Katherine E. Cutitta, SHOxABILITY: ABILITY AND AVOIDANCE OF DAILY ACTIVITY BEHAVIORS IN ICD PATIENTS (Under the direction of Dr. Samuel F. Sears) Department of Psychology, July 2012.

Background: Implantable Cardioverter Defibrillator (ICD) shocks terminate potentially life-threatening arrhythmias. ICD shock may alter patient behavior via patients attempting to avoid daily activities or increasing heart rate. Patients are aware of which activities they have the ability to perform, but may choose to avoid these behaviors. The current study, entitled SHOxABILITY, examined ICD patients' ability and avoidance of progressively exertive behaviors. In addition, the factors of sex, age, shock, and shock anxiety were examined for differences on avoidance behaviors.

Methods: Four hundred forty-three ICD patients across the United States were surveyed using an online measure. The survey included the Duke Activity Status Index (DASI) and the Florida Shock Anxiety Scale (FSAS), and was designed to provide a brief, descriptive assessment of individual ICD experiences.

Results: As expected, many patients reported being unable to participate in more physically exertive activities such as strenuous athletic exertion (68.8%), sex (35.4%), and running a short distance (49.0%). Avoidance rates were also relatively high, as patients who reported being *able* to participate in these activities also reported avoiding them (i.e. strenuous athletics, 55.1%). Similarly, the majority of patients reported ability to engage in sexual activity (64.6%), but many chose to avoid sexual activity (51.0%). Women reported greater shock anxiety than men. Patients aged 65 and older reported significantly greater levels of activity avoidance than younger individuals. Patients who are older reported significantly lower shock anxiety. Having experienced prior ICD shock did not affect the reported level of activity avoidance. As shock history increases,

greater levels of shock anxiety were reported. Multiple reasons were reported for avoiding, including fear of shock, fear of heart rate increase, doctor instruction, no desire, and an “other” option. The effects of sex, age, and shock indicated greater shock anxiety in patients with shock history as well as younger patients.

Conclusion: Many ICD patients experience behavioral limitations due to both a perceived inability and preference to avoid exertive activities, particularly strenuous athletic exertion. Clinical and research attention to ICD patient activity levels and reasons for avoidance may improve daily functioning and return to pre-implant levels of activity.

SHOxABILITY: ABILITY AND AVOIDANCE OF DAILY ACTIVITY BEHAVIORS IN ICD PATIENTS

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CHAPTER I: INTRODUCTION

Implantable cardioverter defibrillators (ICDs) have demonstrated a mortality advantage over anti-arrhythmic medications for the prevention of sudden cardiac arrest (SCA) in at risk patients (Ezekowitz, Armstrong, & McAlister, 2003). ICDs use anti-tachycardia pacing and high energy shock to rescue patients from potentially life threatening arrhythmias. Receiving a shock is widely considered aversive, despite its life saving effects, potentially resulting in psychological distress and behavioral disengagement. Shocked ICD patients may experience fear and anxiety, which may subsequently reduce their desire and motivation to engage in daily activities. Patients may be aware of which activities they have the ability to perform, but may choose to avoid these behaviors for a number of reasons, such as fear, misunderstanding, or lack of intent. The present study examined a set of patient reported measures of ability and avoidance of progressively exertive behaviors, as well as factors such as sex, age, shock, and shock anxiety. This study is also the first ICD study to utilize electronic mail as a means of disseminating a survey to a wide scope of individuals. The primary aims of this study titled SHOxABILITY were (1) to establish norms using descriptive data of typical “ability” and “avoidance” of daily behaviors of a sample of ICD patients, (2) to determine the effect of sex, age, and shock history on the avoidance and ability of daily life exertive behaviors using an internet based convenience sample, (3) to determine the effect of sex, age, and shock on shock anxiety.

This study provides information on daily behaviors of ICD patients, improving clinical clarity in the field of cardiac device implantation. Information from this study may also normalize patients' fears and anxieties by giving a quantitative anchor of other ICD recipients' responses and modifications of daily behaviors. SHOxABILITY results will be used to improve upon patient education and intervention about specific behaviors, all of which are safe to resume and ultimately be incorporated into intervention plans for ICD patients experiencing avoidance behaviors.

CHAPTER II: LITERATURE REVIEW

In the following section, the medical, psychological, and behavioral factors affecting patients living with ICDs will be outlined. The patient's experience with an ICD, at first seems purely medical, with implantation of an ICD to reduce risk for sudden cardiac arrest. Once an arrhythmia has been terminated and a life has been saved, the patient may fall victim to his own thoughts and fears about the device and the high-energy shock. Research shows that ICD shock is associated with psychological distress. In addition, ICD shock and subsequent psychological distress may also increase avoidance of behaviors the patient now associates with defibrillation. Clinical health psychologists become a critical part of the multidisciplinary team in cardiac care as the patient adjusts to daily living with the device. A psychologist may also improve understanding about the pathological maintenance of avoidance behaviors, including operant and classical conditioning methods. The patient's behavior is not an end result, but rather a stepping-stone to an adaptive or maladaptive lifestyle or behavior pattern. Therefore, behavior is important in aiding in the identification of psychological distress.

Sudden Cardiac Arrest

Sudden cardiac arrest (SCA) is the cause of mortality for approximately 300,000 people per year in the U.S. (American Heart Association, 2011). This is a national health problem that can be decreased with a host of primary to tertiary care strategies including the implantation of medical devices. In SCA, the electrical system that manages the heart rate develops a specific and highly lethal irregular rate and/or rhythm. The particular arrhythmia that becomes potentially life threatening is ventricular

tachyarrhythmia which could become ventricular fibrillation and may result in SCA (Compton, 2011).

A patient may first encounter bradycardias, abnormally slow heartbeats, or tachycardias, abnormally fast heartbeats. Upon experiencing a ventricular tachycardia, the patient may experience dizziness or fainting due to the heart's inability to maintain the proper blood pressure to pump consistently. Ventricular tachycardia is dangerous as it may be a precursor to ventricular fibrillation. During ventricular fibrillation, the electricity in the heart becomes erratic, causing a quivering contractile motion, rather than a consistent beat (Sears, Kovacs, Azzarello, Larsen, & Conti, 2004). The faulty electrical conduction restricts the heart from properly pumping blood to the rest of the body; this serious condition leads to a sudden cardiac arrest if heart rhythm is not restored via defibrillation. SCA has a high mortality rate with approximately 95% of patients dying, if treatment is not sought immediately. The high mortality rate is due to the decrease in blood flow to the brain and other organs, which triggers cell death and the need for very rapid emergency response with a defibrillator (National Heart, Lung, and Blood Institute, 2009). Ventricular tachycardias had been traditionally been treated using pharmacotherapy. During the past decade, large-scale clinical trials comparing the ICD across a variety of patients, have demonstrated that the ICD is associated with improved survival compared to medications alone in at risk patients. Today, ICD therapy is the treatment of choice for primary and secondary prevention of SCA.

What are ICDs? Do they save lives?

The ICD is a small device that provides customized diagnostic and treatment functions to identify and terminate potentially life-threatening arrhythmias using high energy

shock. The ICD was first developed by Michel Mirowski in the 1960's as a medical device to be implanted in patients who had prior experience of a cardiac arrest (as a secondary prevention measure) (Mirowski, Morton, Mower, Staewen, Tabatznik, & Mendeloff, 1970). The first human implantation of the implantable cardioverter defibrillator (ICD) was in 1980 at the Johns Hopkins Hospital (Mirowski, 1985) and the Food and Drug Administration (FDA) later approved the device in 1985. The device primordially developed as an abdominal implant, evolving with technology practices over the past three decades. The ICD has experienced much innovation since 1980. Today, the device is much smaller, about the size of a remote control car key, implanted in the upper portion of the chest, near the clavicle, with minimal scarring (Matchett, Sears et al., 2009). The device's battery has the ability to last up to 5 years and the entire unit is replaced at the end of battery life. All of these improvements aid in the reduction of patient burden and the need for superfluous surgical procedures.

ICDs have demonstrated lifesaving capabilities in multiple studies, including the Multicenter Automatic Defibrillator Implantation Trial (MADIT-II). The MADIT-II study evidenced a 31% mortality reduction in patients with an ICD as compared to the group who received treatment as usual. Prior myocardial infarction (MI) and low left ventricular ejection fraction (LVEF) were inclusion criteria, to determine the prophylactic effects of an ICD (Sears & Conti, 2003). Another investigation called Antiarrhythmics vs. Implantable Defibrillators (AVID) (*Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators,* 1997) compared the effects of usual drug therapy to the ICD and showed a reduction in mortality with a 95% confidence interval in the range of 19-59%. More recently, a meta-analysis examined eight trials of the life-saving device against

usual care with antiarrythmic drugs and found that the ICD significantly reduced SCA risk, up to 50%, compared to the alternatives (Ezekowitz, Armstrong, & McAlister, 2003; Epstein et al., 2008). Research has established that ICDs can reduce patient risk of mortality, but the ICD also carries the potential risk for experiencing high energy shock, lead fractures, device recalls, as well as effects of implantation and battery change surgery. Each of these risks can increase the psychosocial demands on patients and families.

Shock

Defibrillator shock is a unique experience, which only ICD patients encounter. Sears and Kirian (2010) recently discussed the critical event that an ICD shock poses to a patient. The authors suggested that a critical event for a patient is defined as "any clinical occurrences that can greatly alter the course of patient adjustment to their condition and the ICD, depending on the effective management strategies by patients and providers" (p. 1437). Upon further examination of ICD shock, it is noted as an acute critical event, where psychological consequences could be experienced immediately. Data from the quality of life study in the Sudden Cardiac Death Heart Failure Trial (SCD-HeFT) suggested that the most significant effects of shock are seen in a 30-day window after shock (Mark et al., 2008). Since ICD therapy has been proven to significantly reduce mortality, compared to pharmacological therapy, ICDs can potentially provide a sense of security to enable a patient to fully function and engage in an active, normal lifestyle on a daily basis. The experience of shock or fear of shock may increase the patient's psychological distress by minimizing any perceived benefits or security.

Psychology and ICDs. Distress

Since the ICD was developed to terminate life-threatening arrhythmias, the psychological impact of the device was not initially examined. After the FDA's approval of the device in 1985, research on ICDs began to show a trend in psychological difficulties due to the unique shock delivered by the ICD, which was distinct from previous studies conducted with pacemaker patients (Fricchione & Vlay, 1986). Patients with ICDs appear to be at an increased risk for psychological distress and disorders, including anxiety, depression, panic attacks, anger, post-traumatic stress disorder (PTSD), and adjustment disorder, compared to the general population (Sola & Bostwick, 2011; Sears et al., 2011; Lemon & Edelman, 2007).

Anxiety

The most prevalent psychological morbidity associated with the ICD patient population is anxiety (Lemon & Edelman, 2007; Sears et. al, 1999), occurring between 13-38%, well above the frequencies of a normative population (Lemon & Edelman, 2007; Sears, Shea, & Conti, 2005). Living with an ICD presents a unique experience, making patients especially vulnerable to anxiety and depressive disorders.

Anxiety disorders are clinically diagnosed by the criteria of the DSM-IV if there are at least 6 months where the individual is experiencing "excessive anxiety and worry" about specific situations, significant difficulty in controlling the anxiety, the presence of at least 3 of the following: feeling tense and restless, easily fatigued, problems concentrating, irritability, muscle tension, and problems sleeping. Also, the patient's symptoms must not be due to another mental disorder, must cause "clinically significant

distress," and may not be due to substance or medical use (American Psychiatric Association, 2000). Anxiety is highly prevalent in the ICD population due to the fear of the shock experience. This fear could potentially cause excessive worry and interfere with functioning and physiological experiences. ICD patients may face a specific type of anxiety termed "shock anxiety."

Shock anxiety is defined by Sears et al. (Sears, Vazquez, Matchett, & Pitzalis, 2008) as "the fear or anticipation of an ICD shock that often results in increased heart-focused anxiety symptoms as well as the development and maintenance of avoidance behaviors to minimize patients' perceived risk of shock" (p. 242). Patients experiencing shock anxiety could avoid previously enjoyable activities as a means of coping because they have come to associate those particular activities with the pain experienced during a shock. They also could perceive that activity increases heart rate and potentially promotes a shock. This increase in avoidance limits the patient's ability to be physically active and experience enjoyment (Kirian et al., 2012). The specific source of the anxiety in the ICD patient is not fully understood whether it is the implantation of the device, arrhythmic death, or the fear of experiencing a shock (Lemon & Edelman, 2007). The Florida Shock Anxiety Scale (FSAS) is a brief self-report measure that was developed to assess anxiety and fears surrounding an ICD shock (Kuhl, Dixit, Walker, Conti, & Sears, 2006). Recently, rates of PTSD have been approximated at 20% of the ICD clinic population (Ladwig et al., 2008; Sears, Hauf, Kirian, Hazelton, & Conti, 2011) and avoidance plays a role in the presentation of PTSD.

Depression

Individuals experiencing depressive symptoms may also exhibit avoidance behavior. Depression is clinically diagnosed by the DSM-IV if at least five of the following symptoms exist: depressed mood, loss of pleasure in usual activities, feelings of worthlessness or inappropriate guilt, inability to concentrate, changes in energy level, changes in sleep, psychomotor agitation or retardation, significant fluctuations in weight, or recurrent thoughts of death/suicide. Anhedonia or depressed mood must be present for at least 2 weeks to achieve a diagnosis of clinical depression (APA, 2000). Depression greatly affects the individual and has implications on daily activity levels. If a patient is encountering depressive symptoms, he will be less likely to engage in typical activities, reporting lower scores on the Duke Activity Status Index (DASI) and potentially lower scores on global health and quality of life (QOL) measures. The DASI (Hlatky, Boineau, Higginbotham, Lee, Mark, Califf, Cobb & Pryor, 1989) is a 12 item self-report scale, which is correlated with oxygen uptake. The DASI asks for self-reported ability of daily activities affecting the patient's overall quality of life.

Sears and Kirian (2010) suggested that the depression rate in ICD patients is equivalent to other disease states of cardiac patients, ranging from 24% to 41%, and affects patient outcomes. Bilge, Ozben, Demircan, Cinar, Yilmaz, and Adalet (2006) reported that nearly half of ICD patients present symptoms consistent with the presence of an anxiety or depressive disorder. As depression manifests in the patient, daily behaviors may change due to the symptoms of decreased interest in pleasurable activities, fatigue, and feelings of worthlessness. The patient may avoid usual behaviors and activities, maintaining depressive symptoms. Whang et al. (2005) found

that depressive symptoms may correctly predict ventricular arrhythmias treated via ICD shock. This study implied that patients who are experiencing a great deal of distress are at greater risk for arrhythmias and shock.

Adjustment Disorder

After implantation of an ICD, patients may undergo a period of distress that is temporary due to living life with a device. Adjustment disorder is clinically defined by the DSM-IV as a disorder with development of emotional or behavioral difficulties due to a remarkable stressor having occurred within three months of the stressor. The disorder may either be identified by excessive distress from what is expected from the stressor or significant social, occupational, or academic impairment. The symptoms must not match those of Bereavement and may not be due to a preexisting diagnosis of an Axis I or II disorder. Also, the symptoms of the disorder must not last longer than 6 months following the removal of the stressor (APA, 2000).

The duration of adjustment disorder is what markedly sets it apart from a diagnosis of Major Depression. Adjustment disorders are clinically difficult to diagnose due to the transient stressor and the response of the individual (Snyder, Strain, & Wolf, 1990). The adjustment disorder diagnosis does not have sufficient behavioral measurements to accurately differentiate from a depressive diagnosis. A study conducted by Snyder et al., (1990) found that the diagnoses are represented by different demographics and patients with adjustment disorder are more likely to be rated by a physician as having improved condition by the end of treatment. Also, in this study, patients diagnosed with adjustment disorder reported better functioning prior to hospitalization. Patients receiving ICDs may be at risk for symptoms of adjustment

disorder due to the sometimes urgent implantation of a device, as well as the adjustment period to living with a device that may elicit a shock or pacing rhythm to the heart.

Aside from the physical implications of receiving a lifesaving shock, there are other identifying factors that could put an individual at risk for psychological distress. Sears and Conti (2003) identified risk factors for poor psychological outcomes such as: having poor premorbid functioning, both psychological and physical, having poor conceptualization of the disease state and the ICD, being young in age (< 50), being a woman, other medical comorbidities and having been exposed to frequent shock. Vasquez et al. (2008) reported that women under 50 years of age are at greater risk of experiencing psychosocial distress due to a fear of shock, body image, or even a fear of mortality. Women's heightened sense of fear and mortality would likely increase avoidance behaviors of the patients. Studies of women living with ICDs are needed to improve understanding of sex differences, in particular as related to daily behaviors.

Behavior

With the ICD shock commonly described by patients as "being kicked in the chest by a horse" (Heller, Ormont, Lidagoster, Sciacca, & Steinberg, 1997, p. 1207), it is understandable that psychological distress may arise. This stunning force to the chest could elicit a multitude of responses by the patient, especially that of anticipation and fear. This "critical event" (Sears & Kirian, 2010, p. 1437) may lead to a fear response and generalization to fear, fear of physical exertion, and possibly avoidance of activities thought to elicit shock.

Behavioral changes in patients may also be due to fear. The fear of physical exertion is common among ICD patients. This fear may be exacerbated by the decreased ability to fully exert oneself. For example, patients with congestive heart failure (CHF) actually experience a physiological intolerance for exercise. Inducible nitric oxide synthase is a protein that exists at increased levels in the skeletal muscles of CHF patients (Hambrecht, Gielen, Mobius-Winkler, Niebauer, & Fiehn, 1999). This enzyme is inversely related to the maximum oxygen uptake of an individual. Therefore, patients with CHF have a preexisting decrease in their exercise capacity and level to which they can exert themselves. This is clinically evidenced in the expression of fatigue and exercise intolerance. CHF patients also have a reduced peak oxygen uptake due to a reduced microvascular density (Duscha et al., 1999). This research suggests that the reduced oxygen uptake precedes further skeletal and muscular transformations in a patient with CHF, eventually leading to decreased exercise intolerance.

Lemon, Edelman, and Kirkness (2004) have explored avoidance behaviors in ICD patients and how classical conditioning affects these behaviors. In this study, Lemon et al. found that 55% of ICD patients avoided activities, objects, and places. Most of the activities avoided by participants in this study involved physical exertion to some extent. Avoidance behaviors detract from the patient's QOL, due to disengagement from pleasurable activities and social support networks. Avoidance warrants further study in order to identify patient reasoning for such behaviors, be it shock history or shock anxiety or other causes. The concern by Lemon et al. (2004) is that there is a misunderstanding between patients with newly implanted ICDs and

doctors. The patients may leave the hospital misinformed about their abilities and use avoidant behaviors. The avoidant behaviors may decrease the patient's quality of life, as well as negatively impact their physical health. Research has not yet explored the relationship between ability and avoidance behaviors in ICD patients.

Young patients have also reported avoiding behaviors post-implantation, regardless of shock history. Sears et al. (2011) found that nearly 85% of children had reports of avoiding behaviors post-implantation. Avoidance behavior was greater in female pediatric patients, and specifically, those patients avoided places more than activities. Females were also more likely to report a lower score on their general QOL as well (Sears et al., 2011). Due to their shock experiences, future studies should focus on this resourceful population when examining the effects of the ICD on behavior and psychological outcomes.

Physical and mental health may direct patient behaviors. Daily behaviors may change due to fear response and decreased interest in pleasurable activities. The patient may feel confined to the "comfort" of his home and fear usual behaviors and activities, maintaining depressive symptoms. The current study, SHOxABILITY, contributes to patient centered outcomes research by providing insight into specific physical activities that are avoided due to fear of shock, as well as other reasons, including doctor's instruction, increase in heart rate, and a lack of desire.

However, shock history does not necessarily need to be present in order to precipitate a change in behavior. Research has debated the effects of shock history having an impact on the patient's behavior. In a review by Magyar-Russell et al. (2011), some researchers reported a small to medium effect of difference in anxiety ratings with

positive shock history patients reporting higher scores, while some studies found the difference between shocked and non-shocked patients to be nonexistent. These data suggest that there are likely other factors that modify the exact effects of shock.

Psychological Health Models- Expression and Maintenance

Psychological theories provide a starting point to evaluate the ICD patient experience, both prior to and after experiencing shock. Among the most common theories are classical conditioning, operant conditioning, and cognitive behavioral theory, as well as the Common Sense Model. These theories are not definitive or exhaustive, but simply help explicate the link between behavior and attitude, body and mind.

Anxiety and other psychological distress may be expressed due to aversive classical conditioning (Godemann, Ahrens, Behrens, Berthold, Gandor, Lampe, & Linden, 2001). In this instance, a shock would be an unconditioned stimulus, eliciting a natural response of surprise and fear. A change in one's heart rate would be the neutral stimulus, originally not eliciting a response, but once paired with the shock eliciting the same fearful response. This would condition a patient to remain sedentary so as to not increase their heart rate for fear of an ICD shock. These feelings of fear and anxiety are suggestively maintained by operant conditioning via negative reinforcement.

Social cognitive theory would suggest maladaptive thoughts and cognitions of fear lead to avoidance behavior. Behavioral activation (BA) is a key component in cognitive behavioral therapy (CBT), providing reinforcement for behaviors that are not aligned with depressive symptoms that a patient is feeling. BA was alluded to in the works of Skinner (1953; Hopko, Lejuez, Ruggiero, Eifert, & Georg, 2003) when the association between depression and the reduction of healthy behaviors performed

became apparent. Behavioral activation acts on the principle that events, which evoke pleasant and rewarding feelings, will maintain and even decrease a patient's avoidant behavior. This may have some applicability to the ICD patient as well. SHOxABILITY survey pinpoints a wide range of generally pleasurable and rewarding activities, which patients may be avoiding. Clinical implications of having this knowledge include the ability for cardiac psychologists to better engage BA treatment and work with individuals to participate in the activities that were once enjoyed.

The Common-Sense Model, developed by Diefenbach & Leventhal (1996), intends to explore the ways a patient adapts and copes with the experience of a chronic illness. This model utilizes a hierarchical system with three main measures, (1) how the illness is represented, (2) the coping response of the individual, (3) the appraisal of coping mechanisms. These three steps help the patient organize external and internal stimuli to better understand how the coping process works and what is useful.

Leventhal studied how high fear messages were more likely to change the physical behaviors of an individual than a low fear message (Diefenbach & Leventhal, 1996). He also reported that a patient is more susceptible to change behavior if a second message is received. For instance, patients who were shocked by their device (high fear message) would be looking for a second message to determine their plan of action. Any message that the patient receives post-shock, direct or implied, could be utilized or misinterpreted to influence patient behavior. The second message could come from misinterpreting a doctor's comment about performing a behavior that "elicited" shock. The second message is likely an effect of the patient being in a

hyperaroused state post-shock. The patient is “tuned in,” looking for a second message to direct her behavior.

The individual’s context of the situation could play a role in the experience of shock. A patient’s life context has supplied him with the problem-solving behaviors and strategies that he uses on a daily basis. If a patient has experienced pain or a previous shock, he may have an automatic and immediate reaction to the physical discomfort, complemented by emotional distress. The coping strategy that is then employed may be one leading to increased emotional distress, such as rumination about the critical event. This rumination would perpetuate until the individual is highly anxious or depressed, then most likely begins to avoid daily activities.

Another critical component of Leventhal’s Common Sense Model is the rule of symmetry (Diefenbach & Leventhal, 1996). Leventhal explained that, as children, we learn what it means to be sick. This schema that is formed is carried into adulthood and the potential for chronically ill patients to form a symptom-illness relationship is high. When the ICD patient feels somatic symptoms, including shortness of breath and palpations, he probes for a label to place on what he is experiencing. The label he is looking for is “sick.” Even though an ICD patient is capable of performing in most ways that a relatively healthy individual could, he might hear the term “sick” or “ill” and fully assume this mentality. The patient may then avoid exertive or even enjoyable activities, thinking they are being compliant to their illness’ needs and doctor’s orders.

In summary, SHOxABILITY will provide physicians and patients with normative data about patient outcomes and how they affect patients’ personal concepts revolving

around the Common Sense Model. This information will aid the patient in a more valid understanding of the disease state and the benefits of an ICD.

Ability and avoidance

Behavior can be affected by mental health as well as physical health and current disease states. Increased physician attention to changes in behavior can lead to doctor awareness of psychological components accompanying the patient's disease state. Behavior reduction and modification can serve as a coping mechanism for the ICD patient. Reducing exertive and pleasurable activities that could potentially cause a shock, may lead to a decrease in expressed QOL. Daily activity measures using self-report are available and include measures such as the Duke Activity Status Index (DASI), daily diaries, leisure activity indices, and tools such as pedometers.

As it was previously stated, the behaviors of ICD patients may be altered due to psychological distress, history of shock, and even the physiological foundation of a heart failure patient. The importance of SHOxABILITY lies in the differentiation between ability and avoidance. There is a clinical difference between being able to perform an activity and actively performing it. The behaviors of an ICD patient should be studied to identify these key differences in perception and performance (Figures 1 & 2).

Figure 1

Simple Ability Schematic

Figure 2

Distressed Ability Schematic

Present Study

The purpose of SHOxABILITY is to identify rates of reported ability and avoidance in patients with ICDs in their daily routine. The Duke Activity Status Index (DASI) (Hlatky et al., 1989) was utilized to assess individual functioning in SHOxABILITY by sampling daily activities of ICD patients. This study is the first study to utilize electronic mail as a means of dissemination and was able to survey a broad range of patients in a nation-wide sample. This sampling technique has not been utilized to this extent in previous ICD patient data collection. The qualitative data received from this study offer a unique snapshot of the ICD patient's behavior and his thoughts on avoided behaviors as well as reasoning behind behavioral choices. Identification of avoided activities and the

reasoning behind these decisions will depict a large sample of the ICD patient's behavior, including daily struggles with returning to a routine. After establishing the typical daily activities of ICD patients, interventions for patients with low activity or high avoidance may be efforts to establish a daily "activity plan" to ensure activity levels associated with desirable health outcomes.

Hypotheses from literature

Comprehensive, descriptive and frequency analyses were completed examining sample characteristics and the variables used in the primary analyses.

Inferential statistics were planned as follows:

Hypothesis 1 Justification: Initial research indicated avoidance behavior at a greater rate in female pediatric patients. Females also reported lower overall scores on QOL measurements (Sears et al., 2011).

Hypothesis 1: It was hypothesized that men aged <49 years would show higher rates of performing exertive daily activities, such as sexual and recreational activities, than would women in the same age group.

Analysis 1: Analysis of variance (ANOVA) was conducted with sex and age as the independent variables and avoidance of functioning categories as the dependent variable.

Hypothesis 2 Justification: ICD shocks are associated with patient-centered outcomes such as anxiety. The influence of shock may vary with intermittent time and QOL appraisal (Pedersen, Broek et al., 2010). Avoidance can be triggered by an effort to avoid the pain and discomfort of shock (Matchett, Kirian et al., 2009). The influence of activity avoidance due to shock is likely to be based on an "avoidance gradient." Shock anxiety likely increases as the behavior becomes more exertive. Epstein and Fenz (1965) found such a gradient that, as there was continuous threat, there was an increase in anxiety, as well as an increase in avoidance of exertive behaviors.

Hypothesis 2: Using shock history splits, consistent with the literature (0 shocks, 1-4, 5-9, and 10 or more), it was hypothesized patients having experienced 5 or more, or 10 or more shocks would report significantly greater avoidance in exertive behaviors, such as sexual and recreational activities, than the 0 shock or 1-4 groups.

Analysis 2: Analyses of variance (ANOVA) procedure was completed with shock history group serving as the independent variable and avoidance as the dependent variable.

Hypothesis 3 Justification: Examination of the relationship between shock occurrence and shock anxiety allows for increased understanding about patient reaction to shock. Hypothesis 3: It was hypothesized that patients with shock history of five of more shocks would report more shock anxiety than patients receiving zero shocks or 1-5 shocks.

Analysis 3: Analyses of variance (ANOVA) was computed with shock history group as the independent variable and shock anxiety (total FSAS score) as the dependent variable.

Hypothesis 4 Justification: Women have been identified as a subset of the ICD population at high risk for psychological distress (Vasquez, Conti, & Sears, 2010). Younger women reported higher levels of shock anxiety than those in the middle or older cohort categories (Vasquez et al., 2010).

Hypothesis 4: It was hypothesized women from 18 years of age to 49 years would report higher levels of shock anxiety than will men of the same age group.

Analysis 4: Analysis of variance (ANOVA) was conducted with sex and age as the independent variables and shock anxiety (total FSAS score) as the dependent variable.

CHAPTER III: METHOD

Participants and Demographics

After institutional review board approval with East Carolina University (see Appendix A), ICD recipients were electronically mailed a survey with one mass-email by a third party research firm. The list was constructed by a device company (Medtronic) and is detailed in the Procedure. The ultimate participants of the SHOxABILITY survey were 443 ICD patients from across the country. Participants were distributed by age with 0.9% (*n* = 4) between age 21-29, 1.1% (*n* = 5) between age 30-39, 3.6% (*n* = 16) between age 40-49, 4.1% (*n* = 18) between age 50-54, 22.1% (*n* = 98) between age 55-64, and 68.2% (*n* = 302) were 65 or older. Three hundred fifty-nine (81%) participants were male and eighty-four (19%) participants were female. Of the women surveyed, 47.61% reported prior shock experience, while 50.14% of the men reported shock history.

Participants in this study predominately identified themselves as White (*n* = 421, 95%), while Black/ African-American/ Caribbean-American was next in frequency (*n* = 8, 1.8%), followed by Asian (*n* = 5, 1.1%), Hispanic/ Latino participants (*n* = 4, 0.9%), other (*n* = 3, 0.7%). Two participants declined to offer their race for demographic purposes and selected “other” on the survey.

Measures

Participants completed a short battery of demographic questionnaires, activity indices, and anxiety scales as described below.

The Florida Shock Anxiety Scale (FSAS). The FSAS is a brief self-report questionnaire, developed to assess patient anxiety and specific fears in relation to experiencing ICD

shock with the purpose of identifying proper psychological referrals in the cardiac health field (Kuhl et al., 2006). The cumulative score is a quantitative measurement of the patient's anxiety surrounding his ICD, using single factor scores. The FSAS has good reliability (Cronbach's alpha = 0.91, split-half reliability = 0.92) and is moderately correlated (r = -.65) with the Multidimensional Fear of Death Scale, demonstrating a beneficial measurement of fear towards the ICD device and events.

The Duke Anxiety Status Index (DASI). The DASI (Hlatky et al., 1989) is a 12 item self-report scale which asks questions of ability of certain activities to assess different aspects of ones quality of life. The questions range from "can you take care of your self, that is eating, dressing, and using the toilet?" to "can you participate in strenuous sports like swimming, singles tennis, football, basketball, or skiing?" (Hlatky et al., 1989). The DASI is moderately correlated with a peak oxygen uptake (r = 0.58) and is considered a valid and reliable measure of perceived functional capability (Hlatky et al., 1989). The DASI is scored using the metabolic equivalence of task or MET unit since the correlation between peak oxygen uptake and total DASI score is so profound.

The DASI Avoidance Modification (DASI-A). In order to study the avoidance of activity, we constructed a set of questions to ask about avoidance of specific behaviors by ICD patients. This measure is identical to the DASI, only modified to examine avoidance of activities. The DASI-A also includes a free response explanation of why the patient avoids those DASI activities.

SHOxABILITY. ICD patients were surveyed using an online measure (SHOCK2010 or Medtronic Protecta Survey) designed to provide a brief, descriptive assessment of individual ICD experiences (see Appendix B). The survey consisted of two scales of

anxiety, including the Florida Shock Anxiety Scale (FSAS) and the Duke Anxiety Status Index (DASI) as well as a multitude of additional demographic and qualitative questions. SHOxABILITY is a study designed from the SHOCK2010 data. SHOxABILITY included a scale aimed to measure the avoidance of patients towards the activities originally presented in the in DASI. After the response of the avoided activities, the patient encounters a section where the reason for avoiding is questioned. Reasons included: fear of shock, increase heart rate, doctor instruction, no desire, and a write in option.

Procedure

Four-thousand four-hundred forty-seven email surveys were distributed to individuals across the country in an implantable cardioverter defibrillator (ICD) recipient data base. Of those emails distributed, 563 survey links were accessed, with 443 surveys completed, providing a completion rate of the SHOCK 2010 survey at 78.69%, for those who accessed the survey. The overall response rate from the original distribution of surveys is 13%. One-hundred-twenty surveys remained incomplete and the remainder of the nearly five-thousand patient sample emails was either never opened or not received (Figure 3). A large number of addresses were invalid because they were collected over an extended period of time (~ 5 years) and no effort has been undertaken to validate and update the e-mail address database. Remuneration was not available for individuals completing the survey.

Figure 3

Analysis Plan

Planned comparisons of the hypotheses were conducted using SPSS (V.19). Simple descriptives of the demographic data were run initially. Next, the frequencies of the reported ability of activities were computed. Frequencies and descriptives of the activities in the DASI, as well as frequencies and descriptives on the avoidant and non-avoidant behaviors were conducted. Lastly, a one-way ANOVA was conducted to determine the FSAS score by the number of shock episodes (not necessarily the total number of shocks). The Tukey HSD procedure was employed as the post hoc test to examine any significant differences between groups.

CHAPTER IV: RESULTS

Analyses were performed using the general linear model function in SPSS v.19. Descriptive statistics were performed first to assess the sample. The sample of 443 ICD patients consisted of 359 (81%) men and 84 (19%) women. Ninety-four percent of the sample were participants over the age of 50 years. The education levels of the sample population were analyzed with 97.3% of the sample having at least graduated high school. The participants mostly identified themselves as Caucasian (95.5%).

Table 1
Which of the following age groups do you fall into?

Age group	Frequency	Percent	Cumulative Percent
< 18 – 49	25	5.6	5.6
50 – 64	116	26.2	31.8
65 +	302	68.1	100.0
Total	443	100.0	

Table 2
What is your level of education?

Level of education	Frequency	Percent	Cumulative Percent
Some high school	12	2.7	2.7
High school graduate	54	12.2	14.9
Some college	106	23.9	38.8
College graduate	135	30.5	69.3
Graduate school	110	24.8	94.1
Technical school	26	5.9	100.0
Total	443	100.0	

Table 3
For demographic purposes only, can you please tell me your race?

Race		Frequency	Percent	Cumulative Percent
	White	421	95.0	95.5
	Black / African-American / Caribbean-American	8	1.8	97.3
	Hispanic / Latino	4	.9	98.2
	Asian	5	1.1	99.3
	Other	3	.7	100.0
	Total	441	99.5	
Missing	Don't know / refused	2	.5	
Total		443	100.0	

Table 4
Which category best describes your yearly household income? Include all sources of income, and all people living in your home.

Yearly household income		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	$0 to $9,999	1	.2	.3	.3
	$10,000 to $19,999	13	2.9	3.4	3.6
	$20,000 to $29,999	36	8.1	9.3	12.9
	$30,000 to $39,999	40	9.0	10.3	23.2
	$40,000 to $49,999	41	9.3	10.6	33.8
	$50,000 to $74,999	93	21.0	24.0	57.7
	$75,000 to $99,999	55	12.4	14.2	71.9
	$100,000 to $149,999	66	14.9	17.0	88.9
	$150,000 and above	43	9.7	11.1	100.0
	Total	388	87.6	100.0	
Missing	Don't know / refused	55	12.4		
Total		443	100.0		

Quantitative data from the sample on reported occasions of shock, reported ability of activity, and reported avoidance of activities are presented below.

Reported Shock

The sample was evenly split with 49.7% of the patients reported having experienced a shock and 50.3% having not reported experiencing an ICD shock. A majority of the shocked patients (30.5%) reported experiencing shock between one and four times.

Activity

The DASI measure consists of 12 items, of differing exertion levels and activities. A majority of the sample reported being able to complete personal care items (99.8%) and low intensity ambulatory activities (91.2% - 98.9%). However, approximately 51%, only a slight majority, of the participants reported being able to run a short distance. Heavy housework (37%) and yard work (27.3%) also showed higher percentages of participants as unable to complete these activities than did light and moderate housework.

Table 5

Can you do this activity today?	No	Yes
Take care of yourself (eating, dressing, bathing, or using the toilet)	1 (.2%)	442 (99.8%)
Walk indoors such as around your house	5 (1.1%)	438 (98.9%)
Walk a block or two on level ground	39 (8.8%)	404 (91.2%)
Climb a flight of stairs or walk up a hill	27 (6.1%)	416 (93.9%)
Run a short distance	217 (49.0%)	226 (51.0%)
Do light work around the house like dusting or washing dishes	8 (1.8%)	435 (98.2%)
Do moderate work around the house like vacuuming, sweeping floors, or carrying in groceries	21 (4.7%)	422 (95.3%)
Do heavy work around the house like scrubbing floors or lifting and moving heavy furniture	164 (37.0%)	279 (63.0%)
Do yard work like raking leaves, weeding, or pushing a power mower	121 (27.3%)	322 (72.7%)
Have sexual relations	157	286

	(35.4%)	(64.6%)
Participate in moderate recreational activities like golf, bowling, dancing, doubles tennis, or throwing a baseball or football	135 (30.5%)	308 (69.5%)
Participate in strenuous sports like swimming, singles tennis, football, basketball, or skiing	305 (68.8%)	138 (31.2%)

Avoidance

The avoidance measure (DASI-A) consisted of a 5-point likert scale, including responses such as all of the time, most of the time, some of the time, rarely, and never. It is most clinically significant to split the responses to the DASI-A measure into two groups, at least some of the time and rarely or never. Holding this split in responses, participating in strenuous sports (80.4%) and running a short distance (74.3%) had the greatest avoidance response rate. Sex (51%), moderate recreational activities (55.5%), and heavy housework (57.3%) were also avoided by more than fifty percent of the sample population

Table 6

Do you avoid doing this activity?	**Yes**	**No**
Take care of yourself (eating, dressing, bathing, or using the toilet)	27 (6.1%)	416 (93.9%)
Walk indoors such as around your house	45 (10.2%)	398 (89.8%)
Walk a block or two on level ground	138 (31.2%)	305 (68.8%)
Climb a flight of stairs or walk up a hill	166 (37.5%)	277 (62.5%)
Run a short distance	329 (74.3%)	114 (25.7%)
Do light work around the house like dusting or washing dishes	83 (18.7%)	360 (81.3%)
Do moderate work around the house like vacuuming, sweeping floors, or carrying in groceries	96 (21.7%)	347 (78.3%)
Do heavy work around the house like scrubbing floors or lifting and moving heavy furniture	254 (57.3%)	189 (42.7%)
Do yard work like raking leaves, weeding, or pushing a power mower	218 (49.2%)	225 (50.8%)

Have sexual relations	226 (51.0%)	217 (49.0%)
Participate in moderate recreational activities like golf, bowling, dancing, doubles tennis, or throwing a baseball or football	246 (55.5%)	197 (44.5%)
Participate in strenuous sports like swimming, singles tennis, football, basketball, or skiing	356 (80.4%)	87 (19.6%)

Ability - Avoidance Matrix

Table 7 better describes the difference in patient ability and avoidance. Those individuals who fall in the "yes" able and "yes" avoid category are seen as patients who know they are able to perform an action, but are avoiding this action.

The most avoided activities among able ICD patients were participating in moderate (55.5%) or strenuous (80.4%) recreation. Approximately 74.8% of individuals indicate they are able to run a short distance, but avoid doing this activity. Similarly, 76.1% of individuals report they are able to participate in strenuous sports (swimming, singles, tennis, football, basketball, or skiing), but avoided them and 52.3% of individuals endorse they can participate in moderate recreational activities, but avoided them.

Table 7

	Able	**Avoid**		
		Yes	**No**	**Total N**
Take care of yourself (eating, dressing, bathing, or using the toilet)	**No**	100.0%	0%	1
	Yes	5.9%	94.1%	442
Walk indoors (i.e. around the house)	**No**	20.0%	80.0%	5
	Yes	10.0%	90.0%	438
Walk a block or two on level ground	**No**	43.6%	56.4%	39
	Yes	30.0%	70.0%	404
Climb a flight of stairs or	**No**	51.9%	48.1%	27

walk up a hill	**Yes**	36.5%	63.5%	416
Run a short distance	**No**	73.7%	26.3%	217
	Yes	74.8%	25.2%	226
Do light work around the house like dusting or washing dishes	**No**	37.5%	62.5%	8
	Yes	18.4%	81.6%	435
Do moderate work around the house like vacuuming, sweeping floors, or carrying in groceries	**No**	33.3%	66.7%	21
	Yes	21.1%	78.9%	422
Do heavy work around the house like scrubbing floors or lifting and moving heavy furniture	**No**	65.2%	34.8%	164
	Yes	52.7%	47.3%	279
Do yard work like raking leaves, weeding, or pushing a power mower	**No**	22.0%	41.3%	121
	Yes	45.7%	54.3%	322
Have sexual relations	**No**	56.0%	43.9%	157
	Yes	48.2%	51.7%	286
Participate in moderate recreational activities like golf, bowling, dancing, doubles tennis, or throwing a baseball or football	**No**	63.0%	37.0%	135
	Yes	52.3%	47.7%	308
Participate in strenuous sports like swimming, singles tennis, football, basketball, or skiing	**No**	82.3%	17.7%	305
	Yes	76.1%	23.9%	138

Reasons for Avoiding

An analysis on the reasons why participants reported avoiding activities was conducted. The greatest percentage of participants reported the "other" response for why they do not currently participate in each of the activities of focus. It is important to note that the response choices included "fear of shock," "increase in heart rate," "doctor's instruction," "no desire," and "other." Many of the participants who reported having "other" reasons

for avoiding the activity did not complete a fill in response to clarify. Some popular responses when “other” was reported in the free response field include: angina, shortness of breath, fatigue, and joint pain.

Table 8

	Reason for avoiding				
Activity	**Fear of Shock**	**Increase HR**	**Doctor Instruction**	**No Desire**	**Other**
Take care of yourself (eating, dressing, bathing, or using the toilet)	0%	0.9%	0%	1.1%	6.8%
Walk indoors such as around your house	0.2%	2.7%	0.9%	6.3%	9.5%
Walk a block or two on level ground	1.8%	8.1%	1.6%	14.4%	23.3%
Climb a flight of stairs or walk up a hill	3.2%	15.3%	2.0%	12.0%	33.2%
Run a short distance	5.2%	15.6%	8.4%	26.9%	36.6%
Do light work around the house like dusting or washing dishes	0.2%	4.1%	0.7%	14.4%	14.4%
Do moderate work around the house like vacuuming, sweeping floors, or carrying in groceries	1.4%	4.7%	1.8%	14.7%	20.8%
Do heavy work around the house like scrubbing floors or lifting and moving heavy furniture	5.9%	14.7%	12.2%	20.5%	27.8%
Do yard work like raking leaves, weeding, or pushing a power mower	3.6%	11.3%	6.8%	17.4%	31.2%
Have sexual relations	3.4%	6.3%	2.3%	24.4%	34.1%
Participate in moderate recreational activities like golf, bowling, dancing, doubles tennis, or throwing a baseball or football	5.4%	10.4%	4.3%	27.5%	29.6%
Participate in strenuous sports like swimming, singles tennis, football, basketball, or skiing	6.8%	16.0%	9.5%	33.6%	33.9%

ANOVAs: The Effects of Sex, Age, and Shock on Avoidance

Avoidance by sex and age. A one-way between group analysis of variance was conducted to explore the impact of age and sex on avoidance, using the DASI-A

modified avoidance measure (M = 42.65), where the higher the score, the less avoidance the patient is reporting. Patients were divided into three age groups, consistent with literature (Group 1, < 49 years of age; Group 2, 50-64 years of age; Group 3, 65 and older). Sex differences were non-significant in the reported DASI-A measurement ($F = 0.274$, $p = 0.601$). Age differences were significant ($F = 5.219$, $p = 0.006$), such that participants aged 65 and older acknowledged avoiding more activities than patients aged 50 to 64 years ($p = 0.012$).

Table 9

ANOVA Data for Activity Avoidance by Age

	Df	***F***	***P***
Between Groups	2	5.219	0.006
Within Groups	440		
Total	442		

Avoidance by Shock. A one-way analysis of variance (ANOVA) was performed on the SHOxABILITY database with the independent variable of shock history groups (grouped by number of shocks experienced) and avoidance (DASI-A total) serving as the dependent variable. This analysis was conducted to explore the impact of number of shocks on avoidance, using the DASI-A modified avoidance measure, where the higher the score, the less avoidance the patient is reporting. Patients were divided into four shock history groups, consistent with literature on multiple shocks (Group 1, 0 shocks; Group 2, 1-4 shocks; Group 3, 5-10 shocks; Group 4, more than 10 shocks). Shock

history differences were non-significant in the reported DASI-Avoidance measurement (F (3,439) = 0.806, p = 0.491).

Table 10

Descriptive Data for Activity Avoidance by Shock History

Dependent Variable:AVOID_Measure

On how many occasions have you been shocked?	Mean	Std. Deviation	N
0	43.6906	9.94663	223
1-4 times	42.1630	9.92826	135
5-10 times	42.6667	9.89772	39
More than 10 times	42.0870	10.81116	46
Total	42.9684	10.02232	443

ANOVAs: The Effects of Sex, Age, Shock on Shock Anxiety

Shock anxiety by sex and age. To investigate the effects of sex and age on shock anxiety, we performed ANOVA procedures with the independent variables consisting of sex (2) and age (< 50, 50 to 64, $\geq$ 65 years of age) with shock anxiety (FSAS total) serving as the dependent variable.

A one-way between groups analysis of variance was conducted to examine the impact of sex on shock anxiety. Shock anxiety reported by male and female patients was significantly different (F (1, 441) = 7.05, p = 0.008), such that women reported greater shock anxiety (M = 16.86, SD = 7.57) than men (M = 14.79, SD = 6.14). Though statistically significant, the effect size mean FSAS scores between men and women were small, with an eta squared of 0.02.

A one-way between groups analysis of variance was conducted to explore the impact of age on shock anxiety, using the total FSAS score (M = 15.18). Patients were divided into three age groups, consistent with literature (Group 1, < 49 years of age; Group 2, 50-64 years of age; Group 3, 65 and older). Results indicated a significant difference with younger individuals reporting greater shock anxiety (F (2, 440) = 17.57, p = 0.00) and each age group differing significantly from the other age groups. The results in Table 11 show that the main effects for age (F (2, 440) = 13.8, p = 0.00) are significant, with a small to medium effect ($\eta^2 = 0.08$). This indicates that the three age groups have differing shock anxiety scores, and sex differences were non-significant. There was no interaction.

Table 11

Descriptive Data for Shock Anxiety by Sex and Age

Dependent Variable:FSAS

Are you...?	Age	Mean	N
Male	< 18 -49	19.8571	14
	50-64	16.3333	78
	65 +	14.0674	267
	Total	14.7855	359
Female	< 18 -49	20.4545	11
	50-64	18.3947	38
	65 +	14.0571	35
	Total	16.8571	84
Total	< 18 -49	20.1200	25
	50-64	17.0086	116
	65 +	14.0662	302
	Total	15.1783	443

Shock anxiety by shock history. A one-way between groups analysis of variance was conducted to explore the impact of number of shocks on shock anxiety, using the total FSAS score (M = 17.45). Patients were divided into four groups, consistent with literature on multiple shocks (Group 1, 0 shocks; Group 2, 1-4 shocks; Group 3, 5-10 shocks; Group 4, more than 10 shocks).

There was a significant difference between the shock history groups in the reported shock anxiety as measured by the FSAS total score (F (3, 439) = 43.250, p = 0.0). The effect size, calculated using eta squared, was 0.228, a medium to large effect. Post-hoc comparisons using the Tukey LSD test indicated that the mean anxiety scores for patients in each of the shock groups differed significantly from the other groups, with individuals experiencing more shock, consequentially experiencing more shock anxiety.

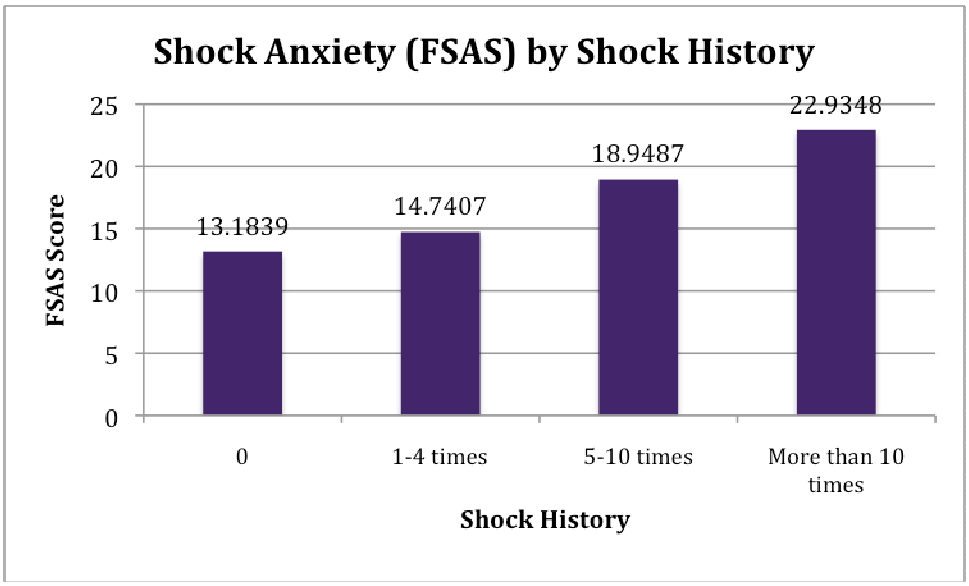
Table 12

Descriptive Data for Shock Anxiety by Shock History

Dependent Variable:FSAS

On how many occasions have you been shocked?	Mean	Std. Deviation	N
0	13.1839	5.12873	223
1-4 times	14.7407	5.26742	135
5-10 times	18.9487	7.63285	39
More than 10 times	22.9348	7.53776	46
Total	15.1783	6.48055	443

Figure 4


Shock Anxiety (FSAS) by Shock History
FSAS Score
25
20
15
10
5
0
13.1839
14.7407
18.9487
22.9348
0
1-4 times
5-10 times
More than 10 times
Shock History

CHAPTER V: DISCUSSION

Summary of Findings

The current study examined ICD patients' ability and avoidance of progressively exertive behaviors. The factors of sex, age, and shock history were also examined for differences on avoidance and shock anxiety. No interaction or main effects of patient sex were found on activity avoidance. In testing the main effects of age and sex on activity avoidance, older ICD patients reported avoiding more activities than younger patients. There was no effect of shock history on levels of avoidance but there were differences on shock anxiety. Lastly, results indicated that many patients with ICDs (6.1 – 80.4%) may experience activity avoidance and shock anxiety due to the implanted device. Many patients reported being unable to participate in exertive, athletic activities (68.8%), sex (35.4%), and running a short distance (49.0%) at relatively high rates. Patients reported ability to perform some daily behaviors, while also reporting avoidance of those same behaviors, such as strenuous athletics (76.1%) and sex (48.2%).

SHOxABILITY also presented evidence that patients avoid strenuous activities at high rates, regardless of reporting their ability to do them. For example, walking a block or two on level ground was avoided by nearly a third of the individuals who reported being able to do this activity. Also, sex was avoided by almost half of individuals who reported being able to do so. Finally, strenuous athletic exertion was avoided by the majority of ICD patients who acknowledged that they were able to do such activity. Collectively, the utility of consideration of both ability and avoidance rates allows for a more complete picture to emerge of ICD patient activities but more information about intervention is needed.

All of the activities included in the DASI are generally considered safe and were avoided for differing reasons. Fear of shock was one reason for avoidance that was important, but fear of increasing heart rate was often more prominent; for example 3.4% of patients reported avoiding sex due to shock fear, while 6.3% avoid due to fear of increased heart rate. These reasons are likely interrelated, but would be important to address. Doctor's instruction and no desire were other factors presented in reasoning for reported avoidance. However, for many behaviors, the "other" or "no desire" response was often the most common response. The "no desire" response can be interpreted broadly and warrants further examination in future studies to rule out depression and other factors that relate to desire and motivation. Future research should target why people who can do activities avoid them.

The findings from SHOxABILITY are consistent with literature on anxiety and ICDs. SHOxABILITY bolsters the findings for sex as a risk factor for poor psychosocial adjustment with an ICD (Sears & Conti, 2002). This study also confirmed that age is critical to the interpretation of shock and young patients experience greater distress due to ICD shock (Sears, Burns, Handberg, Sotile, & Conti, 2001; Sears, Hazelton et al., 2011). SHOxABILITY confirmed that shock exposure leads to greater ICD shock anxiety in patients, lending further support to the measurement and validity of the FSAS (Sears & Kirian, 2010).

From the SHOxABILITY data, it is apparent that psychological factors such as shock specific anxiety, depression, and general anxiety are relevant but not completely the explanation. Other factors play a role in patients avoiding activities, including education at time of implant and the depth of the education provided. If a patient were

recently hospitalized, deconditioning due to hospitalization and disease may impact the patient's daily activity, including muscle loss and decreased activity. Finally, since heart disease impacts the individual as well as the family unit, spousal and familial control over activity and exertion may impact the patient's efficacy and desire to return to full activity.

Clinical Implications

Results from SHOxABILITY provide direction for the clinical care of ICD patients and support the utilization of activity plans, intimacy plans, strenuous plans, and even age plans. For example, activity plans for the ICD patient may be necessary if the patient is reporting avoiding common activities or activities that were once pleasurable for the individual. The activity plan may include a hierarchy of activities that the individual wants to return to participation. Collaboratively, the patient, clinician, and family members would then gradually work through a hierarchy and be exposed to each activity, while rating anxiety using subjective units of distress (SUDs), on a scale from 0 – 100. Strategies such as diaphragmatic breathing, cognitive coping statements, and supportive attention can facilitate goal attainment.

While an activity plan may be useful for some patients, a more specific and focused plan may be necessary for others. If the patient is avoiding sex with their partner or even if the partner is uncomfortable in engaging in intimacy, an intimacy plan may be offered to help. An intimacy plan would essentially work the same way as an activity plan, moving in progression from holding hands and touching to kissing and becoming increasingly more intimate until the couple is ready and able to engage in sex. This intimacy plan would need to be tailored based on the age and sexuality of the

individual in treatment. This type of plan for ICD patients is available in ICD specific patient pages, such as Sexual Health and the ICD patient (Vazquez, Sears, Shea, & Vasquez, 2010).

Strenuous rehabilitation plans could be developed for individuals who are accustomed to an active lifestyle and are able to perform daily activities. The patient in need of a strenuous plan would be the athlete or fit man or woman who may be avoiding activities, such as running up a steep hill because he received an ICD shock the last time he encountered it. Moreover, this patient may be avoiding more strenuous activity in part by hypervigilance of his heartbeat due to the implantation of the device. A strenuous activity plan would work an individual through a hierarchy of strenuous activities, even starting with imagery of the event, location, or action where the individual is having difficulty reconnecting. Similar to the intimacy plan, the strenuous activity plan would have to be tailored to the individual's ability and age in order to provide the best outcome for treatment goals. Collectively, health psychological interventions using cognitive behavioral techniques could be utilized to reduce unwanted avoidance in ICD patients.

Limitations

The current study suffers from specific limitations that should be considered when interpreting its results. The homogeneity of the sample is the most serious limitation to the study. The final sample group contained a largely white population and clearly limits the generalizability of our findings. The use of self-report indices is another limitation in that self-reporting may be subject to bias and social disability. However, participants could reasonably be assured of virtual anonymity. The absence of medical record

review is another limitation, as this study relied on patient self-report of shocks and current ability to perform the activities of focus. Other limitations include being unaware of the ICD patients' mental health history. Patients could potentially be in therapy for existing anxieties or PTSD symptomology that has occurred since implantation of the device. This would affect the way in which the patient completes the survey. Without obtaining psychopharmacological information, the potential for highly anxious ICD patients taking benzodiazepine to answer questions as if they had no or reduced anxiety is present.

Future Aims

SHOxABILITY is a stepping-stone for increasing our understanding of ICD patient care and treatment. The information from this survey provides information on the general capabilities of ICD patients and the rates of avoidance of a variety of progressively exertive behaviors. The SHOxABILITY survey may have more general value as a methodology that could be tailored and disseminated to different disease states in the field of cardiology. For instance patients, living through a sudden cardiac arrest (SCA), with a narrow 5% chance of survival, could benefit from the knowledge gained from this type of widely disseminated survey. Short and complete surveys such as this can aid in modifying the public health sector. Results from this survey could lead physicians to improve the quality of care by knowing what questions to ask and how to identify problems such as avoidance and anxiety in cardiac populations.

Future studies may add to the value of the data collected from SHOCK2010. For instance, a simple avoidance score could be calculated with the DASI-A measurement where individuals are flagged as needing care if more than 2 activities are avoided.

This study could be conducted in a clinic setting to test the reliability of the screening measure or in a fast paced clinic where the patients complete care team spends time ensuring the progression of the patient's care.

Conclusion

The current study suggests that many patients with ICDs (6.1 – 80.4%) may experience activity avoidance and shock anxiety due to the implanted device. Patients who experience shock anxiety tend to have had more shock experience. Patients who are older reported significantly lower shock anxiety. Patients aged 65 and older reported significantly different levels of activity avoidance than younger individuals reporting less activity avoidance. Having experienced prior ICD shock did not affect the reported level of activity avoidance. Physicians should be aware that patients with greater shock history are more likely to experience shock anxiety and younger patients report greater levels of shock anxiety. ICD patients may also report that they are able to do activities that may be avoided due to fear of shock or fear of heart rate increase. These findings will aid in the quality of care which ICD patients receive, giving physicians the ability to better predict shock anxiety outcomes.

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APPENDIX A

UMCIRB #:

RECEIVED
OCT 08 2010
UMCIRB

UNIVERSITY AND MEDICAL CENTER INSTITUTIONAL REVIEW BOARD
REVISION FORM

UMCIRB #: 10-0322 **Date this form was completed:** 10/08/10
Title of research: SHOCK 2010: The United States National Survey of Attitudes and Experiences of Shocks in ICD Patients
Principal Investigator: Samuel F. Sears, Ph.D.
Sponsor: Medtronic, Inc.

Fund number for IRB fee collection (applies to all for-profit, private industry or pharmaceutical company sponsored project revisions requiring review by the convened UMCIRB committee):

Fund	Organization	Account	Program	Activity (optional)
		73059		

Account number is pending final approvals.

Version of the most currently approved protocol: Version 1 – approved on 08/09/10
Version of the most currently approved consent document: Version 1- 09/24/10

CHECK ALL INSTITUTIONS OR SITES WHERE THIS RESEARCH STUDY WILL BE CONDUCTED:

- ☒ East Carolina University
- ☐ Pitt County Memorial Hospital, Inc
- ☐ Heritage Hospital
- ☐ Other
- ☐ Beaufort County Hospital
- ☐ Carteret General Hospital
- ☐ Boice-Willis Clinic

The following items are being submitted for review and approval:

- ☐ **Protocol: version or date**
- ☒ **Consent: version or date** Version 1: 9/24/10: no change
- ☒ **Additional material: version or date** Version 1: 10/08/10

Complete the following:

1. **Level of IRB review required by sponsor:** ☐ **full** ☒ **expedited**
2. **Revision effects on risk analysis:** ☐ **increased** ☒ **no change** ☐ **decreased**
3. **Provide an explanation if there has been a greater than 60 day delay in the submission of this revision to the UMCIRB.** n/a
4. **Does this revision add any procedures, tests or medications?** ☐ **yes** ☒ **no** **If yes, describe the additional information:**
5. **Have participants been locally enrolled in this research study?** ☐ **yes** ☒ **no**
6. **Will the revision require previously enrolled participants to sign a new consent document?** ☐ **yes** ☒ **no**

Briefly describe and provide a rationale for this revision An introduction was needed to guide participants more clearly. This text will be added following approval from IRB:
"The survey you are about to take is part of a medical research study on patient experiences with ICDs. As such, we need your consent to take part in this study. On the next screen you will see a detailed consent which tells you more about the survey and ensures your confidentiality. Please read the consent on the next page and check "I Agree" at the bottom if you'd like to continue."

Samuel F Sears — SAMUEL F. SEARS — 10/8/10
Principal Investigator Signature **Print** **Date**

Box for Office Use Only

The above revision has been reviewed by:
☐ Full committee review on _____ ☑ Expedited review on 10/12/2010

The following action has been taken:
☑ Approval for period of 10/12/2010 to 8/3/2011
☑ Approval by expedited review according to category 45 CFR 46.110
☐ See separate correspondence for further required action.

Michelle Eble — 10/12/2010 — Michelle Eble
Signature **Print** **Date**

APPENDIX B

Medtronic Protecta Survey
Penn Schoen Berland
October 2010

PURPOSE: THE PURPOSE OF THIS SURVEY IS TO GAIN A BETTER UNDERSTANDING OF THE PATIENT EXPERIENCE LIVING WITH AN ICD.

PRE CONSENT

/* DISPLAY */ The survey you are about to take is part of a medical research study on patient experiences with ICDs. As such, we need your consent to take part in this study.

On the next screen you will see a detailed consent which tells you more about the survey and ensures your total confidentiality.

Please read the consent on the next page and select the "I Agree" at the bottom if you'd like to continue.

/* NEW PAGE */

/* QCONSENT */ CONSENT DOCUMENT

Title of Research Study: Shock 2010: The United States National Survey of Attitudes and Experiences of Shocks in the ICD Patients
Principal Investigator: Samuel F. Sears, PhD
Institution: East Carolina University
Address: 115 Rawl Building. Greenville, NC 27858-4353
Telephone #: (252) 328-6118

PURPOSE AND PROCEDURES

The purpose of this study is to examine the patient experience of implantable cardioverter defibrillator shock from multiple vantage points. This study is designed to tap an existing database of over 75, 000 ICD patients who have "opted-in" to participation in an annual survey. This survey will provide a brief, descriptive assessment of the shock experience for many ICD recipients. For shocked patients, we want to understand their experience of ICD shock. For non-shocked patients, we want to know more about the perception of the potential for an ICD shock from a patient perspective. All participants will be asked to complete questions concerning physical health, mental health, quality of life, and personal beliefs. This process will take approximately 30 minutes.

POTENTIAL RISKS AND DISCOMFORTS

There are no foreseeable legal or social risks to you for answering the questionnaires truthfully, as your responses will remain confidential. However, it is possible that answering some of the items may produce mild discomfort. Some minor psychological

risks may be involved if you experience any personal emotional discomfort due to your responses to the questions. If you experience distress or have concerns about the study, please contact Dr. Samuel Sears of East Carolina University at 252-328-6118.

POTENTIAL BENEFITS

All participants will have the opportunity to complete the questionnaires, which may have the benefit of increasing self-awareness in terms of living with an implantable cardioverter defibrillator. On a group level, this project has the potential to help us better understand the patient experience of shock. There may be no other personal benefits from your participation, but the knowledge received may be of value to humanity.

SUBJECT PRIVACY AND CONFIDENTIALITY OF RECORDS

Your privacy and confidentiality will be maintained as the researchers will go to extensive lengths to fully protect your confidentiality. A cardiac device manufacturer, Medtronic, is funding this project. Information received during the study will not be used to market to you; your information will not be placed on any mailing lists or sold to anyone for marketing purposes. Again, the results will not be accessible to anyone outside the research team and responses to questionnaires will not be linked to your name. The results of this project may be presented at conferences or published and would not contain identifying information about you or any other participant. Your participation is voluntary and you may leave the study at any time without penalty.

COSTS OF PARTICIPATION & COMPENSATION

There are not costs to participating in this research other than the time to fill out the questionnaires.

VOLUNTARY PARTICIPATION

Participating in this study is voluntary. If you decide not to be in this study after it has already started, you may stop at any time without losing benefits that you should normally receive. Again, you may stop at any time you choose without penalty.

PERSONS TO CONTACT WITH QUESTIONS

The investigators will be available to answer any questions concerning this research, now or in the future. You may contact the investigators, Dr. Sam Sears at 328-6118 at any time. If you have questions about your rights as a research subject, you may call the Chair of the University and Medical Center Institutional Review Board at phone number (252)744-2914 (days). If you would like to report objections to this research study, you may call the ECU Director of Research Compliance at phone number (252)328-9473.

CONSENT TO PARTICIPATE

Title of research study: Shock 2010: The United States National Survey of Attitudes and Experiences of Shocks in the ICD Patients

I have read all of the above information

Please Check "I agree" if you would like to participate in this research. By checking this box you are agreeing that you have read and understand the information above:

1) I Agree
2) I DO NOT Agree /* TERMINATE */

Screeners

/* DISPLAY */ Before taking this survey, please keep in mind that all answers will be anonymous and will not be traced back to you individually.

1. Are you…?

3) Male
4) Female

2. Which of the following age groups do you fall into?

1) Less than 18 years old
2) 18-20
3) 21-29
4) 30-39
5) 40-49
6) 50-54
7) 55-64
8) 65 or older

3. What is your level of education?

1) Grade school
2) Some high school
3) High school graduate
4) Some college
5) College graduate
6) Graduate school
7) Technical school
8) Don't know / refused

4. For demographic purposes only, can you please tell me your race?

1) White
2) Black / African-American / Caribbean-American
3) Hispanic / Latino
4) Asian
5) Arab
6) Other
7) Don't know / refused

5. Which category best describes your yearly household income? Include all sources of income, and all people living in your home.

1) **$0 to $9,999**
2) **$10,000 to $19,999**
3) **$20,000 to $29,999**
4) **$30,000 to $39,999**
5) **$40,000 to $49,999**
6) **$50,000 to $74,999**
7) **$75,000 to $99,999**
8) **$100,000 to $149,999**
9) **$150,000 and above**
10) **Don't know / refused**

Activity Avoidance

/* METRIC A */ Can you do this activity today?

1) **Yes**
2) **No**

/* METRIC B */ Do you avoid doing this activity?

1) **All the time**
2) **Most of the time**
3) **Some of the time**
4) **Rarely**
5) **Never**

/* METRIC C */ ## IF C1, 2, 3, 4 TO PREVIOUS METRIC B ## Why do you avoid this activity?
/* RANDOM ROTATE CHOICES */ /* MULTIPLE RESPONSES PERMITTED */

1) **Fear of shock**
2) **Increase heart rate**
3) **Doctor instruction**
4) **No desire**
5) **Other** /* SPECIFY */ /* DO NOT ROTATE */

/* REPEAT CODES */ /* RANDOM ROTATE SERIES */

6. Take care of yourself (eating, dressing, bathing, or using the toilet)
7. Walk indoors such as around your house
8. Walk a block or two on level ground
9. Climb a flight of stairs or walk up a hill
10. Run a short distance
11. Do light work around the house like dusting or washing dishes

12. Do moderate work around the house like vacuuming sweeping floors or carrying in groceries
13. Do heavy work around the house like scrubbing floors or lifting and moving heavy furniture
14. Do yard work like raking leaves weeding or pushing a power mower
15. Have sexual relations
16. Participate in moderate recreational activities like golf bowling dancing doubles tennis or throwing a baseball or football
17. Participate in strenuous sports like swimming singles tennis football basketball or skiing

/* END SERIES */

Impact of ICD on Quality of Life

18. Today, how would you describe your **general health**?

    1) Excellent
    2) Very good
    3) Good
    4) Fair
    5) Poor

19. Overall, how much has the ICD affected your **general health**? Is your general health now…

    1) Much better
    2) Somewhat better
    3) About the same
    4) Somewhat worse
    5) Much worse

20. Today, how would you describe your **quality of life**?

    1) Excellent
    2) Very good
    3) Good
    4) Fair
    5) Poor

21. Overall, how much has the ICD affected your **quality of life**? Your quality of life is now…

    1) Much better
    2) Somewhat better
    3) About the same
    4) Somewhat worse
    5) Much worse

22. Today, how would you describe your **general emotional health**?

    1) Excellent

2) Very good
3) Good
4) Fair
5) Poor

23. Overall, how much has the ICD affected your **emotional well-being**? Is your emotional well-being now…

1) Much better
2) Somewhat better
3) About the same
4) Somewhat worse
5) Much worse

24. Overall, how much has the ICD affected your **relationship with your family?** Is your relationship now…

1) Much better
2) Somewhat better
3) About the same
4) Somewhat worse
5) Much worse

25. How would you rate your sense of security with your overall health on a scale of 1 to 7, where 7 means "very secure" and 1 means "not at all secure"?

1) 1 – Not at all Secure
2) 2
3) 3
4) 4
5) 5
6) 6
7) 7 – Very Secure

26. Since you've received your device, would you say you feel more secure, less secure or the same about your overall health?

1) More secure
2) The same
3) Less secure

The ICD Experience

/* DISPLAY */ Now we're going to ask you a few questions about your personal experiences with your ICD.

SHOCK QUESTIONS

27. Have you even been shocked by your device?
1) Yes
2) No

28. ## **IF YES TO PREVIOUS** ## On how many occasions have you been shocked?

1) 1-4 times
2) 5-10 times
3) More than 10 times

29. ## **IF YES TO Q27** ## Did you feel adequately prepared to handle the post-shock experience?

1) I felt well prepared and knew just what to do
2) I felt moderately prepared
3) I could have been more prepared
4) I was not prepared at all

30. ## **IF YES TO Q27** ## If you have experienced a shock, which of the following actions did you take after you received your shock? Please select all that apply. **/* MULTIPLE RESPONSES PERMITTED */**

1) Went to the emergency room
2) Called my physician/nurse/ hospital/clinic
3) Sent my device information to the doctor via my Medtronic CareLink Network
4) Lost ability to make rational decisions/actions

31. ## **IF YES TO Q27** ## How disruptive was the overall shock event to your life? Please rate the disruption on a scale of 1 to 7, where 1 means “extremely disruptive” and 7 means “not at all disruptive”.

1) 1 – Extremely Disruptive
2) 2
3) 3
4) 4
5) 5
6) 6
7) 7 – Not at all Disruptive

Frequency of ICD Shock Fears and Emotions

/* METRIC A */ Now we want to understand your feelings about ICD shocks. Please select the frequency with which you feel the following ways about your ICD.

1) **Not at all**
2) **Rarely**
3) **Some of the time**
4) **Most of the time**
5) **All the time**

/* REPEAT CODES */ /* RANDOM ROTATE SERIES */

32. I am scared to exercise because it may increase my heart rate and cause my device to shock me.
33. I am afraid of being alone when the ICD shocks me and I need help.
34. I do not get angry or upset because it may cause my ICD to shock me.
35. It bothers me that I do not know when the ICD will shock me.
36. I worry about the ICD not shocking me sometime when it should.
37. I am afraid to touch others for fear I'll shock them if the ICD shocks me.
38. I worry about the ICD shocking me and creating a scene.
39. When I notice my heart beating rapidly, I worry that the ICD will shock me.
40. I have unwanted thoughts of my ICD shocking me.
41. I do not engage in sexual activities because it may cause my ICD to shock me.

/* END SERIES */

42. Are there any feelings or comments that you have related to ICD therapy that were not adequately addressed in the questions you just answered? If so, please share them here: **/* OPEN END */**