Graduate School of Nursing Dissertations   Graduate School of Nursing

2007-05-01

The Experiences of Younger Adults (18-40 Years) Living with an Implanted Cardioverter Defibrillator (ICD): A Dissertation

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THE EXPERIENCES OF YOUNGER ADULTS (18- 40 YEARS) LIVING WITH AN
IMPLANTED CARDIOVERTER DEFIBRILLATOR (ICD)

A Dissertation Presented

by

ANNETTE MCDONOUGH

Submitted to the Graduate School of the
University of Massachusetts Worcester in partial fulfillment
of the requirements for the degree of

DOCTOR OF PHILOSOPHY

May 2007

Nursing

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Approved as to style and content by:

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Susan Sullivan-Bolyai

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Carol Bova

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Acknowledgements

This dissertation work would not have been completed without the guidance, patience, and support of many individuals. Great appreciation and thanks are given to my dissertation committee. In particular, my dissertation chair, Dr. Susan Sullivan-Bolyai, who mentored and believed in me as well as offering her expertise and support throughout this process. Dr Carol Bova, committee member, who offered her wisdom, steadfast direction, and great encouragement in helping me achieve this great accomplishment. Dr. Diane Carroll, committee member, who also provided me her expertise and vast research knowledge with ICD patients, helped with participant recruitment, as well as offering her unconditional support and encouragement.

Special recognition and appreciation are given to my fellow classmates who offered invaluable support and friendship: Miki Patterson RNCS, ONC, PhD (c), Kate O'Dell CNM, PhD, Eileen Terrill ANP, PhD (c), Jill Terrien APRN-BC, PhD (c), Lea Ayers, RN, PhD (c), Lisa Ogawa RN, Ph D (c). The information technology department at the University of Massachusetts Medical School educated and supported me in the development of my web-based interview and I am sincerely grateful for their help.

Completion of this doctoral program would not have been possible without the constant encouragement, financial support, and computer support, which my husband, Michael offered throughout this long process and for that I am forever grateful. My parents, Richard and Catherine Romano, and my sisters Lori Richard and Cloie Romano supported me and encouraged me, which offered me great comfort throughout this work.

Special thanks are given to the staff at the Marriott Extended Stay Suites in Livonia, Michigan, where I spent one year of my life completing my doctoral work. They offered their kindness and friendship and treated me like family in my home away from home.

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Abstract

THE EXPERIENCES OF YOUNGER ADULTS (18- 40 YEARS) LIVING WITH AN
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)

May 2007

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Sudden cardiac death (SCD) is responsible for 300,000 deaths in the United States each year. Of these 300,000 deaths, 3,000-5,000 are younger adults (18-40 years) (American Heart Association (AHA), 2005; Sudden Arrhythmia Death Syndromes Foundation (SADS), 2005). Implanted cardioverter defibrillators have become the treatment of choice for individuals with life threatening arrhythmias (Cannom Prystowsky, 2004; Glikson & Friedman, 2001; Josephson, Hein, & Wellens, 2004). Although this life sustaining technology has been found to be effective in terminating life threatening arrhythmias, adjustment to an ICD may be difficult for some patients (Ganz, 2004). Few studies have investigated how younger adults manage life with an ICD (Sears, Burns, Handberg, Sotile, & Conti, 2001). It has been reported that older adults view the ICD as an extension of life, whereas, younger ICD recipients associate the ICD with significant life changes, body image concerns, and decreased independence (Arteaga & Windle, 1995).

The purpose of this study was to describe the day-to-day experiences of younger adults (18-40 years old) [$N = 20$] living with an implanted cardioverter defibrillator. A qualitative descriptive design was used with naturalistic inquiry guiding data collection,

management, and analysis. Using open-ended, in-depth interviews, younger adults were asked to describe their life after ICD implantation, physiological or psychosocial issues related to ICD implantation, and strategies used to manage life with an ICD. Data were managed using NVIVO software and analyzed using content analysis. The results revealed an overarching theme, *A cautious transition to a new normal,* with five subthemes: *Initial diagnosis: anxiety and concern*; *Caution, awareness, and security: daily life with an ICD*; *Childbearing: passing my disease to my children; Financial concerns;* and *Strategies for living with an ICD: be positive and live life to the fullest*.

This study presented some of the unique developmental and transitional issues that younger adults with ICDs are facing and strategies they used to assist in adaptation to life with an ICD. Their experiences can provide the basis for intervention programs that are developmentally sensitive and age-specific.

Chapter I

The Implanted Cardioverter Defibrillator: Evolution and Issues in Younger Adults

(18-40 Years)

Introduction

Implanted cardioverter defibrillator (ICD) studies have been historically performed with older adults (age over 40 years). Little information is available on younger adults (18 to 40 years) who are living with ICDs. Therefore, the purpose of this qualitative descriptive study was to examine the experiences of younger adults (18 to 40 years) living with an ICD.

With the invention of the ICD by Michel Mirowski in the late 1960s, care of patients at risk for sudden cardiac death (SCD) due to tachyarrhythmias has been revolutionized (Cannom & Prystowsky, 2004; Glikson & Friedman, 2001; Josephson, Hein, & Wellens, 2004). Sudden cardiac death accounts for more deaths each year than the total number from AIDS, breast cancer, lung cancer, and stroke. The most common cause of SCD is coronary artery disease, accounting for 75% of these deaths. Conduction abnormalities and cardiomyopathies comprise the remaining 25% (Josephson, et al., 2004). Sudden cardiac death is responsible for approximately 300,000 deaths in the US each year. Of these 300,000 deaths, 3,000 to 5,000 are younger adults (18 to 40 years) (American Heart Association [AHA], 2005; Sudden Arrhythmia Death Syndromes Foundation [SADS], 2005).

The US vital statistics mortality data were analyzed from 1989 to 1998 (Zhi-Jie, Croft, Giles, & Mensah, 2001). Death rates resulting from a cardiac cause were tallied for US residents greater than 35 years of age. In 1998 alone, approximately 720,000 cardiac deaths occurred in adults greater than 35 and among these deaths, 63% were due to SCD.

During this same time period, the rate of mortality from SCD increased 10% in men and 21% in women between 35 to 44 years of age. Factors underlying this increase in SCD in younger adults are not well understood, but the authors speculate an increase in obesity, lack of exercise, and an increase in smoking in adolescents may be responsible (Zhi-Jie, Croft, Giles, & Mensah, 2001).

It has been reported that approximately 200,000 individuals had ICDs placed in 2004 (Josephson, et al., 2004). The number of younger adults with ICDs is not known at present, although it is evident that the number of younger adults requiring an ICD will increase. By the year 2006, it is predicted that there will be twice as many as the current number of individuals requiring ICD implantation worldwide (Josephson, et al., 2004). Given the growing number of individuals, specifically younger adults, who will undergo ICD implantation, it is important for healthcare providers to counsel, educate, and prepare these individuals to live with this life-sustaining technology.

Refinement of the ICD in the 1980s and multiple clinical trials in the 1990s, revealing its superior efficacy over drug intervention, has made the ICD the treatment of choice for patients at risk for life-threatening arrhythmias (Josephson, et al., 2004; Ganz, 2004). Prophylactic insertion guidelines have been developed for patients considered high-risk (long QT-syndrome, hypertrophic cardiomyopathy, Brugada syndrome, and arrhythmogenic right ventricular cardiomyopathy) and clinical trials continue to refine these guidelines (Ganz, 2004). The number of ICD implantations will continue to increase dramatically in all types and ages of patients due to an expanding list of ICD indications (Sinha, Mehta, & Gomes, 2005).

Although this life sustaining technology has been found to be effective in terminating life threatening arrhythmias, adjustment to an ICD is difficult for some

patients (Ganz, 2004). The recent recall of the Guidant ICD in June 2005, (found to be due to development of an internal short resulting in failure to deliver a shock when needed) may have affected as many as 87,000 ICDs (Steinbrook, 2005). In light of this controversy, anxiety and fear among ICD recipients may make adjustment to living with the device even more difficult.

The majority of studies focusing on adjustment to living with an ICD have concentrated on patients older than 40 years of age. Few studies have investigated how younger adults manage life with an ICD (Sears, Burns, Handberg, Sotile, & Conti, 2001). Considering the differences in developmental and psychosocial issues in older adults, such as retirement, loss of sense of usefulness, and illnesses of old age (Erikson, 1997), compared with younger adults, who are concerned with body image, sexuality, career, marriage, and childbearing, (Bolles-Vitale & Funk, 1995; Kroger, 2000), exploration of their unique experience seemed warranted.

The literature review identified gaps in the knowledge about a younger adult's ability to manage life with an ICD. These gaps included developmental (body image, sexuality, career, marriage, and childbearing) and transitional (adolescence through young and middle adulthood) issues that younger adults faced while trying to manage life with an ICD (Bolles-Vitale & Funk, 1995; Erikson, 1997; Kroger, 2000). Further work is needed to identify intervention programs targeted for younger adults that address developmental and transitional issues specific to this population.

Nurses play a key role in evaluating and assessing the patient's ability to manage life with an ICD. This chapter presents the evolution of the ICD, discusses implications for use, describes physiological and psychosocial issues in younger adults related to the

ICD, identifies gaps in the literature, and describes current interventions for ICD recipients.

Evolution of the ICD

Michel Mirowski pioneered the idea of the ICD in the late1960s after the sudden death of a close friend from a lethal ventricular arrhythmia (Cannom & Prystowsky, 2004). While working with a colleague, Morton Mower, a prototype of the ICD was developed. It was then refined, tested on animals, and implanted in a human in 1980 (Cannom & Prystowsky, 2004; Ganz, 2004; Glikson & Friedman, 2001). These early devices were large and bulky. The Food and Drug Administration (FDA) approved the device in 1985, restricting its use to those patients who had suffered two cardiac arrests (Cannom & Prystowsky, 2004; Ganz, 2004).

The original device was non-programmable with an epicardial lead system requiring thoracotomy for implantation. Because of the large size of the pulse generator (containing battery and circuitry) it was originally implanted in the abdomen (Cannom & Prystowsky, 2004; Ganz, 2004). Early studies of ICD effectiveness suggested consistent results in terminating ventricular fibrillation (VF) and ventricular tachycardia (VT), hence resumption of normal sinus rhythm. Widespread use of the ICD was not accepted until the 1990s. After landmark randomized controlled trials such as Antiarrhythmics Versus Implantable Defibrillators (AVID, 1997) and the Canadian Implantable Defibrillator Study (CIDS, 1998) demonstrated its effectiveness, use of the ICD grew rapidly (Josephson, et al., 2004).

The ICD has undergone many refinements and technological advances since its introduction in 1980 (Glikson & Friedman, 2001). The technique for insertion has changed dramatically from a lengthy (4 to 6 hour) open chest surgical procedure, to a

short (1 to 1.5 hour) implantation in the electrophysiology laboratory under conscious

sedation. Because of the significant decrease in size of the pulse generators, almost all

ICDs are implanted pectorally, making it more convenient for the patient and diminishing

long-term lead complications (Glikson & Friedman, 2001).

Components

The device has evolved considerably from the first generation ICD which was

able to defibrillate only, to the fourth generation ICD which has both anti-tachycardic and

anti-bradycardic features (See Figure 1).

Figure 1. Medtronic Marquis Dual Chamber ICD

The ICD is composed of two parts, the lead system and the pulse generator. The

defibrillator leads transmit electrical signals from the heart to the pulse generator for

analysis. After analysis the generator delivers pacing or shocking impulses to the

myocardium (Glikson & Friedman, 2001). The early ICDs (first generation) used an

epicardial lead system requiring the patient to undergo a thoracotomy. These ICDs were

designed to recognize VF only and used high energy shock levels to accomplish

defibrillation. Lead placement later evolved into a complete transvenous system,

therefore eliminating the need for thoracotomy (Cannom & Prystowsky, 2004).

The pulse generator contains the battery and the circuitry which is used for pacing, shock generation, signal analysis, and data storage (Glikson & Friedman, 2001). The lead system of the ICD transmits electrical signals from the heart to the generator for interpretation and then delivers appropriate pacing or shocking pulses. Second generation devices were able to discriminate between tachycardia and fibrillation based on heart rate, enabling low energy shocks and greater treatment specificity (Cannom & Prystowksy, 2004; Glikson & Friedman, 2001).

Third generation devices were more intelligent, introducing the tiered therapy approach. This concept enabled the device to deliver anti-tachycardic pacing (ATP) or overdrive pacing, terminating episodes of VT without initiating painful shocks. These ICDs were able to correct ventricular arrhythmias, employ biventricular pacing, and apply discriminating algorithms that minimize shocks for non life-threatening arrhythmias such as sinus tachycardia, atrial fibrillation, and supraventricular arrhythmias (Cannom & Prystowksy, 2004; Ganz, 2004; Josephson, et al., 2004).

Other functions of third generation ICDs were diagnostic in purpose and included verification of shock appropriateness and storage of electrocardiograms (ECG). Fourth generation ICDs, currently in use today, employ dual chamber pacing with both anti-bradycardic and anti-tachycardic pacing. Along with the advancements to the generator and lead system, the battery life of the ICD has increased. Early devices lasted about two years, while newer devices can last five to seven years. Technical functionality of the ICD will continue to develop and more complex features will be available with each ICD as more studies are undertaken (Cannom & Prystowksy, 2004).

Current studies are exploring metabolic or electrophysiological sensors that could detect an arrhythmia before it occurs and employ pacing maneuvers, infuse appropriate

drug therapy, or regulate autonomic activity to prevent ICD discharge altogether (Cannom & Prystowksy, 2004). These functions could be programmed by the physician and the device could sense the problem and make appropriate device changes as needed. All of these functions could be performed easily, thereby avoiding the distress of the ICD shock to the patient (Cannom & Prystowksy, 2004).

Guidelines for Use of ICDs

The American College of Cardiology (ACC), the American Heart Association (AHA), and the North American Society of Pacing and Electrophysiology (NASPE) (2002) have approved guidelines for insertion of ICDs (Gregoratos et al., 2002). The ICD is recommended for patients with coronary artery disease with reduced left ventricular (LV) function, idiopathic dilated cardiomyopathy, long QT-syndrome, idiopathic VF and VT, Brugada syndrome, hypertrophic cardiomyopathy, arrhythmogenic right ventricular dysplasia, and syncope with inducible sustained VT. These current guidelines consider the underlying disease state and influence the decision to implant an ICD earlier, therefore decreasing the chance of SCD (Gregoratos et al., 2002). The results of a number of clinical trials have shown that the ICD is superior over anti-arrhythmic therapy in reducing mortality and improving survival outcomes from SCD episodes (Arrhythmia Versus Implantable Defibrillators (AVID) Investigators, 1997; Ezekowitz, Armostrong, & McAlister, 2003; Zhi-Jie, Croft, Giles, & Mensah, 2001).

Unfortunately the recent development of the Guidant ICD recall has compromised the effectiveness of ICDs, complicating the many psychosocial issues that ICD recipients already face (Bolles-Vitale & Funk, 1995; Dubin, Batsford, Lewis, & Rosenfeld, 1996). Therefore, this recent development reinforced the need to explore younger adults' experiences of living with an ICD.

Causes of SCD in Younger Adults

Sudden cardiac death in younger adults may be caused by one of many congenital cardiac diseases that are classified as structural or electrophysiological abnormalities (Sovari, Kocheril, Malineni, & McCullough, 2006; SADS, 2003). Structural abnormalities include: dilated cardiomyopathy (DCM), hypertrophic cardiomyopathy (HCM), and arrhythmogenic right ventricular dysplasia (ARVD) (Sovari, Kocheril, Malineni, & McCullough, 2006; SADS, 2003).

Dilated cardiomyopathy is the cause of SCD in 10% of cases. It is caused by an enlargement and weakening of the heart which leads to ineffective pumping that can result in cardiac arrhythmias (Murphy-Lavoie & Preston, 2005).There is uncertainty surrounding the cause of DCM and most cases are idiopathic, although viral, autoimmune, genetic, and environmental causes have been speculated (Sovari, Kocheril, Malineni, & McCullough, 2006; SADS, 2003). Acquired autoimmune deficiency syndrome (AIDS) and other viral conditions (e.g. viral endocarditis, myocarditis, parasites, and protozoa) may increase the risk of DCM. Drugs such as cocaine, methamphetamine, doxorubicin, and heavy metals have also been linked to DCM (Murphy-Lavoie & Preston, 2005).

Hypertrophic cardiomyopathy is an autosomal-dominant genetic disorder and the most common cause of SCD in people less than 30 years of age (Sovari, Kocheril, Malineni, & McCullough, 2006). In patients with HCM, the muscle of the left ventricle enlarges or hypertrophies, obstructing blood flow from the left ventricle. Obstruction of blood flow increases the work of the ventricles which may cause angina and cardiac arrhythmias (Sovari, Kocheril, Malineni, & McCullough, 2006). Arrhythmogenic right ventricular dysplasia is a congenital disorder of the heart muscle in which fatty tissue and

scar tissue replace the muscle cells of the right ventricle, placing the individual at risk for life threatening arrhythmias (Sovari, Kocheril, Malineni, & McCullough, 2006; SADS, 2003).

Electrophysiological abnormalities include long QT-syndrome, Brugada syndrome, and primary electrophysiologic abnormalities (Sovari, Kocheril, Malineni, & McCullough, 2006). Long QT-syndrome is an idiopathic, familial, congenital disorder of the sodium and potassium channels within the heart causing the individual to have a prolonged QT-interval visible on an ECG. The prolongation of the QT-interval puts patients at risk for torsade de pointes, a type of VT. Some patients remain asymptomatic, although others develop syncope or aborted SCD and then are diagnosed with long QT-syndrome (Sovari, Kocheril, Malineni, & McCullough, 2006; SADS, 2003).

Brugada syndrome was first described by Brugada and Brugada in 1992 (Brugada & Brugada, 1992). It is a congenital disorder characterized by right bundle branch block and ST segment elevation in leads V1 to V6. These individuals are at high risk for VF and eventual SCD. Primary electrophysiological abnormalities consist of a group of patients who have no structural heart disease, but have an electrophysiological abnormality that predisposes them to life threatening arrhythmias such as VF or VT (Sovari, Kocheril, Malineni, & McCullough, 2006).

Treatment for the above mentioned disorders consists of ICD implantation and/or antiarrhythmic medication administration (Sovari, Kocheril, Malineni, & McCullough, 2006). The implantation of an ICD has increased the survival rates of patients, who have survived SCD episodes (Cannom & Prystowsky, 2004; Glikson & Friedman, 2001; Josephson, et al., 2004). However, patients must overcome the challenges of adjusting to life with an ICD and both psychosocial and physiological issues have been identified

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after implantation (Dunbar, Jenkins, Hawthorne, Dudley, & Slemmons, 1999; Heller, Ormont, Lidagoster, Sciacca, & Steinberg, 1998; Schuster, Phillips, Dillon, & Tomich, 1998).

Psychosocial and Physiological Issues

Although the ICD is a widely accepted life-saving technology, adjusting to life after ICD implantation may vary among individuals and according to the recipient's age (Sears et al., 2001). After ICD implantation, it is very common for patients to experience psychosocial responses such as anxiety, depression, fear, anger, stress, body image concerns, and sexual concerns (Dunbar, 2005). These psychosocial responses can vary among patients and may persist over time. Factors associated with psychological distress may include age (younger than 50 years), being female, comorbid conditions, ineffective coping behaviors, and limited knowledge of the medical condition and purpose of the ICD (Dunbar, 2005; Sears, Lewis, Kuhl, & Conti, 2005; Shea, 2004).

Both psychosocial and physiological concerns have been expressed after ICD implantation, with anxiety, depression, (Bolse, Hamilton, Flanagan, Carroll, & Fridlund, 2005; Dunbar et al., 1999; Heller et al., 1998; Schuster, et al., 1998; Sears, & Conti, 2003; Sears, & Conti, 2002; Thomas, Friedman, & Kelley, 2001) fear, (Dunbar et al., 1999; Sears & Conti, 2003; Thomas, et al., 2001) and resumption of physical activity (Dunbar et al.,1999; Heller et al. 1998; Schuster et al., 1998) reported as the most common concerns in older adults.

Review of the Literature

Much of the research evaluating psychosocial and physiological issues after ICD implantation have been quantitative descriptive studies, although two randomized

controlled trials, and two qualitative studies were included in the review of the literature (qualitative studies performed in the US only were included in this review).

In an integrative research review of these studies, psychosocial and physiological reactions were compared. Each study had limitations hindering general application of the findings. A major limitation in all studies was the preponderance of male subjects (80%) and the focus on the experiences of adults over 60 years of age (mean age 60 to 65 years). Four studies included subjects under the age of 40, but did not report the age breakdown (Craney, Mandle, Munro, & Rankin, 1997; Dunbar, Warner, & Purcell, 1993; Hamilton & Carroll, 2004; Hegel, Griegel, Black, Goulden, & Ozahowski, 1997). Amount of time since implantation varied greatly (1 month to 8 years), making it difficult to adequately assess psychosocial issues. Psychosocial distress was usually highest immediately after implantation and then tended to decrease over time (Dunbar, 2005).

Sample sizes were diverse ($N = 38$ to 800), with two studies using very small samples (Hegel et al., 1997; Schuster et al., 1998). A variety of variables were measured including anxiety, depression, anger, health status, physical function, quality of life, (QOL), and coping style. Many instruments including the Profile of Mood States (POMS), Ferrans and Powers Quality of Life Index (QLI), Beck Depression Inventory (BDI), Hospital Anxiety and Depression Scale (HAD), Medical Outcomes Study-Short Form (MOS SF-36), Sickness Impact Profile (SIP), Duke Activity Status Index (DASI), Ways of Coping Checklist (WCC), Rand Mental Health Inventory, Physical Inventory Self-Efficacy Questionnaire, Spielberger State Trait Anxiety Inventory (STAI), ICD Psychosocial Index, and the Brodsky ICD Questionnaire were used, although the MOS SF-36, was used most frequently. The MOS SF-36 has well documented psychometric

properties and is a commonly used instrument measuring psychosocial status; however four of the 12 studies used the STAI to measure anxiety.

While these studies provide important quantitative data, the unique perspective of the ICD patient is absent. It is unclear how many younger adults have been included in these studies, but the majority of subjects have been older than 40 years and mostly male. An understanding of the daily experiences of younger adults, including women, (18 and 40 years) with ICDs is warranted and thus provided the impetus for undertaking this study.

<div align="center">Physiological Issues in Older and Younger Adults</div>

In the review of the literature, the most commonly reported physiological issue in older ICD recipients was reduction in physical activity (Arteagea & Windle, 1995; Hamilton & Carroll, 2004; Heller et al., 1998; Schron et al., 2002; Sears et al., 2005). In a study of physical and psychosocial outcomes of ICD recipients ($N = 80$), Craney and colleagues (1997) reported gender was a positive predictor of physical functioning ($p < .01$), and age ($p < .05$) and emotion-focused coping (crying, withdrawal, accepting the inevitable) ($p < .05$) were negative predictors of physical functioning. Essentially, males, younger ICD recipients, and those who were less likely to use emotion focused coping strategies had better physical functioning (Craney et al., 1997).

Pain related to ICD shock was reported in studies of both younger and older adults (Bolles-Vitale & Funk, 1995; Carroll & Hamilton; 2005; Dunbar, Warner & Purcell, 1993; Irvine et al., 2002; Schron et al., 2002). Pain has been described by patients as "feeling like being kicked in the chest by a horse" and "like an electric fence shock," although many patients (50% to 75%) do not experience this degree of pain (Dunbar et al., 1993).

After insertion of an ICD, patients may experience pain due to the incision in the upper part of the chest, which usually resolves within a few weeks as the incision heals (Dunbar, 2005).When patients move their arm or sleep on the affected side they may experience pain or discomfort which can disrupt their sleep. Pain, awareness of the ICD, fear of shocks during sleep, and anxiety may also contribute to sleep disturbances (Dunbar, 2005). The effects of lack of sleep can cause a decrease in quality of life, mood changes, and changes in the length of sleep stages. These changes in sleep stages can increase the risk for arrhythmias related to the increase in autonomic activity that occurs during the rapid eye movement stage (REM) of sleep (Dunbar, 2005). Other physiological symptoms reported included dizziness, nausea, and vomiting (Dunbar et al., 1993; Schuster et al., 1998). Identification, documentation, and assessment of symptoms allow healthcare providers to implement appropriate interventions and improve outcomes.

Psychosocial Issues

Psychosocial issues were reported to some degree in all of the studies reviewed, although anxiety and depression were the most common (Arteaga & Windle, 1995; Bolse, et al., 2005; Burke, 1996; Carroll, & Hamilton, 2005; Craney et al., 1997; Dunbar, Warner, & Purcell, 1993; Duru, et al., 2001; Hamilton & Carroll, 2004; Hegel et al., 1997; Heller et al., 1998; Irvine et al, 2002; Schron et al., 2002; Schuster et al., 1998; Sears et al., 2005). Three of the studies reviewed reported depression or psychological distress in over half of their sample (Craney et al., 1997; Heller et al., 1998; Shuster et al., 1998). Hegel and colleagues (1997) reported similar findings of anxiety and depression in 40% to 63% of their sample ($N = 38$) persisting over the course of one year.

In contrast, Hamilton and Carroll (2004) evaluated the effects of age on QOL and mood states in a younger (21 to 62 years, mean age 51 years) and older group (67 to 84 years, mean age 74 years) of ICD recipients. Although both groups had much less anxiety at six months, the younger group had statistically significant lower anxiety levels (F = 19.2 p < .0001) with both groups reporting anxiety at one year. For most ICD recipients, anxiety and other psychosocial issues decrease over time, although for some, these issues can persist (Dunbar, 2005). However, there is conflicting evidence about the persistence of anxiety over time.

Dunbar (2005) reported that ICD recipients with higher levels of psychological distress (anxiety, depression, anger, stress) may be at an increased risk of developing cardiac arrhythmias. The recent Triggers of Ventricular Arrhythmias (TOVA) study confirmed this finding, reporting that severe symptoms of depression (only depression was assessed) predicted shocks for VT/VF among ICD recipients (Whang et al., 2005). Psychological distress can precipitate arrhythmias by altering the VT cycle length, hence making VT more difficult to terminate (Dunbar, 2005).

Anxiety and depression have also been linked to a reduction in physical activity and were found to be predictors of a decreased QOL, which in turn was related to increased health concerns (Arteaga & Windle, 1995; Carroll & Hamilton, 2005; Heller et al., 1998; Sears, et al., 2005). Other common psychosocial issues reported in the literature included returning to work, social withdrawal, and sexual concerns (Hegel et al., 1997; Heller et al., 1998; Schuster et al., 1998).

Effects of ICD Shock in Quality of Life Studies

Few studies document the specific incidence of ICD-related psychosocial issues. However, more studies address the effects of ICD shocks on QOL, including physical,

emotional, social well-being (Arteaga & Windle, 1995; Carroll & Hamilton, 2005; Duru et al., 2001; Irvine et al., 2002; Schron et al., 2002). Studies assessing QOL after ICD implantation report that most patients adjust to the device within the first six months after receiving the device (Carroll & Hamilton, 2005). However, Hegel and colleagues (1997) reported that more than half of their sample was still having trouble adjusting to the ICD after one year. Fear of device shock and anxiety were common concerns in many QOL studies and were associated with a decrease in physical activity and an increase in psychological distress (Arteaga & Windle, 1995; Carroll & Hamilton, 2005; Hegel et al., 1997; Heller et al., 1998; Schron, et al., 2002; Schuster et al., 1998). Patients tend to decrease their activity or refrain from physical activity altogether because of the fear of device shock. After device shock, psychosocial well-being is significantly compromised and anxiety and depression are commonly seen. Patients tend to lose confidence, withdraw from activity, and become fearful and uncertain about the future (Carroll & Hamilton, 2005; Schron, et al., 2002).

Carroll and Hamilton (2005) reported that patients who received an ICD shock versus those who did not at one year, had worse mental health ($p < .04$) and vitality (vigor) scores ($p < .03$) on the MOS SF-36, and increased anxiety ($p < .015$), and psychological distress ($p < .02$), on the POMS. In the AVID Trial, Schron and colleagues (2002) found similar results in QOL scores when assessing ICD patients versus patients receiving antiarrhythmic drugs one year post-implantation. Patients who received an ICD shock had diminished QOL as compared to those who did not receive an ICD shock.

The CIDS trial, another large randomized controlled trial conducted in Canada, evaluated the effects of ICD shocks on QOL (Irvine et al., 2002). Those patients who received greater than five shocks over a one year period reported a diminished QOL. In

contrast, Duru and colleagues (2001) evaluated pacemaker and ICD recipients (40 to 70 years, mean age 60 years) dividing ICD subjects into those who were shocked versus those who were not. There were no differences between the three groups, although patients in the shocked group reported more activity limitations ($p < .05$) and were more anxious about their device failing ($p < .05$) or running out of battery life ($p < .05$). There was also a greater demand for a support group in the ICD shocked group (42%) versus the non-shocked ICD group (20%) and the pacemaker group (19.7%) ($p < 0.05$).

Two qualitative studies included in the review of the literature (see Table 1) presented similar findings that focused on accepting the ICD, adapting and making changes to incorporate the ICD into their lives, and moving on and living life with a positive attitude (Bolse et al., 2005; Burke, 1996). These studies offered some insight into living with an ICD, but issues and concerns were very different from the few studies of younger adults with ICDs. For example, younger adults were concerned with how they looked in a bathing suit, sexual intimacy, and having children (Bolles-Vitale & Funk, 1995; Dubin, et al, 1996). Concerns and issues presented in these qualitative studies among older adults were focused on activities of daily living including preparing meals, getting to physician appointments, and performing household chores.

Bolse and colleagues (2005) interviewed ICD recipients using "variation in the sample" (age, gender, education, working situation, and medical condition) as a determinant for (sample size) in their qualitative study, although it was not clear whether data saturation was reached. Burke (1996) interviewed ICD recipients longitudinally (one to two days post-implantation, three months, and six months) using a grounded theory approach until theoretical emergence was confirmed by participants. Both study samples included adults over age 40.

Time since implantation differed greatly in both studies: zero to six months post implantation in the Burke (1996) study versus two years post implantation reported by Bolse and colleagues (2005). No explanation was offered as to why these time frames were selected. It has been reported in the literature that adjustment to an ICD may improve over time, therefore time since implantation may affect results (Arteaga & Windle, 1995; Carroll & Hamilton, 2005). Both study samples consisted of adults over 40 years and did not specify the numbers of individual ages, but rather provided the mean age. It is unclear how many younger adults were included in each study, but they were not approached from a developmental perspective.

Psychosocial Issues in Younger Adults

To date, the majority of the literature has focused on older adults and little is known about how younger adults adjust to life with an ICD. Younger adults face unique adjustment concerns because of various developmental transitions and psychosocial issues, including body image, sexuality, childbearing, breast feeding, return to work, and supporting a family (Bolles, Vitale & Funk, 1995; Kroger, 2000). Studies of younger ICD recipients suggest they experience different lifestyle adjustment issues than older adults (Dunbar, 2005; Hamilton & Carroll, 2004; Sears et al, 2001) and are at greater risk for decreased QOL. Younger ICD recipients associate the ICD with significant life changes, body image concerns, and decreased independence, whereas, older adults view the ICD as an extension of life (Arteaga & Windle, 1995). Only two studies have explored younger adults (18 to 40 years) experiences with an ICD (Bolles-Vitale & Funk, 1995; Dubin et al., 1996). No studies to date have used a qualitative approach to describe the day-to-day experience for this age group.

Dubin et al. (1996) evaluated QOL issues (health, exercise, self-image, and social interaction) in younger adult ICD recipients (13 to 40 years, mean age 28 years) two to five years post implantation. During this time four of the eight women conceived and carried their pregnancies to full term, delivering four healthy babies. One participant received multiple ICD shocks during her pregnancy without complications to the fetus or her own health. When rating their overall health, 81% reported their health was excellent and 19% reported their health was good. However, 63% worried about exercise, and 50% reported they were avoided exercise. The majority of young adults (81%) reported being happy most of time, while 12% reported feeling nervous and anxious the majority of the time. All of the patients reported feeling attractive, although 63% were concerned with how their clothing fit with the ICD, and women (89%) were more worried about how they would look in a bathing suit than men. Forty-three of the participants (75%) felt the ICD interfered with social interactions and half (50%) reported avoiding social functions altogether. Sexual intimacy was found to be a concern for this group as 50% reported worrying about sexual interactions and 41% reported avoiding sexual intimacy.

In another study, Bolles-Vitale and Funk (1995) performed a pilot study ($N = 9$) to evaluate QOL in younger ICD recipients (13 to 49 years, mean age 32 years) and found after ICD implantation, 78% reported sleep disturbances and a decrease in energy. Many worried about resuming exercise and were fearful exercising might cause the ICD to fire, confirming Dubin and colleagues (1996) previous findings. Other concerns reported included bearing children, sexual activity, and body image; however, they were not thoroughly explored. Although this study was done with a small sample, the findings revealed issues specific to younger adults. Both of these studies (Bolles-Vitale & Funk,

1995; Dubin et al., 1996) have provided some insight into issues that younger adults with ICDs face. Therefore, they provided the foundation for the present study.

Intervention Studies

Few studies using psychosocial interventions for ICD recipients exist and none were found that were individualized for younger adults. Educational programs, usually hospital based, provide standard content to all ICD recipients (Higgins, 1990; Nichols & Wolverton, 1991; Sirovatka, 1993; Teplitz, Egenes, & Brask, 1990; White, 2000; Yeo & Berg, 2004). ICD recipients are taught about the disease processes, ICD functionality and implantation risks, safety precautions, warning signs, and potential lifestyle modifications. This teaching, however, does not take into account the patient's perspective of the experience, the age of the patient and associated developmental issues (Dougherty, Pyper, & Frasz, 2004). It is possible that an educational program that is developmentally sensitive could be developed and yield positive outcomes.

Informal support groups (Molchany & Peterson, 1994), individual counseling and support groups (Sneed, Finch, & Michel, 1997), and cognitive behavioral therapy (Kohn, Petrucci, Baessler, Soto, & Movsowitz, 2000; Urizar, Sears, Handberg, & Conti, 2004) have been described in the literature. These approaches have been beneficial in reducing anxiety and aiding in adjustment to living with an ICD (Dickerson, Posluszny, & Kennedy, 2000; Dougherty, Lewis, Thompson, Baer, & Kim, 2004; Kohn, et al., 2000; Urizar, et al., 2004).

An integrative research review of these six studies compared the various intervention programs (Dickerson, Posluszny, & Kennedy, 2000; Dougherty et al., 2004; Kohn, et al., 2000; Molchany & Peterson, 1994; Sneed et al., 1997; Urizar et al., 2004). Of the six studies, three used randomized controlled trials (Dougherty et al., 2004; Kohn

et al., 2000; Sneed et al., 1997). Only two described power calculations to determine sample size (Dougherty et al., 2004; Kohn et al., 2000), and one used a two group design without randomization and an extremely small sample ($N = 11$) (Molchany & Peterson, 1994).

Interventions used in the six studies included a combination of weekly telephone follow-up, psychiatric evaluation and support group (Sneed et al., 1997), support group only (Dickerson, Posluszny, & Kennedy, 2000; Molchany & Peterson, 1994), educational intervention and telephone follow-up (Dougherty et al., 2004), and cognitive behavioral therapy (Kohn et al., 2000; Urizar et al., 2004).

Molchany and Peterson (1994) found no differences between ICD recipients in a support group intervention versus those in the control group. However, qualitative data (anecdotal reports) suggested an improvement in coping abilities as demonstrated by participant verbalization and body language. Sneed and colleagues (1997) reported similar findings after testing a three part weekly intervention (telephone follow-up, counseling by a psychiatric nurse, and support group) with ICD recipients and their caregivers versus a control group. No significant differences were found between the two groups. This could be due to the patient's mood state, psychosocial adjustment, and readiness to accept change in the immediate post-implantation period, indicating more time may be needed for change to occur.

Limitations of these studies included a lack of standardized measures to assess anxiety, inadequate power to detect significant differences, sample sizes were small ($N = 11$; $N = 34$), time after implantation varied (6 to 24 months; 5 days to 4 months), interventions varied in length (9 months; 4 months), and the age and specific concerns of the patient were not evaluated. However, significant gender specific issues were

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uncovered in anecdotal reports indicating a need to address issues specific to women, including body image, sexuality, and self-esteem (Molchany & Peterson, 1994).

In another study, Kohn et al. (2000) compared cognitive behavioral therapy to usual care with ICD recipients ($N = 49$) and reported less depression ($F = 4.82$, p < .05) and less trait anxiety ($F = 6.86$, $p < .01$) after nine monthly sessions. Urizar and colleagues (2004) found similar results using a case study approach and cognitive behavioral therapy. Anxiety and depression level scores revealed significant improvements. The results suggest that psychosocial interventions can be developed to optimize health outcomes for all ICD recipients (Urizar, Sears, Handberg, & Conti, 2004). However, studies are needed to determine the most appropriate interventions and to evaluate their effectiveness, especially for ICD recipients (Dunbar, 2005).

More recently, Dougherty and colleagues (2004) used a two group ($N = 168$; age range 51–77) randomized clinical design to compare a telephone intervention and usual follow up care. The intervention and control groups were measured at baseline, one, and three months post implantation. Statistically significant differences between the control group and the treatment group were noted at one and three-month follow up. Participants had less physical symptoms ($p < .05$) in the treatment group than the usual care group at one month, and greater knowledge ($p < .05$) at three months in the treatment group as compared to the usual care group. There was no difference in anxiety ($p = .08$) at three months in the treatment group. Upon completion of the intervention, 96% of participants found the telephone intervention very helpful in managing life with an ICD (Dougherty et al., 2004). Although younger adults were not included in this study, the intervention could be modified for use in younger adults. There are no studies to date that have developed age-specific interventions for younger adult ICD recipients and because of the

increasing number of individuals in this age group requiring ICD implantation, further development of interventions for this age group is warranted.

<div align="center">Gaps in the Literature</div>

From a review of the literature there is some suggestion that younger adults may experience different adjustment concerns than older ICD recipients. Time since implantation may also be a factor in adjustment to an ICD, but more research is needed to clarify this issue (Arteaga & Windle, 1995; Carroll & Hamilton, 2005; Pederson, van Domburg, Theuns, Jordaens, & Erdman, 2005). Insight into the daily experiences of younger adult ICD recipients through qualitative descriptions may aid healthcare providers in developing interventions to improve the experience of living with an ICD. Psychosocial profiles indicate that younger ICD recipients and those with frequent ICD device shocks may experience the most difficult levels of adjustment, although emotional states such as anxiety, anger, and fear are not fully understood, especially in younger populations (Sears et al., 1999).

Dunbar (2005) reported depression and psychosocial distress can predispose ICD recipients to adverse events, in particular, precipitation of arrhythmias (Lampert, Jain, Burg, Batsford, McPherson, 2000; Lampert et al., 2002). Therefore, identifying causes of psychological distress in younger adults with ICDs is important to reduce such events. No studies have explored these issues.

An online discussion with members (18 to 40 years) of the internet news group, ZapLife.org, identified other major concerns. They included ability to bear children, ability to breast feed due to antiarrthymic medications, ability to return to work, ability to support a family, and if their offspring would develop their cardiac abnormalities (ZapLife.org., personal communication, November 14, 2004). The recent recall of the

malfunctioning Guidant ICD in June of 2005 has placed increased concerns of anxiety and fear on many younger adults (ZapLife.org., personal communication June 28, 2005) not to mention the stress of potentially undergoing ICD replacement surgery (Steinbrook, 2005).

Summary

In summary, studies performed with younger adults (Bolles-Vitale & Funk, 1995; Dubin et al., 1996) and concerns voiced from members of an internet news group underscore unique concerns among younger adults after ICD implantation. Yet few studies have explored these issues with younger populations. Limited intervention studies exist for ICD recipients and none have been identified for younger populations. In order to fill these gaps in the literature further research is warranted. Understanding the needs, concerns, and strategies used by younger adults can facilitate the implementation of innovative interventions to promote management of life with an ICD for this population.

Younger ICD recipients are facing many different adjustment concerns and developmental issues such as childbearing, social, and career concerns. Because of the growing number of ICDs in younger adults, development of interventions specific to this population is warranted. The first step is to provide a rich description of concerns and issues presented by younger adult ICD recipients, which was accomplished by undertaking this study. Analysis of these data could potentially create a more developmentally appropriate intervention based on their concerns and needs. Presented with these data, the importance of understanding why ICD recipients suffer these psychosocial and physiological responses underscores the importance of developing interventions specific to these issues.

Chapter II

Developmental Transitions Theory

Introduction

This chapter describes Meleis' Transitions Theory which will serve as the theoretical framework, undergirding this study. A review of her middle range theory follows. The theory includes both developmental and health-illness transition concepts. These concepts may be important factors to explore in relation to the day to day experiences of younger adults with an ICD. Because there are both developmental and health illness transitions associated with placement of an ICD for younger adults, developmental tasks of younger adults and the effects of chronic illness will also be described.

Transitions Theory

Schumacher and Meleis (1994) described the concept of transition, its centrality and significance to nursing, and presented a framework articulating the relationships among the components. Meleis and colleagues (2000) extended this framework by incorporating results of studies examining transitions and developed a middle range theory. Three domains comprise transitions theory and they include the nature of transitions (types, patterns, properties), transition conditions (facilitators and inhibitors), and patterns of response (process indicators and outcomes indicators) [See organizing framework, Figure 2]. For the purpose of this qualitative descriptive study, the transitions theory was used as the theoretical basis undergirding this study.

Transition is defined as a change in abilities, expectations, roles, or health status and requires that an individual must adapt new knowledge, change behavior, and alter their self perception (Meleis et al., 2000).

Nature of Transitions

The nature of transitions is characterized by types, patterns, and properties. Types of transitions can include developmental, situational, organizational, or health and illness. Developmental transitions occur during the transition from childhood to adolescence, and adolescence to young and middle adulthood. Younger adults with ICDs are experiencing a developmental transition as well as a health/illness transition. They must come to terms with the tasks of young and middle adulthood, accept the multiple responsibilities associated with these transitions, and adapt to living with an ICD.

Developmental Tasks of Younger Adults

In order to fully understand the experience of adapting to life with an ICD, it is first helpful to understand developmental issues facing younger adults. Younger adults are faced with the developmental transition of entering the stages of adulthood (young and middle adulthood). This implies that an individual is mature and has attained a certain level of physical, social, and emotional growth to prepare for an active role in society (Jaffe, 1998; Kroger, 2000). They are expected to be self-reliant, responsible, economically independent, and able to make sound judgments. They are partaking in close relationships, attempting to handle the stresses and strains of everyday life by incorporating various coping skills, and determining where they fit into society (Erikson, 1963; Zahn-Waxler, 1996).

Developmental changes can be thought of as occurring in three domains composed of physical, cognitive, and psychosocial (Jaffe, 1998). The physical domain includes normally occurring bodily changes such as growth and sexual maturation and sensory and motor development. Cognitive development includes mental and intellectual

abilities such as logical reasoning, learning, and thinking that continue to change and mature throughout adolescence into adulthood.

Psychosocial development involves the interactions of an individual's personality and social factors that affect changes in motivation, emotions, self-concept, and social behavior. The physical and cognitive domains are usually complete by early adulthood, although psychosocial changes in roles, personality, and relationships with others continue to change well into the adult years (Jaffe, 1998; Kroger, 2000).

Theories of psychosocial development are utilized to predict and explain changes in behavior throughout the lifespan (Jaffe, 1998). Erikson (1963) proposed development was determined by the interaction of the mind, body, and cultural influences. He viewed the sequence and timing of life events as crucial in an individual's development. Adjustment is based on successful completion of tasks that present to an individual at different points throughout their life. He described eight stages of psychosocial development and they include infancy, early childhood, play age, school age, adolescence, young adulthood, middle adulthood, and old age (Erikson, 1963; 1968; 1997).

The developmental transition from adolescence to young and middle adulthood varies among individuals, as does cognitive and psychosocial development. Adolescence is characterized by pubertal changes, forming a self image, and fitting in with peers. Young adulthood begins with the task of asserting their independence, establishing meaningful relationships (love and marriage), and making decisions about career choices. Middle adulthood is characterized by management of a career, parenting, and satisfying the need to be needed (Erikson, 1997; Jaffe, 1998; Kroger, 2000). Experiencing transition can invoke levels of stress in all individuals, but adjusting to a health illness transition

such as living with an ICD may impact psychosocial functioning. In this study, younger adults' descriptive summaries offered insight into the meanings they attribute to living with an ICD and the effect on physiological and psychosocial functioning during the transition process.

Patterns of Transition

Multiple transitions can occur sequentially or simultaneously, in the proposed study, transitions are occurring simultaneously (developmental and health/illness). Transitions can cause feelings of anxiety, uncertainty, vulnerability, and anger (Meleis, Sawyer, Im, Hillfinger, Schumacher, 2000). Understanding the effects of transition on younger adults is important because undergoing a transition can cause an individual to become vulnerable to risks that may affect their health (Davies, 2005).

As healthcare providers, it is important to assess younger adult ICD recipients for patterns of transition, whether transitions are occurring simultaneously or sequentially, and what the relationship is between the events that are causing the transitions. Understanding the transition process can facilitate the development of interventions to help younger adults adapt to change and regain stability in their life (Davies, 2005; Meleis, Sawyer, Im, Hillfinger, Schumacher, 2000).

Properties of Transition

Meleis and colleagues (2000) identified interrelated properties of the transition process and they include awareness, engagement, change and difference, times span, and critical points and events.

Awareness

Awareness is a property of the transitional experience and involves perception, knowledge, and recognition of the transition (Meleis, et al., 2000). In order to be in

transition the individual must have some awareness that the transition is occurring. Meleis et al., (2000) purported that the level of awareness is often reflected in the individual's response to transition. For example, a younger adult who has just received an ICD refuses to talk about the ICD or acknowledge that he has one. He is aware of the change in his health status because he has undergone ICD implantation, but is not yet ready to accept the change. Although he is not exhibiting behavior that signifies he is in transition (acknowledging the ICD, learning how to adapt his life with the ICD), the transition experience will occur regardless.

Engagement

Engagement is the degree to which an individual becomes involved in the transition. Examples of engagement include involvement in care, seeking out information, modifying behaviors, using role models, and preparing for change. The degree to which a person is aware will directly influence the amount of engagement, therefore engagement will not occur without awareness (Meleis, et al., 2000). Becoming involved in an ICD support group is an example of engagement that allows the younger adult to learn more about his/her illness, seek out role models, and learn how others have modified their lives.

Change

Change and difference are properties of transition, but are not synonymous with transition. Transition always involves change, but not all change is equated with transition. For instance, a younger adult is diagnosed with a life threatening arrhythmia, resulting in an abrupt change in his life focus. Whereas, the transition of accepting the diagnosis, adapting to new roles, and understanding the need for the ICD is a long-term process that involves becoming comfortable with change, achieving a sense of balance in

life, and accepting a new sense of identity (Meleis et al., 2000; Meleis & Trangenstein, 1994).

Difference

Difference is a property of change that usually results in seeing oneself as different, seeing others differently, or being perceived as different (Meleis et al., 2000; Meleis & Trangenstein, 1994). A frequent concern of younger adults with ICDs is body image. They are worried about how they look in a bathing suit and if others will perceive them differently because of the upper chest placement of the ICD (Dubin et al., 1996; Bolles-Vitale & Funk, 1995). Perceived differences do not affect all individuals the same nor do they have the same meaning for all individuals, although perceived differences may result in changed behaviors or perceptions (Meleis et al., 2000).

Time Span

Transitions are characterized by time spans, usually beginning with the perception of change, demonstration of change, period of instability, and ending with a period of stability. However, it is impossible to put a time period on transition experiences as individuals will not always follow the same trajectory and they will vary in how they adapt and change (Meleis et al., 2000).

Critical Points and Events

Transitions may be associated with critical points and events such as birth, death, or a change in health status, although not all transitions are associated with a critical point or event. A critical point may be characterized by an awareness of change, becoming more involved in the transition experience, or a period of stabilization after treatment. An example of this would be returning to normal activities after ICD implantation. Occurrence of these critical points can cause uncertainty and anxiety in some patients as

if the transition were recurring, therefore during these critical points it may be helpful to offer additional support (Meleis et al., 2000).

Transition Conditions

Transition experiences are influenced by the perceptions and meanings that individuals attach to health and illness situations. Personal, societal, or environmental conditions can influence outcomes of a transition. In order to facilitate healthy transitions it is necessary to uncover meanings the individual attributes to illness, cultural beliefs, and coping strategies used by the individual. All of these factors can facilitate or inhibit both the process and outcomes of transitions (Meleis et al., 2000).

Patterns of Response

Healthy transitions are evidenced by patterns of response, composed of process and outcome indicators. Process indicators can include the individual becoming involved in the process of change, interacting with others, and developing confidence. Outcome indicators signify completion of healthy transitions, such as mastery of a skill, and adapting to a new sense of self (Meleis et al., 2000).

For example, a younger adult who has redefined his/her life to include an ICD, is able to communicate how their life has changed, is able to make informed decisions about their care, and is displaying evidence of a healthy transition.

Use of the Theory in Research

The transitions framework has been used to study transition in becoming an African American mother (Sawyer, 1999), the menopausal experience (Im & Meleis, 1999), parents of children with chronic illness (Messias, 1995), and family care giving (Schumaker, 1996). Findings from these studies led to the refinement of the framework and development of the middle range theory of transitions (Meleis et al., 2000).

Results of these studies revealed that transitions are multidimensional, complex and unique in nature. Each transition process will vary dependent on facilitators and inhibitors, and often, more than one transition occurs as was the case in these studies (Meleis et al., 2000). For instance, Messias (1995) found in her study of parents of children with CHD, that parents were prepared for the transition into parenthood, but were unprepared for the transition of caring for a child with CHD. Im & Meleis (1999) found that low income Korean women experiencing menopause ignored or neglected the menopausal transition because of other transitions (immigration, new work experiences, and patriarchal cultural heritage) that warranted precedence over menopause.

In a recent study of relatives' experiences of nursing home entry, Davies (2005) reported findings consistent with the domains of the theory of transitions (Meleis et al., 2000), although she presented a limitation to this framework. Interaction between staff and residents was underemphasized and the significance of a reciprocal relationship between nurses and family caregivers in the nursing home setting was not emphasized. This finding provided insight into younger adults experiences of living with an ICD and the importance of recognizing the family caregiver role.

Summary

In summary, we know from the current research that managing life with an ICD provokes feelings of anxiety, depression, (Dunbar et al., 1999; Heller et al., 1998; Sears, & Conti, 2003; Sears, & Conti, 2002; Schuster et al., 1998; Thomas et al., 2001) and fear, (Heller et al.,1998; Dunbar et al.,1999; Thomas et al., 2001; Sears & Conti, 2003) in older adults. Informal support groups and individual counseling have provided some benefit in reducing anxiety and depression in older adults, but more research is needed to

understand developmental changes throughout the lifespan and develop age-specific interventions for younger adults (Urizar et al., 2004; Dougherty et al., 2004).

Today, the journey from adolescence into adulthood is not as well defined as in previous generations. Rites of passage into adulthood such as marriage, having children, and becoming financially independent are often delayed. The average age for a first marriage today is in the 30's as compared to the 20's in previous generations. Because of job insecurity, unemployment, and other social factors, more than 60% of adult children plan to live at home for extended periods of time between jobs or after college, unable to negotiate the hurdle of self responsibility (Gordon, 2005).

Adding to these already stressful demands of younger adulthood, trying to manage life with an ICD may be an overwhelming transition for some younger adults. As healthcare professionals, it is important to understand the process of transition as well as the facilitators and inhibitors associated with transition. These findings may provide some insight into understanding the experiences of living with an ICD so that interventions can be developed to promote a healthy transition into managing life with an ICD. Therefore the following research aims were addressed:

1. Describe the day to day experience of younger adults (18-40 years) living with an ICD.

2. Describe the physiological (physical function, pain, itching) and psychosocial (anxiety, depression, fear, body image, sexual concerns) transitional issues related to ICD management in younger adults.

3. Identify strategies used by younger adults to manage life with an ICD.

Chapter III

Methods

Introduction

This chapter will describe the qualitative study design, organizing framework, and epistemological and ontological underpinnings of the research. Procedures for data collection, management, and analysis will be explained, as well as consideration of human subjects, trustworthiness, and study limitations.

Epistemological/Ontological Underpinnings

Epistemologically, the postpositivist naturalistic paradigm underpinning qualitative description fits well when exploring various developmental issues related to younger adults with ICDs. Using the naturalistic paradigm, there is no a priori commitment to any one theoretical view and the researcher can study the phenomenon in its natural state (Sandelowksi, 2000). The paradigm recognizes the variation of what is "real" in shared experiences; it espouses the relationship between the knower and the known to be interactive and inseparable (Lincoln & Guba, 1985). The postpositivist-naturalistic paradigm encourages pursuance of in-depth, detailed, subjective data, acknowledging that information gained may not be the whole story (Guba, 1990).

Ontologically, the knowledge gained from the various ICD recipients, ranging in age from 18 to 40 years, revealed multiple realities constructed by the individuals. It is anticipated that using a holistic approach to explore the variations of realities among ICD recipients will provide healthcare professionals with insights on how to design interventions specific to this population (Guba, 1990). The qualitative descriptive approach helped to achieve this goal. The data will add to the body of knowledge

regarding responses to ICD implantation among younger adults and provide the basis for interventions that improve adjustment to life with an ICD.

<div align="center">Qualitative Descriptive Methodology</div>

A qualitative design was determined to be the most appropriate method to answer the research questions, although there are several qualitative approaches to choose from. A qualitative design was especially suitable in this particular research instance as the participants are considered to be a vulnerable population.

Qualitative description is a methodological type of naturalistic inquiry that utilizes a pragmatic approach to present an accurate account of an experience, event, or process in easily understood terms (Sullivan-Bolyai, Bova, & Harper, 2005). It has been found to be useful in conducting needs assessments, mixed methods studies with vulnerable populations, concept clarification in scale development, and intervention development or refinement. Qualitative description was chosen as the method of inquiry for the proposed study as little is known about younger adults with ICDs; the information gleaned from this study can be translated into interventions specific to this population (Sullivan-Bolyai et al., 2005). Qualitative descriptive methodology is useful when seeking minimally theorized, straightforward answers to a specific question, such as the research questions posed in this study (Sandelowski, 2000).

<div align="center">Organizing Framework</div>

Organizing ideas and key concepts can be used to construct the organizing framework that will provide clarity and focus when performing qualitative research (Miles & Huberman, 1994; Sandelowski, 1995a; Thorne, Kirkham, & MacDonald-Emes, 1997).The framework guided the proposed study, but changed as data were analyzed and new themes emerged based on the responses to the interview guide (Sandelowski,

1995a). Figure 2 represents the organizing framework used in this study. The subjective experiences of younger adults living with an ICD were examined. The framework outlines the interview process while incorporating Meleis' transitions theory. Moreover, the developmental transition of entering the stages of adulthood (young and middle adult) and the health/illness transition of managing life with an ICD were explored as well as transition patterns, processes, and conditions.

For the purpose of this study, the population of interest was younger adults (18-40 years) who were living with an ICD. Because little qualitative data exist for this age group, the study explored physiological and psychosocial concerns, as well as transitional issues related to living with an ICD. Additionally, participants were asked to identify strategies used to manage life with an ICD in order to link experiences with strategies and facilitate development of age-specific interventions.

Figure 2. Framework for Studying Younger Adults Experiences of Living With

ICDs
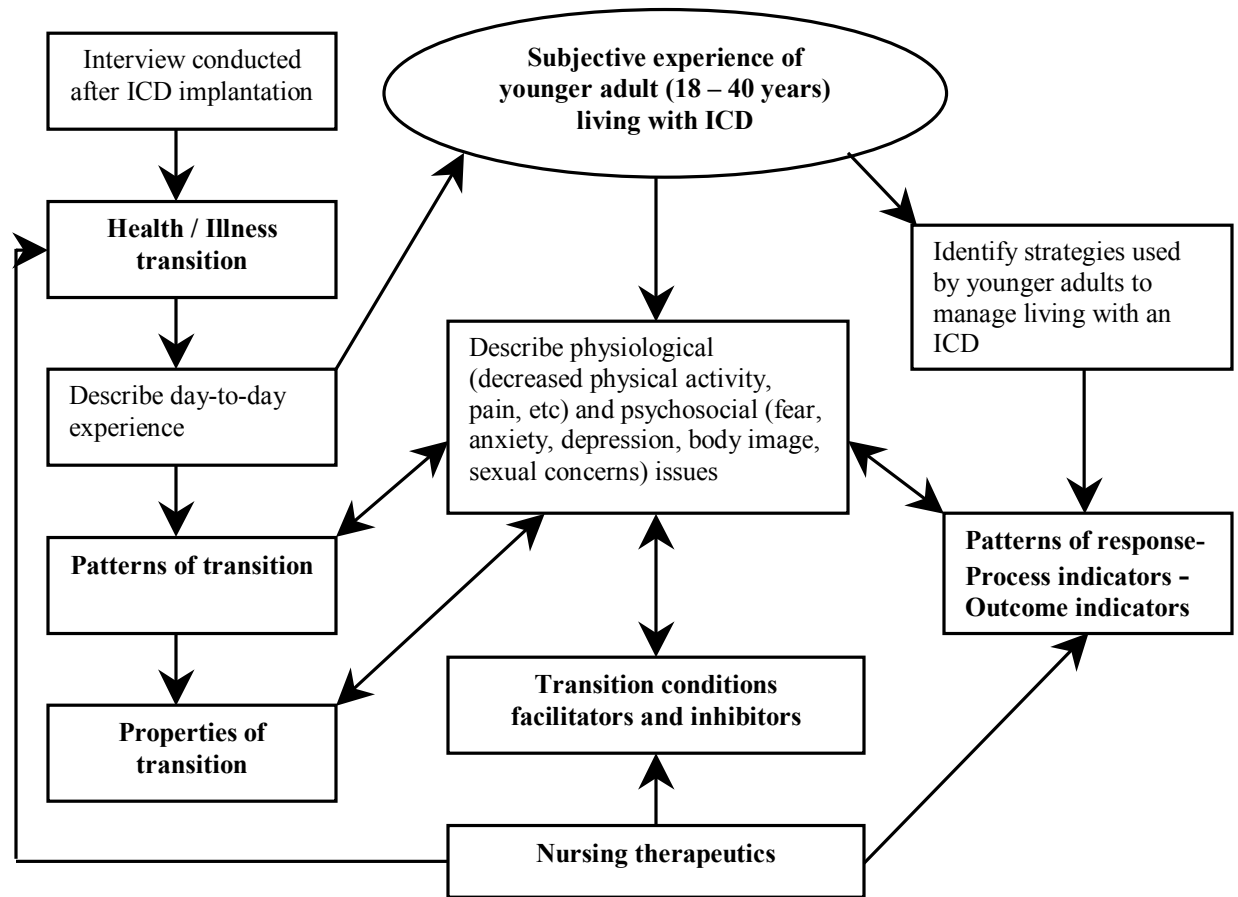
Note: areas in italics are from transitions theory (Meleis et al., 2000).

Operational Definitions

Day-to-Day Experiences: Day-to-day experiences are defined as the individual's routine tasks such as dressing (deciding which items of clothing to wear based on site placement of ICD), attending work or school, performing activities (exercising, running, swimming, hiking, dancing, etc), sexual encounters, breastfeeding, caring for family members, and any other task performed on a daily basis.

Physiological Issues: Physiological issues are defined as changes in physical functioning, pain, dizziness, nausea, vomiting, and itching at insertion site.

Psychosocial Issues: Psychosocial issues are defined as anxiety, depression, fear, anger, loss of control, social withdrawal, sexual concerns, breastfeeding, pregnancy, genetic concerns, financial and career concerns, and body image concerns.

Day-to-Day Management Strategies: Day-to-day management strategies are defined as any technique (meditation, relaxation exercises, individual counseling, support groups, medication) used to manage life with an ICD.

Sample

Purposive sampling was used to recruit subjects for this study. The sample of younger adults aged 18 to 40 years were recruited using maximum variation sampling which allowed the researcher to recruit participants from a wide range of phenomenally and demographically varied cases (Sandelowski, 1995a). Morse (1994) recommends that to elicit the essence of experiences, at least six participants should be included. An adequately sized sample is a matter of judgment and should produce a rich understanding of the experience under study. For this investigation, the researcher began with 15 participants (Sandelowksi, 1995).

Data saturation occurs when themes are well established and no new information is obtained from participants (Lincoln & Guba, 1985). Sample size was determined by the number of participants needed to achieve data saturation and until informational redundancy was achieved (Morse, 1994). To start, six younger adults were identified and agreed to participate via phone interviews; an additional 14 younger adults agreed to participate via ZapLife.org. In addition, three of the participants recruited through Massachusetts General Hospital (MGH) were contacted a second time via telephone to

clarify and probe their responses. Participants recruited through ZapLife.org were also re-contacted via email two to three times to probe and clarify survey responses.

The 18 to 40 year age range was chosen because of the increase in SCD in this age group. Young and middle adulthood is also classified by Erikson as ages 18 to 40 years (Erikson, 1968). There is a need to advance the body of knowledge specific to this age group for nurses who will care for these younger ICD recipients.

Both males and females were recruited and attempts were made to enroll a group of participants that represent the racial and ethnic population of ICD recipients. In 2005, MGH implanted a total of 262 ICDs (Male = 209; Female = 53). Of these patients, 235 were White, 9 were African American, 7 were Asian, and 11 were of Hispanic origin. Between 2002 and 2005, 40 individuals between the ages of 18 to 40 years underwent ICD implantation (D. Carroll, personal communication, January 23, 2006). At this time the number of non-English speaking ICD recipients is unknown, but given the demographic data of ICD implants for 2005, it would be difficult to accurately describe this population. Therefore, participants who communicated only in English were recruited.

Currently, no information exists on the racial and ethnic makeup of ICD recipients who visit ZapLife.org, although all members are able to understand and communicate in English. Members of ZapLife.org provide a profile of themselves which includes where they are from, the type of ICD they have, their occupation, and personal interests. ZapLife.org maintains an accurate number of members, but does not collect information on the racial/ethnic makeup of the site members.

Participants were recruited from varied backgrounds and geographic areas based on initial emailed responses to the Internet posting. Recruitment of a representative ICD

population from MGH was accomplished through the use of brochures posted in the ICD clinic, letters from the patient's electrophysiologist, and with the help of staff in the ICD clinic. Using both methods of recruitment yielded a demographically varied sample.

Inclusion Criteria

Patients were eligible for this study if they met the following inclusion criteria:

1. Between the ages of 18 to 40 years

2. Post ICD implantation

3. Able to understand English

4. Able to respond meaningfully to a 30 to 45 minute telephone or written interview

5. Have access to either a telephone or computer

Setting

Recruitment of participants was accomplished in two ways: via the Internet news group, ZapLife.org, and via the Electrophysiology Service and the ICD Clinic at MGH, Boston, MA. Participants recruited via the Internet newsgroup, ZapLife.org., which was originally launched in 1994 by its creator Jon Duffey, were first made aware of the study by a posting to the newsgroup (http://zaplife.org) after approval by the newsgroup moderator (approval confirmed November 30, 2004) [see posting Appendix A]. All Zaplife.org materials were IRB approved.

Newsgroup moderator and creator, Jon Duffey, suffered a major heart attack with electrical system damage resulting in implantation of an ICD in 1994. During his recovery he was asked to attend a cardiac rehabilitation program and support group for individuals with pacemakers and ICDs. Shortly after this, he was elected president of the support group and began publishing the monthly newsletter, The Zapper (available at ZapLife.org). The newsletters became so popular; it was published online via the

Internet. Since then, approximately 500 ICD recipients visit ZapLife.org on a regular basis from all over the world.

Participants recruited from MGH were identified from the Electrophysiology Service (EP) and ICD Clinic. MGH implants an average of 250 ICDs per year with approximately 10 potential participants in the 18 to 40 year age range. A recruitment brochure [IRB approved] (see Appendix B) was posted in the ICD clinic and potential participants were approached by ICD staff or they were sent a letter [IRB approved] (see Appendix C) signed by the investigator and the participant's electrophysiologist at MGH.

<div align="center">Recruitment of Study Participants</div>

Traditional Recruitment

Participants were recruited by two avenues. First participants who met the inclusion criteria from MGH and expressed interest in taking part in the study were provided a fact sheet by Dr. Diane Carroll, clinical nurse specialist, (see Appendix D) and asked to contact the investigator. If they were interested in taking part in the study, verbal consent was obtained by the researcher to interview and audiotape them via telephone. Their rights as a study participant (participation is voluntary, they may refuse to answer any of the questions, they may withdraw from the study at any time without changes in their healthcare, they will be informed of any changes that may affect participation in the study) were explained to them as well as risks and benefits and privacy and confidentiality of their information (see Appendix E). The study was explained to them and any questions they had were answered. An appointment to contact them by telephone was made for the interview and they were asked if they could be contacted again by the researcher via telephone to clarify responses.

Recruitment via ZapLife.org

Second, participants who met the inclusion criteria and expressed interest in taking part in the study from the ZapLife.org website contacted the researcher by email of their interest after viewing the posting on ZapLife.org. They were then mailed two consent forms (one for their records and one to be returned), a fact sheet (see Appendix F), and a self-addressed envelope and asked to return one signed consent to the investigator. The participant was asked to check a yes/no box on the consent to indicate their agreement to be contacted by the researcher via email if needed to clarify responses after the survey tool had been completed. If the consent form was not returned within seven days, they were contacted via email to see if they were still interested in taking part in the study. If they were, they were asked again to sign and return the consent form in the self-addressed envelope.

Upon receipt of the signed consent form, participants were contacted by email and given a user name and password to complete the interview guide/survey tool (see Appendix H) which took about 30 to 45 minutes to complete. They were then directed to respond to the interview guide/survey tool at:

http://inside.umassmed.edu/SurveyTool/surveys/all/718/index.cfm (user name-ICDSURVEY01; password-Spring) the University of Massachusetts Medical School (UMMS) Graduate School of Nursing universal resource location (URL), commonly known as a website.

Recruitment via an Internet Newsgroup

The number of individuals using the Internet each day is increasing rapidly, with 67% of adult Americans (68% men; 66% women) using the Internet on a regular basis (Fallows, 2005). Within the past few years the Internet has become a new environment

for conducting various types of research because of the vast numbers of individuals online. The majority of Internet-based research studies are quantitative and utilize survey methodology that can be completed via an e-mail or through the use of a newsgroup. However, the use of qualitative and experimental research methodology is increasing (Duffy, 2002; Eysenbach & Wyatt, 2002). In this study, a qualitative descriptive approach was employed using an interview guide/survey tool that allowed participants to provide in-depth descriptions to the questions. The interview guide/survey tool was completed at their convenience and anonymity was maintained.

According to the Pew Internet and American Life Project (2005), home Internet access is highest in the 18 to 29 year old age group and lowest in the 65 year and older age group. The report also confirms that 70% of Internet users are White, 67% are Hispanic, 50% are Black, and 72% are of other origin (Fallows, 2005). Until recently, males were using the Internet more frequently than women, but the recent demographic profiles on Internet use reveal women and men access the Internet almost equally. Racial and ethnic disparities that were present in Internet use in the past have since changed, although people in lower socioeconomic groups may not be represented due to the lack of access to a computer (Fallows, 2005).

There are different strategies that may be used when recruiting participants via the Internet (email lists, search engines, or newsgroups), but for this study a posting (see Appendix A) to the to the Internet newsgroup, ZapLife.org. The posting described the study. Newsgroups are forums for individuals with particular interests. Individuals are able to post messages similar a bulletin board; others can respond by posting additional messages to the same thread. The result is a continuous string of messages in

chronological order that allows the individual the opportunity to view the whole conversation (Birnbaum, 2004).

The ZapLife.org newsgroup was specifically created for ICD recipients and had a large number of members to recruit to potential participants from for this study. In order to become a member of the ZapLife.org newsgroup, individuals must be screened by the newsgroup moderator. The screening involves asking ICD related information such as the reason for the ICD placement, type of ICD and when it was placed, and medications the potential member is presently taking. Individuals interested in using this group for research recruitment must inform the moderator of the study and await approval. All members must adhere to the rules and regulations of the newsgroup such as, dispensing medical information without a license, personal attacks on other members, and the use of profane, obscene, or sexually oriented language. A complete set of rules and regulations can be found at www.zaplife.org/zap9.htm.

There are many advantages to using an Internet newsgroup for recruitment. First, ZapLife.org is open only to individuals with an ICD, or nurses and physicians working with the population. Second, the newsgroup will not tolerate any individual who does not follow the rules and regulations. The newsgroup conversations are continuously monitored for individuals dispensing medical information without a license, negative criticisms or threats, and vulgar language. Most importantly, ZapLife.org screens individuals for spoofing and will prosecute individuals accordingly. Spoofing is the act of adopting another individual's identity for the purpose of confusing and/or committing fraud.

The widespread use of the Internet has provided researchers with an excellent setting for participant recruitment as compared to traditional strategies such as radio and

television advertisements, recruitment posters, and newspaper advertisements (Butterfield, Yates, Rogers & Healow 2003; Im & Chee, 2004). Recruitment via an Internet newsgroup can provide the researcher with large, heterogeneous samples, quick access to specialized populations, and reduced costs for data collection and entry (Birnbaum, 2004; Cotton, 2003; Duffy, 2002; Im & Chee, 2004). Because of the minimal number of ICD recipients between the ages of 18 to 40 years at MGH, Internet recruitment via the ZapLife.org newsgroup offered the availability of accessing ICD recipients from all over the world, from varying experiences and perspectives, and from various points in time after ICD implantation.

<div align="center">Data Collection Procedures</div>

Triangulation of Data Collection Methods

Triangulation involves the combination of two or more theories, data sources, methods, or investigators to describe a single concept (Sandelowski, 1995b; Thurmond, 2001). It offers confirmation of data, enhancement of validity, and an in-depth understanding of the phenomenon while providing various dimensions of the phenomenon through the use of multiple methods or data sources (Boyd, 1993; Thurmond, 2001).

There are several types of triangulation, but the most commonly used is 'methods triangulation' (Boyd, 1993; Shih, 1998, Thurmond, 2001). Methods triangulation incorporates the use of more than one method of data collection within the same study (Shih, 1998). There are also two sub-types of methods triangulation. For this study, within-methods triangulation, a combination of two data collection approaches, in this case telephone interviews, Internet interviews, were used to explore the research questions posed in this study (Boyd, 1993; Thurmond, 2001).

The advantage of within-methods triangulation is that the weaknesses of one method can be compensated for by use of the other method, thereby providing richness of detail and a more complete understanding of the phenomenon (Sandelowski, 1995b; Shih, 1998). In this study, it provided a strategy for recognition of multiple realities and a representation of varied perceptions of the experiences of younger adults living with an ICD. It also provided access to a much larger sample of younger adults with ICDs. This access allowed the investigator to reach informational redundancy.

Data Collection

The semi-structured qualitative interviews were conducted using an interview guide (see Appendix G) to elicit the subjective experience of living with an ICD, physical and psychosocial issues related to the ICD, and strategies used to manage life with an ICD. The interview questions addressed the following aims:

1. Describe the day-to-day experience of younger adults (18-40 years) living with an ICD. Questions in the interview addressed daily life with an ICD and how the ICD has affected or changed the participant's life.

2. Describe the physiological (physical function, pain, itching) and psychosocial (anxiety, depression, fear, body image, sexual concerns) transitional issues related to ICD management in younger adults. Questions elicited specific physical and psychosocial concerns as well as transitional issues related to the ICD.

3. Identify interventions used by younger adults to manage life with an ICD. Questions addressed specific strategies that the participant has used to facilitate management of living with an ICD. Questions within the interview guide were revised to separate each psychosocial issue allowing for more in-depth responses.

Interviews

The telephone interviews were conducted first to further inform how well the interview guide/survey tool (see Appendix G) and interview process worked from both a pragmatic and conceptual perspective as well as to inform the Internet interviews. These interviews helped to refine the data collection process and interview guide and allowed the researcher to become familiar with the data collection tool, participants, and processes (Burns & Grove, 2004). One ICD recipient at MGH was interviewed first after obtaining verbal consent (see Appendix E). The participant was interviewed via the telephone and the interview was audiotaped. The audiotapes and interview forms were labeled with a code and locked in the investigator's office. The participant's feedback provided information that improved the study procedures and informed written interviews with respect to the focus of the questions.

The interview guide/survey tool was administered to a participant (first respondent) recruited through ZapLife.org. after completion of the telephone interviews (see Appendix H). A signed consent form was obtained via postal mail prior to sending the participant the password and identifier needed to access the interview guide/survey tool. This allowed the investigator to assess the process and procedures with the Internet population and make any necessary changes to the interview guide/survey tool. Questions with multiple parts were reworded into separate questions to ensure completeness of responses.

Telephone Interviews

Verbal informed consent was obtained prior to beginning the interviews and participants were asked if they could be re-contacted via telephone to clarify responses (see Appendix E). Six participants from MGH were interviewed over the telephone using

an interview guide and all agreed to be re-contacted (see Appendix G for interview guide). Demographic information was collected during the telephone interview as well (see Appendix I). Each telephone interview took approximately 30 to 45 minutes to complete. The telephone interviews were audiotaped by the investigator and identified with a research number to maintain participant confidentiality. The participants' names were not used during the taping of the interview. All audiotapes were kept in a locked file cabinet in the investigator's office and destroyed after completion of the study. The audiotapes were transcribed verbatim by a professional transcriptionist.

The original data forms were kept in a locked file in the investigator's office. Each form was labeled with a research number that corresponded with the number on the participant's audiotape, informed consent, and all other research documents. A list of research numbers and identifiers were kept in a locked file in the investigator's locked office. Entered data were checked against the original data documents. In addition, backup files of all entered data were created on a regular basis. Only the investigator had access to the computer containing the research files

After reviewing the transcribed data, two of the participants were re-contacted via telephone for clarification of responses. One participant was re-contacted to gain a better understanding of how the ICD shocks affected her daily life. The other participant was re-contacted to clarify what changes if any, she made to her daily life to care for her family. Each participant was mailed a $25.00 stipend upon completion of the interview for their time.

Internet Interviews

Prior to initiation of the interview guide/survey tool with Internet participants, written consent was obtained and the participant was asked if he/she could be re-

contacted to clarify responses (participants checked a yes/no box on the consent form to be re-contacted). They were sent two consents, one for their record and one that was kept in a locked file in the investigator's office. Other information collected via the interview guide/survey tool included the type of ICD, reason for implantation, time since implantation, number of battery changes, if any, and number of ICD changes, if any (see Appendix H).

Participants recruited through ZapLife.org were directed to the UMMS survey website to complete their interview (http://inside.umassmed.edu/SurveyTool/surveys/all/718/index.cfm). Once participants accessed the website they selected the "ICD survey" from the list of active surveys. Then they were directed to enter the user name and password (ICDSURVEY01; Spring) that was emailed to them (each individual was given a different identifier, in order to view which participants had completed the survey). After entering the password, participants were able to complete the questions and submit the interview guide/survey tool. The investigator reviewed responses to the interview guide/survey tool and prepared further probe questions based on the participant's responses. Each participant was re-contacted two to three times via email with further questions to probe and clarify initial responses until a clear understanding of the participant's perspective was obtained.

Analyses of the Internet interview guide/survey tools were ongoing during the recruitment process. Internet recruitment continued until informational redundancy was achieved. During the thirteenth and fourteenth interviews, the investigator noted that no new information or themes were emerging. Therefore, Internet recruitment was completed after 14 participants had responded. Each participant was mailed a $25.00 stipend upon completion of the interview for their time.

Field Notes

During each telephone interview, the investigator used field notes to record notes and reflections (Creswell, 2003). The notes included the date and time of the interview, the participant's tone of voice and reactions to the questions, and length of the interview. The field notes were maintained in a notebook, labeled with an identifying number, and locked in a file drawer in the investigator's office. They were used to provide background and insight during data analysis (Creswell, 2003).

<div align="center">Data Management and Data Analysis</div>

Demographic data (age, gender, marital status, occupation, level of education, reason for ICD, type of ICD, and when it was placed) collected from the sample were analyzed using NVIVO 7.0. The purpose of collecting this data was for descriptive purposes only and was linked to interview data through the NVIVO 7.0 program (Richards, 1999).

According to Knafl and Webster (1988) there is a two-step process involved when doing qualitative analysis such as qualitative description. The first step is data management and the second is data analysis. In this study, the investigator began by having the telephone interview audiotapes transcribed by a professional transcriptionist. The telephone interview transcripts were then checked against the audiotapes for accuracy. They were summarized for tone and context, and then coded; the coding reflected the major elements of the interviews, in order to identify themes that characterized all of the younger adults' experiences (Sandelowksi, 2000).

Across case analysis was performed using the narrative tool, overrreading, described by Poirier and Ayres (1997). Overreading is a strategy to assist the researcher to find implicit meanings within the interview text. The investigator looked for

inconsistencies, repetitions, and omissions within each case. The goal of this strategy was to find commonalities and variations among the experiences of young adults with ICDs in order to develop some generalizations about living with an ICD. From this, significant statements that related to the experience of living with an ICD were identified. These were compared with all other participant transcripts to identify commonalities across participants. The statements were coded into themes and subthemes. At the same time, within case analysis on each theme within each participant's interview was performed to identify commonalities or incongruities. Integration of these analyses techniques led to the development of an overarching theme and five related subthemes.

After completing these processes with the telephone transcripts, the same processes were performed with the Internet interviews. The telephone transcripts and Internet interviews were then compared to assess for similarities and differences between the two methods. The Internet interviews were used as the source data. Both telephone transcripts and Internet interviews were summarized for tone and context by the investigator and compared and contrasted for similarities and differences in thematic content (Sandelowski, 2000).

Confidentiality was maintained with all participant data by utilizing identifying number codes on all audiotapes, interview documents, and transcripts. A list of the codes and corresponding identifiers were kept in a locked file drawer in the investigator's office along with transcripts and interview documents. These were accessible by the investigator only. Demographic data were entered into an NVIVO 7.0 data file and password protected on the investigator's own computer.

NVIVO 7.0 software, a qualitative data management software package, was used for categorization, thematic coding, and for assessment of meanings and relationships

within the text (Richards, 1999). A journal was maintained to record ideas, reflections, and interviewing and coding decisions, in order to develop an audit trail and support trustworthiness (Creswell, 2003).

Codes and categories were checked for accuracy by the researcher and the dissertation chairperson to ensure accuracy and increase validity. Transition related concepts emerged and were isolated from the data and were then categorized. These concepts were modified as insights emerged and were linked back to the transitions framework if appropriate (Sandelowski, 2000). Meanings associated with these categories were summarized and results were reported. The final analysis yielded a descriptive summary of what it is like for younger adults to mange life with an ICD (Sandelowksi, 2000).

Trustworthiness

Lincoln and Guba (1985) purported that trustworthiness in qualitative inquiry is based on four components: transferability, dependability, confirmability, and credibility. Transferability was accomplished by providing thick, rich descriptions of the experiences of younger adults with ICDs within the context of their daily life. Dependability and confirmability involved an auditing of the research process, ensuring that documentation of each step was present (Lincoln & Guba, 1985). The investigator closely consulted with the dissertation advisor throughout the study to ensure the data management and analysis process was fully developed.

A journal was maintained by the investigator to record reflections, field notes, and decisions that were made throughout the study to provide an audit trail. Credibility was established by using member checks, recognizing and documenting personal biases, establishing a trusting and confidential relationship with participants, through the use of

referential adequacy (use of tape recording devices), and with peer debriefing (data coding and interpretation confirmed by colleagues).

Member checks were performed after data analysis to ensure that emerging themes were a true reflection of the participants' experiences of living with an ICD. Two participants (both female, male participants could not be contacted) who were interviewed via telephone were re-contacted via telephone to discuss emerging themes. Both of these participants believed that the themes accurately reflected their experiences of living with an ICD. Three participants (two males; one female) who completed the Internet interview guide/survey tool were re-contacted via email which described the overarching theme and subthemes. They were asked if they agreed or disagreed with the themes that had emerged. All three of the Internet participants responded that they were in complete agreement of the themes that were presented to them.

<div align="center">Protection of Human Subjects</div>

Approval was granted by the Committee for Protection of Human Subjects in Research at UMASS Medical Center, Worcester, MA and Partners Healthcare, Boston, MA. Those participants who were interested in taking part in the proposed study were informed of the purpose and procedures of the study. They were informed of their rights during participation in a research study and made aware that they: could withdraw from the study at any time without jeopardizing their health care, that they could ask questions at any time throughout the study and request a copy of the results, that their information would be kept private and confidential as mandated by HIPAA, and that all documents pertaining to them would be destroyed upon completion of the study. Each Internet participant was asked to sign the IRB approved consent. Verbal consent was obtained from telephone participants as required by MGH/Partners Human Research Committee.

Ethical Considerations

Few standardized guidelines exist for the protection of human subjects when conducting Internet based research (Im & Chee 2002). Informed consent, privacy, and confidentiality are the basic ethical tenets that researchers are required to provide when performing scientific research and this is true for Internet research as well (Eysenbach & Till, 2001). Informed consent involves providing participants with an explanation of the study, ensuring they have an adequate understanding, and that they are competent and able to give their consent voluntarily (Kralik, Warren, Price, Koch, Pignone, 2005).

Obtaining consent via email has been performed, but this method presents a major problem. Consent via email does not provide a hard copy of the written signature and may not be legally binding. Although obtaining consent via postal mail does not guarantee that the signature is that of the participant, there is still a hard copy for documentation purposes (Kralik et al., 2005). For this study, informed consent was obtained through postal mail.

Ensuring the privacy and confidentiality of each participant is the researcher's responsibility and must be addressed within the research protocol (Eysenbach & Till, 2001). Conducting an interview via email is not secure and does not protect the confidentiality of the participant's identity or responses. When receiving email the sender's name is always visible and even if the name is not visible, it may be possible to link by using the domain name (V. Brown, Manager, IRB, UMMS, personal communication, May 26, 2005). Privacy and confidentiality were maintained by using a secure website that participants accessed via a user identification and password to complete the interview guide/survey tool. The website used hypertext mark-up language

(HTML) secured with secure socket layer (SSL) encryption, which prevents intermediate parties from viewing the content of the survey responses (Kralik et al., 2005).

The interview guide/survey tool was a web based survey that offered authenticated access for participants and preserved anonymity of responses (R. Zottola, IT Department, personal communication, June 3, 2005). Although the survey tool did not offer secure transport (responses could be intercepted when the investigator is accessing responses), every attempt was made to keep responses confidential and the participants were made aware of this in the informed consent (D. Drexler, Privacy and Compliance Officer, UMMS, personal communication, June 5, 2005). The researcher successfully completed training with the information technology (IT) department on survey tool preparation via the UMMS secure website in October 2005.

There was minimal risk that participants would experience emotional stress from speaking about their experience of living with an ICD. The researcher is an experienced clinician and if any emotional changes were noted in the participant during the telephone interview, the interview would be stopped. If the participant was too upset and could not continue, the interview would be rescheduled and if necessary the participant would be referred to their primary care physician. Participants were given the opportunity to withdraw from the study if they wished. Although these plans were put in place at the outset of the study, none of the participants experienced any distress from their participation, and no one withdrew from the study.

Summary

The purpose of this qualitative descriptive study was to describe the daily experiences of younger adults living with an ICD, understand the physiological and psychosocial issues related to living with an ICD, and identify strategies used to manage

life with an ICD. Participants between the ages of 18 to 40 years who had undergone ICD implantation were recruited using two different recruitment strategies, via an Internet newsgroup and via an ICD clinic at MGH. These two methods of recruitment yielded a demographically varied sample. Meleis's theory of transitions guided this study. Utilizing an inductive approach, analysis of the data yielded a true description of the experience of living with an ICD and an understanding of the psychosocial and physiological issues related to ICD implantation in younger adults.

Chapter IV

Results

Introduction

Qualitative descriptive methodology was used to describe the experiences of younger adults living with an ICD. The results yielded rich, descriptive summaries of their experiences that included an overarching theme, and six related subthemes. *A cautious transition to a new normal* emerged as the overarching theme with six subthemes: *Initial diagnosis: anxiety and concern*; *Caution, awareness, and security: daily life with an ICD*; *Childbearing: passing my disease to my children; Financial concerns; Physiological and psychosocial issues;* and *Strategies for living with an ICD: be positive and live life to the fullest*. Sample demographics and a detailed description of the overarching theme and subthemes follow, with participant quotes for illustrative purposes. The results are organized by each study aim.

Participants

A total of 20 participants were recruited for telephone ($n = 6$) and Internet ($n = 14$) interviews. If they agreed to participate, a convenient time was arranged for the telephone interview. The telephone interviews lasted 30 to 45 minutes. Individuals responding to the interview via the Internet completed the interview at their convenience within a week after receiving their password and identifier. Data were collected over five months. Twenty-five participants were identified, but only 20 participants returned informed consents and agreed to participate. Of these participants, six participants suffered a SCD episode and awoke with an ICD. Ten individuals had an ongoing cardiac disease, symptoms of cardiac disease, or a significant family history of SCD and learned of their need for an ICD from their physician. Four individuals had sudden cardiac

symptoms or syncopal episodes and learned of their need for an ICD after being treated at an emergency center.

The mean age of the participants was 34 years (range 21-40 years); there were 12 females and eight males. Participants were well educated with a mean of 16 years of education (range 12-24 years). Two-thirds (*n* = 13) of the participants were married and working full-time. The racial breakdown for this sample was predominantly White. This is consistent with the racial breakdown for ICD implants performed at MGH (Alexander, et al, 2002). The mean length of time since implantation was 3.9 years (SD, 3.84 years). Five individuals had their ICD replaced due to an ICD manufacturer recall. Table 1 presents the complete demographic characteristics.

Table 1. Demographics

	Telephone Group	Internet Group	Total Group
Age			
Participants **(N = 20)**	n = 6	n = 14	N = 20
Mean	35.2	32.9 yrs	33.5 yrs
Standard Deviation	7.4 yrs	6.4 yrs	6.7 yrs
Range	21 - 40 yrs	21 - 40 yrs	21 - 40 yrs
Years of Education			
Participants	n = 6	n = 14	N = 20
Mean	17.0 yrs	16.0 yrs	16.3 yrs
Standard Deviation	4.9 yrs	2.0 yrs	3.0 yrs
Range	12 - 24 yrs	12 - 19 yrs	12 - 24 yrs
Gender			
Male	2 (33.33%)	6 (42.86%)	8 (40%)
Female	4 (66.67%)	8 (57.14%)	12 (60%)
Ethnicity			
Asian American	1 (16.67%)		1 (5%)
Caucasian	5 (83.33%)	10 (71.43%)	15 (75%)
Hispanic American		1 (7.14%)	1 (5%)
Native American		1 (7.14%)	1 (5%)
Other		2 (14.29%)	2 (10%)
Marital Status			
Married	3 (50%)	10 (71.43%)	13 (65%)
Single	2 (33.33%)	3 (21.43%)	5 (25%)
Separated	1 (16.67%)	1 (7.14%)	2 (10%)
Working Situation			
Full-time	4 (66.67%)	9 (64.29%)	13 (65%)
Part-time	1 (16.67%)	2 (14.29%)	3 (15%)
Student	1 (16.67%)		1 (5%)
Disabled		2 (14.29%)	2 (10%)
Stay at home mom		1 (7.14%)	1 (5%)
Years with ICD			
Participants	n = 6	n = 14	N = 20
Mean	3.4 yrs	4.1 yrs	3.9 yrs
Standard Deviation	2.0 yrs	4.4 yrs	3.8 yrs
Range	1 - 6 yrs	3 mos - 17 yrs	3 mos - 17 yrs

Table 1. Demographics (continued)

	Telephone Group	Internet Group	Total Group
Etiology of Disease			
HCM	4 (66.67%)	7 (50%)	11 (55%)
DCM		2 (14.29%)	2 (10%)
LQTS	1 (16.67%)	1 (7.14%)	2 (10%)
Idiopathic VT/VF	1 (16.67%)	4 (28.57%)	5 (25%)
ICD Type			
Medtronic	2 (33.33%)	8 (57.14%)	10 (50%)
Guidant	3 (50%)	4 (28.57%)	7 (35%)
St. Jude's	1 (16.67%)	2 (14.29%)	3 (15%)
ICD Replacement			
None	5 (83.33%)	7 (50%)	12 (60%)
Once	1 (16.67%)	5 (35.71%)	6 (30%)
Three or more times		2 (14.29%)	2 (10%)
*(5 ICDs were recalled)			
Battery Replacement			
None	3 (50%)	11 (78.57%)	14 (70%)
Once	3 (50%)	1 (7.14%)	4 (20%)
Three or more times		2 (14.29%)	2 (10%)
*(1 battery was recalled)			
Experienced Shock			
Shocked	3 (50%)	6 (42.86%)	9 (45%)
Never been shocked	3 (50%)	8 (57.14%)	11 (55%)

Telephone versus Internet Interviewing

When interviewing participants via the telephone as compared to the Internet, the only differences noted by the investigator was that additional questions could be asked during the telephone interview, whereas with the Internet interviews, questions to participants had to be re-emailed. When participants were asked about issues concerning sexual activity, only two participants (one Internet; one telephone) elaborated. One of six

telephone participants revealed issues with sexual activity and one out of 14 Internet participants revealed similar issues.

Overarching Theme and Categories

The overarching theme and six subthemes reflect topics the younger adults discussed in describing their experiences, including transitions. The overarching theme, a cautious transition to a new normal, was threaded throughout all interviews. Participants described the experience of transitioning to daily life after ICD placement as not that different as before the ICD, *but with a few more details* and an underlying *caution or awareness* of life situations. The majority of participants were able to accept this *new normal* and live their life with an ICD without much difficulty. They described using caution when performing certain activities and being aware of their physical limits. For example, "I think more about my activities and make sure people are around me." Another participant stated, "Strictly speaking about my ICD and not my disease, everyday life is not so different." "There are small things to consider that you need to keep in mind, such as not walking through metal detectors and not using gas powered tools (i.e. chainsaw)."

Six related subthemes were linked to the overarching theme (see Figure 3). Participants described *anxiety and concern* after their initial diagnosis and learning they needed an ICD. They described using *caution* when performing activities, a new *awareness* of bodily cues, and an added sense of *security* knowing the ICD was there to save their life. *Childbearing: passing my disease to my children* was a concern for all participants as they described the possibility of passing their disease onto their children. Many described *financial concerns* related to ICD replacement and maintenance and

physiological and *psychosocial issues* were also a concern for participants. Finally they described *strategies for living with an ICD: be positive and live life to the fullest.*

These subthemes will be presented framed by the specific aims of the study and linked to the theoretical framework, transitions theory, used in this study.

Figure 3. A Cautious Transition to a New Normal
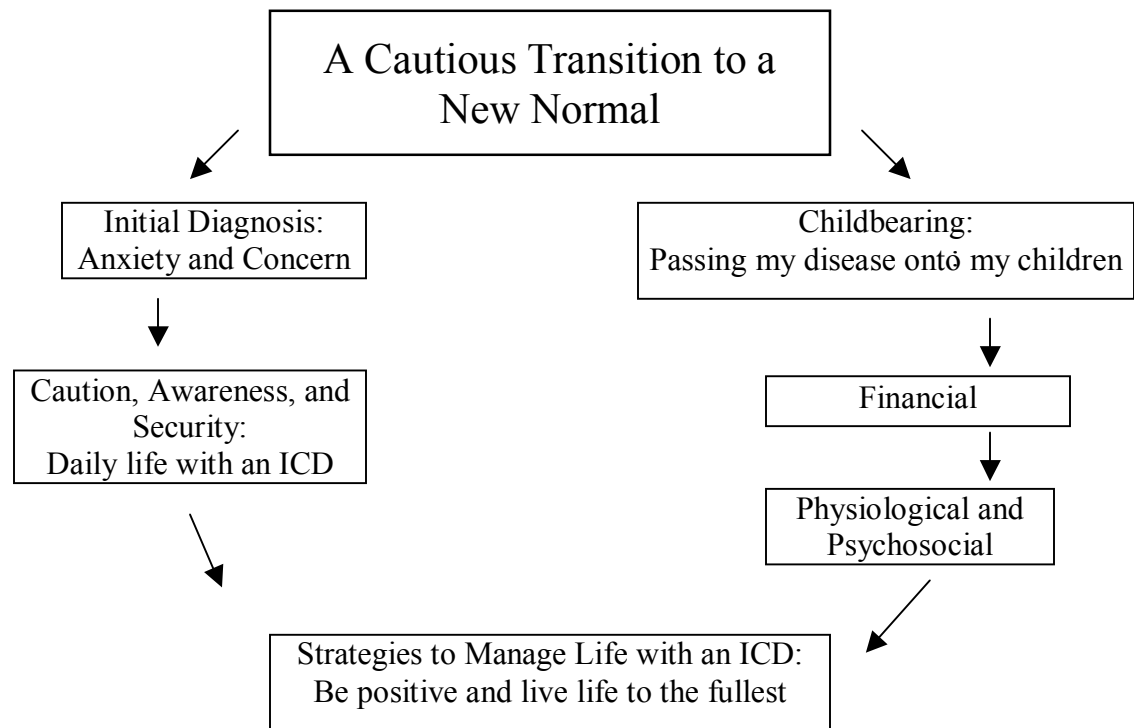
Aim 1

Describe the day to day experience of younger adults (18 to 40 years) living with an ICD.

Initial Diagnosis: Anxiety and Concern

All of the younger adults were able to describe in detail how they learned they would need an ICD and their initial feelings of anxiety and concern. Some used descriptors such as "living with anxiety and fear for the first few months," and "at first I was a basket case, I worried a lot." However, the majority of participants were able to

move past these feelings of anxiety and concern. Many described a period of a few weeks to a couple of months of "getting used to it [the ICD]." They described "easing back into their daily life" and resuming prior activities. Most of the participants returned to work, resumed driving, and returned to playing sports. One participant described her thoughts after implantation:

> At first I would start to do something and I found myself second guessing myself a lot like was it okay to go back to playing hockey and softball and those types of things. I wouldn't say I was depressed, but concerned.

For some of the participants with health-related jobs, it was especially difficult to hear they needed an ICD, describing their reaction as "stunned," "feeling too young to need an ICD," and "having to face mortality." Five of the 20 participants worked either directly or indirectly in the healthcare field (one physician, two nurses, a microbiologist, and a dental hygienist). These individuals had more difficulty adjusting to their new diagnosis because they were experiencing a role reversal: instead of being the caregiver they were now the patient. However, this experience moved one of the nurses to use his illness as an opportunity to help others as he reported,

> The ICD has linked me with a wonderful volunteer opportunity as a camp counselor at Camp Odayin in Minnesota which is a residential summer camp for children with heart disease. This has been an awesome experience and I will return for a fifth year this summer. I have been a counselor at this camp since its inception. It is awesome to be a role model for these children and be with them and allow them to just be normal kids for a week. I am able to network with others with heart disease and others who have ICDs and learn coping skills that I can also use.

Six of the participants sustained SCD episodes and did not learn about their condition or their ICD until after placement had occurred. Many of these individuals described "feeling lucky to be alive" or feeling as though they "participated in a miracle that day." Two of these participants experienced a SCD episode in front of their children. They described this as the most troubling aspect of the whole ordeal.

The majority of participants reported being able to accept the ICD and continue with their daily lives: "I feel very lucky that the ICD has not interfered in my life at all. I am able to workout, play softball, and live life like I did before." Another participant reported: "I haven't given up anything, really. I went back to doing the things I enjoyed before."

After implantation some of the participants expressed feelings of anger ($n = 3$), resentment ($n = 3$), depression ($n = 13$), fear ($n = 13$), and body image concerns ($n = 14$). For instance, when participants were asked how they managed daily life with an ICD, some reported feelings of anger and resentment right after implantation: "I was very afraid, not so much of the machine; I kind of resented the machine. I resented it being there and resented needing it." Another participant reported, "I don't get angry just yet because it hasn't gone off yet, but I do get very angry about the fact that I need one and when it eventually goes off it's going to hurt." However, most of the participants accepted the ICD and transitioned into daily life using caution and awareness. One participant eloquently articulated his transition:

> I think I did better than I thought. In the beginning there are a lot of questions, how am I going to look? I was mad at my body; you think your body has failed you. I'm 39 years old and have a bad heart. I think that would be the same with

any disease, you get mad at your body. Then you come to terms with it and decide how this is going to go for me.

The passage of time after implantation helped many to feel more comfortable living with their ICD. Several participants recalled getting back to their "normal routine" within a few months after ICD implantation. The majority of participants reported that it did get easier to manage life with an ICD as time passed. Most of them described "worrying less" and "becoming more accustomed to the ICD as each day passed." Only one female participant who has had an ICD for three years is still struggling with feelings of anger, as she reported at the end of the interview: "I'm angry, I'm pissed, but on the other hand I had a cousin pass away, it could've been me."

Caution, Awareness, and Security: Daily life with an ICD

More than two-thirds (*n* = 14) of the participants described using caution or awareness when engaging in certain activities: "My activity has decreased because I am being cautious, so it won't go off [the ICD]." When describing the effect of the ICD on daily life, participants consistently brought up caution and awareness. In every aspect of their life they described approaching the task with caution or being aware of their health, surroundings, or activities. Using caution and awareness became part of daily life for participants living with an ICD. Some participants discussed being more aware of their own health or being concerned about performing certain activities immediately after their ICD implant. They described easing their way back into daily life and most resumed activities prior to ICD implantation within a few months. Many of the participants continued with their lives and no longer thought about the device: "For the most part I can ignore its existence," and "It took me a couple of weeks to get used to the fact that there was a new metal box in my shoulder, but after that, I forgot about it."

Almost all ($n = 18$) of the participants expressed feeling an added sense of security after ICD implantation. Many were confident that their device was there to keep them from dying and they described feelings of trust in their device and a sense of comfort knowing the ICD was there for them: "My device has saved me four times in 6 years and just knowing that I am still around is great." Others described worrying less, and being able to sleep better at night knowing they would awaken in the morning: "It's like a whole other level of security for me. In a lot of ways it's helped me sleep easier…"

Childbearing: Passing my Disease to my Children

The majority of the participants ($n = 17$) were very concerned with the possibility of passing their condition on to their children. Fifteen of the participants had a hereditary cardiac illness, the other five had idiopathic ventricular fibrillation which occurred in the absence of cardiac disease and therefore it could not be genetically linked. Two women who already had children had decided with their spouse not to have more because of the risk of passing their condition to their offspring. The other male participant stated he did not want to have children. Both men ($n = 7$) and women ($n = 10$) reacted similarly when discussing the risk of passing their condition to their offspring. They all stated that they would rather their child not have their cardiac disease, although both male and female participants felt that if they did, they at least had the option of having an ICD. All of the participants were very proactive and were having their children tested for cardiac illness. One male participant expressed his concerns about his child potentially needing an ICD, "I would hate for my daughter to have my disease and have to get an ICD, but I would hate much worse her dying."

Two of the female participants had a child who either had an ICD or would eventually need one. One participant had a 10 year old daughter with an ICD. She had

three other family members that required ICD implantation (father, sister, and niece) and lost one family member to SCD. When she was asked about how she felt when her ten year old daughter needed an ICD, she said, "We are all in this together." She knew her daughter would eventually need an ICD and prepared her by educating her and exposing her to others who had an ICD. She also felt very appreciative for the option to have an ICD because the family member she lost did not. The other participant had a 19 year old daughter who would eventually need an ICD. She too described feeling grateful that her daughter had the option to have an ICD. She spoke about providing her daughter with information about her condition, the procedure, and the ICD. Both of these women were very positive and felt their children could lead active, fulfilling lives with an ICD.

Other women ($n = 3$) with children were told by their physician that they should not become pregnant again because of the seriousness of their cardiac condition and the associated risk of death during delivery. Participants who did not have children yet, were either involved in genetic testing or were scheduled to discuss it with their physicians. One woman was distraught by this news and did not like being told that her choice to have more children was taken away from her:

> They pretty much told me don't even go there, and I'm lucky to have a girl and boy, but to be told don't go there makes me want to have another one. I wasn't done having children, but this kind of made me done.

Financial Concerns

When participants were asked if they had financial concerns, many (6 men 3 women) described concerns related to out-of-pocket expenses for reading and re-programming of the ICD, rising insurance premiums, the cost of ICD and battery replacement, and not being able to provide for children financially:

Our medical expenses are very large, and insurance only covers a portion. I will

not be able to work when I have my upcoming surgery and recuperation, and we

have a small child who is in school, needs additional caretakers, etc.

Another participant described his frustration with the costs of reading and reprogramming

the device (ICD) that he is responsible for under his insurance plan. He explained that

besides paying for these costly ICD readings, he must pay a 20% out-of-pocket fee that

he is responsible for each year. These fees are a significant source of stress for him as

they continue to rise.

Others articulated their fears of job stability. Both men and women spoke about

their concerns of losing their job if their health declined. One male participant described

being fearful of his ICD firing and his physician finding out because he knew in some

states they can revoke your license for a period of six months after your ICD has fired.

He was in a sales position and drove for a living; therefore if he lost his license he would

probably lose his job. Another participant described her feelings about her worsening

cardiac condition. Her condition had been managed by medication for many years and

suddenly she was undergoing ICD placement. As a critical care nurse and single mother

of three, she described suddenly facing mortality and the uncertainty of whether she

would be able to continue to work and help her children financially as they grow up, "I

no longer know if I will have a future of stability or if I can help my kids financially as

they grow up because I don't know how my health will hold up."

Other financial concerns presented by participants were inability to purchase life

insurance because of a preexisting condition and remaining in a low paying job because

of the need for medical insurance:

Of course, I need medical insurance so I need to stick with my job that doesn't

pay enough money for me to move out on my own. We just switched medical

insurance carriers which have DOUBLED the amount taken out of every

paycheck but it's something that I need to deal with. I refuse to go without

insurance.

No research currently exists on patient related costs to implantation of an ICD.

Research has been focused on ICD cost effectiveness in patients with differing degrees of

cardiac illness. Implantation of an ICD may cost between $18,000 and $35,000 per

patient (Hlatky & Mark, 2007). The impact of the cost of an ICD has primarily affected

Medicare as the majority of ICD recipients are over age 65. Policy makers are grappling

with the dissemination of effective new therapies and containing the growth of costs

affecting the health care budget (Hlatky & Mark, 2007). Research into patient related

costs after ICD implantation is needed. Healthcare providers need to inform ICD

recipients of potential ICD related costs that they may incur as well as to consult with

their insurance carriers regarding their coverage. Planning for battery changes and device

replacement may also lessen monetary ramifications.

<div align="center">Aim 2</div>

Describe the physiological (physical restrictions, pain, itching) and psychosocial (anxiety,

depression, fear, body image, sexual concerns) transitional issues related to ICD

management in younger adults.

Physiological Issues

Physical Restrictions

Fifty percent ($n = 10$) of the participants described having to accept restrictions in

order to live with their ICD which included reducing their activity levels or avoiding

<div align="center">70</div>

certain activities. Six (two males and four females) of these participants had activity restrictions imposed by their physician, while four (two males and two females) chose to decrease their activity because of fear of device firing or other bodily cues such as shortness of breath, heart racing, or dizziness. They attributed these symptoms to potential worsening of their cardiac disease. One participant described how she had to slow herself down and relax when she felt out of breath or her heart racing because she still suffered from "the anxiety of being shocked." For another younger adult it was especially difficult. She reported:

> My physicians have restrictions on several activities that I love. … my EP (electrophysiologist) tells me not to involve in any activities in which loss of consciousness for a brief moment can pose danger to my life, i.e. swimming, skiing ... (and my doctor is very conservative and cautious, so the list can expand a lot more.) If I do go work out, I try not to do anything that involves repetitive movement of [the] left arm (the side of the ICD) so I don't damage the leads.

Pain and Itching

Some of the participants complained of pain at the ICD insertion site, pain with certain body movements, and occasional fleeting chest pain with activity. Female participants (*n = 2*) reported more difficulty finding a comfortable position for sleeping. Some felt this was due to the size of their breasts or the positioning of the ICD under the muscle or near the clavicle. One participant reported,

> I have an extended life battery and mine is a pacer/ICD so it is big and no matter how I turn it pushes up and against my collar bone it did not help that I am big chested I have always worn a good bra or the weight pulls on my incision. I find it hard to sleep with it due to the discomfort when I turn over and it moves...

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Keloid scarring and tenderness around the insertion site was reported by a few of the participants. Some of them were embarrassed because of the scarring and were not comfortable wearing clothing that exposed the keloid. One participant described both pain and itching at the ICD site, which had formed a keloid.

Pain and Device shock

Nine of the 20 participants (four men and five women) reported being shocked by their ICD at least once. Two of the women stated they did not have pain when shocked, although one woman described it as an instantaneous inability to move. The other three women stated that being shocked was extremely painful as one woman described:

> The shocks that I experienced were very painful, and after two I just cried, fearing
>
> I would get more. People say it feels like a horse kicked you in the chest. To me,
>
> it is more like a bomb goes of inside my heart.

The five men described being shocked as uncomfortable, but not painful enough to incapacitate them. One man was running a race when he was shocked and at first he thought he tripped over something then slowly realized he had been shocked and drove himself to the hospital. Another man, who was employed as a nurse, described being shocked as not too painful and accompanied by some nausea, "The nausea has been the only symptom after a shock and minor pain for a short time (one-half hour) that I would rate at a one or two on a one-to-ten scale." Two other female participants also reported mild nausea after being shocked.

Other Findings: Memory and Concentration

Six participants sustained a SCD episode and were resuscitated. All of these participants reported some problems with memory recall and one reported problems with memory retention and concentration. This participant was vague, but described an

inability to concentrate on his work at times, "I have some problems with concentration and memory retention but I think it's more from my encounter with cardiac arrest." Other participants reported not being able to remember their sudden cardiac death episode and were somewhat confused upon awakening. Two participants described not being able to remember how to perform daily activities (send children to school, make lunch, operate equipment at their job), although this part of their memory returned within a couple of weeks to a few months.

One individual described her ordeal: "I was in a coma for five days and when I woke up I was pretty incoherent. I really didn't understand what happened." She returned to the site of her SCD episode hoping to regain her memories, but unfortunately she did not. The other five reported that bits and pieces of the memory of their SCD experience returned over time.

Psychosocial Issues

Anxiety and Depression

Seventy percent ($n = 14$) of the participants reported feelings of anxiety immediately after returning home, although for most participants these feelings dissipated within a few weeks to a few months. Individuals who were shocked by their device reported more anxiety than those who had not been shocked. Some individuals still experienced anxiety during certain activities such as exercising, driving, and swimming. Participants whose cardiac condition deteriorated described having increased anxiety due to fear of potential device firing.

After implantation, 45% ($n = 9$) of participants described feeling depressed (slightly more women than men) during their recuperation period at home as one individual reported:

I became very depressed after my implantation…. I was also a little depressed

because I was 30 years old when I was implanted and I felt like I was too young

to need a medical device. But I also felt like I was lucky that I finally knew I was

not crazy and that something was very wrong with my heart and this device could

save my life. My emotions went up and down.

Another individual said he had feelings of depression and frustration about his limitations

after having it implanted: "I wasn't able to do a lot for the first 4 months. Now, it doesn't

bother me as much as it did. I've accepted it as part of me." Some felt their depression

was related to their diagnosis and not the ICD. As one individual described, "I do

occasionally feel a bit depressed about it but it isn't so much about the ICD as my whole

diagnosis."

It was especially difficult for women with small children. One young woman,

who had her ICD for almost four years, described her emotional struggle of living with

her heart condition and her ICD while caring for her two small children:

I notice I have become very easily irritated since then [ICD implantation]. My

husband has been understanding and put up with me. But now, I have two

girls/twins, I can't see myself constantly losing my temper with them or losing

control. Also, my medication that controls my arrhythmia makes me very tired

and depressed. I ended up having to take an anti-depressant to feel better.

Other mothers with children described an inability to care for their children because of

their medication or disease related fatigue: "I couldn't carry the kids or laundry and stuff

like that. It's just slowed me down, I don't have the energy," and "Because of my EF

[ejection fraction] it was very difficult for me to take care of them."

Participants who suffered a SCD episode were able to vividly recall their initial feelings and how they reacted to the changes that had occurred in their life.

I got the ICD the day before I was discharged. I don't think I was mentally back to "normal" for several months after I got out of the hospital. By the time the fog lifted, my ICD was just a fact of life.

Others reacted to their SCD episode as feeling like they were lucky to be alive. One participant described a turning point or epiphany that changed her outlook on life:

I did suffer from some depression; I got a lot of insomnia. When I started to feel better probably around May, I had trouble sleeping and my PCP prescribed Xanax to help me sleep and she gave me a couple of names. As she handed me the names, she said of course you're depressed and having trouble dealing with this, but you have to remember how lucky you are, you are alive. Something happened when she said it to me, I said she is so friggin' right, what am I depressed about, I'm alive. That was kind of like a turning point for me. When she handed me the prescription for the Xanax, I went oh my God, what's happened to my life. Something clicked in my head that made me say, that there are so many other people out there that are worse.

Most of the participants that described feeling anxiety and/or depression during their recuperation period returned to their previous life. At the conclusion of this study five individuals (four women, one man) reported still experiencing some anxiety, depression, or fear which lasted from four months to three years after implantation.

Fear

When participants were asked if they were fearful of their ICD firing, more than half (7 women; 5 men)) reported they were. Some described feeling anxiety and fear

simultaneously. Others ($n = 3$) expressed fear of the device firing while they were in a public place or at work. Some felt that bodily cues warned them of possible device firing. For instance, one younger adult felt her heart racing and dizziness right before the device was about to fire. She had experienced many shocks from her ICD and felt it was due to her "rushing" and thought it could be avoided. Participants who had not received a shock reported a fear of the unknown, not knowing what would happen when they were shocked. Still others reported anger and feeling a loss of control related to this situation. One woman described her frustration:

> I am anxious because I have no control over when I have V-tach or when I get shocked. I am angry because I use to be the happiest fun loving smiling person you would ever want to meet. Now I have this new bitterness in me that I cannot figure out and I have to get over because it is not who I am. I am angry at the doctor who did this to me ...and I am depressed because people will always look at me differently....

Fear of device recall was reported by half ($n = 10$) of the participants and due to the recent recall of the Guidant ICD in 2005, this fear was very real for them. Participants were fearful that their device might not work when needed or that the next device recall could be theirs. All of the participants were well aware of what a device recall would entail and they described this fear as always being in the back of their mind:

> As more and more devices are recalled I do get a little more nervous that the next device picked to be changed is mine at which point I'll need to miss another week of work and go through the whole healing process again, but I'm confident.

Participants described their frustration of having to go through the whole process again and the costs related to device replacement surgery. For some participants, they would be

responsible for a portion of the replacement surgery cost because of their insurance coverage. They had to plan for the recuperation period after the replacement surgery, the time missed from work, and some had to pay for childcare while they recuperated. The fear participants were experiencing intersected with financial concerns as they worried about device recall and the costs associated with it.

Those who experienced a device recall ($n = 5$) described feeling stressed, frustrated, and less trusting of the device manufacturers and physicians stating,

> I went through that last year when my ICD was recalled in the US. It was very stressful and frustrating hearing of the news, and waiting for my doctor to give the okay for the replacement. I do not trust the device to work as much as I once did.

One participant who had been involved in a device recall was pragmatic in her understanding that the device was man made, but expected a proactive response from her healthcare provider when there was a potential for a recall,

> I have been in one recall, had one device fail, and have had one lead recalled. These are man-made devices and they will fail. I just hope for timely communication of such matters. I am thankful for the technology even with its failings.

Body Image Concerns

Half ($n = 10$; four men, six women) of the participants expressed feeling uncomfortable swimming in public, removing their shirts, or wearing clothing that left the ICD site exposed. Some felt that others would look at them differently because of the scar, although these feelings dissipated within a few months after implantation. When participants were asked if they chose clothing that covered the ICD site, all of the women agreed that they did. The six women who expressed concerns with others seeing their

scars specifically said they would no longer wear strapless dresses or tank tops and chose clothing that covered the incision: "The scar however is huge and I don't wear tank tops or roll up my sleeves at all unless I'm in front of my close friends who know exactly what happened, my boyfriend or my family," and "I choose clothing that doesn't show the scars."

Two of the men said they would not remove their shirts in a public place because of their scar; the other two did not have a problem with taking their shirt off in public. Two of the women felt much differently about their ICD incision site. One of them responded, "In a contradictory fashion I am also a little proud of my scar, it shows I am a survivor." The other felt her incision site was a great "conversation starter."

Sexual Concerns

Only two participants (one male; one female) stated that they were concerned about the device firing during sexual intimacy and revealed that they had encountered a problem during sexual activity. The other 18 participants stated they did not encounter any problems with sexual intimacy or during sexual activity. They described being open and honest with their partners about the risk of the ICD firing and the possibility of a decrease in libido due to the medications. Two men specifically said that the ICD did not even enter their mind during sexual activity.

One man described how the ICD fired during sexual intercourse. This was the first time his device had fired and he reported feeling worried that it would fire again during intercourse. After speaking with his physician about the episode, his device was reprogrammed. He stated that since the reprogramming, the device has not fired and he no longer worried about his ICD during sexual activity. A woman described feeling angry, depressed, and too tired for sex. After seeing her physician she was started on

antidepressants. Within a few weeks she was feeling much better, although the side effects of the antidepressants decreased her libido and she was unable to achieve an orgasm:

> After the Sotalol, I was so tired that I didn't think I was awake enough for sex. After Zoloft, I feel great, but it takes my libido away. Even if we have sex, it was hard for me to have orgasm, as warned by my primary doctor.

She described feeling relieved that she was not angry and depressed all the time, but was hopeful that there may be another medication in the future that would not affect her libido so adversely.

Aim 3

Identify strategies used by younger adults to manage life with an ICD.

Strate*gies for Living with an ICD: Be Positive and Live Life to the Fullest.*

The majority of participants in this study adjusted very well to living with an ICD. For the most part, they were positive, upbeat, and focused on living life as they did before. All but one of the participants (a young mother) was able to put aside their anger and resentment, focus on the positive aspects, and accept the ICD as part of their life. They used various coping strategies such as taking part in their care, educating others about their ICD, accepting limitations, and reevaluating life. This allowed facilitation of a healthy transition into a "new normal" and enabled them to begin living life with an ICD. Many had similar perspectives and used specific strategies to make living life with an ICD easier. For example, focusing on the positive, listening to bodily cues, engaging in healthy lifestyles, support of others, returning to their normal routine, teaching and educating others, planning for the future and being proactive related to maintenance of the ICD.

When participants were asked about strategies they used to manage life with an ICD, the most common responses were: "I wake up every morning with a positive attitude...," and "I focus on every day and do not think about the negative." Another strategy described was listening to bodily cues ("If I am tired I rest. If I feel dizzy, I sit down."). Some of the participants (two women; one man) had more advanced cardiac disease which caused them to become very tired, dizzy, or short of breath during activity. These individuals learned to pace themselves or chose lower impact activities. For example, the female participants who had worked out three to five times a week before their ICD placement were now working out two to three days a week. Those who were taking one hour high impact aerobics classes had reduced their activity to 30 minutes of low impact aerobics and resting or stopping if they felt they needed to. Male participants who had been playing football or running had now chosen to play golf and walk. Two women who were also stay at home mothers, chose to play quiet indoor activities (in an air conditioned house) with their children as opposed to playing outdoors in the humid climate they lived in, in order to reduce their risk of shortness of breath.

Engaging in healthy habits (eating healthy, exercising, and not smoking) was a common strategy voiced by both men and women. Many participants viewed the ICD as an impetus to choose a "heart healthy" lifestyle by changing their diets to decrease saturated fats, lowering salt intake, and eating meals high in protein. Exercise was also viewed as a necessary part of their new lifestyle. Some of the male participants were not regularly exercising prior to their ICD implant, but had now incorporated it into their new normal. None of the participants were smokers before their ICD implant, although part of their new strategy was to be more aware of second hand smoke.

Support of friends and family was a strategy described by all of the participants. Many described feeling better when they shared information with their family or friends about their fears and concerns of living with an ICD. Others felt more comfortable joining online support groups. One man described how therapeutic it was for him as he poured out his heart in an online ICD support group. He felt a sense of relief knowing there were other individuals experiencing the same feelings, concerns, and emotions that he was: "I also find it very helpful to tell my story to others and attend support groups when available."

Returning to their "normal routine" helped relieve the anxiety for the majority of participants. They described it as feeling "more in control" of their life. Many participants felt returning to school or their jobs helped them to forget about their cardiac illness and their ICD. They shared concerns about how others viewed them and felt returning to their prior lives helped others to see them as "normal" rather than sickly and having a cardiac illness. Participants felt this strategy helped the most in living life with an ICD. Both male and female participants were able to return to their prior lives (jobs, school, and activities) with minimal lifestyle changes. Only one participant (a woman) was not able to return to her prior routine due to the extent of her cardiac illness.

Preparing and educating family members about their ICD and cardiac illness was another strategy employed by both male and female participants. Men who had been used to playing contact sports (i.e. football, hockey) with their children described how they sat down and explained why they could no longer do this. One father encouraged his son to feel the site of the ICD and explained how it worked. Two other men educated their sons on the importance of not directly hitting daddy in the chest anymore because of the possibility of damage to the ICD.

A female college student who described her mother as extremely nervous and controlling about her ICD was able to teach her mother about her ICD and involve her in doctors' visits and programming appointments in order to reassure her that she was capable of caring for her ICD on her own. Teaching her mother about the ICD and involving her in her care, not only reassured her that her daughter could care for herself, but allowed her more control in her own life.

Female participants without children explained to their families and circle of friends how the ICD worked and symptoms (dizziness, shortness of breath, fainting) that could occur. One woman described how caring and concerned her friends were when they spent time together. They would ensure she was not walking too fast or tiring too easily and always chose activities she could participate in. Another woman with small children felt it was important to teach her children what to do if they could not wake up mommy when daddy was away. She taught them how to shake her in bed to see if she would awaken. If she did not wake up, the children were instructed to call 911. Each time her husband went away on business, she watched as her three children demonstrated how to call for help. She described her thoughts on preparing her children:

When my husband goes on a business trip I go over how to call 911 with the kids. That's kind of hard for me to do. But I have to tell them if you ever wake up in the morning and can't wake me up what are you going to do? That drives it home for me, I hate having that talk with them, but what are they going to do if daddy's away and mommy can't wake up. I didn't want to ignore the reality of the situation, but I also hate the reality of the situation. I hate the fact my kids saw me die and I hate that they have to think about that, but I also don't want to ignore it and leave them without skills if something should come up.

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Planning for the future of living with an ICD involves regular visits with cardiologists and electrophysiologists. It requires the ICD recipient to be aware of recalls and problems with both the battery and the ICD device. These recalls may be imparted to the individual by the physician, but most individuals with ICDs check the manufacturer's web site for recalls on a regular basis. Planning for the future also includes taking a proactive stance when battery or device replacement is necessary (5 to 7 years) and discussing and planning surgical arrangements with the physician. For some individuals, battery and device replacement are not fully covered under insurance; therefore planning for replacement lessens the monetary ramifications. Both men and women described this strategy as extremely important in order to feel secure with their ICD and continue with everyday life.

Summary

In summary, an overarching theme, "a cautious transition to a new normal," and six related subthemes (anxiety and concern, caution, awareness, and security, childbearing, financial concerns, physiological and psychosocial issues, and strategies for living with an ICD) were identified after analysis of the participants' descriptive summaries. The findings from this study revealed that almost all of the younger adults were able to transition to a "new normal" that included life with an ICD. For many of the participants, life was not that different than before the ICD and their transition to a new normal was essentially effortless. A few of the participants had more difficulty transitioning due to imposed physical restrictions or disease related symptoms.

Younger adults are facing various developmental issues (marriage, childbearing, and parenting) that are much different than those of older adults. The younger adults in this study were very resilient, although anxiety and depression, passing their disease on to

their children, financial concerns, fear of device firing, fear of device recall, and body image concerns were very troubling for many. Several participants reported feeling an added sense of security after ICD implantation and felt confident that the ICD would be there for them if needed. They were able to put their worries aside, tackle restrictions or changes, and think positively about the future. This study highlighted the daily experiences of younger adult ICD recipients, lifestyle changes they have made, and the psychosocial impact of managing life with an ICD. A heightened awareness of these unique issues is important when planning appropriate interventions for the younger adult population.

Chapter V

Discussion

Introduction

The purpose of this study was to gain an understanding of what it is like for younger adults (18 to 40 years) to manage life with an ICD. The topic was important as very few studies exist for this population. Descriptive summaries from the participants revealed that incorporating an ICD into their daily life was an individual and complex experience. From the findings it was learned that participants faced many developmental transitions (marriage, childbearing, and career concerns), a health-illness transition (the ICD), and physiological and psychosocial issues. The majority of younger adults were able to transition to a "new normal" and accept life with an ICD, despite having to redefine their life to include the ICD. Their experiences of living with an ICD offer healthcare professionals insight into the challenges they face. In this chapter the study findings will be linked to the existing literature and the younger adults' ability to transition to life with an ICD. In addition, nursing implications will be discussed throughout the chapter in regards to each aim. Limitations and future research recommendations will also be presented.

During the interview process, the investigator found that participants who were recruited from and responded via the Internet were more detailed in their responses than the participants who responded by telephone. In seeking to understand this, it could be hypothesized that participants feel less inhibited in an Internet response rather than a verbal exchange. Participants who would not feel comfortable talking about sexual issues or other personal information over the telephone may be more apt to discuss these issues via Internet communication because of the anonymity associated with that medium. It

may be that participants who communicate via the Internet are freer to share information with a stranger, disclosing information that they may not have revealed during a conversation (Metz, 1994).

<div align="center">Aim1</div>

Describe the day to day experience of younger adults (18 to 40 years) living with an ICD.

Younger adults' response to living with an ICD and incorporating it into daily life were similar to those of older adults (Bolse et al., 2005; Burke, 1996). Like older adults, these younger adults described initial feelings of anxiety and concern about their diagnosis and ICD implantation. Some felt anger towards their bodies and resented needing an ICD, but after a period of a few weeks to a few months, most of the participants were able to accept the ICD and return to their prior lives. This study finding supports Burke's (1996) conclusion that after implantation, ICD recipients deliberately chose to accept the ICD into their life. Participants in this study made changes to incorporate the ICD into their life, accepted limitations, and focused on returning to a regular life, which supports Burke's other conclusion in her study of older adults.

This study defined issues specifically affecting younger adults after ICD implantation. Younger adults face psychosocial and developmental tasks that are much different than those of older adults and therefore have a different view than older adults on what returning to a "normal life" is. In the qualitative study older adults with ICDs, conducted by Bolse et al. (2005), participant concerns were focused on being able to care for themselves independently and perform activities of daily living. For participants in this study, they were facing developmental tasks of young/middle adulthood such as marriage, childbearing, and career advancement. Participants were concerned with having children and the possibility of passing their condition onto their offspring, continuing

their career, and financial stability. This population presents unique concerns and adjustment challenges specific to younger adults. Recognizing these concerns can aid healthcare providers in focusing strategies that are age specific and patient centered.

There is no qualitative literature on what it is like for younger adults to manage life with an ICD. New insights into how younger adults manage life with an ICD were revealed in this study. After ICD implantation, participants spoke frequently about using caution and awareness when approaching activities and tasks. Prior to ICD implantation all of the participants were active in some type of sports. After implantation many participants remained physically active (six had imposed activity restrictions) although some chose less strenuous activities because increased activity caused an increase in heart rate and shortness of breath which were indicators of potential device firing. The participants use of caution and awareness when choosing activities reduced their anxiety and fear of device firing. Bolles-Vitale and Funk's (1995) of younger persons with an ICD had similar findings, as they reported that participants were cautious about engaging in activity. They also found that participants chose to engage in less strenuous activities because of fear of device firing.

Dubin et al. (1996) studied quality of life in ICD recipients under the age of 40 and reported that 25% of participants complained of decreased energy. Decreased energy was the second most frequent problem reported by younger adults as reported by Bolles-Vitale and Funk (1995). The findings of the present study support both Dubin et al. (1996) and Bolles-Vitale and Funk (1995), as mothers with young children reported decreased energy levels, which made it difficult for them to meet the demands of caring for their children and manage life with an ICD. Decreased energy levels can be due to the participant's cardiac illness or prescribed medications. Participants handled this problem

by pacing their activities, choosing less strenuous activities to play with their children, taking frequent rest periods, and relying on the support of family.

All of the participants in this study reported that managing life with an ICD became easier as time passed, although it was important to first accept the ICD as part of their life and their "new normal." The participant's acceptance of the ICD is dependent on their sense of feeling safe and secure with their ICD. It is important for health care providers to understand how a patient values a sense of security and the relationship between feeling secure with the ICD and accepting it as part of their life. Safety and security have been found to be key concepts in acceptance of an ICD in prior research (Bolse et al., 2005; Burke, 1996).

Participants were more apt to accept the ICD when they felt it was ensuring their survival and when the ICD was minimally intrusive. All of the participants in this study knew they needed an ICD to survive and many reported feeling an added sense of security after ICD implantation. This reduced their anxiety and allowed them to continue with their everyday lives, forgetting they had an ICD. Today ICDs are much smaller than they were ten years ago, and after implantation most individuals do not find them intrusive. Only two females in this study expressed discomfort with their ICD placement and both attributed the discomfort to their large breasts. They found that wearing a good, supportive bra helped to decrease their discomfort.

Childbearing was the most commonly reported concern in this study. Passing their cardiac disease onto their children was a constant worry for many of the participants as more than half of the participants in this study were treated with an ICD for a diagnosis of hypertrophic cardiomyopathy (HCM). This concern of passing their disease onto their children has not been previously reported in the empirical literature. In this study, two of

the participants had children who either had or were awaiting an ICD and this phenomenon has not previously been reported in existing literature either.

All of the participants were aware that HCM is genetic and there is a 50% chance of passing the gene to their offspring (Maron, 2002).They were all proactive in undergoing genetic screening. Participants who had children that needed an ICD were positive, well adjusted, and had accepted their ICD into their life. They were not overly concerned with their children having an ICD. This could be due to their experience with having an ICD. They were secure with the ICD and felt safe that it would prevent them from experiencing a life threatening arrhythmia and therefore believed their children would be safe as well.

Because HCM and other structural and electrophysiological cardiac diseases have a genetic predisposition, this finding provides insight into understanding the importance of genetic screening, family planning, and counseling. In previous studies of ICD recipients, the samples have consisted primarily of individuals over the age of 65 and family planning was not a concern. Health care providers have an obligation to assess young ICD recipients for these issues and facilitate genetic and family screening and counseling if necessary.

Financial concerns were the next most troubling issue revealed by participants. Many of the participants reported that they were fearful of losing their job and insurance coverage. They also verbalized their fears of not being able to provide financial security for their family. This study finding is supported by Bolles-Vitale and Funk's (1995) study of younger adults in which 89% of the participants reported having financial concerns. Financial insecurity can cause stress and contribute to anxiety and depression making it more difficult to adapt to life with an ICD (Luyster, Hughes, Waechter, & Josephson,

2006). Allowing ICD recipients to verbalize fears and concerns related to their ICD can aid healthcare providers in identifying appropriate resources. This finding provides insight into understanding the various challenges that younger adults are facing when they undergo ICD placement.

No research currently exists on patient related costs to implantation of an ICD. Research has been focused on ICD cost effectiveness in patients with differing degrees of cardiac illness. Implantation of an ICD may cost between $18,000-$35,000 per patient (Hlatky & Mark, 2007). The impact of the cost of an ICD has primarily affected Medicare as the majority of ICD recipients are over age 65. Policy makers are grappling with the dissemination of effective new therapies and containing the growth of costs affecting the health care budget (Hlatky & Mark, 2007). Research into patient related costs after ICD implantation is needed. Healthcare providers need to inform ICD recipients of potential ICD related costs that they may incur as well as to consult with their insurance carriers regarding their coverage. Planning for battery changes and device replacement may also lessen monetary ramifications.

<center>Aim 2</center>

<center>Describe the physiological (physical restrictions, pain, itching) and psychosocial (anxiety, depression, fear, body image, sexual concerns) transitional issues related to ICD management in younger adults.</center>

Many of the participants in this study were able to return to their prior activities without any problems, although some did have to accept activity restrictions. In a study of younger adults (less than 40 years) Dubin et al. (1996) found that 68% of participants were taking part in moderate activity and 31% were involved in strenuous activity. The present study supported the findings of Dubin et al. (1996) and found that half of the

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participants were able to return to prior activities after ICD implantation. Participants who chose to decrease their activity on their own reported that bodily cues (heart racing, dizziness, and shortness of breath) were indicators to them that they needed to slow their activity down as shortness of breath, dizziness, and arrhythmias are signs of worsening cardiac illness (Maron, 2002). A worsening of the cardiac illness can cause an increase in device firing. Decreasing their activity offered the ICD recipient a sense of control which was a way of coping with the uncertainty of when the ICD would fire.

Bolles-Vitale and Funk (1995) reported that pain and itching at the insertion site were the greatest concerns for participants in their study. Contrary to these findings, only two participants in this study complained of pain at the insertion site and only one participant complained of itching. This is most likely due to the fact that participants in the study by Bolles-Vitale and Funk (1995) were interviewed shortly after implantation. Pain and itching at the incisional site are common during the healing process (Dunbar, 2005).

In this study, six participants sustained a SCD episode and were resuscitated. They described the effects of their SCD on their memory; only one participant was still experiencing problems with recall and concentration. This participant minimized his problem with recall and concentration and focused more on how happy he was to have survived. This could be his way of handling the fact that he did not want to recall his ordeal. Problems with memory retention and concentration are most likely due to anoxic brain injury occurring during the SCD (Lim, Alexander, LaFleche, Schnyer, & Verfaellie, 2004). More research is needed with the younger adult population to gain a better understanding of the effects of sudden cardiac death episodes on memory function.

Anxiety and fear related to device shock or device recall were the most common psychosocial responses reported in this study. Participants who had received a shock described being anxious and fearful of being shocked again. Those who had not been shocked yet, were fearful and anxious of the unknown, although it did not prevent them from continuing with their lives. The thought of being shocked seemed to be a stressful event for almost all of the participants. Both men and women described their anxiety and fear of being shocked. This is not surprising as previous studies of older adults (Carroll & Hamilton, 2005; Schron, et al., 2002) and younger adults (Bolles-Vitale & Funk, 1995) confirmed these findings.

Pain related to device shock has been reported in studies of both younger (Bolles-Vitale & Funk, 1995) and older adults (Carroll & Hamilton; 2005; Dunbar, Warner & Purcell, 1993; Irvine et al., 2002; Schron et al., 2002). Both men and women in this study described feeling some type of pain after device shock. Variations in pain intensity from ICD shock are consistent with previous findings by Dunbar et al. (1993). Participants in this study had various reactions to pain after ICD shock. Women described more intense reactions to pain than men did. There is no way to predict how a patient will react to an ICD shock, therefore educating the patient about ICD shocks before and after implantation may reduce some of the fear and anxiety participants in this study experienced.

Participants also expressed fear of being shocked in a public place. This fear was very real for both men and women due to the loss of control, the uncertainty of the outcomes, and the potential for embarrassment in front of others (children, peers, etc). Many of the participants who had been shocked before reported more anxiety and fear of being shocked again. Previous studies of older adults reported these same findings

(Carroll & Hamilton, 2005; Dunbar et al., 1993; Hegel et al., 1997; Schron, et al., 2002). One would assume that after being shocked the participant would know what to expect the next time, but this was not the case, as the experience of being shocked can be different each time. Participants did not have a thorough understanding of what to expect when they were shocked or what to do. They knew that they should go to the hospital if they were shocked, but for most of the participants they were still learning. Some of them had received instructions from their physicians, but most of them did not remember them as they were given to them immediately after the implantation. These findings imply that more education is needed along with an assessment of the patient's knowledge and understanding after implantation. Patients could also benefit from a wallet card or a refrigerator magnet explaining what to expect and what to do after being shocked.

Fear of device recall was a distressing concern for many of the participants. Some of these individuals had experienced a device recall and were fearful of another. Others were concerned with the recent recall of the Guidant ICD in 2005 and this intensified any anxiety and fear they were already experiencing. The thought of a recall caused participants to re-live the whole process of ICD implantation over and over again. Some feared that their device would not work properly and this impacted everything they did. They were less trusting of the device manufacturers and physicians and could be less trusting of all healthcare professionals. The findings of this study revealed that the Guidant ICD recall significantly impacted ICD recipients. To date, no research exists on the psychosocial impact of ICD recall. Timely communication of recalls in the future could avoid the devastating impact this recall had on participants.

There is substantial evidence that individuals with ICDs experience psychosocial distress (Arteagea & Windle, 1995; Friedman, et al., 2007, Heller et al., 1998; Sears, et

al., 2005). There is also a relationship between depression and individuals who are younger and received an ICD at a younger age ICD (Arteagea & Windle, 1995; Friedman, et al., 2007, Heller et al., 1998; Sears, et al., 2005).Our study findings support these previous findings as participants in this study reported depression and anxiety. A few of the participants complained of depression lasting longer than a few months and required treatment with antidepressants. The participants who required treatment with antidepressants were also experiencing a worsening of their cardiac illness (increased shortness of breath and increased arrhythmias) that prevented them from performing some activities. The developmental transitions theory that underpinned this study purports that individuals who are experiencing transition may experience a critical point. A critical point is an awareness of change by the individual (Meleis et al., 2000). In this instance these participants may feel that because their cardiac illness is worsening and preventing them from performing activities they enjoy that their situation may get even worse, causing the depression. They may also come to the realization that they have to live with an ICD the rest of their life and their limitations may increase.

Body image concerns were reported by half of the younger adults in this study. Many described choosing clothing that covered their ICD. Some felt embarrassed by the scar and some were afraid of what others would think or questions they would ask. Conversely, a couple of subjects felt the scar indicated they were a survivor. This is an important aspect in adaptation, whereas the individual acknowledges he or she is a survivor and not a victim. Body image concerns are specific to the younger adult population and have been identified in other studies of younger adults (Bolles-Vitale & Funk 1995; Dubin, et al, 1996). This concern may dissipate over time as the incisional scar fades and the individual becomes more accustomed to the ICD. The author's

findings support the need to assess the developmental and transitional issues associated with the age of the individual when preparing for ICD placement.

Surprisingly, only two participants reported concerns about sexual activity. One participant complained of decreased libido which was due to the antidepressant medications she was taking. The other participant was shocked during sexual activity, but after reprogramming of the ICD he did not report further problems. Given this age group, the investigator expected to find more concerns associated with sexual activity. It is possible that the participants were not comfortable speaking about such a private issue and that may have influenced the findings.

<center>Aim 3</center>

Identify strategies used by younger adults to manage life with an ICD.

Participants reported using various strategies to manage life with their ICDs. The strategies these participants described could be used as the basis for a patient and family education program. Involving ICD recipients in teaching and preparing others could help to lessen anxiety and facilitate an easier transition for new ICD recipients.

Almost all of the younger adults in this study revealed that they concentrated on the positive aspects and tried to minimize negative aspects associated with the ICD. They described joining online support groups, telling their story to others, utilizing the support of family and friends, and enjoying life. Taking a proactive stance and preparing and educating family members about their ICD also helped participants. They became actively involved in teaching and preparing family and friends which allowed them to feel more in control of their lives. This strategy is similar to an educational telephone intervention program developed by Dougherty, Thompson & Lewis (2005) to improve psychosocial adjustment, self-efficacy, and decrease healthcare utilization after ICD

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implantation. These behaviors are described as engagement, which enables the process of change to occur (Meleis, et al., 2000). For the most part, younger adults became actively engaged in transitioning to living life with an ICD. As stated previously, the first step to aiding in adaptation to living with an ICD is acceptance. The individual must accept the ICD in order to facilitate adaptation (Bolse et al., 2005; Burke, 1996).

This study revealed that younger adults are a resilient group of ICD recipients, but displayed a wide range of psychosocial issues much different than those of older adults. Participants revealed that one of the most helpful strategies in adjusting to life with an ICD was being able to talk with other young ICD recipients that were experiencing the same issues as they were. Communication with other individuals like themselves assisted ICD recipients in adapting to life with an ICD and it allowed for appropriate social comparisons.

<div align="center">Study Limitations</div>

The greatest limitation to this study was the lack of face-to-face interviewing. Because of the limited number of younger adults with ICDs, conducting face-to-face interviews was not an option. Selection bias from Internet recruitment was a limitation to the study because of the socioeconomic characteristics of Internet populations (Im & Chee, 2004). The racial and ethnic disparities in Internet populations have since changed, however individuals of lower socioeconomic background may not be represented (Fallows, 2005). To decrease the potential of selection bias, the investigator used other recruitment strategies (e.g. identification of potential participants by the nurse researcher, Dr. Diane Carroll, at MGH; contact of potential participants by the physician through the electrophysiology service at MGH; and posting of a recruitment brochure in the ICD clinic at MGH) along with Internet recruitment. The use of various recruitment strategies

increased the number of participants from diverse socioeconomic and ethnic backgrounds as exhibited by the study sample (Im, Chee, Lim, Bender, Tsai, et al., 2006).

Demographic data such as height, weight, smoking history, dietary intake, and alcohol consumption would have been a valuable addition to this paper. It was not collected during interviewing and this is a limitation in understanding factors associated with SCD. Because of the increase in SCD in both men and women over the past few years, this data could help in understanding factors associated with SCD (Zhi-Jie, Croft, Giles, & Mensah, 2001).

The sample consisted of five participants who were working in the healthcare field. This may not be an accurate representation of all patients with ICDs. As in any research, there may be a systematic bias in who agrees to participate. In this study, these participants were eager to participate because they felt they were helping to advance the limited research available on young adults with ICDs. A larger sample would be necessary to avoid this possibility.

Conclusion

It is clear from the findings of this study that younger adults are facing many different developmental and transitional issues that need to be addressed before, during, and after ICD placement. Their experiences provided rich description and offered insight and understanding into how they managed daily life with an ICD. This study revealed some of the unique issues that younger adults with ICDs are facing and strategies they used to assist in adaptation to life with an ICD. Their experiences may provide the basis for intervention programs tailored specifically for this group. Future research should focus on psychosocial changes in younger adults over the duration of the ICD experience

with larger samples and the outcomes of intervention programs that are developmentally

sensitive and age specific.

References

Alexander, M., Baker, L., Clark, C., McDonald, K. M., Rowell, R., Saynina, O., &
  Hlatky, M. A. (2002). Management of ventricular arrhythmias in diverse
  populations in California. *American Heart Journal, 144*(3), 431-439.

American Heart Association. Heart and Stroke Statistical Update-2005 *Update.* Dallas,
  TX.

Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators. (1997). A
  comparison of anti-arrhythmic drug therapy with implantable defibrillators in
  patients resuscitated from near-fatal ventricular arrhythmias. *New England
  Journal of Medicine, 337*, 1576-1583.

Arteaga, W. J., & Winde, J. R. (1995). The quality of life of patients with life threatening
  arrhythmias. *Archives of Internal Medicine, 155*(19), 2086-2091.

Birnbaum, M. H. (2004). Human research and data collection via the internet. *Annual
  Review of Psychology, 55*, 803-832.

Bolles-Vitale, M.B., & Funk, M. (1995). Quality of life in younger persons with an
  implantable cardioverter defibrillator. *Dimensions of Critical Care Nursing,
  14*(2), 100-111.

Bolse, K., Hamilton, G., Flanagan, J., Carroll, D.L., & Fridlund, B. (2005). Ways of
  experiencing the life situation among United States patients with an implantable
  cardioverter defibrillator: A qualitative study. *Progress in Cardiovascular
  Nursing, 20*, 4-10.

Boyd, C.O. (1993). Combining qualitative and quantitative approaches. In: Munhall PL et
  al (2nd Ed.) *Nursing Research: a Qualitative Perspective.* Norwalk: Appleton-
  Century-Crofts.

Brugada, P., & Brugada, J. (1992). Right bundle branch block, persistent ST segment

    elevation and sudden cardiac death: A distinct clinical and electrocardiographic

    syndrome. A multicenter report. *Journal of the American College of Cardiology,*

    20(6), 1391-1396.

Burke, L. J. (1996). Securing life through technology acceptance: The first six months

    after transvenous internal cardioverter defibrillator implantation. *Heart & Lung:*

    The Journal of Acute and Critical Care, 25(5), 352-366.

Burns, S.K., & Grove, N.B. (2004). *Practice of nursing research: Conduct, critique, and*

    utilization. Philadelphia: W.B. Saunders Co.

Butterfield, P. G., Yates, S. M., Rogers, B.,& Healow, J. M. (2003). Overcoming subject

    recruitment challenges: Strategies for successful collaboration with novice

    research agencies. *Applied Nursing Research, 16*(1), 46-52.

Cannom, D. S., & Prystowsky, E. N. (2004). The evolution of the implantable

    cardioverter defibrillator. *PACE, 27*, 419-431.

Carroll. D. L., & Hamilton, G. A. (2005). Quality of life in implanted cardioverter

    defibrillator recipients: The impact of a device shock. *Heart & Lung: The Journal*

    of Acute and Critical Care, 34(3), 169-178.

Cotton, A. H. (2003). Ensnaring webs and nets: ethical issues in internet-based research.

    Contemporary Nurse, 16(1), 114-123.

Craney, J. M., Mandle, C. L., Munro, B. H., & Rankin, S. (1997). Implantable

    cardioverter defibrillators: Physical and psychosocial outcomes. *American*

    Journal of Critical Care, 6(6), 445-451.

Creswell, J. W. (2003). *Research design: Quantitative, qualitative, and mixed methods*

    approaches (2nd ed.). Thousand Oaks, CA: Sage Publications.

Davies, S. (2005). Meleis's theory of nursing transitions and relatives' experiences of nursing home entry. *Journal of Advanced Nursing, 52*(6), 658-671.

Dickerson, S.S., Posluszny, M., & Kennedy, M. (2000). Help seeking in a support group for recipients of implantable cardioverter defibrillators and their support persons. *Heart & Lung, 29*(2), 87-96.

Dougherty, C.M. (1997). Family focused interventions for survivors of sudden cardiac arrest. *Journal of Cardiovascular Nursing, 12*(1), 45-58.

Dougherty, C. M., Thompson, E. A., Lewis, F. M. (2005). Long-term outcomes of a telephone intervention after an ICD. *Pacing and Clinical Electrophysiology, 28*, 1157-1167.

Dougherty, C. M., Lewis, F. M., Thompson, E. A., Baer, J. D., & Kim, W. (2004). Short-term efficacy of a telephone intervention by expert nurses after an implantable cardioverter defibrillator. *PACE, 27*, 1594-1602.

Dougherty, C.M., Pyper, G.P., & Frasz, H.A. (2004). Description of a nursing intervention program after an implantable cardioverter defibrillator. *Heart & Lung, 33*(3), 183-190.

Dubin, A.M., Batsford, W.P., Lewis, R.J., & Rosenfeld, L. E. (1996). Quality of life in patients receiving implantable cardioverter defibrillators at or before age 40. *PACE, 11*, 1555-1559.

Duffy, M. E. (2002). Methodological issues in web-based research. *Journal of Nursing Scholarship*, *34*(1), 83-88.

Dunbar, S. B. (2005). Psychosocial issues of patients with implantable cardioverter defibrillators. *American Journal of Critical Care*, *14*(4) 294-303.

Dunbar, S. B., Jenkins, L. S., Hawthorne, M., Dudley, W. N. & Slemmons, M. (1999). Factors associated with outcomes 3 months after implantable cardioverter defibrillator insertion. *Heart & Lung*, *28*(5), 303-315.

Dunbar, S. B. Warner, C. D., & Purcell, J. A. (1993). Internal cardioverter defibrillator device discharge: Experiences of patients and family members. *Heart & Lung, 22*(6),494-501.

Duru, F., Buchi, S., Klaghofer, R., Mattmann, H., Sensky, T., & Buddeberg, C., et al., (2001). How different from pacemaker patients are recipients of implantable cardioverter defibrillators with respect to psychosocial adaptation, affectve disorders, and quality of life? *Heart, 85*, 375-379.

Erikson, E. H. (1963). *Childhood and society* (2nd ed.). New York: W. W. Norton.

Erikson, E. H. (1968). *Identity: Youth and crisis*. New York: W. W. Norton & Company.

Erikson, E. H. (1997). *The life cycle completed.* New York: W. W. Norton & Company

Eysenbach , G., & Till, J. (2001). Ethical Issues in qualitative research on internet communities. *British Medical Journal,* 323(7321), 1103-1105.

Eysenbach, G., & Wyatt, J. (2002). Using the Internet for surveys and health research. *Journal of Medical Internet Research, 4*(2), e13.

Ezekowitz, J. A., Armstrong, P. W., & McAlister, F. A. (2003). Implantable cardioverter defibrillators in primary and secondary prevention: A systematic review of randomized controlled trials. *Annals of Internal Medicine*, *138*, 445-452.

Fallows, D. (2005). How women and men use the internet. *PEW Internet and American Life Project,* Retrieved January 16, 2006, from http://pewinternet.org/pdfs/PIP_Women_and_Men_online.pdf.

Friedman, E., Thomas, S.A., Inguito, P., Kao, C.W., Metcalf, M., & Kelley, F. J. (2007). Quality of life and psychological status of patients with ICDs. *Journal of Interventional Cardiac and Electrophysiology,* [Electronic Version]. Retrieved on February 1, 2007 from www://springerlink.com.

Ganz, L. (2004). Implantable cardioverter defibrillators. *EMedicine*, Retrieved September 20, 2004, from http://www.emedicine.com/med/topic3386.htm

Glikson, M., & Friedman P. (2001). The implantable cardioverter defibrillator. *Lancet, 357*(9262), 1107-1117.

Gordon.L. (2005). Adultescence: Helping twenty somethings leave the nest. *Psychotherapy Networker, 29*(2), 1-6.

Greene, J. C. (1990). Three views on the nature and role of knowledge in social science. In E. G. Guba (Eds.), *The Paradigm Dialogue* (pp. 227-245). Newbury Park: Sage.

Gregoratos, G., Abrams, J., Epstein, A. E., Freedman, R. A., Hayes, D. L., & Hlatky, M. A., et al., (2002). ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee on Pacemaker Implantation). 2002. Retrieved June 27, 2005, from www.acc.org/clinical/guidelines/pacemaker/pacemaker.pdf.

Guba, E., (1990). *The Paradigm Dialog,* Newbury Park: Sage.

Hamilton, G.A., & Carroll, D.L. (2004). The effects of age on quality of life in implantable cardioverter defibrillator recipients. *Journal of Clinical Nursing, 13*(2), 194-200.

Hegel, M. T., Griegel, L. E., Black, C., Goulden, L., & Ozahowski, T. (1997). Anxiety and depression in patients receiving implanted cardioverter defibrillators: A longitudinal investigation. *International Journal of Psychiatry in Medicine, 27*(1), 57-69.

Heller, S.S, Ormont, M.A., Lidagoster L., Sciacca, R. R., & Steinberg, J. S. (1998). Psychosocial outcome after ICD implantation: A current perspective. *PACE, 21*, 1207-1215.

Higgins, C. (1990). The AICD: a teaching plan for patients and families. *Critical Care Nurse, 10*(6), 69-74.

Hlatky, M. A., Saynina, O., McDonald, K. M., Garber, A., & McClellan, M. B. (2002). Utilization and outcomes of the implantable cardioverter defibrillator, 1987-1995. *American Heart Journal, 144*(3), 398-403.

Hlatky, M. A. & Mark, D. B. (2007). The high cost of implantable defibrillators. *European Heart Journal*, *28*(4), 388-391.

Im, E. O., & Chee, W. (2002). Issues in protection of human subjects in Internet research. *Nursing Research, 51*(4), 266-269.

Im, E. O., & Chee, W. (2004). Recruitment of research participants through the Internet. *Computers, Informatics, Nursing, 22*(5), 289-297.

Im, E. O., Chee, W., Lim, H. J., Bender, M., Tsai, H. M., Yang, S. O. et al., (2006). Recruitment of oncology nurses for internet research: Issues and future directions. *Oncology Nursing Forum, 33*(2), 249-254.

Im, E. O., & Meleis, A. I. (1999). A situation specific theory of menopausal transition of Korean immigrant women. *Image Journal of Nursing Scholarship,* 31, 333-338.

Irvine, J., Dorian, P., Baker, B., O'Brien, B. J., Roberts, R., Gent, M., et al. (2002). Quality of life in the Canadian Implantable Defibrillator Study (CIDS). *American Heart Journal, 144*(2), 282-289.

Jaffe, M. L. (1998). *Adolescence.* New York: John Wiley & Sons, Inc.

Josephson, M., Hein, J., & Wellens, J. (2004). Implantable defibrillators and sudden cardiac death. *Circulation, 109*, 2685-2691.

Knafl, K. A., & Webster, D. C. (1988). Managing and analyzing qualitative data: A description of tasks, techniques, and materials. *Western Journal of Nursing Research*, *10*(2), 195-218.

Kohn, C. S., Petrucci, R.J., Baessler, C., Soto, D. M., & Movsowitz, C. (2000).The effect of psychological intervention on patients' long-term adjustment to the ICD: A prospective study. *PACE*, *23*, 450-456.

Kralik, D., Warren, J., Price, K., Koch, T., & Pignone, G. (2005). The ethics of research using electronic mail discussion groups. *Journal of Advanced Nursing, 52*(5), 537-544.

Kroger, J. (2000). *Identity development: Adolescence through adulthood.* Thousand Oaks, CA: Sage.

Lampert, R., Jain, D., Burg, M. M., Batsford,, W. P., & McPherson, C. A. (2000). Destabalizing effects of mental stress on ventricular arrhythmias in patients with implantable cardioverter defibrillators. *Circulation, 101*, 158-164.

Lampert, R., Joska, T., Burg, M. M., Batsford, W. P., McPherson,, C. A., & Jain, D. (2002). Emotional and physical precipitants of ventricular arrhythmia. *Circulation, 106*, 1800-1805.

Lim, C., Alexander, M. P., LaFleche, G., Schnyer, D. M. & Verfaellie, M. (2004). The neurological and cognitive sequelae of cardiac arrest. *Neurology*, *63*, 1774-1778.

Lincoln, Y.S., & Guba, E.G. (1985). *Naturalistic inquiry*. Beverly Hills, CA: Sage.

Luyster, F., Hughes, J., Waechter, D., & Josephson, R. (2006). Resource loss predicts depression and anxiety among patients treated with an implantable cardioverter defibrillator. *Psychosomatic Medicine*, *68*(5), 794-800.

Maron, B. (2002). Hypertrophic cardiomyopathy. *Circulation, 106*(19), 2419-2421.

Maron, B.J., Chaitman, B. R., Cochair, M. J., Ackerman, M. J., Bayes De Luna, A., & Corrado, D. et al., (2004). Recommendations for physical activity and recreational sports participation for younger patients with genetic cardiovascular diseases. *Circulation, 109,* 2807-2816.

Meleis, A. I. (3rd Ed.). (1997). *Theoretical Nursing: Development & Progress*. Philadelphia: Lippincott-Raven.

Meleis, A. F., Sawyer, Linda, M., Im, E. O., Hilfinger-Messias, D. K., & Schumacher, K. (2000). Experiencing transitions: An emerging middle-range theory. *Advances in Nursing Science, 23*(1), 12-28.

Meleis, A. I., & Trangenstein, P. A. (1994). Facililtating transitions: redefinition of the nursing mission. *Nursing Outlook, 42*, 255-259.

Messias, D. K., Gilliss, C. L. Sparacino, P.S., Tong, E. M., & Foote, D. (1995). Stories of transition: parents recall the diagnosis of congenital heart defects. *Family Systems Medicine, 3,* 367-377.

Miles, M., & Huberman, A. (1994). *Qualitative data analysis: An expanded sourcebook,* Thousand Oaks: Sage.

Molchany, C.A., & Peterson, K.A. (1994). The psychological effects of support group intervention on AICD recipients and their significant others. *Progressive Cardiovascular Nursing, 9*(2), 23-32.

Morse, J. M. (1994). Designing funded qualitative research. In Denzin, N. K. Lincoln, Y. S. editors. *Handbook of qualitative research*. Sage Publications: Thousand Oaks, CA.

Moss, A. J, Zareba, W., Hall, W. J., Klein, H., Wilber, D., & Cannom, D. S. et al. (2002). Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *New England Journal of Medicine*, 346, 877-883.

Murphy-Lavoie, H., & Preston, C. (2005). Cardiomyopathy, dilated. *EMedicine*. Retrieved March 3, 2006, from http://www.emedicine.com/emerg/topic80.htm.

Nichols, S. K., & Wolverton, C. L. (1991). Outcome criteria for patients with implantable defibrillators. *Dimensions in Critical Care Nursing, 10*(5), 294-304.

Pederson, S. S., van Domburg, R. T., Theuns, D. A., Jordaens, L., Erdman, R. A. (2005). Concerns about the implantable cardioverter defibrillator: A determinant of anxiety and depressive symptoms independent of experienced shocks. *American Heart Journal, 149*(4), 664-669.

Poirier, S., & Ayres, L. (1997). Endings, secrets, and silences: Overreading in narrative inquiry. *Research in Nursing and Health*, *20*, 551-557.

Richards, L. (1999). *Using NVIVO in Qualitative Research*. Thousand Oaks: Sage Publications.

Sandelowski, M. (1995). Sample size in qualitative research. *Research in Nursing Health*, *18*, 179-183.

Sandelowski, M. (1995a). Focus on qualitative methods. Qualitative analysis: what is it and how to begin. *Research in Nursing & Health, 18*(4), 371-375.

Sandelowski, M. (1995b). Triangles and crystals: on the geometry of qualitative research. *Research in Nursing and Health, 18*(6), 569-574.

Sandelowksi, M. (2000). Focus on qualitative methods. Whatever happened to qualitative description? *Research in Nursing & Health*, 23, 334-340.

Sawyer, L. M. (1999). Engaged mothering: The transition to motherhood for a group of African American women. *Journal of Transcultural Nursing, 1*, 14-21.

Schumaker, K. L. (1996). Reconceptualizing family caregiving: Family based illness care during chemotherapy. *Research in Nursing and Health, 19*(4) 261-271.

Schumaker, K. L., & Meleis, A. I. (1994). Transitions: A central concept in nursing. *Image: Journal of Nursing Scholarship, 26*(2), 119-127.

Schuster, P. M., Phillips, S., Dillon D. L., & Tomich, P. L. (1998). The psychosocial and physiological experiences of patients with an implantable cardioverter defibrillator. *Rehabilitation Nursing, 23*(1), 30-37.

Schron, E. B., Exner, D. V., Tao, Q., Jenkins, L. S., Steinber, J. S., & Cook, J. R. et al., (2002). Quality of life in the arrhythmics versus implantable defibrillator trial impact of therapy and influence of adverse symptoms and defibrillator shocks. *Circulation, 105*, 589-594.

Sears, S. F., Burns, J. L., Handberg, E., Sotile, W. M., & Conti, J. B.(2001). Younger at heart: understanding the unique psychosocial adjustment of younger implantable cardioverter defibrillator recipients. *PACE, 24*, 1113-1117.

Sears, S. F., & Conti, J. B. (2002). Quality of life and psychological functioning of ICD patients. *Heart, 87*, 488-493.

Sears, S. F., & Conti, J. B. (2003).Understanding implantable cardioverter defibrillator

    shocks and storms: Medical and psychological considerations for research and

    clinical care. *Clinical Cardiology, 26*, 107-111.

Sears, S. F., Lewis, T. S., Kuhl, E. A., & Conti, J. B. (2005). Predictors of quality of life

    in patients with implantable cardioverter defibrillators. *Psychosomatics, 46*, 451-

    454.

Sears, S. F., Todaro, T. S., Lewis, J. F., Sotile, W., & Conti, J. B. (1999). Examining the

    psychological impact of implantable cardioverter defibrillators a literature review.

    Clinical Cardiology, 22, 481-489.

Shea, J. B. (2004). Quality of life issues in patients with implantable cardioverter

    defibrillators: Driving, occupation, and recreation. *AACN Clinical Issues*

    Advanced Practice in Acute Critical Care. 15(3), 478-489.

Shih, F. J. (1998). Triangulation in nursing research: issues of conceptual clarity and

    purpose. *Journal of Advanced Nursing*, *28*(3), 631-641.

Sinha, S. K., Mehta, D., & Gomes, A. (2005). Prevention of sudden cardiac death: The

    role of the implantable cardioverter defibrillator. *The Mount Sinai Journal of*

    Medicine, 72(1), 1-9.

Sirovatka, B. M. (1993). The implantable cardioverter defibrillator: Patient and family

    education. *Dimensions of Critical Care Nursing, 12*(6), 328-334.

Sneed, N.V., Finch, N.J., & Michael, Y. (1997). The effect of psychosocial nursing

    intervention on the mood states of patients with implantable cardioverter

    defibrillators and their caregivers. *Progressive Cardiovascular Nursing*, *12*, 4-14.

Sovari, A. A., Kocheril, A. G., Malineni, K. C., & McCullough, P. A. (2006). Sudden

cardiac death. *EMedicine.* Retrieved February 15, 2007 from

http://www.emedicine.com/med/topic/276.htm.

Steinbrook, R. (2005). The controversy over Guidant's implantable defibrillator. *New

England Journal of Medicine, 353*(3), 221-224.

Sudden Arrhythmia Death Syndromes Foundation. *Facts about sudden cardiac death in

the younger.* 2003. Retrieved September 20, 2004, from http://www.sads.org.

International Journal of Psychiatry Medicine, 10, 265-272.

Sullivan-Bolyai, S., Bova, C., & Harper, D. (2005). Developing and refining

interventions in persons with health disparities: The use of qualitative description.

Nursing Outlook, 53(3), 127-133.

Teplitz, L., Egenes, K. J., & Brask, L. (1990). Life after sudden death: The development

of a support group for automatic implantable cardioverter-defibrillator patients.

Thomas, S. A., Friedman, E., & Kelley, F. J. (2001). Living with an implantable

cardioverter-defibrillator: A review of the current literature related to

psychosocial factors. *AACN Clinical Issues, 12*, 156-163.

Thorne, S., Kirkham, S. R., & MacDonald-Emes, J. (1997). Interpretive description: A

noncategorical qualitative alternative for developing nursing knowledge.

Research in Nursing and Health, 20, 169-177.

Thurmond V. A. (2001). The point of triangulation. *Journal of Nursing Scholarship,

33*(3), 253-258.

Urizar, G. G., Sears, S.F., Handberg, E., & Conti, J. B. (2004). Psychosocial intervention

intervention for a geriatric patient to address fears related to implantable

cardioverter defibrillator discharges. *Psychosomatics, 45*(2), 140-144.

Whang, W., Albert, C. M., Sears, S. F., Lampert, R., Conti, J. B., & Wang, P. J. et al., (2005). Depression as a predictor for appropriate shocks among patients with implantable cardioverter defibrillators. Results from the Triggers of Ventricular Arrhythmias (TOVA) study. *Journal of the College of Cardiology, 45*(7), 1090-1095.

White, E. (2000). Patients with implantable cardioverter defibrillators: transition to home. *Cardiovascular Nurse, 14*(3), 42-52.

Yeo, T. P. & Berg, N. C. (2004). Counseling patients with implanted cardiac devices. *The Nurse Practitioner, 29*(12), 58-65.

Zahn-Waxler, C. (1996). Environment, biology, and culture. Implications for adolescent development. Developmental Psychology, 32(4), 571-573.

Zhi-Jie, Z. J., Croft, J. B., Giles, W. H., & Mensah, G. A. (2001). Sudden cardiac death in the United States, 1989-1998. *Circulation, 104* 2158-216.

Appendix A

Internet Newsgroup Posting for Recruitment via ZapLife.org

My name is Annette McDonough RN, MS and I am pursuing a doctoral degree at the University Of Massachusetts Graduate School Of Nursing in Worcester, MA. I am conducting a research study about the experience of living with an ICD. I am looking to interview adults age 18-40 years. The study would involve one 30-45 minute written interview asking the participant to describe the experiences of living with an ICD. You will be sent $25.00 upon completion of the written interview. The results of this study will provide the basis for an intervention program(s) to help future ICD recipients manage their life with an ICD. If you are interested in participating in this study please e-mail me at ajm0928@comcast.net.

Recruitment Brochure for ICD Clinic at MGH

Do You Have An Implanted Cardioverter Defibrillator And Are Between 18-40 Years Old?

If So, You Could Be Part of a Research Study Being Conducted At MGH

We are looking for individuals (both male and female) between the ages of 18-40 years old who have an implanted cardioverter defibrillator (ICD) to take part in a research study.

The purpose of the study is to understand what is has been like to be a younger adult and live with an ICD so that researchers can develop programs to help other younger adults adapt to living with an ICD.

If you are interested in taking part in the study:

- **You must have an ICD and be between 18-40 years old.**
- **Agree to one telephone interview lasting 30-45 minutes. You must have access to a telephone and speak English.**
- **You will be sent $25.00 after completion of the interview. If you are interested in taking part in this study please contact: Annette McDonough RN, MS at 781-254-5544.**

Appendix C

Recruitment Letter for ICD Recipients at MGH

Dear Patient,

I am writing to tell you about a research study being conducted. The research study involves younger adult patients (18-40 years old) with implanted cardioverter defibrillators (ICD). The purpose of the study is to understand what it is like to live with an ICD. The results of this study will help researchers to develop programs to help other younger adults adapt to living with an ICD.

If you agree to take part in the study it would require that you agree to **one** telephone interview describing what is has been like for you to live with an ICD. The interview will take about 30-45 minutes and it will be audiotaped. There is a possibility that we may need to call you back to clarify your responses to the questions. You will receive $25.00 after the interview has been completed.

There are no potential physical risks in taking part in this study, although recalling the events that led to your ICD implantation may cause you emotional stress. If that happens we will stop the study and you will be asked if you want to withdraw or continue with the study at another time. The benefit of taking part in this study is that you will be providing information about your experience of living with an ICD so that researchers can develop programs to help other younger adults living with an ICD.

Your audiotaped interview will be kept confidential and only the principal investigator and co-investigator will have access to the audiotape. Your information will not be shared with anyone but the principal investigator and co-investigator. Your name will not appear on any documents, a code number will be used to identify you. We will maintain confidentiality of your information at all times.

If you are interested in taking part in this research study please contact the co-investigator, Annette McDonough RN, MS at 781-254-5544.

Thank-you,

Diane L. Carroll RN, PhD, Principal Investigator

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Fact Sheet for ICD Research Study for ZapLife.org participants

ICD Research Study

Why is it being done?

The purpose of the study is to understand what is has been like to be a younger adult and live with an ICD so that researchers can develop programs to help other younger adults adapt to living with an ICD.

Who can take part in the study?

Individuals who have an ICD, who are between the ages of 18-40 years old, and who have access to a computer.

What does it involve?

To take part in this study you must complete a questionnaire via a secure website through the University of MA Medical School. The questionnaire will take about 30-45 minutes to complete and you will be sent $25.00 upon completion of the survey. There is a possibility that we may need to email you back to clarify your responses to the questions.

Are there any risks involved?

There are no potential physical risks in taking part in this study, although recalling the events that led to your ICD implantation may cause you emotional stress. If that happens we will stop the study and you will be asked if you want to withdraw or continue with the study at another time.

What are the benefits of taking part in the study?

The benefit of taking part in this study is that you will be providing information about your experience of living with an ICD so that researchers can develop programs to help other younger adults living with an ICD.

Your written interview will be kept confidential and only the principal investigator and co-investigator will have access to the transcript. Your information will not be shared with anyone but the principal investigator and co-investigator. Your name will not appear on any documents, a code number will be used to identify you. We will maintain confidentiality of your information at all times.

Appendix E

Verbal Informed Consent Script for MGH

The Experiences of Young Adults (18-40 years) Living with an Implantable Cardioverter Defibrillator (ICD).

Site Principal Investigator: Diane Carroll RN, PhD
Co-investigator Annette McDonough RN, MS

Description of Subject Population: Young adults with ICDs aged 18-40 years

Why is this research study being done?
The purpose of this research is to gain an understanding of what it is like to manage life with an ICD. We are asking you to take part because you are an individual who has an ICD in place and is between the ages of 18-40 years. This information will help researchers to tailor support programs for individuals ages 18-40 years with ICDs. About 25-35 people will take part in this study. We expect to enroll about 10-15 subjects from Mass General Hospital (MGH).

How long will I take part in this research study?
It will take about 30-45 minutes to answer the study questions via the telephone. You may be contacted one additional time via telephone to clarify previous answers if necessary. Is that OK?

What will happen in this research study?
You will be contacted by telephone for one interview. The questions will take about 30-45 minutes to answer and you will be audiotaped. In all records of the study you will be identified by a code number and your name will be known only to the researchers. Your name will not be used in any reports or publications of this study. **Your participation is entirely voluntary.** You may decide not to take part or decide to quit the study at any time, without any changes in the quality of the health care you receive.

What are the risks and possible discomforts from being in this research study?
Risks to you are minimal, except for the time involved. It also may be stressful to talk about your ICD. If at any time while answering the questions you feel it is too physically or emotionally tiring or upsetting, you have the option to stop the session. If the co-investigator notes any emotional problems (depression, suicidal ideation) you will be referred to or your primary care physician will be contacted.

What are the possible benefits from being in this research study?
You may not benefit directly from being in this research study, however, your participation will help researchers to understand what it is like for a young adult (age 18-

40 years) to live with an ICD so appropriate support groups can be developed in the future specifically for this age group.

Compensation: If you complete the study questions when contacted via telephone you will be sent $25.00 for your participation.

CONFIDENTIALITY: Your research records will be confidential to the extent possible by law.   In all records of the study you will be identified by a code number and your name will be known only to the researchers. Your name will not be used in any reports or publications of this study. However, the study sponsor, American Association of Critical Care Nurses or UMASS Institutional Review Board may inspect your research records that pertain to this research study.

QUESTIONS

Before you give verbal consent to participate in this research study, please feel free to ask any questions you may have about the study or about your rights as a research subject. You can call us with your questions and concerns at the following numbers:
Annette McDonough RN, PhD (c) is the person in charge of this research study. You can call her at 781-254-5544 any time. You can also call Diane Carroll RN, PhD at 617-724-4934 Mon –Fri from 8am – 4 pm with questions about this research study.
         If you want to speak with someone not directly involved in this research study, please contact the Partners Human Research Committee Office at 617-424-4100.

Fact Sheet for ICD Research for MGH Participants

ICD Research Study

Why is it being done?

The purpose of the study is to understand what is has been like to be a younger adult and live with an ICD so that researchers can develop programs to help other younger adults adapt to living with an ICD.

Who can take part in the study?

Individuals who have an ICD, who are between the ages of 18-40 years old, and who have access to a telephone.

What does it involve?

If you agree to take part in the study it would require that you agree to one telephone interview describing what is has been like for you to live with an ICD. The interview will take about 30-45 minutes and it will be audiotaped. There is a possibility that we may need to call you back to clarify your responses to the questions. You will receive $25.00 after the interview has been completed.

Are there any risks involved?

There are no potential physical risks in taking part in this study, although recalling the events that led to your ICD implantation may cause you emotional stress. If that happens we will stop the study and you will be asked if you want to withdraw or continue with the study at another time.

What are the benefits of taking part in the study?

The benefit of taking part in this study is that you will be providing information about your experience of living with an ICD so that researchers can develop programs to help other younger adults living with an ICD.

Your audiotaped interview will be kept confidential and only the principal investigator and co-investigator will have access to the audiotape. Your information will not be shared with anyone but the principal investigator and co-investigator. Your name will not appear on any documents, a code number will be used to identify you. We will maintain confidentiality of your information at all times.

Survey Tool/Interview Guide

Subject # _____
Date _____

Survey Tool/Interview Guide

Components of interview	Probe Topic Examples
What is it like for you to manage life with an ICD?	Can you tell about the experience of having an ICD and how did it come about (sudden cardiac death episode, other symptoms)? How has having an ICD affected you?
Can you tell me if there are any physical or psychological problems that you have related to the ICD?	Have you noticed any decrease in activity, pain (related to being shocked or zapped), or other symptoms? Do you have any psychological problems related to the ICD? Are you fearful, anxious or depressed? Are you having any problems with concentration, memory, ability to perform job, or school work? Are you concerned about sexual encounters, about the way you look, about driving? Are there other issues or concerns you would like to discuss (financial, childbearing, family, device recall or malfunction)?
Can you tell me about any strategies you have used to manage living with an ICD?	Is there anything particular you do to make life better with the ICD? Has it gotten easier to adjust to the ICD over time?

Appendix H

Internet Survey Tool/Interview Guide

Please answer the following questions on what it has been like to live with an ICD. Thank-you

ICD Survey

Demographics

* **What is your age?**

\[\]

* **What is your gender?**

\[Please make your selection ▾ \]

* **What is your race/ethnicity?**

\[Please make your selection ▾ \]

* **What is your marital status?**

\[Please make your selection ▾ \]

* **What is your occupation (specify)?**

\[Please make your selection ▾ \]

* **How many years of education do you have?**

\[\]

* **How long (in months) have you had an ICD?**

\[\]

* **What is the reason for your ICD placement?**

\[Please make your selection ▾ \]

* **What type of ICD do you have (manufacturer, model)?**

\[\]

* **How many battery changes have you had since implantation?**

\[none / one / two ▲▾ \]

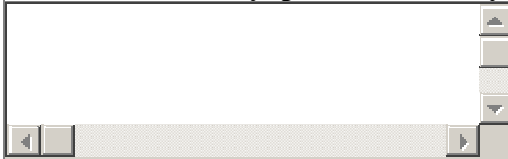* **What is the total number of ICD changes you have had?**

\[none / one / two ▲▾ \]

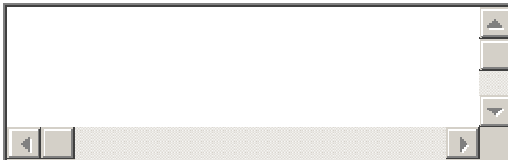**Experience of Living With an ICD**

* What is it like for you to manage life with an ICD? How has having an ICD affected you? Can you tell me about the experience of having an ICD.

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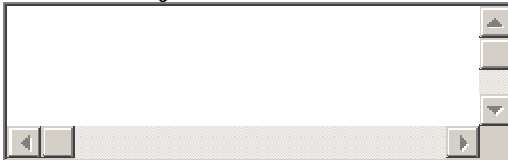
* Do you have any physical problems related to the ICD? Have you noticed any decrease in activity, pain, or other symptoms?

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* Do you have any psychological problems related to the ICD? Are you fearful, anxious or depressed? Are you concerned about sexual encounters? Are you concerned about the way you look? Are there other issues or concerns you would like to discuss?

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* Can you tell me about any strategies you have used to manage living with an ICD? Is there anything particular you do to make life better with the ICD? Has it gotten easier to adjust to the ICD over time?

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Appendix I

Demographic Data Sheet

The following information will be collected during the telephone interviews:

Participant # _____   Date: _____

Demographic	Answer
1. Age at last birthday	_____ years
2. Gender	(1) Male (2) Female
3. Race / ethnicity	(1) Caucasian / White (2) African American (3) Hispanic (4) Asian American (5) Native American (6) Other (Specify)
4. Marital Status	(1) Married (2) Widowed (3) Single (4) Separated (5) Divorced (6) Living with Partner (7) Other (Specify)
5. Occupation (Specify)	(1) Working full-time (2) Working part-time (3) On disability (4) Retired (5) Student (6) Other (specify)
Education	
6. How many years of education do you have?	
ICD Information	
7. How long (in months) with an ICD?	
8. Reason for ICD placement	(1) DCM (2) HCD (3) ARVD (4) LQTS (5) Brugada Syndrome (6) Don't know (7) Other (Specify)
9. Type of ICD	Model: Manufacturer:
10. Number of battery changes since implantation	None, 1, 2, 3, More
11. Total number of ICD changes	None, 1, 2, 3, More