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The Experiences of Women Who Live with an Implantable Cardioverter-Defibrillator (ICD)

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THE EXPERIENCES OF WOMEN WHO LIVE WITH AN IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR (ICD)

by

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Abstract

The implantable cardioverter defibrillator (ICD) is the most effective treatment available for terminating potentially life-threatening ventricular fibrillation and ventricular tachycardia. The ICD detects and attempts to correct these arrhythmias by pacing, cardioversion, and defibrillation thereby providing lifesaving therapy to patients at risk for sudden cardiac death. Currently, 150,000 Americans receive ICDs each year. Although most ICD recipients are men, more women are now qualifying for insertion (Stutts, Cross, Conti, & Sears, 2007).

Despite its established health benefits, ICD implantation is accompanied by psychological factors which merit research attention. This study investigated the experiences of women who live an ICD. The homogenous, purposeful sample consisted of 15 women who had an ICD that was implanted within the last three years and were receiving follow-up treatment at the same north Florida clinic. Data collection was accomplished through a semi-structured interview specific to the areas of pre-implantation, immediate post-implantation, and discharge home. Results were transcribed verbatim and then analyzed. Five core themes emerged from the transcripts along with multiple subcategories. The main themes included: Psychological Reactions, Physical Comfort, Procedural Issues, Body Image, and Feelings Regarding a Shock. Information obtained from this research is beneficial to nurses providing care to women with ICDs and to primary care advanced nurse practitioners in order to improve the overall health outcome and ongoing care of these women.

Chapter I

Introduction

Sudden cardiac death (SCD) takes thousands of lives in the United States each year. The usual cause of SCD is an unstable, fast ventricular rhythm. Ventricular tachycardia (VT) and ventricular fibrillation (VF) are the two arrhythmias that cause most of these deaths. When either arrhythmia occurs, the heart cannot pump enough blood throughout the body. Unless treatment is delivered within a few minutes, death is eminent. Long-term treatment options for people who survive life-threatening ventricular rhythms include medications, surgery, the implantable cardioverter defibrillator (ICD), or combination of treatments. ICDs are devices that sense these life-threatening arrhythmias automatically and deliver electrical therapy or lifesaving shock directly to the myocardium (Chen, Wu, & Ting, 2003).

Indicators for treatment with an implantable cardioverter-defibrillator (ICD) are expanding allowing more patients to qualify for its insertion. According to the 2008 American College of Cardiology/American Heart Association guidelines, basic criteria that are required before consideration of ICD therapy include; prior episode of resuscitated VT and/or VF after exclusion of completely reversible causes, left ventricular dysfunction due to a prior myocardial infarction (MI) that occurred at least 40 days ago, hypertrophic cardiomyopathy, optimization of medical therapy, and expected survival with a good functional status of at least one year (Association for Thoracic Surgery, Society of Thoracic Surgeons, 2008). Approximately 150,000 people in the United States receive ICDs each year (Stutts, Cross, Conti, & Sears, 2007). Patient reaction to the ICD has been an area of interest for researchers since its approval in 1985 (Sola & Bostwick, 2005). In general, most studies have suggested that implantation and activation of the ICD can cause adverse psychological impact on patients. However, since recipients of an ICD thus far have been mostly men, study participants have coincidentally been mostly men. In research that was inclusive of women, the ratio on average was four to one, men to women respectively.

The occurrence of ICD-specific fears and symptoms of anxiety are common psychological symptoms experienced by ICD recipients. These patients must cope with the prospect of life-threatening arrhythmias, rely on the device for the precise delivery of therapy, and live with the potential for the ICD shock. They may experience excessive worry and physiological arousal; in fact up to 38% have diagnosable anxiety. Other negative moods, notably anger, also increased after ICD implantation and were highest at the time of implantation (Carroll & Hamilton, 2008). The shock experience, device malfunction, and death are common ICD-specific fears of patients documented in previous research studies (Sears & Conti, 2006).

Purpose

The purpose of this study was to describe the experiences of women who live with an ICD. Study findings will be used to better represent women's issues caused by their ICD implantation which will aid in better preparation and treatment of such concerns by health care providers. Responses to women's ICD implantation is relevant to nurses since they often prepare patients for this experience and are often the first to hear of patients' unpleasant symptoms.

The framework for this research was based on the theory of unpleasant symptoms (TOUS). Implantation of an ICD may subsequently cause a variety of symptoms unique to women which are necessary to recognize. The TOUS, which is discussed further in Chapter II, focuses on multiple symptoms that coincide and relate to one another. According to this theory, additional symptoms are more likely to impair cognitive and functional performance. However, when one symptom is addressed, others become managed in the process (Gift, 2004).

Chapter II

Literature Review

This chapter will provide an overview of cardiovascular disease, its prevalence in the United States (US), and the underlying pathophysiology leading into coronary artery disease in general, with particular emphasis on sudden cardiac death (SCD). This will be followed by a brief discussion of the various treatments of cardiovascular and coronary artery disease with a focus on implantable cardioverter defibrillators (ICD) for the prevention of SCD. Finally, a review of the available evidence with respect to the patient's physical and psychological responses to the implantation of a cardioverter-defibrillator will be presented.

Cardiovascular Disease in the United States

Cardiovascular disease (CVD) is the leading cause of death in the United States. It is defined as any abnormal condition characterized by dysfunction of the heart and blood vessels. CVD is common in the general population affecting the majority of adults after 60 years of age. A substantial part of CVD progresses abruptly from asymptomatic disease to coronary events such as angina pectoris (chest pain/pressure/discomfort), heart failure (left ventricular dysfunction), cerebrovascular accident (stroke/brain attack), and death. Premature mortality occurs primarily in the part of the population that has more modifiable risk factors (Greenland, Knoll, & Stamler, 2003).

Age and gender differences are prevalent in CVD. For persons over 40 years of age, the lifetime risk of developing CVD is 49% in men and 32% in women. For those reaching 70 years, the lifetime risk is 35% in men and 24% in women. For total coronary events, incidence increases steeply with age, with women lagging behind men by 10 years. For the more serious manifestations of CVD such as myocardial infarction (MI) and SCD, women lag behind men in incidence by 20 years. Beyond menopause, the incidence and severity of CVD increases abruptly, with rates three times those of women the same age who remain premenopausal (Eckel, York, & Rossner, 2004).

Cardiovascular disease as a diagnostic category includes four major areas. One is aortic atherosclerosis and thoracic or abdominal aortic aneurysm. A second is peripheral vascular disease manifested by intermittent claudication and a third is cerebrovascular disease manifested by cerebrovascular accident and transient ischemic attack. The fourth category, coronary artery disease (CAD) which is manifested by MI, angina pectoris, heart failure, and cardiac death will be discussed (Eckel, York, & Rossner, 2004).

Coronary Artery Disease

Coronary artery disease is an abnormal condition that may affect the heart's arteries producing various pathologic effects, especially the reduced flow of oxygen and nutrients to the myocardium. The most common cause of CAD is atherosclerosis, which is the formation of plaque within a hardened arterial wall.

CAD can diminish the myocardium's blood supply until it causes ischemia, where the myocardium's cells remain alive but cannot function normally. Persistent ischemia or complete occlusion of a coronary artery causes infarction, or death of the deprived myocardial tissues. Risk factors for the development of CAD include age, genetics, male gender, dyslipidemia, hypertension, cigarette smoking, diabetes mellitus, obesity/sedentary lifestyle, increased serum markers for inflammation and thrombosis, hyperhomocysteinemia, and infection (McCance & Huether, 2006).

CAD often results in myocardial infarction (MI). This occurs when coronary blood flow is interrupted for an extended period of time. Cardiac cells can withstand ischemic conditions for approximately 20 minutes before cellular death occurs and is followed by tissue necrosis. Structural changes post MI lead to functional irregularities such as decreased cardiac contractility with abnormal wall motion, altered left ventricular compliance, deceased stroke volume and ejection fraction, increased left ventricular end-diastolic pressure, and sinoatrial node malfunction. All of these transformations in combination or unaided often lead to heart failure and life-threatening arrhythmias (McCance & Huether, 2006).

Arrhythmias are disturbances of cardiac rhythm and affect more than 90% of individuals post MI making them the most common complication of MI. Arrhythmias range in severity from occasional "missed" or rapid beats to serious disturbances that impair the pumping ability of the heart, all contributing to heart failure and death (McCance & Huether, 2006). For example, atrial fibrillation (AF) is the disorganized electrical activity in the atria characterized by quivering instead of pumping in an organized fashion (Chen et al., 2003). However, since AF does not affect ventricular contraction, it can be tolerated by most individuals (McCance & Huether). In contrast, a serious arrhythmia that can develop is ventricular tachycardia (VT) which consists of at least three consecutive ventricular complexes with a rate greater than 100 per minute. VT often may lead to ventricular fibrillation (VF) which occurs when the ventricles quiver very rapidly and beat irregularly instead of in an organized fashion. VF allows little or no blood to the body and death occurs if not treated with electrical defibrillation within minutes (National Heart Lung and Blood Institute [NLHBI], 2006).

Patients post MI are at risk for life-threatening arrhythmias which may lead to an unexpected death. When cardiac arrest or cardiac death occurs in this manner, it is termed SCD. This phrase is used to describe cardiac arrest with cessation of cardiac function, whether or not resuscitation or spontaneous reversion occurs; a misleading definition since not all affected individuals actually die (Pires, Lehman, & Steinman, 1999). The World Health Organization developed a clinical definition of SCD as the sudden collapse occurring within one hour of symptoms. However, as implied by the name, SCD is instantaneous and most individuals become unconscious within seconds to minutes as a result of insufficient cerebral blood flow. There usually are no premonitory symptoms. If symptoms are present, they are nonspecific and include chest discomfort, palpitations, shortness of breath, and weakness. Each year, between 250,000 and 450,000 Americans experience SCD, and 95% of them do die within minutes. SCD occurs most often in adults in their mid-thirties to mid-forties and affects men twice as often as women. Treatment of SCD consists of acute resuscitation with electrical defibrillation of most importance followed by long-term prevention of recurrence by pharmacological and nonpharmacological means (NHLBI, 2006).

Treatment of Coronary Artery Disease

Risk reduction is a key component of treatment of coronary artery disease. Three risk factors about which the most effort should be made to correct are hypertension, cigarette smoking, and blood lipid abnormalities. Control of these can significantly reduce the risk of CAD. In addition, control of diabetes mellitus is extremely important. Obesity and physical inactivity should be approached in correspondence with lipid reduction. Exercise is important for weight reduction and regulation of lipids (Edmunds & Mayhew, 2004).

Various pharmacologic treatments of CAD are available. For angina pectoris, nitrates are often used. Beta-adrenergic blockers and angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers are prescribed for hypertension and systolic dysfunction management. Antihyperlipidemic agents are used to aid in dyslipidemia. Aspirin or other antiplatelet agent/anticoagulants are used to aid in anti-thrombus formation (Edmunds & Mayhew, 2004).

Patients with arrhythmias can also be treated with medications. In AF, patients must remain anticoagulated with aspirin or warfarin. Non-dihydropyridine calcium channel blockers, such as diltiazem, and beta-adrenergic blockers, such as metoprolol offer control of the ventricular response seen with this arrhythmia.

Occasionally, cardiac glycosides such as digoxin are added to decrease the ventricular rate also. Patients with more serious arrhythmias, such as VT or VF can be treated with antiarrythmic medications. The most common is the class III antiarrythmic, amiodarone. Amiodarone is used both in emergency situations such as during the sudden cardiac arrest and prophylactically for patients at risk for lethal arrhythmias. Amiodarone does possess significant risks for adverse events however. It carries a black box warning due to its variable absorption and its prolonged elimination averaging 60 days. Patients using this medication are at risk for pulmonary and/or hepatic toxicity. Opposite of its desired action, is amiodarone's proarrhythmic effects including arrhythmia exacerbation, significant heart block, or sinus bradycardia (Edmunds & Mayhew, 2004).

Alternatives to pharmacologic therapy are available for the treatment of ventricular arrhythmias. Radiofrequency ablation can be an effective treatment for AF and VT. Surgery and cardiac transplantation are also options for certain arrhythmias. First line therapy for treatment of SCD is placement of an ICD since it has proven more effective for improving survival than any other (Sola & Bostwick, 2005).

ICD Functions and Components

An ICD can deliver life-saving electrical treatment and may be used to help correct an arrhythmia. An ICD is a small electronic device implanted in the body to monitor the heart continually. It functions as a pacemaker for slow heart rates but when ventricular arrhythmias occur, it treats the rhythm with the specific type of electrical therapy required. The three types of electrical therapy are:

rapid-pacing, low-energy shock, and high-energy shock. Depending on patient needs predetermined with results of an electrophysiology study, electrical therapy is delivered via pacing, a shock, or a combination of the two. For example, if VT occurs, the ICD may deliver small electrical pacing pulses to correct the rhythm which the patient does not feel. If a normal rhythm is not restored, the ICD will then deliver a shock. The ICD also records and saves information about any therapy delivered which aids in discovering what occurred during each episode (Mayo Clinic, 2005).

There are three elements of the ICD system: sensing electrodes, defibrillation electrodes, and the pulse generator. Sensing (or the ability of the ICD to "see" intrinsic activity) is accomplished by closely spaced tip and ring electrodes that provide high amplitude narrow electrograms. These sensing electrodes are positioned transvenously on the right ventricular apical endocardium during implantation. The electrodes record normal beats that are sufficiently large enough for analysis during ventricular tachycardia and fibrillation. Dual chamber ICDs have an additional electrode in the right atrium for atrial sensing and pacing. The defibrillation electrodes have a relatively large surface area and are positioned to maximize the density of current through the ventricular system. The lead systems utilize the "active can" technology in which the metal housing of the ICD serves as one of the shocking electrodes, which requires that the pulse generator be implanted in the pectoral region. The pulse generator, which is about the size of a stopwatch, contains the sensing circuitry as well as the high voltage capacitors and battery. After detecting a tachyarrhythmia, the pulse generator responds by antitachycardia pacing or by delivering low- or high-energy shocks (Sola & Bostwick, 2005).

ICD Implantation

Traditional implantation of an ICD usually requires two incisions. Usually, local anesthesia is administered to numb the area of the incisions and intravenous sedation medication is used for relaxation and comfort. The ICD lead systems are typically placed transvenously via the axillary, subclavian, or cephalic vessel through a puncture in the skin. They are passed to the heart using X-ray equipment to follow the progress, then are positioned and tested before connection to the ICD. Proper functioning is tested by the physician shocking the heart in such a way to create a fast ventricular rhythm. The patient does not feel the arrhythmia or shock due to the general anesthesia administered at this point. The pulse generator is then inserted through a 2-3 inch incision created for a subpectoral or subfascial pocket in the left chest wall (a right sided implant may be performed but is not preferred). The pocket incision is then closed with subcutaneous sutures and steristrips (Mayo Clinic, 2005).

This particular placement type may pose more of a problem for women specifically. Both visible scarring and bulging around the implant site are produced by placement of the 78gram/40cm^3 device underneath the skin; a location women's clothing often leaves exposed. The incision may be swollen and red for weeks and after the puffiness subsides, the outline of the generator and leads may be seen. The weight of the breast itself may pull and tear on incision, making the scar larger still. Practical limitations of bra straps, purse straps, and seat belts may affect the female ICD implant recipient because of this location (Sowell, Kuhl, Sears, Klodell, & Conti, 2006).

Immediate Post-Operative Care

After ICD implantation, nursing care is imperative. A pressure dressing over the ICD incision site is applied for the first 12 hours in order to maintain the integrity of the newly constructed body pocket. Hospitalization usually consists of one overnight stay. Patients are on bed rest for two to six hours or until the following morning in order to prevent slippage of the generator out of the surgically formed pocket. Pain in the upper chest area incision may occur. Patients are instructed to not raise the arm past shoulder height on the ICD side for four weeks in order to avoid misplacing the leads. An arm sling is often provided to discourage movement of the affected side's arm for the first post-operative day since ambulation is expected. Before discharge home, a chest X-ray is taken to guarantee proper placement remains. The ICD is also interrogated to ensure proper function and adjustments are made to settings if necessary (Mayo Clinic, 2005).

Discharge Home

There are multiple instructions for patients discharged home after immediate ICD implantation. Showering is permitted 48 hours post implant and the steristrips may be removed in two weeks if still attached. Vigorous activities or exercises that cause the arm to be stretched behind or raised above the shoulder are prohibited for four weeks which allow formation of scar tissue around the lead and lead anchors. Patients are encouraged to wear the sling at bedtime if they are likely to sleep with their arms over their head. Driving is restricted until the health care provider allows. Since five to ten seconds pass before the ICD senses the arrhythmia and provides a shock, patients may become dizzy or lightheaded, which could endanger safety of all drivers (Mayo Clinic, 2005). The time of the greatest risk for recurrent events is six months post implant which is the normal driving restriction. However, once the ICD discharges, the six-month driving restriction is reinstituted (Chen et al., 2003).

Activity and effects of electrical equipment on the ICD should be addressed at discharge. Contact sports are prohibited since an impact can be harmful to the ICD even after scar tissue formation. Airport security metal detectors will not harm the ICD but may be activated by the device which is why the ICD identification card should always be carried. Because of potential interference, patients with ICDs must remain farther than eight feet from an arc welder and also avoid powerful magnets and any heavy industrial equipment. Most providers recommend cellular phones be kept at least six inches from the ICD and on the opposite side. ICD recipients must not lean over a running engine and can never have a magnetic resonance imaging (MRI) test (Mayo Clinic, 2005).

Indications for implantation of an ICD are expanding. The ICD is now recommended not only for survivors of sustained VT and/or VF (due to successful resuscitation) but for those at high risk for SCD. Generally stated, patients who are at risk of developing ventricular arrhythmias, including heart failure patients, qualify for an ICD. Increased indications for ICDs are a result of their proven superior outcomes compared to pharmacologic therapy. Antiarrythmic medications help prevent ventricular arrhythmias but their accompanied side effects and toxicity are of concern to patients and providers. While an ICD will not prevent lethal ventricular rhythms, it will reverse them as they occur without the previously described adverse effects of antiarrythmic medications (Chen et al., 2003).

Evidence of Psychosocial Issues

Anxiety is a common finding amongst many studies concerning patients with ICDs. A literature review performed by Sears and Conti (2002) surmised that it is particularly common, with approximately 24-87% of ICD recipients experiencing increased symptoms of anxiety after implantation with up to 38% of patients eligible for a clinical diagnosis of anxiety. They stated that as long as the ICD is seen as a "shock box," it will remain a significant source of anxiety. They also found it likely that ICD recipients will need an amount of psychological adjustment evidenced by 9-15% of patients having clinically diagnosed depression. Another researcher, Dunbar analyzed transcripts of stories told by ICD patients from her previous phenomenological studies in order to obtain a description of the experience of living with an ICD after a sudden cardiac death (2005). Three themes that emerged, and essentially led to the constitutive summary of redefining life while forestalling death were; 1. losing control: technology as lifesaving yet changing everything, 2. getting on with living, regaining control or conditional acceptance, and 3. creating a new vision, transformation or tenuous truce. Both studies' researchers suggested routine consideration of psychosocial needs as part of the clinical care of ICD patients. They further recommended that advice measurement and interventions should focus on patient acceptance of the device.

The personal impact of the device on families and/or partners of recipients emerged from previous studies. In 2004, Albarran, Tagney, and James performed an exploratory qualitative study with interviews of eight partners of ICD patients; six wives and two husbands. Through their findings, they suggested that partners of ICD recipients progress slowly through various difficult and adaptive stages when learning how to best support the patient. Partners start by acknowledging the patient's need for the ICD, then reacting to it. The partners then tend to safeguard the patient; finally reaching the point when they are able to assume control and normalize their lives. Carroll (2006) conducted a descriptive qualitative study with ten men and two women in an attempt to discover their experiences of returning to sexual activity after ICD insertion. Results of semistructured interviews suggested that patients with ICDs approached sexual activity with anxiety, apprehension, and varied amounts of interest and patterns of activity. All participants expressed a need for more information and sexual counseling. The anxiety of the partners of ICD patients in this study also often resulted in overprotectiveness of the patient with the ICD.

In addition to discovering studies which validate psychosocial issues of patients with ICDs, causation of these issues and aid in extinguishing them also surfaced from the literature review. A randomized, controlled, prospective study in the UK investigated the effects of a 12 week comprehensive cardiac rehabilitation (CCR) program on patients with an ICD. Participants included 14 men and 2 women. CCR appeared not only safe, but it improved exercising ability thereby lowering levels of psychological distress. Researchers therefore proposed that CCR reduces levels of anxiety and depression of patients with an ICD (Fitchett et al., 2003). Also, Tagney (2004) explored the confidence and competence of nurses in preparing patients for insertion of an ICD and for home life post discharge. She used questionnaires on 152 cardiology-associated nurses as her method and sample. Results of her study suggested that nurses were not confident in their ability to prepare these patients. Therefore, educating the nursing staff for pre-implantation and prescribing CCR post-implantation may pose solutions to decreasing the number of psychosocial issues of patients with ICDs.

Less Evidence of Psychosocial Issues

While performing this literature review, some research findings contradicted the idea that patients with an ICD experience psychosocial issues. While the majority of research pointed to a psychological problem, some were not so clear.

A recent cross-sectional correlational design study that included 46 women of the total 174 subjects investigated quality of life, mood states, and global adjustment after ICD implantation. Researchers found four subscales; fear/anxiety, attitude, preparation, and body awareness. Perceived adjustment was good for the majority of participants and was unrelated to sex, age, and shock experience. They witnessed no gender differences, but noted disparity in body awareness, physical functioning, and fatigue (Beery, Baas, & Henthorn, 2007).

Two different groups of researchers in the UK performed two literature reviews in order to investigate psychological impacts of ICD implant on patients. Both reviews concluded that psychological problems probably result more from the underlying disease instead of the direct response to the implant itself. The meta-analytic review of 20 studies was conducted at a time when more patients were being treated with medication instead of the ICD and so reported no significant differences in the psychosocial outcome between ICD patients and medication-maintained patients or between pre- and post- implant ICD recipients. Researchers pointed out that ICD recipients did report significantly worse psychological and psychosocial functioning than other cardiac controls (Burke, Hallas, Clark-Carter, White, & Connelly, 2005). The other team paraphrased data from a large randomized trial by suggesting, "...ICD therapy is neutral or possibly beneficial with regard to QOL and patients can expect to feel as well [or as poorly] as they did prior to implantation" (McCready & Exner, 2003, p. 68). The researchers from this literature review admitted that ICD patients are at risk for adverse psychological symptoms and poor quality of life (QOL) but rarely in direct response to the ICD itself.

Additional contradiction to development of mental concerns of patients with ICDs was suggested by another pair of research teams who both performed studies concerning changes over time pertaining to quality of life (QOL) and other psychologic issues. One study's researchers used a QOL index and Mishel's

Uncertainty in Illness Scale. Results of their study were that the overall QOL and health/functioning of patients with an ICD were unchanged over time. They did point out that the first year post implantation was the most stressful and uncertain time since this was before the patients had accepted and adapted to their changed situation. The researchers' overall suggestion was that QOL for most patients with an ICD was reasonably good after implantation once they had passed the first year post implant (Flemme et al., 2005). The other research team utilized a prospective, descriptive, repeated, measures design which consisted of questionnaires completed by 19 females and 51 males. They investigated changes in perception of health status, psychological distress, and QOL from baseline to six months, and then 12 months post implantation. Researchers found no significant changes in the physical and mental health composite summary scores over the first year. The authors claim their study identified an improvement in psychological distress over time with a reduction in negative psychological distress from baseline to six months. They recommended further research since they confess, "...the effects of ICD living are not well understood" (Carrol, Hamilton, & Kenney, 2002, p. 213).

Despite nonsupporting evidence of psychosocial issues in patients with an ICD in this section, all researchers recommend further research. None of the four projects discussed were clear and concise. The fact that the majority were all foreign and not very current should be considered.

Increased Stress, Risk, and Lack of Women Subjects

Some study results' dismissal of the idea that patients with an ICD have psychological issues might give justification to cease research pertaining to it. However, all studies discussed thus far have had an unequal representation of women versus men as participants. Also, research has proposed that cardiac arrhythmia and increased stress have a positive relationship. While most authors recommended more research in this area, all stated that women need representation too.

As noted at this point in this literature review, the UK has a few recurrent researchers interested in patient reaction to the ICD, such as Tagney and Dunbar. Tagney (2003) had another work of a literature review published on the subject. Some of her findings included that fear and anxiety relating to the anticipation and unpredictable nature of the ICD shocks are common whether patients had experienced a shock or not. She also found a link between adverse psychological reactions and prospective predictors for occurrence of subsequent arrhythmias and shocks. Another author who noted the relationship between increased stress and increased risk of ventricular arrhythmias was Dunbar. She reminds other researchers that persistent, negative emotions are associated with increased serum levels of catecholamines, which result in vasoconstriction, increased heart rate, and automaticity. This stimulates corticosteroids which causes decreased healing and potentiates the effects of the catecholamines. Hence, higher levels of psychological distress may affect health by increasing the risk of cardiac arrhythmias (2005). Therefore, negative emotions may be a cause, not a consequence of arrhythmia events. Both Tagney and Dunbar noted the need to further discuss women's issues.

Further in her literature review, Dunbar commented on the need for written women's reactions to the ICD. She noted that being female is one factor associated with increased psychological distress and reduced functioning. She reported that, "...the ICD takes on special meaning" (p. 295) for women in relation to roles and concerns about childbearing and routine mammograms. Compared to men, women have increased pain during recovery due to the sensitivity of breast tissue and women's greater use of their arms in daily activity.

Another recent domestic literature review regarding anxiety and QOL of patients with ICDs was done by researchers from the Mayo Clinic. Congruent with previous study findings, Sola and Bostwick (2005) stressed the importance of attending to the psychosocial issues of patients with ICDs. They justify this caution since negative emotions are associated with increases in arrhythmias and psychiatric illness can interfere with recovery from medical illness. These researchers also stated inconclusiveness of gender-related susceptibility to ICD induced psychopathology, with reason that subjects are mostly men. They reported that some authors in their literature review suggest that women with ICDs have an independent risk of developing mood disorders and experiencing decreased QOL.

The three discussed studies questioned the idea of a relationship between psychological problems and cardiac arrhythmias. All of these researchers addressed the lack of women subjects. Therefore, more research is needed to further clarify these issues.

Evidence of Women-Specific Issues

The clinical effectiveness of the ICD has been well established for treating patients with life threatening ventricular arrhythmias. However, as demonstrated thus far, available research has mainly involved men. This phenomenon allows for study findings to be generalized to all patients allowing for the unique health concerns of women in this area to go misrepresented.

Depression and anxiety are a common finding in studies of patients' reactions to ICD implantation. A quantitative study performed in Turkey which aimed to evaluate the emotional status of patients with an ICD, indicated the presence of depression and anxiety in nearly half of the sample. Subjects noted that they had more limited lifestyles and 6% reported that they did not even leave their homes after implantation. In females, depression and anxiety levels were found significantly higher compared to males, with housewives having the highest mean scores. Even though this study had an uneven amount of female vs. male subjects (22: 79), the authors were able to suggest that female gender was an independent predictor for increased anxiety scores (Bilge et al., 2006).

Other issues specific to women were pain and sleep. A study of 20 ICD recipients performed in Sweden suggested that though sleep disturbances were the greatest problem in both men and women, it was significant in women (Carlsson, Olsson, & Hertevig, 2002). A more recent and domestic study of gender differences in ICD insertion also asserted that women had more sleep difficulties than men. Since increased amounts of pain were noted in the female subjects of this study, pain could be a factor in their difficulty in sleeping (Smith, Dunbar, Valderrama, & Viswanathan, 2006).

Previously referenced researchers in this literature review performed yet another study of patients' experiences of learning to live with an ICD. The UK researchers conducted a qualitative, descriptive study using interviews of eight patients; two female, six male. Though all experienced varying degrees of psychological, social, and physical adjustment both pre- and post- ICD implantation, some issues of pain and sleep were unique to female participants. One woman in this study described continued pain from her sub-mammary incision site which restricted her sleeping positions for six months after implant. She was quoted as, "I was getting a pain under my shoulder blade. I can't lie with this arm underneath my breast anymore" (p. 198). She also reported that due to this, she had to restrict her bra type worn post implant, specifically no underwire bras (Tagney, James, & Albarran, 2003).

A specific study on women with ICDs was completed in the United States by Walker et al. regarding women's unique issues (2004). Researchers reported that a woman's identity as a caretaker and caregiver might be threatened by the actual and perceived activity limitations imposed by the ICD or the underlying heart condition. They also found that both reproductive and sexual health are important issues for women since 25-50% of female patients with ICDs reported concerns in this area. Due to the emphasis on women's physical attractiveness, body image was also of concern. The ICD's scar and lump in the pectoral area can become an issue. This is parallel to the previously discussed study where one female subject reports that she thinks, "...one breast is higher than the other now" (Tagney et al., 2003, p. 199).

Implanted cardioverter-defibrillator implantation does seem to pose unique issues for women. Women share problems of anxiety and pain with men, but sleep disturbances, body image, and reproductive health are specific to women. There still seems to be an absence of complete, empirical, research data on the impact of these concerns.

Theoretical Framework

The theory of unpleasant symptoms is an appropriate theory to guide research on the experiences of women who live with an implantable cardioverter defibrillator. As this literature review demonstrates, most patients living with this device experience a variety of unpleasant symptoms. More specifically, research shows women have many unique symptoms which could be treated more efficiently if this theory was incorporated into their plan of care (Sears & Conti, 2006).

The middle range theory that fits this research project is the theory of unpleasant symptoms (TOUS). The TOUS was formulated as a result of another project, where two researchers, Drs. Linda Pugh and Audrey Gift were in the process of defining management of two separate symptom models, fatigue and dyspnea, when they noted similar models and interventions could be applied to both symptoms with good results. The researchers realized that since their two symptoms were so multiplicative, this relationship could be applied to other groups of symptoms as they occur in a dynamic clinical situation, thus the TOUS was developed. The TOUS would provide nurses with one model to aid in understanding and managing all unpleasant symptoms (Gift, 2004).

Since its development and after a revision in 1997, the TOUS can be found thoroughly used in research and in the clinical setting. Although not conducted to test the theory, several published studies regarding other symptoms such as nausea, pain, and additional gastrointestinal symptoms have yielded findings consistent with the TOUS. Secondary analyses and subsequent studies by the theory's developers and colleagues have contributed support by relating it to fatigue during pregnancy, childbirth, and the postpartum period and in dyspnea in patients with asthma and chronic obstructive pulmonary disease (Lenz, Pugh, Milligan, Gift, & Suppe, 1997). The TOUS has performed well at describing, predicting, and explaining similarities of the management of groups of unpleasant symptoms.

Research has suggested that patients with an ICD experience a variety of unpleasant symptoms (Sears & Conti, 2006). Therefore, utilizing this theory to guide this research was appropriate. Using this theory in the care of women with an ICD seems suitable as well since, if a nurse can tackle all or at least group the symptoms together in order to treat with the same interventions, patients could be managed more efficiently.

Although this study is qualitative in nature and so has no hypothesis, primary, or secondary research questions, assumptions of results were still made. According to research, all patients with an ICD experience some amount of depression and anxiety. However, symptoms of pain, difficulty sleeping, and decreased quality of life are more significant in women than in men. Studies have also shown that women with an ICD have issues specific to them like sexual and reproductive health, body image, and changes in their perceived role as caregiver (Sowell, Kuhl, Sears, Klodell & Conti, 2006). It was presumed therefore, that this study would yield similar findings.

The TOUS concepts can be applied to this study in reference to prior research results. As previously stated, the majority of studies show that women must make psychological, social, and physical adjustments to their ICD. This is congruent with the minor concepts under influencing factors of physiologic, psychologic, and situational of the TOUS. These factors influence symptoms which lead to consequences of the symptom experience (Lenz et al., 1997). This reciprocal phenomenon has surfaced in research performed regarding women with an ICD and was assumed to take place in the study.

In conclusion, the theory of unpleasant symptoms was an applicable concept to guide the research study of the lived experiences of women with an implantable cardioverter- defibrillator. Since women with an ICD encounter many symptoms pre- and post-implantation, and immediately upon hospital discharge, it can be assumed that these symptoms vary. However, with the help of the TOUS, management and prediction of these unpleasant symptoms would become more obvious.

Chapter III

Methodology

This level one descriptive qualitative study examined the experiences of women who live with an ICD. This chapter will provide an overview of the setting and sample, methods, and procedures used in the study. Analysis and protection of the human subjects are addressed and the incorporation of the theory of unpleasant symptoms is provided.

Setting and Sample

The sample for this research study was attained from a cardiac clinic in northern Florida. The clinic had 236 current ICD patients with 55 of them being female at the time of data collection. Because qualitative samples are small in size and sampling needs may change as the study progresses, it is important to not incorporate too many participants at the onset of the study. Therefore, the target population for this study was met with a purposeful, homogenous sample consisting of the typical 15 participants used in a thematic analysis (Norwood, 2000). The inclusion criterion was adult, cognitively intact females who had the ICD for less than three years. Exclusion criterion was patients awaiting discharge from the hospital after implantation. In order to ensure participant comfort and convenience, interviews were undertaken after follow up appointments in a private room at the clinic and lasted no longer than 60 minutes.

Procedure

Qualified women were invited into the study by telephone call by an appointed staff member of the clinic who was familiar to them (See Appendix A). After participants agreed to participate, the date, time, and place of the interview were verified. A semi-structured interview schedule developed around the areas of pre-implantation, immediate post-implantation, and discharge home was the instrument used (See Appendix B). Open ended questions and prompts were utilized to help elicit the unique experiences, beliefs, and attitudes of the women subjects. In conjunction with the theory of unpleasant symptoms, various complaints by the women were captured. After obtaining written informal consent, the interviews were tape-recorded and then transcribed. Field notes were kept in the case of participants giving further relevant information before and after the taped interview.

Data Analysis

During data analysis, control and validity issues were addressed. In order to maintain truth value, the researcher asserted that the study remained subject-oriented instead of researcher-imposed. Responses were carefully monitored by maintaining a journal and debriefing with a colleague to ensure objectivity. In order to declare external validity, the researcher strived for informational adequacy and continued to perform careful data-analysis techniques. Fittingness was granted once the researcher left a clear decision trail so that any reader can follow the progression of the interview, understand the logic, and can arrive at the same conclusions as the researcher in interpreting the data. The content of each transcription was independently analyzed in order to obtain the sense, meanings, and context of the women's experiences. Selected quotes and textual passages were assigned codes and then verified by the thesis chairperson in order to validate analysis and interpretation of the participants' experiences (Norwood, 2000). This process allowed themes and categories to emerge. The appropriateness of the theory of unpleasant symptoms as a framework for the study then further surfaced.

Ethical Issues

Approval for the study was attained from the Mayo Clinic Institutional Review Board (IRB) (See Appendix C) and from the University of North Florida IRB (See Appendix D). Informed consent was required for all participants and was retrieved just prior to the interview (See Appendix E). Also at the initiation of the interviews, participants were briefed on the interview procedure and reminded that they have the right to withdraw at any time and to refuse to answer any of the questions. In order to maintain anonymity, all participants were assigned and referred to as a lettered number. All of the recorded tapes were destroyed once transcribed.

Chapter IV

Results

Actual demographics for this study were comparable with the researcher's anticipation. Twenty-four eligible women were contacted in order to obtain the targeted number of 15 participants. Three women refused, two did not return a phone call, three did not meet criteria, and one woman did not show for her scheduled interview. All participants were currently receiving care at the same clinic and all but three had their ICD implanted by the clinic's affiliated electrophysiologists. Forty percent were inserted by a particular surgeon followed by another who inserted 20% of the devices. Of the 15 participants, four had received a high voltage, symptomatic shock. The majority or nine participants were over 65 years of age (yoa); 27% were 79-83 yoa, 33% were 70-74 yoa, and 20% were 62-69 yoa, and 49-55 yoa respectively. The 15 participants were of white race and maintained a mid- to upper socioeconomic status. All had their devices for less than three years at the time of data collection. Forty percent had ICD implantation three years ago, 33% had it two years ago, and 27% had it less than two years before.

Five core themes emerged from the analysis of the women's transcriptions along with multiple subcategories. The main themes include: Psychological Reactions, Physical Comfort, Procedural Issues, Body Image, and Feelings

Regarding a Shock. Discussion of the themes with examples of each are provided next.

Psychological Reactions to the ICD

The narratives illustrate an overwhelmingly positive reaction to the functions of the ICD. Psychological reactions derived mostly from the interview question regarding the ICD's major effect on the participant's life. Eighty percent of the participants made some sort of reference to feelings of reassurance of having the ICD in case they need it and are the 12 participants discussed here. Three of those 12 participants related the ICD's functions to the Emergency Medical Service (EMS) surmising that the ICD is more efficient at defibrillation since the ICD, "...would take care of it (a cardiac arrest) immediately instead of having to wait for some paramedic to come and do it'" and that, "It would be better than 911." One participant referred to her ICD as her "...own portable device" and her own "...life jacket" implying by the remainder of her discussion that she feels secure with the ICD; an idea most of these 12 participants shared.

Half of the 12 participants referenced under this theme commented on that idea of protection but actually say the words "safe" or "secure." For example, one woman reported that the ICD "...is my safeguard..." while another stated, "...it makes me feel secure." One participant demonstrated strong conviction regarding safety by her quote, "I am thinking that if anything goes wrong with my heart, the thing will do its number and save me, so you can say I feel safer." Satisfaction and reassurance were evident in several transcripts. One woman who did not elaborate much except in this area of Psychological Reactions, reported that the ICD provided a "…security of knowing it is there…if something happens, I got it." Yet, another participant was relieved to have her ICD since she no longer felt she had to agonize over her risks of SCD reporting that "…I didn't have to worry about whether I was having a heart attack every time I felt a twinge somewhere…I just felt the most amazing sense of relief about that…I feel better."

Further positive Psychological Reactions were evident in the 12 participants' transcripts. Many viewed the ICD with a sense of assurance. Two women quote the word "insurance" and go on to report that the ICD has already saved their lives. One participant remembered exclaiming that she, "…was going to live!" after first receiving the recommendation for the ICD. Five in this group of 12 used favorable descriptions when commenting on their general reactions to the ICD. Words like; "great," "wonderful," "excellent," "grateful," "very blessed," "awesome," "thankful," and "satisfying" dominated the majority of their narratives regarding this theme. In general, most participants were, "…glad to have it."

Multiple participants remarked on the technology of the ICD itself. Two participants made references like, "…the technology is here, it's awesome," and "I think it is a great thing myself that you have something that can help you," and "they can check you (she referenced ICD interrogations) and find out what is going on…that is very satisfying." Eight of the 12 participants implied that their device was "smart."

While most of the 12 participants discussed under this theme verbalized encouraging descriptions of Psychological Reactions to their ICD, some demonstrated more neutral views. Along with commenting positively, 33% of the women also reported a lack of worry about the ICD and/or their health, and that the ICD, "...doesn't bother..." them and that they "don't think about it." Many of them implied that if the ICD was what they need, then that "is the way it is." One participant gave mixed comments saying, "It really hasn't done much for me." She however, went on to very casually say that the ICD's prevention of SCD is a good thing and that "...they are great *evidently*." Twenty-five percent of participants expressed some doubt that their ICD would always help them; quoted by one as, "I hope it lasts" and another hesitantly stated, "I *guess* I feel more confident." Within this group of participants, it seemed that the longer the participants had the ICD, the less positive comments they had regarding its effects on their lives.

Physical Comfort

The core theme of Physical Comfort arose mostly from the interview questions regarding immediate discharge home after implantation of the ICD. Eighty-seven percent of women remarked in some noteworthy manner on physical comfort from the implant whether it was immediate post operative or still continues today. It is interesting to note that the three participants who had no significant remarks regarding pain had their ICD implanted the furthest time ago, had a harder time recalling events than the other 12, and were aged 70, 74, and 80 years.

Four of the 13 women referenced under this theme reported some degree of immediate post operative discomfort. Three of those four stated intense discomfort by recalling the pain as severe and lasting for an excessive amount of time. Some of their stated feelings post operatively were; "...really, really quite painful, " "...the pain was terrible," the pain, "...was the worst thing," and "...it lasted so long." One participant, a retired nurse, recalled her immediate encounter with the pain as, "Honey, I had to lay down and keep still, just lay in bed. I couldn't do anything. I couldn't have a conversation with you, it was so bad." She was implanted three years previously, which suggests her experience as intense as she recalled the events easily. It is interesting to note that the only other nurse who participated in this study was also one of these four participants who reported intense postoperative discomfort.

Some participants recalled specific reactions/occurrences immediately post operatively, but with less negative emotion than described in the previous paragraph. Two women reported that waking up after the surgery was not painful and that the incision was not really uncomfortable. However, they both go on to criticize the dressing of the incision, stating, "...they put a pressure tape on the area and it was cutting into me...that was the only pain I was really having," and, "...it felt funny; all that gauze." One of those two women went on to say that she did have some discomfort once the anesthesia wore off. She reported increased discomfort from keeping her left arm on pillows in order to abide by the activity restriction given to her as she recalled it.

Two participants voiced concern of addiction to the narcotic pain medication prescribed upon discharge. One woman was so apprehensive that she did not even fill her prescription, stating she "...just took Tylenol." The other convinced herself that the "...discomfort could be in my head so I figured I am not going to get addicted to anything…" She allowed her husband to dispense the narcotic at his discretion as if to save her from becoming addicted.

Three study participants within this group described discomfort related to the position or placement of the ICD post operatively and currently. Of interest is that the most complaints related to this subcategory of position/placement were from one of the three participants who had her ICD implanted by a non-clinic affiliated physician. She recalls her initial discovery of the ICD's positional discomfort and how it still feels today:

> I could feel it rubbing against my collarbone…It was painful and it hurt to even lie down at night to sleep because of it rubbing on my collarbone. It has shifted down a bit and I can put my thumb between the collarbone and the ICD now… If I were lifting something out of the closet I would have to be careful because then it really shifts it back up again…

She went on to report that she is used to it most of the time. In congruence with this particular participant's discomfort while sleeping, two other women had similar characterizations which were also in line with previous research (Tagney, James, & Albarran, 2003). One woman described a pinching sensation when she sleeps on her side and has to,"…get it [the ICD] just right." Another woman depicted sleeping as, "…if I lay on that side, I feel it and it kind of hurts…I put pillows on so there is not so much pressure but you are aware of it that way."

Thirty-one percent of the participants discussed in this Physical Comfort theme depicted the ICD as not causing true pain, but more of a sensation of its awareness. One participant reported that after one year of her implant, the device itself remains somewhat sensitive. She worries about someone, "bumping into it" and that she doesn't, "want anyone to hit it." Another woman who was very thin, stated that, "cold weather seems to bother mine...when I'm cold, it seems like it aches." All four mentioned that the seatbelt and/or their bra straps currently irritate the ICD site, which is also congruent with previous research (Tagney, James, & Albarran, 2003).

Twenty-three percent of the women depicted among this core theme denied any physical distress related to their ICD. It is important to note that all of these women had their devices implanted three years prior to their interviews and reported no pain both immediate post operatively and today. One participant compared her implant procedure to her open-heart surgery seven months prior expectantly describing the ICD implantation as the "easier one." She stated she is totally unaware of the ICD unless she physically touches it which then she thinks, "Yes, I have this thing in me." Throughout her transcripts, she was repeatedly quoted as saying, "It hasn't bothered me at all." Another participant was in agreement with those ideals as demonstrated by her stating, "It doesn't bother me a bit. In fact, I hardly know it is there sometimes. I feel it if I touch myself but it doesn't ever give me any kind of feelings.... it has never bothered me."

Procedural Issues

A third theme, Procedural Issues, emerged from the transcripts and encompassed the highest number of comments. The interview schedule was mainly composed of questions regarding pre and post ICD implant and discharge home which explains this theme's size. Multiple subcategories surfaced mostly in the area of education and preparedness for ICD implant and will be discussed next. All fifteen participants commented in this area and will be represented here.

Noteworthy discussion from participants' recollected thoughts upon first hearing they needed the ICD transpired from 27% of the sample. None portrayed any sense of alarm upon learning that they needed the ICD, which was incongruent to other research (Bilge et al., 2006). In fact, the most negative comment observed was, "…well naturally I was a little apprehensive…" However, a counterbalance of her opinion was later made with, "… if that is what we needed, then that is what we needed." The idea of doing just what the doctor suggested was evident in all 27% of the participants discussed under this subcategory. One woman who had just rehabilitated after open heart surgery and had to have her ICD implanted emergently, stated, "I wasn't upset (when she received the recommendation for the ICD) because I knew it wasn't anything to worry about." Another participant described her recall of the recommendation as threat-like stating, "…he (the doctor) said you will not leave this hospital alive if you do not have that (the ICD)…. so I said, alright, let's get with it!" Still another seemed to let the physician take total control of her care as stating, "I would do whatever he'd (the doctor) say. It's ok with me." One woman saw her ICD's recommendation as more of a contract between her and her doctor as evidenced by her statement, "He [the doctor] explained it to me. We agreed on it."

Six participants commented on the level of information given and amount of preparedness they felt pre-operatively regarding the procedure itself. Most felt they were well informed and possessed a sense of readiness. One participant was, “not nervous” because, “We (she and the nurses) had various educational little summits… They were very good about explaining things to me. If they couldn’t, they would get somebody who could…I think I was well-informed.” Another woman commented on preparedness stating:

> I was assured that I would be taken care of so I wasn’t afraid. I had been prepped in a sense of what was coming and what to expect…everything was discussed…literally, every minute I was told everything that was happening. Actually, I was relaxed.

All six participants held the nurses responsible for their level of preparedness. Even the woman, who had the most negative experience in the sample, had only the nurses to thank for any information given. She describes her experience as:

> No one talked to me much about what was going on… I knew nothing about the pacemaker before they put it in… I think all along the line, people assumed someone else was giving me the info and no one was giving me the info. I didn’t even know enough to ever ask the nurses… the last little nurse helped me so much, she would say, ‘what don’t you understand?’…I don’t’ understand anything! I don’t know enough to ask you any questions I told her.

Most participants used fond adjectives such as, “amazing,” “reassuring,” “wonderful,” “very helpful,” “impressionable,” and “comforting” when describing the pre-procedural nurses which is contrasting to a previous discussed study that implied nurses were not confident in their ability to prepare ICD patients (Tagney, 2004).

Despite voicing adequate preparation, anxiety levels differed among half of the participants. The woman who was post open-heart surgery stated that the ICD procedure, “…made me nervous initially.” The two nurses in the sample both expressed feelings of anxiety about the procedure and incidentally had the most detailed recollection of the events. One described actually being placed in the holding area as, “I remember I was thin then and the table was very cold and very hard, and they strapped me in which was pretty scary; you know because I pretty much knew what was coming.” The other reported, “I was scared to death. I was very scared.”

As previously indicated, most of the study’s participants mentioned the nurses from the clinic, holding area of the hospital, and/or hospital unit in their transcriptions when questioned about procedural issues. Half of these participants specified a particular nurse from the clinic as the person who provided their education. One woman stated, “I love her... she was very, very encouraging and just answered all of my questions... she was actually better than the doctor to a certain degree.” Four women generalized nursing as an important, helpful necessity during the ICD implantation. They viewed nursing staff as reassuring, informative, and caring and seemed pleasantly surprised by the degree of those characteristics. For example, one woman reported, “... there are nurses out there I discovered that will give you the information you want.” Another stated, “You [nurses] don’t realize what an impression you make on people.” Most participants mentioned a nurse at least once throughout their interview; mostly without disclosure of his/her name.

The physician who implanted the majority of this sample’s ICD, was repeatedly referred to with high regards. He was described as, “an angel,” “a rare human being,” “one of the most reassuring guys in the world,” “such a caring man,” “wonderful,” and “a good doctor.” Two women reported that they would not have had the ICD implanted unless he performed it, evidenced by statements like, “You know, nobody wants anyone but him.” His demeanor and going “above and beyond his call of duty” seemed to be at least some of the reason he has such positive responses. For example, one participant’s eyes seemed to light up when she described how he personally telephoned her family and reassured them, which later proved as very important to her. In fact, most of the women's eyes lit up when speaking of him.

This man was not the only physician the participants spoke of. The physician who implanted the next highest amount of ICDs was regarded by his three patients but with more neutral connotations. He was referred to as, “ok” and “very thorough.” One participant, as implied previously, claimed that the nurses were more informative than he. A different physician was regarded as, “absolutely wonderful” by two of his patients in this study. The patient with the thoroughly negative experience who was implanted by a physician affiliated with another group, exhibited an attitude of betrayal by saying, “I just kept trusting them …those [the doctors] are the people you are supposed to be able to trust.” She goes on to say that once her care was transferred to the north Florida clinic, she had answers and that she feels, “better than I have in two or three years.”

Forty-seven percent of these participants grade their ICD implant experience as generally positive. Most say that they have nothing bad to say about the staff, hospital, or the clinic which is the reason given that they have minimal recollection of the experience. Four participants state in some manner that there was, “…nothing alarming” about the incident and again, attributed that to their forgetfulness. One reported, “I just remember being well taken care of… it was just a sense of almost routine." All those who could not recall the procedure were overly apologetic to the interviewer and seemed slightly embarrassed. They all went on to say how much they love the clinic.

Upon exploration of immediate post procedural memories, three participants discussed specifications about the wound itself. All expressed apprehension regarding the incision with statements like, "I was afraid of looking" and, "I had an incision and I know it is there, initially I was very frightened." One participant recalled with observed disgust, frustration regarding the dressing of the incision, "I couldn't get them to listen- to take off the tape because they kept saying it had to be there. Consequently, I have a scar from where the tape was cutting me..." Others' recollections were less negative, just more of a sense of acquiring an incision as demonstrated by, "I remember waking up pretty drowsy and sore and I had this lump in my chest here (points to site)." Also, "I actually felt that weight...like I was carrying a bowling ball there..." It seemed that after criticizing the wound, participants made sure to conclude with a more positive note. For instance, the lady who referred to the ICD as a bowling ball goes on to say, "...but that [the feeling] is gone. That dissipates with a little time." She also states that she had "absolutely no problem with the wound." The lady recorded as saying that she was afraid of looking at it later reported, "Then when I did look at it the very first time after the second week, I thought, that's not your incision- that's nothing! It really was nothing. It still is nothing." The participant who complained of the scar from the dressing contradicts herself as, "....I wasn't really pleased...but it heals."

A final subcategory of Procedural Issues dealt with restrictions and immediate discharge home. Thirty-three percent of the total sample expressed opinions regarding driving. Two reported that it was more of an independence issue, demonstrated by statements such as, “The horrible thing was that he (the doctor) told me that I couldn’t drive for six months. I just looked at him and said, ‘six months!’ I needed a friend to drive me around” and, “I just wanted to drive again. I don’t like being dependent on other people. It was a little frustrating…” They did convey understanding of the driving restriction exemplified by the comment, “I certainly did not want to become unconscious should that device kick in and cause an accident…I understood, but I didn’t like it.” Others questioned what would happen if they were driving and the ICD delivered therapy, which seemed to display ongoing concerns with driving but not as a restriction per se. Still another participant stated that the driving restriction, “…was not a concern really.”

Twenty percent of the participants under this theme of Procedural Issues articulated concerns over immediate discharge home. Activity restriction was one of those anxieties. One woman worried about taking a shower while another had a hard time remembering to, “…not reach behind or anything.” She went on to say that she was in disbelief over the lifting restriction of less than five pounds exclaiming, “That’s ridiculous! I can’t even go to the grocery store! Sugar is a five pound sack! Flour is a five pound sack!” Two participants expressed concern over electrical considerations and the ICD. For example, they both stated that they worried about going through security in the airport since now it would take a longer time and that they had to make sure they carried the correct paperwork with them at all times. One woman said it was difficult at first to remember to use her cell phone with the opposite hand from the side of the ICD.

Forty percent of the participants' narratives demonstrated a large amount of anxiety upon immediate discharge home while two seemed to display an amount of despair. One described the feeling as, "…you go home and feel like, am I going to be alright? Is this thing going to go off? What if I am driving?" The other stated, "There was so much I didn't understand….Should I not push the vacuum cleaner? Should I not pick up my grandchild?" Still another stated with less anguish, that she didn't understand but that she, "learned on the way."

Despite anxiety regarding immediate discharge home, 33% of participants in the Procedural Issue theme were without apprehension. They stated that they felt prepared and that the discharge instructions given to them in the hospital by the nurses and the physician were easy to understand. They were well informed and felt comfortable leaving the hospital especially since they knew the sequence of events to come. Two of the women who had concerns over the driving restriction closed with a positive note implying that the restriction was not forever and that it worked itself out. All had at least one good thing to say about their readiness for discharge home.

Body Image

Another core theme, Body Image, emerged from 53% of participants' transcripts and will be discussed here. Summarizations with examples of those eight particular women's narratives will be represented. These ideas emerged spontaneously since there was no specific question related to body image in the interview schedule.

Sixty-three percent of the participants in this theme commented on size of the ICD. Two women complained about its dimension but with a sense of acceptance since their complaints were mostly from their initial sight of it post-operatively. For example, one woman reported, "…I was surprised how big it was…It was kinda funny having it, a big hump right there. It was awkward at first." The other stated, "I wish it wouldn't be so big and ugly…but there is nothing you can do about that." The remaining three of the five participants discussed in this paragraph used words like, "bulgy," "bulky," and that it "sticks way out" when describing their ICD's appearance. In relation to how others see the ICD, one woman remarked that, "…it *still* sticks out," and that, "…the kids go 'eww!' when they see it." Another participant who seemed the most bothered by the ICD itself stated, "It still sticks out a lot and I don't know if most people have a square box on their chest." Her ICD was placed in an uncommon, elevated location on her chest area due to her breast implants as reported by her.

Thirty-eight percent of the participants here portrayed issues related to clothing after receiving their ICD. One woman joked that she would not be able to wear a strapless dress, "…but at 83 [years old], nobody would look anyway." She went on to say that since others can always see her ICD, she is, "…not going to have a neckline (laughs)…I am too old for that kind of stuff." In contrast, another woman declared, "The worst part is vanity…so I changed necklines." A different participant also used the word "vanity" as the only apprehension she had in regards to her ICD's appearance. Another woman did not alter any of her clothes after her implant, stating, "...little shirts, I wear them."

Half of the women discussed in this theme of Body Image actually stated that they have not had any substantial reactions to their ICD's appearance. For example, the woman who wished her ICD was not "so big and ugly" went on to say that the way it looks, "...doesn't bother me a bit in the world." The elderly lady who joked about wearing strapless dresses described a relationship with her ICD saying, "...it's a part of me." Another woman said she can feel it with her hands but doesn't notice it visually. The eldest participant in this study, 85 yoa, said she changed, "...absolutely nothing" about her clothing after receiving her ICD implant. Though eight women mentioned something about body image related to their ICD, it seemed that this theme was not as apparent as portrayed in previous research (Sears, 2004; Tagney, James, & Albarran, 2003).

Feelings Regarding a Shock

The last theme that emerged from the narratives concerned 87% of participants' thoughts about defibrillator shocks from the ICD. Of the 15 total participants of this study, only 27% experienced an actual symptomatic shock that they recall and/or were aware of. Subcategories such as; viewing a shock as a warning, knowing what to do if it did happen, apprehension of an incoming shock, along with the detailed occurrences from the four women who had the shocks will be presented here.

Eight of the 13 participants who commented noteworthy on defibrillator shocks saw them in a positive light. Many expressed feelings of gratitude that they had the ICD since if it shocked them; it was saving their lives. For example, one woman reported, "…I know if my heart stops, you know that is kind of a good feeling that it would get kicked." Some shared the same idea that if they were shocked, the ICD did "what it was supposed to do" and that it would be okay to be shocked since then they would know it was working. Most saw the device as a source of protection, similar to the subcategory under Psychological Reactions.

The participants also viewed a shock as a warning; that they had better find out what they are doing incorrectly and change it. Thirty-one percent of the women depicted in this theme expressed very similar theories as to why they would ever receive a shock even though none had ever had one. For example, they reported that if it shocked, then "something bad is going on" and they must take initiative to change it since it is their responsibility. For example, one woman's response to the interview question of "How do you feel about defibrillator shocks from the ICD" is quoted as:

> I would be concerned. Thankful. But I would be concerned that I needed to change my diet, regulate pills better, or that I would have to do more…I would be concerned that it was telling me to 'fix something!' And then I would have to search it down and find out what to do.

It is interesting to note that none of the women with this attitude had ever experienced an actual ICD shock.

When asked what they would do if they ever experienced a shock, most had someone in mind that they would call initially. One woman reported, "…I would call family and get people here." Another said," I would call the doctor, my daughter- I would call everybody." However, three women sought out validation from the researcher that their plan was accurate. Two examples are, "I think that

I would know to go and call the doctor- is that correct?" and "...I would probably call the doctor. I wouldn't know what else to do. I am assuming that is the procedure? I don't know (looks at researcher for the answer)."

Thirty-one percent under the Shock theme voiced concern of where or when a shock may take place. Two women expressed concern of receiving a shock while driving. For example, they were quoted as, "My main concern with it was, of course, if I happen to be driving...you are going to be in trouble" and, "...I wouldn't want to be driving and cause somebody to get hurt." Even though they communicated concerns of being shocked while driving, none drove any less. One woman uttered concerns of what she might do to facilitate a shock and if she was out in public, "Is this going to jolt me and right in the middle of work or right in the middle of church, and what's going to happen?" Along the same idea, another woman, who had received a shock stated, "...I think, oh God, I don't know if I should be doing this, but mostly when it (raises her arms) is over my head...so I think about it then. Then I think, oh if this thing ever went off, but that's all." Two ladies reported that even though they sometimes think about ongoing limitations, the thought of an ICD shock does not restrict their activities; summed up by one woman as, "It won't keep me from doing anything. I swim and do everything."

Whether these 13 participants experienced an actual shock or not, all voiced at least a small amount of apprehension regarding one. Statements like, "It would make me nervous," "I would freak out," and "I would panic probably" dominated the narratives in regards to initial reactions to a shock. One woman verified her feelings of anxiety towards a shock by saying, "I don't think I would enjoy the feeling of the pain being so great it would drive me to my knees." Another participant stated that apprehension of a shock, "was one of my worries." Three women stated that they hope the ICD "never goes off," however one of those three who had had a shock expressed that idea with much more conviction by exclaiming, "I hope to hell that it never goes off!" She later goes on to say that she thinks about it shocking her again, "once in a while." Another woman commented on being shocked again as, "It would be like having an experience of being in an automobile accident and going back driving an automobile and it would come back."

Though multiple participants expressed apprehension regarding an ICD shock, most went on to also say that they do not continuously think about it. Four women stated that the thought of a shock does not bother them and/or they do not worry about it. The lady that compared her recollection of her shock to an automobile accident reports that that memory, "...gets less as time heals." Another woman who also experienced a shock reported that the fear of another one, "...finally faded after I guess about four months." The lady that reported she would initially panic if she was shocked says she wouldn't panic as much now since she has received more education regarding its proposed feeling.

As previously stated, 27% of participants experienced an actual symptomatic defibrillation. One woman had little to say regarding its feeling, even after much prompting. Her only statement was, "...it got me back on track." Another woman had a better detail of the experience as it happened on her way to the dining room of her assisted living facility. A shock was delivered yet she still continued to enter the room as described by her as, "…Oh God, I sort of felt, all of a sudden, a sharp pain…so I sat down…I said [to her son] I'm fine. So in we went [to the dining area] and that was it." She reported later that the shock, "didn't hurt," and that, "It wasn't any great shock. It was just a little one," and, "…that's the only time it's ever done it. I'm still hoping it never goes off again."

A different woman received multiple shocks from her ICD. She reported the experience as traumatic since she had one episode where her ICD went off three times in ten minutes. She reported that, "…it takes your breath away." She was quoted as saying, "somebody described it to me like being kicked in the chest by a mule…it's more like being kicked in the chest by an elephant…pretty scary experience." She goes on to say that that the ICD did what it was supposed to do and that it, "…was not the end of the world." Despite her seemingly appreciation for the shock, she admitted that she, "toys with the idea of turning it off."

The last woman in this study with a history of ICD shocks had a more detailed recollection of the experience. She described it as a frightening, horrifying, distressing, and traumatizing event. She was quoted as:

> I woke up and this thing went- JOLT! Of course, you jump a mile! It is sort of like an electrical shock. I can't describe it really. And then it was at intervals. It would shock me and then maybe in 15 minutes, it would do it again, and again, and again. And that is frightening!

She went on to illustrate that though the physical feeling was horrible, the psychological sensation of not knowing what to do and others around her feeling scared was just as dreadful. For example, she recollected the incident as, "…but it is a very frightening experience and it's because you don't know what's happening….and that was more so because the people around me didn't know either." She repeatedly mentioned that her husband could feel the shocks when putting his hands on her for comfort which she conveyed as very bothersome to her. She stated she finally felt some relief upon arrival to the hospital but that she remembers the event very vividly.

Chapter V

Discussion

Health care providers can utilize the documented experiences of women who live with an ICD from this study to better prepare and help manage concerns of these patients pre- and post-implantation. Acknowledging that there are needs specific to women who have an ICD is important to nursing practice and to any female patient's coping mechanism. Responding to concerns regarding ICD implantation is relevant specifically to nursing since nurses prepare patients for the experience and are often the first to hear of patients' unpleasant symptoms.

The Theory of Unpleasant Symptoms

In the theory of unpleasant symptoms (TOUS), three categories of variables are recognized: Physiologic Factors, Psychologic Factors, and Situational Factors. Within each category, several interrelated aspects should be considered and can be applied to multiple scenarios. All of the aspects relate to one another and may interact to influence the symptom experience (Gift, 2004). The five core themes that emerged from this research can be divided into these three categories and will be discussed next.

Physiological Factors

Physiological Factors as explained by the TOUS are multiplicative. Examples are: normally functioning bodily symptoms, existence of any pathology, trauma occurrence, and level of energy. The core theme of Physical Comfort can be categorized here. Any operation can be regarded as a type of trauma as does the surgical insertion of an ICD. Women's voiced concerns of pain post operatively provide for an example of a normally functioning bodily symptom. The women under this theme experienced pain in the incision itself and/or generalized discomfort immediate post surgery and some today. It is possible that pain can increase the intensity of other symptoms as in the case of one patient who reported that due to her pain, she experienced decreased levels of energy which also qualifies as an aspect in the Physiological Factor group.

Another theme from the research that could be applicable under Physiological Factors of the TOUS is; Feelings Regarding a Shock. When describing the actual sensation of defibrillation from the device, all women described it at least as uncomfortable. Most comments were of more intense descriptions. The physical feeling of a shock can be classified into this category since again, pain can intensify other symptoms.

Psychological Factors

Many women from the study experienced aspects of the Psychologic Factors category and was an area of focus from two different core themes. The first, Procedural Issues, supplied examples of mental states and mood. For example, six participants commented on the level of information given, amount of preparedness, and subsequently, their mental state before their ICD insertion with anxiety. The degree of uncertainty, or mood was observed when the women expanded on their appreciation of the nurses' education regarding the ICD insertion procedure.

Another core theme of Body Image fits into this category of Psychological Factors. Many women saw the ICD's size post procedure as negative which could be classified as an ineffective response to it as the TOUS explains. The reaction to the incision and ensuing scar was demonstrated as unconstructive in 33% of the sample. Other participants stated they had no substantial reactions to the appearance of the device or its scar, which in contrast, could be labeled as an effective response which would not intensify the degree of any other symptoms.

Situational Factors

The core theme, Psychological Reactions can be listed in the third and last category of the TOUS, Situational Factors. The fact that the majority of the sample were of middle to high socioeconomic status and possessed functioning support groups could have affected their lived experiences. All participants had direct, easy access to health care and its resources. Only one member of the sample was overweight; the others took pride in remaining active. These situational factors could have influenced the way they perceived their symptoms.

Limitations to the Study

There were multiple limitations to this study. The sample demographics could arguably provide for biases. The setting of the interview may have had an impact on the answers given by participants. Reasons the patients qualified for the ICD were varied. The rapport established between participant and researcher could have played a role on responses given by the women.

Study participants lacked diversity possibly contributing to bias. All women were of white race, over the age of 49, and of mid to high socioeconomic status. Inclusion of younger women and of a lower socioeconomic status may have provided a more complete representation of the female population receiving ICD implantation.

The majority of the sample received the ICD only as prophylaxis with a needed bi-ventricular pacemaker to aid alleviation of symptoms of heart failure, not exclusively for treatment of survivors of SCD as the researcher had strived for. Therefore, many women's responses to interview questions pertained to the improvement the pacemaker made on their chronic illness symptoms, not of the shock itself; evident by only 27% of participants ever actually receiving a shock. Some women even referred to their ICD as a pacemaker, not an ICD. However, the majority of the sample was able to demonstrate the distinction if specifically questioned.

The clinic where the sample was collected has a reputation for striving for excellence in education, research, and patient care. All of the participants were currently under the care of this clinic and all portrayed a sense of pride in such. With that being said, receiving preparation, care, and membership at such a renowned institution brings much positivity to the overall opinions of its members. For example, every participant made at least one encouraging remark about the clinic; most supplied multiple comments. Patients from random institutions may have allowed different views on their experiences.

The setting of the interview may have interfered with some patients' remarks to questions. All participants' interviews took place directly after a follow-up appointment possibly contributing to melancholy which may have influenced their answers. Some of the patients did receive grim news regarding their prognosis just prior to the interview. For example, one woman was recommended placement on the heart transplant list a few minutes before her interview. Another was in the midst of heart failure exacerbation while being questioned. It could be argued that the mere showing up for the appointment is a reminder of inevitable mortality. This may have guided their answers in that multiple members of the sample did not think the ICD was really helping them.

Answers to the interview schedule could have been swayed by the choice of methodology used in the study. The researcher's inexperience in interviewing and amount of rapport established could have played a role in how much information the participants provided. Thankfully, the sample was probably large enough to account for this possibility. The researcher's comfort with and fondness of elderly women probably worked to her advantage and as a counterpart to her inexperience as an interviewer. However, it still deserves mentioning as a limitation since the entire sample was not elderly. Also, in congruence with self-report research, answers to interview questions may have been influenced by characteristics of how the participant thought she should respond and how she wanted to be perceived.

Implications for Nursing Practice

The personal thoughts, opinions, and impressions given by the 15 participants in this study allow for multiple suggestions to practicing nurses. An awareness that some of the women displayed was how much knowledge nurses actually possess. Therefore, study results could encourage nurses to take a stand for what they know and not be reluctant to share with patients. More than any other health care professional, nurses focus on the impact a disease/condition has on the daily lives of patients and are therefore in the front line in all aspects of ICD implantation. Nurses educate, offer support, and provide both physical and mental comfort throughout patients' experiences.

Many participants appeared to respond better to the nurses than the physicians especially immediate post-implant. Since ICD implantation is an overnight stay in a hospital, staff nurses are given an ample opportunity to educate, reinforce, and prepare patients for the immediate discharge home. Patients from this institution do receive much education though a lack of understanding and/or recollection of it was apparent in some transcriptions. More or repetition of the pre-procedural teaching with a focus on gender should be instilled.

With regards to discharge home, nurses could serve to continue education and allow for support. For example, a follow-up phone call to all recipients from a nurse may provide assistance and encouragement. Nurses should stay abreast of support groups and promote their use. Support groups are available yet, are not always taken advantage of especially by women. The option of online international forums should also be encouraged. One such online blog is The Zapper (www.zaplife.org) which provides nonprofit information sessions and individual postings. Witnessing that many of the entries from this site's chat room were made from women, creation of women-specific support groups, whether online or in person may be beneficial.

Several important implications from this study become apparent for the Advanced Registered Nurse Practitioner (NP). The majority of NPs practice in the primary care setting where most chronic disease conditions are managed. Being knowledgeable about sudden cardiac death, cardiac arrhythmias, and subsequent treatment with an ICD, will ensure better assessment of patient status. It is important for NPs to understand the latest treatment options available and how to manage the care of a patient who has a unique device like an ICD. They should stay abreast of how it operates, follow up schedules with the cardiology staff, and the option to disable the ICD when the time comes. It is important not only that NPs have the ability to explain to their female patients how an ICD works and how it is inserted, but now with information from this study, be able to report what the experiences of living with an ICD is like from a female patient's perspective.

Once the NP is aware of her patient's plan to receive an ICD, she could take part in its preparation on regular visits. She might discuss pain medications and encourage the patient to ask the electrophysiologist for a type of pain medication that has worked for her in the past. Since a few participants expressed concern over narcotic addiction, she should mention the need and proper use of pain medication making sure to also speak directly to the family as to help alleviate fear and uncertainty. Most participants had issues with the incision itself and the ICD's size and weight, therefore the NP should reiterate realistic expectations.

Immediate discharge home was an issue with many of the women in this study. The NP is in a position to educate and reinforce driving and activity restrictions, making sure to use layman's terms. She could clarify specific actions to do or not do as participants articulated in the study such as specific household duties, church attending, and handling grandchildren and pets. Promotion of involvement of their support systems in their presence since many women shared the idea of "burdening" others should be accomplished at these visits. Since multiple participants conveyed doubt during the interviews on what to do if shocked, the NP should encourage development of a specific plan if the ICD administered therapy and continue to remind them and update it on subsequent visits.

Considering how much female patients revere nurses and all they have to offer, staff nurses should encourage support groups and discussion with their NP about their ICD at the time of hospital discharge home. Since many participants in this study demonstrated positive psychological responses to the ICD, the NP should encourage and nurture those feelings. However, the NP should not discourage expression of pessimistic feelings regarding the ICD. As suggested in this study, some patients seemed less enthusiastic as time progressed, so NPs could periodically remind them of the ICD's functions. Counseling and coping support should be offered at every office visit. She should be realistic and support any decision or exploration of patients' thoughts of disabling the ICD also at any time.

Implications for Future Research

Further research is warranted to bring awareness to the experiences of women who live with an ICD. Few studies here in the US have been conducted using a large sample of women specifically on reactions to the ICD. This study adds to the research that has identified some unique issues specific to women with an ICD. More research can only strengthen these findings and educate healthcare professionals regarding these gender specific issues of living with an ICD.

Appendix A

Topic of Telephone Script:
This telephone script will be used to recruit participants into the study.

Introduction:
"Hello, this is Jennifer Crain calling from the Mayo Clinic in Jacksonville. May I

please speak to ________________________?"

***If the person is there, continue with the script.

***If the person is not there, ask when it would be a good time to call to speak with ______________________?

Describe the Reason for the Call:

(*Example of phone call to potential participant*)

I am calling to invite you into a research study we are conducting to help us learn about the experiences of women who live with an ICD. Please understand that your current or future medical care at the Mayo Clinic will not be jeopardized if you choose not to participate. Is this something you would be interested in gaining more information about?

If no: *Thank them for their time and stop the recruitment process.*

If yes: *The primary investigator, Jenea Smith is a UNF graduate student in the Nurse Practitioner Program. She is going to perform one interview with you where she will ask you questions about your experiences related to your ICD. The interview will last no more than 30 to 60 minutes and will take place at the Pacer Clinic. Once you agree to participate, I will set up an interview date and time. Of course, whenever possible, I will schedule your interview around the time of your next follow-up appointment. Would you like to participate?*

***If questions*:* Answer questions in order to clarify interview process only.

***If no questions and in agreement to participate: verify date, time, and place of interview. *Thank you for participating in our research study. Please understand that your answers will remain confidential. Good-bye.*

Appendix B

Interview Schedule

PARTICIPANT AGE:______ DATE IMPLANTED:______________

TIME START:____________ TIME END________

Pre-implantation of ICD

1. Can you tell me what you remember of the events leading up to you having the ICD implanted?

PROMPTS:

-Specific/related hospital admission

-How do you feel about this?

Post-implantation of ICD

2. What particular concerns did you have at the time before leaving the hospital?

3. In what ways were you prepared for discharge home?

PROMPTS:

-Any suggestions to nurses who educated you?

Discharge home

4. Think back to when you were first discharged home after implantation of the ICD, how did you personally cope during those first few weeks?

5. What do you recall as your immediate practical concerns at that time?

6. Overall, what would you say have been the major effects that having ICD has had on you?

ICD shocks

7. How do you feel about defibrillator shocks from the ICD?

PROMPTS:

-Have you experienced one?

-How do you think it would affect you?

Appendix C

Mayo IRB Approval

Principal Investigator Notification:

From: IRB

To: Jenea Smith

CC: Study Team Members that are marked as wishing to receive correspondence regarding the protocol/grant application

Re: Application # 07-004210
Click the link below to access the protocol/grant application information in your IRBe workspace, as well as the approved consent document(s)/Rough Word consent
document(s) that need to be used when submitting consent changes as part of a modifications request (if applicable) under the Documents tab:
07-004210

Please note that all correspondence (modifications, progress reports, reportable events) related to this study/grant application must be submitted electronically in the IRBe system.

The following is a REVISED excerpt from the minutes of the Expedited Review A of the Mayo Clinic Institutional Review Boards meeting dated 7/17/2007:

The Committee reviewed and approved for human studies the protocol entitled "The Lived Experiences of Women with an Implantable Cardioverter Defibrillator (ICD)." from Ms. Jenea Mary Smith. The Committee noted that the human studies aspects involve an **audio** taped interview of female subjects who have had their implantable cardioverter defibrillator less than three years. A maximum of 15 adult female participants with an ICD are approved for enrollment in this protocol at Mayo Clinic Jacksonville. Due to participant contact, written HIPAA authorization and informed verbal consent (which is obtained by participants completing the interview) must be obtained. Documentation of verbal consent (as a CEN) and a scanned HIPAA form should be placed in each participant's medical record. The telephone script and interview schedule were approved as written. The HIPAA Authorization form was approved with revisions. The IRB office will provide the final approved form on the IRBe workspace for this item. The Committee determined that this constitutes minimal risk research, and therefore was eligible for expedited review in accordance with 45 CFR 46.110(b)(1) and 63 FR 60364, item 6. This approval is valid for exactly one year unless during the year the IRB determines that it is appropriate to halt or suspend the study earlier. 07-004210

Tremaine, William J. M.D. , Chair
Gina Dahlgren , Specialist
Mayo Clinic Institutional Review Boards Expedited Review A

Appendix D

UNF IRB Approval

UNF
UNIVERSITY of
NORTH FLORIDA.

Office of Research and Sponsored Programs
1 UNF Drive
Jacksonville, FL 32224-2665
904-620-2455 FAX 904-620-2457
Equal Opportunity/Equal Access/Affirmative Action Institution

MEMORANDUM

DATE: September 11, 2007

TO: Jenea Smith

VIA: Dr. Lillia Loriz,
Nursing

FROM: Dr. David Kline, Chair
UNF Institutional Review Board

RE: Review by the UNF Institutional Review Board IRB#07-110:
"The Lived Experiences of Women with an Implantable Cardioverter Defibrillator (ICD)"

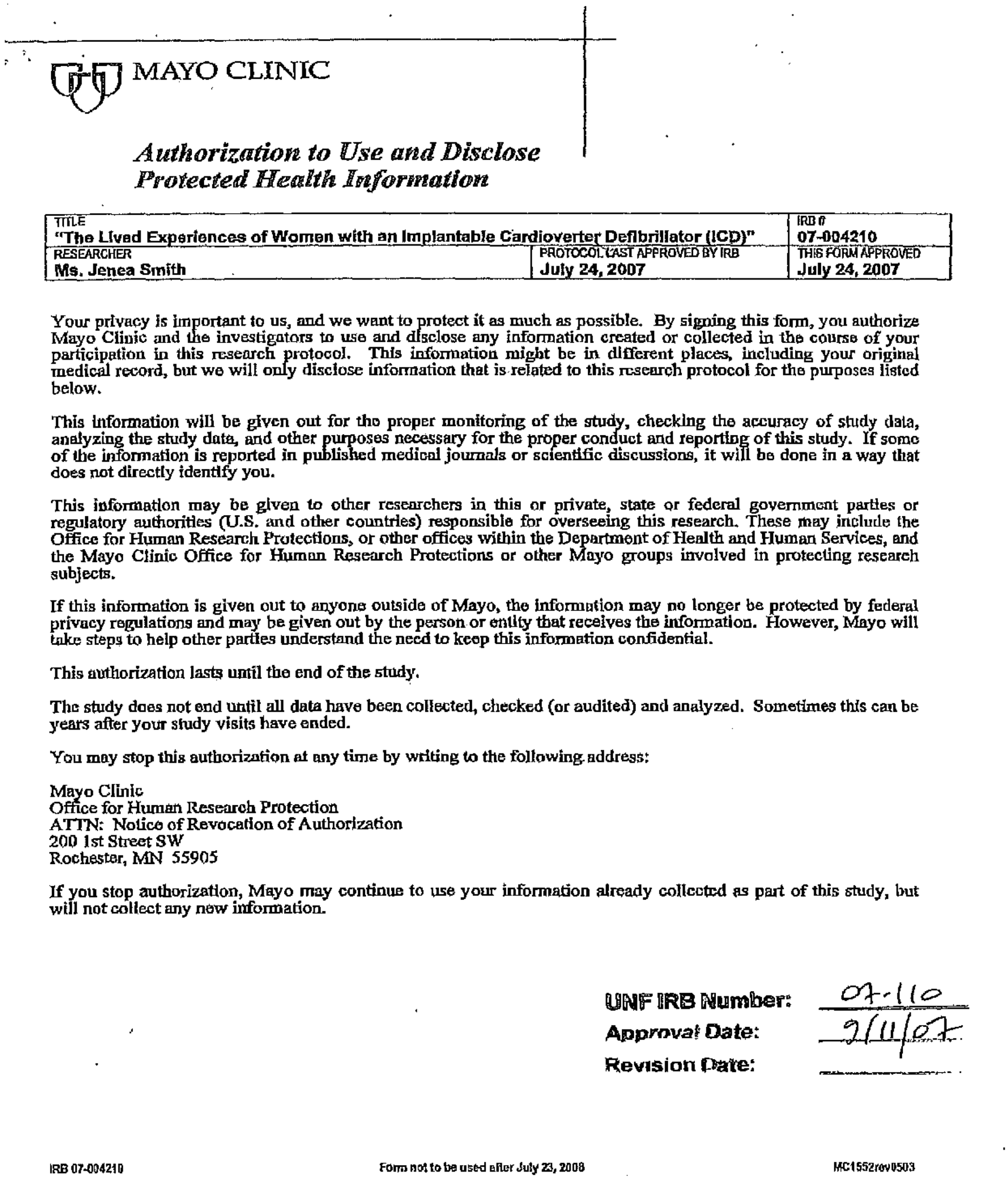
This is to advise you that your project, "The Lived Experiences of Women with an Implantable Cardioverter Defibrillator (ICD)," has been reviewed on behalf of the UNF Institutional Review Board and has been declared exempt from further IRB review.

This approval applies to your project in the form and content as submitted to the IRB for review. Any variations or modifications to the approved protocol and/or informed consent forms as they relate to dealing with human subjects must be cleared with the IRB prior to implementing such changes.

Should you have any questions regarding your exemption or any other IRB issues, please contact Nicole Sayers, Assistant Director of Research Integrity, at 620-2498.
Thank you.

Appendix E

Consent Form



MAYO CLINIC

Authorization to Use and Disclose Protected Health Information

TITLE **"The Lived Experiences of Women with an Implantable Cardioverter Defibrillator (ICD)"**		IRB # **07-004210**
RESEARCHER **Ms. Jenea Smith**	PROTOCOL LAST APPROVED BY IRB **July 24, 2007**	THIS FORM APPROVED **July 24, 2007**

Your privacy is important to us, and we want to protect it as much as possible. By signing this form, you authorize Mayo Clinic and the investigators to use and disclose any information created or collected in the course of your participation in this research protocol. This information might be in different places, including your original medical record, but we will only disclose information that is related to this research protocol for the purposes listed below.

This information will be given out for the proper monitoring of the study, checking the accuracy of study data, analyzing the study data, and other purposes necessary for the proper conduct and reporting of this study. If some of the information is reported in published medical journals or scientific discussions, it will be done in a way that does not directly identify you.

This information may be given to other researchers in this or private, state or federal government parties or regulatory authorities (U.S. and other countries) responsible for overseeing this research. These may include the Office for Human Research Protections, or other offices within the Department of Health and Human Services, and the Mayo Clinic Office for Human Research Protections or other Mayo groups involved in protecting research subjects.

If this information is given out to anyone outside of Mayo, the information may no longer be protected by federal privacy regulations and may be given out by the person or entity that receives the information. However, Mayo will take steps to help other parties understand the need to keep this information confidential.

This authorization lasts until the end of the study.

The study does not end until all data have been collected, checked (or audited) and analyzed. Sometimes this can be years after your study visits have ended.

You may stop this authorization at any time by writing to the following address:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

If you stop authorization, Mayo may continue to use your information already collected as part of this study, but will not collect any new information.

UNF IRB Number: 07-110
Approval Date: 9/11/07
Revision Date: ______

IRB 07-004210 Form not to be used after July 23, 2008 MC1552rev0503

MAYO CLINIC

Authorization to Use and Disclose Protected Health Information

I have had an opportunity to have my questions answered. I have been given a copy of this form and understand that a copy will be placed in my medical record.

Printed Name of Participant	Mayo Clinic Number
Signature of Participant **X**	Date of Signature
Printed Name of Representative Signing for Participant (if applicable)	Representative's Relationship to Participant (if applicable)
Signature of Representative Signing for Participant (if applicable) **X**	Date of Signature

UNF IRB Number: 07-110

Approval Date: 9/11/07

Revision Date: ____________

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Author Note

Jenea Smith graduated from the University of North Florida (UNF) in 2004 with a Bachelor of Science in Nursing. She began her Master of Science in Nursing with emphasis in Family Nurse Practitioner at UNF in 2006 and will graduate April, 2009. Jenea's nursing career includes extensive cardiac/cardiovascular experience for Mayo Clinic at St. Luke's Hospital then at the new Mayo Clinic Hospital both in Jacksonville, Florida. She has also provided private home nursing to a resident in Jacksonville. Jenea authored an article accepted for publication and scheduled for release in the November, 2009 issue of ADVANCE Journal for Nurse Practitioners. She is a member of the National Association of Professional Women, the Northeast Florida Advanced Registered Nurses Association, the Sigma Theta Tau International Society of Nursing (Lambda Rho Chapter), and Phi Kappa Phi Honor Society. Upon certification, Jenea intends to work as an Advanced Registered Nurse Practitioner with the geriatric population in the Jacksonville area.