the focus of my research was to study the humanistic perspective of community-dwelling, older adults who have been living with an ICD for at least one year. I recruited study participants from the ‘device clinic’ of a tertiary care hospital affiliated with a medical university in an urban setting. Dr. Ernie was one of the 24 clinic patients who agreed to be interviewed by me after his ICD was interrogated.

Interrogation is a term that refers to activities such as checking battery life and reviewing data about device functioning. The process of interrogation is similar to having an electrocardiogram (EKG). An EKG records the electrical activity of the heart at that moment, whereas ICD interrogation retrieves retrospective data about the electrical activity of the heart and the response of the ICD from the memory of the ICD computer. Interrogation is a non- invasive procedure and usually not uncomfortable for the patient. The term "interrogation" initially might sound harsh, but, as described by another study participant [see below], it is an accurate representation of the computer-to-computer encounter.

> *Interrogation is when the device tells what has been going on. The two computers talk to each other – the ICD computer is placed in my chest. The computer asks my ICD questions and the ICD answers. That's what is called having an interrogation done.*

After receiving a good report about the functioning of his ICD, Dr. Ernie found me in the waiting room. We moved to clinic room that had been reserved for our interview, where we could talk in private and without interruption. The room was furnished with an exam table, a desk with chairs, and a box containing patient education pamphlets on the floor behind the door. One chair was positioned in front of the desk, and three others were lined up against the wall next to the desk. I sat in the chair facing the desk. Dr. Ernie sat in the second chair from the desk, leaving the chair between us empty.

The research interview began somewhat awkwardly. My questions on his decision-making process for getting the implantable device elicited apparent obligatory responses from Dr. Ernie. But when the focus of my questions progressed to exploring the personal meaning of living with the ICD, I perceived an unsettling shift in the room as shown in the following interchange. I had asked him what he thought it was like for his wife and children to witness the physical jolt to his body during a device shock.

"*Doesn't affect them at all."*

"Does the suddenness of the…"

> *"Yeah it scared them because they were there for the one episode when the thing went off, but you know I was standing up, and I did not fall down or anything. I was still standing up. I just went 'Oh,' you know it upset them a little bit, you know, not a huge deal."*
>
> *"Do you talk to anyone about the ICD?"*
>
> *"Nobody."*
>
> *"Is there a need to talk to anybody?"*
>
> *"No. Don't need to talk about it. I got it. I understand it. It's there and that's all. I don't think about it. It's there in reserve. That's all. It's a safety gadget."*

His reference to safety gadget reflected the meaning of the ICD to him; however, that implication was not congruent with my experience of defibrillation, either external or implanted. I recalled many evening shifts working as a nurse in the emergency room and having to externally defibrillate a dangerous cardiac rhythm. I remember strategically placing the paddles on a person's chest, straightening my arms to increase pressure, shouting "all clear," and then pushing both thumbs at the exact same time into the orange buttons on top of the paddles. I remember feeling good when the person's body jerked because it indicated that there was a response to the electrical jolt. All eyes in the room would move quickly to the small green monitor screen, perched on top of the code cart - hoping to see a rhythm that could sustain life. The external defibrillation was violent but necessary. However, at the time, I viewed an implanted defibrillator as an invasive, complex, and sophisticated piece of technology positioned in a person's body by a highly skilled electrophysiologist but something necessary for the same purpose.

Because we both had medical backgrounds, we shared a clinical perspective, but I also knew that I lacked the background to understand his personal perspective. Thus, I asked him if he had had any second thoughts when he was asked to consent to the ICD.

> *The ICD seemed to be the sensible option. I don't worry about it at all or think about it. I'm better going fishing by myself with that in place than without it. So, but I don't worry about it. [….] I don't worry about it. I mean I'm 73 years old with a wiped out inferior wall and I'm in heart failure but it's controlled.*

When I asked about concerns over his other medical conditions, including chronic obstructive lung disease, he replied, "Little bit, maybe." I then asked him to move to the empty chair between us, hoping our conversation would become more relaxed if we were sitting next to each other, but explaining that his voice would be easier to capture on my digital recorder if he sat closer to the microphone. He complied and described the events leading up to implanting the ICD and then interestingly described his experiences with ICD shocks.

> *Three months after I got the thing, I started playing tennis and I got into too fast a game at too high altitude and I served twelve deuces and then it went bang. So, I then sat down, excused myself and changed to golf. That was that. That was the end of tennis. I gave up tennis and skiing. Switched to golf and hunting and fishing. Which was fine, only then it went off; I had driven three days straight to South Dakota to go pheasant hunting. We hunted hard all day and then went to have some dinner…and all of a sudden it goes bang and I knocked over a glass of water. That was it, went bang, I finished dinner and that was that. Did not see the local doc there because I didn't figure they knew very much about this stuff in [name of small town], South Dakota and I felt all right. They probably could have taken care of it there, but the situation was one car and another guy and two dogs, and it would have been a real hassle to start messing with the local hospital so we just let it go. It would have messed up the other guy's trip, basically. That*

> *was the problem and I didn't want to mess up his trip. The thing that bothered me most was that, I think it made him nervous with me driving all the way back here.*

Although Dr. Ernie's actions on his hunting trip may be an expression of confidence in the utility of the ICD, they also indicate the importance of managing normalcy and personal control. At the end of the interview, we stood to shake hands. He paused, and in a softer voice, said, "You have made me think about things that I hadn't thought about but maybe should."

Surprised by his statement, I held his hand a second longer and he glanced downward repeating what he had said at the interview's beginning, "It just doesn't affect me." We walked down the hall toward the desk of the clinic's clerk where he scheduled his next clinic appointment, and as I started to say good-bye, he interrupted.

> *My aunt turned 85 and didn't want to stay home to wait and die so she went to Nairobi and ended up getting pneumonia, was hospitalized there, and came home OK. We've gone to Berlin a few times and Russia. My wife, the picture of health, fell and broke her wrist, no problem; we went to a hospital in Moscow and took care of it. I don't travel too far because of this ticker I have here.*

Dr. Ernie patted his upper chest, just left side of his sternum as he spoke. From my nursing experience, I know how common it is for patients to state the crux of their concern without prompting at the end of a medical encounter. Likewise, Dr. Ernie's parting comment about his "ticker" was stated after our interview was over. I was therefore left with many answered questions. I wondered what he meant by the term, "ticker." Was it a reference to his heart, his ICD, or to some other entity that symbolized the co-existence of heart and device? I wondered how "travel too far" is determined - when and by whom? I wondered if these interpretative boundaries are stationary or moveable. In addition, I wondered about the impact of his “ticker” in the context of his daily life and how he personalized the meaning of being a person with an ICD? I was especially intrigued by the dissonance between his last comment and his earlier comments: “There is no need to talk about it [the ICD]. I got it. I understand it. It’s there and that’s all.” On the other hand, as the interview came to a close, the reference to his ticker as a limiting factor indicated there were areas yet unexplored about the impact of the ICD on decisions that are made post-implant. The goal of this study is to explore further how having an ICD impacts on daily living and also to explore the personal meaning of the ICD from the perspective of an older adult with at least one year ICD-related experiences.

Problem Statement and Rationale

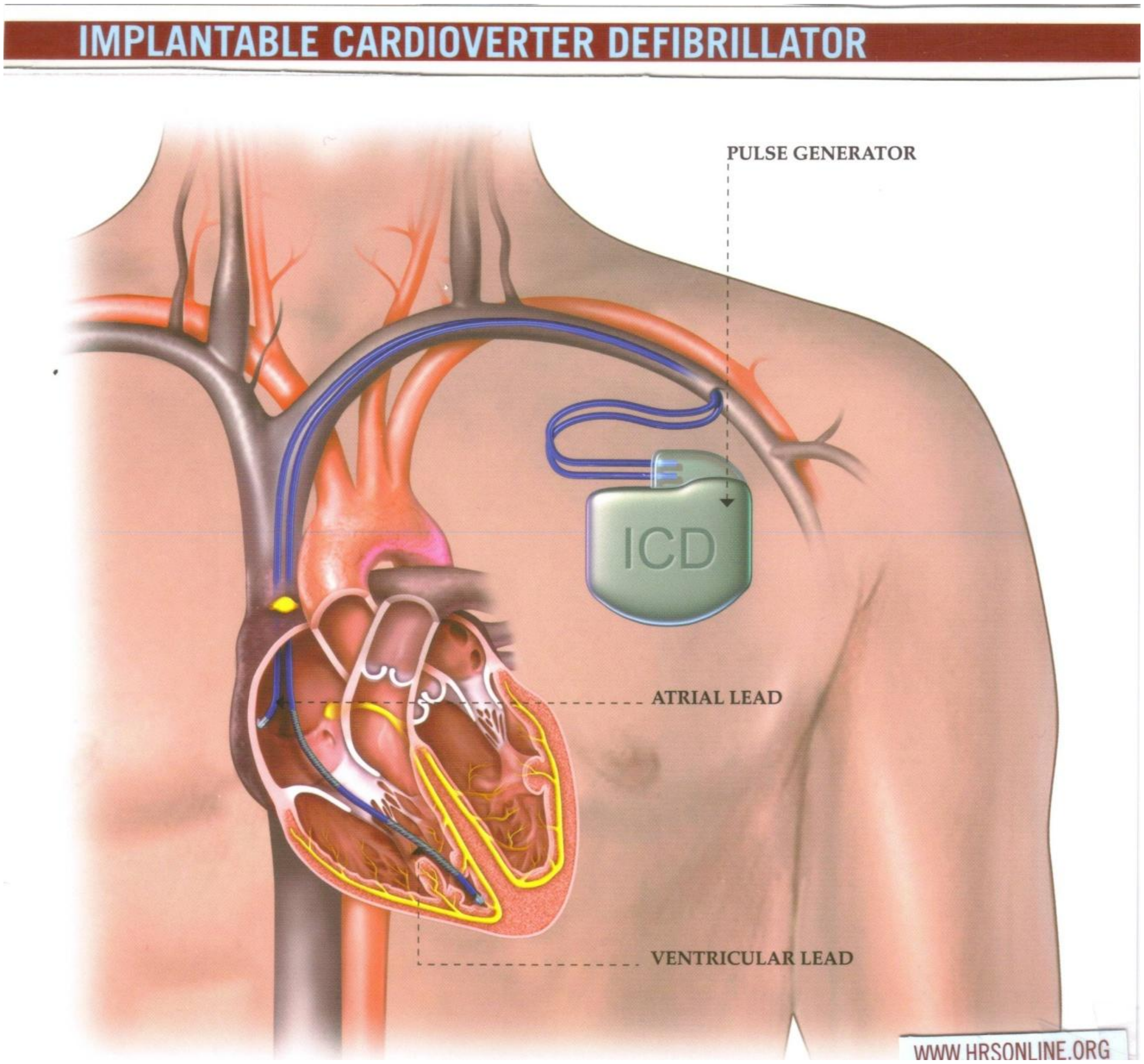
Heart disease is responsible for more deaths, annually, than all the cancers combined. Approximately half of these deaths are unexpected, sudden, and attributed to coronary heart disease (Kung, Hoyert, Xu, & Murphy, April 24, 2008). Many survivors of sudden cardiac arrest, in addition to those deemed at highest risk for sudden cardiac death (SCD), receive a prophylactic implantable cardioverter defibrillator (ICD). Although one of the most innovative medical advances of the 20th century, with recognized utility for reducing mortality, the personalized perspective of the individual age 65 years and older with such a device, has been understudied. The significance of this gap in the research is magnified when one considers that ICD implants are accruing at a rate of 10,000 per month, and Medicare beneficiaries account for 68 percent of the patients (S. C. Hammill et al., 2010). As a result, the elderly are rapidly becoming the largest cohort of ICD recipients, while at the same time; there is a dearth in knowledge about the unique characteristics of this group.

Furthermore, few studies have questioned whether the fear of an unanticipated death would be completely put to rest after the ICD becomes part of an individual’s heart or if the ongoing presence of the ICD would be a reminder of a life saved or a life threatened. These unanswered questions are of particular concern when considering at least two of the findings recently reported by the ICD National Registry (2009). First, 78 percent of the ICDs are placed for primary prevention, which means these individuals have never experienced sustained ventricular arrhythmias, but have been told that they are at highest risk for SCD. And secondly, *two-thirds* of individuals receiving an ICD for primary prevention have existing coronary artery disease. Therefore, it can be argued that personalized understandings of the ICD are influenced by factors that extend beyond the individual’s understandings of the utility of the ICD and include perceptions of wellness, illness, and disease developed along a continuum of lived experiences. Furthermore, the lack of data on the subject of personal meaning and impact denies the patient, the doctor, and the family the opportunity to plan for situations throughout the post-implant years when the meaning of having an ICD may fluctuate greatly between interpretations of its efficacy as life-saving, life-threatening, or death-prolonging.

Given the increased rate of implantations and longer life span at older ages, an understanding of this personal dimension is essential for optimizing the health of those living with this advanced technology functioning inside their bodies.

Figure 1

Implantable Cardioverter Defibrillator



Study Aim

This qualitative study used grounded theory methodology to understand the perspective of community-dwelling, older adults (≥65) who have been living with an ICD for at least one year. Interest in the topic evolved through years of nursing practice that framed a desire to understand the view from the patient’s world. I was interested in pursuing questions such as: how do older adults view risk after the ICD becomes part of their heart, how is the ongoing presence of the ICD interpreted, and lastly, how does the personalized meaning of the ICD reveal something essential about the individual that might not otherwise be apparent? Based on my thirty plus years involved in hospital nursing, I posit that while these questions are rarely discussed between patient and physician, the answers are important and exist at the intersection of treating disease and understanding the experiences of the individual. For these reasons, the aim of this study is to move beyond the efficacy of the ICD as a technology and examine the personal impact and meaning of living with an ICD, as conveyed by the participants in the study.

Organization of Chapters

A preface begins Chapter One to orient the reader to the topic of interest, followed by the problem statement, rationale, and study aims. A background summary follows addressing the public health impact of sudden cardiac death (SCD) and situates the breadth and depth of cardiac disease. This is followed by a discussion of the expansion of ICD technologies and indications since 1985. Included in this section is a chronological synthesis of the key randomized controlled trials (RCTs) that led to the broadening of selection criteria that is currently used for identifying potential ICD candidates for both secondary and primary prevention of SCD.

Chapter Two, Synthesis of the Literature, is foundational for informing the reader about what is known from the individual's perspective and what areas require further study. The common approach for studying the perspective of the ICD recipient in the literature is through quality of life measures. The earliest quality of life studies compared perceptions of ICD therapy to antiarrhythmic drug therapies, subsequent studies measured quality of life in terms of the impact of a device shock, device malfunction, uncertainty, and social support. These studies focus primarily on predetermined measures of an individual's quality of life rather than the experiences of the individual, especially the elderly individual.

Chapters Three and Four discuss the study design. Chapter Three explains the theoretical framework that was initially used to guide the study. Mishel's Uncertainty in Illness Theories along with other theories informed the study design. Symbolic Interactionism (SI), as both a theory and methodology guided data collection and analysis. As a method, SI in Chapter Four explains the qualitative approach of grounded theory methodology that was used to gain an understanding of the antecedents, conditions, and consequences of the core process that emerged from the data.

Chapter Five reports on the analysis of the data that was obtained from interviews with 24 individuals, age 65 years and older, who have lived with an ICD from two to 19 years. Study participants, recruited from the same device clinic of a tertiary care hospital, offered their stories so that we might better understand their experiences. In all quotations, participants' names were changed to protect their anonymity. The chapter begins with general applications of the partnership concept in health care and the specific application of the concept for categorizing the emerging themes from study data. The overarching theme of Living in Partnership was characterized by three major phases: *Entering into the Partnership, Managing the Partnership, and Contemplating or not Contemplating Dissolving the Partnership.* Each phase is chronologically discussed from the perspective of study participants' description of their ICD-related experiences during that phase. Because the third phase comments are about future actions and expectations; these are speculative projections, not lived experiences.

Chapter Six discusses the application of Mishel's Uncertainty in Illness theories and introduces Brandstader and Greve's adaptation model of the aging self for understanding study findings. The value of Symbolic Interactionism for understanding data representing shifting interpretations is highlighted as the essence underpinning of the Living in Partnership model in process. Chapter Seven discusses the application of study findings in the clinical setting and suggests directions for future research.

Background

Incidence of SCD

Sudden cardiac death (SCD) is reported to cause approximately 450,000 deaths annually in the United States and nearly 50% of all cardiovascular deaths worldwide (Goldberg & Lampert, 2006). However, the precise incidence of SCD is unclear, ranging from less than 200,000 to more than 450,000 deaths annually. The most widely used estimates are in the range of 300,000 to 350,000 SCDs annually (Zipes, 2006). This broad estimate range is attributed to the sudden onset of life threatening symptoms, the complexity of paths leading to SCD, and the tools available for surveillance of SCD. An understanding of the public health impact of sudden cardiac death (SCD) provides foundational information for orienting the reader to risk of an unanticipated death caused by a life threatening ventricular arrhythmia (LTVA). In order to understand the defining features of SCD, it is necessary to understand the defining characteristics of the diagnosis and the complexities of pathways leading to sudden cardiac arrests.

Sudden onset of symptoms

The generally accepted definition of SCD includes the following: a non-traumatic event that resulted in sudden death, that was not expected, and that occurred from instantaneous to one-hour duration from onset of acute cardiac symptoms. For many, a sudden cardiac arrest is the first sign of cardiac disease, and, while over 30 years of ongoing research is continually refining the process for identifying those at highest risk for SCD, less than 25% of all SCDs occur in individuals previously identified as high risk by current risk-stratification algorithms (Sukhija, Mehta, Leonardi, & Mehta, 2007). In addition to the challenges in identifying those at risk, the range in estimates for identifying the magnitude of the public health burden of SCD is further complicated by the complexity of paths leading to SCD.

Paths leading to Sudden Cardiac Death

The complex paths leading to SCD influence how the diagnosis is made in or outside a hospital setting. Death from an unexpected circulatory arrest occurring within an hour of the onset of symptoms is usually due to a cardiac arrhythmia (Zipes, 2006). For the most part, ventricular tachycardia with ventricular fibrillation (VF) is the rhythm most often recorded at the time of a sudden cardiac and is described as the final common path to death; however, bradyarrhythmias are also thought to contribute to an estimated 15-20% of SCDs. (Cobb, Fahrenbruch, & Copass, 2002). In addition, asystole or PEA (pulseless electrical activity), noted in older persons with chronic co-morbid medical conditions, leads to SCD and is not responsive to defibrillation (Cobb et al., 2002). Even when the cause of death is arrhythmic in nature, death might not occur suddenly as in the case of the admitted patient who dies from hemodynamic collapse that had been triggered by an event of sustained ventricular tachycardia (VT) in the emergency department. Although in most cases, a myocardial infarction or a tachyarrhythmia is the underlying cause, about 5-10% of SCD cases are the result of an aortic dissection, ruptured aortic aneurysm, or pulmonary embolism (Priori et al., 2002). The variability in clinical presentation and in the electrophysiology of an unstable heart challenges application of the defining concepts of SCD. As result, the inclusion criteria used in individual studies also vary.

ICD: Standard for Treating Risk of SCD

Expanding Technologies and Indications

Prior to the introduction of the ICD in 1980, the only options available to prevent SCD were drugs and surgery. Michel Mirowski and Morton Mower developed the concept of an automatic implantable defibrillator during the late 1960s as a sequence to the successes of external cardiac defibrillation. After five years of clinical trials, the ICD was approved by the Food and Drug Administration in 1985 (Food and Drug Administration, 1985). A year later, fewer than 800 individuals had Automatic Implantable Cardioverter-Defibrillators (Pycha, Gulledge, Hutzler, Kadri, & Maloney, 1986). Approximately 20 years later, however, the National ICD Registry reported 339,076 procedures involving ICD implantations from January 2006 through December 2008. In just two decades, the ICD evolved from an experimental and controversial treatment for individuals awaiting a heart transplant to the accepted standard of care for treating risk for SCD from both secondary and primary treatment indications.

Effective January 1, 2006, The National ICD registry was created to be the sole repository of data about ICD implants. Hospitals are required to report the ICD implantations in Medicare beneficiaries for primary prevention indications only; however, 77% of hospitals voluntarily submit data from all ICD recipients, regardless of age or indication (S. C. Hammill et al., 2009). Seventy five percent of the procedures reported during the first two years were the person’s first ICD, and 25% were replacement ICDs for battery end of life, device upgrade, or device failure; the average ICD recipient was 68 years of age; 74% were male and 83% were white (S. C. Hammill et al., 2009). The key factors that produced the current popularity of ICDs include:

improvements in the surgical procedure for insertion; advancements in the programming capabilities; and the broadening of selection criteria to identify secondary and primary indications for ICD therapy.

Improvements in Surgical Insertion Approach

Initially, the generator component of the ICD was about the size of a deck of cards that could be surgically inserted in the lower abdomen of a patient's body during a 4-6 hour procedure. The insertion approach required a midline thoracotomy with general anesthesia for implantation of epicardial screw-in leads, designed to sense tachycardia, and one or two epicardial patches to deliver the shock lead wires into the epicardium (Knight, Livingston, Gawlinski, & DeLurgio, 1997). Perioperative complications were as high as 40% (Bardy et al., 2005). During the following years, the size of the implanted generator became smaller, and the insertion approach was simplified with the development of the Endotak lead. The Endotak lead allowed for transvenous insertion through the subclavian or cephalic vein, and positioning of the lead wire inside of the right sided chambers of the heart and superior vena cava. This procedure reduced the operative risks that had been associated with the prolonged surgery required in the earliest ICD implantations (Winter, Vestr, & Kuhls, 1993).

Evolution of Programming Capabilities

Advances in ICD programming also increased the numbers of ICD implants. Initially, the ICD could only recognize the rapid heart rate of a ventricular arrhythmia and deliver a fixed high-energy shock that was painful for the patient; and data could not be stored about the precipitating arrhythmia for later recall (Vlay, 1986). In the mid-1990s, the third generation of ICDs, as it was called, introduced options for storage of arrhythmia data and device programming.

Modern ICDs have multiple programming options. For example, they can be programmed to respond differently to tachycardia rhythms in multiple rate tiers, allowing therapy to be tailored for each tachycardia that a person experiences. Delivering multiple levels of energy to terminate arrhythmias reduces the level of pain associated with the earlier one-level high voltage device shocks. Other features optimize therapy for a wider range of high risk cardiac patients including cardiac resynchronization therapy (CRT). Patients who experience symptoms of advanced heart failure (HF) benefit from CRT as an approach that simultaneously paces both ventricles (also referred to as biventricular or BiV pacing). CRT or BiV pacing improves left ventricular function, thereby improving the quality of life that had been compromised by decreased cardiac output. CRT can be achieved with an implanted device designed only for biventricular pacing (CRT-P) or as a device that combines CRT and ICD therapies (CRT-D) (Jensen, Galvin, Thompson, & Rasmussen, 2007). As the knowledge of electrophysiology as a branch of cardiology develops further and as the technology of treatment approaches continues to progress, the utilization of ICDs increases. Another factor contributing to the increase in ICD implants is the result of study findings from a series of large clinical trials that lead to the profiling of those at highest risk of SCD.

Expansion of Selection Criteria

The criteria used to identify the earliest potential ICD candidates required survival of at least two episodes of cardiac arrest not associated with an infarction, and ventricular fibrillation (VF) had to be documented at least once (Cannom & Prytstowsky, 2004). In comparison to this narrowly defined selection criterion, present-day candidates are required to meet a considerably wider range of criteria, categorized in terms of secondary or primary indications. Secondary indication refers to the patient who has survived a cardiac arrest, a life threatening ventricular arrhythmia, or unexplained syncope most likely resulting from a ventricular tachyarrhythmia. In contrast, patients who receive an ICD for primary indications have not experienced a life-threatening ventricular arrhythmia but have high risk characteristics for SCD, such as a previous myocardial infarction (MI), low ventricular ejection fraction (EF) caused by ischemic or nonischemic cardiomyopathy or they have high risk genetic conditions such as Brugada's Syndrome which is associated with a peculiar pattern on the electrocardiogram consisting of a pseudo-right bundle branch block and persistent ST segment elevation in leads V1 to V3in an apparently normal heart. Three different patterns of ST elevation have been described. The following section describes the key studies that underscored the evidence that substantiated secondary and primary indications for ICD therapy.

Randomized Control Trials (RCTs)

Secondary Prevention Studies

Three RCTs --the Antiarrhythmics Versus Implantable Defibrillators (AVID), the Canadian Implantable Defibrillator Study (CIDS), and the Cardiac Arrest Study Hamburg (CASH) conducted from 1990-2003 -- defined the utility of the ICD in the treatment of the highest risk patients (AVID Investigators, 1997; Irvine et al., 2002; Kuck, Cappato, Siebels, & Ruppel, R. for the CASH investigators, 2000). In each study, the subjects had been resuscitated from a hemodynamically-significant ventricular tachycardia (VT) or ventricular fibrillation (VF).

All three trials demonstrated the superiority of the ICD over anti-arrhythmic drugs in treating patients with moderate to very severe left ventricular dysfunction as measured by their cardiac ejection fraction (EF). The ejection fraction measures the percentage of blood that is pumped out of the left ventricle with each contraction. Patients are often aware of a low EF because they fatigue easily and experience shortness of breath with minimal exertion.

AVID was the largest and the best known trial and the only study with findings that were statistically significant (HR, 0.66; 95% CI, 0.51-0.85; P<.02). The combined data from the AVID, CIDS (HR, 0.85; 95% CI, 0.67-1.10; P=.09) and CASH (HR, 0.82; 95% CI, 0.60-1.11; P=.08) trials is recognized as providing the most precise and the least biased estimate of the benefit of secondary prevention with an ICD (Goldberger & Lampert, 2006).

A meta-analysis of these three trials showed a 27% reduction in total mortality with an ICD compared with drug therapy (p=0.006) and a 51% reduction in arrhythmic mortality (Connolly, Hallstrom, Capato, Schron, & Kuck, 2000).

Primary Prevention Studies

Encouraged by findings from the secondary prevention trials, a series of RCTs designed to identify individuals at risk for a potentially fatal first arrhythmic event followed. The subjects of the primary prevention trials had never experienced sustained ventricular arrhythmias but were at high risk based on low EF due to either ischemic or nonischemic cardiomyopathy, genetic conditions or other high risk characteristics. The first large RCT designed to study prophylactic ICD therapy was the Multicenter Automatic Defibrillator Implantation Trial (MADIT) (Moss et al., 1996). This study randomized 196 patients into groups of either ICD therapy or conventional medical therapy. Eligible study participants had sustained an acute myocardial infarction (AMI) three weeks or more prior to enrollment, had had an episode of asymptomatic, unsustained VT unrelated to an AMI, an EF of ≤ 35%, New York Heart Association (NYHA) functional class I, II or III, and had not received bypass grafting or coronary angioplasty within the past three months. NYHA function class is a system that stages symptoms of heart failure in terms of everyday activities and quality of life. Class I is mild or no limitation of physical activity; Class IV is severe or unable to carry out any physical activity without discomfort. Exclusion criteria included a previous AMI within three weeks of enrollment; VT causing syncope that was not associated with an AMI; or symptomatic hypotension while in a stable rhythm. The study was terminated by the safety and monitoring committee prior to the completion date because the ICD treatment arm achieved a statistically significant reduction in total mortality with ICD therapy compared with amiodarone antiarrhythmic therapy (HR, 0.46; 95% CI 0.26-0.92; p=0.009).

The Multicenter Unsustained Tachycardia Trial (MUSTT), published three years after MADIT, was not initially designed to evaluate the ICD. The original hypothesis compared invasive electrophysiological guided therapy with conventional therapy in decreasing arrhythmic death. However, a subgroup analysis of study findings revealed the decrease in arrhythmic death/cardiac arrest was due entirely to the ICD (HR, 0.69; 95% CI, 0.32-0.63; p<.001), thereby supporting the MADIT findings (Buxton et al., 1999).

A second MADIT study, (MADIT II), recruited 1232 patients with coronary artery disease and EF of 30% or less, similar to the first MADIT study. Participants were randomized to either conventional medical or ICD therapy. Similar to findings from the first MADIT study, there was a reduction in total mortality with ICD therapy compared to conventional therapy (HR, 0.69; 95% CI, 0.51-0.93; p=.02) (Moss et al., 2002). In contrast, the selection criterion in the Defibrillator in Acute Myocardial Infarction Trial (DINAMIT) found differing results from MADIT II. In the DINAMIT study, 674 patients who had had a recent acute myocardial infarction (within 4 to 40 days of enrollment) randomly assigned to receive an ICD or conventional medical therapy. Findings demonstrated no reduction in death from any cause with an ICD (p=.66); however, the risk of arrhythmic death was lower with ICD therapy (p=.009) (HR, 0.69; 95% CI, 0.32-0.63; p<.009) (Hohnloser et al., 2004). The difference in findings between DINAMIT and MADITT II have been attributed to the lower event rate and smaller sample size in the DINAMIT study (Goldberger & Lampert, 2006). Another study that showed no benefit of primary prophylaxis with an ICD in specific populations was the Coronary Artery Bypass Graft Patch Trial (CABG-Patch Study). In this study, prophylactically implanting an ICD in patients scheduled for coronary artery bypass graft (CABG) surgery showed no reduction in total mortality with ICD therapy compared to CABG surgery plus conventional therapy (HR, 1.07; 95% CI, 0.81-1.42; p=0.64) (Bigger J. & for the Coronary Artery Bypass Graft (CABG) Patch Trial INVESTIGATORS, 1997).

In 2004, findings from Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) added additional, although not conclusive, evidence in support of the ICD for management of primary risk prevention (Kadish et al., 2004). The

DEFINITE study had the largest sample (n=458) of three small trials conducted between 2002 and 2004 that compared defibrillator mortality with conventional therapy in a sample of people with nonischemic cardiomyopathy. The main findings from DEFINITE noted a reduction in death from any cause that approached but did not reach statistical significance (p=0.08) and a reduction in death from arrhythmia with ICD therapy (p=0.006) (HR, 0.65; 95% CI, 0.40-1.06). Due to the lack of statistical significance of the study findings, the ICD could not be recommended as routine therapy for all patients with nonischemic cardiomyopathy and severe left ventricular dysfunction.

The following year, the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) provided sufficient evidence to demonstrate the utility of an ICD for primary prevention (Bardy et al., 2005). The study enrolled 2521participants with congestive heart failure (CHF). The cause of the heart failure was both ischemic (52%) *and* nonischemic (48%) cardiomyopathy. Nonischemic cardiomyopathies are not related to coronary artery disease. The impact on heart failure on daily function stage of study participants was staged as either New York Heart Association (NYHA) functional class II (70 percent of sample) or III (30 percent of sample) – mild to moderate impact. However, their left ventricular ejection fraction (LVEF) was ≤ 35 % (mean LVEF was 25%). Participants were randomly assigned to conventional therapy plus placebo (n=847), conventional therapy plus amiodarone (n=845), or conventional therapy plus a conservatively programmed, shock only, single lead ICD (n=829). The intent of not including any dual-chamber or biventricular devices was to treat only rapid, sustained VT or VF. The primary end point was death from any cause. Findings determined that as compared with placebo, amiodarone was associated with a similar risk of death (HR, 1.06; 97.5% CI, 0.86-1.30; p=0.53). ICD therapy was associated with a decreased risk of death of 23% (HR, 0.77; 97.5% CI, 0.62 -0.96; p=0.007), and ICD therapy was associated with a 7.2% decrease in the five year mortality rate in the overall study population. The findings from the SCD-HeFT study is important because it showed ICD benefit extending to 5 years, independent of heart failure etiology (ischemic vs. non-ischemic) causes of CHF.

Individuals age ≥65 years with an ICD

As a result of findings from SCD-HeFT and other smaller studies, Medicare coverage was extended to Medicare beneficiaries for primary ICD indications. Although the median age of the individuals in SCD-HeFT study was approximately 60 years (inter-quartile range, 52 to 68) and only about 35% of the patients were greater than 65 years of age with only 9% older than 75 years (Bardy et al., 2005).

A secondary analysis of data of MADIT-II data targeted participants' ≥75 years. Findings demonstrated an equivalent reduction in mortality (HR 0.56; p = 0.08) with no compromise in quality of life in the oldest group of participants when compared to participants <75 years of age (HR, 0.63; p = 0.01) (Huang et al., 2007). Another retrospective analysis of MADIT-II data further sub-divided age into three subgroups: <65 years; 65-74 years; and ≥75 years of age. A similar risk reduction for SCD was found in patients 65-74 years of age group and ≥75 years of age. Moreover, the most prominent benefit of ICD therapy for the endpoint of all-cause mortality was among patients age 65-74 years (37% reduction, p = 0.03), intermediate among patients ≥75 years (30% reduction; p =0.35), and lowest in patients <65 years (21% reduction; p =0.35) (Goldenberg & Moss, 2007).

A recent meta-analysis (Santangeli, et.al, 2010) summarized the evidence about the effectiveness of ICDs verses standard medical therapy for the primary prevention of SCD in differing age groups with ischemic and nonischemic cardiomyopathy and severe left ventricular dysfunction (left ventricular ejection fraction ≤0.40) who received an ICD for *primary prevention* (Santangeli et al., 2010). That is they had not experienced a major arrhythmic event. The elderly were defined as ≥60 years and younger patients were defined as ≤60 years. The systematic review summarized subgroup data from five trials (MADIT-II, DEFINITE, DINAMIT, SCD-HeFT, and IRIS). The observed survival benefit in elderly patients was smaller and not statistically significant; although, it was not clear if an ICD benefits older patient who might have a higher risk of dying from other causes compared to a younger patient (Santangeli et al., 2010).

Chapter Summary

Since 1985, the implantable cardioverter defibrillator (ICD) has emerged from a restricted last resort to a broad-reaching preemptive therapy for treating risk of SCD in selected high risk populations. Post-implant, individuals may live for decades with an ICD, yet little is known about the perspective of older adults who are living with an ICD. The intent of targeting a sample of older adults with an ICD is to focus inquiry on the experiences of an understudied group that is rapidly increasing in numbers. The next chapter focuses on a synthesis of the literature to date that has explored the personal experience of living with an ICD, specifically the perspective of the older adult living with an ICD.

Chapter II

Synthesis of the Literature

The clinical efficacy of ICDs has been convincingly demonstrated in clinical trials; however, the impact on day to day living is less certain. The purpose of this chapter is to interpret the relevance of previous research-the focus, quantity, and quality- with particular emphasis on the significant gaps.

Earliest Studies

One of the earliest studies, Pycha, Gulledge, & Hutzler (1986) examined the humanistic perspective of the implanted defibrillator examined psychological responses to the defibrillator in a small group of hospitalized patients (Pycha et al., 1986). The study was conducted at a time when the implanted defibrillator was still quite controversial in the cardiology community and relatively unknown in the non-medical community. A sample of 2 women and 16 men, ranging in age from 42 to 72 years received psychiatric assessment, during and after their hospital stay. The assessment included patient’s perception of the device and their subjective sense of well-being. A questionnaire, administered by telephone and personal interviews, was designed to assess adaptation. Six patients also completed the Minnesota Multiphasic Personality Inventor (MMPI) and the California Personality Inventory (CPI). Findings yielded descriptions of: hyper-vigilance and fear that the ICD might misfire; sleep disturbances; cessation of sexual activities out of fear of dying or injuring one’s partner; and limitations on travel due to proximity of device expertise. One patient described the device as “a constant reminder that my life is on a precipice” (Pycha et al., 1986) (p.843). Even though, patients described an overall appreciation that the ICD was available, they also described anxiety and depression that appeared to be due to a sense of lost security and control. Over a period of time, ranging from several months to one or two years, patient adjustments to the device were observed by the doctors and nurses (personal communication, May, 21, 2011). The observers noted that patients began "to accept the device as a 'condition of their existence', a positive 'human-machine' alliance appeared to be established, but always with a consciousness that a 'foreign object is present" (Pycha et al., 1986) (p.842).

A decade after Pycha's findings were published, findings from a series of randomized control trials were published that established the effectiveness of the ICD for prolonging life in specified groups of individuals. The demonstrated efficacy of the ICD led to an increase in the utilization of the device. As a result, the design of many studies began to focus on the perspective of the ICD-recipient. The focus on quality of life as an outcome variable was a shift from the more typical endpoints that measure mortality and morbidity of ICD recipients. Quality of life in patients with an ICD was determined by how the person perceived their ability to function normally in society after the ICD had been implanted (May, Smith, & Murdock, 1995).

Comparing ICD and Drug Therapy

Whether or not a patient experienced an ICD shock emerges as a central theme in the series of studies that compared the implanted defibrillator to medical management of arrhythmias. Subsets of the populations that participated in the large multi-centered studies that provided prospective and retrospective data about how study participants perceived differences in their quality of life between the two treatment strategies – an implanted defibrillator or antiarrhythmic medications, primarily amiodarone (Irvine et al., 2002; Schron et al., 2002). The first large, randomized control study that prospectively measured the impact of an ICD on a person's daily life was a sub-study of the AVID trial (Schron et al., 2002). AVID investigators randomized 800 patients from the larger study population (n=1016) to determine the impact of ICD and antiarrhythmic drug therapies on patients' self-perceived quality of life. Participants in the AVID trial were predominately (>73% in all categories) white males with at least a high school education, living with a partner. The average age was 64.3 ± 10.5 years. Variability in device characteristics and programming features was not identified. All study subjects received an ICD for secondary indications, specifically VF or symptomatic VT. Quality of life measurements included an evaluation of physical, psychosocial and emotional factors. In an effort to minimize the impact of missing data resulting from deaths, only patients surviving one year were included in the primary analysis.

Measurements were obtained from patient's self reported responses on three instrument scales: the Medical Outcomes Short Form 36-item questionnaire (SF-36), an adapted patient concerns checklist relative to patients with VF or symptomatic VT, and the cardiac version of the Quality of Life Index (QL index). Data were gathered at baseline (before randomization) and at 3, 6, and 12 month intervals after randomization. Adverse physical symptoms (labeled as cardiovascular, pulmonary, neurological, ocular, dermatological, gastrointestinal, genitourinary, musculoskeletal, endocrine, or infectious) were assessed, recorded and categorized as mild to moderate to severe *by the researchers* instead of the ICD recipient which may have skewed findings due to the interpretative bias of researchers. Findings drawn from composite summary scores for mental health at implantation were lower in patients who received an ICD than in the patients who received antiarrhythmic drug therapy. During the 12 months of follow-up, no further differences were identified between groups. Patients, who experienced shocks during follow-up, reported reductions in physical functioning and mental well-being as well as increased anxiety.

The impact of device shocks was also examined in a sample of 317 patients that had been taken from the original 400 patients that participated in the CIDS trial (Irvine et al., 2002). The most significant finding from this secondary aim of the CIDS study determined that adverse effects on quality of life were only observed in the group of ICD recipients who had received *more than four shocks*, compared to the group of patients treated with the antiarrhythmic drug, amiodarone. Furthermore, participants from both the AVID and the CIDS studies, who did not report shocks, reported a similar or superior quality of life when compared to participants receiving antiarrhythmic drugs - after controlling for disease severity factors and baseline quality of life. Findings in AVID and CIDS studies also observed differences in the emotional health measurement scales suggesting a direct relationship between numerous shocks and poorer emotional functioning.

Namerow, et.al, (1999), was one of the first studies that focused solely on the impact of the ICD on quality of life rather than compare the ICD to other cardiac treatment approaches (Namerow, Firth, Heywood, Windle, & Parides, M. for the CABG Patch Trial Investigators and Coordinators, 1999). Participants from the Coronary Artery Bypass Graft (CABG) Patch Trail (Bigger J. & for the Coronary Artery Bypass Graft (CABG) Patch Trial INVESTIGATORS, 1997)were randomized to ICD verses no ICD. Data assessing quality-of-life was obtained six months after CABG surgery. Patients in the ICD group reported lower levels of psychological well-being than those in the control group. In addition, patients who had received an ICD shock also reported feeling less healthy and had reduced physical and emotional role functioning (Namerow et al., 1999). The prophylactic insertion of the ICD prior to surgery may have been an influencing factor on this finding.

Comparing ICD and Pacemaker

Duru (2001) explored the psychological adaptation, affective disorders, and quality of life between recipients of an ICD with another cardiac implanted device, the pacemaker (Duru et al., 2001). A pacemaker and an ICD are both implanted in the pectoral area for management of cardiac rhythm. Whereas pacemaker stimulation with electrical impulses is hardly felt by the patient, an ICD discharge (electrical shock) is often painful and unpredictable. Study findings determined there was no difference in the anxiety and depression levels between the pacemaker and ICD group except when ICDs delivered a shock. The individuals, who had received shocks, were more likely to report limitations in leisure activities. In that, they perceived their device as prolonging their life, they had greater anxiety about battery depletion and technical problems (Duru et al., 2001). Again, the main variable on differentiating ICD experience from either drug or pacemaker experience was experiencing the unpredictable nature of shock and degree of frequency. Receiving an ICD shock was found to negatively affect mental health and emotional adjustment, causing mood disturbances with higher levels of anxiety scores (Carroll & Hamilton, 2005; Dougherty, 1995; Hegel, Griegel, & Black, 1997; Schron et al., 2002).

Another study, compared patients with ICDs to other cardiac patients who did not have an ICD. The comparison found the patients who had been shocked described significantly worse quality of life (Sears & Conti, 2003). Numerous studies found that receiving an ICD shock negatively affected mental health and emotional adjustment, causing mood disturbances with higher levels of anxiety scores (Carroll & Hamilton, 2005; Dougherty, 1995; Hegel et al., 1997; Schron et al., 2002).

Findings from the sub-study of the Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) trial are particularly interesting in that the sample targeted in the DEFINITE study reflected the new guidelines that broadened the selection criteria for determining ICD candidacy. The targeted study sample, therefore, recruited patients with symptomatic systolic dysfunction and ventricular arrhythmias, *not caused by* coronary artery disease. In other words, these individuals received the ICD for primary prevention of SCD not secondary prevention indicators. Overall, there were no significant differences in the health-related quality of life (subjective perceptions of physical, psychological, and social functioning and well-being) throughout the trial between patients randomized to an ICD or standard medical therapy. However, the patients who had experienced one or more ICD shocks declined in the emotional scale of the Minnesota Living with Heart Failure Questionnaire (p=.04) and on the mental component score of the 12-item Medical Outcomes Short-Form Health Survey (p=.04). In addition, the impact of the shocks was explained as unlikely to reach a clinically observable alteration in the measures of health-related quality of life *until five or more shocks* were experienced (Passman et al., 2007).

Frequency of Device Shock(s)

A consistent thread that connected the majority of the studies, discussed thus far, suggested that even though most patients described the shocks as relatively severe, they tolerated them because they were viewed as life saving in the context of their experiences with an acute myocardial infarction or had already manifested life-threatening ventricular arrhythmias. Ahmad, et al. (2000) surveyed and interviewed 119 patients, chosen randomly from a follow-up device clinic and queried with an unidentified 14-item questionnaire about their self perceived shock experiences (Ahmad, Bloomstein, Roelke, Bernstein, & Parsonnet, 2000). Patients' estimation of the number of shocks received was validated by the researchers' review of the stored telemeter information in each patient's medical record. The patients estimated the number of shocks reasonably well. About 55% were correct within a 10% margin, 29% underestimated and 16% overestimated the total number of shocks received. Of particular interest, three patients reported never experiencing a shock when, in fact, they had received one (identified during device interrogation). The characteristics of the patients who did not recognize a shock were missing as were data identifying shock appropriateness or the specifics of the patients' self perception of shock experience. These gaps are significant since they are based on potential variability between programming approaches in the 14 different ICD models implanted in the study patients.

The study (Ahmad, 2000) also found that the longer patients lived with an ICD, the less accurate their self report about shock numbers received. Although the correlation between the ICD therapy duration and shock reporting accuracy was not determined to be statistically significant, the patients experiencing more shocks tended to rank them as more severe than patients with lower shock frequencies (p=0.088).

Impact on Quality of Life

In contrast to the numerous quantitative studies that have explored the impact of the ICD on quality of life issues, qualitatively designed studies have not been as profuse. The focus of many studies has been on the shock experience. For example, one such study identified the lack of control individuals experienced after an ICD shock and a factor that contributed to feelings of anxiety and powerlessness (Eckert, 2002). Other qualitative studies found that experiencing a painful shock resulted in worrying that it would happen again and therefore, altered their physical and social activities to prevent loss of control and a sense of panic (Carroll & Hamilton, 2005). Cooper (1986) found that the most significant emotional response was fear, not from the shock itself but from apprehension due to the inability to anticipate a shock event (Cooper, Luceri, Thurer, & Myerburg, 1986).

Another theme in qualitative studies focused on the development of post-implantation strategies to assist individuals' return to a close approximation of what their life had been like before they received the ICD (Hsu et al., 2002; White, 2002). A study conducted in Australia examined how individuals cope with the permanency of the device and found that a central theme of *getting on with it*. This central theme characterized individuals who accepted the presence of the device and then put it aside while they continued living (Williams, Young, Nikoletti, & McRae, 2007). The demographics of the study participants or features of the ICD were not published. However, it was noted that some of the study participants had been recruited from a selforganized support of ICD recipients and their caregivers as a strategy for minimizing their experience of psychological distress associated with the ICD. Thus, the findings were biased by the apparent motivation of the study participants.

Kamphuis, et al., (2004) reported findings from the qualitative aspect of a mixed model study. The objective of the larger quantitative study was to assess the quality of life and well-being of cardiac arrest survivors who had received an ICD or other treatment (Kamphuis et al., 2004). In the qualitative portion of the study, the researchers conducted 63 semi-structured interviews of approximately 90 minutes each with 21 patients during their first year after implantation. The interviews identified topics similar to findings of previously mentioned qualitative and quantitative studies, including: physical deterioration, cognitive changes, perceived social support, dependency, and contact with the doctor, confrontation with mortality, and uncertainty surrounding having a shock. In the process of content analysis, the interviewers attempted to make a distinction between situations caused by the ICD and how the individual experienced these situations as survivors of a cardiac arrest.

Burke (1996), clarified sensations, symptoms and psychological aspects specific to ICD use in contrast with general aspects of chronic disease management in a small sample analysis of data obtained from interviewing 24 individuals, including ten women and 14 men between 22 and 78 years of age. Even though the study restricted data collection to only the first six months post-implantation, salient categories characterizing the experience of living with an ICD were identified. Categories of perspectives provided by ICD recipients included: choosing life with technology, integrating technology into life, and living through technology

Excluding those at the end of their lives due to advanced diseases, older individuals have rarely been a targeted study sample with the exception of one study. Hamilton and Carroll (2004) divided 70 individuals hospitalized for insertion of ICD insertion into two groups with mean ages of 51 years (range 21 to 62 years) and 74 years (range 67 to 84). Each subject completed three sound psychometric surveys administered at time of implantation and 6 and 12 months later. Measurements of physical functioning demonstrated improvements in the younger age group, while older ICD recipients appeared to need psychosocial interventions to help maintain physical functioning. Interventions that provided support and education were most often sought by recipients of the ICDs (Hamilton & Carroll, 2004).

Impact of Device Malfunction

Along with the benefits of a prolonged life, however, cardiac patients living with an ICD also experience device-related disruptions and are vulnerable to short and long-term complications due to potential device failures such as fractioned lead wires. One recent study of 990 patients found the annual lead failure rate in both newer and older device models significantly increased with time, reaching 20% in 10 year-old leads ($p<0.001$) (Saxon, Kumar, & DeMarco, 2008). Findings from the task force convened by the Heart Rhythm Society identified infection rates for pectoral implantations and lead dislodgement, in addition to acute complications such as pneumothorax and perforation during the implantation phase (Carlson et al., 2006). While these complications impact on patient’s hospital length of stay and recovery period after ICD implantation, they are not unique post-operative complications. A pertinent finding from the SCD-HeFT study was that single-lead ICDs proved beneficial despite a 5 percent rate of acute device-related complications and a nine percent rate of chronic complications in patients with ischemic and non-ischemic disease (Bardy et al., 2005).

Post-implant complications unique to the ICD reported in the literature include: lead fracture, lead dislodgement, battery failure and inappropriate shocks (Alter, WAldhans, Plachta, Moosdorf, & Grimm, 2005; Brigadeau et al., 2006; Carlson et al., 2006; Kleemann et al., 2007; Maisel, Sweeney, Stevenson, Ellison, & Epstein, 2007). While complications typically affect an individual's experience during the post-implantation phase, few studies have focused on the individual's interpretation of the impact of these complications on their experience of day-to-day life. Furthermore, very few studies have examined the psychological aspects of cardiac devices and recalls. Sears and Conti (2006), in a discussion of the psychological aspects of cardiac devices and recalls, concluded that "…virtually no data exist on the impact of implantable device recalls on patients" (Sears & Conti, 2006) (p. 566). Since 2006, multiple manufacturer recalls have been issued on models due to potential for serious malfunction and even patient death. Recently, Undavia, Goldstein, Cohen, et.al, (2008) investigated the impact of manufacturer's recalls on patient's anxiety, depression, and quality of life (Undavia, Goldstein, Cohen, Sinthawanaron, & et al., 2008). Data was obtained from a survey instrument as well as a series of Likert-type scales to examine the patient's overall perception towards the news of a recall. With the exception of a reduced quality of life noted in the group of patients subject to class I recall, no difference was found in levels of anxiety, depression, and quality of life. Recalls are defined as class I when there is a reasonable probability that as a result of the defect, the product will cause serious adverse health consequence or death (Undavia et al., 2008).

The impact of the ICD on leisure-time activities was surveyed by Kobza, Duru & Erne (Kobza, Duru, & Erne, 2008). Specifically the study examined the occurrence of a device shock. The study was designed to investigate lifestyle activities in the ICD population in Switzerland. Only 2% or the 79% that reported driving a motor vehicle experienced a device shock when driving and none of these individuals lost consciousness or were involved in a traffic accident as a result of the shock. The study also found that while ICD recipients accepted that they disqualify from participation in competitive sports, they were encouraged to participate in sports that involved low-to-moderate intensity.

Impact of Uncertainty on Living with an ICD

Uncertainty, as a variable that may directly influence individual perception of the device during the post-implant years, was measured in a study that looked at the impact of uncertainty and long-term quality of life in patients with an ICD who had survived sudden cardiac arrest or an episode of a life-threatening ventricular arrhythmia (Flemme et al., 2005). In this study, living with serious and threatening arrhythmic disease was fore grounded in contrast to an emphasis on living with an ICD. Nevertheless, measurements with the Quality of Life Index indicated that overall quality of life and health/functioning were unchanged over time once individuals had passed the first year of their illness. Findings from Mishel’s Uncertainty in Illness Scale found that in the small sample (n=35) of patients who had completed the follow-up, uncertainty was a predictor of low quality of life. Sossong (2007) implied hardiness and resilience, exhibited in older adults, as potential attributes that may affect quality of life and uncertainty (A. Sossong, 2007a).

Carroll & Hamilton, (2008) found improved mental health and a decrease in psychological distress for ICD recipients over time - from implantation to four years later (Carroll & Hamilton, 2008). In another longitudinal study of 12 month duration, survival after a cardiac arrest had a greater impact on quality of life and well-being than the type of treatment received after the event (Kamphuis, deLeeuw, Hauer, & Winnubust, 2002).

While the consensus of the majority of current research is that living with an ICD requires adaptation, few studies have studied precisely how patients successfully adjust to life after ICD implantation and adapt to their diagnosis and treatment. Sossong (2007) suggests that education, provided at the time of implantation, might need to be revisited after a shock and possibly with a different format as the patient is situated in a different context for learning about the ICD and arrhythmic disease (A. Sossong, 2007a). Furthermore, the study found a statistically significant relationship between uncertainty and quality of life; whereas, the extent of knowledge about the ICD was not significantly related to uncertainty or quality of life. Further exploration of the types of educational experience received and expected outcomes based on the type of intervention might provide more insight into the relationship of knowledge about ICD and uncertainty or quality of life. For example, generically scripted education about the life-saving utility of the device might increase device knowledge without addressing the impact and meaning of the device for the individual.

Impact of Social Support

The expressed need for social support has been identified in numerous studies with both quantitative and qualitative designs. Burke (1996) was one of the initial qualitative studies to identify the essential need to find and connect with another ICD recipient within the person’s network of family and friends or through the help of a nurse. This connection provided crucial social support to helping patients adjust to the ICD. Participation in on-line or hospital-based groups filled gaps in the information received from the medical clinic staff about the technology as well as a source of social support (S. Dickerson, 2002; S. S. Dickerson, 2005; S. S. Dickerson, Wu, & Kennedy, 2006; Eckert, 2002; Friedmann, Thomas, Inguito, Kao, & Metcalf, 2006).

One of the few studies that examined characteristics of ICD patients, prospectively measured history of depression, trait anxiety, dispositional optimism, and social support as predictor variables for post-implant outcomes (Sears, Lewis, Kuhl, & Conti, 2005) Findings indicated that psychological variables were as strong as, or stronger than age, ejection fraction, and ICD on determining outcome. Although the homogenous study sample was cited as a study weakness. The 88 participants, recruited from two geographically diverse locations, were demographically restricted to older, male, Caucasian patients. The demographic profile was, however, consistent with the typical ICD recipient when the study was conducted.

Impact of Chronic Medical Conditions

In one of the few studies that sample-targeted individuals of advanced age, Hamilton and Carroll (2004) examined the effects of age on the quality of life of 70 individuals (51 males, 19 females) hospitalized for insertion of ICD. Data was obtained at three intervals during the first year post insertion using a repeated measures design. The sample was divided into two groups, less than age 65 years (n=31) or greater than 65 years of age (n=39). The older age group scored as less physically active, less satisfied with their physical functioning, and with slightly more anxiety than their younger counterparts (Hamilton & Carroll, 2004). Ninety-two percent of the older ICD recipients had known heart disease and experienced symptoms of their cardiac disease even after the ICD was inserted.

In an earlier study Burke (1996) concluded that patients who had received an ICD after surviving a cardiac arrest or life threatening arrhythmia, “deliberately accepted technology to secure life so that vulnerability and intrusions associated with the threat of life-threatening dysrhythmia were reduced” (Burke, 1996) (p. 363).

The majority of recently published age-related studies have targeted individuals who are either older when the decision to implant an ICD is being made or older when end of life decisions are being made. Dissimilarly, the intent of this study is to understand the perspective of community dwelling individuals who are currently living with an ICD and are at least age 65 years or older. This research strives to fill the gaps in what is known about how ICD recipients who are chronologically closer to the end of their life, experience the life sustaining technology in a context situated in a higher proportion of co-morbidities, life experiences, and motivation for prophylactic treatment.

Chapter Summary and Areas for Further Study

The synthesis of the literature has provided an overview of topics that have been identified in the research as factors influencing on the experience of living with an ICD. Previous research has predominately focused on the impact of the ICD shock on an individual’s quality of life through quantitative measurement. Additional research is needed to explore the impact of perceptions of the aging process on how individuals assign meaning to the ICD and how that meaning influences interpretations of a device shock as well as a lack of shock.

The vast majority of individuals who die from SCD are elderly because, while the age-adjusted mortality attributed to CHD has decreased over the past fifty years, the prevalence of chronic ischemic disease has increased in proportion to the escalating size of the aging population in the United States (Kung et al., April 24, 2008). There is no age restriction for ICD therapy, and, while over 25 years of research has identified those at highest risk for SCD as potential ICD candidates, less than 25% of the participants in these studies were 65 years or older (Pellegrini et al., 2008). The lack of sufficient representation of older adults is problematic because the 65+ age group comprises the largest growing portion of ICD candidates. As ICD selection criteria have broadened with a concomitant increase in implantations, more research attention needs to be directed to the sequel after implantation, particularly in individuals of advanced age.

Furthermore, as individuals advance in age and survive longer after the ICD is inserted, the core processes for determining the impact of the ICD may shift focus from securing life through technology acceptance (Burke, 1996) to a focus on dealing with technology through disease acceptance. Additional research is needed to explore the impact of individuals' and societies perceptions of aging at various times along the post-implantation life span. The value of age focused research while identifying perceptions of an increasing large cohort of ICD recipients can also increase knowledge about how a reduction in all cause mortality while statistically significant for supporting device utility is perceived by the individuals that may have the highest motivation to seek life prolonging treatment strategies.

After a careful and comprehensive review of the literature, a plethora of engaging questions emerged, for example: If device acceptance is determined by the basic desire to survive, does the meaning of the ICD vary between individuals who receive it for primary versus secondary risk prevention? And a corollary question includes: How do prior experiences adjusting to chronic disease management impact perception of potentially unpleasant device effects in a cadre of patients living with co-morbid medical conditions? Additionally, how does the uncertainty of the functioning of the device impact on the perceptions that interpret risk of sudden death? And then how then does an older adult transfer control of what had been an automatic life sustaining and vital cardiac function to technology implanted in the chambers of their heart? Furthermore, it is unclear how recipients of this complex technology of ICD technology reflect on the essence of the technology or if simply accept the intervention as routine medical care. This query further opens Pandora’s Box to consider if living with an ICD is accepted as routine care for how then are the sudden and unexpected events of device related disruptions such as manufacturer recalls, advisories, or device shocks to be interpreted? What day-to-day events and conditions alter perception of device role and responsibility over the trajectory of a person’s life?

CHAPTER THREE

Theoretical Frame

The theoretical frame that underpinned this dissertation study drew from my clinical nursing experience, interviews with patients and the theoretical concepts identified prior to conducting the dissertation and during the analysis of data. Exploring the meaning and impact of living with an ICD from the perspective of older adults, was guided by theoretical concepts identified prior to conducting the dissertation and included concepts from Mishel's Uncertainty in Illness Theory (UIT) (Mishel & Braden, 1988b).and the Reconceptualization of the Uncertainty in Illness Theory (RUIT) (Mishel, 1990). These concepts were particularly helpful in the development of a semi-structured interview guide and in the preliminary analysis of the study interviews.

Uncertainty in Illness (Mishel)

During the 1970s considerable research focused on the importance of stress in the process of recovery from illness. Mishel recognized a premature focus in the nursing literature on reducing stress without first identifying the processes and conditions producing different stress reactions (Mishel, 1981). To fill this research gap, Mishel (1981) investigated uncertainty as one of the conditions for producing stress in hospitalized patients. Uncertainty, defined by Mishel is "a cognitive state created when an event cannot be adequately structured or categorized because sufficient cues are lacking" (Mishel, 1984) (p. 163). Although the concept was in the literature, there was no substantive exploration of how uncertainty was developed or was resolved by ill individuals prior to Mishel's work (Mishel, 1988). In an unpublished dissertation study (1980) (as cited in Mishel, 1981), Mishel postulated that signs of stress are an indicant of the person's inability to resolve uncertainty in a situation" (Mishel, 1981) (p. 259). The negative connotation of unresolved uncertainty, implied by this quotation, was expanded in subsequent publications to include situations where unresolved uncertainty is beneficial. For example, when the diagnosis of cancer is still speculative prior to the biopsy results, the connotation of unresolved uncertainty is hopeful. Influenced by the works of cognitive scientists in psychology (Bower 1978, Budner 1962, Shalit 1977), Mishel describes uncertainty as a complex cognitive stressor and not an emotional state (Mishel & Clayton, 2003).

The Perceived Uncertainty in Illness model led to the development and testing of Mishel's Uncertainty in Illness Scale (MUIS) (1981). The Mishel Uncertainty in Illness Scale (MUIS-Adult or MUIS-A), is a widely used tool in the ICD related literature (Carroll, Hamilton, & McGovern, 1999; Flemme et al., 2001; Searle & Jeffrey, 1994; A. Sossong, 2007b).

Development of the Mishel's Uncertainty in Illness Scale (1981)

The initial step for constructing a scale that would measure uncertainty as experienced by hospitalized patients consisted of an exploratory study to identify events perceived as uncertain. Forty five patients were informally interviewed about their experiences with illness and hospitalizations. Mishel centered the interviews on the four illness related tasks described by Moos (1977). While not clearly stated because of an interchange of words, it appears the four tasks are what Mishel previously described as four general classes of events in illness treatment situations: (1) events that involve discomfort, incapacitation, and other illness symptoms, (2) events that entail management of treatment procedures and side effects, (3) events relating to the unfamiliar routines of technical environments and lastly, (4) events that focus on assessing the future and reassigning independence (Moos, 1997) (as cited by Mishel, 1981).

A list of statements were compiled from the interviews and subjected to group judgment. A statement was judged as reflecting uncertainty if it contained one of the following eight dimensions: (1) vagueness, (2) lack of clarity, (3) ambiguity, (4) unpredictability, (5) inconsistency, (6) probability, (7) multiple meanings (8) lack of information (Norton, 1975). A total of 62 statements found to reflect uncertainty were rewritten into 54 items that were then cast into a matrix consisting of four classes of illness events by eight dimensions of uncertainty.

> From the matrix, four subscales (factors) were predicted by collapsing some of the uncertainty dimensions and considering the clusters of items across dimensions and classes of events. Ambiguity was predicted as a general factor, reflecting items from all four classes of illness events. The second predicted factor was lack of information, the third was unpredictability and the fourth was lack of clarity (Mishel, 1981), (p. 259).

An initial 54-item scale titled, the Mishel Uncertainty in Illness Scale (MUIS) (Mishel, 1981) was reviewed by a group of nurses, doctors, and patients to check question wording prior to administering the scale to a sample of 259 hospitalized patients. It was assumed that the four dimensions of uncertainty (ambiguity, lack of information, unpredictability and lack of clarity) would emerge as factors that would account for the observed correlations in data. However, a double-factoring procedure confirmed two robust factors rather than four as originally hypothesized.

Factor I “Multi-Attributed Ambiguity,” referred to the patient’s judgment of multiple illness-related events as ambiguous and Factor II “Unpredictability” summarized the items relating to the patient’s ability to predict symptomatology and illness outcome (Mishel, 1981). The resulting 34 item scale measures perceived uncertainty about symptoms, diagnosis, prognosis, treatment, and relationships with caregivers using a 5-point Liker-type format that ranges from strongly agree to strongly disagree. Reliability of the two factors was estimated using coefficient alpha to determine the internal consistency. The multi-attributed ambiguity factor had a standardized alpha of .91, indicating a high degree of homogeneity within this factor. The unpredictability factor had a standardized alpha of .64 which Mishel considered adequate for a four-item factor (Mishel, 1981). Fifty-one of the 259 patients were selected at the diagnostic phase of illness to demonstrate construct validity of the scale. Mishel proposed that ill patients without a diagnosis would meet the theoretical definition of uncertainty because the illness-related events are unclear and contain a large number of cues or lack familiar cues. Study findings in all population groups tested supported Mishel’s assumption that the scale was a valid indicator of the concept. For example the group of cardiac catheterization patients demonstrated significantly more uncertainty than dialysis patients who had a definite diagnosis (Mishel, 1981).

Findings derived from application of the tool depict uncertainty as a recognized variable that influences post-implantation life. The impact of uncertainty has been studied in the context of surviving life-threatening arrhythmias (Carroll et al., 1999; Doolittle & Sauve, 1995; Hsu et al., 2002; Searle & Jeffrey, 1994). No studies have specifically focused on the impact of uncertainty in the context of living with an ICD in an older population.

In a recent publication, statistically significant relationships were found between uncertainty and quality of life, but knowledge about the ICD was not found significantly related to uncertainty or quality of life (Sossong, 2007). This finding implies that an individual's perception of living with an ICD may be framed by other influences beyond technical knowledge of device utility. One's sense of control over the underlying illness and its treatment have been proposed as the most significant factor in determining quality of life for ICD patients rather than experiences that related directly to the ICD and its therapy(Frizelle, Lewin, Kaye, & Moniz-Cook, 2006). Sossong (2007) further posited that the perceptions of an older device recipient may be impacted by age specific characteristics such as hardiness and resilience. It may be that older adults who are engaged in a process of reviewing their lives and making sense of their past would give different interpretations to living with an ICD than younger age groups. These perspectives offer guides for framing this proposed study by raising new questions about how an older adult perceives the utility of an ICD in the context of other chronic medical conditions and life experiences at later life stages.

Seven years after the publication of the MUIS, Mishel published the Uncertainty in Illness Theory (1988) followed by the Reconceptualized Uncertainty in Illness Theory published two years later in 1990 (Mishel, 1988; Mishel, 1990). Data obtained from application of MUIS in diverse populations of patients provided Mishel with information that assisted the process of formulating these two theories of uncertainty.

Subsequent research identified that application of the original UIT was limited to individuals experiencing the acute phase of illness. In contrast, situations of chronic illness, appraisal of uncertainty fluctuates over time; hence, the RUIT provided a reformulation of the outcome portion to address situations of temporal variability. Mishel attributed the failure to include how phenomenon evolves over time in the original theory to a cultural bias toward stability and control. “Little attention is given in psychological theories toward exchange between system and the environment or to irreversible processes” (Mishel, M. 1990, p.257). Of note, the outcome portion of the model assumes uncertainty can be neither dreaded nor desired until the implications of uncertainty are determined.

The purpose of the Uncertainty in Illness Theory (UIT) (Mishel, 1988) was to explain how persons construct meaning for illness events, with uncertainty indicating the absence of meaning (Mishel & Braden, 1988a). Mishel developed the Uncertainty in Illness Theory (UIT) (1988) from a synthesis of the research on cognitive processing and managing threats as well as clinical data and discussion with colleagues (Mishel & Clayton, 2003) The model used in Mishel’s UIT represents a structuring of ideas about acute illness or cases with a poor prognosis to address uncertainty during the diagnostic and treatment phases of illness or in cases of illness with a downward trajectory. Understanding the relationships and definitions of terms used in the structural model of UIT requires careful reading of the narrative provided by Mishel. The following is my understanding of the definitions of the two major concepts of the theory and the nature of the relationships between the three themes depicted by the linear structure of the theory.

Mishel identifies *uncertainty* and *cognitive schema* as the two main concepts in the theory. Uncertainty, recognized as central to the theory is structurally situated after the stimuli frame indicating a cause and effect flow and is defined as “the inability to determine the meaning of events and occurs in situations where the decision-maker is unable to assign definite values to objects and events and/or is unable to accurately predict outcomes” (Mishel & Braden, 1988, p. 98).

The second major concept, cognitive schema is defined as “the person’s subjective interpretation of illness, treatment or hospitalization” (Mishel, 1988, p. 225). In that uncertainty results when a cognitive schema cannot be formed from the information that is processed by the patient, this second major concept is actually part of the first.

Major Themes of Uncertainty Model

Mishel (1988) identifies four stages of the uncertainty in the illness model: (1) the antecedents generating uncertainty, (2) the appraisal of uncertainty, (3) the coping efforts to either reduce uncertainty appraised as a danger or to maintain uncertainty appraised as an opportunity, and (4) the state of adaptation resulting from effective coping (Mishel, 1988).These stages are linearly structured with no feedback loops. In a later publication, Mishel appears to merge the stages of coping and adaptation in describing the organization of the UIT around three major themes: antecedents of uncertainty, appraisal of uncertainty, and coping with uncertainty (Mishel, 2003).

Antecedents of uncertainty

The theme of antecedents of uncertainty structures ideas that are characterized in terms of: stimuli frame, structure providers and cognitive capacities. The variables of cognitive capacity and structural providers influence how an individual process the components on the stimuli frame. The structural location of the stimuli frame infers that it is the major path to uncertainty. The stimuli frame is composed of three components: symptom pattern, event familiarity and event congruence. Mishel describes it as the form, composition and structure of the stimuli that the person perceives in illness and treatment-related events (Mishel, 1988). Given the importance of the definitions of each of these components for understanding the strategic position of the stimuli frame in the model, I decided to directly quote Mishel:

> Symptom pattern refers to the degree to which symptoms present with sufficient consistency to be perceived as having a pattern or configuration. Event familiarity refers to the degree to which the situation is habitual, repetitive, or contains recognized cues. When events are recognized as familiar, they can be associated with events from memory and their meaning can be determined. Event congruence refers to the consistency between the expected and the experienced in illness-related events. This consistency implies reliability and stability of events, thus facilitating interpretation (Mishel, 1988, p. 225).

Uncertainty results when one of these components is missing. For example if s*ymptom pattern* is missing, a person cannot perceive a pattern from which they can infer meaning of symptoms. Mishel makes a distinction between symptom pattern and event familiarity. Symptom pattern refers to the structure of physical sensations, whereas event familiarity refers to the structure of the health care environment. Mishel describes the structure of the health care environment as patterns that define “the habitual or repetitive nature of the structure of the environment” (Mishel, 1988, p. 226). Mishel pulled from her previous research (Mishel, 1981, Mishel 1987) and further postulated that familiar events are associated with lower levels of uncertainty and when novelty does not abate over time, higher levels of uncertainty are evident.

Event congruency, the third component of the stimuli frame, creates questions concerning predictability and stability of the event which also generates uncertainty. A lack of congruence occurs when expectation of cure are shattered, when an expected time frame for an outcome is not met, when treatment does not produce a change in how a person felt or treatment is required in the absence of concrete symptoms. Lack of congruence creates questions concerning predictability and stability of the event thereby generating uncertainty.

Process of Uncertainty Appraisal

An event is perceived as uncertain when one of three situations is operative: (1) the event is not recognized, (2) the event is recognized but not categorized, (3) the event is recognized but categorized incorrectly - it is misperceived (Mishel, 1981).The experience of uncertainty, described as neutral, is neither desired nor avoided until it has been appraised. Appraisal of uncertainty involves two major processes: inference and illusion (Mishel, 1988). Inferences build on personality dispositions that represent a person’s general beliefs about themselves and their relationships with the environment. The beliefs are derived from one’s general experience and knowledge.

Uncertainty is also appraised through the process of illusion. Illusion defines beliefs constructed out of uncertainty, with a general emphasis on favorable aspects. It is through appraisal, that uncertainty is viewed either as a danger or an opportunity. Thus, appraisal of danger or opportunity determines the method selected for coping with uncertainty. When uncertainty is appraised as a threat, coping is directed toward reducing uncertainty and conversely, when uncertainty is appraised as beneficial, uncertainty is promoted.

Coping with uncertainty

Coping with uncertainty occurs after uncertainty has been appraised as a danger or an opportunity. Uncertainty, appraised as danger leads to a two tier coping approach that is not clearly illustrated in the structure of the model. The first step involves mobilizing strategies of direct action, vigilance and information seeking. When the mobilizing techniques are not effective in reducing uncertainty, affect-control strategies are called into action to manage emotional responses. According to Mishel, emotional reactions to stress are exhibited when direct action or intra-psychic modes (vigilance and avoidance) of coping do not lessen the appraisal of threat (Mishel, 1981). Anxiety, recognized by Mishel as the most common emotional response to uncertainty appraised as a threat occurs when the person believes nothing can be done to modify their uncertainty (Mishel, 1988).

In contrast, when uncertainty is appraised as beneficial activities are generated toward maintaining uncertainty. Building on the work of Folkman et al. (1979), Mishel hypothesizes about the adaptive value of maintaining uncertainty when it facilitates hope as a method for buffering or blocking input of new stimuli that may alter one's view of uncertainty as beneficial. The endpoint of the model is labeled as adaptation. Mishel posits that if the coping strategies are effective, adaptation will occur. Adaptation is defined as "biopsychosocial behavior occurring within person's individually defined range of usual behavior" (Mishel 1988, p. 231). Strategies of adaptation include avoidance, selective ignoring, reordering priorities and detaching self characteristics from characteristics noted in patients who are failing (Mishel 1988). Mishel concludes that if the coping strategies are effective, adaptation will occur, however the need for further study is recognized to explain the influence of uncertainty appraisal on adaptation (Mishel et al., 2003). Most of the studies on uncertainty and adaptation have operationalized adaptation “as psychosocial adjustment, recovery, stress, life quality, or health” (Mishel, 1988, p. 231).

Gaps in the Uncertainty in Illness Theory (Mishel, 1988)

When the individual cannot cognitively recognize and classify stimuli from the antecedent link, their ability to adequately appraise a situation is hampered. A covert assumption therefore of Mishel’s theory is that a person’s response to illness-related stimuli is logical, systematic and process orientated which ignores the inherent human capacity for being emotional and illogical especially when faced with what cannot be recognized and classified. The introduction of emotion in the last stage of the model appears to contradict the emphasis on uncertainty as a cognitive state. Although not clearly stated, it appears that Mishel distinguishes between the cognitive state of recognizing, categorizing and appraising uncertainty, and the emotional response to uncertainty perceived as a threat. The introduction of emotion in this context also creates negative adaptive connotations without a feedback mechanism for reappraisal or adaptive progression over a person’s life span.

A limitation for applying the theory is due to complexity of relationships and excessive verbiage. For example, in the description of structure providers, Mishel limited the components to only human resources without considering influences of non-human resources such as pharmaceuticals or technology. Mishel distinguished symptom pattern as representing physical sensations whereas event familiarity refers to patterns in the health care environment. An argument can be made that an ICD fits in both definitions. An ICD is physically implanted hence influencing physical sensation while also a foreign body that belongs to the hospital environment in terms of treatment approach. Furthermore, in Mishel's structural model a direct connection between structure providers and cognitive capacities is indicated by an arrow however by definition, the components of structure providers modify disruptions in cognitive capacities rather than the components of the stimuli frame.

The description of event familiarity centers on an assumption that patterns in the health care environment can be discerned. However, given the rapid evolution of technological advances used to treat illness and disease, event familiarity may be only vaguely recognizable. It can be argued that event familiarity implies a routinization of interaction that excludes variables that contribute to the uniqueness of each encounter and thereby influencing individual's perception.

Mishel (1988) also postulated that when symptoms form a pattern, less uncertainty exist; however, because of the large number of internal sensations that are vague, diffuse and subjective, identifying symptom patterns is a continual activity. Further explanation of the impact of Mishel's acknowledgement of the temporal influences would help to clarify the role of socially constructed meaning over a person's life span on how patterns are formed and re-formed by uncertainty. For example, given the context of the end stages of a disease, stimuli perceived with uncertainty shifts from an appraisal of danger to opportunity.

Uncertainty in the theoretical model is defined as “the inability to determine the meaning of events and occurs in a situation where the decision-maker is unable to assign definite values to objects and events and/or is unable to accurately predict outcomes” (Mishel & Braden, 1988, p. 98). Hence there is inconsistency between how Mishel structurally depicts uncertainty as the outcome of a person’s perception of variables that comprise the antecedents and how the definition of the concept implies that uncertainty is inherent to illness-related events or situations which is a limitation of the linear structure of the model that situates uncertainty in the center of successive stages without mechanisms for feedback loops

The relationships between and among the components of theme one are complex and involve excessive verbiage which limits accessibility however aspects are well substantiated and are applicable for framing research about the experience of living with an ICD in the conceptualization of uncertainty. However, the original uncertainty in illness model is best applied in the context of acute illness rather than the long term experience of living with an ICD which resembles chronic illness or illness with a treatable acute phase and possible eventual recurrence. As will be described in the next section, the re-conceptualization of the UIT expanded the view of uncertainty to include situations of chronic illness or situations of remission of acute diseases.

Questions about the UIT emerged after Mishel examined the role of uncertainty in Western society in an effort to further understand the concept within the delivery of Westernized health care. The perspective of critical social theory was used to raise questions of “Why does the patient continue to seek certainty?” “Why is certainty held in such high value in this society?” “Is the promotion of the goals of control, predictability and certainty the result of the socio-historic values of this society?" (Mishel, 1990, p. 257).Mishel explored answers to these questions during the process or developing a re-conceptualization of her original theory.

Based on the assumption that Western society adheres to a mechanistic viewpoint, Mishel explored the separate works of Sampson (1985, 1989) and Toffler (1984) (as cited in Mishel, 1990) to acquire a foundational understanding of how a society that adheres to a "mechanistic orientation" values accuracy and fears uncertainty. By definition, a mechanistic orientation values precision, predictability, control and mastery (Mishel, 1990). The emphasis is on hard scientific, objective data with an expectation that cause and effect can be determined. Uncertainty is, therefore, seen as deficient and attempts are made to avoid it or cast it as a temporary situation.

The idea that managing short-term uncertainty while living with enduring uncertainty may produce a state of personal growth was explored as a factor influencing how a person's experience of uncertainty may shift over time (Mishel, 1990). The idea of temporal variability is incongruent with the cultural bias toward stability and control. In a qualitative investigation of uncertainty (King & Mishel, 1986) (unpublished paper cited in Mishel, 1990) findings indicated that the longer chronically ill patients lived with continual uncertainty, the more positive they evaluated the uncertainty. This finding implies that the appraisal of uncertainty is not solely a linear process as described in the UIT. Furthermore, as depicted in the original theory, opportunity and danger were structurally parallel to each other. The structural positioning of outcome implied the patient must chose one and only one path which does not allow for fluctuations over the course of a long-term illness situation. While reflective of the mechanistic orientation, a dichotomous outcome scenario limits exploration of multiple scenarios that are reflective of a process rather than a specific state.

The Re-conceptualization of Uncertainty in Illness Theory (RUIT)

A modified model was developed to include aspects of the process that an individual experiences while living with continual uncertainty. Mishel (1990) sought to reformulate the existing theoretical statements and linkages of the UIT to increase its applicability to the experience of persons living with continual uncertainty in illness. The expansion of the theory incorporated the themes of (a) change over time, (b) evolution in the appraisal of uncertainty, (c) emphasis on the person as an open system, (d) an orientation toward increased complexity (Mishel, 1990).

Drawing from chaos theory (Pool, 1989) (as cited in Mishel, 1990), Mishel asserts that when the system self-organizes a new level of complexity is achieved to achieve a new level of stability (Mishel, 1990). Uncertainty is thus viewed as natural and an inherent part of reality rather than as an enemy that must be eliminated. When uncertainty is viewed as an inescapable part of reality, the model asserts that “people are motivated to work at creating the trusting relationships and mutual support necessary in a world where no one can have a sure or final answer” (Mishel, 1990, p.261). The assertion orients the person, their sources of social support and health care providers toward a paradigm that is probabilistic rather than mechanistic. In a mechanistic paradigm, uncertainty is viewed as the enemy that must be eliminated assuming that all aspects of the illness can be linearly determined. Consequent, the concepts of self-organization and probabilistic thinking were added to the antecedent theme of the UIT without altering the linear structural model.

Self-organization represents the re-formulization of a new sense of order that accepts uncertainty “as the natural rhythm of life” (Mishel & Clayton, 2003, p.31). Probabilistic thinking represents “a belief in a conditional world in which the expectation of certainty and predictability is abandoned” (Mishel & Clayton, 2003)(p.31). The outcome is the formation of a new life perspective.

Utilization of Mishel’s Uncertainty in Illness Theories

Mishel’s conceptualization of illness has developed from a linear model that presumed stability and control to a model that allows for multiple possibilities compatible with the disease trajectory of chronic illnesses. Theories of uncertainty and the MUIS scale have been applied in quantitative and qualitative research in a variety of patient samples including persons with diabetes (Nyhlin, 1990), chronically ill men (Charmaz, 1994), HIV patients (Katz, 1996), persons with schizophrenia (Baier, 1995), spouses of heart transplant patients (Mishel & Murdaugh, 1987), family caregivers of AIDS patients (Brown & Powerll-Cope, 1991), breast cancer survivors (Nelson, 1996; Pelusi, 1997), and women recovering from cardiac disease (Fleury, Kimbrell, & Kruszewksi, 1995) (Mishel et al., 2003). However, few studies have applied the RUIT. The re-conceptualized theory is well suited for qualitative research where uncertainty is explored as a process that evolves over time, in particular, studies that investigate an individual’s transition to accepting uncertainty in illness as a part of life (Mishel & Clayton, 2003).

Christman, McConnell, Pfeiffer, Webster, et.al., (1988) applied the MUIS scale in a longitudinal explanatory study that examined the influence of uncertainty in illness and use of coping methods on emotional distress and recovery as the adaptive state of the model is operationalized in 70 patients following a myocardial infarction; the potential effects of age, education and severity of illness were also explored (Christman et al., 1988).Emotional distress The MUIS was the instrument selected to measure the patients' perceived uncertainty about their symptoms, diagnosis, prognosis, treatment, and relationship with caregivers however, the entire theoretical framework of the Uncertainty in Illness theory was not published until after this article was received by the publisher. Data about emotional distress, coping methods, indicators of recovery and severity of illness were obtained by other measurement tools.

Repeated measures analyses of variance demonstrated that uncertainty and emotional distress were positively and significantly related at all three measurement times. Hierarchical regression used to examine the influence of uncertainty and coping methods on emotional distress for each measurement time demonstrated uncertainty had a strong direct effect on distress.

The findings of the study supported the notion of perceived uncertainty as a variable influencing the stressfulness of illness experiences. However recovery, as indicated by physical activity level, was not explained by uncertainty, coping or distress. In summary, the authors concluded that study findings support the role of uncertainty in influencing patient's responses to illness and treatment. However, the researchers acknowledged that uncertainty is not always avoidable in illness situations where care is based on the educated use of probabilities (Christman, 1988).

The study conducted by Christman, et al., (1988) is an early example of research that examined the theoretical link postulated by Mishel (1988) between symptom pattern and uncertainty in a population of acutely ill cardiovascular patients. Severity of illness, representing the symptom pattern component of the stimuli frame, was explored as an antecedent of uncertainty. Findings of the relationships decreased over time which was attributed to patients becoming more aware of the chronic nature of the underlying disease process. Although published before the RUIT (1990) was developed, this study supports a construct where perceptions of uncertainty shift within the same illness context.

Ten years later Sossong (2007) utilized the RUIT in conjunction with, Life Transition Theory (Selder, 1989) to explore the relationship of ICD knowledge, uncertainty and quality of life. The MUIS was selected to measure the variable of uncertainty in a population of patients living with a chronic cardiovascular diagnosis requiring lifetime implantation of an ICD. Statistically significant negative relationships were found between uncertainty and quality of life, but ICD knowledge was not found to be significantly related to uncertainty or quality of life. Sossong noted participants in the study often felt the ICD was given to them as a gift of life even though their daily lives had been disrupted and having an ICD implanted creates some uncertainty in their life (A. Sossong, 2007b). Sossong speculated that the patients’ perception of the event and experience of uncertainty attributable to living with an ICD may not be as stressful as perceived by health care professionals. Findings indicate that uncertainty may be viewed as a phenomenon in which instability and fluctuation are natural and produce an increasing range of possibilities.

In the UIT, uncertainty resulted in dichotomous options. Expansion of the outcome portion of the UIT to provide for a process involving multiple options was the major revision noted in the RUIT. As was evident by Sossong's findings, an individual's perception of meaning may extend beyond the adequacy of information they have about an ICD. Mishel's (1990) theory implies that while an individual may adjust to living with uncertainty over time, it is never absent.

Two studies published in 1996 explored adaptation to uncertainty using Mishel's RUIT from varying research approaches. Adaptation to the uncertainty of multiple sclerosis in women was examined through a quantitative study design that used a slightly modified form of the MUIS scale, designed by the researchers to better measure uncertainty in community-based populations (Crigger, 1996). Uncertainty was identified as one of the stressors that may compromise one's sense of mastery or one's sense of control, which was identified as an indicator of successful adaptation. However, a goodness-of-fit analysis of the theorized model failed to support the model (Crigger, 1996).

In a separate study, Nelson (1996) used Hermeneutic phenomenology and photographic hermeneutics to describe and interpret uncertainty for post-treatment breast cancer survivors. Five themes of uncertainty among women with breast cancer were uncovered that supported the validity of the construct in Mishel's Reconceptualization of Uncertainty in Illness Theory (1990) and the explication of growth-producing aspects of uncertainty(Nelson, 1996). The five themes that surfaced during data analysis represented commonalities among this population of individuals and were described as: (1) vicissitude of emotions, (2) relying on support through relationships, (3) transitions: learning new ways of being in the world, (4) reflections of self in the world, and (5) gaining understanding: putting uncertainty into life's perspective (Nelson, 1996). This study has several implications for providing insight into aspects of living with continual uncertainty that includes optimism. Furthermore, study findings support the assumption that uncertainty varies over time throughout the survival trajectory. In support of Mishel's RUIT, this study illustrated how uncertainty is a dynamic phenomenon that may be better understood using a perspective that is different from a pre-illness orientation. Research that focuses on the how individuals integrate a different perspective into their perception of uncertainty allows a fuller understanding of the human experience.

Anticipated Utility of Uncertainty in Illness Theory

The thrust of this critique of Mishel's work captured the development and evolution of the concept of uncertainty in illness from an approach for understanding uncertainty as a stress producing condition for acutely ill hospitalized patients to an approach that may enhance adjustment within the broader context of living with the uncertainty of long term illness. Living with implantable cardiac technology creates a process with attributes of chronic illness that evolves over time and is subject to cyclic disruptions of varying impact and meaning for the person.

Mishel's RIUT will provide guidance for understanding transition through uncertainty as a fluid process resembling life as a process of life rather than a series of isolated events. In this framework signs of stress are an indicant of the person's inability to resolve uncertainty in a situation however the goal is not always to resolve uncertainty in accordance to Mishel's initial assumption. Examples of informing themes suggested by Mishel include: "revised life perspective, new ways of being in the world, growth through uncertainty, new levels of self-organization, new goals for living, evaluating what is worthwhile, redefining what is normal, and building new dreams" (Mishel &

Clayton, 2003, p. 39). The potential of these themes emerging in my dissertation data analysis is particularly relevant when exploring the process of gradual acceptance of uncertainty from the perspective of the individual situated within the larger context of living life after the period of decision making and point of implantation.

Concept Analysis:
Mishel's Uncertainty of Illness Theory

In a concept analysis of Uncertainty in Illness, McCormick reviewed the literature that Mishel used as a guideline in examining the concept of uncertainty. According to McCormick (2002) a struggle in discussing the concept of uncertainty results from difficulty in separating uncertainty as a neutral cognitive state from value-laden situations in which uncertainty is embedded (McCormick, Second Quarter 2002). As previously described, Mishel assumed that uncertainty was generated by events characterized as "vague, ambiguous, unpredictable, unfamiliar, inconsistent, or lacking information (Mishel, 1984). McCormick critiqued the relationship of these situations to uncertainty, concluding that they represented a person's perception of situational attributes and, while they may overlap in uncertain situations, they are not present in every situation. In contrast, characteristics of probability, temporality and perception are conceptual attributes present in each case. The three characteristics described by McCormick are assumed to have simultaneous influence on each other in every case of uncertainty. A description of each characteristic follows:

Probability - Patients weigh the odds of potential outcomes of diagnosis and treatments and *move beyond appraisal* to manipulate how information about the odds is managed as an approach for maintaining uncertainty especially when what is known is too threatening.

Temporality - Uncertainty prevails when it is unknown what the future holds or how much time will be required until the ambiguity, unpredictability or vagueness of a situation is clarified. In situations of illness and disease the notion of temporality is apparent when individuals inquire about the duration (how long?), pace (how fast?), and frequency (how often?) implying that the future is unforeseeable from their perspective.

Perception - For a situation to be uncertain it must be perceived and recognized as uncertain after a process seeking clarification, predictability and stability was not able to link a pattern of occurrences to an existing frame of reference (McCormick, Second Quarter, 2002).

While identifying components of uncertainty, McCormick's concept analysis also suggested that uncertainty was not a loss of control. McCormick hypothesized that one's sense of losing personal control or desire to regain control is not synonymous with uncertainty because perceived control is a factor of personality with an emotional component that is incongruent with the neutral cognitive state of uncertainty as defined in Mishel's model.

Other Models of Uncertainty

The Minimax Hypothesis (Miller, 1979)

Another perspective presented by The Minimax hypothesis (Miller, 1979) that has been referenced in the early studies on perceived control, may provide additional insight into understanding the role of control when studying the phenomenon of uncertainty in illness (Miller, 1979). The Minimax hypothesis proposes that having control in stressful situations reduces the impact of the stress as stated below:

> A person who has control over an aversive event insures having a lower maximum danger than a person without control. This is because a person with control attributes the cause of relief to a stable internal source-his own response-whereas a person without control attributes relief to a less stable, more external source (Miller, 1979) (p.294).

Miller (1979) situated the hypothesis in data obtained during behavioral psychology research on pain reactions that showed that as anxiety increased so did the experience of pain. Thompson (1981) described the usefulness of the Minimax hypothesis for illustrating a more common theme centering on the impact of personalized meaning (Thompson, 1981). Comprehensive exploration of control as a theoretical framework will not be discussed in this paper. However based on findings obtained during data collection and analysis during dissertation study the concept may require further exploration to fill in the gaps of uncertainty theory. For instance, an approach for understanding the experience of living with an ICD includes an exploration of how individuals perceive uncertainty when living with an ICD in the context of a life threatening cardiac diagnosis.

Folkman's Revised Stress and Coping Model (2008)

An updated version of Folkman's Stress and Coping Model (Folkman, 2008) may also prove useful for understanding how individuals perceive the meaning of their device when faced with a high risk of SCD. Folkman (2008) introduced the concept of "meaning-focused" coping. Meaning-focused coping was defined as an appraisal-based coping in which the person draws on his or her beliefs, values, and existential goals to motivate and sustain coping and well-being during a difficult time. This approach is in addition to previous stress-coping research that supported problem focused and emotional focused coping. Folkman (2008) concluded that the strategy used to regulate positive emotions were not the same strategies used to regulate stress (Folkman, 2008, p. 6). This finding is of particular significance considering the previously assumed relationship of uncertainty to stress. The finding supports further inquiry to the role of positive emotions, with adaptation significance, for living with elements of uncertainty.

Symbolic Interactionism (SI)

Symbolic Interactionism (SI) is discussed in the literature as both a theoretical framework and a methodological approach for conducting qualitative research. SI as described by Blumer (1969), places an emphasis on action (Blumer, 1969). Experiential meaning is regarded as socially embedded and diverse. The prevailing notion in SI is that individuals are reflective and live subjectively in the world. Reflection involves internal dialogue with an imagination to consider self as viewed by others. This reflective process recognizes endless possibilities of how things work at micro and macro levels. According to Blumer, the endless possibilities of how things work is determined by agency and structure. Agency depicts how a person views the world of their own making while structure identifies activities that are grounded in patterns and rules.

The experience of living with an ICD from the perspective of SI cannot be completely captured by a survey format for data collection because understanding the individual’s experience requires an interactive process that unfolds and is not static. The SI perspective is useful in understanding the process of managing chronic disease because it endorses an iterative process for data analysis. The iterative process facilitates an in-depth exploration of shifting dynamics.

In SI, individuals are actively engaged in creating meaning. The philosophical underpinning of SI assumes persons re-interpret previously accepted views and construct new meanings (Charmaz, 1980). The first premise of this framework established by Blumer (1969) describes how individuals act toward things on the basis of what meanings the things have for them. Things include: physical objects, other human beings, institutions, and guiding ideals in addition to situations encountered through daily activities. This premise raises the question of how a person's actions are affected by the symbolic meaning that an ICD has for them. For instance, although the technology is implanted in the body of the ICD recipient, others may have a differing perception of what an ICD means.

The second premise of SI theory establishes that the meaning of objects or things is derived from or arises out of the social interaction that one has with others. Lastly, SI posits that meaning is handled in and modified through an interpretive process that is influenced by the things an individual encounters (Blumer 1969). The sophistication of ICD technology exists within a social world that exposes the recipient to a variety of social contexts. These include not only designing engineers, manufacturer product representatives, medical providers at various practice and subspecialty levels, reimbursement system personnel, public information and marketing media people but also most importantly the ICD recipients themselves and their families and friends. All are situated in the context of this highly specialized technology that has a well substantiated medical efficacy. While medical journals have recorded the details of this exciting new life-sustaining technology, these accounts have not dealt with the personal impact on the day-to-day lives of ICD recipients as they live with this device and what that means to them not only physically but emotionally. As a theoretical framework, SI is valuable for guiding the underpinnings of the grounded theory methodology that will be used for data collection and analysis. In so far as it will facilitate an emerging understanding of what meaning experiences have for individuals, how interaction with others and selves influences meanings and as a way of understanding individuals' perceptions about living with an ICD in varying social contexts.

Chapter Summary

Advances in medical technology continue to develop at a pace that exceeds our understanding of the patient's experience. The future of providing comprehensive nursing care depends on the ability of nurses to plan care from their understanding of the patient's experience that is informed by more than the survival utility of the intervention. The increase in age of ICD recipients is one of the most significant demographic shifts in the typical ICD recipient as individuals live longer with chronic medical conditions. The application of a theoretical frame results in a "creative and rigorous structuring of ideas to project a tentative, purposeful, and systematic view of phenomena" (Chinn & Kramer, 1999) (p.91). Situating nursing practice within a theoretical frame allows for the multiple dimensions of the patient's experience to be recognized and incorporated into the design of nursing care. Study findings may extend the plan of care beyond device related activities to include the experiential needs of patients.

CHAPTER FOUR

METHODS

Design

Grounded theory was utilized as the methodological basis for answering the question, “What are the experiences and impact of living with an ICD for an older adult?” Human subjects’ approval was obtained from the sponsoring university’s human subjects committee. In addition, the recruitment site approved the study before the study was started. Confidentiality and anonymity were maintained according to the guidelines established by the sponsoring university’s human subjects committee. Participants’ names were changed to protect their anonymity. The recruitment site approved the study before the study was started.

Sample

Twenty-four older adults (≥65) who had lived with an ICD from two to 19 years were recruited from the device clinic of a large urban tertiary care hospital in Northern California. All demographic data was supplied by the study participant as part of the data collection process. The goal was to focus less on the medical history of the study participant and more on their perceived state of well-being as it was framed by illness and disease.

Inclusion/Exclusion Criteria:

1. Adults, at least 65 years old at the time of the study - No upper limit on age.
2. Both male and female participants were recruited.
3. Adults who have currently in place an ICD that is programmed for defibrillation.
4. Adults, at least 12 months from the date of implantation.

5. Adults with access to a telephone or computer with internet access for contact communication.
6. Adults unable to have a face to face interview but were amenable to an audio-taped phone interview.

Potential adult participants were considered ineligible for this study if they meet one or more of the following exclusion criteria:

1. Compromised health status that limited their ability to be interviewed for at least one hour at a time.
2. Inability to speak or read English.
3. Without a phone or email for contact.
4. Adults unable to participate in a face to face and unable to participate in a phone call interview.

The criterion that was integral to data collection and analysis was the age of study participants and the number of years that individuals had an ICD.

Recruitment Procedures

Recruitment was from an urban university cardiac device and arrhythmia clinic in Northern California. Referrals through snowballing from study participants or colleagues familiar with the research were also accepted. Additional data was collected through participant observation during clinic appointments, remote monitoring activities, or during interactions within their community of friends and family.

Data Collection Procedures

Pilot study

A pilot study was conducted between September, 2007 and March, 2008 to provide preliminary data that would inform the design of the semi-structured interview guide. Pilot study participants (n=6), ranged in age from 58 to 70 years (mean age: 63.8 years), four male, 2 female. Each participant was interviewed twice by co-PI using a semi-structured interview guide that was revised between interviews in response to findings from concurrent and ongoing analysis of data. Each interview was digitally recorded and transcribed verbatim by co-PI. Comprehensive field notes and reflective memos were completed within 1-3 days after the interview was conducted, followed by a process of coding line by line. In addition excerpts from data and memos were selected by Co-PI and discussed with a small group of qualitative researchers familiar with GT methodology and the overall goals of pilot study. Twenty four codes emerged from the data. These codes were collapsed into four groups of personal ICD-related experiences: connecting; technology as caregiver; to worry or not to worry; and learning parameters. The following paragraphs provide a brief overview of these groups or categories of findings.

“Connecting” explained interpretations from three aspects of the participants’ experience. First, the implanted presence of the ICD in the individual’s body and secondly, scheduled and unscheduled device interrogations that kept the individual connected to the clinic. Lastly, connecting also identifies how a person connects their current experiences to their pre-implantation experiences. Of interest, was the desire of each study participant to connect the reason for their ICD with past life experiences.

“Technology as Caregiver” explains how an ICD treats a “broken heart” and rescues individuals who face death with scant time to spare. This category includes themes about: trusting the expertise of technology; preserving and valuing life; evolving advances and limitations of technology; competency of medical staff in utilizing, understanding, and managing technology; notions of security and comfort.

"To Worry or Not to Worry," the third category encompasses how individuals described the uncertainty and ambivalence of living with an ICD. This category includes codes of normalizing and *pathologizing* the need for an ICD as it is been perceived and interpreted through interactions with the health care system and interactions with family, friends, strangers and the public media. Coded sections of interviews placed in this category describe the experience of treatment without symptoms and diagnosis based on a "high risk" for sudden death.

"Learning parameters," the last category identified in the pilot study, includes individualized actions associated with recognizing how living with an ICD subtly changes daily life. For example: codes in this category identified a heightened awareness of body sensations and associations between physical activities and the potential for a device shock (predictability vs. unpredictability; dependence vs. autonomy; perceptions of certainty through technology vs. perceptions of outcomes attributed to technology). Travel plans, family and social gatherings, recreation, intimate sexual relations are some of the areas where parameters of activity are re-defined. Of note, is that the coded content of this category did not reflect "cardiac cripple" viewpoints. Instead, sections of coded transcripts revealed post-implantation activities of engagement not withdrawal.

In summary, the sensitizing concept of: "Living with Disruption and Ambivalence," revealed the 'double-edged sword' aspect of an ICD. Individuals described the ICD as opposite sides of the same coin. One side was described by the certainty of avoiding SCD with an ICD and the flipside of the coin was described by the uncertainty of what living with an ICD involves. The pattern or theme identified as core throughout all the pilot interviews encompassed a wide range of non-sequential and fluid experiences along a continuum of positions. At one extreme, a position of dread and mortal fear of experiencing the intense pain triggered by a device shock and at the opposite extreme was a position defined by notions of comfort and security that an implanted ICD would protect from sudden cardiac death. Ambivalence depicted vacillating perceptions of the device in terms of friend or foe; between notions of comfort and security, and dread or mortal fear.

> Example of comfort: *"Because the alternative I didn't particularly care for. So that's how I sort of describe it. It's something, it's my angel. It's keeping me alive, maybe, maybe not. But that's how I think of it for myself."*
>
> Example of security: *"Well….it means I'm not going to go out there and be standing over a putt on the golf course and fall over dead from ventricular fibrillation, most likely."*
>
> Example of dread and mortal fear: *"…I was petrified by this time in the emergency room. But it was fear of getting shocked again-not fear of dying. I was afraid of the device-not afraid of the problem. And I guess I didn't equate the problem with being potentially fatal as much as I was afraid of the pain of the device going off."*

Collapsed Codes that described this sensitizing concept:

mitigating circumstances – what were/were not doing that may have triggered device discharge
trusting – no other options available
self-protecting – behaviors that attempt to control device

comparing to other chronic illnesses – situating device in a medical context
benefiting – appreciating device
timing – why me? why now?
watchful waiting – uncertain about what is going to happen or not
losing control – of how body responds as a result of disease
validating experience – checking in with medical experts
malfunctioning – not performing as planned, or as intended
living with uncertainty – what is known, what is unknown
sharing experiences – what others know or don't know

In summary, findings from the pilot study provided sensitizing concepts that formed what Charmaz (2006) referred to as "points of departure" that were used for developing interview questions and probes during data collection in the dissertation study:

1. How does an ICD recipient take up identity as a high tech cardiac patient?
2. Are individuals influenced by chronological age and perceptions of the aging process?
3. Do individuals compare heartiness and fragility of their heart, of the ICD technology?
4. How do individuals interpret loss – of function, of life, prepare for, expect, and or accept malfunctions?
5. What is meant by having insurance?
6. How do individuals perceive implications of uncertainty, define uncertainty
7. In what ways do the use of labels for heart and device underscore personal meaning?
8. How do individuals perceive control of dying or life changes?

9. What does it mean to experience or anticipate a device discharge, or lack of and then what determines response?

Dissertation Study

Research study was introduced to clinic patients who met selection criteria by the clinic nurse. If interested, the study was explained by the researcher, questions were answered and if the patient agreed to participant, written consent was obtained. All interviews were voluntarily conducted in a private clinic exam room; audio recorded and lasted approximately 30-60 minutes. A semi-structured interview guide was loosely followed. To be consistent with grounded theory methodology, the interview questions evolved as data was gathered. The researcher transcribed verbatim and then checked transcriptions with audio recordings. Data was also collected in the form of analytic and self-reflective memos in addition to positional maps.

Participant interviews and observations were the primary source for data collection. Other data sources such as public news items about ICD manufacturer recalls or personalized stories contextualized the social environment that also impacted on interpretation of the ICD. An example was device recalls. Additional information such as, educational materials, list of medications or device identification cards, as relevant for understanding the individual's perceptions and voluntarily provided by study participant were also included. Data about the previous medical history and programming capabilities of the ICD was only obtained from patients. Their medical records were not accessed.

Analysis of Study Data

Data collection and analysis occurred in alternating sequences as initially described by Glaser and Strauss (1967) and further informed by Charmaz (2006) and Clarke (2005). The direction of each subsequent interview was determined through iterative analysis of all previously collected data (A. Strauss & Corbin, 1998). Open coding examined minute sections of text followed by axial and selective coding in order to determine salient themes and properties that emerged from the data. Open coding referred to by Strauss and Corbin (1990) is a process that examines minute sections of the text, made up of individual words, phrases and sentences. The language of the participants was identified with short descriptors that were used to guide the development of code and category labels.

Data similarities and differences were identified through constant comparison. Constant comparison is a technique of analysis that recognizes data similarities and differences as emerging patterns or dimensions of the individual's experience (Charmaz, 2006). The outcome of comparisons is not the generation of new data rather the identification of patterns. In addition to interviews, data was collected in the form of analytic and self-reflective memos to make the researcher's implicit thoughts explicit. Theoretical and methodological notes were maintained regarding decisions made during the process. The qualitative strategy for data analysis termed "positional mapping" (Clarke, 2005) was used as an approach for further development of sensitizing concepts and theorizing about an emerging concept that is consistent with Situational Analysis within the Grounded Theory framework (Clarke, 2005). The location of positions between the mapped axes represents the differences and similarities involved in the decision making processes that transcend the experiences of the individual and categorize patterns of socialized experiences.

Establishing Qualitative Research Integrity

Methodological soundness and adequacy will be verified based on criteria proposed by Lincoln and Guba, (1989) to establish trustworthiness and authenticity (Denzin & Lincoln, 1994).The process for recruitment and consent procedures were documented according to the guidelines approved by the Committee on Human Subjects Research, University of California San Francisco. Interviews with participants were audio-taped and transcribed verbatim. The transcript of the interview was checked for accuracy against the audio version of the interview. The iterative process for grounded theory data collection and analysis allowed the researcher to follow up with participants to clarify or expand upon information discussed in previous interviews. Data analyzed with a constantly comparative approach helps to keep the researcher grounded in the language of the study participants.

Regularly scheduled peer review sessions substantiated the data interpretation and analysis through review and debriefing discussions with other qualitative researchers. This strategy helped to build trustworthiness of findings and provide support of how well interpretations and explanations ‘fit’ with the data. In addition, these interactions also provided multiple interpretations of accumulated data. Discussion of findings with content experts and senior researchers also was included to gain additional insights and assistance with coding and analysis.

An audit trail of the research process was maintained through detailed and transparent recording of each step of participant recruitment, consent process, data collection and analysis and publication of findings. Data from the study was reviewed by research colleagues familiar with grounded theory methodology to ensure that interpretations and decisions about the data made by the researcher were grounded in the participants' language. The use of audio recording devices to capture raw data, writing field notes promptly after the completion of interviews, frequent and timely memos of emerging patterns and themes while analyzing verbatim transcripts of the interviews strengthened the accuracy of data interpretation and my analytic reflections.

Consent Process and Documentation

Informed consent was discussed in detail at the beginning of the interview or prior to the first interview, with an emphasis on confidentiality and the potential emotional consequences of participation. The potential participant had the option of reading the informed consent form or having the form read to them. Two participants requested that the consent be read to them. Prior to each interview, the participant was given as much time as needed to review the informed consent form and have all questions answered.

Only the researcher, the researcher's faculty advisor, and a trained transcriptionist had access to the audio recorded interviews. No identifying information was retained on the written or audio records after the audio recordings have been transcribed. The recorded interviews will be erased at the conclusion of the study. Any identifying information in the transcripts was replaced with codes. The key to the codes will be kept in a separate, locked location away from the transcripts and other study files. When study results are released, the information will be presented in aggregate to prevent individual identification. The author of quoted excerpts from the transcripts will identified by a pseudonym and any potentially identifying details will be sufficiently disguised.

Maintaining Confidentiality and Privacy

Interviews were conducted in an environment that the participant approved as private and comfortable. At the beginning of each session, the participant was reminded of his/her right to terminate the interview at any time, for any reason, and choose not to answer any question. The participant was encouraged to inform the interviewer of any distress, and the interviewer monitored the participant for signs of distress as exhibited through body language, changes in voice tone and content of verbal responses. If signs of distress appear, the interview would be terminated and the participant would be encouraged to discuss their concerns with a counselor or the medical staff in the device clinic. None of the interviews were terminated at the request of the participant. However the length of time was often shortened at the request of the participant or based on my interpretation of the participant’s desire to begin concluding the interview. Many participants also voluntarily provided their phone number if I wanted to contact them with future questions. As part of the recruitment process, each study participant received written contact information for questions about the study and for questions about a research subjects rights.

Financial Considerations

Neither the study participant nor their insurance company was charged for any aspect of the study interview. Upon completion of each interview, the participant received a gift certificate valued at $5.00 and redeemable at designated vendors as a token compensation for the time they spent talking with the interviewer. The maximum that any participant received was $10.00 for completion of longer interviews.

Chapter Summary

Grounded theory methodology provided the researcher with a systematic approach to collecting and analyzing data that allowed the emergence of humanistic themes and concepts that were dimensionalized into categories representing the individual's experience. Developed categories provided a foundation for creating a theoretical framework that may guide decisions made in clinical practice and generate questions for future research.

CHAPTER FIVE

Results

Characteristics of Study Participants

The narratives, provided by 24 participants in the study, drew from 2-19 years of ICD-related experiences, a span of time during which the technology of implanted defibrillators and medical knowledge about cardiac electrophysiology evolved rapidly. Over half (13/24) of the study participants had their ICD for at least five years. Twenty participants were men and four women, a gender disparity consistent with the 74/26 male/female ratio reported in the recent annual report of the National ICD Registry (S. C. Hammill et al., 2009).

There were no indications that ICD-related medical costs created a financial hardship for any participant. Nor were there any indications that one's personal financial status impacted on treatment decisions or follow-up maintenance. At time of study enrollment, the mean age was 76 years (range 65-91). Nineteen (79%) participants were ≥ 65, and had Medicare as their primary insurance payer when their ICD was first implanted; Three (13%) received Medicaid funding and two (8%) were <65, employed with private insurance, when their ICD was initially implanted In the Fourth Annual Report from the ICD Registry, 68% of ICD implants had Medicare/Medicaid as their primary insurance payer (S. C. Hammill et al., 2009). Reference to Medicare/Medicaid was not clear in the report if coverage was dual versus either or both. All participants in this study were ≥ 65 and therefore eligible for Medicare coverage to replace ICDs for battery end-of-life, device upgrade, or device failure

All were community-dwelling adults living in the urban setting of the San Francisco Bay area; and all but one were described feeling connected with a local family member or lifetime friend(s). The majority (13/24) were married, four widowed, four divorced, and three participants described their marital status as single. Twenty-one were retired, including three on disability retirement. One was self-employed full time as a music and arts teacher in her neighborhood. Two were continuing professional careers part time.

As a whole, the participants in this study are considered survivors because they have lived until at least age 65 and are able to manage their medical conditions in an ambulatory care setting. Their view is characteristic of older adults who experience their ICD in the context of day-to-day living with chronic, yet progressive, cardiac disease. However, they are not representative of all ICD recipients. When asked at the beginning of the interview why they have an ICD, the reason most often stated (n=12) was a medical diagnosis from the following list: arrhythmia (n=4), syncope (n=3), heart failure (n=2), sudden cardiac arrest (n=1), or multiple heart attacks (n=1). Other reasons for having an ICD grouped into three categories: “I don’t know”/“doctor preferred it” (n=6), “heart is in danger” (n=3) or, “to fix my heart” (n=3). In that the majority acknowledged that they had a problem with their heart, none admitted to knowing that they actually had ventricular arrhythmic disease before being told they were a candidate for an ICD. When the ICD was first suggested, only one or two study participant knew about the device because they had a medical background or had a family member with an ICD. The majority stated that they had never “heard of such a thing.” On the other hand, all were familiar with a cardiac pacemaker.

Study findings revealed the core process, *Living in Partnership,* characterized by three phases, *Entering into a Partnership*, *Managing the Partnership,* and *Contemplating or Not Contemplating Dissolving the Partnership.* The first phase explains how participants decided whether or not they should get an ICD. The second phase explains how their lives changed or stayed the same, and the third phase offers conjecture about their need to ever discontinue the ICD. Insofar as these phases are generally linear and sequential, for organizational purposes, the three phases are discussed in order of occurrence. However, study findings revealed, that personal meaning was influenced less by chronological time and more by circuitous and interactive processes that involved checking, regrouping and transforming actions. Thus, meanings were used and revised as tools for shaping actions. , Findings provided insights into the ways in which older adults assign meaning to their experience as they cycle through states of varying interpretations of well-being but also uncover how they continue to assign the nexus of responsibility for the decision to obtain and maintain the device to medical experts.

Entering into the Partnership

Phase One

“I’m 71.
“I’m at the age where friends and acquaintances,
Have had open heart surgery and it’s happening all the time.
People come back from it, in some cases not so good, in other case, great.
Its miracle stuff, and that’s how I view this stuff.
And now they put this little thing in and that’s it, nothing, forget it.
Do your stuff. Take your grandchildren to a movie. It’s fabulous.
I never cease to be amazed by what’s happening in the life of sciences today.”
-Mr. Mercedes, 2009

Cardiac electrophysiologists determine whether an individual is at highest risk of SCD, and therefore an ICD candidate, through both non-invasive and invasive tests. Non-invasive tests include an echocardiogram that provides a moving picture of the heart and an ambulatory cardiac monitor that provides a continuous electrocardiogram over a period of usually 24 to 48 hours. The invasive electrophysiology study involves inserting a small catheter in the area of the groin or near the neck. The catheter is fed into the heart where the speed and flow of electrical signals are recorded and studied. The majority of participants lacked the medical knowledge to completely understand the results from electrophysiologic testing; however, each placed ultimate trust in their doctors’ medical opinion

On the day when the doctor initiated the discussion about the ICD the majority of participants described feeling unhindered by symptoms of their ventricular arrhythmic disease. However, they remembered the feedback they received about the scenario or circumstance that lead to the implant discussion. Some remember being told they had been "revived from death," and others remember a conversation during a routine clinic appointment when they had been told "it was time to add a defibrillator to your pacemaker." The language of sudden cardiac death (SCD), risk, medical technology, and survival used by medical professionals, emerged as having the strongest impact on decision-making processes. In addition to the impact of life and death language, the meaning attached to being in a medical environment as a patient, also impacted on the ways the stimulus to have an ICD was interpreted.

Impact of medical environment

The mode of entry into the medical environment was described as voluntarily going to a clinic or being taken to the hospital by ambulance with scant recollection of what happened. Entering the medical environment on an ambulance stretcher symbolized loss of control in the context of a sudden, unanticipated cardiac event. These individuals described feelings of personal vulnerability that was not evident in narratives from clinic patients. The group that arrived at or were taken to the hospital in a medical crisis appeared to assume a more passive role in the decision-making process, similar to being a victim in a threatening situation that caught them unaware, ill-prepared, and dependent on others for rescue. The level of urgency associated with critical care settings emerged as a high-risk alert, the red flag that was hard to ignore, when deciding about the ICD [see below].

> <u>Mr. John James:"</u> *I went through a very harrowing emergency situation and my general diagnosis of congestive heart failure, and arrhythmia problems were probably, you know, pretty much in my future. I wasn't sure of that because I wasn't sure that they'd been in my past but I'm in the hospital and seeing a*

> *doctor because of the things I don't know and not because of the things I know. At that time he started talking to me about the possibility of an ICD."*

In comparison, the situation that preceded Ms. Parker's discussion with her doctor about implanting an ICD was a routine clinic appointment. In this environment, she implied that she anticipated there would be additional ways to treat her heart disease as a result of her age and life style choices [see below].

> <u>Ms. Parker:</u> *"So they put the one with the defibrillator in [after her doctor suggested it during a clinic visit]. The first one [the pacemaker]did not have the defibrillator. I'm too old not to have it because my heart is enlarged, and you know, it's just that I ruined my health smoking for about 30 or 40 years, so there you go."*

Ms. Parker was not unique in her description of the ICD as something that was added, and she was not alone in referring to the ICD as something added to the pacemaker; nor was she the only person who was under the impression that the ICD was 'routine' treatment for the elderly. Rather, she represented the group of study participants who were informed of their candidacy status during a clinic appointment. Members of this group indicated that deciding to get an ICD was an expected next step for taking care of their heart. In some ways, they viewed their decision as assuming a proactive stance.

Mr. John James's expressed uncertainty about what he did not know contrasts with Ms. Parker's apparent acceptance of new information. Both individuals describe feeling out of their realm of experience and, therefore, more dependent on the views of others for becoming oriented. Nevertheless, they differed in how they were affected by the information. This suggests that the environment in which the information is relayed impacted on interpretation. Specifically, a critical care setting invoked a sense of urgency and serious illness whereas the setting of a doctor's office suggested routine care of chronic and progressive disease. Common to both settings was the shared sense of being dependent on medical opinion for becoming orientated in situations of uncertainty.

In another scenario, a pre-implant hospital experience foreshadowed dependency on the post-implant process of device interrogation for validating how the partnership was working. Mr. Glen's narrative [see below] reports the impact of receiving information about how he felt from a bedside telemetry monitor's recording of his heart's electrophysiology.

> Mr. Glen: *"And they'd say you look like you don't feel too good, and it was the monitor telling them that heart was a little high. I just remember coming back out of it and hearing their voices-the doctor and the nurse-pounding on me trying to get me back."*

Mr. Glen associated the memory of being resuscitated with what the cardiac monitor had 'told' the nurse. Hence, 'interpretative authority' was assigned to technology and to the medical person who makes sense of the device data. The meaning of this deference is further discussed in subsequent sections.

Impact of medical relationships

Older adults are usually familiar with the medical environment and therefore often have established a doctor-patient relationship as one of the benefits of chronic disease management. Participants in this study described discussing healthy lifestyle choices, medication regimens, and treatments involving cardiac surgeries with their doctor over a period of years. As a result, a degree of familiarity emerged. One participant explained that his children went to school with his doctor's children. Another explained he had known his cardiologist's father, and a third talked about how sailing was a shared Connecting on a personal level invoked a level of trust through familiarity and exposure over time.

While all participants expressed trust in medical opinion, for some the implant decision followed a circuitous process that involved, “weighing the alternatives.” Initially I assumed ‘alternatives’ referred to the option of living or dying.. However, in the case of these narratives, weighing the alternatives referred to whether or not they actually had ventricular arrhythmic disease because it could not be proven. In other words, the differential diagnosis could also have been, “fall asleep while driving a car,” or an “isolated” idiopathic occurrence. One participant described the speculative nature of assigning risk as: “It’s very close to yes and very close to no.” However, for at least one study participant, the need for proof beyond a reasonable doubt may have jeopardized his life. Dr. Ernie, a practicing physician, admitted to denying the potential severity of recurring symptoms up-to-and-until the day when he actually saw the dysrhythmia on the cardiac monitor. In that scenario, he described the importance of having “hard evidence that was very persuasive.”

The narrative given by another participant in the study who also valued hard evidence is particularly interesting due to his medical background (see below).

> <u>*Mr. DocSci:*</u> *I was an active doc and then became a scientist […] I would be very favorably disposed to the ICD in principle, in a sense, because my very first published scientific paper was in the lab that actually discovered how to do cardiac massage and we were defibrillating dogs and then bringing them back to life.[…]It’s just that it’s such a huge temptation to do it, and I think my indication was right on the cusp of being justified/non-justified and we went over to doing it and I think an argument could be made that we shouldn’t but not one that’s overwhelming.*

Likewise, Ms. Jean struggled with unsubstantiated evidence during the decision-making process. Ms. Jean had a sudden cardiac arrest while teaching a class in a medical university in 1990, before advance cardiac life support had become a routine emergency procedure. After a month of in-hospital monitoring and testing, the still controversial internal defibrillator was suggested and agreed upon in a context of uncertainty about both the medical diagnosis and implantable defibrillation (see below).

> Ms. Jean: *So they thought it was a heart attack, but it wasn't. So they could rule that out; it was just a failure of the electrical system. [...]They couldn't do anything else. I just trusted that that was a good idea since it had come out of the blue and nobody knew why.*

Even after a series of randomized control trials had substantiated the efficacy of the ICD and thereby mitigated the uncertainty once described in the cardiology community, some participants described feeling uncertain about their candidacy status. When the ICD was first being implanted during the late 1980s, the device represented a life thread because death appeared imminent unless a transplant heart became available (Pycha, 1986). In noticeable contrast, two decades later, Ms. Stallion's describes dissonance between how she interprets her doctor's deductive logic and her own feelings of being unhindered by cardiac disease. Her narrative begins with an account of a congenital cardiac malformation that was identified after it became symptomatic about 8 years ago. After the malformation was surgically repaired she noticed a marked improvement in her energy and physical endurance. Ultimately, she acquiesces to her doctor's recommendation because of their inference to the potential impact of advancing age.

> Ms. Stallion: *They [doctors] were intimating that my heart wasn't good enough to keep going on its own and I had just experienced that it was doing quite well, better than it ever had before... but as I get older, there's a possibility that I might need it.*

Mr. Mercedes [see below] implies treating heart conditions is an expected part of the aging process that he interprets as routine and ordinary.

> Mr. Mercedes: *"I'm 71, so I'm at the age where friends and acquaintances and friends of friends have had open heart surgery. And whenever I hear that, – knowing how common it is….And now they put this little thing in and that's it. Nothing. Forget it. Do your stuff. Take your grandchildren to a movie. It's fabulous. I never cease to be amazed by the types of discoveries that are happening in the life-sciences today."*

Impact of familiarity with implanted technology

Prior knowledge about a cardiac pacemaker appeared to demystify the process of treating heart disease by inserting a cardiac device into one's body. At the same time, merging the functional differences into perceptions of having only one device creates confusion in decision-making scenarios such as preparing end-of-life preferences. As Mr. Chaps explained, however, knowing the correct name was important to "just the medical field." His conclusion raises an important issue that illustrates personal comfort with being uninformed. Knowledge of the specifics was interpreted by the majority of study participants as relevant only within the larger arena of device sophistication and complexity that extended beyond their level of comprehension. This analysis may explain personal preference for assigning the nexus of responsibility for decision-making to the medical profession and thereby assuming less personal responsibility. Lack of use of proper terminology when referring to the implanted device may also have implications for interpreting the meaning of the ICD as “life saving” in all life and death scenarios without fully understanding the definition of an ICD-preventable death. While the ICD prophylaxis always reduces arrhythmic death, it does not always reduce all-cause mortality in light of competing risks resulting from co-morbid conditions. Mr. White Socks explained his ICD as “an improvement over just a pacemaker because it gets the left ventricle.” The pacemaker was described as the device that was “always doing its job,” whiles the “ICD is only needed in an emergency.” For most, the ICD was described as the latent part of the pacemaker, “As far as I know it’s never done its job. It never had to.” Never having to do its job meant “a *real* emergency” had yet to occur and… might never occur. In the meantime the ICD acts as insurance until the next best approach for managing heart failure comes along, “I think they’re great, and I hope they can keep improving on them.”

Positions of Decision-Making

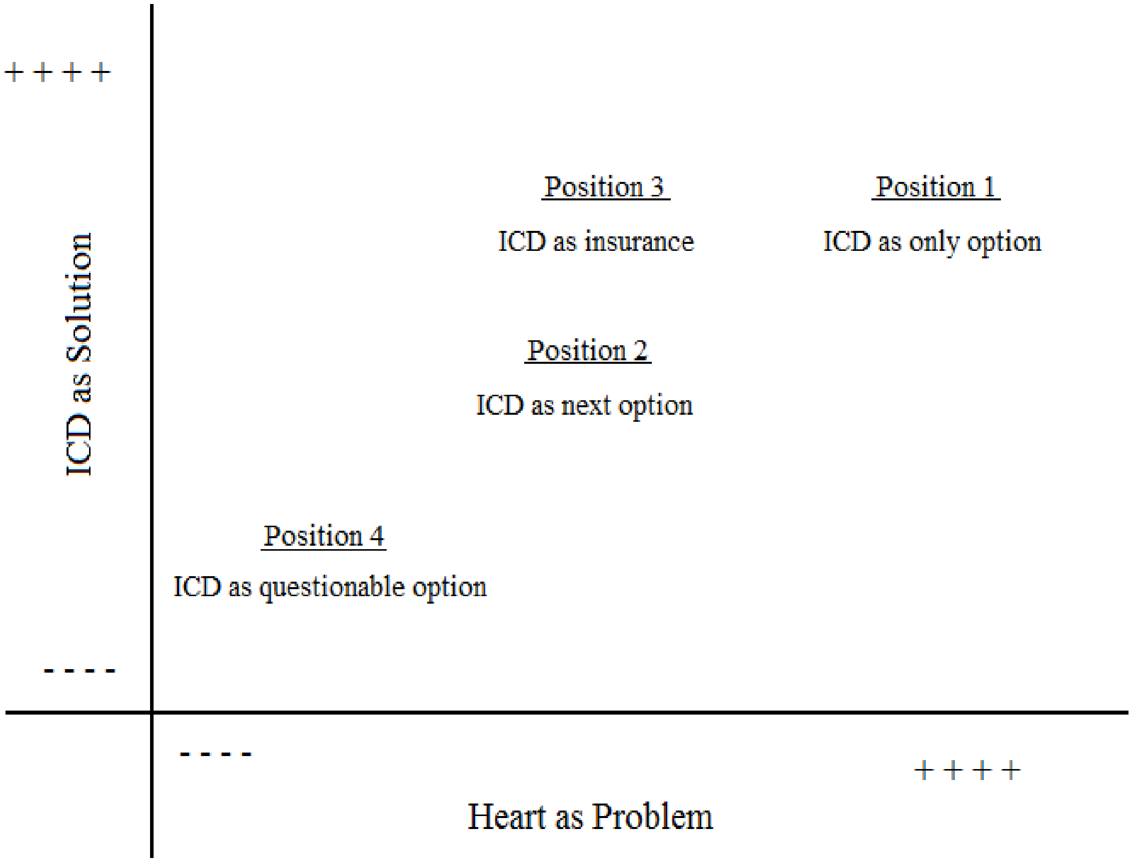
The impact of trusting medical opinion in the context of advancing age initially emerged from the data as four basic positions that were mapped for comparative analysis using the iterative process of grounded theory methodology: *ICD as only option, ICD as next option, ICD as insurance option, and ICD as questionable option*. These four heterogeneous positions were plotted between the intersecting X and Y axes laid out in terms of, more versus less (Figure 2).

Self interpretation of perceived vulnerability of one’s heart and the expectation that one will experience a device shock intensifies with distance from the intersection of the X and Y axis. The decision not to receive an ICD, the missing position in data, exists at the intersection of the X and Y axes. While this position did not emerge during the decision-making processes, a few individuals described second guessing their decision when they were experiencing the extremes of lack of shocks or excessive shocks. One individual also stated that if his device was recalled he would want it removed immediately. While some speculated about not having to deal with the device, not one participant actively discussed or formulated directives to remove or deactivate the ICD in a particular context.

Directly opposite the intersection at the top right, the first position holds assumptions that without the ICD, death will occur. Decisions made from Position 1 depicted the highest probability of SCD. Moving to the left of the first position, inward on the X axis and downward on the Y axis, the next position holds decisions that heart disease is progressive and that the ICD is the next treatment strategy. The third position, placed in the middle of the map, holds decisions that the ICD will provide insurance protection for an aging heart. Yet, the last position, Position 4, further holds that deciding to receive an ICD is questionable and potentially harmful.

Figure 2

Position Mapping: Evolving into the Partnership



Through a process of focused coding the four positions for decision-making were collapsed into two primary positions: *ICD as only option* and *ICD as next option.* Focused coding is a strategy consistent with grounded theory methodology that involves sorting through initial codes or groups of codes to incisively categorize data. The position of *ICD as questionable option* was collapsed into the position, *ICD as only option*, and the members of the position, *ICD as insurance* were moved into the position of *ICD as next option.* Insofar as the notion of having insurance motivated all individuals from different experiences by the same fears and longings, the interpretation of the *ICD as* *insurance* emerged as characteristic of Living in Partnership rather than a distinct position for decision-making. The rational for moving members in the ICD as insurance position into the ICD as next option position drew from the described expectation that they would always be having some kind of treatment and the ICD was yet, the next step recommended by their doctor. Likewise, all study participants described some degree of ambiguity during the decision-making process. The three participants that further questioned their doctors' recommendation expressed their concern about the potential harm of an implanting a "foreign body" or "thing" in their heart, especially since they were feeling "just fine." In the end, each acquiesced to their doctors' recommendation because the life or death nature of their decision was emphasized. Study participants, therefore, separated into two main groups of decision-making positions for entering into the partnership (Table 1). The positions are labeled as *ICD as only option* or *ICD as next option*.

Table 1

Entering into the Partnership

Position determining decision	**Defining determinate**	**Characteristic pattern**	**Expectation for ICD**
ICD as Only option	Controlling timing of death	Reactive and Decisive	Life saving
ICD as Next option	Managing symptoms	Expected and routine	Life extending

An interesting finding, yet not surprising, is the striking demographic difference between the membership of the two groups (Table 2, Table 3). All members that framed their implant decision in terms of “only option” also experienced external cardiac resuscitation after an unanticipated, cardiac event. As previously discussed, the experience of being taken by ambulance to the hospital or “waking up” in the intensive care unit of a hospital, creates a vivid life-experience. Hence, the main distinction between “only option” and “next option” is one’s interpretation of the medical environment in terms of routine or emergent. As a result, members in the ICD as Next Option position viewed their risk of SCD as slight compared to the group that had actually experienced a life threatening event.

This distinction is illustrated by an excerpt from the interview with Mr. LD [see below].

> Mr. LD: *“My regular doctor was on vacation at the time when I was having some kind of a problem, and I went to the hospital and they kept me there for a couple of days. The doctor who was filling in for my doctor, came to the conclusion that I was a candidate for sudden death so it was well that I should have this ICD installed. I didn’t object to it. I thought it was a good idea. My heart was in danger of going into fibrillation [He pauses to take a breath before preceding] means that it suddenly starts beating fast and it doesn’t do its job* - *it just gets out of sync. That’s what heart attacks are.*
> Interviewer*: “So the ICD* - *were there other ways of treating?”*
> Mr.LD*: “No, none others were suggested. I was already taking a lot of drugs. I still do.”*

Mr. LD apparently felt increased heart failure symptoms, although did not describe a sudden cardiac arrest. He was not taken to the hospital by ambulance, nor did he wake up in critical care during or after cardiac resuscitation as was the case with members comprising the only option position. As a result, for Mr. LD, the level of urgency associated with surroundings was low to mild and his interpretative risk of SCD was less compared to descriptions that emerged from interactions in an emergency setting. Mr. LD did not indicate feeling vulnerable, nor did he express feeling a loss of control over what had happened to his body prior to going to the hospital. Instead, he suggests that the ICD was recommended for symptom management of chronic disease. He infers that other options weren't offered because he "was already taking a lot of drug - *I still do*." Thus, his medication regime was not replaced by the ICD; rather, the device was added next to his treatment plan.

Table 2

Decision Position: ICD as Only Option

Only Option Position	Age Years	Female Gender	Unexplained Syncope	Implant Date	ICD Years	Device Shock
Glen	79		Yes	2003	6	Yes
Frank	81		Yes	2000	9	
Larry	74		Yes	2005	4	Yes
Ernie	73		Yes	2001	8	Yes
Mercedes	71		Yes	2004	5	Yes
Jackie	69	Female	Yes	2007	2	
John James	72		Yes	2003	6	Yes
DocSci	69		Yes	2006	3	
Jean	71	Female	Yes	1990	20	Yes

Table 3

Decision Position: ICD as Next Option

Next Option Position	Age Years	Female Gender	Unexplained Syncope	Implant Date	ICD Years	Device Shock
Sixties	65			1999	10	Yes
LD	83			2002	7	Yes
Oscar	66			2003	6	
Irish	76			2005	4	
Parker	74	Female		2007	2	
Elder	91		unknown	1999	10	unknown
Chaps	83			2002	7	
Leo	80			2006	3	
Harvey	86			2007	2	
Virginia	76			2005	4	Yes
White Socks	84			2000	9	
Joe	79			2005	4	
Stallion	69	Female		2001	8	Yes
Writer	76			2005	4	
Andy	81			2007	2	

ICD as only option

Participants in this group described the impact of receiving medical care in an acute setting in terms of life and death urgency. The interesting narrative thread highlighted a decision process that was primarily externally driven. The emotional component for classifying themselves at highest risk for SCD after surviving a sudden cardiac arrest is interpreted through interactions with witnesses to the life threatening event. While the majority of members of the group who experienced a sudden cardiac arrest absorb the feedback they received from others into the fabric of their story, some describe the emotional burden of being reminded that they almost died (see below).

> Ms. Jackie: "*And half the time I'd be walking [in the hospital] and I'd have the nurses say, do you remember me? No, I'm sorry I don't. And they'd tell me I took care of you when you first came in. Everybody told me I was really in bad shape. And my son said they had to take you and turn you upside down, however they do, to get your heart – it was literally dead.[…] So okay, I'm walking now and no, I don't remember you. You tell me I was in bad shape. Then how you expect me to remember you if I was in as bad of shape as you claim?"*

In cases of unexplained syncope, memories of personal recall are scant and often alarming. Unfolding the story of what happened, therefore, becomes an interactive process that tends to emphasize someone else's interpretation and inflection. Findings revealed that the focal point emerged in terms of *what didn't happen, rather than on what did happen.* Quotations (Table 4) suggested the emotional intensity of a victim, caught unaware and ill-prepared. The re-telling of their survival stories of what almost happened always concluded with expressions of appreciation. They were in the right place, at the right time, to receive emergency and skilled medical care; they felt "lucky." From the position of only option, individuals concluded that the 24/7 availability of the ICD would remove their dependency on timing and location for skilled intervention.

Table 4

Reconstructing Sudden Cardiac Event

Recollection of Threatening Event	Attributing Meaning to Life Threatening Event
I started breathing heavily, gasping. The last thing I remember is telling her I’m not going to make it.	*I think I was dead for about 10 minutes, because I have a 4 hour gap that is gone. I don’t know what happened. If it had been 5 minutes later I wouldn’t be sitting here talking to you.*
I stopped at a light, light changes to green. I go across and blacked out and smashed into a parked car.	*So the doctor says, [during testing] do you feel anything? And I said nothing…. I was in a very dangerous situation that if I’m undergoing an arrhythmia or something, I’m not going to feel it.*
I was wondering what time the trays were coming up and the next thing I know the room was full of people putting needles everywhere.	*[If] I would have been on the bridge, I would have been dead, if I’d got discharged I wouldn’t have made it home. It would have been all over. I would have been dead.*

ICD as Next Option.

Compared to the sudden disruption of a medical emergency, events leading to the implant decision from the position of next option were described as gradual and consensual. Implanting an ICD was viewed as yet another way for treating their cardiac disease. They also described feeling lucky however from a slightly different perspective than had been described by members in the *ICD as Only Option* position. Rather than being influenced by a critical care environment, members from this group interpreted the clinic setting as underpinning a notion of routine progression in managing chronic cardiac conditions. In the context of the clinic, perceptions of good luck were described in terms of having benefited from a long-term relationship with medical expertise that “had kept me alive.” Evidence of the doctor’s role in their longevity was situated in years of interactions about lifestyle choices, medication adjustments, and other invasive cardiac treatments. Many participants also had prior cardiac surgeries performed by their doctor. As a result, the implant decision was considered the next step for receiving the best ‘cutting edge’ treatment available.

The significance of this finding appears to de-emphasize influences such as patient preferences regarding end-of-life care, patient-directed goals of care, invasiveness of treatment approaches, and the context of other treatments as influencing factors while emphasizing the impact of medical opinion. The model of “shared-decision making,” introduced during the early 1980s encourages medical providers to actively involve patients and their families in discussing the benefits and burdens of a particular treatment. Even though the value of this approach is discussed and recommended in the Heart Rhythm Society Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) (Lambert, 2010), participants in this dissertation study chose not to assume an active role in decision-making processes. Although all appreciated having their doctors explain what was going to be done, they did not understand the specifics and thus deferred to their doctor’s knowledge.

Summary of Phase One

The decision to have an ICD implanted emerged as a process that was firmly situated in the medical setting and influenced by mode of entry into that setting. The one recurring narrative thread emphasized how medical expertise guided decisions towards implantation with risk of sudden death as an alternative option. For instance, in response to the query about other options I was told, “I’m already taking drugs.” In that the ICD had medically framed as the option, participants in the study fell into one of two positions from which they formed their decision in terms of only option or next option. The only option position emerged in the context of an emotionally charged life threat and suggested active response to the threat. In contrast, decisions made from the next option position, suggested passive involvement with less emotive connotations. Assigning the nexus of responsibility to confirm diagnosis and direct treatment to medical experts surfaced as the driving force behind both positions.

Managing the Partnership

Phase Two

"In the mid-1960s, people began to appreciate that sudden death
Was a major public health problem
That ventricular fibrillation was the mode of exodus
And that prompt defibrillation of the heart was lifesaving."
-Morton M. Mower

After the implant decision was made, individuals entered a second phase that involved dealing with the close structural and functional relationship between themselves and the device. Strictly speaking, the second phase begins after the ICD is surgically implanted. However, for the purposes of this study the exploration of this experience began one year after the device was implanted. The rationale is grounded in the ICD literature. Findings from previous research generally recognized that after the first year most patients are fully recovered from surgery related issues (Burke, 1996; Dougherty, 1995; Flemme et al., 2001; Flemme et al., 2005). Hence, after the first year, the model of *Living in Partnership* captures the tension between dealing with the unpredictable nature of the ICD while striving for normalcy.

In 1986, a psychiatric clinical nurse specialist, Colette Pycha, teamed with two physicians to describe the psychological aspects of having an implantable defibrillator from the perspective of the patients in their hospital (personal communication, February 2, 2011). The observational study found: with time, the device was accepted "as part of their existence" in terms of a "positive human alliance" (Pycha, 1986, p. 842). Similarly, participants in this study pragmatically described a supportive and vital union between person and technology. However, rather than viewing this as an alliance the participants portrayed this relationship as a partnership. An alliance is defined in the Oxford American Dictionary as a *state of being joined or connected* (Soanes, C. 2004). In comparison, a *partnership relationship is defined as an association* (Soanes, C. 2004). Distinguishing between being joined and having an association is germane to the significance of the findings from this study. Compared to findings from over a quarter century ago, implanting technology into one's heart was viewed with less notions of detachment by the participants in this dissertation study. Instead, they described actively managing their ICD throughout a continuum of interpretative states of well-being with fluctuating meanings.

Living in Partnership throughout a Continuum of Interpretative States of Well-being

A variety of situations emerged throughout a continuum of post-implant experiences relative to psychological states of well-being. When grouped together, as categories of assigned meaning, the emerging theme suggests ambiguity of what is yet uncertain even after the ICD has been implanted. Hence, findings depicted ambiguity in terms of "opposite sides of the same coin." On one side, certainty of SCD had been removed; on the flipside, uncertainty was driven by the unpredictable nature of device discharges.

In that the goal of implanting the ICD was to remove risk of SCD, the post-implantation goal is to reduce probability of experiencing a device shock. The absence of a device shock invoked negative and positive interpretations about quality of life. Mr. Andy interpreted the inactivity of his ICD as follows: “As far as I’m concerned, I don’t think the defibrillator has done anything. I think its insurance and whoever paid for it--I didn’t--it’s so far wasted money.” Similar to other participants’ lack of definitive statements, the words “so far” suggest that at some point, it might not be wasted money. Others interpreted device inactivity from the more active perspective of, “it’s doing its job.” Supporting evidence for “a job well done” was described in terms of being “still alive.”

At times, family members, in the role of primary caregivers, expressed alternative views from the person with an ICD about what the presence or absence of a device shock meant. An interaction between Mr. Harvey and his daughter, Sue [alias], illustrates this inconsistency. Sue remained in the room during the interview. She had a gentle kind manner when addressing her father and appeared to care very much for him. Mr. Harvey, a widower is a healthy appearing 86 year old gentleman. He ambulates slowly with a walker. Signs of his progressing heart failure were evident by his frequent pauses to take a breath when talking. When asked if he had heart failure, Mr. Harvey explained, *“not yet.”* The phrase, ‘not yet,’ expressed by other study participants, illustrates another example of being uninformed by medical terminology. Mr. Harvey, and others, appeared to apply the literal translation in terms of the end of heartbeats, whereas, in the medical context that I am familiar with, heart failure denotes a broad and encompassing medical condition in which the heart is insufficiently pumping blood volume to meet the needs of the body. Mr. Harvey anticipates that his heart will fail and that if he were to receive a device shock it would be foreshadow death [see below]

> <u>Mr. Harvey:</u> *"It [a device shock] would be unusual but it wouldn't be unexpected. I'm not going to live forever; something has to happen eventually. It might be the first beginnings of it or something."*

Mr. Harvey further explained how he has already outlived the life expectancy predicted by his doctor years ago. In contrast, his daughter interjected that if her father experienced a device shock it would just mean "*his heart is out of whack <u>again</u>*." Implying, once again, it could be corrected during a Device Clinic appointment. Moreover, she attributed his recently noted "slow decline " to daily pain that he's been experiencing since he fell a couple weeks ago, oddly enough while getting onto the exam table to have his ICD interrogated. Both Sue and her father are discussing the same scenario of slow decline, yet, each attributes different causes and anticipates different results. Concerns about the implications of a device shock on different members of the family members were determined by the eye of the beholder.

In the context of chronic disease management, confounding variables emerge when the dyad consists of elderly caring for elderly. During the process of obtaining consent to participate in the study, Mr. Larry and his wife both expressed significant concern that the ICD "is an awful problem at night that affects his sleep." Although, once his wife went to the waiting room, Mr. Larry minimized the sleep issue, "it doesn't hurt, it just aggravates; it just annoys for about two hours when I first go to bed." His concern centered more on how the ICD impacted on his wife's blood pressure now that she has had a stroke. Out of concern for his wife's general health, he no longer talks about the ICD shocks that he previously described in terms of experiencing "an earthquake." Rather, he is now absorbed with the uncertainty about how his ICD impacts on his wife's illness [see below].

> <u>Mr. Larry:</u> *"She continues to worry more about me than she does about herself because her blood pressure goes up sometimes. In fact, when she had a stroke it was almost 200 on the top end, and that's almost dead."*

The absence of data, stated from the perspective of those closest to the ICD recipient, is a limitation and strength of the study design. Thus, data from the third person perspective about the impact of the ICD on the ICD recipient is not available. At the same time, focusing only on the perspectives of the ICD recipients includes how their assumptions of what others are thinking influence their interpretations. For example, participants discussed how they mitigated their own concerns as a protective approach towards family members.

The *shock event*, often the pivotal focus in ICD research, was not emphasized with the same level of personal impact by participants in this study as was the *aftermath of the shock.* Dealing with the aftermath persisted for varying periods of time and strongly contributed to the emotional angst associated with *anticipating* a device shock. At the extreme, the impact of anticipating a device shock was categorized in terms of Living for Shock.

Living for a Shock

Living for a shock is characterized by an emotional toll that is devastating and at times immobilizing. All activities of daily living are dramatically affected. One of the most poignant descriptions of the profound effect it has on daily routines describes the phenomenon known as defibrillator storm. Medically defined, defibrillator storm is a <u>clustering</u> of two or more ICD shocks (appropriately or inappropriately triggered) in succession during a 24-hour period. Defibrillator storm is experienced by 10% to 20% of ICD recipients and most often occurs within 9 ±12 months after implantation (O'Brien, M.C., et.al, 2005). The 4 out of 24 (17%) participants that describe experiencing defibrillator storm explained dealing with the memory of that experience over months of intense psychotherapy and taking sedating medications before they were able to move past psychological impact

> *"I got so bad that I was afraid to leave the house to go out to the mailbox. I was afraid to go into the shower by myself with my wife downstairs in the house. I would ask her to come upstairs and stay close while I took a shower because I was afraid something would happen to me while I was in the shower and I wouldn't be able to get help if I needed it."*

The triggers that lead to the intensity of these fears were his frequent experiences with defibrillator storm which describes the clustering of two or more ICD shocks within a 24-hour period. This phenomenon, although depicted as rare in the medical literature, may be caused by an appropriate or an inappropriate trigger causing the ICD to discharge (O'Brien, M.C., et.al, 2005). The meaning of the ICD dramatically and temporality shifts during these experiences (see below).

Mr. John James is retired and lives alone. The wife he was divorced from has since died. They had a daughter that he is in touch with and at times lives with when his health is particularly poor. His age is 72 and he has had an ICD for 6 years. The ICD was implanted after a sudden cardiac arrest resulted from a ventricular arrhythmia during hospitalization for pneumonia. He reports that he is a "reformed alcoholic" and is struggling "to keep on top of things." He wore a plaid flannel shirt inside of another shirt and under a windbreaker jacket. Fingers and nails were dirty as was his hair. Overall he looked unkempt and may be homeless. In his narrative, Mr. John James describes three distinctly different experiences with a device shock that are all connected to his decision to keep the ICD. In the first scenario he did not lose consciousness and finds out later that the discharge was caused by a malfunction.

> Mr. John James: *When it was first put in, it went off a few times; it hurt, and I did not pass out. When I came to the hospital and got checked outpatient style, the technicians looked at it and said, well, you know, this really shouldn't have gone off. It's not suppose to you know; it wasn't that big of a deal.*

His next experience involves a loss in consciousness and was deemed appropriate during device interrogation, therefore was interpreted as beneficial, "a boom."

> *Mr. John James: One time that I know of – I wouldn't be a bit surprised if it was juggling pharmaceuticals that made me vulnerable – I passed out on the street. The thing revived me. And I wasn't even aware of what had gone on, except that I had fallen down and cut my nose. And so it was easy for me with that experience to think of the thing as definitely a boom.*

However, in the third scenario, his emotional response to the shock event dramatically shifts, "I remember the thing going off every few minutes practically beating me to dead. So this is when it changed from a life saver to being a life threatener- this thing in my body, you know, that is my enemy." During hospitalization, he explains that once he was "turned over to the experts," they told him that his ICD was "chasing his heart, a futile action." After an indeterminate amount of time, his view of the ICD shifted back to the role of benefactor and things became generally good again. However, he adds, "But it could go either way; it could be a lifesaver--or you'd be walking around with a bomb, and you don't know when it's going to hurt you

Interpreting Device Shocks outside of the extreme

Study participants described experiences with appropriate and inappropriate discharges that were caused by faulty technology that malfunctioned and may be subject to manufacturer recalls; or the discharges were caused by problems with device programming or medication dosing. The underlying cause was most often mechanical and correctable through reprogramming or replacing the ICD, or adjusting anti-arrhythmic medications. However, a distinguishing feature of these inappropriate device shocks, as described by participants in this study, was that they did not lose consciousness when the device discharged. As a result, the increase in their awareness of the shock yielded greater untoward emotional consequences, often lasting until they received psychological and or pharmaceutical interventions.

The meaning of the shock, therefore, evolved fundamentally out of the way it was defined through interactions with others (Blumer, 1969). The interpretive meaning of receiving, or anticipating, a device shock significantly impacted on quality of life perceptions. Those who described living for a shock admitted to constantly thinking about the ICD with conflicting emotions; "It's not trying to hurt me; it's trying to help me." From the personal perspective, they assumed that the probability of a device shock high. The unpredictable nature of a device shock trigged intense emotional responses that appeared to be attributed to perceptions of losing control over how their body acted. Mr. Sixties' account of his experience raised a poignant yet, paradoxical perspective [see below].

> Mr. Sixties*: "I'm angry with it; it's not doing something to me; it's actually helping me. But it's so unpredictable that I'm left petrified.. Why am I so damn scared of this thing going off? I know all it's going to do is go off. And that means*

> *that I need to have it looked at. My situation has changed. I have this melancholy heart that decides to do different things.*

In the last sentence, Mr. Sixties further personifies his heart as being melancholy. Historically, melancholy was another term for black bile – one of the four bodily humors once thought to determine people's health and emotional state. Mr. Sixties personified his heart's independent, yet counterproductive actions as "deciding to do different things." Thus, the unpredictable nature of one's heart doing different things argues that the meaning assigned to the ICD results from interpretations of how the person and the device interact in a partnership relationship.

Two study participants who were continuing to work part-time emphasized the importance of not receiving a device discharge while working. Dr. Ernie explained that when was in his medical role it was important that he present himself without handicaps; "I'm supposed to be the healthy guy. I'm taking care of the people." Ms. Jean extensively described the far reaching impact of actually experiencing a device shock in her work setting.

Ms. Jean is the study participant who has lived with an ICD the longest. Similar to summations made by other participants, her sentiments reflect that she is "used to it now." Throughout the interview with me, she described receiving a variety of shocks during the 19 years that she has had an ICD. However, she remembers experiencing the greatest emotional toll when her ICD discharged a shock during a routine day at work (see below).

> Ms. Jean: *"I had a brief 5minute video clip to show in the middle of my lecture. I went and sat down in the front row of the audience to watch the video, and during that time I had another jolt and when you have these, your whole body jerks. I*

> *don’t know if anyone noticed because people would think I just had a sneeze or something. And then, if you can believe it, I went back up and finished my lecture, and it was a great lecture and people really liked it. But I was a wreck.”*

The meaning of a public demonstration of a device shock implied losing control over personal identity in circumstances when projecting a position of power and control was deemed important. The impact of experiencing an “identity rupture” (P. Fox, personal communication, May 6, 2010) exemplifies what can and cannot be controlled when presenting ‘self’ to others (Goffman, E., 1959). The importance of presenting oneself as appearing competent and physically intact emerged as particularly important in the context of advancing age.

Impact of advancing age

Mr. LD was age 78 years when he consented to have an ICD implanted after his doctor recommended it. At the time of implant, Mr. LD clearly stated that the reason he needed an ICD was due to the threat imposed by arrhythmic disease, a risk that was not necessarily caused by advancing chronological age [see below].

> <u>Interviewer:</u> *I’m just asking for my own clarification--an arrhythmia happens when the body starts to wear out more…?*
> <u>Mr. LD</u>*: Not necessarily. I don’t think it’s a normal thing. It’s something abnormal. I don’t think you have to be old for it to happen. People die of heart attacks--I had a friend that died of a heart attack--he was in perfect health—apparently, and he was 45 years old and had a heart attack and immediately died. So sometimes you don’t know.*

Mr. LD participated in the study five years after he had an ICD implanted. During the period of time symptoms associated with his multiple medical conditions including cancer, chronic obstructive lung disease, and chronic renal failure became more debilitating along with a narrowing of his social boundaries. However, his intense desire to stay alive as long as possible was not altered. The three events of device shock that he experienced during these five years shaped his interpretation of the ICD as life-prolonging, an interpretation that was couched between expectation for a longer life and appreciation for experiencing a device shock rather than a sudden cardiac arrest. Furthermore, he expected to retain the ICD and intimated that death will occur from other causes that may be attributed to his advanced age [see below].

> Mr. LD*: "In terms of the future, it means that I'll probably have one for the rest of my life."*
> Interviewer*: "Will there ever be a time when you would not need one?"*
> Mr. LD: *"No I don't think so [pause as if reflecting and as I started to ask the next question, he interjected]. Well, I don't know; I'm 83 years old and I don't know how much time I have left anyway but I'm not in any hurry. I don't know how to explain it. I think it's a fine device. Maybe saved my life and I think it may again."*

Anticipating future need is a theme that emerged throughout all phases of having an ICD. The future was consistently discussed in terms of a future time when they reached old age. As previously discussed, the reason Ms. Stallion agreed to the device implant was her understanding that, "I don't need it this foreign thing [now], but I as I get older, there's a possibility that I might need it."

Dealing with a heart that is aging or "misbehaving," was deemed more of an issue than dealing with ICD technology wearing out or malfunctioning. For instance, having surgery to replace lead wires because of a manufacturer's recall was taken in stride in terms of expected maintenance when compared to dealing with progressing heart failure that was not as easily corrected [see below].

> Mr. Chaps:“*Nothing is perfect. I mean I’m 73 years old. The heart failure is more of a worry than the rhythms, really. Well, if they have a heart attack and your heart was too badly damaged. Excuse me. That wouldn't be the defibrillator's fault. So I'd say that it's like anything else. It’s an aide, not a replacement. It is sort of an old automobile that has been in an accident and then repaired, was limping along but still needed a lot of help. It happens to everybody. God knows it’s happened to a lot of my friends--all of a sudden you sit up and look around and you’re all by yourself.”*

Mr. Elder at age 91 years related, “Future?--I have no future. I’m 91 years old. So I don’t have to think about it or worry about it.” In the eldest (≥75) subgroup of study participants (n=13/24), only two had received an ICD shock during the 2 to 11 years that they had been living with an ICD. For them, an emphasis on the efficacy of the ICD emerged as secondary in the context of their daily lives. Instead, symptoms of heart failure had greater impact on how they assigned meaning to their daily experiences as community-dwelling elders. Personal assumptions about processes generally associated with aging appeared to underpin instances when they described extending the nexus of responsibility for the maintaining the device to medical experts, similar to how they deferred to medical expertise during decision-making processes. In the context of having a heart that is tiring from years of working, the ICD was explained as an aid that metaphorically functions as jumper cables for the heart. Another automobile analogy compared the physical force of hitting the accelerator pedal in the car real hard to the physical feeling of a device-delivered electrical jolt [see below].

> Mr. Joe:*”You know a car has a turbo and when you hit the gas real hard, it kicks in and goes faster? Well that’s what this does, to my heart. When the heart starts beating real slow, the defibrillator’s the booster for my heart.”*

Factors influencing these interpretations include signs of device function and symptoms of advancing heart failure. Instead of distinguishing between the unique functions of the heart and the ICD, individuals described dealing with a functional whole.

Just Living

The majority of narratives revealed life moving along the continuum much as it had before. The ICD becomes "part of my life but not part of my life like my nose, my feet. It's there. I'm really not conscious of it most of the time. And I'm happy it's there and working." Thus, comments such as, "not even knowing it's there" were widely found. Assertions such as, "I never talk about it, there's just nothing to talk about, and it's just there," indicated interpretations of passive awareness. However, responding to how the device looked, felt and acted in their body in addition to viewpoints from others, influenced ways that the ICD triggered changes in routine activities. These changes were couched within the context of normalcy, and most often explained as having little personal consequence. Accommodations were described as personal strategies, rather than doctor generated recommendations. For example, some assumed certain positions when washing under the arm closest to the ICD when taking a shower, "because of the wires up there." Others described not using soap to wash over the site of insertion; and still others described *gently* washing because, "how dirty can it get?" Most denied problems with sleeping although no one slept on the side where the ICD was implanted. In cases when an ICD was implanted on one side and a pacemaker on the other side, the person slept on the pacemaker side, "just to be careful." Other behaviors included not wearing the shoulder strap of the seatbelt because it might cause undue pressure across the device generator. One elderly grandmother sacrificed cuddling with her grandchildren so the device won't get poked. She also didn't want to have to deal with the questions of young children about the lump that she described as *"It's sort of ugly."*

Another factor closely related to the subtle changes in daily behaviors was how they perceived themselves in social contexts, as well as how they assumed others viewed the ICD. These generally fell into perceptions of being disfigured or being unable to control the ICD. Perceptions of feeling disfigured emerged from both male and female narratives. Both altered their clothing to conceal visibility to others. Women most often avoided situations that might lead to physical touching. Men most often talked about the impact of a protruding medical device on their sense of virility and interpretations of fitness, regardless of chronological age or relationship status.

The majority of study participants were retired; hence daily activities were mainly social and involved interactions with other senior citizens or family members. Tactics to conceal the ICD as evidence of their cardiac disease frequently emerged in terms of "not broadcasting" that they had an ICD. One participant explained that his bridge partners were more interested in how he played the game, not in his "physical makeup." Some individuals disclosed they had an ICD implanted in certain safe contexts, but rarely were explicit details provided about how a random device shock might appear to them (see below). Ms. Jackie chose not to forewarn her trusted friends that she might receive a random device shock, given the severity of her underlying cardiac disease (she is on the heart transplant list).

> Ms. Jackie: "*So when I'm going to do my karaoke I'm at peace. I'm relaxed I have friends that go there. We meet like a little family, we greet each other. There's hugging and there's all of this stuff. And we sing together."*
> Interviewer: *"Do they know about your ICD?"*

> Ms. Jackie: "*Oh yes. Bob had something with his heart and I had to get a device for my old ticker. I said old ticker want to act up on me. So we joke and stuff like that."*
>
> Interviewer: *"Do they know what it is? What it does?"*
>
> Ms. Jackie: "*No they don't know that. All they know is some stuff.*

Limitations on travel and social engagements were also cited for a reason I had not expected. Instead of wanting to stay close to a particular doctor that they trusted or were familiar with, study participants wanted to stay close to a particular medical center. From the perspective of the participants, many hospitals did not have access to the technical expertise of ICD programming experts. Programming experts are most often representatives from ICD manufactures that were equipped with a programming computer for their model of ICD. This finding infers an assumption that after the ICD is implanted, medical management of ventricular arrhythmic disease centers on intervening with the device rather than other proven interventions for advance life support that are available at all hospitals. In another example of a behavior change that may also illustrate a shift from dependence on medical expertise to dependence on technology expertise, Mr. Chaps explained that he routinely canvasses restaurant walls when he's out to dinner with his wife to locate where the automatic external defibrillator is hung.

Impact of interrogation findings

During the post-implant years, the Device Clinic is the location where the ICD is routinely interrogated. In the context of managing other chronic conditions, checking-in at the device clinic every 3 months was described as a "piece of cake" compared to receiving dialysis or Dobutamine infusions three times a week. Mr. Leo explained that he has been receiving treatment for cardiac disease for 30 years. His first coronary artery bypass graft (CABG) was when he was 43 years and, in comparison, the ICD was not a bother; *"*It was recommended and that's what I did." At age 80 years, Mr. Leo is a member of the oldest group of study participants. Many study participants described their experiences with treatments that at one time were innovative but now are considered routine and common, at times even outdated [see below]. Others described experiencing symptoms of ventricular disease that were determined idiopathic because diagnostics that could determine cause had yet to be developed or were not routinely available.

> Mr. Leo: *"But I'll tell ya, since the first and the second (CABGs) they've made a lot of progress. The first one in 1980, it was brutal. They didn't have any idea about bypasses at that time. Not like today, they do them today like frying eggs."*

Device interrogation can also be accomplished in other hospital settings or remotely, depending on availability of a programming computer. Similar to the weight given to findings from the medical tests during the decision-making process, findings obtained through device interrogations influenced how the meaning of the ICD is interpreted during the post-implant years. Since study data was collected after, not during, device clinic interrogations, study participants explained the personal implications of the findings based on how they interpreted what the medical experts told them.

When Mr. Oscar came to Device Clinic, he assumed the interrogation process would yield information about why he was feeling weaker and weaker every day. He insinuated that once identified, malfunctioning medical technology could be fixed. Although when the findings from the interrogation revealed a device that was functioning without problems, thus not requiring reprogramming, Mr. Oscar's visible agitation and frustrations appeared to stem from the implication that his increasing weakness was not a symptom that was not caused by how the ICD was or was not working. Hence, his hope that symptoms would be remedied by reprogramming the ICD was not realized.

Frustration with

> Mr. Oscar: "*Well, they look to see if the device is working, and that's nice if it's working you know; if it isn't working, then they can do something about that, but what about me? I don't care necessarily if the device is working. I'm a different subject matter than the device. It just seems I'm getting weaker and weaker from day to day, day by day, and I feel like I'm dying or something.* [Physically] *it's all wearing down or something; I don't know what it is."*

Likewise, Mr. Sixties expressed similar emotions after his ICD was interrogated. As a self-described expert on device shocks, Mr. Sixties has experienced a variety ~~of device shocks~~ during the past ten years. Unlike the impact of symptoms of progressing cardiac disease described by Mr. Oscar, Mr. Sixties explained being driven by symptoms related to device-discharges. Anticipating a device shock now determines how he lives each day. In addition to dealing with risk of a potential device shock during his waking hours, he is also dealing with being awakened with nighttime shocks. Much to his chagrin, medical findings obtained from device interrogation on the day of his interview with me determined that these nighttime shocks are actually, 'phantom shocks.' Phantom shocks are perceived as real by the individual but are not recorded in the computer memory of the ICD and hence cannot be substantiated by the computer technology. As a result, Mr. Sixties' earlier description of pre-implant years of living free and enjoying life while riding his motorcycle, markedly contrasts with how he describes his present day feelings of living strictly confined with scant quality of life.

> Mr. Sixties: *"I am just in a quandary about when it's going to happen again. It's surprised me several times. Out of the blue, POW!! And I don't take it lightly. I mean it's a serious situation. Like I say, I've been here [in device clinic] one day and everybody says everything's peachy, and [I] go home and have the damn thing goes off the next day. I'm at a point now where I've had it discharge so many times that I'm dreaming about the damn thing and that must say something to someone. Waiting for it to happen again can make you quite nervous. I don't know whether I should go fishing, if this thing is going to go off while I'm out there in the middle of the woods someplace. Should I just stay home here and watch TV and wait for it to happen, chain smoke, and drink malted milk? I'll just have to learn how to deal with it. I didn't spend all this time trying to keep living to stop living."*

Summary of Phase Two

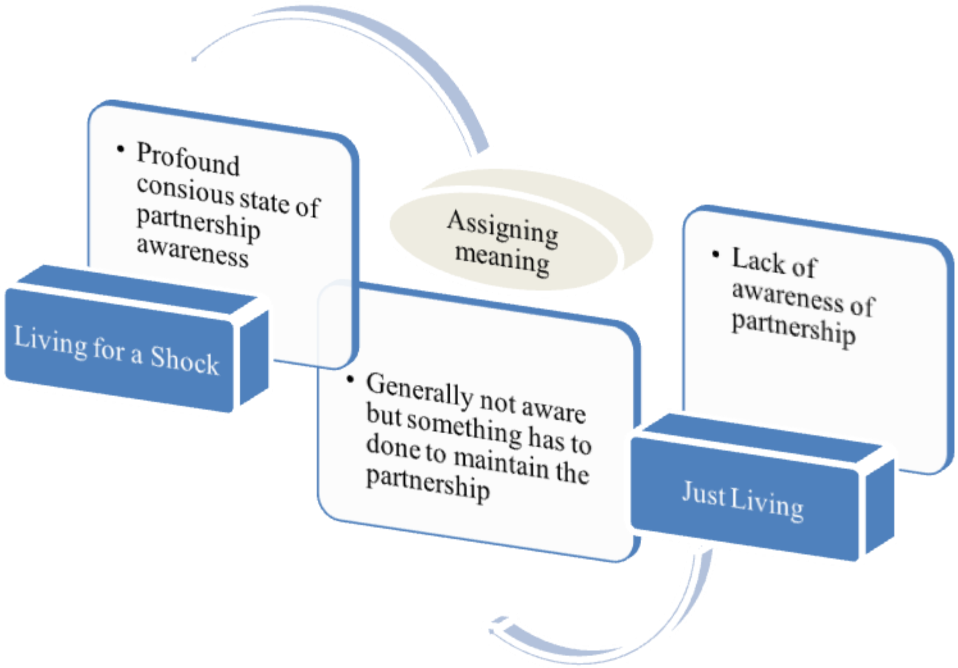
In the purest sense, the ICD was perceived as a tool for prophylactic management of what was viewed by many as an improbable scenario. The prevailing belief was, "better be safe than sorry." The structure of the model depicting Phase Two is a three dimensional representation of random movement in and out of analytical states that exist between extremes of "Just Living" and "Living for a Shock" (Table 3). In general, characteristics of both extremes influenced how meaning is assigned to the ICD in varying contexts.

The majority of participants interpret what the device means in the context situated around the center of the model. This location describes a level of disengagement in that the ICD is rarely talked about it except during the process of interrogation during a Device Clinic appointment. Device Clinic appointments are in an ambulatory care setting and described as a routine part of maintaining the device during the post-implant years. In addition to receiving information about how the partnership relationship is working, the encounter provides data about the remaining life-span of the battery.

Replacing the battery involves another cardiac surgery and hospitalization that most participants did not embrace. Some described replacing the battery as routine, whereas others expressed concern about the possibility of post-operative complications. Few, as will be further discussed in Phase Three, explored the option of not replacing the battery with their doctor. And for many, the meaning assigned to the remaining life-span of the generator battery symbolized the remaining life-span of the person, in the context of progressing disease and thereby, increased dependency on the ICD for prolonging life. In this context, after making the implant decision, deciding about battery replacement emerged as another opportunity for choosing between risking SCD and prolonging life with prophylactic ICD therapy.

Table 3

Living throughout the Continuum



Contemplating or Not Contemplating Dissolving Partnership

Phase Three

"The device controls me to stay longer….a little longer."

-Mr. Irish

The content of speculative discussions about when the ICD might no longer be needed was scant in the data. When I introduced the topic, preferences for end-of-life care only included disabling the ICD in the context of significant physical and mental deterioration. The motivation to enter a partnership relationship between person and device, described during Phase One of the process, centered on prolonging life years. In contrast, speculation about dissolving the partnership emphasized the quality of life in the context of debilitating illness or failing health, instead of in the context of receiving unwanted device shocks. Ironically, the narratives described scenarios when they would have limited awareness of the quality of their daily life as the time when deactivation might be explored. Suggesting, once again, how importance it was not to be viewed by family and caregivers in a context that would violate their sense of personal dignity.

Mr. Sixties told me that he has made "proper arrangements that a man my age should take care of […] when Dad [referring to himself] ain't [*sic*] here anymore," but when asked if he spoke with his daughter about when he would no longer want to be resuscitated by the ICD, he shook his head and said: "No I don't think so." In keeping with the spirit of living in partnership, participants in this study planned not to separate from the partnership. Furthermore, limited dialogue, if any, had been pursued between individual and doctor or individual and family member about device de-activation. One reason for this silence was implied when Dr. Ernie insinuated that once the ICD is implanted "it's there and that's all." Other participants expanded on Dr. Ernie's comment when they explained that the ICD had become something they were "used to." A few mentioned having 'directives'; yet, no one had included their ICD in their plans. Hence, although most had thought about their deaths and scenarios of when prolonging their lives would not be their choice, they also viewed the ICD as part of the long-term.

The case of Mr. Leo [see below] further illustrates the range of incongruence between understanding how the ICD works and what is involved in cardiac resuscitation. Mr. Leo is an 80 year old gentleman who ambulates slowly, severely hunched over his walker. He comes to Device Clinic accompanied by his daughter. When I asked him if he had heart failure, his response indicated his literal interpretation of heart failure:

> Mr. Leo: *"It's coming; it could happen at any time, and they asked me if I wanted any type of life support, and I said, absolutely not! If the heart fails or stops or whatever, I don't want to try to revive me or so forth."*

Later in the interview, I asked him what the ICD does, how it works. His response [see below] contradicted his earlier statement:

> Mr. Leo: *"Well, just in case the heart stops, it was supposed to give you a shock and revise [sic] you. Other than that, I don't even know it's there except for this bump here [rubs area where ICD is located, moving shirt around the protruding device] but it doesn't seem to bother me in any way, I still do most of the things I like to do; of course, they're getting somewhat limited."*

An awareness of being able to do less was a common finding across interviews, expressed at the end of the statements extolling the ICD while also situating the technology within the context of the aging process. Individuals explained that when normal processes progress to the point of when they “could not get out of bed on their own,” or “if I’m a vegetable,” they would no longer want to be living; however, they were also quick to point out that those scenarios were in the distant future. One participant speculated that if he ever “got end-stage cancer or a terrible stroke where I can’t eat, it might be appropriate,” to deactivate the ICD; yet, he had not discussed these scenarios with his wife or doctor. The defining determinate of the third phase of the partnership emerged from the view that it was not their decision to make. Some individuals believed death would come when it is supposed to, whether they have an ICD or not, “Even the ICD couldn’t bring back poor Michael Jackson.” Others explained that their doctor or family had taken the lead in the decision to implant the ICD and therefore they can decide when it isn’t needed and a few explained that God decides when they will die, with or without an ICD.

Three participants initiated informal conversations with their doctors, and touched on device deactivation. Only one participant remembered asking before he consented to have the ICD implanted about other patients with an ICD. He wanted to know about their experiences with device shock and posed the hypothetical scenario:

> <u>*Mr. Glen:*</u> *“[What about the patients] whose device goes off all the time and they beg him to take the machine out because they can’t take that explosion in their heart in the middle of your chest. It really bothered them. [He pauses, and then in a slower, more serious tone, adds] and he said he can’t do that, and he’s telling me that you’re better off with it because you [otherwise] wouldn’t be.”*

In comparison, Mr. Mercedes related a conversation he had with his doctor about what would it mean if the device never discharged. His doctor told about one of his patients that had been 67 when the ICD was implanted and now is 91. The ICD went off only once during all the interim years, but one time might have been enough to save his life. The personal meaning of this illustration for Mr. Mercedes was summarized as: “There is no argument to have it disabled. The argument is only to keep it there.” Hence, talking about when the ICD might no longer be needed was a moot discussion. Participants in the study revealed the tension between being treated and not being treated for what is certain and what is not certain, “I’d prefer to have it out now. But the preference is very mild.” There is always a sense of waiting for the metaphorical, other shoe to fall. This phenomenon also emerged during the decision-making process and underpinned interpretations of receiving prophylactic therapy. At the beginning of each interview, I asked the participant about other chronic medical conditions and was often told, “Yes, [I have that] but it has not caused any problems we know of yet” or I was told, “Yes, but in the past.” Clearly, living in the present was the primary focus for this older group of individuals with cardiac and non-cardiac chronic conditions and a plethora of life experiences that have influenced on their general approach to “deal with the future when it gets here.”

Unlike colon cancer, which Mr. DocSci can discuss in the past tense, being treated for risk of SCD invokes a nebulous temporal context. Mr. Glen recalled posing a hypothetical scenario to his doctor to ascertain what would happen if a patient “begged” his doctor “to relieve him” of the negative impact of what is medically defined as ‘ventricular storm.’ In response, his doctor explained that he could not remove the ICD as requested by that hypothetical patient. It can be argued that his doctor, from the medical view of treating disease, did not feel it was in the best interest of his patient to deactivate the ICD. Mr. Glen related the story of that the conversation to support his expectation that his ICD would never be removed because the doctor deemed it as permanent.

The foreshadowing of this reasoning had emerged during Phase One when Mr. Mercedes described how the presence of arrhythmic disease was confirmed by his doctor and, as such, it existed although he could not directly attach lived experiences with symptoms. Likewise, individuals with advance care directives did not specifically talk about the ICD but explained that their doctor would know what needed to be done --when the time comes. The consensus was that the time would come in the future, when they were "old." Although participants described symptoms of the aging processes and often referred to signs of advancing age; the majority described themselves as actively engaged in life and not old, yet. Hence, there was no need to talk about specifics about future wishes, plans.

Dr. Ernie, the participant with the most experience caring for elders nearing the end of their life, explained that his wife did not need to know about his wishes for deactivating or continuing the defibrillator because it would be up to the doctor. Dr. Ernie's rationale was that the doctor has more knowledge about the technology than his wife would have or "needs to have." Once again, the emphasis is on deferring to technical expertise and medical knowledge rather than exploring personal preferences and the humanistic impact of continuing an implanted device that may deny a non-lingering death or increase the pain and discomfort of debilitating illness. Upon further inquiry, Dr. Ernie stated that the status of his health would be the deciding factor [see below].

> <u>Dr. Ernie:</u> *"If I get cancer or bad heart failure, then we'll say maybe forget about it. If I'm doing as well as I am now since the heart valve was fixed – if that*

> *holds, and the brain holds, and nothing else happen, no lung cancer, then we put another one in. If I'm a tottering old guy, don't know what day it is, forget it."*

"Putting another one in" refers to replacing the device battery. Ms. Jean and others [see below] mentioned when replacing the ICD battery or the device itself might not be their choice when they were nearing the end of their life. Interestingly, not replacing the device battery appeared to be less dramatic than deactivating the ICD. Insofar as the excerpts below exemplify how replacing the device battery is interpreted in the context of their longevity, they also exemplify how study participants passively view phase three (Table 5) and continue to assign the nexus of responsibility for the decisions relating to the ICD to their physicians throughout all three phases of Living in Partnership.

> Interviewer: *"Is that something you've spoken to your family about?"*
> Ms. Jean: *"Not really. I've talked to my doctor a little bit about it. But since I'm not old and not ill yet, it's not quite the time--unless I completely lost my mind and then I have directives not to resuscitate--I don't think the physicians would just have my defibrillator keep zapping me – eventually it would wear itself out anyway."*

> Mr. Harvey: "*Well, we all have to die sometime, according to what I've read and seen. So when it happens to me, it happens."*
> Interviewer: "*Will you ever need -- not need to have this device working?"*
> Mr. Harvey: *"Oh, I don't intend to replace the device or anything, or take it away. As long as it does its job, I'll be here I guess."*

My rationale for including contemplations about the ICD in a future context, as a section of the Results Chapter instead of a discussion point for future study, is to emphasize the distinction made by participants in this study between removing the ICD because it was causing them problems and deactivating it at the end of life. As has been illustrated by the selected interview excerpts, the complexity of interpreting what will be important in a future context presupposes that what is important in the present context in terms of quality of life will involve the same domains. In the elderly population, the hardiness and resilience inferred in Sossong's dissertation study (2007) also surfaced in the ways the participants in my dissertation study interpreted the burdens and the benefits of having an ICD and their inclination to explore all treatment options when suggested by medical experts.

Table 5

Contemplating Partnership

Position determining decision	**Defining determinate**	**Characteristic Assumption/Pattern**	**Interpretation of Meaning of ICD**
Not Contemplating Dissolving Partnership	Not my Decision To Make	Doctor decides Family decides God decides Timing isn't right Avoiding conversation Doctor unwilling Family unable (lack of knowledge, pain of loss)	Death deferring Living on Borrowed Time Life isn't over… …just slowing down
Contemplating Dissolving Partnership	Quality of Life	Expectations of Aging Life is no longer worth living	Death Accepting Outcome of Aging Ultimate Control

CHAPTER SIX

Discussion

Initially, the interview questions were designed to flesh out the meaning and impact of the ICD on the life of an older person. In hindsight, I realize my naiveté in assuming what story would be told. After interviewing 24 individuals, I discovered that, from the perspective of the individual, the ICD offered insurance with long-term consequences and uncertainties. The story that emerged focused less on the ICD as a "thing" or a "machine" impacting on activities of daily living, and more on the impact of situations of daily living that shaped the ways meaning was attached to the ICD. As such, meanings were formed in and through the activities of people as they interact.

During the decision-making process, described as Phase One, participants in this study described themselves as the "lucky ones" because they had survived an unexplained event of syncope; or had been resuscitated from an arrhythmia that triggered sudden cardiac arrest; or because they had the best doctors. Indeed, the participants in this study are survivors. Cardiac disease notwithstanding, they are community-dwelling adults that have lived past age 65, and continue to receive medical care in an ambulatory setting. Their story of having an ICD is complex and depicts a circuitous journey that has potential to involve decades of personal experiences with the stability of a device programmed to defibrillate threatening ventricular arrhythmias and the instability of a human body destined to succumb to advancing age.

The dissonance between the predictability of the device to remove risk of SCD and the unpredictability of symptoms of progressing disease was augmented by the unpredictability of a device shock. Hence, the presence or absence of a device shock emerged as a personal measurement for determining the progression of their cardiac disease. The ICD became a barometer for living on “borrowed time,” as well as an indicator for determining the life-prolonging benefits (compared to the phrase, “life-sustaining” benefits) of the ICD. In other words, the experience of waking up each day meant their life was prolonged by the ICD, rather than saved in an emergency setting.

Application of Uncertainty Theories

Two theories of Uncertainty in Illness, the Uncertainty in Illness (UIT) (Mishel, M., 1988) and the Reconceptualization of the Uncertainty in Illness Theory (RUIT) (Mishel, M., 1990) provided the initial framework for this study. Examples of informing themes suggested by Mishel included: “revised life perspective, new ways of being in the world, growth through uncertainty, new levels of self-organization, new goals for living, evaluating what is worthwhile, redefining what is normal, and building new dreams” (Mishel & Clayton, 2003) (p. 39). These themes emerged in the findings of the study as they were particularly relevant in understanding the processes associated with a gradual acceptance of uncertainty from the perspective of the individual situated within the larger context of living life after device implantation. The RUIT provided guidance for understanding transition through uncertainty as a fluid process resembling life as a process rather than a series of isolated events.

However, the emerging theme of “just living” was not adequately captured by the UIT and RUIT theories. In addition, the fluctuations in how personal meaning was assigned in varying contexts, was not accounted for by the linear direction of these models. Study data indicates that, although symptoms of a device shock formed a basic pattern of a physical sensation generated by receiving an electrical shock to the heart, recognition of the pattern did not necessarily reduce uncertainty nor invoke a pattern of consistent response.

Uncertainty and Chronic Illness (Mishel, 2001)

Mishel's diagram of the state of chronic illness illustrates uncertainty as a temporal process rather than an orientation to a specific state. An unsystematic line inserted inside of a one directional arrow represents both the invasion of sustained uncertainty into broader areas of one's life *and* the growing instability of previously informed conceptions of what the ICD means. Next along the arrow shaft is a patterned circular portion that represents the re-patterning and reorganization of revisions of the view of uncertainty (Mishel, M., 2008). In the diagram illustrating RUIT, uncertainty is initially appraised as a danger that evolves over time to the appraisal of an opportunity.

Although, this expansion of the original Uncertainty in Illness Theory (UIT) (Mishel, 1988), increased its applicability to include conditions where uncertainty is a continual experience, it still depicts a linear structure with one end point – uncertainty as opportunity. Findings from my qualitative study that utilized a grounded theory approach for data collection and analysis indicated that older ICD recipients experience stability-of-self within a fluctuating range of positions or situations. This perspective can be further explained by integrating the concept of adaptation discussed by Brandtstadter and Greve (1994) with the concept of uncertainty discussed by Mishel. The theoretical framework of The Aging Self discusses adaptation as characteristic of older adult experiences (Brandtstadter & Greve, 1994).

The Aging Self: Concept of Adaptation (Brandtsadter and Greve, 1994)

The purpose of Brandtsadter and Greve’s (1994) theoretical framework is to elucidate processes developed during the later phases of life in response to life-course changes. Their approach emphasizes activities that stabilize, defend, or flexibly adapt a person’s self-conception and de-emphasizes the negative connotations of impairment and losses, typically associated with aging. This theory provides insight into how aging individuals shape responses to disruptive life events with stability, resilience, and resourcefulness as a dynamic phenomenon that is adaptive and protective.

According to Brandtsadter and Greve (1994), three distinct families of processes function independently of each other to enhance stability and resiliency for aging individuals to construct a positive self-concept. These processes, which are functionally interrelated, are termed: assimilative strategies, accommodative processes, and immunizing mechanisms. As previously mentioned, each of the processes can be activated by life events or developmental changes that alter self-perception. The process viewed as most salient for reducing or preventing problems of self-esteem and identity is determined by personal and situational conditions. For example, activities denoted as *assimilative* are ones that involve problem-directed actions aimed at transforming the circumstances to increase agreement with how the person views their normative self. The emphasis therefore is placed on one’s sense of personal control over the outcome. Daily activities that depict, *“just living”* with an ICD may exemplify assimilative strategies in that the ICD is described as exerting limited alteration in self-perception. In contrast, when the decisions that are made each day are influenced by “*living for a shock;”* daily events are altered and self-percepts of control are extinguished. Hence, “living for a shock" exemplifies *accommodative* processes that alter personal goals, to better fit the situation or constraint. In the extreme scenario of *living for a shock*, accommodation severely hinders quality of life, although may be personally interpreted as a stabilizing and self-protective process that centers on attempting to regain one's sense of feeling in control.

The third family of processes, labeled, *immunizing mechanisms* depends on the strength of beliefs, credibility of feedback and the availability of alternative interpretations. Thus, the attitude of the individual shapes perception and assumes the personal scope of being able to self-protect. Findings from this dissertation study revealed boundaries to being able to self-protect, given the unpredictable nature of a SCD as well as receiving a device shock. The relationship between each of these three families of processes mutually inhibits and to some extent excludes each other. For example, an individual is able to persist in the assimilative mode only as long as they perceive success, and the utility of their efforts is interpreted as worthwhile. On the other hand, the accommodative mode becomes an option when active-assimilative efforts are met with repeated failure and interpreted as failing to alter the situation. Immunizing processes tend to reduce both assimilative efforts as well as the readiness to accommodate goals because these approaches tend to negate or create a euphemistic interpretation of self-threatening evidence. The structure of the model is therefore formed through the interrelationships of these processes "which, taken together, form a family of processes that cooperate in preserving integrity and continuity of the aging self" (Brandtstadter, J. 1994, p. 59). The degree to which assimilation and accommodation are enacted and maintained as self-corrective intentions depends on the belief that one has control over the course of their personal development and aging.

In contrast to the outcome driven actions described by Brandtstadter, symbolic interactionism provides a theoretical perspective that informs how participants in this study interpreted living with ambiguity and contradictions as a process rather than as self-threatening evidence requiring stabilization. In contrast, findings from this study illustrate a model that embodies the fluid dialectic of ongoing movement of activity that keeps making meaning and adjusting and moving forward through social interactions.

Conceptual Relationship of Adaptation, Uncertainty and Symbolic Interactionism

In the uncertainty theories, adaptation results when the coping strategies are effective. Adaptation in the uncertainty model includes strategies of avoidance, selective ignoring, reordering priorities and detaching self characteristics from characteristics noted in patients who are failing (Mishel, M. 1988). Adaptation is therefore portrayed as an end-state, consistent with the cultural preference of Western society, to achieve equilibrium. Mishel further posits that “difficulty in adapting indicates inability to manipulate uncertainty in the desired directions” (Mishel, M. 2008, p. 62). Mishel’s focus on a particular direction and outcome limits the usefulness of Mishel’s theory to a broad range of aging research. In comparison, Brandtstadter proposed that the processes which enhance stability and resilience of the self in old age are self-protective and dynamic in a broader sense. Stability is disrupted by developmental changes and biographical events during the transition to later adulthood. However, stability is also impacted by mechanisms and activities that are “capable of dampening the detrimental impact of these problems on the individual's construction of self and personal continuity" (Brandtstadter, J. 1994, p. 55).

In both models, the experiences of uncertainty results in opportunity for personal growth and change. The difference between the models centers on how the outcome of adapting to uncertainty is structurally depicted as linear or dynamic. The linear structure of the uncertainty model illustrates a pre-determined trajectory with an end point that views uncertainty as opportunity; whereas the inter-related functions of the aging model allows for movement and alterations in perspective. This is a salient point for understanding the perspective of the older ICD recipient because of the potential for device related events to alter the life trajectory of the ICD recipient. As a result, notions of uncertainty and certainty fluctuate in response to what an ICD means in varying situations that may preclude perceptions of opportunity. For example, as individuals physiologically age, one's interpretation of device shocks tends to shift from appreciation for its life saving utility to a resignation that it is foreshadowing the inevitability of pending death.

In the aging self model, response to life threats in an older cohort of individuals reflects a shift from the assimilative to accommodative modes. For the aging adult, the accommodative mode does not signify resignation, escapism or depression (negative coping outcomes); it merely depicts adaptive managing of the accumulation of irreversible events that is essential for maintaining and regaining a positive self image (Brandtstadter, J., 1994). This transition toward accommodating to changes is illustrated by the findings from this study that depict *living along a continuum*.

Sections of coded transcripts revealed more activities of engagement with the ICD and less with complete withdrawal from the implanted presence. For example, daily activities that include washing and dressing visually remind the person of the implanted presence of the device and routine device interrogations remind the person of the functional role of the device. In contrast to the linear pattern depicted by Mishel's diagram of evolving views of uncertainty, findings from this study implied a dynamic sinuous movement between extremes with gradual and inconsistent movement in and out of the center of the continuum. In other words, in certain scenarios, interpretations of the device cycles closer to the endpoints and with time and additional experiences, cycles further away. The vibrancy of these experiences along a non-linear continuum reflects more closely the model put forth by Brandstandter and Greve, however the theoretical and philosophical stance of symbolic interactionism that guides Grounded Theory as a method of qualitative methodology accounts for the significant impact of social interactions on how participants in this study viewed themselves as having personal integrity.

Given recent data challenging the survival benefit of ICDs and the perception that they enhance quality of life, (Arnous, S. 2010; Botswich, J.M. & Sola, C.L., 2011; Epstein 2009) {{379 Goldenberg, I. 2008; Rich, C.R., Hauptman, R.J; Pellegrini, 2008; 460 Sanders, Gillian D. 2010; }}, data uncovered how older adults assign the nexus of responsibility for the decision to obtain and maintain the ICD to medical experts. The significance of this finding underpins how the uncertainties involved in dealing with an ICD are determined in the context of medical diagnosis and treatment. The concept of uncertainty, depicted in the models of Uncertainty in Illness (Mishel, 1988, 1990), coupled with the concept of adaptation as an example of self- protective processes, central to Life Span theories (Brandtsadter and Greve, 1994); provided a framework that is directed towards conquering and reducing ambiguity and uncertainty. Whereas, the central concepts of Symbolic Interactionism, discussed in Chapter Three, situates the paradoxical nature of the logically inconsistent phenomenon of living with two conflicting views of the ICD as life-sustaining and death-prolonging. In summary, through studying what is involved in daily managing the implanted defibrillator, one comes to a new understanding that is situated within the larger context of life and death but framed by highly individualized interpretations that are shaped by social interactions.

CHAPTER SEVEN

Conclusion

The finding that is most relevant for informing practitioners involved in the care of older adults that have ICDs is the perceived lack of opportunity for discussing personal concerns either in the medical setting or home environment. Over time, reiterations of the structure and functional relationship between the heart and the device did not appear useful. Rather, providing an opportunity to discuss interpretations of living in partnership between *person* and device throughout a continuum of evolving personal meaning appeared to be needed. Given the issues raised by participants in this study, concerns are not so much about *when* it is appropriate to give information about future options when the burden associated with managing the ICD may exceed the benefits of maintaining the ICD; or when the option of deactivating the ICD should be explored, at least not in terms of individual preparedness of "when do you want to be told?" Rather, concerns are about the lack of information about always having an option for deactivating the ICD.

Findings framed the ICD as a lifelong partner, 'until death do we part.' Yet, in reality, divorce is an option that is rarely explored. In the recently published HRS Consensus Statement on the Management of Cardiovascular Implanted Electronic Devices (CIEDs) in patients nearing the end of life or requesting withdrawal of therapy (Lampert, R., et.al, 2010), a guide is provided for the timing conversations about device deactivation. The guide suggests a progression of steps beginning prior to implantation, followed by discussions after an episode of increased or repeated firings from an ICD, in the context of progressing cardiac disease, when a Do Not Resuscitate order is considered, and then concluding at the end of life. Each of these steps is situated within emotive scenarios. Another step suggested by findings from this study is when surgical consent is obtained for replacing device battery or the device itself due to malfunction, manufacturer recall, or because the lifespan of the battery or generator has been met. Continuing with the *ICD as insurance* metaphor, indications for an additional ICD-related surgery are also opportunities to explore individual preferences for *extending their insurance.* At this more neutral juncture of ‘insurance renewal,’ ICD recipients can draw from device-related experiences when determining if the ICD is still a desired strategy for meeting personal goals. The resulting dialogues may help guide knowing what decisions can be made and what impact on heart function/life expectancy they will have. Knowledge of the individual’s perspective explained in the findings from this study may enhance the content of education that future and current patients with cardiac arrhythmic disease receive. However, *more importantly,* the findings may heighten the sensitivity of medical experts to how the meaning of the ICD is constructed through personal reflections on social interactions. For example, a public ‘demonstration’ of a device shock creates a situation where *symptoms* of ventricular arrhythmic disease cannot be hidden. The phenomenon centers on the self-assumed stigma associated with being perceived by others as diseased and possibly *under the control of the device*.

Future Research

It has been said that completing a dissertation is only the beginning of developing a program of research study. I agree. Findings from this study suggest a plethora of directions for further research. Some of which will be suggested in the conclusion of this paper. First, extending the sagacious and often cited work of Burke, (1996) findings from this study suggest exploring a recent shift in focus from “securing life through technology acceptance” (Burke, 1996) to “dealing with technology through changing life situations.” For example, additional research is needed to explore the ways that individuals’ and society’s perceptions of aging with cardiac disease impacts on how meaning is assigned to the ICD in the long term. Medical technology, such as an ICD, brings with it the prospect of sustaining life through a battery-powered machine placed inside the body for increasingly longer periods of time. As such, it raises important questions, including (but not limited to), how future decisions are made, when, and by whom and in what contexts? Findings from this study begin to answer these questions.

Further research, is indeed needed to move beyond determining if quality of life is or is not improved by an ICD and explore instead how older adults interpret the meaning of “symptoms” of their cardiac disease in the context of perceptions of aging. Increased technological innovation and duration in the use of cardiac implanted electronic devices generates greater dependence on medical professionals especially during the later years of one’s life span. At a time when telehealth applications enable patient monitoring and managing chronic illnesses from a distance are widely being employed, focusing on the loss of personal contact during in person device interrogations may further limit opportunities for non-crisis driven discussions about personal expectations for and understandings of living with an ICD for prolonged periods of time and evolving life events

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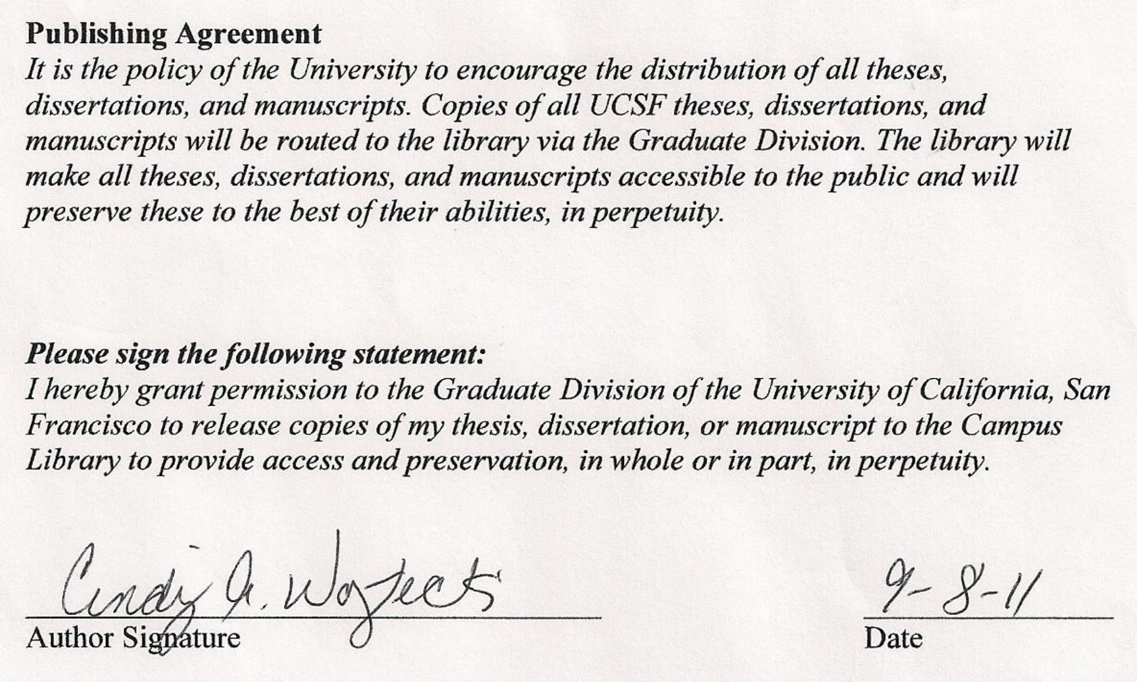

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