Anthony Garrett Hazelton, DECISIONAL BALANCE AMONG POTENTIAL ICD RECIPIENTS: DEVELOPMENT OF THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR DECISION ANALYSIS SCALE (ICD-DAS) (Under the direction of Dr. Samuel F. Sears) Department of Psychology, June 2011.

Sudden cardiac death is a well-documented public health problem resulting in 400,000 deaths in the U.S. annually. The Implantable Cardioverter Defibrillator (ICD) has demonstrated benefit in reducing mortality in at risk patients. Despite the benefits of this device in treating life threatening ventricular arrhythmias, prospective patients have specific concerns about the challenges of living with an ICD. These concerns include biomedical risks, social deficits, psychological difficulties, and existential beliefs. However, there are no known measures that assess patient's perceptions of the ICD prior to implantation. In the current study, a measure regarding beliefs about the ICD was created, and then a sample of prospective ICD recipients completed the measure by rating their beliefs about the ICD. Factor analysis was performed to assess the relationship between the variables. Measures of psychopathology, quality of life, religious health fatalism, and locus of control were also completed by participants for preliminary validity estimates and to assess relationships between variables. The current study examined patient decision-making regarding the ICD and developed a 2-factor pro and con measurement approach. The ICD-DAS is comprised of 22 essential items with 2 factors labeled: ICD Pros and ICD Cons. The utility of this measure will allow for the provision of patient driven education and counseling and can be used in developing decision aid materials for prospective ICD patients.

Decisional Balance among Potential ICD Recipients: Development of the Implantable Cardioverter Defibrillator Decision Analysis Scale (ICD-DAS)

A Dissertation

Presented to the Faculty of the Department of Psychology

East Carolina University

In Partial Fulfillment of the Requirements for the Degree

Doctor of Philosophy in Health Psychology

by

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July, 2011

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Acknowledgements

I would like to offer my sincere thanks to Dr. Sam Sears, who directed this dissertation and served as my graduate mentor. I would also like to thank Dr. Karl Wuensch for his statistical prowess. Thanks to Dr. Susan McCammon, Dr. Kathleen Row, Dr. Lesley Lutes, and Dr. Derrick Wirtz for the invaluable time, assistance, and insight that each contributed to this project and my graduate training. Thanks to all my friends and family who have been a listening ear for me over the years of my schooling. Thanks to my parents, Tony and Wanda Hazelton, and to my parents-in-law, Bob and Myra Johnson, for their wisdom and support. Thanks to my daughter, Olivia, for her inspiration and her zest for life. Finally, a very special thanks to my amazingly graceful wife, Brooks Anne Hazelton, for her unconditional love and support over the past 10 years.

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CHAPTER 1: LITERATURE REVIEW

Sudden Cardiac Death

Sudden cardiac death (SCD) occurs when the heart unexpectedly and swiftly ceases to function. In the U.S. alone, at least 400,000 people are affected annually (Goldberger et al., 2008; Turakhia & Tseng, 2007). The onset of SCD is called sudden cardiac arrest (SCA) and is most commonly caused by a ventricular tachyarrhythmia (VT) that degenerates into ventricular fibrillation (VF). The electrical system of the heart begins to malfunction and an individual can die within approximately 10 minutes.

In many cases, patients with SCA have no prior symptoms. It has been estimated by the Center for Disease Control (CDC) that U.S. survival for SCA is approximately 5% (Zheng, Croft, Giles, & Mensah, 2001). When patients survive SCA or are found to be at risk for VT/VF, the most common treatments to prevent recurrence are anti-arrhythmic medication and/or an implantable cardioverter defibrillator (ICD). Frequently prescribed anti-arrhythmic medications include ACE inhibitors, beta-blockers, and calcium channel blockers to achieve heart rate and rhythm control. In most cases, these medications are used in combination with the ICD. Many SCA patients have a compromised left ventricular ejection fraction, which is the fraction of blood pumped with each heartbeat from the left ventricle. Normal ejection fractions can range between 55-75%. Reduced ejection fraction is one of the few reliable predictors of SCA.

The Implantable Cardioverter Defibrillator (ICD)

The ICD has established life-saving benefits in several randomized trials of patients at risk for life-threatening ventricular arrhythmias (Bardy, Lee, Mark, et al., 2005; Buxton et al., 1999; Connolly et al., 2000; Kuck, Cappato, Siebels, & Ruppel,

2000; Moss et al., 2002). The ICD is a device used to treat patients at risk for recurring, sustained ventricular tachycardia (VT) or ventricular fibrillation (VF). The device is typically implanted and fixed under the clavicle in the left pectoral region of the upper portion of the chest. Inside the device is a pulse generator that is powered by a battery. The battery life is typically 4-6 years, but this depends on the amount of pacing utilized and the number of ICD discharges (Kenny, 2006). Leads from the pulse generator are attached to the right chambers of the heart including the right atrium or right ventricle. The device circuitry constantly records heart rhythms, evaluates their potential for lethality, and follows a treatment algorithm programmed by the attending physician. The primary purpose of the ICD is the detection and termination of arrhythmias by providing an electrical shock. If the ICD detects VT/VF or other problematic rates/rhythms, it shocks the heart to restore a normal rate and rhythm and aborts the potentially life-threatening arrhythmia. The ICD also has extensive memory capabilities allowing for precise diagnostics and triage of cardiac rate and rhythms.

ICD Indication

The ICD was originally designed for the secondary prevention of SCD following the survival of SCA. The first human implant was achieved in 1980, and the ICD was FDA approved in 1985 (Mirowski, 1985). By 1990, implantation rates were at about 10,000 each year and climbed in 2000, reaching up to 90,000. More recently, U.S. rates of implantation were estimated at 200,000 for 2007. Major randomized clinical trials comparing medications to ICD including the Antiarrhythmics Versus Implantable Defibrillators (AVID) trial (AVID Investigators, 1997), the Canadian Implantable Defibrillator Study (CIDS) (Connolly et al., 2000), and the Cardiac Arrest Study Of

Hamburg (CASH) (Kuck et al., 2000), demonstrated the superiority of the ICD in preventing mortality. These studies, presented in Table 1, provided the empirical evidence for secondary prevention indications over anti-arrhythmic medication alone in preventing SCD. The relative risk reduction of ICDs versus anti-arrhythmic medications ranged from no benefit to a 69% decrease of mortality, depending on the timing of implantation, type of disease, and degree of disease severity in the population studied.

As previously mentioned, the survival rate for SCD in the U.S. is 5%, meaning 95% of patients could possibly be targeted at the primary prevention level. A dramatic increase in recipients has resulted due to a set of successful and progressive clinical trials highlighting the value and utility of the ICD, including the Multicenter Automatic Defibrillator Implantation Trial (MADIT) (Moss et al., 1996), The Coronary Artery Bypass Graft Patch Trial (CABG-PATCH) (Namerow, Firth, Heywood, Windle, & Parides, 1999), the Multicenter Unsustained Tachycardia Trial (MUSTT) (Buxton et al., 1999), the Multicenter Unsustained Tachycardia Trial II (MADIT II) (Moss et al., 2002), the Prophylactic Defibrillator Implantation In Patients With Nonischemic Dilated Cardiomyopathy Trial (DEFINITE) (Kadish et al., 2004), the Prophylactic Use Of An Implantable Cardioverter-Defibrillator After Acute Myocardial Infarction Trial (DINAMIT) (Hohnloser et al., 2004), and the Sudden Cardiac Death In Heart Failure Trial (SCD-HeFT) (Bardy et al., 2005), which consistently showed the unique and added mortality prevention benefit over the effects of optimal medical therapy. These trials are summarized in Table 1. After these trials, patients with (a) New York Heart Association (NYHA) class I, II, or III with prior myocardial infarction, (b) those with a left ventricular ejection fraction (LVEF) of less than 35%, (c) those with documented asymptomatic

unsustained ventricular tachyarrhythmia, or (c) those with inducible, non-suppressible ventricular tachyarrhythmia were indicated to receive the ICD. These results triggered new Medicare guidelines for the primary prevention of SCD that broadly covered the financial cost of ICDs for Medicare patients. After SCD-HeFT (Bardy et al., 2005), the Center for Medicare and Medicaid Services made an aim to “support the development of additional evidence that can help doctors and patients make more informed decisions” (McClellan & Tunis, 2005, p. 223). To make informed decisions, patients must have accurate and relevant information concerning the risks and benefits of the ICD; however, little is know about the relative considerations of ICD patients at this time.

Table 1

Important ICD Trials

Trial Name	Primary vs. Secondary Prevention-Indication	Publication Year	N	Relative Risk Reduction
MADIT	P	1996	196	.46*
AVID	S	1997	1016	.62*
CABG-Patch	P	1997	900	1.07
CASH	S	2000	191	.83
CIDS	S	2000	659	.82
MADIT-II	P	2002	1232	.69*
DEFINITE	P	2004	458	.65
DINAMIT	P	2004	674	1.08
SCD-HeFT	P	2005	1676	.77*

* Statistically significant difference between groups.
Note. A relative risk of < 1 means all cause mortality is less likely to occur in the ICD group than in the comparison group.

Until 2005, each year since the ICD was first introduced (Mirowski, 1985), implantation rates had increased in the United States indicating progressive acceptance of the ICD by physicians and patients. However, since 2005, implantations rates have begun to level off or drop slightly (Feder, 2008), with some suggesting that an initial overestimation of ICD benefits occurred based on flawed clinical trials (Tung, Zimetbaum, & Josephson, 2008). Others argue that these very thorough clinical trials may have had flaws, but these do not discount the life saving benefits of ICD therapy

(Epstein, 2008). Generally, the downturn could be attributed to both physicians and their patients deciding the risks of the ICD outweigh potential benefits. Specifically, downturn in utilization could possibly be the result of negative device perceptions about value, safety, and utility. Because ICDs save lives, choosing the ICD has often been presumed to be the correct choice, and in turn, psychosocial research has focused on the care for poorly adjusted patients who have received a device.

Pre-Implant Versus Post-Implant Psychosocial Care

Some ICD patients experience lower quality of life and increased anxiety and depression, and the primary patient care strategy has been to treat patients who are not adjusting well. Specifically, the focus of the existing research on assessment (e.g., Sears & Conti, 2002) and intervention (e.g., Kuijpers, Honig, & Wellens, 2002; Pedersen, van den Broek, & Sears, 2007) has been on the post-operative end. Despite effective efforts, the day-to-day standard of care for patients both before and after implant often falls short in addressing concerns and problems with daily functioning (Steinke, Gill-Hopple, Valdez, & Woostr, 2005). The focus of the current research emphasizes the need for assessment and intervention prior to implantation as a part of the decision-making process for prospective ICD patients.

With thousands of Americans receiving an ICD each year, anticipating the potential challenges to adjustment and acceptance of the device is imperative to the quality of life of many cardiac patients. Through this anticipation, providing patient-centered assistance in making an informed decision can target patient concerns and misconceptions. By assisting patients in weighing the pros and cons of the ICD, providers will be enabled to assess individualized concerns and eventually allow for

education and treatment specification prior to implant. With this patient relevant risk/benefit information available, an objective format for providers can be utilized.

The ability to provide more precise interventions prior to implant would be financially efficient, save provider time, and most importantly, prevent unnecessary patient distress. Moreover, this strategy would permit individualized and more appropriate informed consent. Most importantly, acknowledging and attempting to resolve patient concerns about the ICD is of grave importance. More specifically, patients who do not receive clinically indicated ICD therapy experience chances of death that are significantly increased with each year compared to that of ICD recipients (Koller et al., 2008). If patients decide against the ICD because they have not been appropriately or adequately informed, the potential benefit of the ICD is lost.

Educational Procedures for Prospective ICD Patients

Current educational procedures for ICD-indicated patients are not standardized and are likely to provide only very basic risk/benefit information about the various treatment options for their condition. While their providers review some risks and benefits of the ICD to patients, many ICD recipients may hold misconceptions about the ICD, with more than half believing ICDs would save 50% of lives over the course of 5 years (Stewart et al., 2006). A more accurate statement would be that 25% would be saved over 5 years, using the SCD-HeFT data as a guide. Moreover, greater than 95% overestimate the number of lives saved by the device (Bardy et al., 2005). Despite the effectiveness of the ICD, these misconceptions may represent a chasm between the facts of the ICD and patient beliefs. This might suggest that ICD patients are not recalling information reliably or accurately or current informed consent procedures fail to

meet patient needs. With these patient misconceptions present, more comprehensive risk and benefit information and clarification is needed.

Providing patients the best objective information about the facts of any procedure is the goal. Ajzen and Fishbein (1980) noted there are ethical considerations to be considered any time information is provided to patients, as this is a form of persuasion. They state that with persuasion inherent in the provision of information, the goal should be to include all relevant information in an accurate manner. Ideally, when providing the facts about the ICD, characteristics of the patient, the decision, the physician, and the method of information delivery should be considered. Most importantly, providers can accommodate patient preferences for treatment to help patients reach an informed medical decision. However, educational procedures are largely based on scripted discussion of facts mixed with some subjective interpretation of patient needs, prognosis, and beliefs about the patient. Also, limitations in the educational process are generally acknowledged as a result of (a) the limited time schedules of providers, (b) the challenges of doctor-patient communication, (c) patient factors such as distress, educational level, or comfort level of decision making, and (d) a lack of evidence to promote a change in the current information-sharing strategies. Provision of educational materials is often seen as a legal obligation, rather than an opportunity to help the patient make a highly customized decision based on the available information (Paling, 2006). Unless patients request detailed information, they likely will not obtain knowledge of many of the advantages and disadvantages to either the receipt or refusal of the ICD. The lack of current educational standards surrounding the ICD highlights the need to identify the beliefs about the ICD for prospective patients. Identifying these factors is

difficult because there are a multitude of potential influences on the decision-making process of potential ICD patients.

Decisional Influences

Decision research also details an array of cognitive, emotional, and social factors which influence decision-making (Patel, Kaufman, & Arocha, 2002; Tversky & Kahneman, 1974). The following review examines important factors that influence patient decision making with an emphasis on those factors that have particular relevance for the ICD decision. The intent of this review is to provide a rationale for this study's consideration of how these influential factors may play a role in medical decision-making, rather than providing a complete review of all possible decisional influences. Specifically, research on medical decision-making emphasizes the influence of characteristics of the patient, the decision itself, the physician, and the manner in which information about the decision is presented (See Table 2 below).

Table 2

Salient Decisional Influences

Decision	Presentation	Patient	Provider
Magnitude	Framing of Risks & Benefits	Belief System/ Culture/ Demographic Characteristics	Presentation Style
Time to Decide	Presentation of Numbers	Competency/ Literacy/ Education	Confidence in Treatment or Recommendation
Continual versus Discrete	Quantity of Information	Decision Specific Knowledge	Motivational Factors

Reversibility	Rationale	Heuristic tendencies /Emotions	Available Evidence

Many patients who are presented with an ICD choice are facing the reality of their mortality for the first time. As this news may be alarming, patient involvement in medical decision-making can vary considerably. When patients do take time to fully consider the pros and con of a decision, this is labeled as “systematic processing” (Chaiken & Maheswaran, 1994). When a patient is limited in their willingness or ability to process information, heuristic tendencies (Tversky & Kahneman, 1974) may guide decisions more strongly. For example, some patients do not want to make shared decisions, often preferring that the doctor make the final call (Robinson & Thomson, 2001). This reliance on the physician has been labeled as the “expert opinion heuristic” (Chaiken, Liberman, & Eagly, 1989). In addition, the availability heuristic (Tversky & Kahneman, 1974) is potentially problematic for patients as their prediction of the frequency of an event is based on how quickly one comes up with an example. If a patient readily thinks of a person who experienced frequent shocks or thinks of a device recall attorney commercial, bias may inordinately lead the decision maker to a particular decision. When heuristics are used in medical decisions, patients may choose without full understanding of the facts. Heuristics have differential influence, as there is a partial influence from (a) social norms, habits, and other personal characteristics and (b) the framing of the decision (Tversky & Kahneman, 1981).

A patient’s personal characteristics have a varying influence on their ultimate health decision (Tercyak et al., 2001). Research suggests that men have a greater tendency toward reliance on physician advice (Arora & McHorney, 2000). Other

characteristics associated with reliance on expert opinion heuristics include: patients who are older (Arora & McHorney, 2000; Ende, Kazis, Ash, & Moskowitz, 1989), lower cognitive abilities (Cutilli, 2007; Vellinga, Smit, Van Leeuwen, Van Tilburg, & Jonker, 2004), lower literacy (Cuculi, Herzig, Kobza & Erne, 2006), lower education level (Arora & McHorney, 2000) and less decision specific knowledge (Damasio, 1994). By placing total trust in the physician, patients are less likely to take an active role in their future healthcare (Anderson & Dedrick, 1990), and this external locus of control is frequently detrimental toward positive health-related choices (Trento et al., 2008).

One study examined the decision-making styles of those who must make treatment decisions for heart failure. Two groups were distinguished and labeled active (55%) and passive (45%) decision makers. The study evaluated decision-making among 22 patients using descriptive theme analysis in an iterative process to analyze responses to the question: "Can you tell me about any important or difficult decisions you have had to make about your heart condition?" Those who used an active decision-making style identified interventions including ICDs, medications, and transplants to be difficult decisions. Active decision makers cited concerns for side effects, family, and quality of life as factors that carry weight in these treatment decisions. Those with passive decision-making styles did not typically identify a difficult decision and reported factors such as trust in God, trust in the physician, and power of the physician as reasons for being passive (Matlock, Nowels, & Bekelman, 2010).

In some circumstances, such as when patients endorse religious health fatalism, providers may have minimal influence on treatment decisions (Franklin, Schlundt, & Wallston, 2007) and while some aspects of religiosity are often associated with the

promotion of health, religious health fatalism may be associated with poorer health outcomes (Caplan & Schooler, 2003; Powe & Finnie, 2003). This reliance on, or faith in the doctor, has been demonstrated as relevant in more severe medical illnesses, such as choice of cancer treatment (Patel et al., 2002; Roberts, Brown, Elkins, & Larson, 1997). In general, patients who are involved in reaching a treatment decision report increased satisfaction, reduced decisional conflict, and improved compliance with treatment (Anderson et al., 1995; Jahng, Martin, Golin, & DiMatteo, 2005).

Since providers can have a strong influence on patient choice for treatment by way of their recommendations, the manner in which risk and benefit information is framed is important. For example, patients may choose a variety of treatments more out of fear of consequences than they do the potential benefits (Sedgwick & Hall, 2003). Most patients are more affected by risks than benefits, as they overestimate the likelihood of risks (Alaszewski & Horlick-Jones, 2003), because emotional aspects can impact decisions for which they are not experts (Damasio, 1994).

The ICD decision is unique because it is a major life decision that must be made in a relatively short time period and, since implantation is not easily reversible, changing one's mind is not always a reasonable option. When a lack of awareness to potential biases in decision-making exists, the process of provision of education information for potential ICD recipients may not be optimally effective. Because there are health and psychosocial risk factors regardless of the patient's decision, adjustment to life with an ICD relies, to some extent, on the ability of healthcare providers to provide patients with appropriate information and guidance. Some researchers (Lewin, Coulton, Frizelle, Kaye, & Cox, 2007; Sears, Shea, & Conti, 2005) have asserted that prospective ICD

patients need information on the functioning of their device, the possibility of device recall, the clarification of possible changes in daily activities, and guidance on planning for shock. While it may be true that this information is important for patient success, the information may only be presented from the point of view of what providers believe is relevant to patient success based on their own experiences. This process may underrate the salience of specific factors from the patient's perspective.

The manner in which providers interact with prospective ICD patients may influence patient choice, and patient characteristics may influence how providers present information. Despite similar rates of SCD, initial research in this area suggests that the ICD is more likely to be recommended to elderly and male patients (Lin et al., 2008) and black and female patients are more likely to refuse recommendations (Hernandez et al., 2007). Others have shown that geography plays an important role, which is closely related to racial disparity in those who are offered the device in various regions (Groeneveld, Matta, Suh, Feifei Yang, & Shea, 2007; Thomas, Al-Khatib, Kelsey, Bush, Brosius, Velazquez, et al., 2007). These disparities remain, even after controlling for differences in incidence and severity of disease (Peterson et al., 1997), access to healthcare (Giles, Anda, Casper, Escobedo, & Taylor, 1995), health insurance (Carlisle, Leake, & Shapiro, 1997), financial incentives for doctors (Whittle, Conigliaro, Good, & Lofgren, 1993), and clinical indications (Conigliaro et al., 2000). Other explanations for these differences have been asserted, such as bias in treatment recommendations (van Ryn, 2002) and variation in patients' willingness to accept recommendations (Gordon, Paterniti, & Wray, 2004; Whittle, Conigliaro, Good, & Joswiak, 1997).

ICD patients tend to be composed of a more elderly population, which may mean potential recipients prefer their doctor to make the decision for them. In fact, for many prospective ICD patients, there is a general reliance on their doctor's advice (Agard, Lofmark, Edvardsson, & Ekman, 2007) as is consistent with other research for such a complex and life changing decision. Those who are approached about ICD placement tend to be older in age, which lends more problems with competency and other cognitive issues. Potential literacy gaps may also prevent full understanding of a decision and may be especially problematic with the high degree of sophistication inherent in the ICD. Many patients are not particularly knowledgeable about the ICD, and without appropriate education, patients may simply rely on their providers for their decisions.

Patient factors such as demographics, the emotional content of the decision, cognitive abilities, and heuristic tendencies should be considered when providing risk and benefit information. While physician reliance for decisions may be seen as a problem, the intent of the current research is not to prevent this phenomenon. Rather, the goal is to understand what information patients deem relevant in making their decision, rather than subjecting them to an excessive range of information that they may not process fully or appropriately. Decision analysis is often used in research to examine and clarify relevant factors in decision-making.

Decision Analysis

Decision Analysis is a scientific approach to examining and clarifying the influences on decision-making. This process has been studied in various fields of research such as economics, law, political science, organizational science, and medical

informatics. As such, there are a number of theoretic approaches and philosophies to studying decision processes. Decision analysis is typically viewed as the use of various procedures, methods, and tools for identifying, clearly representing, and formally assessing the important aspects of a decision situation. While normative or rational models of decision making do not account for the irrational or unexpected choices humans make, descriptive models recognize that the correct or gold standard may differ significantly between individuals. Regardless of theoretical orientation, the typical goal of decision analysis is to remove ambiguity from choice and focus attention on the uncertainties that may change or impact one's decision. The use of decision analysis in medical settings often comes in the form of decision aids, which may help medical patients make informed choices (O'Connor et al., 2001).

Significant controversy exists in the literature as to whether the theoretical underpinnings of decision tools fully and accurately represent the "real world" decisions of patients (Patel et al., 2002; Shafir & LeBoeuf, 2002). The current research attempts to address this issue by not prescribing a correct decision. Instead, the current research aims at addressing aspects of the decision that are important to the patient, prior to providing any additional education on the risks and benefits of their choice.

Decision research in medical settings has primarily focused on two objectives: (1) understanding how decisions are made by healthcare providers and patients and (2) developing ways to make the decision process better. The importance of these objectives is evident when considering the variability in how patients adjust to their life with an ICD. Patient acceptance (Burns, Serber, Keim, & Sears, 2005) has been defined as the adjustment to living with an ICD. This concept is important to the current

study because, theoretically, patient acceptance is partly the result of the quality of a patient's decision.

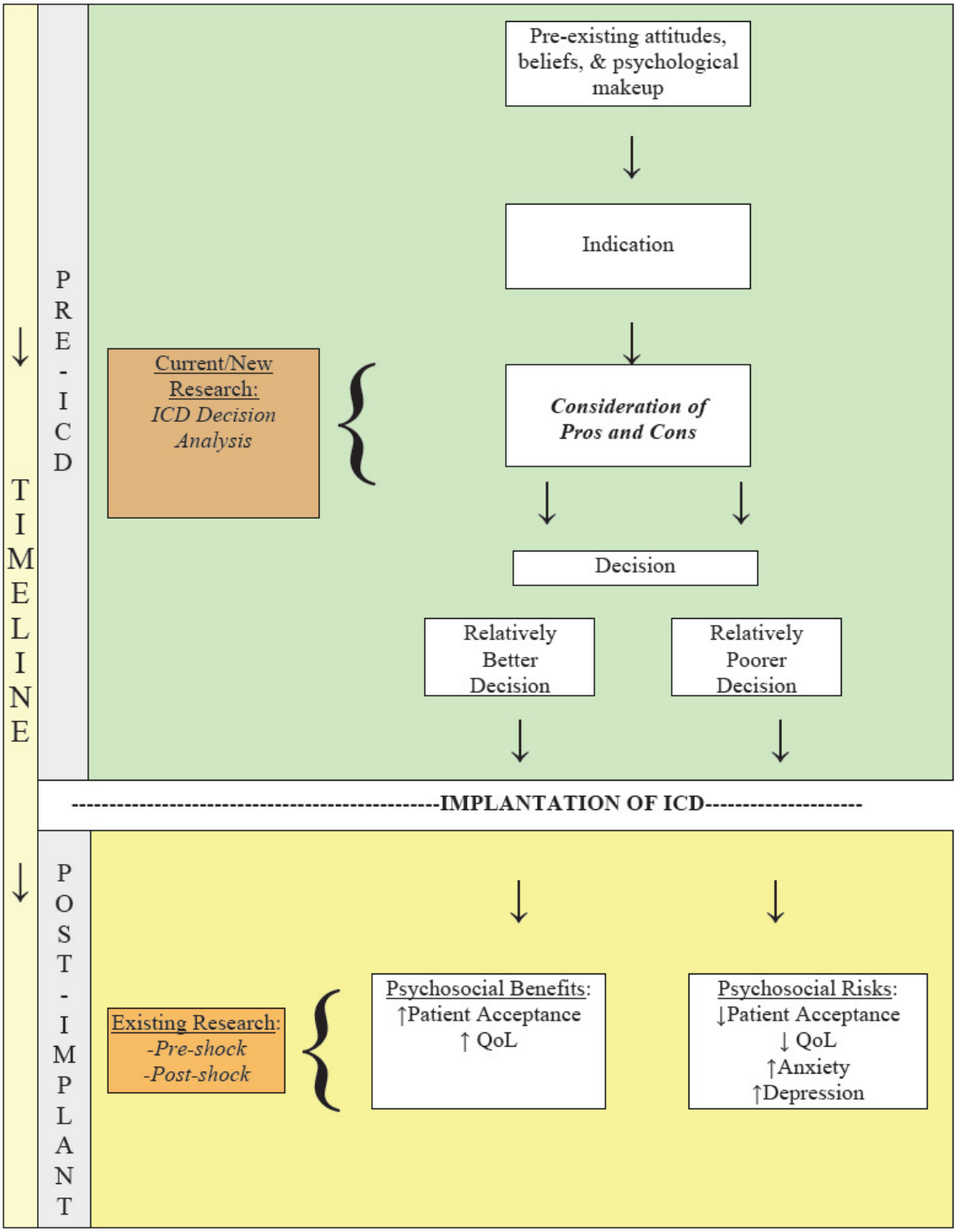
The clinical importance of understanding the decision-making process is reflected in recent ICD-related decision-making research. In a study among 19 patients with an ICD, approximately 50% indicated that they would have their device deactivated if their condition were to decline; however, only 2 of these individuals recalled having had a discussion about this choice with their physicians (Habal, Micevski, Greenwood, Delgado, & Ross, 2011). This study by Habel and colleagues suggests that at least some providers may not engage with patients in discussions of important ICD decision before or after implant. Additional research has examined decision-making related to sports participation in youth with pacemakers and/or ICDs, suggesting that patients continue to weigh the pros and cons of the device even after implant (Beery, Smith, Kudel, & Knilans, 2011).

The goal of analyzing patient ICD decision-making processes are to improve the educational procedures by laying a foundation for pre-implant assessment, providing assistance in making a quality ICD-related health decisions, and thereby, attempting to prevent post-implant difficulties. Although previous research has documented a variety of positive and negative perceptions about the ICD, no studies are available which address the ICD decision by a decision analysis approach. Figure 1 depicts how the current study is the initiation of a relatively new line of psychosocial research among the ICD patient population.

To help patients make informed choices, decision analysis will be utilized in this patient population. However, theory must be utilized in order to analyze the specific decision with which potential ICD must contend.

Figure 1

Graphical Representation of ICD Decision Analysis



Application of Theoretical Models

The application of theory provides researchers the ability to specifically target the multidimensional fundamentals of a behavior (Rothman, 2004). Without acknowledging these fundamentals, researchers may not be able to fully indentify the factors that are important in patients' decisions as to whether or not they choose the ICD.

The Biopsychosocial-Spiritual Model

The following is a review of commonly cited risks and benefits of the ICD, followed by important cognitive, emotional, and social factors that influence decision-making processes. The research literature examining ICD patient decision-making reveals few direct reasons why some ICD indicated patients choose implantation, while others patients do not. However, the literature provides a number of benefits and consequences of getting an ICD, which may be considered in ICD decision-making.

Most health psychology research organizes risks and benefits by use of the Biopsychosocial Model (Engel, 1977). This model was constructed to account for the missing role of the patient in the biomedical mode (Engel, 1980). From a biomedical perspective, choosing the ICD would almost always represent the “correct choice.” However, when considering quality of life, the impact on social relationships, and spiritual/existential beliefs, the “correct choice” is not always as clear. Providing intervention that is tailored and theoretically informed by the biopsychosocial model is not currently part of medical standard practice for prospective ICD patients. Although efforts have been made in specifying connections between biological, psychological, and social processes in the ICD literature, the full potential of the Biopsychosocial Model in health care has not been fully utilized. In a more recent review of Engel’s 1997

model by Suls and Rothman (2004), they recommend that to better utilize this model research must continue to seek to understand and utilize linkages among biological, psychological, social, and macrocultural variables. The present research applied a Biopsychosocial-Spiritual Model, with the spiritual component representing the macrocultural component asserted by Suls and Rothman (2004).

The Biopsychosocial-Spiritual Model may be a more holistic perspective with which to conceptualize patients whose treatments relate to life versus death (King, 2000; McKee & Chappel, 1992). Previous research suggests that spirituality might be an important aspect of the quality of life (QOL) of cancer patients (Brady, Peterman, Fitchett, Mo, & Cella, 1999). This study examined 1610 patients from an ethnically diverse sample and found that a measure of spirituality was found to be significantly associated with QOL to the same degree as physical well being, and the association between spirituality and QOL was unique, remaining after controlling for core QOL domains as well as other possible confounding variables. Furthermore, spiritual well-being was found to be related to the life enjoyment in the presence of medical symptoms. The authors suggested that the spiritual domain might be an important clinical target. While spiritual may be an important domain considering the life threatening context of the ICD decision, there is limited evidence that incorporates spirituality in the ICD patient population.

Biological/Medical Considerations for the ICD. Biomedical pros and cons are the factors that receive the most attention by both providers and patients. Improved survival stands as the most recognized benefit of the ICD; clinical trials have demonstrated the ICD as the primary treatment option for the prevention of sudden

cardiac death based on clinical trial data (Bardy et al., 2005). A simple principle for at risk patients might be: The sooner an ICD is received, the better. The only exception to this principle is the acute myocardial infarction patient who has ongoing mortality risk secondary to ischemic management, consistent with the DINAMITE trial. Patients at risk for SCD face a significantly increased chance of death each year without an ICD compared to that of ICD recipients (Koller et al., 2008). Therefore, providers and patients may discount the complete set of risks of an ICD since they have known risk of SCD that is potentially being offset. The most relevant cons include surgical and infection risk (Klug et al., 2007), inappropriate and appropriate shock (Daubert et al., 2008; Poole et al., 2008; Vollmann, Luthje, Vonhof, & Unterberg, 2005), device recalls (Gibson, Kuntz, Levenson, & Ellenbogen, 2008; Maisel et al., 2006), and electromagnetic interference (Barbaro et al., 1999; Gimbel & Cox, 2007; Occhetta, Plebani, Bortnik, Sacchetti, & Trevi, 1999; Shellock, Tkach, Ruggieri, & Masaryk, 2003; Tandogan et al., 2005; Yerra & Reddy, 2007).

Risk of death during implantation is a reasonable initial concern, although this risk is very low, occurring in less than 1% of patients. Other rare risks associated with implantation include swelling, bruising, bleeding, or infection in the area of implantation. There is also potential for a collapsed lung or blood vessel, heart, or nerve damage from procedural complications. Additionally, some patients may react negatively to the anesthesia used in surgery; however, this is a reversible effect. Implantation also tends to leave some degree of scarring and a bulge from the ICD. While the ICD has been shown to correctly detect arrhythmias 99% of the time, the device still has some limitations in its ability to terminate all arrhythmias (Klug et al., 2007).

Shocks that occur due to arrhythmias that are not necessarily life threatening are often referred to as “inappropriate shocks.” For example, patients in atrial fibrillation are often asymptomatic (meaning that they do not perceive the fibrillation occurring), and their condition is not immediately life threatening. In this scenario, the ICD may apply shock because of atrial oversensing when the shock is not necessarily needed. Recent research indicates that inappropriate shocks remain a significant problem with 11.5% of primary prevention patients receiving one or more shocks and those episodes amounting to 31.2% of all shock episodes (Daubert et al., 2008). Inappropriate shock may lend a small risk for death (Poole et al., 2008; Vollmann et al., 2005), but there is insufficient evidence to claim a consequent of the device is that inappropriate shock can lead to death. In any case, devices can be reprogrammed and medication regimens can be altered to help prevent shocks from occurring inappropriately; however, shocks (appropriate or inappropriate) cannot be eliminated altogether.

Over the last few years, many of the leading device manufacturers have experienced a US Food and Drug Administration recall or advisory indicating a significant problem with the device (Gibson et al., 2008). As in all biomedical technology, recall is an ongoing threat, but with the ICD, recall has not been a common problem. However, reports show that ICD replacement resulting from device malfunction increased by both number and rate between 1996 and 2002 (Maisel et al., 2006). In 2007, Medtronic Incorporated posted an online advisory letter that reported data indicating an estimated 3% per year fracture/failure of their Fidelis leads (Medtronic Inc., 2007). Until the Medtronic Fidelis recall, device recalls were seen as extremely rare with the highest estimates at .0268% of patients having hardware flaws such as

battery problems or electrical problems (Maisel et al., 2006). While actual overall recall numbers remain low, decreased utilization of the device may be a result. Specifically, a media advertised recall might have a strong influence on a potential recipient's choice of treatment for an ICD (Cuculi et al., 2006). Clearly, negative perceptions are increased by these events and the resulting media coverage.

Electromagnetic interference is another potential concern and can result from any high powered electric or magnetic signal that obstructs the functioning of the ICD (Yerra & Reddy, 2007), such as security systems (Gimbel & Cox, 2007), medical imaging (Shellock et al., 2003; Yerra & Reddy, 2007), or cellular phones (Barbaro et al., 1999). Most experts agree that MRI is a contraindication for patients with ICDs because of the potential to disturb programming and heat the elements of the ICD (Shellock et al., 2003; Yerra & Reddy, 2007). Recent research suggests that there does not seem to be any interference from wireless communication devices (Tandogan et al., 2005). It is recommended that patients with ICDs not carry or place an active digital cellular telephone within 6 inches of the device (Occhetta et al., 1999). Fortunately, due to the improved technology of the modern ICD, such interferences are now quite uncommon (Yerra & Reddy, 2007).

Critical events surrounding the use of the ICD include device implant, ICD shock events, device recalls, and end of life issues. For example, regarding end of life, patients can be shocked at the time of death resulting in a non-peaceful death. Clinical management of these critical events has been suggested that includes patient education, provision of psychosocial information, activity prescriptions, recall planning,

and shock planning (Sears, Matchett, & Conti, 2009). These critical events exemplify the connection between biomedical and psychosocial considerations for the ICD.

Psychosocial Considerations for the ICD. While many patients report a sense of security due to the protective qualities of the device (Lemon & Edelman, 2007), a substantial minority experience significant difficulties with anxiety (Burke, Hallas, Clark-Carter, White, & Connelly, 2003; Dougherty, 1995; Hamner, Hunt, Gee, Garrell, & Monroe, 1999; Irvine et al., 2002; Kuck, Cappato, Siebels, & Ruppel, 2000a; Luderitz, Jung, Deister, & Manz, 1994; Namerow et al., 1999; Neel, 2000; Passman et al., 2007; Pedersen, van Domburg, Theuns, Jordaens, & Erdman, 2004; Sears, Todaro, Lewis, Sotile, & Conti, 1999; Sears & Conti, 2002; Sears et al., 2007; Shemesh et al., 2006; Sowell, Sears, Walker, Kuhl, & Conti, 2007; Stutts et al., 2007), depression (Bilge et al., 2006; Carney & Freedland, 2003; Goodman & Hess, 1999; Luyster, Hughes, Waechter, & Josephson, 2006; Sears et al., 1999; Sears & Conti, 2002; Whang et al., 2005), and a poorer quality of life (QoL) when patients begin to limit their activities or have an unhealthy focus on their cardiac disease (Finch, Sneed, Leman, & Watson, 1997; Francis, Johnson, & Niehaus, 2006; Passman et al., 2007; Prudente, 2005; Schron et al., 2002; Sears et al., 2000; Sears et al., 2006; Steinke et al., 2005). Some recipients of the ICD appear to be predisposed to experience adverse psychosocial outcomes. Patients who experience adverse psychosocial outcomes may have risk factors such as younger age (<50 years of age), female sex, having experienced shock in the past, or a pre-morbid psychiatric history that predispose them to having greater psychological issues following the distress of ICD implantation (Sears & Conti, 2003).

Psychological distress among ICD recipients is influenced by pre-morbid conditions, such as inadequate social support, deficits in physical functioning, and a history of psychological distress (Luyster et al., 2006). Recent research has explored how personality factors might influence outcomes among recipients of ICDs. Patients with Type D or “distressed” personalities are those who display negative affect and have trouble communicating their emotions. Those with such personalities have been identified as being at risk for poor psychosocial outcomes (Pedersen & Denollet, 2003; Pedersen et al., 2004). While psychosocial morbidity can be a precursor of device implantation, research indicates that living with the device can exacerbate or ignite psychological distress, low treatment satisfaction, and poorer treatment outcomes (Ladwig, Deisenhofer, Simon, Schmitt, & Baumert, 2005).

As noted above, anxiety is a considerable consequence of the ICD, with 13-38% of ICD patients experiencing symptoms (Burke et al., 2003; Sears et al., 1999; Sears & Conti, 2002). Anxiety in ICD patients may be due in part to the fear of potential shock (Connolly et al., 2006), device recall (Stutts et al., 2007), or a general fear of death due to their condition (Pauli, Wiedemann, Dengler, Blaumann-Benninghoff, & Kuhlkamp, 1999). Several studies have shown that as number of shocks increase, adjustment difficulties also rise (Irvine et al., 2002; Kuck et al., 2000; Luderitz et al., 1994; Namerow et al., 1999). PTSD rates among ICD patients have been reported as approximately 20% (Kapa et al., 2010; Ladwig et al., 2008; Sears, Hauf, Kirian, Hazelton, & Conti, 2011) which is plausible with the potential of unpredictable and aversive shocks (Hamner et al., 1999; Neel, 2000). Interestingly, spouses often experience more anxiety and distress than recipients themselves, as a result of device implantation and shock

experienced by their significant other (Dougherty, 1995; Pedersen et al., 2004; Sowell et al., 2007). A study by Keren and colleagues (2011) found no differences between patients at risk of a lead recall compared to controls; however, patients who had experienced a lead fracture had greater anxiety and depression scores compared to control patients. The psychological morbidity was primarily related to inappropriate ICD shock rather than recall.

Significant problems with depression have in fact been documented as well, occurring in 24-41% of ICD patients (Bilge et al., 2006; Sears et al., 1999). Depression may be common because these patients experience actual and perceived losses or limitations in social functioning (Goodman & Hess, 1999), ability to engage in preferred activities (Lemon & Edelman, 2007), and physical functioning (Kohn, Petrucci, Baessler, Soto, & Movsowitz, 2000). Depression can be especially debilitating because it may affect mortality, morbidity, and cardiovascular symptoms by weakening a patient's ability to properly cope and manage their disease (Carney & Freedland, 2003). Depression may also arise from the knowledge of having a greater risk for sudden cardiac death (Sears & Conti, 2002). Also, ICD patients may experience a type of "learned helplessness" as more shocks may lead to greater levels of depression and anxiety (Goodman & Hess, 1999). Moreover, issues such as device recall may also contribute to a patient's feelings of helplessness as well. The Triggers of Ventricular Arrhythmias Study (TOVA) established in initial assessments of 645 ICD patients that approximately 18% were depressed, with more severe levels of depression related to increased frequency of shock longitudinally (Whang et al., 2005), which may suggest a dose response relationship between the frequency of shock and level of depression.

QoL is often adversely affected by shock (Schron et al., 2002), as seen in patients whose fear of ICD shock prevents them from engaging in preferred activities such as sexual (Steinke et al., 2005) or other physical activities (Sears et al., 2000). Additionally, temporarily losing one's privileges to drive after receiving ICD shock negatively impacts quality of life for many patients (Finch et al., 1997). A recent meta-analysis reported that quality of life remained the same in a majority of patients receiving an ICD; however, the greater part of these randomized studies found that patients receiving shocks experienced worsening QoL (Francis et al., 2006). An analysis demonstrated that there is no evidence to suggest that patients receiving an ICD for primary prevention have subsequent poorer QoL or greater distress than patients receiving an ICD after cardiac arrest (Pedersen, Sears, Burg, van den Broek, 2009). More recently, research has found that the experience of even one ICD shock decreases QoL in recipients, but clinically significant deficits do not appear to occur until the experience of 5 or more device discharges (Passman et al., 2007).

Spiritual/Existential Considerations for the ICD. Shock and shock storm (i.e., receiving 5 or more shocks within 24 hours) also play a large role in a patient's quality of death (Poole et al., 2008). This concept has come to light in recent ICD literature as failure to deactivate the device may cause shock at the time of death, resulting in a non-peaceful death (Sears et al., 2006). Quality of death emphasizes that there are factors that are important to ICD patients beyond the difficulties associated with a diagnosis of heart dysfunction or experiences such as shock or device recall.

Spirituality has been mentioned as an important consideration among ICD patients since an article by Ocampo (2000) described the need of a shift in focus from

evaluating biomedical outcomes of ICD treatment to an evaluation of the emotional, spiritual, and psychological variables. A study reported that ICD patients in the United States reported significantly higher psychological-spiritual satisfaction than Swedish patients both before and after ICD implantation (Bolse et al., 2002). Not only are there spiritual differences between diverse ICD samples, but also, spiritual quality of life has been shown to decrease in the first year after ICD implant (Flemme, et al., 2005). In a more recent study (Bolse, Johansson, & Stromberg, 2010), researchers examined the educational materials and discussions provided to ICD patients and found that biological information was predominant. Emotional, intellectual and socio-cultural dimensions were rarely provided, and there were not references or discussions related to the spiritual-existential domain.

Presumably, the previously mentioned device-related pros and cons influence patients in different ways and to varying degrees, affecting choice of the device, as well as adjustment to life with a device. It is clear that the pros and cons of the ICD are numerous. Patients must consider the factors in the ICD decision and somehow make a significant life decision.

Once the ICD has been medically indicated, patients' choices for or against the device may be based on correct perceptions, but also may be based on misperceptions. These misperceptions prevent understanding of the potential negative (e.g., aversive shock) or positive (e.g., prolonged life expectancy) effects of their choice. Health behavior models such as the Transtheoretical Model (Prochaska & Velicer, 1997), the Health Belief Model (Janz & Becker, 1984), and the Theory of Planned Behavior (Ajzen & Fishbein, 2005; Ajzen, 1991), emphasize how beliefs may play an important role in

the decision to perform health-related behaviors. These theories emphasize that decisions are affected by the cognitive and social contexts of a decision.

The Transtheoretical Model

The Transtheoretical Model of Change provides an excellent framework for understanding how patient weigh pros and cons (Prochaska & Velicer, 1997). An individual's weighing of advantages (pros) and disadvantages (cons) has been termed "decisional balance" (Janis and Mann, 1977; Velicer, DiClemente, Prochaska, & Brandenburg, 1985). The Transtheoretical Model of Change emphasizes five stages of change: pre-contemplation, contemplation, preparation, action, and maintenance. Those making decisions in the Transtheoretical Model of Change can move back and forth between the specific stages. Patients faced with the ICD decision cannot step back toward previous stages once the device is implanted, because the procedure is not easily reversible and patients face considerable risk in order to have the ICD removed. However, this model describes how an individual is capable of making a behavior change decision only if they have begun contemplating the pros and cons of their current thoughts and behaviors. This theory has been useful in the initiation of many health behaviors as individuals are aided in specific health decisions (Prochaska et al., 1994). Some of the most successful uses include decreasing alcohol use (Migneault, Velicer, Prochaska, & Stevenson, 1999) and smoking cessation (Lafferty, Heaney, & Chen, 1999). Prior to their "final" decision, those who are indicated for an ICD have a limited time to weigh the pros and cons of the ICD, and their perceptions and beliefs about their condition and the protective ability of the ICD may influence their decision.

The Health Belief Model provides valuable rational for attempting to understand the beliefs on these pros and cons on patient choice.

The Health Belief Model

The Health Belief Model (Rosenstock, 1990) focuses on people's attitudes and beliefs in an attempt to explain and predict their health behaviors. The Health Belief Model been adapted to explore a variety of health behaviors, such as sexual risk behaviors (Zimmerman & Olson, 1994) and breast self-examination (Norman & Brain, 2005). The model has also been applied to health decisions similar to that of the ICD choice, such as medical imaging for various health conditions (Ludwig & Turner, 2002). In a study about health beliefs regarding medical imaging, a survey of 200 participants found that less than half of responders agreed with experts regarding the low risk of radiation exposure from various sources. The Health Belief Model is based on the understanding that a person will take a health-related action (i.e., choose the ICD) if that person feels that a negative health condition (i.e., SCD) can be avoided, has a positive expectation that by taking a recommended course of action a negative health condition will be avoided (i.e., the ICD will be effective at preventing SCD), and believes that a recommended health action can be taken on with success (i.e., use of the ICD will produce confidence in choice and a higher quality of life).

Despite the important role of beliefs in the ICD decision, the Health Belief Model does not assess the intent of a patient to choose or not choose the ICD. Behavioral intent was utilized in the present study because an actual medical decision is not uniformly made at the time of a particular visit with their physician. Behavioral intent of ICD choice, rather than actual ICD choice, is the construct that is subsequently

described in this manuscript. Due to the wide range in medical severity, some patients may be forced into an immediate decision, while others may go home to contemplate their decision. Therefore, planned behavior was the closest proximity to actual choice that could be uniformly assessed across patients.

While there appears to be no theory that fully accounts for all influences on patient decision-making for or against an ICD, the Theory of Planned Behavior provides the theoretical underpinning for the current study by describing how patients plan to make health decisions. The Transtheoretical Model of Change describes how decisions might be influenced by a variety of pros and cons, and the Theory of Planned Behavior describes how factors beyond the actual pros and cons receiving an ICD. The discussions of these health-related decision-making models provide evidence that the beliefs of a potential ICD recipient are critical elements in decision-making.

The Theory of Planned Behavior

With behavioral intent in mind, the Theory of Planned Behavior (Azjen, 1991) is a model that was most applicable to the present study. This model asserts that behavior is led by "behavioral beliefs," "normative beliefs," and "control beliefs." When an individual's "attitude toward the behavior" and the "subjective norm" are positive, and his/her "perceived behavioral control" is strong, the stronger the person's intention to engage in a particular behavior will be. If there is sufficient "actual behavioral control," individuals tend to engage in the behavior if the situation presents (Ajzen & Fishbein, 2005). The model has been applied to healthcare, and these studies have demonstrated improvement in the prediction of behavioral intentions such as with condom use (Albarracin, Fishbein, Johnson, & Muellerieile, 2001), exercise (Nguyen,

Potvin, & Otis, 1997), and diet (Conner, Kirk, Cade, & Barrett, 2003). A primary consideration when assessing planned behavior is acknowledging that this is not an actual ICD decision; however, Azjen and Fishbein (1980) note that the more factors that can be addressed/assessed in a measure of conditional intention, the better the measure's ability of predicting future behavior. They also indicate that specifying a condition (e.g., if your doctor recommends the ICD) increases the likelihood that intent will be highly related to the behavior. By adding the multidimential aspects of the Biopsychosocial-Spiritual Model as components of a measure of conditional intent of ICD choice, the intention behavior gap would theoretically be reduced.

Unfortunately, these models do not specify how to identify relevant beliefs that influence decisions. Decisional tools can assist patients in receiving tailored information about the ICD, and they may therefore move toward an action related to the ICD with more knowledge and confidence. A recent review by Mulsow Feeley, and Tierney (2011) describes how most surgical patients generally have a limited understanding of the procedures and possible outcomes of many procedures. They also describe the lack of data to support the use of educational handouts, but they report that patients with lower educational levels may gain most from additional interventions. Decision aids on the other hand are routinely used with patients making decisions regarding breast cancer treatments. A recent review of breast cancer decision aids by Belkora and colleagues (2011) reported that there are significant gains in knowledge and reductions in decisional conflict. Again, those with the lowest knowledge appeared to profit the most from these interventions. Decision analysis is needed to indentify the relevant

beliefs related to the ICD decision so that a theory informed and empirically validated ICD decision tool can be effectively implemented.

Summary

The most effective treatment and preventative measure of sudden cardiac arrest (SCA) is the Implantable Cardioverter Defibrillator (ICD). ICD Indication is fairly straightforward for most patients who have experienced an episode of SCA. Despite the efficacy of the ICD in a number of large-scale studies and clear indication guidelines (Epstein, 2008), patients who are offered the opportunity to receive an ICD do not always elect to do so. Unfortunately, many patients do not have the time, understanding, or ability to process the pros and cons of the ICD, and decisions made on a lack of information may not be desirable. Researchers and clinicians have no empirical method of assessing the factors that patients consider in this important medical decision. Because ICD technology is complex and choice is influenced by a variety of factors, assisting patient in ICD decision-making is a matter of improving educational procedures for prospective ICD Patients. Decision analysis for medical treatments has been utilized in various medical decisions; however, there are practically no assessments or interventions for patients who are in the decision-making phase regarding the ICD choice. The Biopsychosocial-Spiritual Model helped lay a framework for ICD pros and cons and the Transtheoretical Model was reviewed because the approach provides a rationale for systematically accounting for the pros and cons of ICD treatment. Given the practical limitation of assessing patients who may or may not be asked to make a decision at the time of recruitment, the Theory of Planned Behavior

was considered to provide a coherent reason for assessing the conditional behavioral intent of ICD choice.

Present Study

The objective of this project was to take a first step into creating an empirically validated decision aid to improve ICD decision-making. To achieve this objective, the goal was to design a measure assessing the importance of various ICD biopsychosocial-spiritual pro and con factors that may influence ICD decision-making by examining the set of factors that have weight in the decisional balance of the ICD. We also wanted assess the predictive validity of the proposed ICD measure (i.e., Implantable Cardioverter Defibrillator – Decision Analysis Scale) on behavioral intention to receive the ICD. While providing an opportunity for patients to rate the most personally salient pros and cons, practitioners can quantitatively assess the patients' perceptions of risks and benefits of the device. As patients weigh pro/con items in a variety of ways, information can be given that targets their specific concerns and/or misperceptions. This will offer a higher standard of patient care by providing the most comprehensive educational information, while also allowing for more personalized intervention to be undertaken prior to and following implantation, should that choice be made.

Assessments of each patient's biological, social, psychological, and spiritual domains were considered necessary as the literature review provided examples of important considerations for each of these domains. For purposes of discriminative validity, comparisons between the ICD-DAS and other psychosocial measures that could represent each of the tenets of the Biopsychosocial-Spiritual Model was also

considered necessary. The Medical Outcomes Study-Short Form-12 Health Survey (SF-12), provides physical quality of life scores, tapping into the biological tenet of the Biopsychosocial-Spiritual Model, while also provides a measure of psychological quality of life (Ware, Kosinski, & Keller, 1996). The Hospital Anxiety & Depression Scale (HADS) (Zigmond & Snaith, 1983) assesses depression and anxiety, tapping into the psychological tenet of the Biopsychosocial-Spiritual Model. Form C of the Multidimensional Health Locus of Control (C-MHLC) scale (Wallston, Stein, & Smith, 1994) assesses beliefs about how decisions are made in terms of factors in one's personal control and factors outside of one's own control. This measure taps beliefs about the influence of social and, to some extent, on spiritual domains in one's life when considering this measure's assessment of "powerful others." The Religious Health Fatalism Questionnaire (RHFQ) (Franklin et al., 2008) assesses fatalistic religious beliefs, tapping into the spiritual tenet of the Biopsychosocial-Spiritual Model.

Specific Aims

The first aim was determining a set of pros and cons of getting an ICD and using these items as variables in an ICD-related measure. More specifically, part 1 of the study sought to compile the risks and benefits of the ICD by way of a review of the literature and expert review of the items, and the conclusion of part 1 was accomplishing the initial design of the Implantable Cardioverter Defibrillator – Decision Analysis Scale (ICD-DAS).

The second aim was to measure the importance of pro/con perceptions in relation to the conditional behavioral intent of choice of the ICD. Behavioral intent was measured by asking patients, "If your doctor recommended an ICD, how likely would

you be to get one?" A sub-aim of the part 2 of the study was to analyze associations between the ICD-DAS, the behavioral intent to choose an ICD, and the additional psychosocial measures, socioeconomic variables, and demographic variables.

Hypotheses

While the current study was exploratory, there was an expectation that factor analysis would reveal a 4-factor solution, with a biological component, a psychological component, a social component, and a spiritual/existential component. This hypothesis was expected due to the theoretical underpinning of this study, as a 4-factor solution would represent each of the 4 tenets of the Biopsychosocial-Spiritual Model. Regarding discriminative validity, it was hypothesized that the ICD-DAS would better predict behavioral intent to choose the ICD than a standard set of psychosocial measures representing biological, psychological, social, and spiritual/existential domains. This prediction was based on the premise that the ICD-DAS would be more tailored by containing ICD-specific information. It was also predicted that African American participants would be less likely to have behavioral intent to choose the ICD and have higher scores on religious health fatalism. This prediction was based on research that has shown higher rates of ICD refusal among African American patients (Hernandez et al., 2007) and research that has shown higher rates of fatalism among African American patients with cancer (Powe & Finnie, 2003). It was also predicted that patients with lower ejection fractions would be more likely to have behavioral intent to choose the ICD because of greater disease severity. No other specific predictions were made in terms of group differences.

CHAPTER II: METHOD

The current research was segmented into 2 parts including an initial design of the ICD-DAS via use of theory and research (part 1) and an assessment phase where the initial DAS was administered to potential ICD patients for scale development and validation (part 2).

Part 1

The first aim of the present study was to develop a scale consisting of important ICD pros and cons. This was accomplished by compiling the risks and benefits of the ICD by way of a review of the literature. The following is a description of the methodology of the initial development of the Implantable Cardioverter Defibrillator – Decision Analysis Scale (ICD-DAS).

Procedure

Examination of the ICD Literature. In constructing this questionnaire, a list of items that could influence potential ICD recipients in their choice for or against implantation was compiled. A generation of items began with a literature review by utilizing Pubmed searches. In addition, Google.com email alerts provided updates of the latest relevant Google results (web, news, journals, magazines, etc.) using the query of "implantable cardioverter defibrillator." Benefits and consequences cited in the literature were listed in an excel spreadsheet. The literature review process provided a compilation of 121 items.

Initial Item Reduction and Organization. Next, a rational grouping of variables allowed for reduction of total items to 24 (See Table 3). Specifically, the 24 subsequent items broadly represented the 121 original items revising the collapsed items with a high

degree of redundancy by placing the items into groupings by similarity. To provide a framework for the risks and benefits revealed in this literature search, these 24 items were organized by use the Biopsychosocial-Spiritual Model. This holistic approach emphasizes various dimensions of a patient's experience with illness and health. Table 3 lists frequently noted pros and cons of the ICD organized by 1) rational groupings and 2) use of the Biopsychosocial-Spiritual Model.

Expert Review of Items. Next, semi-structured qualitative interviews with providers were used to: 1) confirm the face validity of this refined list of relevant information pertaining to patient choice of the ICD and 2) to adjust the label of each of the 24 items to help best describe and represent the underlying items. Those interviewed included 2 cardiologists, 1 electrophysiologist, and 1 cardiac psychologist. These individuals were given a document with the individual cells in Table 3, as headings with a subset of the original 121 items below each heading. First, expert reviewers were asked if they believed that the 24 items were an accurate representation of the important pro and con domains of the ICD. Next, experts were asked circle any item they did not believe to belong in a certain group. Subsequently, they were asked to indicate if any item identified as being out of place could be placed in another of the 24 groupings. Finally, experts were queried regarding their suggestions for alternate descriptions of the headings of each group. Adjustments were made to the wording to satisfy each reviewer. When there was contradictory feedback provided by the various reviewers, the principal investigator decided on what information would be retained.

Part 2

The aim of the second phase of this study was to conduct an empirical test of the Biopsychosocial-Spiritual Model through patient assessment and factor analysis. Specifically, this was accomplished by recruitment of patients who rated items on the initial ICD-DAS and patient ratings were analyzed with factor analytic procedures. A sub-aim of this second phase was to analyze associations with the intent to choose an ICD and other psychosocial, demographic (i.e., gender, race, disease severity, and site), and socioeconomic variables (i.e., income, health insurance status, and educational background).

Participants

In the second phase of the study, 103 patients with a diagnosis of heart failure or coronary artery disease (CAD) receiving care at Pitt County Memorial Hospital, East Carolina University Physician Clinics, and associated satellite facilities in Greenville, NC. Stanford University Medical Center in Palo Alto, CA served as an additional site to allow for a more diverse sample. Those eligible for inclusion were individuals with ejection fractions (EFs) less than 50% and/or met criteria for an ICD. To participate in this study, patients were also required to be able to speak and read English, be at least age 18, and be deemed cognitively able to complete questionnaires by medical staff and research assistants. There were 89 patients who declined to participate because they were either ready to leave the clinic due to their long appointment times, did not have reading glasses, were deemed cognitively unable to complete the questionnaire, or declined with no reason given.

In the current sample, 67 participants were male and 36 participants were female. Patients ranged in age from 19 to 90 with a mean age of 54.86. The sample was 40.8% African American, 46.6 % Caucasian, 5.8% Hispanic, and 6.8% were classified as “Other.” The majority of patients was married (53.3%), followed by single (29.3%), widowed (10.9%), and divorced (6.5%). Stanford University participants comprised 36.9% of the total sample. East Carolina University (ECU) patients comprised 63.1% of the total sample. The majority of these patients had an ejection fraction of 50% or below; however, 5 participants with normal ejection fractions met medical criteria for implantation of the ICD and were recruited at Stanford. Also, 63.1% of the participants had EFs less than 35, 31.1% had EFs equal or greater than 35, and 5.8% did not have their EF recorded by research assistants.

This study received separate IRB approvals for East Carolina University (ECU) and Stanford University. A portion of the subjects at ECU were compensated $10.00 for their participation once funding was procured; however, some of the initial participants recruited at ECU and all of the Stanford participants were not compensated for their participation. More specifically, some participants were not compensated because grant funding was acquired after recruitment had begun. Table 4 shows the sample by recruitment site. The goal was to recruit as many potential ICD patients as possible that were in the actual process of making the ICD decision at the time of recruitment.

Measures

Participants completed a short battery of psychosocial questionnaires. Patient decisional factors were assessed by the *initial Implantable Cardioverter Defibrillator – Decision Analysis Scale (ICD-DAS)*. The scale consisted of 24-item, each of which was

placed on a 5-point rating scale designed to reveal the level of importance of pros and cons which most influence patient decision for or against the ICD. The scale also had an item placed on a 7-point rating scale ranging from “definitely no” to “definitely yes”: “If your doctor recommended an ICD, how likely would you be to get one?” Since inclusion criteria were expanded beyond those who were indicated for the ICD, behavioral intent provided the closest approximation of actual choice available.

General health-related quality of life was assessed with the *Medical Outcomes Study-Short Form-12 Health Survey (SF-12)*, a 12-item revision of the SF-36 Health Survey (Ware et al., 1996) designed to reproduce the Physical Component Summary (PCS), and the Mental Component Summary (MCS) scores of the original measure. Compared to its predecessor the SF-36, each of the *SF-12* summary scales accounted for over 90% of the variance in the SF-36 scales, demonstrated strong test-retest reliability (.89 for the PCS; .76 for the MCS) and correlated highly with the SF-36 summary scales (Ware et al., 1996).

The *Hospital Anxiety & Depression Scale* (HADS) (Zigmond et al., 1983) is a 14-item measure that assesses depression and anxiety. HADS is a well-known, widely used instrument assessing levels of anxious (HADS-A) and depressive (HADS-D) symptomatology with Cronbach's alphas for HADS-A varying from .68 to .93 (mean .83) and for HADS-D from .67 to.90 (mean .82) in patient samples (Bjelland, Dahl, Haug, & Neckelmann, 2002).

The *Religious Health Fatalism Questionnaire* (RHFQ) (Franklin et al., 2008) is a 17-item measure of fatalistic beliefs. The RHFQ was created to understand fatalistic beliefs to a greater extent in African American religious communities and was

developed and tested within African American churches. Pilot and validity testing of the RHFQ (*N* = 292) showed that the measure had sufficient variability and construct validity and moderate internal consistency (alpha = .67).

Form C of the Multidimensional Health Locus Of Control (C-MHLC) scale (Wallston et al., 1994) is an 18-item, general purpose, condition-specific locus of control scale that could easily be adapted for use with any medical or health-related condition. The standard MHLC is composed of 3 subscales: (1) internal health locus of control, which assesses the belief that one's own behaviors affect one's health status; (2) powerful others health locus of control, which assess the belief that powerful other people, such as doctors, nurses, family and friends have control over one's health status; and (3) chance health locus of control, which assesses the belief that one's health condition is a matter of fate, luck or chance. Each subscale is comprised of 6 items, totaling 18 items on the questionnaire. Internal consistency ranged from .70 to .87 in 2 separate samples (Wallston, Stein, & Smith, 1994). Form C has adequate concurrent validity as the measure has significant correlations with the appropriate subscales from versions A and B of the MHLC (Wallston, Wallston, & DeVellis, 1978). Form C breaks the powerful others subscale down into 2 separate subscales with 3 items each and labeled "doctors" and "other people," resulting in 4 total subscales for the measure.

A standard *demographic questionnaire* was utilized to document age, gender, ethnic status, educational status, marital and employment status, and family income.

Procedure

The set of measures was administered to participants. Individuals were excluded from the study if they were (1) less than 18 years of age, (2) unable to read and write in English, or (3) were observed as cognitively impaired by recruiting healthcare providers. Potential participants, identified by their physician, were recruited following indication, referral, and the standard patient education for the ICD. Patients were checked into the clinic, where a research assistant approached them. Patients were asked about their interest in participating in a study that seeks to understand patient perceptions of the ICD. Research assistants explained the study and obtained informed consent. Following the informed consent process, patients were asked to complete the assessment battery.

The battery consisted of a packet of questionnaires including the initial ICD-DAS, as well as a set of other psychosocial measures (i.e., HADS, SF-12, C-MHLC, and RHFQ). Medical record review and case report forms established demographic, socioeconomic, surgical, and medical factors related to response patterns on the decision analysis questionnaire. Patients also had the opportunity to list any pros or cons of getting the ICD that were not listed in the questionnaire. The conditional behavioral intent for ICD choice was assessed at the time of recruitment for all patients. Specifically, participants were asked to rate how likely they would be to choose the ICD (on a 7-item rating scale), if the device were to be recommended by their physician. Patients were thanked for their participation. Some of the patients received compensation for their participation, which was implemented when funding was received for the project. The patients then completed their medical visit. The final procedure of the project was the psychometric evaluation of the initial ICD-DAS.

Proposed Analyses

Part 1

A thorough review of the ICD literature was proposed as the method for identifying pros and cons of the ICD that would be relevant for subsequent analysis. Items were to be placed in rational groupings based on similarity. Finally, qualitative analyses were planned to be conducted by expert reviews by cardiac experts in order to confirm themes from the rational groupings. Any discrepancy between experts' reviews was to be adjudicated by the principal investigator. The final themes that emerge form this process were to be used as items in the initial design of the ICD-DAS.

Part 2

The current study proposed to subject participant ratings of items on the initial ICD-D to factor analysis, and it was expected that a four-factor solution (representing each of the 4 tenets of the Biopsychosocial-Spiritual Model) would result. This statistical procedure was used because of its ability to take a single set of variables and then form coherent subsets (Tabachnick & Fidell, 2007). Use of Cronbach's Alpha was planned as a measure of internal consistency of the total scale and any sub-scales. Multiple regression analyses were planned to assess the degree to which 1) the ICD-DAS (or any subscales) and 2) a set of psychosocial measures (representing tenets of the Biopsychosocial-Spiritual Model) could predict behavioral intent to choose the ICD. It was predicted that the ICD-DAS would be superior to the set of psychosocial measures in predicting ICD behavioral intent. Finally, several t-tests were planned to determine differences between demographic groups on the ICD-DAS, psychosocial measures, and socioeconomic variables.

CHAPTER III: RESULTS

Part 1

Each of the 24 items identified (See Table 3) were placed on a rating scale with 5 choices. Participants could choose one of the following for each item: “Not Important at all”; “Slightly Important”; “Moderately Important”; “Very Important”; “Extremely Important.” The scale asked participants to rate the level of importance for each statement in terms of making their decision for or against the ICD. These 24 items, with an additional item assessing the behavioral intent of patients to choose the ICD: “If your doctor recommended an ICD, how likely would you be to get one?” Conditional behavioral intent was assessed because there was no method available to assess the patient’s final decision until they actually accepted or refused the device. Since we were unsure of the number of patients who would make a final decision at the time of recruitment, this allowed us to assess the closest construct to actual ICD choice.

The 24 rating scale questions and the item that asked the likelihood of choosing an ICD comprised the original Implantable Cardioverter Decision Analysis Scale (ICD-DAS). The initial ICD-DAS is shown in Appendix B. Note that the “Agree/Disagree” and qualitative portions of the initial ICD-DAS were not examined in the current study.

Table 3

Highlighted Pros and Cons of the ICD

	Biological/ Medical	Psychological	Social	Spiritual/ Existential
Pros	Extends life (e.g., Koller et al., 2008). ***DAS item 1***	Perceived safety (e.g., Lemon & Edelman, 2007). ***DAS item 24***	Ability to engage in social activities (e.g., Lemon &	Getting another chance at life (e.g., Agard, Lofmark, Edvardsson, &

			Edelman, 2007). ***DAS item 21***	Ekman, 2007). ***DAS item 4***
	Prevents death (e.g., Bardy et al., 2005). ***DAS item 3***	Confidence to be active (e.g., Zimetbaum & Discussant, 2007). ***DAS item 6***	Spousal comfort (e.g., Sowell et al., 2007). ***DAS item 13***	Faith that the appropriate referral has been made (e.g., Agard, Lofmark, Edvardsson, & Ekman, 2007). ***DAS item 8***
	Well-studied treatment option (e.g., Epstein, 2008). ***DAS item 9***	Equal or better quality of life, anxiety, and/ or depression after implant (e.g., Francis, Johnson, & Niehaus, 2006). ***DAS item 10***	Desire to continue relationships as long as possible (e.g., Burns, Serber, Keim, & Sears, 2005). ***DAS item 11***	Faith that the ICD is the best option (e.g., Agard, Lofmark, Edvardsson, & Ekman, 2007). ***DAS item 12***
Cons	Shock (e.g., Daubert et al., 2008). ***DAS item 2***	Depression (e.g., Whang, Albert, & Sears, 2005). ***DAS item 14***	Spousal/familial distress (e.g., Anderson, 2007). ***DAS item 15***	Preference for natural death (e.g., Zimetbaum & Discussant, 2007). ***DAS item 16***
	Recall/ device replacement/ battery replacement (e.g., Gibson, Kuntz, Levenson, & Ellenbogen, 2008). ***DAS item 17***	Anxiety (e.g., Sowell, Sears, Walker, Kuhl, & Conti, 2007). ***DAS item 18***	Fear of shock/ embarrassment (e.g., Steinke et al., 2005). ***DAS item 19***	Low faith that the appropriate referral has been made (e.g., Zimetbaum & Discussant, 2007). ***DAS item 20***
	Surgical risk/ infection (e.g., Klug et al., 2007). ***DAS item 5***	Lower quality of life (Passman et al., 2007). ***DAS item 22***	Body image concerns (e.g., Sowell, Kuhl, Sears, Klodell, & Conti, 2006) ***DAS item 23***	Against religious or spiritual beliefs (e.g. Franklin, Schlundt, & Wallston, 2008). ***DAS item 7***

Part 2

A total of 192 patients were approached to participate in the study, and 103 agreed to participate. Table 4 below shows the recruitment totals and recruitment by

site. A thorough discussion of the sample's general characteristics can been seen on pages 42-43. While many of the patients at Stanford and some patients at ECU were near their decision point to make a final choice of getting or not getting an ICD, all patients were assessed based on their conditional behavioral intent. Some patients were not asked by their physicians to make a final choice regarding the ICD, and for a subset of patients, actual patient decision was not applicable because they did not meet full-criteria for the ICD. Data regarding actual choice is not presented in this manuscript. Further analysis of actual receipt of the device may be the focus of a subsequent analysis of a future manuscript.

Table 4

Recruitment Totals and Recruitment by Site

	Recruitment Site		
	East Carolina	**Stanford**	**Total**
	N	***N***	***N***
Sample	65	38	103
Male	42	25	67
Female	23	13	36
EF < 35	41	24	65
EF ≥ 35	23	9	32
White	22	25	47
Black	41	2	43
Other	2	11	13

Sample Psychosocial Characteristics

Means and standard deviations for the sample's psychosocial characteristics are shown in Table 5. The current sample's depression and anxiety scores were assessed with the Hospital Anxiety and Depression Survey (HADS). A score of 0 to 7 for either HADS subscale is regarded as being in the normal range, a score of 8 to 10 suggesting

of the presence of the respective state, and a score of 11 or higher indicating probable presence of a diagnostic anxiety or depressive disorder (Snaith, 2003). The current sample had 53.92% of participants with anxiety in the normal range, with 17.64% of participants with anxiety in the medium range and 28.43% in the higher range of anxiety symptoms. The current sample had 70.59% of participants with depression in the normal range, with 9.80% of participants with depression in the medium range and 19.61% in the higher range of depressive symptoms. Most participants had normal levels of anxiety and depression; however, a substantial number of participants endorsed significant levels of affective distress.

The SF-12 was used to assess physical and mental quality of life in the current sample. The SF-12 uses standardized scores (M = 50, SD=10) for normative comparisons. The sample was more than 1 standard deviation below normative standards on the physical quality of life. The sample was within normative standards on the mental quality of life. The current sample would be expected to have lower physical quality of life given the physical limitations associated with heart failure. Overall, the current sample appears to have fairly normal mental quality of life with suggests psychological and emotional adjustment to physical limitations.

The Religious Health Fatalism Questionnaire (RHFQ) was used to assess religious health fatalism in the current sample. Higher levels of fatalism are associated with relatively higher scores. The current sample had a mean score of 51, which is also the median score on this measure. This indicates that, as a whole, the sample was relatively balanced in terms of religious health fatalism.

The Multidimensional Health Locus of Control - Form C (C-MHLC) was used to assess locus of control in the current sample. Overall, the sample expressed relatively higher levels of internal locus of control (M = 24.15) than chance locus of control (M = 16.38). The sample was comparable to the means and standard deviations to the normative groups used to validate the C-MHLC (Wallsten, Stein, & Smith, 1994). Means and standard deviations for the current sample on C-MHLC are shown in Table 5 below. These results are consistent with other chronic disease samples (i.e., rheumatoid arthritis, cancer, chronic pain, and diabetes) that were analyzed in the construction of the C-MHLC (Wallsten et al., 1994).

Table 5

Sample Means and Standard Deviations on Psychosocial Measures

Measure	***Possible Range***	***M***	***SD***	***N***
HADS Anxiety	0-21	7.78	5.15	102
HADS Depression	0-21	5.98	4.98	102
SF-12 Physical Component Score	0-100	37.56	10.89	98
SF-12 Mental Component Score	0-100	48.78	10.91	98
Religious Health Fatalism	17-85	51	18.76	98
C-MHLC Internal	6-36	24.15	6.60	98
C-MHLC Chance	6-36	16.38	6.96	97
C-MHLC Doctors	3-18	15.58	2.67	101
C-MHLC Others	3-18	11.35	3.75	100

Factor Analysis

An exploratory principal factors analysis procedure with direct oblimin rotation was performed using PASW 18 software (formerly SPSS). PASW Factor was utilized to

examine 24 items in a sample of 103 prospective ICD recipients. Principal components extraction was used prior to principal factors extraction to estimate the number of factors, the presence of multicollinearity, and the factorability of the correlation matrices. An exploratory principal factors analysis procedure was then chosen to analyze the current data because of its ability to take a single set of variables and then form coherent and reasonably independent subsets (Tabachnick & Fidell, 2007). Therefore, we examined and interpreted the factors solutions to determine the number and nature of factors.

Prior to running the analysis, the first step was to assess the suitability of the data for factor analysis. Sample size is an important consideration, and the general consensus appears to be that the larger the sample, the more accurate and generalizable the results of the factors. Also, the sample size must exceed the number of variables being analyzed. The current study had 103 participants and 24 variables. While some statisticians estimate that the sample should be at least 10 times the number of variables for the correlation coefficients to be reliable (Tabachnick & Fidell, 2007), others conclude that a sample size is sufficient if the variables have several high loading marker variables above .80 (Stevens, 1996).

The current sample has more participants than variables, several high loading marker variables, and is a relatively large sample considering the practical limitations of recruiting potential cardiac device patients who met criteria for the study. When communalities are high, this has been found to reduce the effect of relatively lower sample size (MacCallum, Widaman, Zhang, & Hong, 1999).

To determine normality in the sample prior to factor analysis, SPSS Frequencies was used to display skewness of each of the items under consideration. Many of the variables were negatively skewed, some were normally distributed, and others were positively skewed. As such, significance testing was therefore not performed. It is an acknowledgeable limitation of the current study that the lack of normality of many of the items may have slightly weakened the analysis due to lower correlations with R. This could result in some cases having undue influence on the solution. Skewness was not dramatic on any of the items and nonlinear monotonic transformations to reduce the skewness were not considered necessary.

As previously described, principal components extraction was initially used to estimate the number of factors, the absence of multicollinearity, and the factorability of the correlation matrices. Six factors with eigenvalues ≥1 (1 being the minimum level for a factor to be considered strong enough for further analysis and interpretation) were extracted in 17 iterations, accounting for 70.75% of the variability in the scores (see Table 6 below).

Table 6

Initial Principal Components Analysis

Total Variance Explained

Component	**Initial Eigenvalues**		
	Total	**% of Variance**	**Cumulative %**
1	9.170	38.209	38.209
2	3.115	12.979	51.188
3	1.248	5.201	56.389
4	1.214	5.057	61.446
5	1.154	4.808	66.254
6	1.079	4.496	70.750
7	.926	3.858	74.608

8	.793	3.304	77.912
9	.704	2.932	80.844
10	.604	2.517	83.361
11	.551	2.296	85.657
12	.475	1.978	87.635
13	.467	1.944	89.579
14	.390	1.623	91.202
15	.350	1.457	92.660
16	.335	1.397	94.057
17	.293	1.220	95.276
18	.257	1.070	96.346
19	.208	.867	97.212
20	.177	.737	97.949
21	.167	.696	98.645
22	.123	.514	99.159
23	.102	.425	99.585
24	.100	.415	100.000

*Extraction Method: Principal Component Analysis.

Multicollinearity and singularity can be a problem with factor analysis. Regarding multicollinearity, if tolerance is too low for any of the variables, the tolerance may be adjusted to prevent the items from being removed from the subsequent analysis. If singularity exists, one or more of the variables may be deleted since there may be at least 2 items measuring the same dimension. Problems with multicollinearity or singularity did not exist in the current data. More specifically, the PASW FACTOR correlation matrix (not shown due to the excessive size of the table) presented several correlations greater than .30, and therefore patterns in the item responses were anticipated. Also, the anti-image correlation matrix was also reviewed and there were several low correlations between variables, and high correlations along the axis (not shown due to the excessive size of the table).

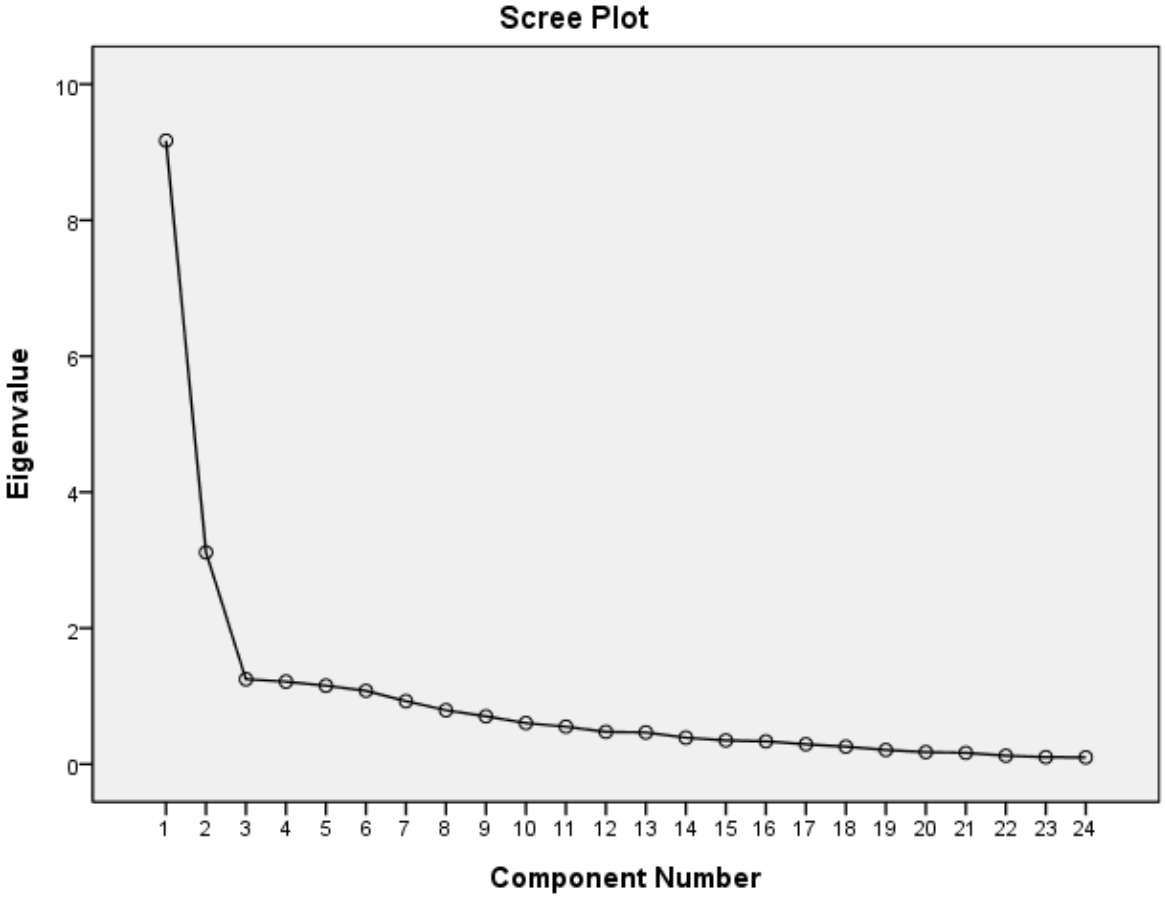
The principal components extraction was also used to assess the strength of the inter-correlations among the items. Kaiser's (1974) measure of sampling adequacy

(MSA) was employed. Small values of MSA indicate that the correlation between variables is unique or not related to the remaining variables outside each simple correlation. Kaiser has described MSAs above .5 as acceptable, although .8 or better is ideal. The KMA of the current sample was .824 with principal components extraction. The partial correlations found in the Anti-Image Correlation Matrix (not shown due to the excessive size of the table) revealed large MSAs with the majority above .80.

As shown previously, the principal components extraction revealed 6 factors with an eigenvalue greater than 1 (see Table 6). Next, a scree plot was used to graphically represent the factor solution and the percentage of variance explained by the solution (see Figure 2). Only 2 of the 6 factors with eigenvalues above 1 were above the elbow in the scree plot, indicating the likelihood that only 2 factors should be retained for further analysis.

Figure 2

Scree Plot



An exploratory principal axis factor analysis was then used to analyze the variables, forcing the extraction of only 2 factors based on the information gathered previously. Items with loadings of 0.45 or higher on one of the factors that did not have a loading of 0.30 or higher on any other factor were considered to be “good” measures of the factor on which they loaded (Grimm & Yarnold, 1997). A varimax rotation was initially utilized but produced 4 of 24 items loaded highly with both factors, failing to meet the loading criteria just described. Rather than remove all 4 items, a direct oblimin rotation was then employed to improve the interpretability of factor loadings. The principal axis factor analysis with direct oblimin rotation produced 2 factors that had 2

items (i.e., surgical risk and social activity) that loaded with relative strength on each factor (see Table 7).

Table 7

Factor Analysis with 24 items and 2 Factors

Pattern Matrix

	Factor	
	1	**2**
Anxiety (18)	.870	
Low QOL (22)	.776	
Shock humility (19)	.772	
Body image (23)	.741	
Unhappy (14)	.727	
Family worry (15)	.687	
Against beliefs (7)	.678	
Natural death (16)	.661	
Device repair (17)	.657	
Doctor diffidence (20)	.605	
Shocks (2)	.597	
Surgical risk (5)	.423	.312
Social activity (21)	.391	.388
Faith (12)		.760
Efficacy (9)		.721
Safety (24)		.706
Family comforted (13)		.698
Longer life (1)		.682
QOL (10)		.628
Relationships (11)		.591
Activity confidence (6)		.574
Doctor confidence (8)		.515
Another chance (4)		.493
Prevents death (3)		.485

Extraction Method: Principal Axis Factoring.
Rotation Method: Oblimin with Kaiser Normalization.
Rotation converged in 6 iterations.

These 2 items were removed from the subsequent analysis because they failed to load well on either of the factors.

The principal axis factor analysis with direct oblimin rotation was again used to analyze the 22 remaining items related to ICD Intent. This final use of the SPSS FACTOR procedure revealed 2 factors, each with 11 distinct items (see Table 8).

Table 8

Factor Analysis with 2 Items Removed

Pattern Matrix

	Factor	
	1	2
Anxiety (18)	.868	
Low QOL (22)	.767	
Shock humility (19)	.764	
Body image (23)	.735	
Unhappy (14)	.723	
Against beliefs (7)	.678	
Family worry (15)	.676	
Natural death (16)	.662	
Device repair (17)	.649	
Doctor diffidence (20)	.606	
Shocks (2)	.592	
Faith (12)		.764
Efficacy (9)		.724
Longer life (1)		.687
Safety (24)		.682
Family comforted (13)		.677
QOL (10)		.638
Relationships (11)		.599
Activity confidence (6)		.571
Doctor confidence (8)		.524
Prevents death (3)		.487
Another chance (4)		.483

Extraction Method: Principal Axis Factoring.
Rotation Method: Oblimin with Kaiser Normalization.
Rotation converged in 5 iterations.

The eigenvalues for the 2 factors were extracted in 5 iterations. The 2 factors accounted for 47.35% of the variance in scores. These 22 items were retained for further evaluation. The first factor consisted of 11 negative consequences of receiving the ICD. The second factor included 11 advantages of receiving the ICD. These 2 factors formed in a structure that was congruent with hypothesized pros and cons of the ICD and were therefore accepted as appropriate to proceed with assessing reliability estimates of the factors. The factors were named “ICD Pros” and “ICD Cons” accordingly.

Reliability Estimates

Reliability of the unit-weighted subscales was assessed in terms of internal consistency. Cronbach’s Alpha assessed all possible split-halves to determine if items intended to measure the same general construct produced similar scores. A Cronbach’s alpha of 0.91 was obtained for the ICD Cons factor. Alpha could not have been improved by removal of any of the items (See Table 9).

Table 9

Cronbach's Alpha if “ICD Con” Item Deleted

Item-Total Statistics

	Scale Mean if Item Deleted	**Scale Variance if Item Deleted**	**Corrected Item-Total Correlation**	**Cronbach's Alpha if Item Deleted**
Anxiety (18)	31.14	101.527	.781	.895
Low QOL (22)	31.29	102.139	.748	.896
Shock humility (19)	31.69	100.905	.696	.899
Body image (23)	31.69	100.096	.728	.897
Unhappy (14)	31.40	104.838	.660	.901
Against beliefs (7)	32.05	102.974	.602	.905

Family worry (15)	31.08	106.481	.617	.903
Natural death (16)	30.74	106.646	.597	.904
Device repair (17)	30.53	110.181	.647	.903
Doctor diffidence (20)	30.92	105.291	.631	.902
Shocks (2)	31.22	109.295	.547	.906

A Cronbach's alpha of 0.88 was obtained for the ICD Pros factor. Alpha could not have been improved by removal of any of the items. Both ICD Pros and ICD Cons had strong reliability estimates (See Table 10).

Table 10

Cronbach's Alpha if an "ICD Pro" Item Deleted

Item-Total Statistics

	Scale Mean if Item Deleted	**Scale Variance if Item Deleted**	**Corrected Item-Total Correlation**	**Cronbach's Alpha if Item Deleted**
Efficacy (9)	40.86	47.174	.686	.865
Faith (12)	41.01	45.305	.697	.863
Longer life (1)	40.53	49.033	.660	.869
Safety (24)	41.07	44.531	.604	.870
Family comforted (13)	41.02	45.780	.575	.872
Activity confidence (6)	41.08	45.517	.631	.867
Doctor confidence (8)	40.89	47.342	.540	.873
QOL (10)	40.82	47.662	.640	.868
Relationships (11)	40.88	47.034	.625	.868
Prevents death (3)	40.71	49.330	.419	.881
Another chance (4)	40.88	46.693	.540	.874

A Cronbach's alpha of 0.92 was obtained for the entire measure that included all 22 retained items. Alpha could not have been improved by removal of any of the items. The total scale as well as both ICD Pros and ICD Cons had strong reliability estimates (See Table 11). The final ICD-DAS is shown in Figure 3 below.

Table 11

Cronbach's Alpha if an ICD-DAS Item Deleted

Item-Total Statistics				
	Scale Mean if Item Deleted	**Scale Variance if Item Deleted**	**Corrected Item-Total Correlation**	**Cronbach's Alpha if Item Deleted**
Longer life (1)	75.06	255.599	.473	.915
Shocks (2)	76.30	245.778	.492	.915
Prevents death (3)	75.25	257.499	.263	.918
Another chance (4)	75.43	247.582	.514	.914
Activity confidence (6)	75.62	244.290	.619	.912
Against beliefs (7)	77.16	235.729	.571	.913
Doctor confidence (8)	75.42	249.323	.497	.914
Efficacy (9)	75.41	251.757	.522	.914
QOL (10)	75.35	250.334	.570	.914
Relationships (11)	75.43	249.941	.531	.914
Faith (12)	75.52	247.868	.563	.913
Family comforted (13)	75.57	251.582	.377	.917
Unhappy (14)	76.47	237.483	.647	.911
Family worry (15)	76.15	238.284	.658	.911
Natural death (16)	75.87	240.522	.557	.913
Device repair (17)	75.58	246.144	.626	.912
Anxiety (18)	76.18	236.045	.691	.910
Shock humility (19)	76.75	235.730	.586	.913
Doctor diffidence (20)	76.03	236.204	.641	.911
Low QOL (22)	76.41	233.911	.714	.910
Body image (23)	76.80	230.548	.700	.910
Safety (24)	75.61	247.985	.435	.916

The final ICD-DAS is shown in Figure 3 below. The 2 removed items that were removed after completion of the factor analysis are in bold font.

Figure 3

The Final Implantable Cardioverter Defibrillator – Decision Analysis Scale

The ICD is designed to provide a shock to prevent sudden cardiac arrest. Special medications may reduce the number of serious heart rhythm problems, but do not reduce the risk of sudden cardiac arrest. Some patients decide that receiving the ICD is their best option. Other patients decide to decline the ICD and do not receive therapy to prevent sudden cardiac arrest. Below are some statements that describe what some people find important in their decision regarding whether or not to get the ICD, Please rate how important the following statements are to you by checking the most appropriate box.

		Not Important at all	Slightly Important	Moderately Important	Very Important	Extremely Important
1	The ICD increases my chances of a longer life +	1	2	3	4	5
2	The ICD may give me a strong shock -	1	2	3	4	5
3	The ICD prevents death +	1	2	3	4	5
4	The ICD gives me another chance at life +	1	2	3	4	5
5	**There is a surgical risk and chance of infection if I get the ICD -**	**1**	**2**	**3**	**4**	**5**
6	The ICD gives me confidence to be physically active +	1	2	3	4	5
7	It is against my beliefs to get the ICD -	1	2	3	4	5
8	The doctor seems confident that I should get the ICD +	1	2	3	4	5
9	The ICD is a well-studied treatment option +	1	2	3	4	5
10	Most people who get an ICD have a good quality of life and mental health +	1	2	3	4	5
11	The protection of the ICD allows me to continue relationships as long as possible +	1	2	3	4	5
12	I have faith that the ICD is my best option+	1	2	3	4	5
13	My spouse and/or family will be comforted if I get the ICD +	1	2	3	4	5
14	Some people with ICDs become depressed after getting the device -	1	2	3	4	5
15	My spouse/ family members may be worried if I am shocked by the ICD -	1	2	3	4	5
16	I prefer to have natural death without being	1	2	3	4	5

	shocked by the ICD -					
17	At some point, parts or all of the ICD may need to be replaced -	1	2	3	4	5
18	Some people with ICDs become anxious after getting the device -	1	2	3	4	5
19	I fear the embarrassment of getting shocked around other people -	1	2	3	4	5
20	The doctor does not seem confident that I should get the ICD -	1	2	3	4	5
21	**The ICD will provide the ability to engage in activities with other people +**	**1**	**2**	**3**	**4**	**5**
22	Some people with ICDs have a lower quality of life after getting the device -	1	2	3	4	5
23	I do not want other people to see my scar or ask me questions about my condition -	1	2	3	4	5
24	I will feel safer with an ICD +	1	2	3	4	5

Note: Pro and con items are respectively denoted with (+) or (-). The 2 items removed from the measure are denoted with bold font.

Defining ICD-DAS Subscales

The ultimate aim of this project was to identify the factors, or subscales, so that they could be utilized in clinical and/or research activities. Therefore, a regression analysis was utilized to define subscales on the ICD-DAS, with a subscale representing each of the 2 factors. Each participant's factor score was obtained by multiplying their standardized scores on the variables by the standardized scoring coefficients. PASW was used to output the factor scores of each participant into the data set for use in subsequent procedures. Next, multiple regression analysis was then utilized to predict ICD Intent from factor scores on the ICD Pros and ICD Cons. Basic descriptive statistics and regression coefficients are shown in Table 12. The only predictor variable that had a significant ($p < .01$) zero-order correlation with ICD Behavioral Intent was ICD Pros,

but both the ICD Pros and ICD Cons had significant ($p < .01$) partial effects in the full model. The two predictor model was able to account for 34% of the variance in ICD Intent, $F(2,74) = 18.97$, $p < .001$, $r^2 = .34$.

Table 12

ICD Intent Related to ICD Pros and ICD Cons (N = 30).

	Zero-Order *r*			**β**	***sr***	***b***
Variable	ICD Cons	ICD Pros	ICD Intent			
ICD Pros			.429*	.626*	.560	1.092
ICD Cons		.447*	-.161	-.440*	-.394	-.763
				Intercept =		5.57
Mean	-0.003	-0.009	5.56			
SD	0.95	0.95	1.65	R^2 =	.34*	

*$p < .01$

The means and standard deviations for the final measure based on actual scores are shown in Table 13 in below.

Table 13

Mean and Standard Deviations on the ICD-DAS Subscales and Total Measure

Measure	***Possible Range***	***M***	***SD***	***N***
ICD-DAS Total	22-110	79.49	16.34	79
ICD Cons	11-55	34.38	11.20	85
ICD Pros	11-55	45.18	7.49	83

Using Psychosocial Measures to Predict ICD Intent

With the 2-factor ICD-DAS solution appearing to be useful in predicting ICD Intent, there was interest in determining if a standard set of psychosocial measures (i.e., HADS, C-MHLC, SF-12, and RHFQ) could also predict ICD Intent.

A sequential multiple regression analysis was utilized to predict ICD Intent. On the first step, HADS-A, HADS-D, C-MHLC Internal, C-MHLC Chance, C-MHLC Doctors, C-MHLC Others, SF-12 Physical, SF-12 Mental, and RHFQ were entered into the model. This set of predictors was not significantly correlated with ICD Intent, $F(9, 70) = 1.142$, $p = .348$, $R^2 = .14$, 95% CI [.325, 8.237]. On the second step, ICD Pros and ICD Cons were entered simultaneously, resulting in a significant increase in R^2, $F(2, 59) = 19.36$, $p < .001$. The full model R^2 was significantly greater than zero, $F(11, 70) = 5.017$, $p < .001$, $R^2 = .48$, 95% CI [.738, 7.292]. Other than ICD Pros and ICD Cons, none of the predictor variables had a significant zero-order correlation with ICD Intent. These results suggest that the ICD-DAS (ICD Pros and ICD Cons) may be more useful in attempting to understand patient choice than a set of general measures. More specifically, the ICD-DAS may provide additional or more efficient clinical utility than already established measures. Discriminative validity was demonstrated as the ICD-DAS scales was better at predicting ICD-Intent, than the set of psychosocial measures.

Comparisons by Recruitment Site

To determine if there were any significant differences on a number of socioeconomic variables between East Carolina and Stanford participants, independent samples t-tests were utilized. Means, standard deviations, sample sizes appear in Table 14 below. Scores with significant differences were given confidence intervals and effects sizes. Stanford participants had a significantly higher educational background than East Carolina participants, $t(60.51) = 2.437$, $p = .018$, $d = .62$, 95% CI [.1065, 1.1228]. Stanford participants also had significantly higher yearly income (in thousands) than ECU participants $t(27.28) = 4.608$, $p < .001$, $d = 1.17$, 95% CI [.5748, 1.7430]. In

addition, Stanford participants were significantly more likely to have health insurance than ECU participants, $t(77.11) = 3.852$, $p < .001$, $d = .80$, 95% CI [.3734, 1.2297].

Independent samples t-tests were then conducted to test differences between Stanford and East Carolina patients on several psychosocial variables, including ICD Pros and ICD Cons. Means, standard deviations, sample sizes appear in Table 14 below. Scores with significant differences were given confidence intervals and effects sizes. Stanford participants had significantly higher physical quality of life scores than East Carolina participants $t(96) = 3.980$, $p < .001$, $d = .83$, 95% CI [.4025, 1.2522]. East Carolina participants had significantly higher depression scores than Stanford participants $t(97.61) = 5.260$, $p < .001$, $d = 1.08$, 95% CI [.6459, 1.5036]. East Carolina participants had significantly higher anxiety scores than Stanford participants $t(99.25) = 3.647$, $p < .001$, $d = .75$, 95% CI [.3305, 1.1597]. East Carolina participants had significantly higher scores on religious health fatalism than Stanford participants $t(96) = 4.312$, $p < .001$, $d = .89$, 95% CI [.4662, 1.3174]. East Carolina participants had significantly higher scores on ICD Cons than Stanford participants $t(77) = 2.858$, $p = .005$, $d = .68$, 95% CI [.2008, 1.1637]. Finally, Stanford participants reported significantly higher behavioral intent to choose the ICD than East Carolina participants $t(90.94) = 2.442$, $p = .017$, $d = .50$, 95% CI [.0913, .9121].

Table 14

Site Comparisons

Measure	**Site**					
	East Carolina			**Stanford**		
	M	***SD***	***N***	***M***	***SD***	***N***
Yearly Income*	29.29	21.84	39	106.64	83.73	26

(Thousands)						
Insurance Coverage*	0.72	0.45	58	0.97	0.16	38
Years of Education**	12.50	2.65	57	14.24	3.75	37
ICD Intent**	5.44	1.63	62	5.83	1.46	38
HADS Anxiety*	9.02	5.56	64	5.71	3.59	38
HADS Depression*	7.55	5.37	64	3.34	2.67	38
SF-12 Physical Component Score	34.38	10.40	61	42.79	9.70	37
SF-12 Mental Component Score	47.24	11.31	61	51.32	9.85	37
Religious Health Fatalism Questionnaire*	56.98	16.47	60	41.55	18.44	38
C-MHLC Internal	24.53	6.83	62	23.50	6.23	36
C-MHLC Chance	15.95	7.49	60	17.08	6.04	37
C-MHLC Doctors	15.51	2.88	63	15.72	2.34	38
C-MHLC Others	11.16	4.16	62	11.66	3.01	38
ICD Cons**	0.21	0.84	53	-0.42	1.08	26
ICD Pros	-0.09	0.97	35	0.19	0.88	26

* = $p < .001$.
** = $p < .05$.

Comparisons by Race

To determine if there were any significant differences on a number of socioeconomic variables between Caucasian and African American participants, independent samples t-tests were utilized. Means, standard deviations, sample sizes appear in Table 15. Scores with significant differences were given confidence intervals and effects sizes. Caucasian participants had a significantly higher educational background than African American participants, $t(76.08) = 2.838$, $p = .006$, $d = .64$, 95% CI [.1849, 1.0934]. Caucasian participants also had significantly higher yearly income than African American participants, $t(44.34) = 3.309$, $p = .002$, $d = .89$, 95% CI [.3262,

1.4404]. In addition, Caucasian participants were significantly more likely to have health insurance than African American participants, $t(44.47) = 4.148$, $p < .001$, $d = .91$, 95% CI [.4374, 1.3786].

Independent samples t-tests were then conducted to test differences between African American and Caucasian patients on several psychosocial variables, including ICD Pros and ICD Cons. Means, standard deviations, sample sizes appear in Table 15. Scores with significant differences were given confidence intervals and effects sizes. African American patients in the sample reported higher levels of depressive symptoms, $t(87) = 1.984$, $p = .050$, $d = .42$, 95% CI [-.0007, .8409], religious health fatalism, $t(83) = 5.138$, $p < .001$, $d = 1.12$, 95% CI [.6579, 1.5782], and ICD Cons, $t(70) = 3.688$, $p < .001$, $d = .87$, 95% CI [.3826, 1.3508] than Caucasian participants.

Table 15

Racial Comparisons

Measure	**Race**					
	African American			**Caucasian**		
	M	***SD***	***N***	***M***	***SD***	***N***
Yearly Income** (Thousands)	30.45	31.43	24	81.06	79.73	33
Insurance Coverage*	0.64	0.49	39	0.98	0.15	44
Years of Education**	12.22	2.61	36	14.17	3.50	43
ICD Intent	5.35	1.70	40	5.83	1.46	47
HADS Anxiety	8.71	6.18	42	7.28	4.25	47
HADS Depression**	7.48	5.52	42	5.34	4.63	47
SF-12 Physical Component Score	37.49	10.35	39	36.51	11.53	46
SF-12 Mental Component Score	48.94	11.15	39	47.98	10.49	46
Religious Health	61.63	15.52	38	43.83	16.17	47

Fatalism Questionnaire*						
C-MHLC Internal	25.00	6.94	41	22.82	6.28	45
C-MHLC Chance	16.20	8.22	40	16.62	6.25	45
C-MHLC Doctors	15.07	3.17	42	15.72	2.34	46
C-MHLC Others	11.12	4.52	41	11.26	2.82	46
ICD Cons*	0.42	0.89	35	-0.33	.84	37
ICD Pros	-0.11	1.12	35	0.07	0.75	37

* = $p < .001$.
** = $p \leq .05$.

Comparisons by Gender

Independent samples t-tests were also conducted to test differences between male and female patients on several outcome variables, including ICD Pros and ICD Cons. Means, standard deviations, sample sizes appear in Table 16. Scores with significant differences were given confidence intervals and effects sizes. Male patients in the sample reported higher levels of internal health locus of control, $t(96) = 4.359$, $p < .001$, $d = .92$, 95% CI [.4837, 1.3499] and lower levels of ICD Pros, $t(77) = 2.161$, $p = 0.34$, $d = .50$, 95% CI [.0387, .9672] than female participants.

Table 16

Gender Comparisons

Measure	**Gender**					
	Male			**Female**		
	M	***SD***	***N***	***M***	***SD***	***N***
Yearly Income (Thousands)	60.55	69.52	42	59.65	63.46	23
Insurance Coverage	0.78	0.42	64	0.91	0.30	32
Years of Education	13.11	3.43	60	13.43	2.87	30
ICD Intent	5.68	1.51	65	5.77	1.63	35

HADS Anxiety	7.15	4.97	66	8.94	5.35	36
HADS Depression	5.56	4.53	66	6.75	5.70	36
SF-12 Physical Component Score	38.04	11.02	64	36.64	10.76	34
SF-12 Mental Component Score	48.95	10.18	64	48.46	12.34	34
Religious Health Fatalism Questionnaire	50.79	18.90	66	51.44	18.76	32
C-MHLC Internal*	26.14	5.95	63	20.57	6.27	35
C-MHLC Chance	17.26	7.06	62	14.83	6.60	35
C-MHLC Doctors	15.72	2.55	65	15.33	2.91	36
C-MHLC Others	11.33	3.79	64	11.39	3.74	36
ICD Cons	0.02	0.98	50	-0.04	0.95	29
ICD Pros*	-0.17	0.10	50	0.30	0.78	29

* = $p < .001$.
** = $p < .05$.

Examination of Site and Race Differences

As noted in Table 4, the Stanford sample was predominantly comprised of Caucasian participants, and a relatively larger proportion of the ECU sample was African American participants. As such, there was interest in further examining site and race differences. Post-hoc analyses consisting of several t-tests were conducted to examine within site and within race comparisons. Because there were only 2 African American participants within the Stanford group, differences between Caucasian and African American participants on socioeconomic and psychosocial variables at Stanford were not made. Also for this reason, comparisons were not made between Stanford's African American participants and East Carolina's African American participants. Because there were significant differences between Stanford and East Carolina participants in terms of family income, years of education, and insurance, and these

same differences appeared when Caucasian and African American participants were compared within the entire sample, comparisons between Caucasian and African American participants were made within the ECU group only, as well as within Caucasian participants between each site. Also, because there were significant differences between Stanford and East Carolina participants in terms of anxiety, depression, religious health fatalism, and ICD Cons, and differences in anxiety, religious health fatalism, and ICD Cons also appeared when Caucasian and African American participants were compared within the entire sample, differences by race were examined within the East Carolina group only, as well as between Caucasian participants at each site.

Differences by Race within the East Carolina Sample. Socioeconomic comparisons between Caucasian and African American participants within the ECU sample only revealed no differences in terms of income or education. Caucasian participants *(M = 0.95, SD = 0.23)* were still significantly more likely to have insurance coverage than African American participants *(M = 0.62, SD = 0.49), t*(55.69) = 3.377, *p* = .001, *d* = .95, 95% CI [.3684, 1.5299]. Psychosocial comparisons by race were also examined within the East Carolina group only. African American participants *(M = 37.40, SD = 10.52),* reported significantly higher physical quality of life than Caucasian participants *(M = 29.77, SD = 8.30)*, *t*(57) = 2.904, *p* = .005, *d* = .78, 95% CI [.2317, 1.3253]. African American participants *(M = 61.92, SD = 18.85)* also reported significantly higher religious health fatalism than Caucasian participants *(M = 48.36, SD = 13.21), t*(56) = 3.358, *p* = .001, *d* = .91, 95% CI [.3485, 1.4614]. Finally, African American participants *(M = 0.48, SD = 0.82)* reported significantly higher ICD Cons than

Caucasian participants *(M = -0.26, SD = 0.64)*, $t(50) = 3.303$, $p = .002$, $d = .96$, 95% CI [.3569, 1.5600].

Differences by Site between Caucasian Participants. Stanford's Caucasian participants *(M = 118.24, SD = 90.67)* had significantly higher family income than East Carolina's Caucasian participants *(M = 36.44, SD = 25.25)*, $t(20.10) = 3.661$, $p = .002$, $d = 1.28$, 95% CI [.4778, 2.0578]. Stanford's Caucasian participants *(M = 5.64, SD = 3.20)* had significantly lower anxiety scores than East Carolina's Caucasian participants *(M = 9.14, SD = 4.59)*, $t(45) = 3.058$, $p = .004$, $d = .89$, 95% CI [.2879, 1.4913]. Stanford's Caucasian participants *(M = 3.24, SD = 2.82)* had significantly lower depression scores than East Carolina's Caucasian participants *(M = 7.73, SD = 5.16),* $t(31.58) = 3.632$, $p = .002$, $d = 1.06$, 95% CI [.4251, 1.6842]. Finally, Stanford's Caucasian participants *(M = 43.69, SD = 10.68)* had significantly higher physical quality of life scores than East Carolina's Caucasian participants *(M = 29.77, SD = 8.30)*, $t(44) = 4.551$, $p < .001$, $d = 1.34$, 95% CI [.6946, 1.9797].

Comparisons by Disease Severity

Independent samples t-tests were then conducted to test differences between participants with EFs below 35 versus those with EFs 35 or greater on several outcome variables, including ICD Pros and ICD Cons. Means, standard deviations, sample sizes appear in Table 17 below. Scores with significant differences were given confidence intervals and effects sizes. Participants with EFs below 35 reported lower levels of anxiety symptoms than patients with EFs 35 or greater, $t(94) = 2.936$, $p = .004$, $d = .64$, 95% CI [.2000, 1.0679]. Patients with EFs below 35 reported higher chance locus of control than patients with 35 or greater, $t(90) = 2.169$, $p = .033$, $d = .48$, 95% CI [.0395,

.9226]. Patients with EFs below 35 reported lower educational background reported than patient with EFs 35 or greater, $t(83) = 2.915$, $p = .005$, $d = .67$, 95% CI [.2073, 1.1345]. There were no significant differences between patients with high versus low EFs on ICD Pros or ICD Cons.

Table 17

Disease Severity Comparisons

Measure	**General Estimate of Disease Severity**					
	EF < 35 "Higher Severity"			***EF ≥ 35 "Lower Severity"***		
	M	***SD***	***N***	***M***	***SD***	***N***
Yearly Income (Thousands)	59.56	67.40	42	52.17	60.68	20
Insurance Coverage	0.82	0.39	60	0.81	0.40	31
Years of Education**	12.32	3.11	57	14.32	2.65	28
ICD Intent	5.59	1.73	66	6.00	1.05	28
HADS Anxiety**	6.80	4.56	66	10.23	6.06	30
HADS Depression	5.61	4.74	66	7.27	5.66	30
SF-12 Physical Component Score	37.56	10.93	62	37.18	10.23	30
SF-12 Mental Component Score	50.16	9.68	62	45.88	12.79	30
Religious Health Fatalism Questionnaire	52.37	18.19	63	50.03	19.21	29
C-MHLC Internal	25.16	6.21	64	22.53	7.31	30
C-MHLC Chance**	17.19	6.88	62	13.93	6.50	30
C-MHLC Doctors	15.48	2.86	65	15.93	2.39	30
C-MHLC Others	11.45	3.41	65	11.03	4.51	30
ICD Cons	0.02	1.02	52	0.08	0.88	22
ICD Pros	-0.04	0.96	52	0.05	0.87	22

* = $p < .001$.
** = $p < .05$.

Correlations

Table 18 below provides the correlations between the various psychosocial and socioeconomic variables.

Table 18

Correlations

Correlations

	Education	Income	Insurance	ICD Intent	HADS Anx	HADS Dep	SF-12 Phys	SF-12 Mental	RHFQ	C-MHLC Internal	C-MHLC Chance	C-MHLC Doctors	C-MHLC Others	ICD Cons	ICD Pros
Education	1	.464**	.132	.074	-.192	-.237*	.228*	.097	-.209	-.140	-.208	.075	-.037	-.123	.066
Income		1	.238	.293*	-.245	-.258*	.229	.214	-.220	.031	-.057	.126	.084	-.087	.215
Insurance			1	.046	-.288**	-.307**	.116	.311**	-.246*	-.266*	-.065	-.071	.059	-.219	.009
ICD Intent				1	-.183	-.176	.009	.178	.036	.217*	.109	.174	.214*	-.161	.429**
HADS Anx					1	.818**	-.320**	-.589**	.053	.060	-.025	-.063	-.359**	.145	-.005
HADS Dep						1	-.464**	-.607**	.095	.051	.046	-.080	-.349**	.147	-.020
SF-12 Physical							1	.454**	.037	-.077	-.064	.126	.097	.035	.041
SF-12 Mental								1	-.003	-.080	-.066	-.043	.321**	.016	.085
RHFQ									1	.319**	.246*	.245*	.250*	.364**	.097
C-MHLC Internal										1	.393**	.425**	.187	.195	.166
C-MHLC Chance											1	.158	.295**	.147	.080
C-MHLC Doctors												1	.389**	.200	.219
C-MHLC Others													1	.120	.118
ICD Cons														1	.466**
ICD Pros															1

*. Pearson correlation is significant at the 0.01 level (2-tailed).

**. Pearson correlation is significant at the 0.05 level (2-tailed).

CHAPTER IV: DISCUSSION

Summary of Findings

The current study examined patient decision-making regarding the ICD and developed a 2-factor pro and con measurement approach. The ICD-DAS is comprised of 22 items, with 2 factors labeled ICD Pros and ICD Cons. The factors (and total scale) were found to have high internal consistency and were then used as scales to predict whether patient participants would want an ICD if it were recommended by their physician. A set of psychosocial measures (i.e., physical and mental quality of life, depression, anxiety, locus of control, and religious health fatalism) that assessed biological, psychological, social, and spiritual/existential domains were not significantly predictive of ICD-Choice, suggesting that the ICD-DAS is a more efficient and accurate predictor of patient behavioral intent for the ICD than a combination of these general measures. It appears that site differences may have accounted for much of the difference in intention to choose the ICD.

Stanford participants had a significantly higher educational background, yearly income, and were significantly more likely to have health insurance than East Carolina participants. In addition, East Carolina participants had significantly lower physical quality of life scores and significantly higher depression, anxiety, religious health fatalism, and ICD Cons than Stanford participants. Finally, Stanford participants had significantly higher behavioral intent to choose the ICD than East Carolina participants. Caucasian participants had a significantly higher educational background and yearly income than African American participants, and were more likely to have health insurance than African American participants. African American patients in the sample

reported higher levels of depressive symptoms, religious health fatalism, and ICD Cons than Caucasian participants. Within the East Carolina sample, Caucasians participants were significantly more likely to have insurance coverage than African American participants. Also, within the East Carolina group, African American participants reported significantly higher physical quality of life, significantly higher religious health fatalism, and higher ICD Cons than Caucasian participants. Stanford's Caucasian participants had significantly higher family income, lower anxiety scores, lower depression scores, and higher physical quality of life scores than East Carolina's Caucasian participants. Male patients in the sample reported higher levels of internal health locus of control and lower levels of ICD Pros than female participants. Those with EFs below 35 reported lower levels of anxiety symptoms and higher chance locus of control. Those with relatively lower EFs had lower educational backgrounds. There were no significant differences between patients with high versus low EFs on ICD Pros or ICD Cons.

Formulation of the ICD-DAS

The primary aims of the current study were the initial design and validation of the ICD-DAS. This study analyzed selected pros and cons of the ICD that were derived from the existing research literature related to health psychology, decision making, and ICD patient focused studies, as well as discussions with device experts from both health care and the device industry. The items appear to have face validity as they were derived directly from the literature regarding risks and benefits and were written in plain, easy to read language, and were subjected to expert review. Factor analysis revealed a 2-factor solution with 11 pros and 11 cons of the ICD. With ICD Cons representing a

greater percentage of overall variance, this is consistent with research indicating that most patients are more affected by risks than benefits (Alaszewski & Horlick-Jones, 2003).

The final factor analysis utilized an Oblimin procedure with Kaiser normalization that converged in 5 rotations. The 2 factors were labeled ICD Pros and ICD Cons, respectively. ICD Pros and ICD Cons are a simple compilation of the various biopsychosocial-spiritual dimensions that were included in the 24-item ICD questionnaire that was examined. It was expected that a 4-factor solution would be revealed, representing each of the 4 tenets of the Biopsychosocial-Spiritual Model; however, the actual solution included each of these 4 components subsumed within the ICD Pros and ICD Cons scales. The goal of the following discussion on group differences is to explore some of the potential psychosocial, demographic, and socioeconomic influences on ICD decision-making.

The participants enrolled in the present study included a diverse set of patients (i.e., regional, disease severity, racial, gender, socioeconomic, and educational background), which may allow for generalization of findings across settings. As might be expected due to differences in the cost of living, differences in income appeared to be accounted for by regional site differences, with higher levels of income reported among Stanford's Caucasian participants than East Carolina's Caucasian participants. Differences in insurance coverage appeared to be primarily related to race, at least in the East Carolina sample, with African American participants reporting coverage less frequently than Caucasian participants. Psychosocial differences appear to be accounted for by a combination of geographical and racial factors. More specifically,

Stanford's Caucasian participants had generally more favorable psychosocial scores than East Carolina's Caucasian participants (i.e., anxiety, depression, and physical quality of life). Also, in terms of race within the East Carolina sample, Caucasian participants had generally more favorable psychosocial scores than African American participants (i.e., religious health fatalism, physical quality of life, and ICD Cons).

In the East Carolina sample, there were higher percentages of African American participants, lower SES participants, and participants with a lower educational status than in the Stanford sample. These results might suggest that demographic factors potentially influenced behavioral intent to choose the ICD. However, when comparing the entire sample's Caucasian participants with African American participants, and when comparing these groups within the East Carolina sample only, there were no differences in term of behavioral intent to choose the ICD. Therefore, it appears that site differences accounted for most of the difference in intention to choose the ICD. With African-American patients reporting higher levels of depressive symptoms, religious health fatalism, and ICD Cons than Caucasian participants, it appears that some combination of cultural and socioeconomic factors play an important role in the intention to choose the ICD. Unfortunately, we were unable to compare African American patients between sights do to the low sample of African American patients in the Stanford sample.

Previous research has described ICD disparities and several finding have been noted including that African American patients are more likely to refuse recommendations (Hernandez et al., 2007), and that geography/region plays an important role with lower rates of ICD implant in the southern United States and in

regions with larger populations of African Americans (Groeneveld et al., 2007; Thomaset al., 2007). Some have suggested that differences in implantation rates are due to bias in treatment recommendations (van Ryn, 2002), while others have asserted that differences are more related to variations in each patient's willingness to accept recommendations (Gordon et al., 2004; Whittle, Conigliaro, Good, & Joswiak, 1997).

The site and race differences in terms of ICD behavioral intent in the current study may suggest that individuals in the Stanford region are more comfortable with the technology of the ICD, which could be attributed to higher education levels, having more income, and having insurance coverage to pay for treatment. However, these differences could also be due to the higher rates of religious health fatalism and lower understanding of the ICD technology in the East Carolina region. The results may also suggest that African American patients are more reluctant to receive the ICD because the technology is contrary to their spiritual/existential beliefs, as is consistent with their higher rates of religious health fatalism compared Caucasian participants. The findings may also suggest that having lower socioeconomic status, such as was found in the East Carolina sample, leads to a lower likelihood of accepting the ICD, because the technology may be neither affordable nor well understood. With higher ratings of ICD Cons, this might indicate that African American patients have a relatively greater desire to avoid the negative implications of the device, or these factors create less cognitive dissonance in terms of relatively higher rates of fatalistic religious beliefs. With the current sample of African American patients reporting relatively higher levels of depression, this may also suggest poorer emotional adjustment to cardiac disease, or a more negatively focused cognitive schema, as would be consistent with depression.

Having higher depressive symptoms may also contribute to a negative perception of the ICD. Interestingly, Stanford's Caucasian participants had significantly lower depression scores than East Carolina's Caucasian participants. This lends support to the possibility that the differences in depression may be less attributed to race than to region. Overall, it appears that both region and race play important roles in terms of patient perceptions of the ICD.

Male patients in the sample reported higher levels of internal health locus of control and lower levels of ICD Pros than female participants. Males may be less likely to give weight to the benefits of treatment recommendations (relatively lower ICD Pros) and be less likely to follow the advice of their physician (relatively higher internal locus of control). Alternatively, females may be more likely to follow the advice of their physician (relatively lower internal locus of control) and give more weight to the benefits of a treatment than men (relatively lower ICD pros). This is an interesting finding from which conclusions are not easily drawn, and therefore, further exploration in a subsequent analysis may be worthwhile.

Those with EFs below 35 reported lower levels of anxiety symptoms and higher chance locus of control. Again, this is an interesting finding that might suggest that patients with greater disease severity have accepted their disease more (and therefore have lower anxiety), and lend control to external factors (higher chance locus of control) since they may perceive their behavior as less predictive of improvement in their health. Those with relatively lower EFs had lower educational backgrounds, which could potentially suggest that lower socioeconomic status is related to poorer health in our sample. It is notable that there were no significant differences between patients with

high versus low EFs on ICD Pros or ICD Cons, which may indicate that patient weight pros and cons in similar ways no matter how severe or threatening their illness. Despite East Carolina participants having relatively higher EFs than Stanford participants, they reported lower physical quality of life than Stanford patients. This discrepancy may be attributed to socioeconomic or psychosocial factors.

The group differences just described on biological, psychological, social, and spiritual dimensions support the current study's conceptualization applying the Biopsychosocial-Spiritual Model of health. This model, combined with theories of health related decision-making (Transtheoretical Model and Theory of Planned Behavior), was utilized in order to create a testable measure informed by the literature. Informed by these theories, the current study sought to design a measure that could be empirically validated by assessment of important ICD-related factors.

The Biopsychosocial-Spiritual Model was utilized to account for a holistic set of factors that could be assessed to best predict the conditional behavioral intention to choose the ICD. While there was no specific method to confirm this model in the final ICD-DAS measure, the final set of items on the measure included items from all 4 tenets of this model. The health psychology literature clearly suggests that biological, psychological, and social factors interact to influence behavior; however, there is relatively limited evidence to support adding a spiritual/existential dimension to the well-accepted 3-factor model. Our current study suggests that spiritual factors may be important to ICD patients, but this does not assume that a fourth dimension should be added to the Biopsychosocial-Spiritual Model because spirituality can be conceptualized as a psychological or social variable. On one hand, there may negative implications

related to fatalism, and on the other hand, patients have the right to choose treatment options based on their beliefs about life and death. Incorporation of spirituality/existentialism items into the ICD decisional model appears important, in part because a life changing decision is being made. While spirituality can be conceptualized as a social factor (e.g., religious community) or even a psychological factor (e.g., belief or cognition), if ICD patients perceive their spirituality as a determining decision factor, simply addressing cognitive and social facets may come across to patients as insufficient.

The Transtheoretical Model and the Theory of Planned Behavior appear to provide useful frameworks for the items on the ICD-DAS. The Transtheoretical Model's concept of weighing the pros and cons of a decision was confirmed in this study, with ICD pros and ICD cons being retained as distinct subscales on the ICD-DAS. However, there was no method of confirming what stage of change an individual was in during their rating of behavioral intent to choose ICD. Future analyses may compare individuals who were actually making the ICD choice with those who were not. The Theory of Planned Behavior, with its focus on relevant beliefs and normative influences was applicable, as ICD Pros and ICD Cons successfully predicted behavior intent to choose the ICD when recommended by their physician. A next phase of the study might attempt to use behavioral intent to predict actual ICD choice. The concept of assessing beliefs is important as heuristic tendencies may at times appropriately guide decisions, while factors such as physician reliance, availability heuristics, depression, or religious health fatalism may influence patients to choose the ICD without full understanding of the facts. The use of decision analysis attempts to account for these decisional

influences by clearly representing, and formally assessing the important aspects of a decision situation with the goal of removing ambiguity from choice and focusing attention on the uncertainties that may change or influence one's decision. Although previous research has documented a variety of positive and negative perceptions about the ICD, no studies are available which address the ICD decision by a decision analysis approach.

The ultimate improvement of pre-implant education and allowing for interventions with potential ICD recipients was the heart of this study. There are a variety of post-implant educational and cognitive-behavioral interventions that could be applied to potential ICD recipients. The current study demonstrated that behavioral intent to choose the ICD might vary depending on demographic, regional, and socioeconomic variables. Future efforts will focus on assessing and improving patient readiness with similar interventions that are tailored to the factors they rate as important on the ICD-DAS. It is predicted ICD-indicated patients, who are referred through this process that includes assessment and subsequent implementation of tailored education and intervention, will make informed and confident decisions regarding treatment with an ICD.

If patients choose to refuse the ICD based on an inclusive array of information about the pros and cons of ICD-treatment, then hopefully their quality of life and psychological well being is spared as they will not experience the negative implications associated with ICD cons such as shock or cognitive dissonance with their spiritual beliefs. If patients choose the ICD more often because of an inclusive array of information about the pros and cons of ICD-treatment, then ICD treatment for sudden

cardiac arrest will be utilized to a greater degree, which will lead to prevention of unnecessary or untimely deaths.

Limitations

In part 1 of the study, the initial ICD-DAS was constructed after a literature review and use of a Biopsychosocial-Spiritual Model for conceptualization purposes. In assessing Biopsychosocial-Spiritual Model, the current study may not have used the best items to tap dimension to accurately test the model. To keep the measure relatively brief, there were only 3 pros and 3 cons for each of the 4 dimensions that were analyzed with the ICD questionnaire. Ideally, the measure would have kept several of the initial 121 items to be analyzed; however, there would have been insufficient participants in this study to test such a large number of items. Further, the subject burden in a clinically ill sample was a limitation that needed to be considered. As a result, from that outset of this project, a rational item development approach was used that was less than ideal in order to reduce the items and limit the time necessary to participate in the project. Another potential limitation is that some of the items were worded in too complex a way. Simpler concepts may have reduced potential differences in the interpretation of items.

Once the items were identified, experts reviewed the items; however, there were no assessments of inter-rater reliability. Methodology was not formal between the principal investigator and expert interviewees while they reviewed the proposed set of items. Ideally, there would have been a formal qualitative assessment of patients prior to the administration to experts. Then, experts would rate each item blindly to prevent bias toward confirming the preconceived rational groupings of items. Another planning

issue included an initial overestimation of the number of patients who were actually going to be making the final ICD decision at the time of our assessments. This led to broadening the inclusion criteria to include patients who would not be making impending decisions. In part 2 of the study, patients were administered the initial ICD-DAS and other measures. Investigators reported that a number of patients appeared confused when scoring portions of the ICD-DAS (i.e. Agree/disagree items and qualitative portions). Ideally, the questionnaire would have been designed to ask all 24 agree/disagree items first and then subsequently ask each of the 24 importance items. The inclusion of the Religious Health Fatalism Questionnaire inherently put a negative spin on the items that assessed spiritual considerations. Ideally, a measure that could distinguish positive from negative religious coping would have been potentially less stigmatizing and more encompassing of a range of consequences of spirituality and religiosity.

While there was diversity between the 2 participating sites, samples from Eastern North Carolina (East Carolina University) and Palo Alto, California (Stanford University) are unique groups and a national or international sample would have allowed for greater generalizability. Nonetheless, the current sample did have a wide range of income, educational status, race, gender, and disease severity. Unfortunately, there were only 2 African American participants in the Stanford sample, which did not allow for within group comparison by race, or between group differences between African American participants. There were also insufficient participants from other ethnic groups to determine other culturally related distinctions.

In terms of disease severity, there were no differences on any measure between patients with low versus high EFs. High versus low cutoffs were selected to reflect ICD indicated vs. non-ICD indicated. Additional research with a focus on only patients who are at the actual decision point for choosing whether or not to receive the device may still be warranted to confirm whether the results would be the same solely for patients in the actual decision context of the ICD. Additional attention to the relationship between disease and symptom severity and ICD intent/ICD choice is warranted. Moreover, future investigators may want to control for primary versus secondary prevention reasons for implantation of a device. Regarding ejection fraction as a measure of severity of illness, our sample assessed 5 patients with relatively high EFs, but who still met criteria for the ICD (e.g., structural heart defect). In this light, EF is not necessarily the best measure of disease severity especially when considering the medical diversity in this sample. Unfortunately, other measures of cardiac severity were not consistently collected or available and could not be used in the current set of analyses. The inclusion of additional biomedical clinical data for more accurate markers of disease severity would add to the validity of the findings being reported and should be considered in future research. Nonetheless, previous studies have demonstrated how psychosocial adjustment is poorly predicted by disease severity in both congestive heart failure and ICD samples (Carels, 2004; Sears et al., 2004).

Finally, there is uncertainty as to whether or not this measure will ultimately improve a patient's readiness to make a decision regarding the ICD or eventual device acceptance if a patient does choose the device. The ultimate utility of the ICD-DAS was not fully tested here. As in most decisions, satisfaction is often independent of weighing

pros and cons and is often based on if the decision turns out well or not. Nonetheless, if efforts to utilize this measure only manage to improve patient knowledge, provide peace of mind during their decision, or instill confidence in their decision, this would be sufficient to justify the development and use of the ICD-DAS. However, there is hope that that this measure can be utilized to reduce distress and improve patient satisfaction in patients after treatment decisions are made. With patient acceptance an uncertainty, it is believed that education of patients will be improved regardless, as pro/con discussions are not universally the standard of care when ICDs are recommended.

Future Implications and Aims

The initial use of the ICD-DAS will be to help patients make more informed device decisions. The evidence provided by the current research indicates that there is potential benefit from the ICD-DAS prior to device choice as a tool to guide patient specific education. Patients will rate pro and con items by importance in their ICD-decision, and this will allow for more candid discussions with their providers. In addition, the ICD-DAS could also be utilized for targeted treatment and simple educational modules to be applied to individual items that patients can rate as relatively more important on the ICD-DAS. An example of these simple modules has been developed for decision-making regarding treatment for breast cancer and was found to be acceptable and not cause distress in patients (Sepucha, Ozanne, Partridge, & Moy, 2009). In this set of modules, patients are assessed regarding their knowledge about treatment options, their most salient goals and concerns, and their readiness to make a treatment decision. A subsequent phase of this project will be the development of treatment and education modules for prospective ICD recipients.

Another step will be to analyze patients who, for example, rate cons as high and pros as low, yet still have relatively high behavioral intent to choose the ICD. This may offer insight into the patient's decision making patterns and allow for a better understanding of motivational factors in making the ICD choice. Alternatively, it would be interesting to further explore patient presentations with, for example, low cons, high pros, and low behavioral intent to choose the ICD. By gaining a greater appreciation of how patients ultimately make their decision, we may be able have more informed conversations with patients. If patients eventually decide to proceed toward device implantation, this tool could be used to improve patient acceptance of the ICD by reducing instances of patients having unaddressed concerns pre-implant.

Finally, future research should compare device recipients who have normal education pre-implant versus those who receive tailored patient education based on this measure. Both groups would take the ICD-DAS pre-implant, but only a randomized subset of participants would receive tailored treatment and/or education. Future investigations should also involve test–retest comparisons.

Conclusion

Optimizing patient decisions regarding device technologies remains a critical consideration for informed consent. Decision-making for new and improved technologies will increasingly become more difficult given the chasm between patient understanding and the advance of technology. The current research suggests that assessing pros and cons of the ICD may predict their choice for the ICD. The ICD-DAS is an empirically based starting point for attempting to improve the ICD decision making process and warrants more research. Further exploration of the design and practical implementation of this scale will be addressed in future work. If intervention can address patient concerns and provide meaningful knowledge, the quality of patient decisions is likely to improve.

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APPENDIX A: IRB DOCUMENTATION

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board Office
1L-09 Brody Medical Sciences Building• 600 Moye Boulevard • Greenville, NC 27834
Office **252-744-2914** • Fax **252-744-2284** • **www.ecu.edu/irb**

TO: Samuel Sears, PhD, Department of Psychology, ECU, 104 Rawl Building

FROM: UMCIRB

DATE: January 10, 2011

RE: Expedited Continuing Review of a Research Study

TITLE: "Decisional Balance Among Potential ICD Recipients: Development of the Implantable Cardioverter Defibrillator Decision Analysis Scale (ICD-DAS)"

UMCIRB #09-0010

The above referenced research study was initially reviewed and approved by expedited review on 1/9/09. This research study has undergone a subsequent continuing review using expedited review on 1/7/11. This research study is eligible for expedited review because it is research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.). The Chairperson (or designee) deemed this **Medtronic** sponsored study **no more than minimal risk** requiring a continuing review in **12 months**. Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.

The above referenced research study has been given approval for the period of **1/7/11** to **1/6/12**. The approval includes the following items:

- Continuing Review Form (dated 12/28/10)
- Protocol summary
- Informed consent: Main (received 1/4/11)
- Informed consent: (received 1/7/11)
- Patient data form
- Defibrillator analysis scale
- Hospital anxiety and depression scale
- SF-12 health survey
- Multidimensional health locus of control scale
- Religious health fatalism questionnaire

The Chairperson (or designee) does not have a conflict of interest on this study.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

APPENDIX B: INITIAL ICD-DAS

Patient ID# _____ ICD Decision Analysis Project

The Implantable Cardioverter Defibrillator Decision Analysis Scale

A) PLEASE READ THIS:
The ICD is designed to provide a shock to prevent sudden cardiac arrest. Special medications may reduce the number of serious heart rhythm problems, but do not reduce the risk of sudden cardiac arrest.

- Some patients decide that receiving the ICD is their best option.
- Other patients decide to decline the ICD and do not receive therapy to prevent sudden cardiac arrest.

B) PLEASE READ THIS:

- Now you know a little about the ICD and the treatment options for those at risk for sudden cardiac death.
- We would like to know whether you agree with the following statements and how important the statements would be in influencing your choice for or against the ICD.

C) PLEASE READ THIS:
Below are some statements that describe what some people find important in their decision of whether or not to get the ICD.

- First, tell us if you agree with each statement below by marking either "Agree" or "Disagree".
- Then, tell us if the following statements are important for you in the decision to get or to not get the ICD. *Please rate how important the following statements are to you by checking the most appropriate box.*

	Do you agree with this statement?		How important is this statement in your decision to get or not get the ICD?				
	Agree	Disagree	Not Important at all	Slightly Important	Moderately Important	Very Important	Extremely Important
1. The ICD increases my chances of a longer life	☐	☐	☐	☐	☐	☐	☐
2. The ICD may give me strong shocks	☐	☐	☐	☐	☐	☐	☐
3. The ICD prevents death	☐	☐	☐	☐	☐	☐	☐

Patient ID# _____ ICD Decision Analysis Project

	Do you agree with this statement?		How important is this statement in your decision to get or not get the ICD?				
	Agree	Disagree	Not Important at all	Slightly Important	Moderately Important	Very Important	Extremely Important
4. The ICD gives me another chance at life	☐	☐	☐	☐	☐	☐	☐
5. There is a surgical risk and chance of infection if I get the ICD	☐	☐	☐	☐	☐	☐	☐
6. The ICD gives me confidence to be physically active	☐	☐	☐	☐	☐	☐	☐
7. It is against my beliefs to get the ICD	☐	☐	☐	☐	☐	☐	☐
8. The doctor seems confident that I should get the ICD	☐	☐	☐	☐	☐	☐	☐
9. The ICD is a well studied treatment option	☐	☐	☐	☐	☐	☐	☐
10. Some people who have the ICD have a good quality of life and mental health	☐	☐	☐	☐	☐	☐	☐

Patient ID# _____ ICD Decision Analysis Project

	Do you agree with this statement?		How important is this statement in your decision to get or not get the ICD?				
	Agree	Disagree	Not Important at all	Slightly Important	Moderately Important	Very Important	Extremely Important
11. The protection of the ICD allows me to continue relationships as long as possible	☐	☐	☐	☐	☐	☐	☐
12. I have faith that the ICD is my best option	☐	☐	☐	☐	☐	☐	☐
13. My spouse or family will be comforted if I get the ICD	☐	☐	☐	☐	☐	☐	☐
14. Some people with ICDs become unhappy after getting the device	☐	☐	☐	☐	☐	☐	☐
15. My spouse or family members may be worried if I am shocked by the ICD	☐	☐	☐	☐	☐	☐	☐
16. I prefer to have natural death without being shocked by the ICD	☐	☐	☐	☐	☐	☐	☐

Patient ID# _____ ICD Decision Analysis Project

	Do you agree with this statement?		How important is this statement in your decision to get or not get the ICD?				
	Agree	Disagree	Not Important at all	Slightly Important	Moderately Important	Very Important	Extremely Important
17. At some point, parts or all of the ICD may need to be replaced	☐	☐	☐	☐	☐	☐	☐
18. Some people with ICDs worry more after getting the device	☐	☐	☐	☐	☐	☐	☐
19. I fear the embarrassment of getting shocked around other people	☐	☐	☐	☐	☐	☐	☐
20. The doctor does not seem confident that I should get the ICD	☐	☐	☐	☐	☐	☐	☐
21. The ICD will provide the ability to engage in activities with other people	☐	☐	☐	☐	☐	☐	☐
22. Some people with ICDs have a lower quality of life after getting the device	☐	☐	☐	☐	☐	☐	☐

Patient ID# _____ ICD Decision Analysis Project

	Do you agree with this statement?		How important is this statement in your decision to get or not get the ICD?				
	Agree	Disagree	Not Important at all	Slightly Important	Moderately Important	Very Important	Extremely Important
23. I do not want other people to see my scar or ask me questions about my condition	☐	☐	☐	☐	☐	☐	☐
24. I will feel safer with an ICD	☐	☐	☐	☐	☐	☐	☐

D) If your doctor recommended an ICD, how likely would you be to get one?
(Place at check by your choice and choose only one.)

Definitely no	Probably no	Leaning to no	I don't know	Leaning to yes	Probably yes	Definitely yes
☐	☐	☐	☐	☐	☐	☐

If you have **not** answered *definitely yes* to the above question, please list your uncertainties below:

1.

2.

3.

4.

5.