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Quality of Life and Mental Health Outcomes in Implanted Cardioverter Defibrillator Treatment: Potential Effects of Informational Media History and Treatment Knowledge

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Abstract

Social workers in all care venues are increasingly responsible for clinical and case management services for people being treated with sophisticated medical interventions. Unfortunately, opportunities to aid in the promotion of quality of life (QOL), mental health, and informed consent are often not understood by social workers, other care providers, or patients. These missed opportunities may lead to attenuated effectiveness of medical interventions and negative impact on patients' QOL. One such technological treatment is the implantable cardioverter defibrillator (ICD), a lifesaving therapy which carries risk to patients' QOL. Moreover, patients frequently do not accurately understand the benefits, limitations, and possible risks associated with ICD therapy. A small body of literature exists addressing experimental and demographic groups at risk of QOL decrements among the ICD patient population, including those who have been shocked more than five times, older adults, female patients, and those who have experienced a life threatening cardiac event. A much more limited body of literature addresses the quality of some forms of patient educational activities and materials. No research to date has attempted to characterize potential relationships between patient information acquisition, treatment knowledge, and QOL/mental health outcomes in this patient group.

Using a cross-sectional survey of ICD patients being treated at the University of Colorado Hospital (UCH), this dissertation project uses a social-ecological approach to describe the media through which ICD patients learn about device therapy, how well they understand their treatment, QOL and mental health outcomes, and any relationships between these constructs. The project was conducted in iterative phases, including the creation of two new measures assessing patient informational media history and ICD treatment knowledge, a pilot survey of 100 randomly selected patients to assess the quality of the new measures, and a larger survey of the remaining 655 potential ICD patient participants.

A total of 205 ICD patients responded to the survey, with a mean age of 60.7 years (sd=14.53), 34.1% of whom identified as female, 10.2% of whom are African American, and 37.5% of whom live in a household with an annual income of less than $40,000. Findings from survey responses revealed both the viability of the new informational media history and ICD treatment knowledge measures, as well as broad use of a number of specific forms of media to learn about treatment. Older adult patients illustrated significantly lower treatment knowledge and use of fewer forms of informational media than their younger counterparts. Multiple regression analyses revealed significant relationships between patient history of having been shocked, health related depression, and QOL, but failed to replicate earlier findings linking these problems to demographic indicators. Each of these findings highlight opportunities for improved social work research and practice with ICD patients, including the need for improved patient education processes for older adults with these devices, and the importance of mental health status, particularly depression, to patient QOL.

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Quality of Life and Mental Health Outcomes in Implanted Cardioverter Defibrillator Treatment: Potential Effects of Informational Media History and Treatment Knowledge

Chapter 1: Introduction

Social workers in health care and medical settings must increasingly work with patients being treated with sophisticated and invasive medical therapies. Unfortunately, in many cases, the psychosocial challenges and advocacy opportunities relevant to invasive patient care are poorly understood and under-appreciated by many professionals. As a result, evidence-based measures and methods meant to alleviate patient suffering and prevent adverse outcomes have not been widely infused into social work education or applied to practice in healthcare. Advancements in the technical practice of medicine have outpaced developments in psychosocial medical practice, and this trend is not showing any signs of changing. In their 2001 “call to arms” titled *Crossing the Quality Chasm*, the Institute of Medicine (IOM), highlights the challenge thusly:

> *Medical science and technology have advanced at an unprecedented rate during the past half-century. In tandem has come growing complexity of health care, which today is characterized by more to know, more to do, more to manage, more to watch, and more people involved than ever before...if the system cannot consistently deliver today’s*

> *science and technology, it is even less prepared to respond to the extraordinary advances that surely will emerge during the coming decades.(p.1)*

While social workers as a professional group, including those working in academic and research settings, are known for their passion and commitment to the plight of those experiencing various forms of systematic disempowerment, the sense that medical patients experience a form of marginalization is often absent. A slightly different theoretical context holds that a form of marginalization is an unfortunate consequence of extended interaction with the healthcare system. Patients being treated with complex therapies are often overburdened by the requirements of these treatments. This burden reduces their opportunities to meaningfully participate in the decisions regarding their goals and desires and increases the risk of making decisions without fully comprehending the ramifications for themselves and their families. For older patients, others who are being treated with chronic illnesses and/or with complex therapies, those nearing the end of their lives, or any combination of these issues, any embodied experience of disempowerment within the healthcare system only serves to compound those occurring within society more generally. Having an ability to participate in one’s own care and medical decisions is diametrically opposed to marginalization theoretically. Therefore, facilitating an exchange of information with care providers on the patient’s own terms in service to helping patients understand their health and treatments, may be a promising approach to preventing further decrements to the dignity and well being of older adults and others who encounter extended interaction with the healthcare system.

Fortunately, there are several practical opportunities across the lifespan of medical care in which social workers and other professionals employed in varied health service venues can intervene with, advocate for, and otherwise assist their clients being treated with these types of advanced therapies (Knoepke & Johnson-Koenke, *in press*). Of particular importance are the unrealized opportunities in research and development addressing care processes beginning for use when patients are deciding whether to engage in therapy, while patients adjust to invasive, cumbersome, or simply confusing treatments, and continuing through the end of the patient's life. Each stage of medical intervention offers critical intervention points during which infusion of social work scholarship, accompanied by socially-informed theory, practices, values, ethics, and ecological conceptualization of human activity may positively affect both clinical and patient-centered outcomes (i.e. QOL).

One method of increasing a social work presence within the evidentiary basis of complex care processes is to apply an ecologically-focused conceptualization of the provision and acceptability of information and support provided to patients being treated with such therapies. While such models represent the dominant paradigm of training for clinical social workers, they have not been historically endorsed by physicians and other medical practitioners, who are trained in plurality and most rigorously in the biomedical model of care (Engel, 1980). The potential impact of more commonly including such impact conceptualization into clinical care for patients being treated for chronic, life-threatening conditions has not been broadly investigated.

In the current study, such a conceptualization is applied to care using the case of implantable cardioverter defibrillators (ICDs). ICDs are sophisticated cardiac rhythm devices that monitor recipients' hearts for dangerous rhythm disturbances and deliver therapeutic electric shocks to restore healthy rhythms. A detailed description of the use and functionality of ICDs is found in Chapter 2. Treatment outcomes associated with ICD therapy are attenuated, at least in part, by quality of life (QOL) problems experienced by a proportion of patients treated. This study aims to use knowledge gained by the study of ICDs to develop a model to improve the experience of patients being treated with similarly complex treatments. In these ways, such improvements meet primary goals of social work scholarship by improving the quality of life for people whose medical circumstances have historically limited their ability to participate in the decisions which impact their lives, and which may increase the acceptability of new and innovative treatments to members of historically marginalized groups, especially older adult patients.

Implantable Cardioverter Defibrillators: A Context for Empirical Inquiry into Social Work Interventions in Health Care

In claiming more than 300,000 victims each year, sudden cardiac death (SCD) is the leading cause of death in the United States (Heron & Tejada-Vera, 2009; Kong, Fonarow, Peterson, Curtis, Hernandez, Sanders... & Al-Khatib, 2011) a problem which has created a need for ever-evolving and improving technologies geared toward initial prevention and prophylaxis against further episodes. One of the most common of these SCD-reduction interventions is the implanted ICD. ICDs have enjoyed a great deal of clinical and academic support for use in treatment of cardiac pacing problems, as an adjunctive therapy for some forms of coronary artery disease (which may damage the electrical circuitry of the heart muscle), and overall reduction of risk of SCD. ICDs have demonstrated a consistent ability to increase survival rates among victims of ventricular arrhythmias (AVID Investigators, 1997; Greenberg, Case, Moss, Brown, Carroll, & Andrews, 2004) and congestive heart failure (Bardy, Lee, Mark, Poole, Packer, Boineau, … & Ip, 2005). This evidence has made the ICD a popular first-line treatment option for patients at risk of cardiac arrest, and is now implanted in more than 160,000 new patients in the United States annually (Hauser & Almquist, 2008). As many as 500,000 Medicare beneficiaries may meet contemporary indications for ICD treatment, and more than 50,000 are implanted in patients over the age of 65 annually in the United States (Kremers, Hammill, Berul, Koutras, Curtis, Wang … & Rumsfeld, 2013). While these data may seem impressive, more recent large scale analyses indicate that ICD's are grossly underutilized among Medicare patients who have had a myocardial infarction (Pokoney, Miller, Chen, Thomas, Fonarow, de Lemos,… & Wang, 2015), leading to the possibility that use among this patient group could increase massively in the near future. The penetration of this therapy into medical practice and the scope of the population potentially affected by any issues iatrogenic to ICD treatment further highlight the need for evidence-based social work practice with these patients and their families.

Concurrent to these possible survival and other medical benefits, there is emerging recognition of psychosocial issues associated with this form of therapy. While descriptions of quality of life decrements have been proffered by a number of prominent sources (Irvine, Dorian, Baker, O'Brien, Roberts, Gent, ... & CIDS Investigators. 2002; Sears, Todaro, Lewis, Sotile, & Conti, 1999), prevalence of these problems has proven difficult to define. Within the myriad descriptions of the types of challenges faced by ICD patients exist a wide variety of clinical concerns, ranging from health-related anxiety and depression to increased disease severity and mortality secondary to an inability to effectively manage their illness (Carney & Freedland, 2003; Dougherty, Benoliel, & Bellin, 2000). Patients being treated with these devices are at increased risk of hospitalization (Goldenberg, Moss, Hall, McNitt, Zareba, Andrews, & Cannom, 2006) and often experience high levels of pain near the end of their life (Goldstein, Lampert, Bradley, Lynn, Krumholz, 2004); both of these factors represent threats to QOL and human dignity. Historically, marginalized groups appear to be at an even greater risk of developing iatrogenic psychosocial problems in the course of defibrillator treatment, including patients in the US not from a European background and patients with prior history of mental illness. In these ways, and in a dynamic similar to that observed in other medical therapies, these embodied experiences of disempowerment within the healthcare system often serves to compound those occurring within society more generally.

Perhaps indicating a general ineffectiveness of current patient educational processes is evidence that many patients do not understand many basic questions of fact related to their device. Recent findings suggest that patients generally do not understand the clinical limitations of ICD treatment, including being unaware of alternative or adjunctive treatment options (Stewart, Weintraub, Pratibhu, Semigran, Camuso, Brooks, ... & Stevenson, 2010), and not understanding that their doctors can deactivate their device should the patient ask them to do so (Goldstein, Mehta, Siddiqui, Teitelbaum, Zeidman, Singson, … Morrison, 2008; Lewis, Stacey, & Matlock, 2014). The implications of the last point of knowledge is critical to advanced care planning, as an informed patient may elect to deactivate their device at a number of points in an effort to preserve a less chaotic death (Matlock & Stevenson, 2012). Patients who are unaware of the option of deactivation may inaccurately believe that it is necessary to surgically remove the ICD in order to do so, and would weigh their perception of risk associated with surgery against any gains their advanced care plans would provide.

This lack of understanding on the part of patients about their treatment and prevalence of QOL disruptions points to a systematic inefficacy of the relatively haphazard approach taken toward educating patients about their treatment, at least with respect to those treated with these devices. This gap may be due, at least in part, to physician-centric standard care processes, which carry the unacknowledged assumption that agency lies only with healthcare providers in the provision and procurement of clinical information (Knoepke & Lutfey, in review). To date, no investigations have attempted to examine impact on patient education at the level of media actually used by any group of patients. Moreover, possible relationships between level of patient information or understanding about treatment and their quality of life or mental health (or other patient-centric outcomes) in this medical population have not been described or reported.

Theoretical Conceptualizations of QOL Among ICD Patients

Components of a social-ecological conceptualization of ICD patient informational needs have been described in limited ways. The recognition that patients' needs and preferences will differ is both directly and tacitly acknowledged. Directly, the evidence supporting the efficacy of varied specific psychotherapeutic interventions (Sears, Sowell, Kuhl, Kovacs, Serber, Handberg ... & Conti, 2007; Frizelle, Lewin, Kaye, Hargreaves, Hasney, Beaumont, & Moniz-Cook, 2004; Kuhl, Sears, Vazquez, & Conti, 2009) illustrates a salutary effect of customized support on mental health and quality of life outcomes as well as acceptance of device treatment. In fact, a recent review of psychotherapies for patients with ICDs indicates that future interventions must better meet the idiosyncratic needs of patients (Habibović, Burg, & Pedersen, 2013). Such evidence points to the need to improve current understanding of how patients learn in order to include this knowledge in the design of future interventions. Existing materials and care processes which attempt to fill this need include conversations with care providers, device manufacturer or industry organization-developed brochures (Hazelton, Al-Khatib, Fonarow, Thomas, Hayes, Sanders, et al., 2013), newsletters, support groups meeting both in person and online (Dickerson, 2005), internet message boards (Knoepke, 2012), and manualized psychosocial therapies for patients experiencing problems.

Study Purpose

The current study seeks to expand on prior efforts at describing patient informational media use, treatment-specific knowledge, and QOL and mental health outcomes by prospectively assessing these constructs along social-ecological lines with a sample of ICD patients being treated at the University of Colorado Hospital. The study aims to: 1) identify the informational media used by patients to learn about their ICD treatment, 2) assess the relationship between informational media used by patients and their levels of ICD treatment-specific knowledge, and 3) examine the relationship between patients' ICD treatment-specific knowledge and their quality of life and mental health outcomes. These aims are meant to provide foundational findings related to patient activity within the social context, relationship of knowledge to generalized well-being, and assessment of treatment knowledge in this patient group. As such, findings from the study are intended to provide additional theoretical support and context for additional prospective investigations into means of improving QOL among patients being treated with varied sophisticated and potentially cumbersome interventions, including both medical and contextual care processes.

Chapter Summary

This chapter discussed in broad strokes the importance of social work services in health care and medical settings, especially in instances where patients are being treated with emerging, highly complex, and often burdensome treatments. These patients are often older adults, being treated for chronic conditions, are nearing the end of their lives, or any combination of those three. The ICD presents social work and affiliated professionals with a useful model by which to attempt to understand the role that treatment-specific knowledge plays in QOL. A review of the theoretical and empirical literature relevant to the study is presented in the following chapter.

Chapter 2: Literature Review

The preceding chapter noted the evolving nature of highly sophisticated and burdensome medical therapies, and the resulting need for social work research aimed at investigating psychosocial care strategies for individual patients and their families. The implantable cardioverter defibrillator (ICD), and its application to patient care and social work services, is discussed in the current chapter. Literature directly relevant to the current study, particularly studies addressing informational media and treatment knowledge among this patient group, and theoretical conceptualizations regarding QOL problems and existing means meant to alleviate such issues will be examined. Gaps in the current literature will be identified, especially where they align with the specific aims of the study.

ICD Background, Clinical Uses, & Popularity

Despite the extensive attention paid to the QOL, health status, or care process problems in this report, the implanted defibrillator remains something of a marvel of modern medical technology. Current models of the device represent a dramatic evolution from those originally developed by a team led by cardiologist Michael Mirowski during the late 1960’s and early 1970’s (Deyell, Tung, & Ignaszewski, 2010). These devices are implanted under the skin, typically below the patient’s collarbone. Electronic “leads” run between the device and the lower chambers of the patient's heart (National Heart, Lung, & Blood Institute: NHLBI, 2011). Once installed, an ICD monitors the individual's heart for disturbances in the heartbeat's rhythm that may occur secondary to problems in the transmission of the electrical impulses throughout the organ. These problems may be the result of congenital abnormalities, damage to the heart caused by disease, surgery, trauma, or other reasons. Common overarching types of problems addressed by these devices (including devices with additional functionality) include bradycardia, tachycardia, and fibrillation/arrhythmia.

When the ICD senses a potentially dangerous problem in the heart, it can transmit pulses of electricity in an effort to restore a healthy rhythm. It delivers this shock much like one thinks of a pacemaker doing, but with a different form or pulse. Depending on the type of pulses that are necessary, these may cause considerable pain for the patient, while the impulses sent by a pacemaker do not (NHLBI, 2011). It bears noting that the current generation of implanted defibrillators are capable of delivering both types of shocks. However, for the purposes of this paper, the term "shocks" will generally refer to those delivered to terminate arrhythmia, rather than the typically imperceptible pacing shocks delivered by pacemakers. As part of ongoing treatment, devices are interrogated to determine patient history of arrhythmia and/or shocks and provide medical professionals with a considerable amount of clinical data that may be used to alter treatment regimens. Using the same transdermal technology, ICDs can be reprogrammed or deactivated by medical professionals on a computer without surgery, providing a virtually limitless ability to alter the type of treatment delivered by the device without any of the characteristic risks of surgery.

The clinical popularity of these devices is highly relevant to both patients themselves and to the healthcare system more generally. For patients, consistent evidence identifying ICDs as the critically lifesaving component in treatment for ventricular arrhythmia (John, Tedrow, Koplan, Albert, Epstein, Sweeney, ... & Stevenson, 2012), must be weighed against risks to QOL and other associated idiosyncratic concerns. With respect to the healthcare system, the estimated $2 billion spent annually on ICD implantation procedures and care by Medicare alone (Kramer, Matlock, Buxton, Goldstein, Goodwin, Green, … & Mitchell, 2015), highlight the potential for direct costs attributable to ineffective patient management practices. Such costs are critical because they often limit the availability of services in other care sectors without providing expected levels of health improvements (Bodenheimer & Grumbach, 2012), potentially impacting clients' access to other necessary health services. With the understanding that ICD utilization is far from uniform across US communities (Matlock, Kutner, Emsermann, Al-Khatib, Sanders, Dickinson., ... & Masoudi, 2011), epidemiologists have proposed using ICD penetration as a community health quality indicator (Bonow, Ganiats, Beam, Blake, Casey, Goodlin, ... & Wong, 2012). Given the rising popularity of these devices, particularly among older adult patients (Pokoney, Miller, Chen, Thomas, Fonarow, de Lemos,… & Wang, 2015), the fact that they are being used to treat clients served in social work venues is clear. The continuing expansion of indications will mean that more people overall, including clients of social workers employed in any service venue, will be treated with these (and similar) devices.

QOL Issues Among Implanted Defibrillator Patients: Risks & Current Perspectives

Much of the medical literature addressing the survival benefit associated with ICD treatment remains impressive, leading many patients to choose device therapy despite psychosocial risks. Existing psychological literature addressing psychosocial problems is both robust and theoretically reductive. Social work scholars, to this point, have not been engaged in scholarly efforts to define and/or mitigate these issues. However, empirical and descriptive studies have been conducted by scholars representing the fields of medicine, psychology, nursing, and law. The quality of the psychosocial scholarship and resulting care processes in invasive therapies such as this would benefit from the inclusion of social workers.

Even among seminal clinical trials assessing utility of ICDs in various clinical populations, there exists considerable disagreement about QOL among this patient group. For example, three seminal trials, the Antiarrhythmics Versus Implantable Defibrillators (AVID: Schron, Exner, Yao, Jenkins, Steinberg, Cook, … & Powell, 2002,), the Sudden Cardiac Death in Heart Failure (SCD-HeFT: Mark, Anstrom, Sun, Clapp-Channing, Tsiatis, Davidson-Ray, … & Bardy, 2008), and the Multicenter Automatic Defibrillator Implantation Trial (MADIT-II: Noyes, Corona, Zwanziger, Hall, Zhao, … & Dick, 2007), illustrated similar QOL between patients being treated with ICDs and those being treated primarily with medication, while the Coronary Artery Bypass Graft (CABG-Patch: Namerow, Firth, Heywood, Windle, & Parides, 1999) and Canadian Implantable

Defibrillator Study (CIDS: Irvine, Dorian, Baker, O'Brien, Roberts, Gent, … & Connolly, 2002) showed worse and better QOL outcomes among ICD patients respectively. This uncertainty about the impact ICD treatment may have on QOL may be attributable to changes in the technology of devices themselves, methods by which QOL was assessed, and differences in study populations, but may also indicate an incomplete conceptualization of the etiological forces influencing patients' experience (Dunbar, Dougherty, Sears, Carroll, Goldstein, Mark, ... & Zeigler, 2012). Nevertheless, a number of demographic and experiential risk factors for poorer QOL outcomes have been identified among ICD patients.

Demographic risk groups. While the state of compromise and marginalization experienced by many types of medical patients is itself an area of social work concern, how particular problems associated with the care process affect individuals from historically vulnerable groups bears particular understanding. Social work scholars and practitioners are particularly well versed in the presence and mechanics of oppression and marginalization. They also carry the ethical mandate to infuse these understandings into systems that illustrate evidence of systematic effects on people belonging to marginalized groups. It should be noted that the majority of existing research on differential quality of care or life in ICD treatment has addressed differences between Caucasian and African Americans and between men and women. A greater focus on other historically-oppressed groups, including LGBT individuals, Latinos, older adult patients (Kramer, Matlock, Buxton, Goldstein, Goodwin, Green, … & Mitchell, 2015), and people insured through public insurance programs would greatly improve the breadth of understanding of these problems. The dearth of research in these areas represents a considerable conceptual gap in existing literature for this and other technological medical care processes.

While the healthcare access barriers which contribute to total lack of care (Institute of Medicine, 2004), and to reception of high quality care (Franks, Clancy, & Gold, 1993), which harms medical and social outcomes among members of historically-marginalized groups are of great concern and are well-documented, there exist peculiarities and systematic problems specific to ICDs. These peculiarities come in the form of a seeming effect of group membership on both the likelihood of being offered ICD therapy and patient QOL once treatment has begun. Within the supposition that being appropriately offered ICDs as a treatment option is a useful proxy for the quality of care being provided, there exists disappointing evidence regarding the quality of care received by historically-marginalized groups. Recent research has shown that doctors are less likely to suggest ICDs for African American patients as they are for Caucasians, even when controlling for income and access to healthcare (Voigt, Ezzeddine, Barrington, Obiaha-Ngwu, Ganz, London, & Saba, 2004). Large sample analyses of Medicare data also indicate that women are 65% less likely than men and African Americans are 31% less likely than Caucasian patients to be offered device treatment (Gauri, Davis, Hong, Burke, & Knight, 2006).

This discrepancy may be due, at least in part, to the professional background of the physician making the recommendation either for or against treatment. In one representative sample of cardiologists and electrophysiologists, neither race nor gender of hypothetical patients related to the likelihood of recommending device therapy, although electrophysiologists were more likely to pursue aggressive treatment (Al-Khatib, Sanders, O'Brien, Matlock, Zimmer, Masoudi, & Peterson, 2011). A separate survey of primary care providers revealed a significant difference in the physicians' perception of the survival benefit associated with ICD treatment among African Americans and women (Sherazi, Zareba, Daubert, McNitt, Shah, Aktas, & Block, 2010). In the same survey, physicians identified perceived ability to pay as a factor affecting their recommendations for treatment, leaving the quality of care offered to women and African Americans in large measure subject to possible latent racist and misogynist stereotypes on the part of providers. These indicators of practice variation are not uncommon across sophisticated medical therapies in which numerous care providers are typically involved, but the seeming interaction of race, age, gender, geographic location, and perceived ability to pay are socially problematic.

Interestingly, this dynamic of possible "under-treatment" of patients coming from historically-disadvantaged backgrounds appears to be the inverse of that observed in end-of life (EOL) cancer care, where African Americans often receive much more aggressive treatment than their white counterparts, putting them at increased risk of distress near death (Trice-Loggers, Maciejewski, Paulk, DeSanto-Medeya, Nilsson, Viswanath, … Prigerson, 2009). Both scenarios are problematic for patients belonging to these groups because, despite risks associated with treatment, care providers must remember that defibrillator treatment (or at least having the option of being treated) is considered a hallmark of high quality care for all patients meeting clinical indications. Incongruence between indication for ICD treatment and actualizing an opportunity to be treated with a device could thus be framed as members of disadvantaged groups receiving poorer care, and avoiding incongruence in care requires a delicate balance between clinical recommendations and consideration of patient QOL.

Incongruence in care also exists at the community level. As mentioned earlier, some investigators have advocated for using ICD penetration as a community healthcare quality indicator (Bonow, Ganiats, Beam, Blake, Casey, Goodlin, ... & Wong, 2012). If this were so, it might further illuminate discrepancy in care received by those living in the most racially diverse regions in the United States. National Medicare data point to as much as a 4.5 factor increase in likelihood of ICD reception between the areas of lowest and highest penetration (Matlock, Kutner, Emsermann, Al-Khatib, Sanders, Dickinson, … & Masoudi, 2011), with below-average areas concentrated most heavily in the diverse Mid-Atlantic and West Coast regions, as well as the socioeconomically depressed rural areas of the Mountain States. These discrepancies found among Medicare patients, (who by definition all have access to health insurance), are likely amplified among groups who have been disproportionately represented historically among the uninsured and underinsured, including members of racial and ethnic minority groups, LGBT individuals and couples, and part-time employees (Bodenheimer & Grumbach, 2012, pp. 24-28).

Extant literature has also outlined the characteristics believed to be related to increased risk of poor psychosocial adjustment after ICD implementation. Findings from this literature disagree about the impact of age on risk of QOL problems, however. One analysis of health-related QOL found that patients over the age of 65 experience somewhat higher anxiety, greater levels of dissatisfaction with their functional abilities than younger ICD patients, and that these issues seem to ameliorate at a greater rate among younger patients as well (Hamilton & Carroll, 2003). Separate findings, however, indicate that patients under the age of 50 experience increased incidence and severity of QOL decrements (Bilge, Ozben, Demircan, Cinar, Yilmaz, & Adalet, 2006). Indeed, depression, anxiety, and decreased daily activity are reportedly elevated among younger recipients (Conti & Sears, 2001), despite the fact that younger ICD patients have long reported little to no activity or lifestyle restriction years after implantation surgery, including vocational activities, exercise, and pregnancy (Dubin, Batsford, Lewis, & Rosenfeld, 1996).

On the other hand, older patients' risk for these QOL issues are heightened by their increased susceptibility to serious complications (Reynolds, Cohen, Kugelmass, Brown, Becker, Culler, & Simon, 2006) which could condition a negative affective response to the device (note that the theoretical limitations of this behavioral conceptualization of the genesis of psychosocial adjustment issues are outlined later in this chapter). A distinct possibility for this confusion is a seeming moderating effect of ICD indication: patients for whom the device was indicated for "primary prevention" tend to be older on average than patients whose device was implanted secondary to a cardiac event, and QOL and health status outcomes among primary prevention patients tend to be more favorable (Pedersen, Hoogwegt, Jordaens, & Theuns, 2013). It may be necessary to address this confusion with improved assessment instruments, components, and coverage, which could theoretically assess for differences in mental health outcomes and possible attributability of perceived physical ability to these constructs.

In addition to age, differences in psychosocial adjustment and mental health outcomes have been observed among marginalized groups. This includes people belonging to racial minority groups, women, and individuals with pre-existing mental illness. White patients treated with an ICD in a recent sample indicated higher scores on an instrument measuring acceptance of treatment than did their African-American counterparts (Wilson, Engelke, Sears, Swanson, & Neil, 2012). A recent survey of Japanese patients illustrated a greater likelihood to report depression and severe pain, as well as greater difficulty in adapting to changes in physical functioning among females when compared to male patients (Rahmawati, Chishaki, Sawatari, Tsuchihashi-Makaya, Ohtsuka, Nakai, ... & Chishaki, 2013). In a sample of over 3000 Swedish patients, scores for anxiety, depression, and overall health related QOL were all poorer among women (Thylén, Dekker, Jaarsma, Strömberg, & Moser, 2014).

Individuals with pre-existing mental illness, particularly depression, are also at dramatically increased risk of experiencing clinically-significant psychosocial decrements following treatment (Sears, Lewis, Kuhl, & Conti, 2005), which may explain more controversial findings which related the presence of “Type D” Personality characteristics among ICD patients and the risk of developing a diagnosable anxiety condition (Van den Broek, Nyklicek, Van der Voort, Alings, & Denollet, 2008). This personality structure is characterized by the prominence of negative affectivity, which these authors theorized contributes to increased hypervigilance and somatic sensitivity, but may also be indicative of a pre-existing mood disorder. While risks associated with these demographic groups have not been shown to be particularly malleable, they provide critical social context to the experiential risks which would be the target of micro-level social work and medical interventions.

Experiential risk groups. While the pathogenesis and effect of anxiety, depression, and other QOL decrements among ICD patients is not well established in the extant literature, a number of theoretical constructs attempting to explain anxiety in ICD patients include generalized health related worry, anticipatory hypervigilance, trauma symptoms secondary to cardiac events and the resulting perioperative exposure to the healthcare system, and conditioning artifact to experience of prior shocks (Conti & Sears, 2001). A recent expert consensus addressing mental health-related QOL reported that patients are only at significant risk of decrements to QOL if they experience five or more shocks or are subjected to device recalls (Dunbar, Dougherty, Sears, Carroll, Goldstein, Mark, ... & Zeigler, 2012), particularly patients who have had an ICD "storm", meaning several shocks in rapid succession (Kovacs, Feigofsky, Goff, Saidi, Curtis, Conti, et Al., 2006).

These findings support a cognitive-behavioral theory of the development of QOL problems among these patients, in that they are primarily conditioned responses to traumatic events (Ford, Sears, Shea & Cahill, 2013). This development is predictably characterized by a parallel process in which patients who have been shocked become fearful of subsequent shocks, constructing a constellation of distorted cognitions and beliefs related to the individual's health, particularly "catastrophic interpretations of bodily signs" (Pauli, Wiedemann, Dengler, Blaumann-Benninghoff, & Kuhlkamp, 1999, p. 75), and avoidance of activities believed to increase risk of being shocked (use of electronics, physical exertion, sexual intercourse etc.) (Kovacs, Feigofsky, Goff, Saidi, Curtis, Conti, et Al., 2006).

Another area of inquiry that has gained prominence in the QOL literature is the psychosocial adjustment to treatment of romantic partners. The adjustment experiences of partners are often as difficult as that of the individual who has the device. In one study, partners of ICD recipients reported significantly greater shock and death anxiety than did the patients themselves, irrespective of the partner's gender expression (Sowell, Sears, Walker, Kuhl, & Conti, 2007). Another construct that may be related to relationship adjustment problems and distress is sexual health and functioning. Vasquez and colleagues recognized that lack of physical intimacy and communication between partners was a common problem. They attribute these problems, at least partially, to development of anxiety and avoidant behaviors around sexual intercourse (Vasquez, Sears, Shea, & Vasquez, 2010). These fears include both fear on the patient's part related to exertion and subsequent risk of triggering the ICD and fear of shocking their partner during intercourse, both fears which, it should be noted, are factually unfounded. These findings demonstrate the stress experienced by the social systems in which patients with ICDs live, and the relative influence of informational/educational constructs on the level of patient/family stress, both of which are issues which should be of particular interest to social work scholars and practitioners.

Within this developing theoretical construct, it would not be difficult to imagine circumstances in which patients who have a device experience some form of iatrogenic detriment to their QOL, but believe that there are no other forms of treatment available to them and that their device cannot simply be switched off. In this case, patients are likely to inaccurately assume that the only options they have are to either have their device surgically removed (placing themselves at greater clinical risk) or continue to suffer. This theoretical dynamic may partially account for the mixed relationship between device acceptance and subjectively assessed knowledge of treatment observed in previous attempts at passive intervention design (Kuhl, Sears, Vazquez, & Conti, 2009). Hopelessness, anxiety, and other self-imposed restrictions on daily activities would logically follow in the wake of low levels of treatment-specific information on the part of patients. It may therefore be possible that mental health and other QOL decrements thought to have their provenance in conditioned responses to adverse events are partially attributable to lack of treatment-specific knowledge among patients, although this possibility has not yet been directly examined.

Indeed, existing conceptualizations of how best to help patients who are suffering from these QOL decrements consistently highlight the importance of patient understanding of treatment (see Habibović, Burg, & Pedersen, 2013 for a review), there is no literature to date to empirically connect patient knowledge of therapy with QOL, health status, or other patient-centric outcomes. The theories informing the majority of these investigations also operate with the tacit assumption that the primary media through which patients acquire medical information is from their healthcare providers. Further investigations into improving QOL among this patient population would benefit politically if a relationship between patient knowledge and QOL was observed and may rationalize treating patient knowledge as its own investigatory endpoint.

Assessing Mental Health & QOL Concerns Specific to ICD Treatment

Recognition, assessment, and description of structural problems related to ICD patients' QOL is not straightforward. The general lack of understanding of the dynamics and mechanisms underlying QOL problems in these patients has contributed to the paucity of generally accepted assessment standards, tools, and supported practices.

Present psychosocial evaluation methods have been designed solely with practitioner productivity in mind, thus placing a premium on the time necessary to implement and to the ease of analyzing results. Qualitative, narrative, or other methods have not been empirically examined in the extant literature, even though one could easily argue that most of what currently constitutes psychosocial assessment with any patient is done in an unstructured, non-manualized, and highly interpretive fashion. For example, many doctors certainly ask their patients "how (they) are doing", or more specifically, whether they have any concerns about the surgery or device. Investigating the value of these interactions, including their impact on patient and their families and the types of information made available to care providers during these informal encounters would more richly contribute to the literature addressing patient education and psychosocial support on QOL outcomes across diseases. Understanding how interactions that are unceremoniously lumped into "bedside manner" affect patient outcomes could guide training of new care providers and the development of improved educational materials and supportive processes.

These broad limitations notwithstanding, the current state of practice with respect to assessment of QOL problems among ICD patients in mired heavily in psychologicallyreductive self-report assessments such as the *Hospital Anxiety and Depression Scale* (HADS: Bjelland, Dahl, Haug, & Neckelmann, 2002) and QOL measures developed for general medical populations (e.g. the *Short-Form Health Survey* - SF-36: Ware & Sherbourne, 1992) or cardiac care patients (such as the *Kansas City Cardiomyopathy Questionnaire* or KCCQ-12: Green, Porter, Bresnahan, & Spertus, 2000). The most recent care process recommendations (Lampert, 2013; Dunbar, Dougherty, Sears, Carroll, Goldstein, Mark ... & Zeigler, 2012) also include the use of the *Patient Health Questionnaire* (PHQ: Kroenke, Spitzer, & Williams, 2003) as a component of initial and ongoing assessment of general psychosocial wellbeing. The PHQ is favored for ongoing use in both specialty and primary healthcare practice in part owing to its ease of administration as it features a built-in two-question short from screening measure (the PHQ-2), but is distinctly disadvantaged by having no demonstrated ability to discriminate between primary and secondary depression symptoms (which is the primary design feature of the HADS).

The *Florida Patient Acceptance Scale* (FPAS: Burns, Serber, Keim, & Sears, 2004), and the *Self-Efficacy Expectations and Outcome Expectations* (SE-ICD and OE-ICD: Dougherty, Johnston, & Thompson, 2007), reviewed below, are both designed to specifically capture and qualify the experience of patients being treated with this device. For these reasons, these measures were selected for inclusion in the survey battery for this project (further described in the following chapter). The process through which each of these measures were created, however, are enlightening with respect to challenges associated with assessment of patient treatment knowledge, as well as theoretical limitations which this project seeks to address.

Investigators have noted that the FPAS, the only measure designed specifically to assess psychosocial problems in this patient group, has several different practical strengths and theoretical limitations (Burns, Serber, Keim, & Sears, 2004). The construct targeted for assessment, "device acceptance", logically represents a complex and idiosyncratic phenomenon which the research team eventually defined both according to patients' "derivation of benefit" in a variety of medical and psychosocial domains and "understanding of the advantages and disadvantages" of the device itself (p. 386). The assessment of the second of this two-pronged definition of device acceptance presents several methodological and epistemological considerations. While understanding the device itself is a seemingly appropriate component of acceptance of any treatment, (and corresponds to the apparent treatment goals associated with many manualized psychosocial interventions for ICD patients), "understanding" or treatment knowledge could imply subjective understanding, objective knowledge, or both, and could hypothetically be assessed accordingly. In the FPAS, "understanding" was only measured from the subjective viewpoint of the patient, (i.e. two of the items in the final version of the FPAS were "I know enough about my device" and "I am knowledgeable about how the device works and what it does for me"). While it may seem logical to assume that subjective understanding may correspond to patient confidence and/or self-efficacy related to treatment, this argument becomes psychometrically moot as the above items were not included in any subscales or the total FPAS score. The article did not specify whether these items had been tested and removed during the factor or item analyses, but it was stated that they were included because they "hold clinical and research utility for device patients" (p. 387).

Absent these items, "device acceptance", as actually assessed by the FPAS, only consists of the first prong of the definition (e.g. derivation of medical and psychosocial benefit). Thus, in order to fully assess the second prong of Burns and his colleagues' definition of "device acceptance", (an "understanding of the advantages and disadvantages" of ICD treatment), it would be necessary to derive a formal, objective measure of patient knowledge specific to treatment (which other literature consistently alludes to as low and thus potentially problematic), as well as a robust assessment of whether the abject strengths of device treatment are congruent with patient goals and values.

The *Self-Efficacy Expectations and Outcome Expectations* (Dougherty, Johnston, & Thompson, 2007), while still reducing patient ability to manage ICD treatment to internal psychological factors, does acknowledge the importance and malleability of social-cognitive constructs. Self-efficacy and outcome expectations, which the authors acknowledge extends from Albert Bandura's theoretical work, do appear to relate to QOL among ICD patients (Sears, Serber, Lewis, Walker, Conners, Lee, … Conti, 2004). While the validation and reliability testing of the SE-ICD and OE-ICD was conducted in a manner similar to the FPAS, and illustrated clinical utility in assessing for patient belief in themselves as capable of overcoming the challenges associated with treatment over time, it specifically avoided the issue of the developmental trajectory of these phenomena, including timing (at the time of diagnosis, pre/post implantation, after some period of time living with the device, etc.). An expansion of these scales' utility into earlier stages of treatment may only require further validation testing, and an expansion of the scales themselves to assess informational and supportive needs of patients and their families could prove beneficial. As a conceptual parallel, the supportive and informational needs of cancer patients and families change over time (Wen & Gustafson, 2004) and are related to clinical and QOL outcomes (Rutten, Arora, Bakos, Aziz, & Rowland, 2005). Recognizing the social dynamics of these changes allows for greater specificity in patient education and psychosocial support.

Use of Informational Media Among ICD Patients

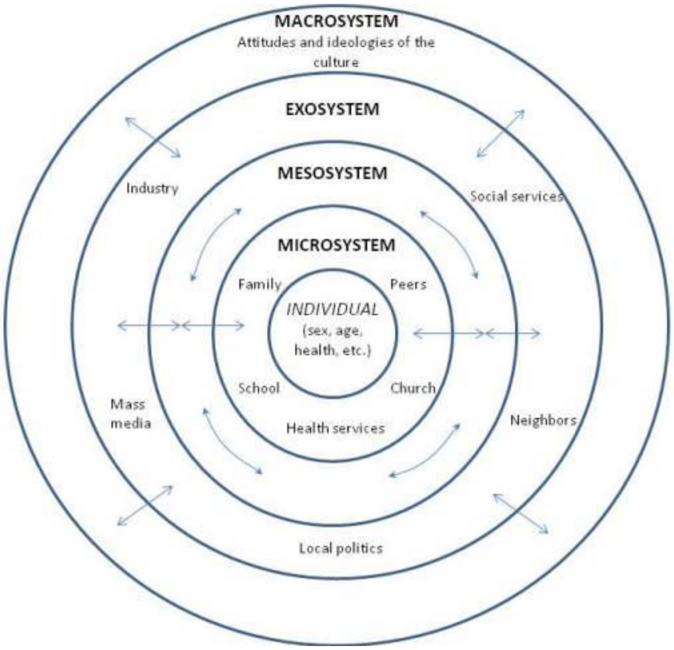
Perhaps the greatest theoretical distance between the experiential realities of being treated with ICDs or other complex devices and the measures intended to ensure the best prognoses can be seen in the difference between how information is provided to patients and the media through which they actually access it. While a number of different types of media are made available to patients as formal components of their care process (e.g., direct conversations with the surgeon, nurses and other care providers, written brochures which are published by device manufacturers and some large health care systems, and psychoeducational information provided as a component of post-hoc therapeutic interventions for patients identified as experiencing distress), any assessment of the informational efficacy of these care processes is limited by their failure to acknowledge the agency of patients to access information via social and technologically-mediated channels.

When these physician-centric processes are inaccessible or unacceptable to patients, they may attempt to acquire this knowledge, including what they should expect out of treatment, what to do in case of a problem, and what an aftercare plan should entail, through other means. In an ideal case, a patient being treated would simply contact either their care provider or another expert to get individualized advice and counsel (which would be provided either without reimbursement or at the individual expense of the patient). The actualization of such an experience relies heavily on highly variable patient constructs and abilities, including healthcare literacy, access to (and ability to understand) scientific information, social capital, and financial means. More commonly, patients without these resources will logically either continue with treatment without information, or reach out to sources of knowledge that are of dubious quality (e.g., the experiences of friends or relatives who have no particular expertise in ICD care, Internet message boards, etc.) (Dickerson, Flaig, & Kennedy, 2000; Knoepke, 2012). Each of these courses leaves these patients susceptible to remaining in a state of low treatment-specific knowledge. The development of a sophisticated understanding of how information from these media interact in patients’ social systems is necessary to design educational interventions which are maximally effective.

Shown in Figure 2.1, Bronfenbrenner & Morris’ ecological systems theory (1998) below provides a structure to understand where advice and information is socially located, and how use of varied informational media may impact the experience of being a device patient. Bronfenbrenner held that human beings develop continually, both physiologically and psychosocially, within an environment of resources situated within concentric social levels. Within this model, conversations with healthcare and behavioral health providers, active or passive use of the internet, reading of product brochures, and interactions with non healthcare professionals all interact, potentially relating to patient understanding of treatment, mental health, and QOL. Each informational source lies within corresponding ecological levels, with patients situated at the center of the model, family and close friends immediately outside, cultural and societal influences on the far outside, and online venues and professional care providers situated intermediately (with their distance from the center again theoretically tied to personal preferences). Resources may situate themselves either more distally or proximally in the lives of individual patients, owing to idiosyncratic preferences for information and support. For example, someone who has a strong alliance with their physician may locate healthcare providers closer to the center of the model. Conversely, an individual who has little or no relationship with their care provider may be more likely to seek information through an online source.

Patients are likely to interact with information at all of these levels over the course of treatment, yet previous efforts to try to improve the types and amount of information patients receive have not attempted to incorporate the social nature of patient information acquisition. To date, the value of such media has only been investigated indirectly. Serber and colleagues (2009) described group-based preferences for information and support media among ICD patients, including effects for race, ethnicity, and age, including the finding that internet as a medium of information and support is actually favored among young and male ICD patients, while in-person discussions with healthcare providers, support groups, or behavioral health professionals are favored by older and female patients.

Figure 2.1
Bronfenbrenner & Morris' Ecological Systems Theory (1998)



While all available forms of informational media should logically fit within a heuristic and inclusive ecology of information for patients, they each carry their own strengths and limitations, as highlighted in some cases by recent reviews. Logically, the standard of care with respect to education for patients is comprised of pre- and postoperative interaction with their doctors and other healthcare providers (Raab, 2004), accompanied by take-home materials provided to patients that includes brochures, educational videos, newsletters, and tools. Under this theory of practice, interaction with healthcare professionals provides the primary venue in which patients learn basic information about their heart condition and device treatment, ask questions specific to their personal and medical circumstances, predict issues which may impede their ability to effectively adapt to treatment, and support patients' autonomy with respect to a variety of treatment decisions (Kramer, Brock & Tedrow, 2011).

Patients' perceptions regarding their relationships with their healthcare providers, specifically whether they characterize the support provided by HCPs as being "constructive" rather than "nonconstructive", are associated with global acceptance of ICD therapy, and may specifically moderate otherwise deleterious effects of shock anxiety and acceptance (Morken, Norekvål, Bru, Larsen, & Karlsen, 2014). This theory is embodied in the current standard of practice with ICD patients even though information acquisition on the part of the patient may be compromised by any number of issues, including difficulty understanding information as portrayed by healthcare providers, difficulty maintaining attention during the informed consent consultation, or simple preference for receiving advice in other forms (written versus verbal, online versus in person, etc.) or from other trusted individuals.

The discrimination between treatment-specific knowledge and health literacy, and how the current study will address the difference, warrants further discussion. Health literacy refers generally to patient ability to read, comprehend, and make use of medical information to understand or improve their own health status (Nutbeam, 2000), and has been connected both theoretically and empirically to clinical outcomes in the treatment of various chronic conditions (e.g. in diabetes self-management by Schillinger, Grumbach, Piette, Wang, Osmond, Daher, Palacios, Sullivan, & Bindman, 2002).

This definition, and the measures designed to assess for it, rely heavily on absolute literacy and ability to cognitively abstract scientific information as driving factors for these outcomes, rather than an essential understanding of treatment which may be derived through informational media which do not necessarily require an advanced understanding of scientific information. A competing “fuzzy trace”-based theory of patient treatment knowledge (Reyna, 2008) would logically hold that the ability to understand scientific specifics is less impactful than the ability to comprehend the general gist of information holding idiosyncratic importance to the patient, which again may be available to patients in a variety of formats. To this point, a number of investigations have highlighted patient informational needs or preferences across general cardiac patient populations (e.g. Ashton, 1997; Suhonen, Nenonen, Laukka, & Valimaki, 2005; Scott & Thompson, 2003) focusing on the content of patient educational materials rather than the media through which patients seek information, thereby conforming to a “banking” theory of education in which patients’ agency is limited to their ability to take in data and advice proffered by care providers (Friere, 1970). For the purposes of this project, the means by which patients report acquiring information about ICD treatment, and their absolute knowledge of treatment, will be considered without the lens of absolute literacy or ability to comprehend scientific data.

Facilitated physician/patient information exchange. While the facilitation of an exchange of information between care providers and patients is the ostensible goal of an informed consent process, the standard of practice in this area is a series of unstructured conversations with healthcare providers. Assessments of the qualities of these interactions with ICD patients have led to a number of critiques. Despite the fact that QOL represented a prominent concern to patients participating in a focus group, very little information or discussion within the physician encounter was devoted to these risks (Hauptman, Chibnall, Guild, & Armbrecht, 2013), which instead primarily emphasized even modest survival benefits. Cardiologists, electrophysiologists, and other recommending physicians themselves have expressed a preference for painting ICD therapy in a decidedly positive light, lest patients make a "bad decision"(p. 1638) and elect to pursue other forms of therapy (Matlock, Nowels, Masoudi, Sauer, Bekelman, Main, & Kutner, 2011), a point of distinct import with respect to ICD care as many of the limitations of treatment have to do with psychosocial, QOL, or dignity of death concerns rather than absolute survival. This dynamic is theoretically in line with findings from a 1991 structural analysis of physician responses to psychosocial complaints among a wide variety of medical patients. The most common responses to such concerns included the prescription of psychotropic medication, explicit expectations about the patient's behavioral responses, and referral to mental health practitioners (Waitzkin, 1991). Considering the latent paternalism evident in Matlock and other's findings, it may not be overly pessimistic to believe that, in a plurality of circumstances, ICD patients presenting to care providers with emotional concerns would be met with similarly reductive responses.

Some attempts have been made to manualize these encounters and the types of information provided to patients, albeit with mixed benefits. The written artifacts used in concert with these discussions frequently fall short of expectations. One recent review of eighteen prime examples of such materials - half of which were authored by device manufacturers and the other half by interested professional groups such as the American College of Cardiology and the Heart Rhythm Society - revealed a number of fundamental deficiencies through semi-qualitative content critical analysis (Hazelton, Al-Khatib, Fonarow, Thomas, Hayes, Sanders, & Sears, 2013). No tools were rated in their totality as either “excellent” or even “very good”, only four of were consensus rated as “good, may need revisions, but sufficient for use”, and three were rated as “poor, inadequate for use (p.361). Criticism of these tools was most evident in their “effectiveness” subscale, which in part assessed how well the tool did at providing information about therapeutic options, emphasizing that personal values needed to be taken into account, and encouraging an values and informational exchange with care providers. An assessment of each tool’s’ “content”, including whether they provided accessible information regarding capabilities of ICDs as well as risks and benefits of treatment, highlighted nominally better performance, but even the highest scoring tools were rated as having “marginal quality and need for revision prior to use”(p.361) in clinical practice. The variability of quality evident in these materials, especially when coupled with the logical variability of quality of interactivity and therapeutic alliance among physician care providers, inevitably leads to a compromised state of psychosocial practice. In the instances where patients’ informational and/or supportive needs have not been adequately addressed by care providers, they are left either continuing along their treatment plan without information, or accessing other media in an attempt to buttress their knowledge.

Online medical information. The Internet as an informational medium available to medical patients has gained considerable stature and garnered a significant amount of research interest. The internet as a medium of support is actually favored among young and male ICD patients, while in-person discussions with healthcare providers, support groups, or behavioral health professionals are favored by older and female patients (Serber et al., 2009), falling mostly inline with the more general finding that individuals who seek health information online are more likely to be younger, have higher educational achievement, and higher income than groups who do not prefer this mode of information acquisition (Powell, Inglis, Ronnie, & Large, 2011).

To begin describing the ways in which some ICD patients use Internet message boards as a medium for information and support, this investigator (Knoepke, 2012) analyzed one year's worth (96 total) member-submitted discussion threads to the ICD-specific section of the *Pacemaker Club* website. Major themes identified in this study included notions related to patient education that included descriptions of medical problems, describing the shock experience, and seeking medical advice. As in the examples provided in Table 2.2, psychosocial themes dominated in number and included expressions of apprehension, expressions of frustration, expressions of gratitude, seeking of affirmation, and seeking psychosocial advice.

Considered concurrently, these themes suggest that at least some patients treated with these devices attempt to learn about their treatment, including advice on medical aspects of their treatment and as a means of support. To date, no prospective efforts have been undertaken in an effort to determine the quality of information patients receive online, or whether or not the receipt of online information relates to psychosocial adaptation to treatment.

Patient education as a core component of existing psychosocial interventions for ICD patients. A number of rigorously evaluated psychosocial interventions for people with ICDs have been developed. The plurality of these efforts place considerable emphasis on patient education as a core component, obliquely supporting its importance to the improvement of patient experience, at least at the theoretical level. Specific investigation into the role education and knowledge play in specific improvements, however, are still lacking in the literature.

The majority of these interventions have been designed as post-hoc responses to known issues of QOL among individual ICD patients, and the forms patient education takes within these programs varies. For example, many of the same efficacy studies supporting cognitive-behavioral psychotherapeutic interventions mentioned elsewhere, (Frizelle, Lewin, Kaye, Hargreaves, Hasney, Beaumont, & Moniz-Cook, 2004; Sears, Sowell, Kuhl, Kovacs, Serber, Handberg, ... & Conti, 2007), indicate that interventions which include substantial emphasis on patient education and the correction of misinterpreted or otherwise inaccurate understanding on the part of the patient can positively affect anxiety, depression, and in Sears case, the presence of biological markers of stress.

Table 2.2
Themes & Examples from Pacemaker Club Qualitative Data (Knoepke, 2012)

Theme	***Example***
Describing medical problems	*"I went in for a routine procedure last week and the Dr. refused to do the procedure because my heart rate was between 28-32 bpm"*
Describing shock experience	*"I got the shock of a lifetime. Bright flash of light, like an explosion going off inside my body."*
Expressions of apprehension	*"(I am) way nervous of being alone...This thing in my chest scares the daylights out of me."*
Expressions of frustration	*"I know it has been a short time, but was hoping for improvement." "I just want to know if this is normal. It is really aggravating."*
Expressions of gratitude	*"You all have no idea how you've helped me cope."*
Seeking affirmation	*"I just want to know if this is normal"*
Seeking medical advice	*"During these little episodes I've been having, my blood pressure sitting down is normal 125/65, then when I stand. it jumps to like 155/97 and my pulse would read 90's. Is this normal?."*
Seeking psychosocial advice	*"Now I'm having anxiety and living my life in fear. I start counseling tonight but if anyone has any advice it is greatly appreciated."*

Further, in Sears' "ICD Shock & Stress Management Program" (2007), the experimental therapeutic protocol included educational information about the device itself, what it is used for, data regarding survival benefits, information about activities which device treatment may limit, and what happens when a shock is triggered as well as ICD-specific cognitive beliefs and appraisals (with the goal being to identify and replace faulty or anxiogenic beliefs and thoughts with more accurate or "adaptive" ones). Interestingly, patients assigned to the multi-session support group did not fare considerably better than patients in the workshop format (which served as an active control group), but still better than those receiving no intervention, evidencing an ability to affect mental health and QOL indicators in a single encounter which focused primarily on education and facilitated discussion about device therapy.

Both similarity of these interventions and the specific mention of the importance of including patient education within psychotherapeutic protocols for this patient group (Habibović, Burg, & Pedersen, 2013) would seem to imply a consensus belief that such efforts are crucial to effective patient support. However, the largest ongoing RCT addressing QOL outcomes among ICD patients is inadvertently testing the viability of this assumption. A new intervention being tested as a component of the larger Reducing Vulnerability to ICD Shock Treated Ventricular Arrhythmias (RISTA) Trial uses a more strictly-interpreted stress reduction treatment (SRT) in an effort to reduce objectively assessed anger, hostility, QOL, health-related anxiety and depression, perceived social support, subjective stress, and concerns about ICD treatment. According to the investigators (Donahue, Lampert, Dornelas, Clemow, & Burg, 2010), the SRT intervention includes group-based didactic sessions emphasizing the relationship between physiological tension, cognitive stress, emotion, and behavior, as well as group practice of individual stress reduction techniques, communication training, and time management strategies. As the inclusion of ICD-specific information and knowledge is notably absent from that description, forthcoming findings regarding differential efficacy of such an intervention will provide structural context to the theoretical approaches most favored in the next generation of interventions for ICD patients.

The form, content, and media through which proactive educational and supportive efforts are provided may impact the efficacy of these interventions, however. While continuing to make use of many of the same psychoeducational elements employed by Sears' and Frizelle's, and perhaps simultaneously reducing barriers to treatment access, a Dutch group has been investigating whether these cognitive-behavioral principles can be efficaciously adapted for use as a modular, individual, Internet-based intervention since as recently as 2009 (Pedersen, Spek, Theuns, Alings, van der Voort, Jordaens, & van den Broek). The fact that no findings from this program have yet been reported may be indicative of a lack of significant findings, however. Also, a preventative intervention in which nurses provided mindfulness training and basic ICD education over the phone failed to yield improvements in state anxiety among ICD patients in a recent pilot trial (Tagney, 2013).

In a fully functioning and efficient system of patient education, these efforts would work in a complementary fashion meeting patients' educational and supportive needs heuristically, but extant literature on gaps in patient knowledge reveal gaps in this process. Other investigations into patient education efforts in heart failure (e.g. Fredericks, Beanlands, Spalding, & De Silva, 2010) have focused on the content of various informational materials, the amount of informational materials provided, and the medium of interaction with healthcare providers (including static materials provided by nurses, such as videos and informational pamphlets) finding that educational interventions delivered in a multi-modal format with individualized information in one-to-one settings predicted improvement in self-care behavior and knowledge. Just as is the case with information available online, no efforts to date have attempted to fully describe what value these media have with respect to patient education, or through what mechanisms patient understanding is related to QOL/mental health outcomes. Such efforts are needed if supportive efforts seek to be responsive to the particular needs of patients, while also realistically fitting within current care processes.

The theoretical limitedness of these interventions notwithstanding, and for a number of reasons which fall outside the scope of this review, well-researched and ostensibly efficacious programs unfortunately suffer from limited support and a lack of widespread expertise among providers, preventing translation into large-scale practice. The resultant combination of patient trouble, increased strain on care providers, and few available methods of care has lead some non-behavioral health professionals to attempt to design their own psychosocial interventions, both reactionary and prophylactic in nature. Existing anecdotal reports of physicians who purposely shock their patients without sedating them in the hope that doing so in a safe environment will decrease risk of anxiety or depression (J. Cooper, personal communication, May 2008) belie the importance of creating and disseminating efficacious, humane, and theoretically-sound interventions on the behalf of patients and their families. Designing, validating, and disseminating programs found to be most effective are all viable avenues through which social work ethics and scholarship can benefit patients and their families.

Summary of ICD Treatment & Associated Problems

ICDs are a popular, and growing, first-line treatment in the prevention of sudden cardiac death, which is the leading cause of death in the United States. While there are a number of theories and approaches to understanding the etiology of such problems, a number of QOL and mental health issues have been identified among this group of patients. Concurrently, recent evidence illustrates a suboptimal level of patient understanding of ICD treatment. Unfortunately, studies to date have not focused on understanding the relationship between treatment knowledge and QOL/MH outcomes. An improved understanding of the social ecology of patient informational acquisition is critical to informing the next generation of educational materials and care processes.

Specific Aims and Hypotheses

An important first step in developing a model that is appropriate for conveying information to patients is based on expanding the prior work of Dickerson (2000, 2005) and Serber (2009) that examines ecological preferences and needs of informational care for patients with ICDs. Approaching the issue in this way represents a fundamental departure from previous investigations because it recognizes that patient activity within their social context may impact a person’s adaptation to device therapy, rather than only their interaction with care providers or the content of passive informational materials. Given that so many sources of information and support exist, and that preferences for source differs by group (Serber et. Al, 2009), it stands to reason that interactive effects of group and source of information on QOL and level of patient information may exist. Identifying informational avenues that predict or define understanding of treatment and/or beneficial patient-centric adaptation to therapy may be useful in guiding the development of the next generation of psychosocial, educational, and medical interventions aimed at increasing patients' QOL. As such, the current study has three specific aims:

Aim 1: To identify the type of informational media used by patients to learn about ICD treatment.

Aim 2: To assess the relationship between use of healthcare providers as the primary source of medical information and level of ICD treatment-specific knowledge. *Hypotheses 1) Having received information from healthcare providers will be positively related to levels of treatment-specific knowledge. 2) Older patients will have lower treatment-specific knowledge than younger patients.*

Aim 3: To examine the relationship between ICD treatment-specific knowledge and QOL and mental health outcomes among study participants. *Hypotheses: 1) Treatment-specific knowledge will be positively related to improvements in QOL and mental health outcomes. 2) Self-efficacy associated with ICD treatment will moderate the relationship between treatment-knowledge and QOL.*

Chapter Summary

This chapter traced both the theoretical and evidentiary underpinnings of the project described in Chapter 1. Included in this review of scientific literature was a discussion of the basic functions of implantable defibrillators, current conceptualizations of QOL problems attendant to treatment, and the relative theoretical weight granted to treatment-specific knowledge in efforts to prevent or intervene in the lives of patients who are struggling. Examples of the various media available to patients attempting to learn about their disease, device therapy, and expectations of treatment were provided, as well as the ecological and substantive limitations of even the most promising exemplars of each. The chapter concluded with a brief overview of the purpose and specific aims of the current project, the methods for which will be described in greater detail in the following chapter.

Chapter 3: Methods

The previous chapter presented an overview of literature relevant to quality of life problems and determinants, as well as means through which treatment-specific information is acquired, among people being treated with implantable defibrillators. This chapter describes the methodology and analytic approaches used to examine the study's primary questions. The methodological approach to this project included three distinct processes: 1) creation of new items to assess treatment-specific knowledge and informational media used by a sample of ICD patients; 2) a pilot test of these items with a randomly-selected subset of patients; and 3) a survey of remaining device patients using study materials refined in light of pilot survey results. Study samples and each of these steps are described below.

Study Measures: Steps Used to Create New Measures

New measures were constructed to assess both informational media history and preference and knowledge of ICD treatment. These measures were created using a sequential combination of the clinical expertise of subject matter experts and the experience of current ICD patients. The resultant items for both the informational media history and treatment knowledge measures were tested for general feasibility as part of the pilot survey (described below) before being used in the larger project survey.

At the beginning of this process, drafts of items for potential inclusion into each of the two new measures were derived by this investigator with guidance from subject matter experts Drs. Daniel Matlock, MD, MPH (General Internal Medicine and Geriatrics, University of Colorado), Raphael Sung, MD (Cardiac Electrophysiologist, formerly of the University of Colorado) and Jonas Cooper, MD, MPH (Senior Cardiac Electrophysiologist, Butler Health System, Pittsburgh, PA). Items for inclusion in the informational media measure were adapted from content areas defined in Serber and colleagues (2009) assessment of group informational preferences. These items were then discussed with three patients in separate individual interviews as work preparatory to research, with each patient providing feedback on the most recent revision. Patients spoke with the investigator for at least one hour each, providing individual feedback for each item in the new measures. These patients differed from each other in terms of age and means by which their treatment had been reimbursed. The first patient being a Caucasian woman, approximately 70 years old, whose care is covered by Medicare; the second was a Hispanic male, aged approximately 20 years, whose care is covered under his parents' private insurance; and the third a Caucasian woman, aged approximately 55 years, whose care is being managed by the Canadian National Health Service.

Patients' feedback included the addition of several forms of informational media, a number of fact-based questions about ICD treatment, clarifying language to include in survey items and directions, and suggestions for response options to demographic items. A final version of the survey was reviewed by Professors Matlock, Jenson, and Hasche and, following review and approval from COMIRB, was used in the subsequent pilot survey. The survey, found in Appendix A, originally included items that addressed demographic information (except for age, gender, and device-related information), birth city and city in which participants spent the most time prior to age ten, informational media use, and treatment-specific knowledge in addition to several existing measures. Birth city and early childhood information was collected to aid Dr. Raphael Sung in his assessment of a possible relationship between altitude exposure in early life and risk of cardiac rhythm disturbance development.

Selection of Existing Measures

Domains tested by survey components were chosen to adequately address the project's specific aims. The measures were chosen, at every possible juncture, to be validated and reliable with respect to these domains, while concurrently not being overly burdensome to complete. In addition to the ICD treatment and information medium measures developed in the previous phase, the survey battery included the following self-report scales:

Primary outcome measures.

Kansas City Cardiomyopathy Questionnaire, Short Form (Green, Porter, Bresnahan, & Spertus, 2000). The KCCQ is a twelve-item scale developed to aid in rapid assessment of various patient-relevant QOL facets in both clinical practice and research, and is now one of the most commonly used among such measures with heart failure patients. Validity data were initially described through convergent validity with existing longer measures of health status. Reliability statistics for each subscale of the English version (cited above), all sit above .6, including those for physical limitation (α=.90), symptoms (α=.88), QOL (α=.78), social limitation (α=.86), and self-efficacy (α=.62). Most critical to this project, reliability for summary scores sits considerably higher, including for functional status (α=.93), and overall KCCQ summary score (α=.95). The above-cited validation and reliability demonstration article included results from a number of cohorts. Most relevant to this project, a cohort of patients who had been in recovery from "decompensated congestive heart failure" for a period of three months illustrated a mean KCCQ Summary Score of 64.1 and mean QOL Subscale Score of 60.5 (no distribution statistics were reported). Each scale score ranges from 0-100 with increased scores denoting improved quality of life and general level of functioning.

Hospital Anxiety & Depression Scale (HADS: Bjelland, Dahl, Haug, & Neckelmann, 2002). The HADS, a fourteen item measure assessing symptoms of anxiety and depression among general medical patient populations, structured similarly to other short inventories utilized in mental health practice. In the most recent literature review covering all versions of the HADS (Bjelland, Dahl, Haug, & Neckelmann, 2002) the measure illustrated superior ability to discriminate between depressive symptoms, cognitive anxiety, somatic anxiety, and somatic symptomatology common among medical patients which are not necessarily indicative of psychosocial distress when compared to general depression and anxiety indicators. The review highlighted 21 different reliability studies which each indicated sufficient internal reliability for self-report measures (defined as a Cronbach's alpha coefficient of at least .60), with no studies finding the HADS to be unreliable. The same review indicated that the HADS maximally balances sensitivity and specificity of anxiety and depression identification in medical populations when a cutoff of 8 (out of a possible 21) is applied to either construct. The anxiety and depression subscale scores are used in the analyses in this project; subscale scores are both measured continuously and using the clinical cutoff score of 8 to indicate clinically significant depression or anxiety.

Florida Patient Acceptance Scale (FPAS: Burns, Serber, Keim, & Sears, 2004). This 15 item scale, which measures patient acceptance of ICD or pacemaker treatment along biological, psychological, and social characteristics represents the shortened version of a 47 item original version. In its original validation study, FPAS total score significantly correlated with all eight subscales of the previously existing SF-36, evidencing validity in assessing patient quality of life. Further, a factor and item analysis revealed the FPAS to contain four reliable factors in addition to the total score: return to function (α=.89), device-related distress (α=.79), positive appraisal (α=.82), body image concerns (α=.74), and total FPAS score (α=.83). (The scale includes three non-scored items, two of which ask for patients' subjective assessment of their own knowledge about treatment). During validation, ICD patients illustrated a mean FPAS score of 76.0 (out of possible 100); this score was significantly lower than that of pacemaker patients (m=85.4, p<.01). Note that high scores on the FPAS indicate higher acceptance of device therapy. Patient acceptance was included as a secondary outcome measure, although it is not included in any specific analyses described in the analysis plan (Table 3.6).

Baseline and Covariate Measures.

Self-Efficacy Expectations in ICD Treatment (SE-ICD: Dougherty, Johnston, & Thompson, 2007). This instrument, built on a social-cognitive theory of adjustment to device treatment, assesses patients' belief in themselves as capable of overcoming challenges associated with ICD treatment. In the above-cited validation analysis, the SE-ICD correlated moderately with existing scales of self-efficacy, including the General Self Efficacy Scale (r=0.48, p <.01) and the Social Self Efficacy Scale (r=0.36, p <.01). Internal reliability analysis revealed total SE-ICD score to be highly reliable (α=.93). In the same dataset, a mean self-efficacy score of 8.32 (sd=1.63) out of a possible 10 was observed. Self-efficacy is used as an interaction term in the third specific aim.

Chart review and data abstraction. To aid in the future assessments of possible clinical covariates, a data abstraction form was created and approved by COMIRB. As shown in Appendix B, this tool serves to standardize clinical data collection for the purpose of this and future studies, to minimize the presence of PHI in materials which were delivered through the mail and over the internet, and to eliminate the possibility of incorrect participant reporting regarding medical history (Hauptman, Chibnall, Guild, & Armbrecht, 2013). For the purposes of this project, this form included participant date of birth, gender, date of earliest ICD implantation, and indication for ICD therapy (discussed below). The form also included a number of other variables that may be of interest both to future analyses conducted by this author and Dr. Sung in his project described above (e.g. presence of pulmonary disease, treatment with various medications, severity of heart failure, method by which ejection fraction was determined, etc.).

Decision rules defined in data abstraction process. During the chart review session in which these data were gathered, and in collaboration with Special Committee Member Dr. Matlock, this author defined a number of discriminant rules that were applied to standardize data entry. These rules were necessary in some cases as exact date of device implantation and/or indication for treatment (primary or secondary SCD prevention) were not always explicit. These rules were:

1. For instances in which precise implantation date was not available, two rules were defined. If only month and year could be determined (e.g. an office visit note indicating "Patient had ICD implanted in February of 2008"), then the implant date was entered as the first of that month (2/1/2008 in the example above). This was necessary in two cases. This estimation does not impact "time since implant" as assessed in this project, however, as the time was only estimated to the nearest month. In instances where only the year was available in patient medical charts, the date was entered as June 30 of that year. This was done to minimize both the amount of missing data and the amount of error inherent in the adjustment (as it would only be possible to miss the real number of months since implant by 6 months in either direction). These corrections were necessary in 6 total cases, all of which were patients who had their devices implanted at a hospital which was not UCH and who had only recently established a clinical relationship there.

2. In instances in which indication for ICD therapy (i.e. primary versus secondary) was not available, a number of general rules were created to apply to information which was available. The term "primary prevention" in this context is meant to describe indicated treatment with an ICD without patient history of sudden cardiac death, syncope, or sustained (>30 seconds in duration) ventricular tachycardia (VT) (AVID Investigators, 1997). These include patients with varied

> forms of heart failure, hypertrophic cardiomyopathy, and ischemic cardiac disease, but who have no recorded experience of these life-threatening cardiac events. Patients indicated for therapy as “secondary prevention”, on the other hand, have experienced such an event.
>
> In the vast majority of circumstances, narrative notes made by physicians who implant these devices include an affirmative statement of whether the ICD was indicated for primary or secondary prevention of SCD. In instances where such a statement was not present, this author would interpret clinical notes made by care providers. Instances in which a history of syncope was mentioned were coded as secondary prevention, as were any instances in which a history of VT which was either noted as “sustained” or for which an observed episode exceeded 30 seconds in duration. If a history of VT was reported without either of these two aggravating statements, the indication was coded as primary.

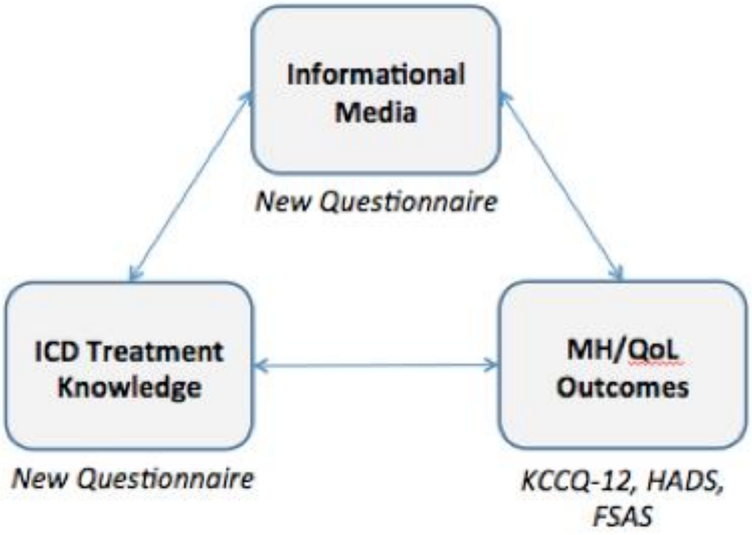
In all cases, patient date of birth and gender (reported dichotomously as male/female) were available and recorded.

Thus each of the new informational media history and ICD treatment knowledge measures, as well as the list of validated outcome measures listed earlier in this chapter, were tested on a pilot survey of 100 randomly-selected ICD patients being treated at UCH. Samples for the pilot study and final survey administration are described below.

Study Samples

Subjects were recruited for the pilot and main surveys from a list of all ICD patients receiving care related to their devices from the University of Colorado Hospital in Aurora. The list was, compiled by electrophysiologist Dr. Raphael Sung by querying PACEART, a tracking database used by the University of Colorado Hospital to maintain contact information for all patients with implantable devices, including not only implantable defibrillators, but also pacemakers and other therapies. The purpose of this program is to assist in identifying patients who need information or assessment in the event of a device recall and to store patient medical data. Designated exclusion criteria included patients who are either younger than 18 or older than 99 years of age, non English speaking, or who lack decisional capacity due to cognitive impairment or other similarly limiting condition. Pilot and main survey samples are presented below. Specific findings pertaining to each sample are found in Chapter 4.

Figure 3.1
Conceptual Model of Current Study with Associated Measures



Sample and survey procedures for the pilot survey. The complete survey battery was sent via standard mail (with both a printed version of the survey and accompanying business reply mail envelope, directions for how to complete the survey online through the version available through the University of Denver's Qualtrics account, and a $1 coin as a global inducement) to 100 randomly selected potential participants. Recruitment occurred via standard mail, with the initial mailing including a brief introductory letter explaining the purpose of the study, contact information for this author and the approving IRBs (with appropriate notice of received IRB waivers), and the above-described survey battery. In keeping with COMIRB mandates, the cover letter provided to participants also informed them that returning their surveys would constitute receipt of informed consent, as this author and Dr. Matlock successfully applied for a waiver of consent for this project.

Participants were given the option of completing their survey either online or via paper-and-pencil in order to facilitate a maximal response rate. All potential participants were mailed a second follow-up letter two weeks after the initial recruitment materials reminding them of their opportunity to participate and another copy of the printed survey and business reply envelope, although no additional inducements were included in this second mailing. All recruitment materials made clear that the choice of whether or not to complete the survey belonged solely to the participants, and their choice of whether or not to participate will not impact their care in any way (including the survey cover letter attached). Participants who elect to return their surveys via mail were able to do so at no cost, and these materials (which contain no directly identifying information as any potentially sensitive protected health information was gathered only through chart review) were returned to the investigator's locked mailbox at the Graduate School of Social Work at the University of Denver to be manually entered.

Table 3.2

Characteristics of Pilot Survey Respondents

		ICD Patients, n=22	Pacemaker Only, n=5
Age, m(sd)		60.31(11.54)	59.4(8.91)
Gender, % male (n)		59.09(13)	40(2)
Months since implant, m(sd)		64.14(38.49)	N/A
ICD indication, % primary prevention (n)		72.73(16)	N/A
Ethnicity:	Hispanic, %(n)	8.7(2)	0(0)
	Non-Hispanic, %(n)	91.3(20)	5(100)
Race:	White/Caucasian, %(n)	30.4(7)	4(80)
	Black/African American, %(n)	8.7(2)	0(0)
	Asian, %(n)	0(0)	0(0)
	Multiethnic, %(n)	8.7(2)	0(0)
	Native American/Alaska Native, %(n)	8.7(2)	0(0)
	Hawaiian/Pacific Islander, %(n)	8.7(2)	0(0)
	Other, %(n)	17.4(4)	1(20)
Annual Income:	$0-20,000, %(n)	30.4(7)	2(40)
	$20,000-40,000, %(n)	8.7(2)	1(20)
	$40,000-60,000, %(n)	0(0)	1(20)
	$60,000-80,000, %(n)	8.7(2)	0(0)
	$80,000-100,000, %(n)	8.7(2)	0(0)
	$100,000-150,000, %(n)	8.7(2)	0(0)
	More than $150,000, %(n)	17.4(4)	1(20)
Education:	Less than high school, %(n)	8.7(2)	0(0)
	High school/GED, %(n)	4.3(1)	0(0)
	Some college, %(n)	26.1(6)	0(0)
	Associates degree, %(n)	13.0(3)	2(40)
	Bachelors degree, %(n)	26.1(6)	1(20)
	Masters/Professional degree, %(n)	17.4(4)	1(20)
	Doctorate, %(n)	4.3(1)	1(20)
Times shocked by ICD:	0, %(n)	78.3(18)	N/A
	1-5, %(n)	4.3(1)	N/A
	5-10, %(n)	13.0(3)	N/A
	More than 10, %(n)	4.3(1)	N/A

Valid percentages reported throughout

. Twenty-two (of the original 100) ICD patients returned the pilot survey. An additional five pacemaker-only patients returned survey materials. Demographic characteristics of pilot survey respondents are shown in Table 3.2. The low rate of response observed in the pilot survey necessitated a number of minute changes to the recruitment strategy. First, in order to reduce the possibility that a patient who may not be fully aware of what type of device they are being treated with elects not to participate, any references made to “implanted defibrillator” were removed from the participant cover letter and name of the online survey in favor of the more general “cardiac device” terminology. Second, the link to the online version of the pilot survey was taken directly from Qualtrics, meaning that it was both case sensitive, long, and included no recognizable words - each of which logically increases the likelihood that potential participants would have trouble accessing the survey and may then elect not to participate. The link for the broad survey was thus transformed using Tinyurl.com so that it read simply “tinyurl.com/denvercardiosurvey”.

Finally, using recommendations for recruitment type and frequency from Dillman (2011), the committee and the investigator elected to add both an email recruitment between the first and second paper mailing (for non-respondents to the first mailing for which email addresses were available in the contact file provided by Dr. Sung), and a third paper mailing for individuals who had not yet responded to any of the earlier three recruitment contacts. In total, potential participants would be contacted at up to four points instead of two, and would be provided with more intuitive access to the online survey.

Amendments made to survey items and protocol in light of pilot trial data. Data gathered in this pilot survey illustrated a number of practical and evidentiary points for consideration when making final changes to the battery ahead of the larger general survey. Preliminary findings were presented at the University of Colorado's Palliative Care Research Days (Knoepke, Sung, & Matlock, 2014) and are described in detail in Chapter Four. These findings were also reviewed with the dissertation committee, who recommended several final changes related to demographic questions and the recruitment procedure.

No changes were recommended for the informational media or treatment knowledge items, or for the use of any of the previously-developed measures, despite a modicum of concern expressed over the possibility of a limited variability in the Self-Efficacy in ICD Treatment measure (Dougherty, Johnston, & Thompson, 2007) due to a possible ceiling effect. However, the fact that four participants noted that they were not treated with a defibrillator (but rather with only a pacemaker, which was later verified by Dr. Sung via individual chart review), necessitated the need to assess with which type(s) of devices the participants were currently being treated. This was accomplished by simply adding two dichotomous questions: "Do you have a pacemaker?" and "Do you have an implanted defibrillator?"

Sample and procedure for the main survey. Potential participants were recruited according to the process flow outlined in Figure 3.3. While the same list of ICD patients was used (provided through a PACEART query performed by Dr. Sung), participants who had been contacted for the pilot survey were not contacted for the main survey, regardless of whether or not they had responded in any fashion. Mirroring the process from the pilot survey, potential participants for the main survey were mailed (via USPS) copies of the revised survey and cover letter, as well as a $1 coin acting as a global inducement. A total of 655 patients were contacted in this wave of recruitment.

Figure 3.3

Process Flow of Main Survey Recruitment in Light of Pilot Survey Findings

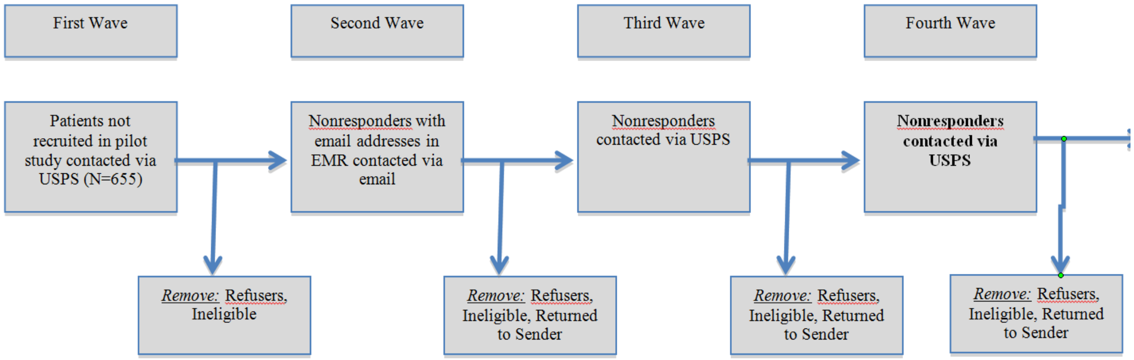
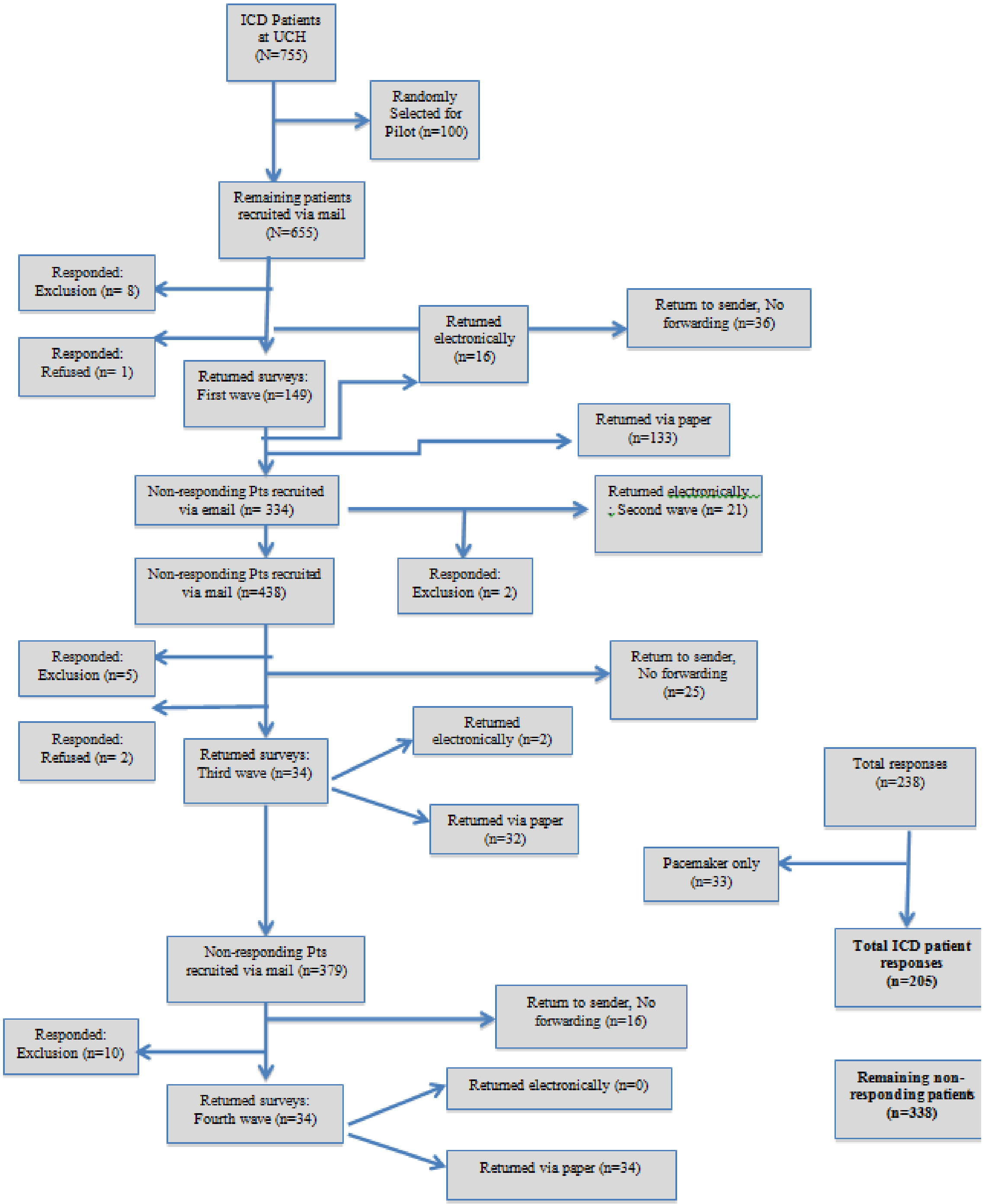


Figure 3.4

Participant Recruitment Process & Response by Recruitment Wave



After three weeks, individuals who had not respond to the first contact, and for whom the PACEART file included a valid email address were emailed a second recruitment, with a cover letter mirroring the content from the printed version, including a direct link for those who wished to participate electronically. A total of 334 patients were recruited electronically, which included 11 patients whose initial USPS mailing had been returned to sender.

Three weeks following the email recruitment, a second USPS recruitment mailing was sent. This included content that was identical to the initial mailing, with the only exceptions being that there no longer was a $1 coin and references to the coin were removed from the cover letter. A fourth contact (the third USPS mailing) was sent, with identical contents, to non-responders to each of the previous attempts at contact. 438 and 379 ICD patients were recruited via USPS mail in the third and fourth recruitment waves, respectively.

In response to these recruitment requests, a total of 238 individuals (36.3%) returned study materials with useable data. 38 (16.0% of these respondents) supplied their data using the online version of the survey, while 198 (83.2%) did so by returning paper materials. Three patients contacted this investigator indicating that they refused to take part in the project, while 25 patients (3.8% of the total sample) returned information indicating that they were ineligible to participate. 33 participants (14.0% of respondents) returned study materials who are only being treated with a pacemaker, and whose data will not be used in these analyses.

Table 3.5

Characteristics of Main Survey Respondents

		ICD Patients, n=205	Pacemaker Only, n=33
Age, m(sd)		60.7(14.53)	64.2(14.15)
Gender, % male (n)		65.9(135)	69.7(23)
Months since implant, m(sd)		71.48(44.00)	N/A
ICD indication, % primary prevention (n)		73.7(151)	N/A
Ethnicity:	Hispanic, %(n)	2.9(6)	6.1(2)
	Non-Hispanic, %(n)	90.2(185)	87.9(29)
Race:	White/Caucasian, %(n)	81.0(166)	93.9(31)
	Black/African American, %(n)	10.2(21)	0(0)
	Asian, %(n)	2.0(4)	3(1)
	Multiethnic, %(n)	1.5(3)	3(1)
	Native American/Alaska Native, %(n)	1.5(3)	0(0)
	Hawaiian/Pacific Islander, %(n)	0(0)	0(0)
	Other, %(n)	3.4(7)	0(0)
Annual Income:	$0-20,000, %(n)	23.4(48)	12.5(4)
	$20,000-40,000, %(n)	14.1(29)	18.8(6)
	$40,000-60,000, %(n)	17.6(36)	15.6(5)
	$60,000-80,000, %(n)	9.3(19)	6.3(2)
	$80,000-100,000, %(n)	6.8(14)	12.5(4)
	$100,000-150,000, %(n)	11.7(24)	21.9(7)
	More than $150,000, %(n)	11.7(24)	12.5(4)
Education:	Less than high school, %(n)	5.9(12)	0(0)
	High school/GED, %(n)	13.7(28)	3.3(11)
	Some college, %(n)	26.3(54)	24.2(8)
	Associates degree, %(n)	10.2(21)	9.1(3)
	Bachelors degree, %(n)	22.4(46)	9.1(3)
	Masters/Professional degree, %(n)	16.6(34)	21.2(7)
	Doctorate, %(n)	2.4(5)	3(1)
Times shocked by ICD:	0, %(n)	62.9(129)	N/A
	1-5, %(n)	24.4(50)	N/A
	5-10, %(n)	6.8(14)	N/A
	More than 10, %(n)	5.9(12)	N/A

Valid percentages reported throughout

In total, 205 (31.3%) eligible patients returned surveys either partially or totally completed, and whose data will be represented in later reporting. Despite not realizing the recruitment goal of 300, the investigator was successful in exceeding the targeted recruitment of African Americans and Native Americans/Alaska Natives when compared to the original Targeted/Planned Enrollment Table (Appendix C). Proportionally, the project was successful in recruiting a sample of ICD patients with 34.1% female representation, nearly exactly in line with targeted recruitment goals. Complete demographic characteristics for main survey respondents are in Table 3.5.

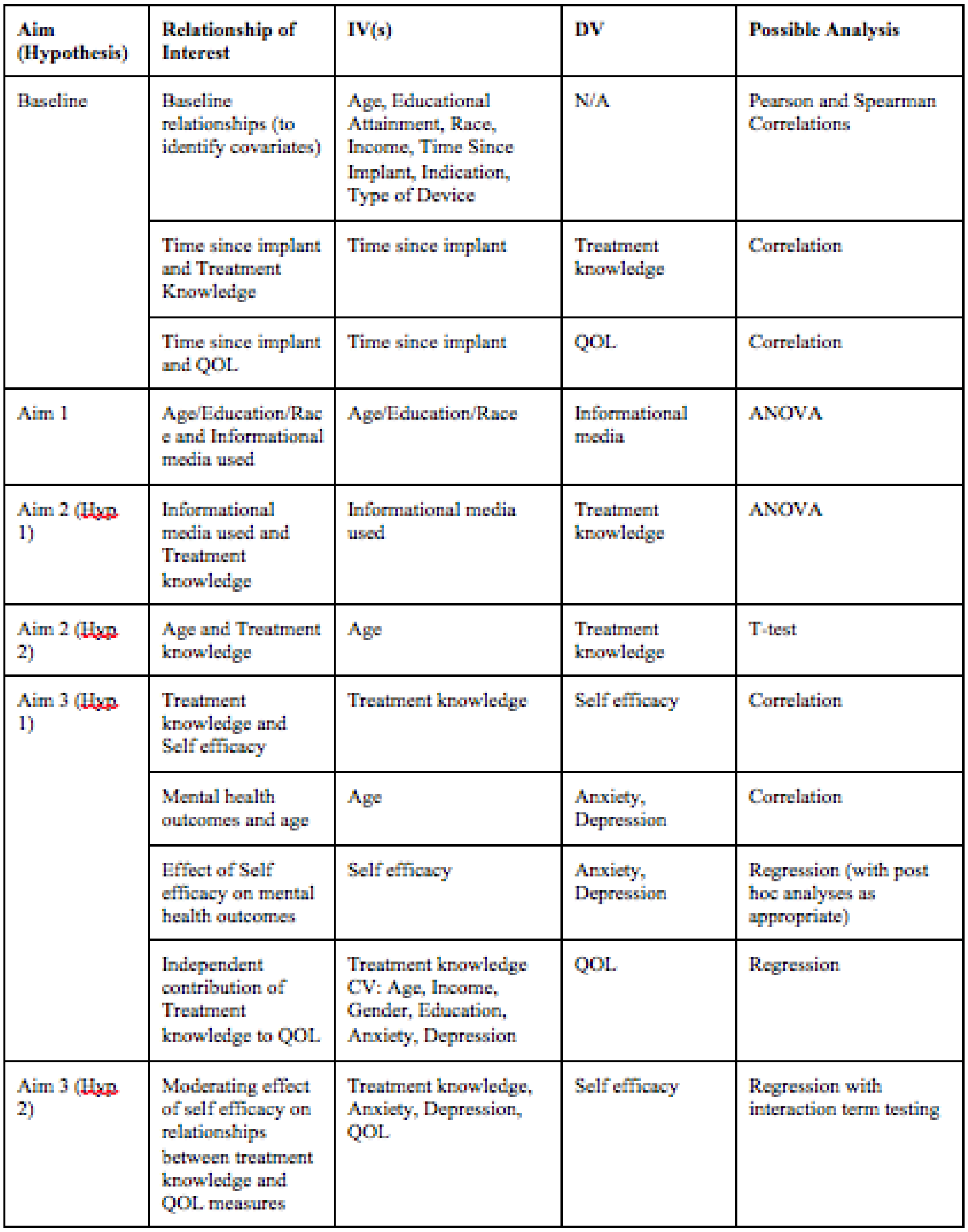
Analysis Plan

The study's key analyses are shown in Table 3.6. A variety of quantitative techniques were used first to examine the psychometric reliability of the new informational media history measure, then to describe relationships within specified participant constructs. Responses to the new informational media measure were analyzed using exploratory factor analysis (EFA). The purpose of this analysis was to detect internal factors by that would be useful in defining subscales. These subscales, in turn were analyzed for internal reliability using Cronbach's alpha to examine item cohesiveness and illuminate the presence of unreliable items.

As shown in Table 3.6, descriptive analyses and correlations were conducted and examined to determine the presence of any a priori demographic and/or experiential relationships that impacted aim-specific analyses. Chi square analyses were conducted to examine whether informational media use differed by group according to age, educational attainment, or race. Both Pearson product correlations and one-way analysis of variance (ANOVAs) were used to examine relationships between informational media use and treatment knowledge, age and treatment knowledge, age and anxiety/depression, and treatment knowledge and self-efficacy. Least squares regression analyses were conducted to determine the individual contribution of self-efficacy and treatment knowledge on QOL when accounting for the impact of demographic and experiential variables. Regression with interaction term testing was used to assess the potential for self-efficacy to moderate any relationship between treatment knowledge and QOL.

Table 3.6

Analysis by Specific Aim/Hypothesis



Aim (Hypothesis)	**Relationship of Interest**	**IV(s)**	**DV**	**Possible Analysis**
Baseline	Baseline relationships (to identify covariates)	Age, Educational Attainment, Race, Income, Time Since Implant, Indication, Type of Device	N/A	Pearson and Spearman Correlations
	Time since implant and Treatment Knowledge	Time since implant	Treatment knowledge	Correlation
	Time since implant and QOL	Time since implant	QOL	Correlation
Aim 1	Age/Education/Race and Informational media used	Age/Education/Race	Informational media	ANOVA
Aim 2 (Hyp. 1)	Informational media used and Treatment knowledge	Informational media used	Treatment knowledge	ANOVA
Aim 2 (Hyp. 2)	Age and Treatment knowledge	Age	Treatment knowledge	T-test
Aim 3 (Hyp. 1)	Treatment knowledge and Self efficacy	Treatment knowledge	Self efficacy	Correlation
	Mental health outcomes and age	Age	Anxiety, Depression	Correlation
	Effect of Self efficacy on mental health outcomes	Self efficacy	Anxiety, Depression	Regression (with post hoc analyses as appropriate)
	Independent contribution of Treatment knowledge to QOL	Treatment knowledge CV: Age, Income, Gender, Education, Anxiety, Depression	QOL	Regression
Aim 3 (Hyp. 2)	Moderating effect of self efficacy on relationships between treatment knowledge and QOL measures	Treatment knowledge, Anxiety, Depression, QOL	Self efficacy	Regression with interaction term testing

Post hoc analyses were conducted as appropriate. Analyses involving specific factors (either discovered in new measures or existing in standardized ones) will also be considered.. CV= Covariate, IV=Independent Variable, DV=Dependent Variable

Chapter Summary

This chapter described the methodology employed across the stages of this project. This process began with the SME and participatory action-informed process by which new measures assessing patient informational media use and treatment specific knowledge, continued through a pilot survey of a random subset of ICD patients and subsequent changes to the survey design and recruitment approach, followed by the larger main survey of remaining ICD patients being treated through the University of Colorado, and concluding with an *a priori* analytical plan (guided by the specific aims). The means by which the sample was identified and recruited, as well as assurances for the protection of human subjects were outlined. Study findings are presented in Chapter Four.

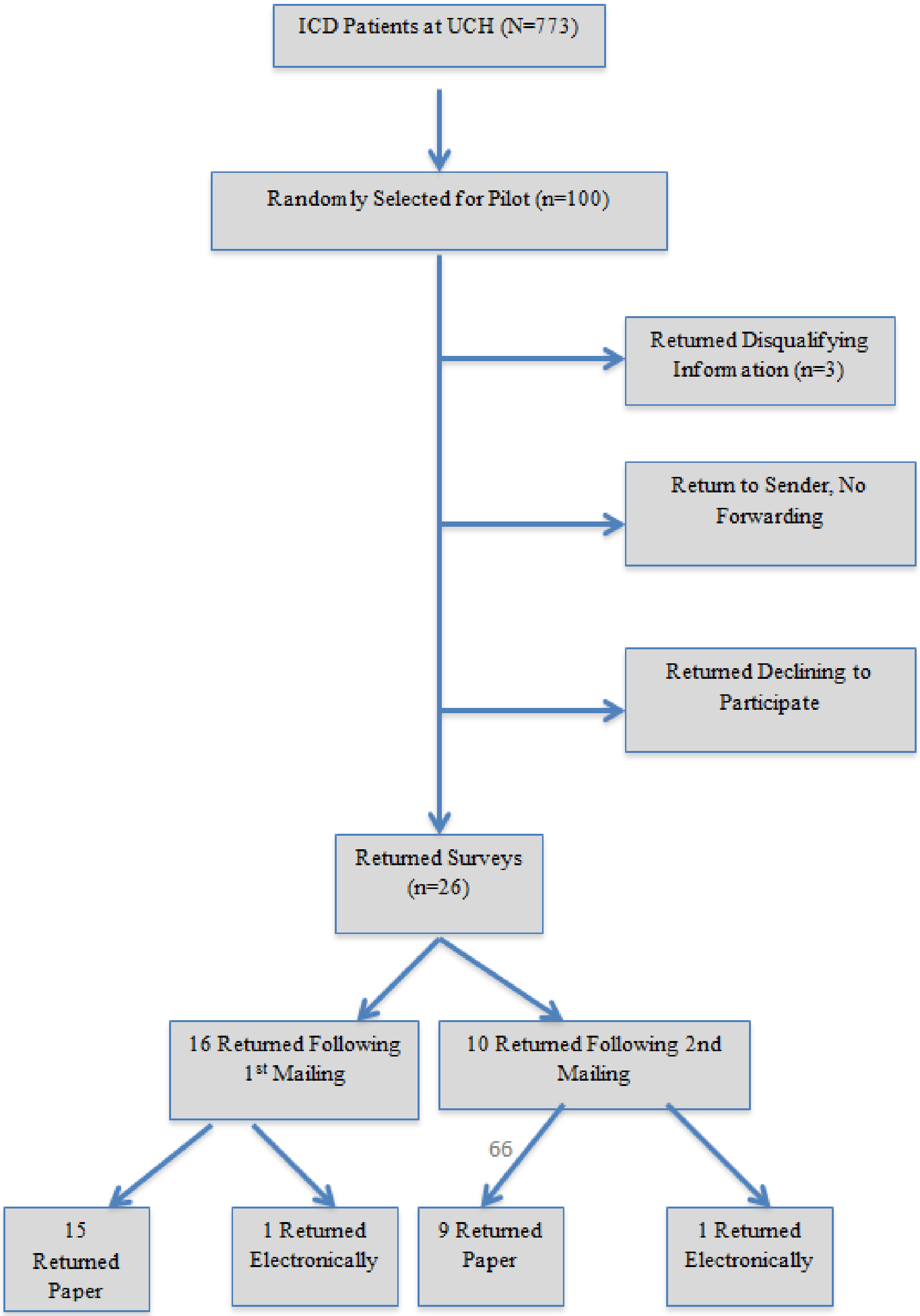
Chapter 4: Results

This chapter includes a presentation of the study's major findings. The chapter begins with a review of data obtained during the pilot study followed by findings from the main survey defined along the lines of the project's specific aims and analytic plan. These include investigations into 1) reported use of informational media by ICD patients, with specific attention paid to patterned differences found by age, educational attainment, and race; 2) possible relationships between treatment specific knowledge or age and informational media used; and 3) the predictive value of treatment knowledge with respect to improving patient quality of life (QOL).

Pilot Study Findings

The purpose of the pilot study was to determine estimates of participant response rates as well as patterns of responses and viability of items contained in the newly developed treatment knowledge and informational history scales. As shown in Figure 4.1, 26% of the UCH device patients randomly selected for inclusion in the pilot study pool were returned over the course of two recruitment waves. Of these, only two were returned via the electronic option; the other 24 surveys were returned via the paper format. Three patients replied with disqualifying information (two of whom had their device removed, one had died), three others were returned to sender by the USPS, and one affirmatively declined to participate. Pilot study participant characteristics are shown in Table 3.2.

Figure 4.1
Pilot Study Participant Flowchart



Response Characteristics Observed in New Measures. Responses to each item of the new ICD treatment knowledge measure are presented in Table 4.2. Each item was comprised of a statement refined through subject matter expert and patient conversations preparatory to research described in Chapter 3, followed by three response options: “True”, “False”, and “I Don’t Know”. Of the nine items, only one (“ICDs are not designed to cure heart disease”) was answered correctly by more than 90% of respondents. Two items (“As long as I stay at least 9 inches away from most large electrical appliances, it won’t affect my ICD” and “Every time an ICD shocks, it means that a person’s heart was having a big problem”) were answered correctly by less than 35% of the sample respondents. The variability observed in item difficulty, coupled with a fully inclusive and variable observed range of total scores, suggested the inclusion of all scale items in the main survey. Pilot study participants correctly answered 6.04 of 9 treatment knowledge questions correctly on average (sd=2.254).

Table 4.3 provides response characteristics observed for the new informational media history measure in the pilot study. Each of these items provided an example of a venue through which patients are often offered information about their ICD, followed by a five point Likert-type scale asking participants to estimate how much information they acquired from these materials. Response options included “No Information”, “A Little Information”, “Some Information”, “A Good Deal of Information”, and “ A Lot of Information”, which were then coded as ranging from 1 to 5.

Table 4.2

ICD Knowledge Scale Response Distribution

Item	True	False	Don't Know	*n*	*% correct*
The main purpose of an ICD is to shock a patient's heart if it's having a dangerous rhythm	23*	2	1	*26*	*88.4*
In order to turn off an ICD, a doctor has to surgically remove it	2	16*	8	*26*	*61.5*
ICDs are not designed to cure heart disease	25*	0	1	*26*	*96.2*
As long as I stay at least 9 inches away from most large electrical appliances, it won't affect my ICD	8*	8	10	*26*	*30.8*
Every time an ICD shocks, it means that a person's heart was having a big problem	14	9*	3	*26*	*34.6*
If someone's ICD was turned off, they would die almost immediately	2	19*	5	*26*	*73.1*
Most people with ICDs can return to work if they want to.	23*	0	3	*26*	*88.5*
Even if a patient's doctor says it's ok, they probably shouldn't exercise.	1	20*	4	*25*	*80.0*
If someone is shocked while having sex, the shock wouldn't injure their partner.	14*	4	7	*25*	*56.0*

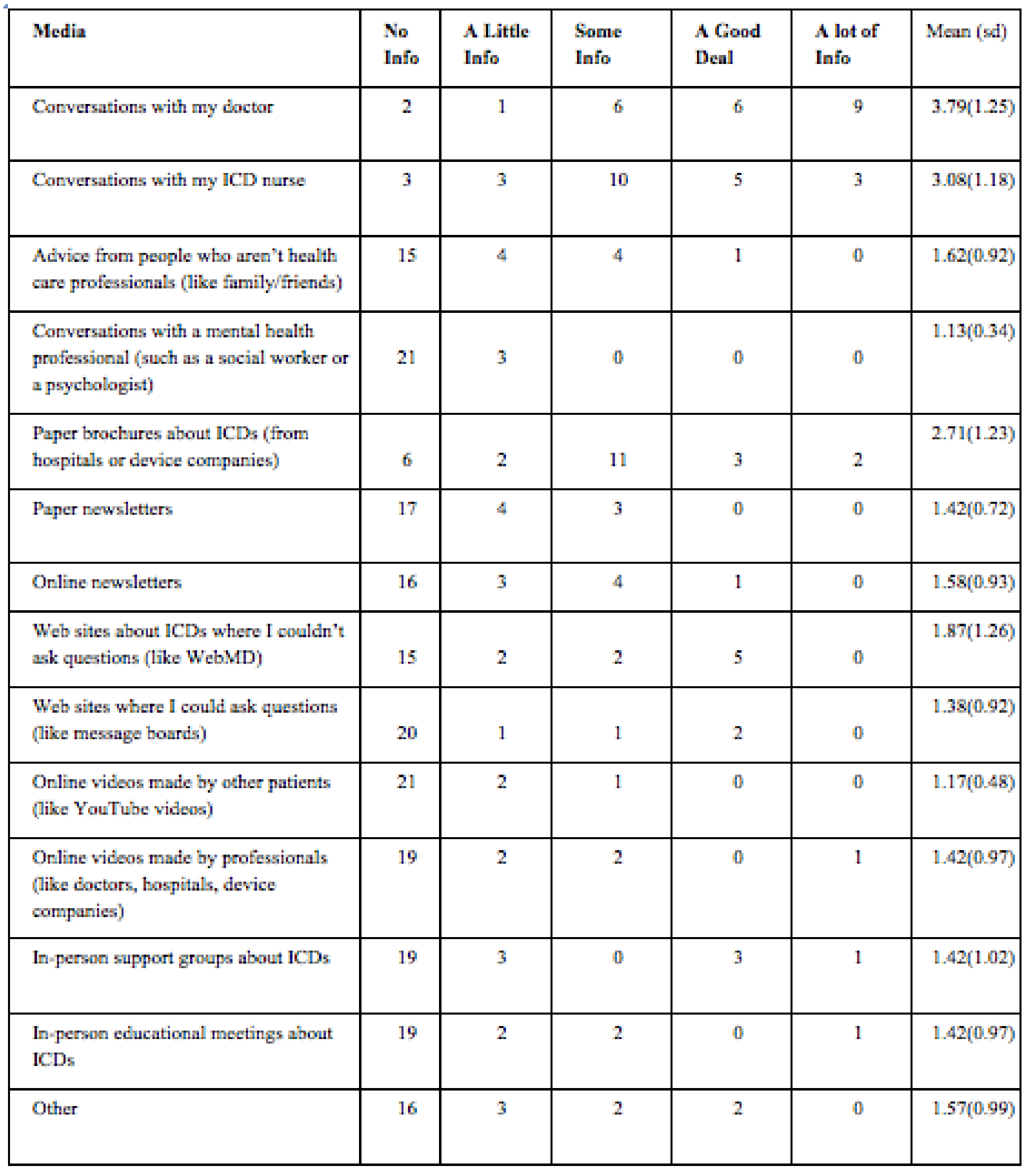
** Correct answer*

As shown in Table 4.2, levels of reported use and variability of use were higher for selected types of information, ("Conversations with my doctor", "Conversations with my ICD nurse", and "Paper brochures about ICDs (from hospitals or device companies)." Other items, while lower, were deemed important to the study and were subsequently retained in the main survey. This was done to ensure that the greatest variability of informational types were represented, even when only a few participants report using them.

The relationship between patient self-efficacy and ICD treatment was assessed using the SE-ICD (Dougherty, Johnston, & Thompson, 2007; Table 4.4). Despite the problem of missing data discussed in Chapter 3, this measure was retained in the main study due to both the sufficiency of variability within item responses and the measure's importance to the theoretical model being tested in Aim 3.

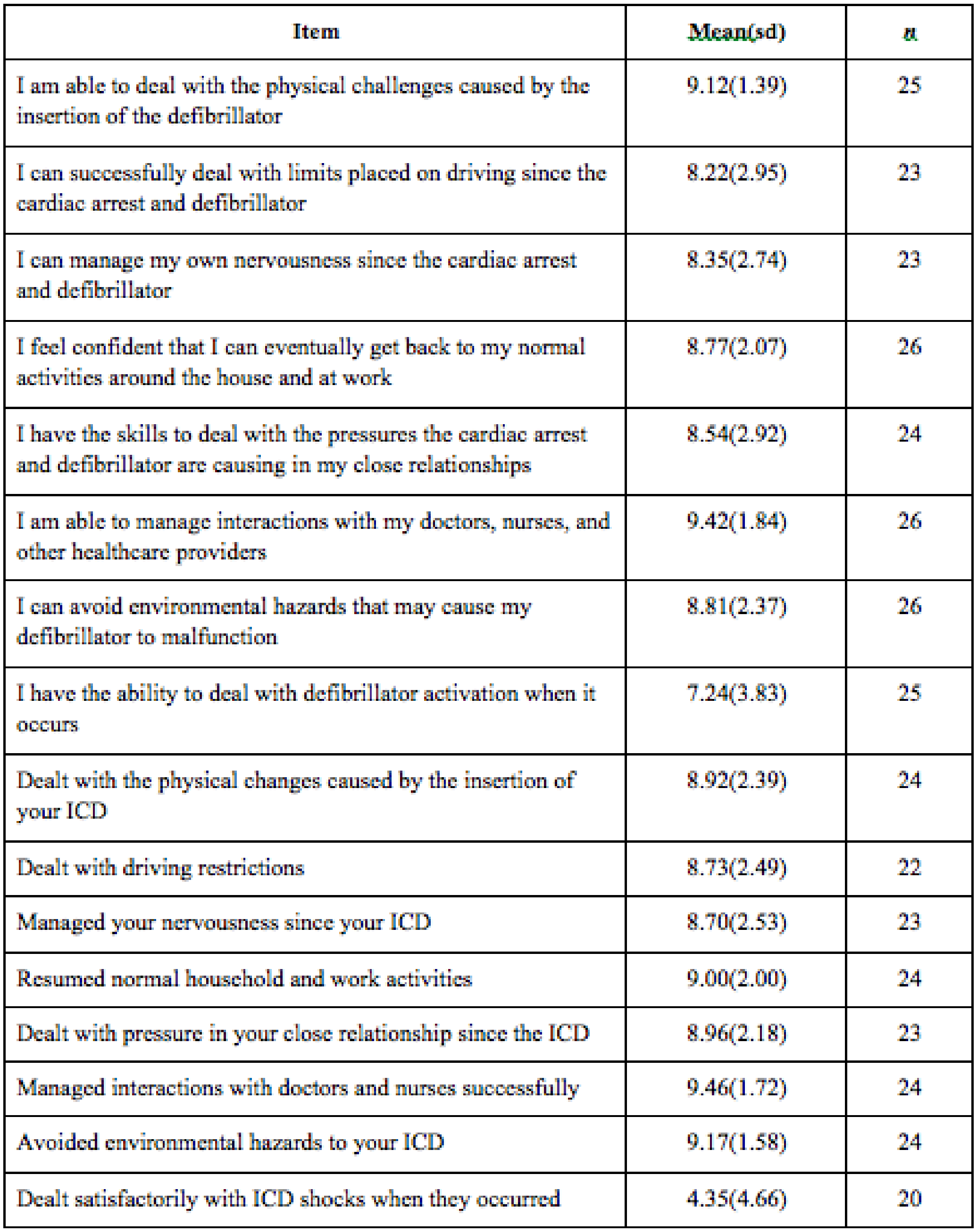
Table 4.3

Informational Media History Response Distribution (n=24, Range= 1-5)



Media	**No Info**	**A Little Info**	**Some Info**	**A Good Deal**	**A lot of Info**	Mean (sd)
Conversations with my doctor	2	1	6	6	9	3.79(1.25)
Conversations with my ICD nurse	3	3	10	5	3	3.08(1.18)
Advice from people who aren't health care professionals (like family/friends)	15	4	4	1	0	1.62(0.92)
Conversations with a mental health professional (such as a social worker or a psychologist)	21	3	0	0	0	1.13(0.34)
Paper brochures about ICDs (from hospitals or device companies)	6	2	11	3	2	2.71(1.23)
Paper newsletters	17	4	3	0	0	1.42(0.72)
Online newsletters	16	3	4	1	0	1.58(0.93)
Web sites about ICDs where I couldn't ask questions (like WebMD)	15	2	2	5	0	1.87(1.26)
Web sites where I could ask questions (like message boards)	20	1	1	2	0	1.38(0.92)
Online videos made by other patients (like YouTube videos)	21	2	1	0	0	1.17(0.48)
Online videos made by professionals (like doctors, hospitals, device companies)	19	2	2	0	1	1.42(0.97)
In-person support groups about ICDs	19	3	0	3	1	1.42(1.02)
In-person educational meetings about ICDs	19	2	2	0	1	1.42(0.97)
Other	16	3	2	2	0	1.57(0.99)

Table 4.4
Self Efficacy-ICD Item Descriptive Statistics and Responses



Item	Mean(sd)	*n*
I am able to deal with the physical challenges caused by the insertion of the defibrillator	9.12(1.39)	25
I can successfully deal with limits placed on driving since the cardiac arrest and defibrillator	8.22(2.95)	23
I can manage my own nervousness since the cardiac arrest and defibrillator	8.35(2.74)	23
I feel confident that I can eventually get back to my normal activities around the house and at work	8.77(2.07)	26
I have the skills to deal with the pressures the cardiac arrest and defibrillator are causing in my close relationships	8.54(2.92)	24
I am able to manage interactions with my doctors, nurses, and other healthcare providers	9.42(1.84)	26
I can avoid environmental hazards that may cause my defibrillator to malfunction	8.81(2.37)	26
I have the ability to deal with defibrillator activation when it occurs	7.24(3.83)	25
Dealt with the physical changes caused by the insertion of your ICD	8.92(2.39)	24
Dealt with driving restrictions	8.73(2.49)	22
Managed your nervousness since your ICD	8.70(2.53)	23
Resumed normal household and work activities	9.00(2.00)	24
Dealt with pressure in your close relationship since the ICD	8.96(2.18)	23
Managed interactions with doctors and nurses successfully	9.46(1.72)	24
Avoided environmental hazards to your ICD	9.17(1.58)	24
Dealt satisfactorily with ICD shocks when they occurred	4.35(4.66)	20

Table 4.5 presents descriptive data of the remaining study measures, including the FPAS, HADS, and KCCQ. Twenty-seven patients returned surveys; completion of each subscale varied considerably between participants, with only 16 completing all FPAS

items and all 27 completing the Anxiety subscale of the HADS. 39.5% and 58.0% respondents reported clinically significant anxiety and depression respectively, and device acceptance was considerably lower than published averages (Green, Porter, Bresnahan, & Spertus, 2000; m=61.53,sd=5.04). KCCQ-12 QOL Subscale (m=69.32, sd=32.90) and Summary scores (m=68.66, sd=33.26) reveal highly variable reported QOL and mental health indicators among respondents.

Table 4.5

Descriptive Statistics for Remaining Previously Existing Study Measures in Pilot Study

	n	**Minimum**	**Maximum**	**M**	**sd**
Florida Patient Acceptance Scale (FPAS)	16	52	68	61.69	4.91
Kansas City Cardiomyopathy Questionnaire – 12 (KCCQ)	23	7.29	100	68.41	31.59
Hospital Anxiety & Depression Scale: Anxiety	27	0	11	14.04	3.88
Hospital Anxiety & Depression Scale: Depression	26	3	11	15.19	2.56

Summary of Pilot Study Findings

A pilot study of 100 randomly selected UCH device patients was conducted to determine the form and rate of participant response and to preliminarily assess the acceptability and usability of study measures for the main study. The pilot study yielded a lower response rate than originally anticipated, particularly with respect to the number of electronic surveys returned. After consultation with Committee members, it was determined that all study materials performed adequately for inclusion in the main study, including the new informational media history and ICD treatment knowledge measures created in an earlier project phase. Please note that changes made to recruitment processes and demographic questions included in study materials were discussed in Chapter 3.

Main Study Findings

Findings from the main project survey are detailed below. These include descriptive statistics from the new Informational Media and ICD Treatment Knowledge measures, an exploratory factor analysis (EFA) and item reliability analysis of the Informational Media measure, an analysis of missing data for all study measures, and results from analyses detailed in the analytic plan found in Chapter 3. Descriptions of all analyses,, including those conducted on a *post hoc* basis, are noted.

Main Survey Recruitment Process

Following the completion of the pilot study, survey materials were sent to the remaining 655 device patients identified by querying UCH's PACEART program. Non-responders were contacted up to a total of four times (according to the recruitment process flow outlined in Figure 3.1). Participant responses were tracked by survey wave and study ID, modality of response (paper vs. electronic), and materials returned to sender by the USPS were noted. Study IDs were later matched to participant name and medical record, allowing for chart reviews necessary to retrieve additional data.

Response patterns. 236 of the 655 (36.0%) UCH patients recruited to participate in the main survey returned study materials; 68 mailings (10.4%) were returned to sender without forwarding information, 16 significant others (2.4%) replied that the potential participants were deceased, 9 (1.4%) were returned with indications that the participants were ineligible for another reason, and 31 surveys 4.7%) were completed and returned by patients being treated with a pacemaker only. As shown in Figure 3.4, this resulted in a final response rate of 38.6%.

A variety of reasons were found for ineligibility. Eight subjects reported having received a left-ventricular assistance device (LVAD) and had their ICDs removed. One participant suffered from advanced dementia, 3 others had heart transplants and no longer required ICD therapy, and one potential participant indicated that he only had a pacemaker and felt the survey was not relevant to his experience. Forty participants returned survey materials electronically alongside 196 returned via paper-and-pencil. Additional challenges in accurately describing and reporting response rate are discussed in Chapter 5.

The *ICD Treatment Knowledge Questionnaire* and *IDK Index*. Univariate descriptive data from the new *ICD Treatment Knowledge Questionnaire* revealed a level of treatment knowledge among main survey participants similar to that observed in the pilot survey (m=6.56, sd=1.65). In addition to creating scale scores for treatment knowledge (by first coding all item responses dichotomously as either “correct” or incorrect/don’t know” and then adding correct responses together for a total knowledge score), this dataset allowed for the possibility of creating a secondary experimental measure of how many times participants responded that they did not know the answer to a specific item. This new variable, called the *IDK Index*, served as a functional proxy for patient confidence in their knowledge of the device’s purpose, capabilities, and the limitations on activity ICDs create for most patients. Scores on this measure varied from

0 to 9 (m=.86, sd=1.28). Furthermore, as was observed in later analyses (Table 4.12), the IDK Index's distribution of observed values was highly skewed and peaked, making it a poor measure for use in parametric testing at this juncture.

Factor and item reliability analyses of new *Informational Media History* measure. Principle components factor analysis with varimax rotation was used to reduce items on the informational media history measure to its simple structure. All informational media items featured very low levels of missing data (all were below 2.5% and 8 of the 13 items were at 1%). It was therefore deemed appropriate to pursue additional analyses via pairwise deletion of incomplete cases. To ensure that the factors chosen for retention accounted for an acceptable amount of variance (>60%), were composed of enough items to maintain sensitivity, and met a modicum of face validity, analysis was limited to include those factors with eigenvalues >1. Item analyses were then conducted on each retained factor (with at least three items) in order to maximize the internal consistency within each.

Initial exploratory factor analysis (with varimax rotation) revealed 5 factors underlying the original 14 items. These factors were extracted in 6 iterations and collectively accounted for 67.1% of the total variance in reported informational media use (Table 4.6).

Table 4.6
Informational Media Factors Extracted in EFA

	Initial Eigenvalues			Rotation Sums of Squared Loadings		
Factor	**Total**	**% of Variance**	**Cumulative %**	**Total**	**% of Variance**	**Cumulative %**
1	3.855	27.534	27.534	2.541	18.150	18.150
2	1.696	12.115	39.649	1.900	13.572	31.722
3	1.521	10.866	50.515	1.823	13.018	44.740
4	1.228	8.772	59.287	1.641	11.721	56.462
5	1.101	7.863	67.150	1.496	10.688	67.150
6	.917	6.547	73.697			

Extraction Method: Principal Component Analysis.

Item loadings on identified factors were further analyzed to discriminate these factors from each other and to remove poorly performing items. To be included in the analyses, items must have had an observed loading of at least .5 on a factor and must not have loaded equally on any other factor (defined for this analysis as a difference of >.25 in absolute value of loading observed). As shown in Table 4.7, 12 of the original 14 items, covering all four identified factors, were retained following this process. While three separate two-item factors were identified, they were retained to maintain maximal amount of variance explained and because the measure was valued for used in brief clinical and research encounters (in which parsimony, simplicity, and brevity are highly valued).

Internal item analysis was then conducted on the remaining individual factor with three items (Factor 1, “Online Patient Information”). In its original format, which addressed reported use of passive websites, active websites, and online videos made by professionals, the factor revealed a Cronbach's alpha of .682, Two factors, "Conversations with Healthcare Professionals" and use of "In-Person Meetings", demonstrated adequate internal reliability (defined as $\alpha \geq .70$), and 2 additional scales were between α=.60 and α=.69, ("Paper Patient Information" and "Online Patient Information"). The remaining factor, "Advice from non-Healthcare Professionals", included only two items and had a very low reliability estimate (α=.47), and was therefore dropped from the scale and subsequent analyses.

Table 4.7

Informational Media Item Loadings by Identified Factors, Varimax Rotated Component Matrix

	Component				
	1	2	3	4	5
1) Conversations with my doctor	.122	.076	-.015	**.875**	-.019
2) Conversations with my ICD nurse	.017	.098	.111	**.850**	.064
3) Advice from people who aren't health care professionals (like family/friends)	-.013	.184	-.006	.016	**.720**
4) Conversations with a mental health professional (such as a social worker or a psychologist)	.170	.266	-.023	.058	**.758**
5) Paper brochures about ICDs (from hospitals or device companies)	-.102	**.642**	.075	.349	.143
6) Paper newsletters	.177	**.858**	.059	-.004	.118
7) Online newsletters	.515	.624	.099	.037	.123
8) Web sites about ICDs where I couldn't ask questions (like WebMD)	**.804**	-.108	.081	.143	-.068
9) Web sites where I could ask questions (like message boards)	**.738**	.087	-.017	.024	.238
10) Online videos made by other patients (like YouTube videos)	.623	.300	.414	-.073	.173
11) Online videos made by professionals (like doctors, hospitals, device companies)	**.725**	.159	.249	.023	.104
12) In-person support groups about ICDs	.131	.142	**.901**	.042	-.013
13) In-person educational meetings about ICDs	.173	-.027	**.887**	.082	.039
14) Other	.257	-.309	.131	-.004	.535

Extraction Method: Principal Component Analysis. Rotation Method: Varian with Kaiser Normalization. a. Rotation converged in 6 iterations. **Boldface** = observed item loadings onto identified factors.

Table 4.8

Internal Reliability of Informational Media Factors/Subscales

Factor	**Items**	**Cronbach's α**	**# needed for α ≥ .80****	***n***	**M(sd)**	**Min.**	**Max**
Conversations with Healthcare Professionals	1,2	.70	2	202	7.84 (1.85)	2	10
Advice from non-Healthcare Professionals	3,4	.47	7	N/A	N/A	N/A	N/A
Paper Patient Information	5,6	.63	3	201	4.67 (1.90)	2	10
Online Patient Information	8,9,11	.68	3	202	4.69 (2.37)	3	15
In-Person Meetings	12,13	.84	0	203	3.33 (2.17)	2	10

** number of additional items, as determined using Spearman-Brown Prophecy formula, N/A=not calculated as factor was removed

In sum, a total of 9 items contributing to 4 subscales were retained for use in later analyses. Total scores and variability were calculated for each of the 4 informational media history domains (Table 4.8). Each item is rated on a 5-point Likert-type scale ranging from 1 (No Information" to 5 ("A Lot of Information"). Scores on each item were combined with others in their domains for total scores.

Analysis of missing data in remaining scales. Processes used to ensure the integrity of data collected included both design and statistical diagnostic elements. First, missing data were minimized for patient demographic information by limiting the type and number of questions asked of participants and by using medical chart reviews. This resulted in no missing data for participant gender, age, ICD indication, and months since first ICD implant. Second, the nature of survey response answers reduced opportunities for missed or incorrectly entered participant responses, as all variables used in the analyses were multiple choice or otherwise “closed” in their response set. Third, the high proportion of paper surveys received (83.2% of the total number returned) reduced data entry errors because data were entered using a multiple-choice form exactly like the electronic version provided as an option to all respondents. As shown in Table 4.9, univariate missing values analysis of the remaining self-report demographic indicators revealed minimal data loss for these variables. Income, race, and reported number of times patients have been shocked by their ICD are the only three of these demographic variables addressed in previous literature addressing QOL and mental health outcomes among ICD patients, and were thus the only ones included in regression analyses. With .5%, 5.4%, and 0% data missing from these variables respectively, it was determined that listwise deletion of incomplete cases for such analyses was appropriate.

Table 4.9
Missing Data for Self-Reported Demographic Variables

	n (valid)	**n (missing)**	**% missing**
Ethnicity	191	14	6.8
Race	204	1	.5
Income	194	11	5.4
Education	200	5	2.4
Shocks	205	0	0

Table 4.10 displays missing data information and results from Little’s MCAR Test (Little, 1988) for the version of each study measure used in this project. In the cases of the new ICD knowledge and informational media questionnaires, as well as both the anxiety and depression subscales of the HADS and the KCCQ QOL subscale and summary scores, data were found to be missing completely at random (MCAR). This suggests that missingness did not follow a detectable pattern and is thus “ignorable”

(Rubin, 1976). After considering these findings alongside the corrected observed percentages of missing data for each measure, only one of which (the KCCQ QOL subscale) was observed to be higher than a 5% “rule of thumb” (Tabachnick & Fidell, 2007, p. 63), it was determined that it would be appropriate to impute missing data using SPSS’ “linear trend at point” function (SPSS Inc; Chicago, IL) for the purposes of both exploratory and inferential analyses. This approach is desirable because it avoids artificially biasing standard errors in medium sized data sets such as the one described here (Tabachnick & Fidell, 2007), while still preserving the otherwise moderate sample size.

Unfortunately, missing data in two scales were not missing completely at random. Little’s test results for missing data within the FPAS (χ^2 = 484.848, df = 279, p = 0.00) and the modified version of the SE-ICD (χ^2 = 365.382, df = 253, p = 0.00), reveled missing data from these measures to be patterned in some fashion. Fortunately, the FPAS was included in this project as a secondary outcome measure and was not assigned exclusively to any particular analysis within the analytic plan described in Chapter 3. It was therefore possible to eliminate the FPAS from these analyses, reserving the HADS subscales and KCCQ for the exploratory and inferential analyses into relationships with and effects on mental health and QOL outlined in the analytic plan.

The SE-ICD, however, presents a number of other problems and considerations. It was included in the original analytic plan as a covariate and it represents the only *a priori* measure to assess participant self-efficacy relevant to ICD treatment as an analytic construct. Not only are the chi-square coefficient and significance levels observed in

Little's test problematic, but the fact that more than 5% of SE-ICD response datum are missing (5.85%) made further analysis to determine what levels of caution to use when interpreting self efficacy-inclusive results imperative..

Table 4.10
Little's MCAR Test Results for Study Measures

	% missing	χ^2	***df***	**p**
ICD Knowledge	2.03	58.265	50	.197
Informational Media History[1]	1.31	42.273	40	.373
HADS Anxiety	3.06	53.376	44	.157
HADS Depression	2.90	31.010	43	.914
FPAS	2.45	484.848	279	.000**
SE-ICD[2]	5.85	365.382	253	.000**
KCCQ Summary	6.19[3]	152.265	134	.134
KCCQ QOL Subscale	6.35	5.103	2	.078

[1] As revised following EFA; [2]As revised in light of visual analysis of data, removal of final item, [3] Percent missing inflated by single item with 21% missing, with that item removed, % missing for KCCQ drops to 4.85**Retain null hypothesis: data not missing completely at random (MCAR)

A one-way ANOVA was conducted to determine whether missing data in the modified SE-ICD variables were associated with any dependent variables. First, a dummy variable was created in which a score of "0" was assigned to any case in which the SE-ICD Total Score was expressed as missing and a "1" was assigned for all other values. This step provided a dichotomously categorized "missingness" variable in the SE-ICD dataset. Table 4.11 shows ANOVA results examining whether scores on dependent variables (from the analytic plan) differed between participants with complete and incomplete modified SE-ICD data.

The lack of observed relationships between groups defined by whether SE-ICD data were complete or not on dependent variables provided evidence that the data were missing at random. Missing SE-ICD data is thus still ignorable, leaving the option of imputing missing data using “linear trend at point” (SPSS Inc; Chicago, IL) for analysis. These analyses should be nonetheless interpreted with caution, as the issue of having nearly 6% of data missing from all SE-ICD items persists. This level of missing data, even when doing so at random, can induce bias by inflating the error term and increase the possibility of Type II Error.

Table 4.11

ANOVA Table Describing Relationship of Missingness Within SE-ID Data to Study DVs

		Sum of Squares	**df**	**Mean Square**	**F**	**Sig.**
HADS Anxiety Subscale Score	Between Groups	2.427	1	2.427	.209	.648
	Within Groups	2118.442	182	11.640		
	Total	2120.870	183			
HADS Depression Subscale Score	Between Groups	4.153	1	4.153	.509	.476
	Within Groups	1500.326	184	8.154		
	Total	1504.478	185			
KCCQ-12 Summary Score	Between Groups	304.701	1	304.701	.772	.381
	Within Groups	57984.381	147	394.452		
	Total	58289.082	148			
Total Knowledge Score	Between Groups	2.568	1	2.568	.941	.333
	Within Groups	553.919	203	2.729		
	Total	556.488	204			
"IDK" Index	Between Groups	.021	1	.021	.013	.910
	Within Groups	336.155	203	1.656		
	Total	336.176	204			

Key Findings by Study Aims

The following section includes a sequential description of analyses performed on study data. Except as explicitly noted, these analyses include only those defined in the *a priori* analytic plan, which was defined to align with the research questions and specific aims outlined in Chapters 1 and 2.

Univariate statistics, tests for normality, and background relationships between major IVs & DVs. Table 4.12 provides univariate statistics of relevant study measures. All major continuous variables, including age, number of months since implant, the HADS anxiety and depression subscales, treatment knowledge scores, and all but one informational history composite scales revealed skewness & kurtosis scores below +/-2, implying suitable normality for parametric testing (George & Mallery, 2010). SE-ICD revealed a kurtosis value of 2.07, further highlighting the need for caution when interpreting models including self-efficacy. Similarly, the marginally peaked observed distribution of scores in reported use of online medical information requires caution when interpreting parametric tests. However, reported use of online medical information was subsequently used in ANOVA tests to address the first specific aim, a procedure that is characterized by a unique robustness against the impact of kurtosis (Glass, Peckham, & Sanders, 1972). This robustness, coupled with a conservative post-hoc analysis approach in associated ANOVAs (the Bonferroni correction) lends a degree of credibility to the specific analyses described herein. In light of its dramatically peaked distribution, the “IDK Index” remains an experimental and artifactual measure that is not included in any predictive models or parametric tests.

Two statistically significant bivariate relationships were found within the continuous variables shown in Table 4.13. The ICD knowledge score revealed both a weak and negative association with age (r=-.179, p=.010), and a weak and positive relationship with QOL (r=.149, p=.033). Contrary to theory, time since implant was not significantly related to ICD knowledge, as assessed both by bivariate correlation and by one way ANOVA with time since implant (divided into quartiles) acting as the independent grouping variable. Nearing statistical significance, and consistent with the logical notion that older participants may have had their devices longer, was the relationship between age and months since the ICD was first implanted (r=-.137, p=.051).

Table 4.12
Descriptive Statistics for Study Measures, n=205

	Min.	**Max.**	**M**	**sd**	**Skewness**	**Kurtosis**
Age	23	90	60.70	14.532	-.610	-.086
Months Since Implant	3	208	71.48	44.002	.924	.244
HADS - Anxiety	0.0	12.0	14.09	3.2481	-.521	-.553
HADS - Depression	0.0	12.0	15.16	2.7168	-1.001	.411
KCCQ Summary	9.9	93.8	68.52	16.9036	-1.156	1.391
KCCQ QOL	0.0	62.5	38.54	14.66	-1.142	.343
ICD Knowledge	0	9	6.56	1.6516	-1.134	1.697
SE-ICD	29	154	129.06	25.24782	-1.450	2.070
IDK Index	0	9	.863	1.2837	2.378	8.432
Informational History Subscales						
Conversations w HCPs	2.00	10.00	7.85	1.84156	-.783	.306
Paper Patient Info	2.00	10.00	4.68	1.88692	.658	.190
Online Patient Info	3.00	15.00	4.71	2.36367	1.722	3.154
In-Person Meetings	2.00	10.00	3.34	2.15558	1.641	1.745

Table 4.13

Observed Relationships Between Major Study Independent & Dependent Variables

		Age	**Months Since Implant**	**KCCQ Summary**	**ICD Knowledge**
Age	Pearson Correlation	1	.137	.060	-.179*
	Sig. (2-tailed)		.051	.393	.010
	N	205	202	205	205
Months Since Implant	Pearson Correlation	.137	1	.011	.099
	Sig. (2-tailed)	.051		.879	.160
	N	202	202	202	202
KCCQ Summary	Pearson Correlation	.060	.011	1	.149*
	Sig. (2-tailed)	.393	.879		.033
	N	205	202	205	205
ICD Knowledge	Pearson Correlation	-.179*	.099	.149*	1
	Sig. (2-tailed)	.010	.160	.033	
	N	205	202	205	205

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

Findings are presented by Study Aims below.

Aim 1: To identify the type of informational media used by patients to learn about ICD treatment.

As shown in Table 4.14, basic descriptive statistics were used to describe participants' reported use of different types of informational media. . Note that raw informational media data were used, rather than imputed data utilized in other analyses. Patients reported receiving much more information from their doctors (m=4.19, sd=.963), ICD nurses (m=3.65, sd=1.142), and paper device brochures (m=3.00, sd=1.196) than from any other media. Nearly all patients received at least some information form their doctors and ICD nurses (98.0% and 95.0% respectively), and all but three forms of media (conversations with mental health professionals, online videos made by patients, and others [not directly assessed]) were reportedly used by at least 20% of respondents.

Table 4.14
Descriptive Statistics for Reported Informational Media Use, All Ranges = 1-5

	n	**M**	**sd**	**% used***
Conversations with my doctor	203	4.19	.963	98.0
Conversations with my ICD nurse	202	3.65	1.142	95.0
Advice from people who aren’t healthcare professionals (like family/friends)	200	1.65	.965	41.0
Conversations with a mental health professional (like a social worker or psychologist)	203	1.25	.690	14.8
Paper brochures about ICDs (from hospitals or device companies)	203	3.00	1.196	86.7
Paper newsletters	201	1.67	1.021	37.3
Online newsletters	202	1.50	.916	29.2
Web sites about ICDs where I couldn’t ask questions (like WebMD)	202	1.77	1.105	38.6
Web sites where I could ask questions (like message boards)	203	1.39	.913	20.2
Online videos made by other patients (like YouTube videos)	203	1.21	.634	12.8
Online videos made by professionals (like doctors, hospitals, device companies)	203	1.52	1.011	26.6
In-person support groups about ICDs	203	1.64	1.154	29.6
In-person educational meetings about ICDs	203	1.69	1.175	31.5
Other	160	1.36	.920	16.2

* “% used” represents the valid percent of respondents indicating they received at least some information from each source

Next, to identify differential use of information media long age, education, and racial group lines, three separate one–way analyses of variance (ANOVAs) were used. Age quartiles, educational attainment, and race served as independent variables, with scores on each informational media factor acting as dependent variable for the analyses. Each ANOVA was run with Bonferroni ad hoc analysis for multiple comparisons. These results speak to the relative differences in use of various informational media among demographic groups in this sample of ICD patients.

With respect to age, only two significant mean effects for age quartile within the sample were observed; both of these findings pertained to use of online patient information. Use of these resources was significantly different between the youngest age quartile (those under the age of 52.5) and the oldest (those aged over 71.5) (p=.015). Similarly, the second age quartile (those between the ages of 52.6 and 64.0 years) differed significantly in their reported use of these resources from the oldest quarter of participants (p=.047).

Informational media use did not differ by educational attainment or race. Initial mean difference results indicated a difference in use of online patient information between participants with an advanced degree and those with more education than high school, but less than an advanced degree (including Bachelor's degree holders). However, this difference did not meet the Bonferroni-adjusted p value (p=.092).

Aim 2: To assess the relationship between use of healthcare providers as the primary source of medical information and level of ICD treatment-specific knowledge.

Hypothesis 1) Having received information from healthcare providers will be positively related to levels of treatment-specific knowledge. To assess the relationship between receipt of information from healthcare providers and treatment knowledge, a Pearson product correlation between the Conversations with Healthcare Providers composite scale score and treatment knowledge was produced. This analysis provided evidence of a statistically significant, weak-to-moderate relationship between having received information from healthcare providers and score on the treatment knowledge questionnaire (r=.229, p<.01).

Hypothesis 2) Older patients will have lower treatment-specific knowledge than younger patients. Pearson product correlation results indicate that there was a small, negative, yet statistically significant relationship between age and ICD treatment knowledge (r=-.179, p=.01). To further examine this relationship, ICD treatment knowledge scores for the highest and lowest age quartile subsamples were compared using an Independent samples T-test. Findings revealed a main effect for age quartile in terms of ICD treatment knowledge score, with the youngest quarter of the sample (those 52.5 years of age and younger) scoring significantly higher (M=6.94, sd=1.80) than the oldest participants (those 71.5 years of age and older; M=6.02, sd=1.70).

Aim 3: To examine the relationship between ICD treatment-specific knowledge and QOL and mental health outcomes among study participants.

Hypotheses: 1) Treatment-specific knowledge will be positively related to improvements in QOL and mental health outcomes. 2) Self-efficacy associated with ICD treatment will moderate the relationship between treatment-knowledge and QOL. OLS regression methods were used to assess the impact of independent variables on patient QOL (as separately assessed by scores with the KCCQ's Summary Score and QOL subscales), with an *a priori* focus on the contribution of treatment knowledge to this construct. Other independent variables included in the described models were broken down into four conceptual areas, derived logically and through their relationship to previous literature addressing QOL among ICD patients. These areas included demographic information (participant age, gender, whether they identify as Caucasian, and annual household income), experiences related to ICD treatment (ICD indication, reported history of ICD shocks, & months since ICD was first implanted), mental health variables (depression and anxiety, both as assessed by the HADS), and study variables of interest (treatment knowledge and self efficacy [as assessed with the SE-ICD and modified as discussed earlier]).

Two separate variable modifications were conducted to accommodate these models. In terms of KCCQ Summary Score, patients in this sample who reported having been shocked more than five times (M=65.28, sd=17.982) did not significantly differ from patients who had been shocked less (M=68.99, sd=16.742). However, scores on the KCCQ QOL Subscale revealed that patients who were shocked five or more times (M=33.17, sd=16.180) scored significantly worse (p=.045) than those who were shocked less than five times (M=39.32, sd=14.311). These findings, while highlighting the unresolved and often contradictory role of shocks in QOL (Dunbar, Dougherty, Sears, Carroll, Goldstein, Mark, ... & Zeigler, 2012), required a more inclusive definition of patients who were likely to have been impacted by the shock experience. Therefore, reported history of being shocked was coded dichotomously for patients who had been shocked (n=76, 37.1% of respondents) and those who had not (n=129, 62.9% of respondents) for subsequent use in regression models.

Additionally, while annual household income was assessed categorically, for the purposes of regression analysis, this variable was coded dichotomously according to whether participants reported earning more or less than $60,000 per year. This cutoff point was chosen so as to maximally balance the size of the two defined groups, with 113 participants (58.2% of valid total) reporting annual income below $60,000 and 81 participants (or 41.8% of valid total) reporting income above that point.

Multivariate Results

Preliminary analyses were conducted to assess the characteristics of the data, including univariate statistics of each included variable (Table 4.12) and bivariate correlations between and among predictor/control variables (Table 4.15). As discussed above, study variables were deemed to be sufficiently normally distributed to allow for parametric testing without transformation.

Bivariate correlations between independent and control variables were used to assess whether the assumption of independence would be met in subsequent models. While several significant correlations were found between these variables, only three were of sufficient strength to arouse concern with respect to multicollinearity. These associations included anxiety and depression ($r=.478$, $p<.01$), self-efficacy and depression ($r=.628$, $p<.01$), and anxiety and self efficacy ($r=.494$, $p<.01$). These relationships stand on both practical and theoretical grounds, and it stands to reason that they may share a considerable amount of variance when modeling impact on QOL. While none of these variables will be transformed, considerable caution will be exercised in interpreting these models.

Table 4.15
Bivariate Correlation Products Between Model IVs

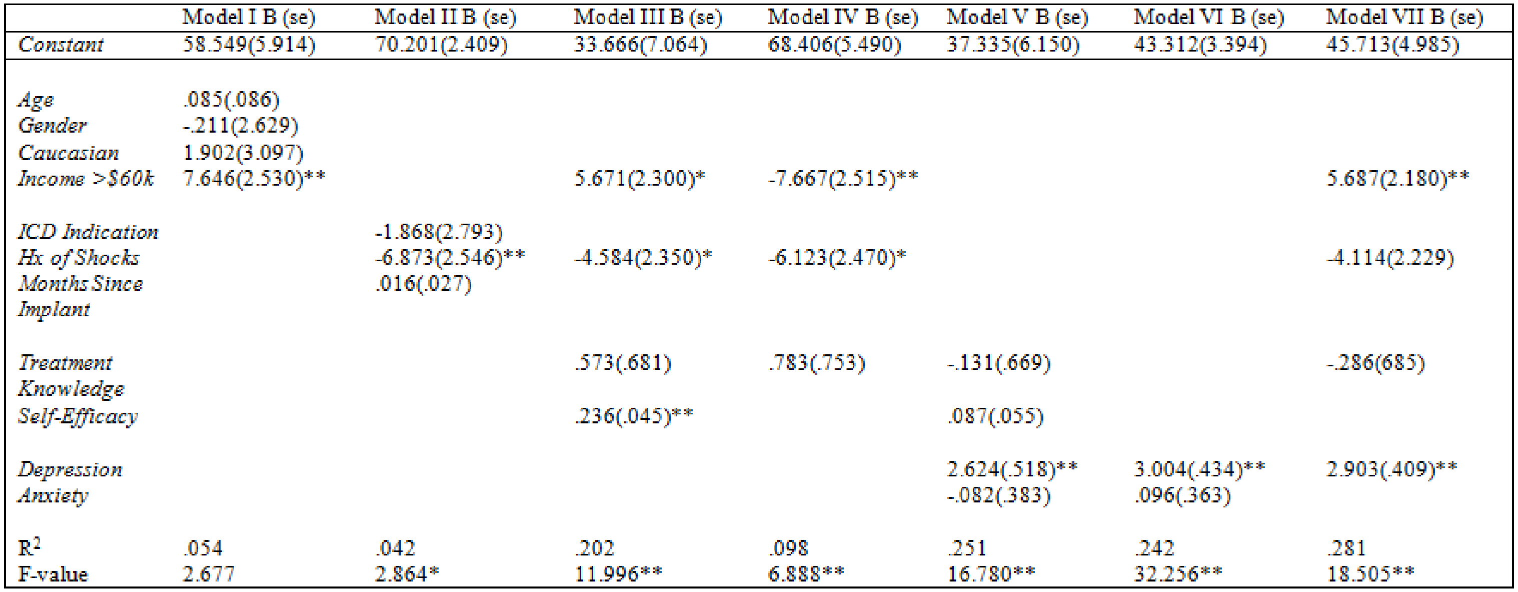
Age										
Gender	.153*									
Caucasian	.034	.052								
Income >$60k	-.114	.123	.128							
ICD Indication	.020	-.056	-.040	.075						
History of Shocks	-.022	.105	.030	-.057	.156*					
Months Since Implant	.137	.009	.040	.089	.038	.147*				
Treatment Knowledge	-.179*	-.042	.308**	.140	-.043	-.016	.099			
Self Efficacy	.085	.039	.193**	.118	-.078	-.123	.022	.257**		
Anxiety	.348**	.064	.152*	-.073	-.096	-.199*	.004	.041	.494**	
Depression	.076	.057	.139*	.108	-.092	-.145*	-.021	.305**	.628**	.478**

*p<.05, **p<.01

Table 4.16 illustrates a multiple linear regression analysis that was first conducted to determine the relative contributory value demographic control variables have on the KCCQ Summary Score. As observed in Model I, only having a reported annual income greater than $60,000 was significantly related to the KCCQ Summary Score among this patient group, with this level of income revealing a more than 7 point increase in QOL score (B=7.646, p<.01). Perhaps conflicting with previous research were findings that age, gender, and being Caucasian were not significantly related to QOL, and a model including all of these variables accounted for only 5.4 percent of the variance in KCCQ Summary Scores. Findings related to ICD treatment experience variables in Model II were similar as only a reported history of having been shocked was significantly related to KCCQ Summary Scores, with having been shocked predicting relating to a 6.8 point reduction in QOL (B=-6.873, p<.01).

Table 4.16

OLS Regression Models Associating With KCCQ-12 Summary Scores



	Model I B (se)	Model II B (se)	Model III B (se)	Model IV B (se)	Model V B (se)	Model VI B (se)	Model VII B (se)
Constant	58.549(5.914)	70.201(2.409)	33.666(7.064)	68.406(5.490)	37.335(6.150)	43.312(3.394)	45.713(4.985)
Age	.085(.086)						
Gender	-.211(2.629)						
Caucasian	1.902(3.097)						
Income >$60k	7.646(2.530)**		5.671(2.300)*	-7.667(2.515)**			5.687(2.180)**
ICD Indication		-1.868(2.793)					
Hx of Shocks		-6.873(2.546)**	-4.584(2.350)*	-6.123(2.470)*			-4.114(2.229)
Months Since Implant		.016(.027)					
Treatment Knowledge			.573(.681)	.783(.753)	-.131(.669)		-.286(685)
Self-Efficacy			.236(.045)**		.087(.055)		
Depression					2.624(.518)**	3.004(.434)**	2.903(.409)**
Anxiety					-.082(.383)	.096(.363)	
R^2	.054	.042	.202	.098	.251	.242	.281
F-value	2.677	2.864*	11.996**	6.888**	16.780**	32.256**	18.505**

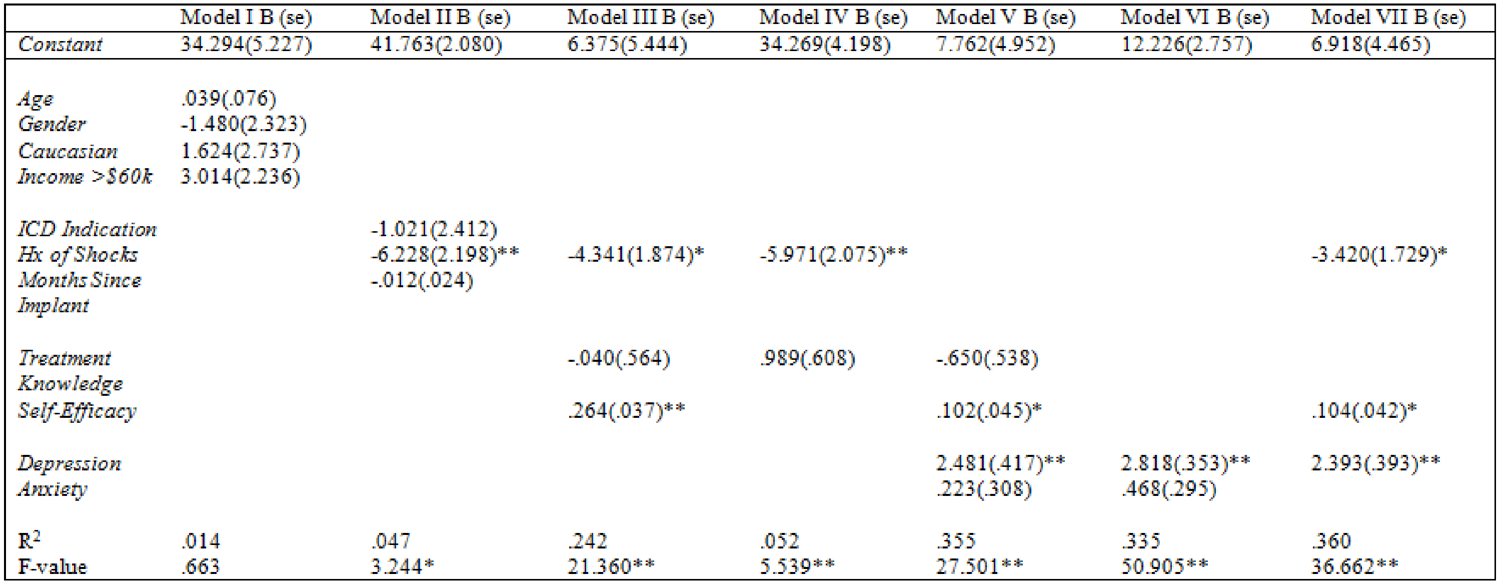
*p<.05, **p<.01

Assessing the total value of each OLS model is complicated both by contrasting characteristics and at least one clear instance of multicollinearity in the data. For example, Model III is advantaged by a maximal value of parsimony, a predominance of statistically significant factors, and a comparatively moderate coefficient of determination. The R^2 for this model was .202, indicating that the variables included in this model accounted for 20% of the variance in KCCQ Summary Score. In this model, annual income above $60,000 was related to more than a 5-point increase on the KCCQ (B=5.671, p<.05). Having a history of shocks (B=-4.584, p<.05) and a 1-point increase on the self-efficacy measure (B=.236, p<.01) were associated with a 4.5-point decrease and .2 increase in KCCQ Summary Score respectively.

Meanwhile, Model VII features an R^2 of .281, meaning that its variables accounted for 28.1% of the variance in KCCQ Summary Scores. Given the level of under-specification present in these models - evidenced by 28.1% being the greatest amount of variance accounted for in any one - the 8% difference observed between Models III and VII is substantial. In addition to a greater coefficient of determination, Model VII includes measures of income greater than $60,000 (B=5.687, p<.01) and history of having been shocked (B=.236, p=.073). The inclusion of a measure of depression in this model is important because depression appears to share a large proportion of variance, as evidenced by its impact on variable slope coefficients across models, including reducing the observed significance of both history of shocks and self efficacy and "flipping the sign" of the slope of treatment knowledge between Models IV and V.

Table 4.17

OLS Regression Models Associating With KCCQ-12 QOL Subscale Scores



	Model I B (se)	Model II B (se)	Model III B (se)	Model IV B (se)	Model V B (se)	Model VI B (se)	Model VII B (se)
Constant	34.294(5.227)	41.763(2.080)	6.375(5.444)	34.269(4.198)	7.762(4.952)	12.226(2.757)	6.918(4.465)
Age	.039(.076)						
Gender	-1.480(2.323)						
Caucasian	1.624(2.737)						
Income >$60k	3.014(2.236)						
ICD Indication		-1.021(2.412)					
Hx of Shocks		-6.228(2.198)**	-4.341(1.874)*	-5.971(2.075)**			-3.420(1.729)*
Months Since Implant		-.012(.024)					
Treatment Knowledge			-.040(.564)	.989(.608)	-.650(.538)		
Self-Efficacy			.264(.037)**		.102(.045)*		.104(.042)*
Depression					2.481(.417)**	2.818(.353)**	2.393(.393)**
Anxiety					.223(.308)	.468(.295)	
R^2	.014	.047	.242	.052	.355	.335	.360
F-value	.663	3.244*	21.360**	5.539**	27.501**	50.905**	36.662**

*p<.05, **p<.0

Similar to the dynamic observed in the models associating with KCCQ Summary Scores, and counter to extant literature on the topic, none of the demographic variables included in Model I were significantly related to participant scores on the KCCQ QOL Subscale (Table 4.17). All four of these variables (age, gender, identifying as Caucasian, and annual income greater than $60,000) combined for only 1.4% of variance on QOL Subscale scores, leaving 98.6% unexplained in an overall model that was not statistically significant (F=.663, p=.618). Also similar to the models addressing Summary Scores were the observed relationship to treatment experience variables (Model II), with specific attention paid to the observed value of reported history of shocks, which reduced QOL scores by more than 6 points (B=-6.228, p<.01). Model II also suffered from massive underspecification, accounting for only 4.7% of variance in QOL Subscale Scores, leaving 95.3% unexplained.

Models V through VII proved to be slight improvements over the corresponding models in the previous analysis, with Models V and VII accounting for 35.5% and 36% of the variance in QOL scores respectively. This finding may be explained by the significant variation attributable to depression (B=2.393, p<.01 in Model VII) and history of shocks (B=-3.420, p<.05). Model VII is again advantaged by maximal parsimony, inclusion of only statistically significant relationships to QOL subscore, and a comparatively high coefficient of determination. In this model, having been shocked at least once is associated with a nearly 3.5 point decrease in QOL score, while a one-point increase on the HADS Depression Subscale is associated with a 2.3 point increase. It bears noting that issues related to possible multicollinearity related to depression persisted in these models, including problematic bivariate correlations with anxiety and self efficacy, reducing the explanatory value of history of shocks between Models IV and VII, and again “flipping the sign” of the slope coefficient of treatment knowledge between Models IV and V.

No significant effects were found for treatment knowledge with respect to either the KCCQ QOL Subscale or Summary Scores. As such, no analysis for an interaction with self-efficacy was conducted. In Model VII, however, self-efficacy was significantly related to QOL scores ($B=.104$, $p<.05$); however, a 1-point increase on the self-efficacy measure yielded only a .1 increase in reported QOL.

Chapter Summary

Findings from both the project’s pilot and main survey of implanted defibrillator patients were presented. Exploratory analysis of factors underlying responses to the new informational media history measure was described, resulting in the creation of four subscales for use in later analysis. Measures undertaken to ensure integrity of the data used were discussed, including a missing data analysis for all study measures and description of imputation procedure. A sequential discussion of major findings for each study aim and hypothesis was also presented.

These analyses moved through defining the presence or absence of theoretical relationships between informational media use and demographic groups, treatment specific knowledge and informational media use and age, and finally two separate multiple regression analyses predicting related QOL outcome measures. Study findings and implications for social work policy, practice, and research, as well as study limitations are discussed in the final chapter.

Chapter 5: Discussion

The final chapter begins with a summary of the study described herein, including research questions identified in Chapter 1, specific aims derived from the literature review found in Chapter 2, and an overview of survey and analytic methodology used. Results from Chapter 4 are discussed within the theoretical context described in the first two chapters. This discussion will focus on how findings from the main survey contribute to the evidence base surrounding ICD care, including relationships observed between informational media use, treatment knowledge, and QOL measures. Implications for future research and policy will be noted alongside a discussion of the project's methodological and practical limitations.

Summary of Study Problem & Methodology

Due to advancing medical and technological sophistication, social workers employed in health care venues and elsewhere are increasingly encountering patients with complex psychosocial needs, often including potential threats to quality of life (QOL) posed by these same technological medical therapies. A clear example of the care process challenges posed by highly effective and technologically sophisticated treatments is the implantable cardioverter defibrillator (ICD). ICDs have become a popular first-line treatment option for patients at risk of both primary and secondary cardiac arrest over the last two decades, and the use of ICDs as a primary treatment for cardiac problems is expected to increase in-line with the older adult population and incidence of cardiovascular disease (Kramer et Al. 2015). While widely recognized for their lifesaving capabilities (AVID Investigators, 1997; Greenberg, Case, Moss, Brown, Carroll, & Andrews, 2004), psychosocial problems persist among a subset of patients being treated with these devices (Irvine et al., 2002; Sears, Todaro, Lewis, Sotile, & Conti, 1999). Problems of quality of life QOL in this patient population include anxiety, depression, and activity restriction (Dougherty, Benoliel, & Bellin, 2000), as well as increased risk of hospitalization (Goldenberg et. al, 2006), and suffering near the end of their life (when the device has not been deactivated) (Goldstein, Lampert, Bradley, Lynn, Krumholz, 2004).

Many of these risks to QOL and human dignity are disproportionately borne by members of historically disadvantaged groups, including older patients (Hamilton & Carroll, 2003), African Americans (Wilson, Engelke, Sears, Swanson, & Neil, 2012), women (Thylén, Dekker, Jaarsma, Strömberg, & Moser, 2014), and patients with a history of life-threatening cardiac events (Pedersen, Hoogwegt, Jordaens, & Theuns, 2013). Prior studies indicate that not only do older patients experience somewhat higher anxiety and greater levels of dissatisfaction with their functional abilities than younger ICD patients, but that these issues more commonly improve among younger patients as well (Hamilton & Carroll, 2003). Complicating the risk assessment calculus for QOL decrements, a recent expert consensus addressing mental health-related QOL reported that patients are only at risk of decrements to QOL if they experience five or more shocks or are subjected to device recalls (Dunbar, Dougherty, Sears, Carroll, Goldstein, Mark, ... & Zeigler, 2012). This assertion supports the theory that QOL problems are also the result of conditioned responses to adverse events.

Processes meant to help inform ICD patients about their device, its capabilities and risks, and what to expect from treatment are imperfect; this is supported by the accounts of who report not knowing fundamental questions of fact related to their ICD. Recent findings suggest that patients generally do not understand the clinical limitations of ICD treatment (Stewart et al., 2010), are unaware of alternative or adjunctive treatment options (Matlock, unpublished data), or do not know that their doctors can deactivate or otherwise reprogram their device should they ask them to do so (Goldstein et al., 2008). Given the opportunity to do so, a proportion of patients fail to understand many aspects of their medical treatment (Knoepke, Sung, & Matlock, 2014). These gaps in patient knowledge may be insignificant were it not for evidence indicating that outcome expectations and understanding of treatment are malleable and important to include in post hoc interventions meant to improve QOL among patients (Sears, Serber, Lewis, Walker, Conners, Lee, et Al, 2004; Sears, Vasquez Sowell, Kuhl, et.Al., 2007).

The question of which informational venues patients acquire information about ICD treatment remains primarily unresolved, however. The recognition that patients' informational needs and preferences will differ is both directly and tacitly acknowledged in extant literature. Directly, the evidence supporting the efficacy of varied specific psychotherapeutic interventions (Sears, Sowell, Kuhl, Kovacs, Serber, Handberg ... &

Conti, 2007; Frizelle, Lewin, Kaye, Hargreaves, Hasney, Beaumont, & Moniz-Cook, 2004; Kuhl, Sears, Vazquez, & Conti, 2009) illustrates a salutary effect of customized support on mental health and quality of life outcomes as well as acceptance of device treatment. Tacitly, the existence of such varied materials and care processes as conversations with care providers, device manufacturer-developed brochures, newsletters, support groups meeting both in person and online (Dickerson, 2005), internet message boards (Knoepke, 2012), and manualized psychosocial therapies for patients experiencing problems (such as the three cited above) would suggest a perception among device manufacturers, patient advocates, and care providers that availability of differing media will increase access and acceptability to patients with diverse needs. Serber and her colleagues (2009) directly described group-based preferences for information and support media among ICD patients, including effects for race, ethnicity, and age, but did not assess for differences in patient treatment knowledge or quality of life associated with these preferences or demographic indicators.

In view of these concerns, the purpose of this study was to expand current knowledge about QOL and mental health concerns among this patient group, while concurrently beginning a description of how accurately patients understand their device therapy, and where they reported acquiring information about treatment. Data were collected via a cross-sectional survey of device patients receiving care for their devices through the University of Colorado Hospital in Aurora, Colorado.

Survey materials included like versions of both online and paper forms in the hope that more than one format would maximize rate of return. After removing data from respondents who were not being treated with an ICD, the sample included 205 patients. This sample was comparatively remarkable for its sociodemographic diversity, with a mean age of 60.7 years (sd=14.53), a 34.1% female representation, 10.2% African American representation, and 37.5% of the sample reporting an annual household income of less than $40,000. Study measures included two new informational media history and treatment knowledge questionnaires (created as part of this project). The *Hospital Anxiety & Depression Scale* (HADS: Bjelland, Dahl, Haug, & Neckelmann, 2002), *Self-Efficacy Expectations in ICD Treatment* questionnaire (SE-ICD: Dougherty, Johnston, & Thompson, 2007), *Florida Patient Acceptance Scale* (FPAS: Burns, Serber, Keim, & Sears, 2004), and the *Kansas City Cardiomyopathy Questionnaire, Short Form* (Green, Porter, Bresnahan, & Spertus, 2000) were also used in the study.

Review & Discussion of Key Findings

Study processes and analyses were driven by three separate specific aims. In the section that follows, findings related to each of these aims (and associated hypotheses, where applicable), will be reviewed and discussed in an effort to contextualize their value to the literature addressing QOL and patient education among ICD patients. Finings from additional *post hoc* analyses will be included and noted, as will a discussion of findings related to the measures created in this project.

Specific Aim 1: to identify the type of informational media used by patients to learn about ICD treatment. The first aim sought to describe information acquisition behavior among a sample of defibrillator patients in greater detail than in extant literature, as defined through self-reported use of various forms of informational media. Findings related to use of such media came in both surprising and unsurprising forms. Clearly, patients indicate that they receive the greatest amount of information about their treatment in conversations with their healthcare providers. This is not surprising given the physician-centric models of patient education and informed consent processes that dominate the clinical landscape. Troubling, however, were findings pointing to the lack of consistent reported information acquired from conversations with social work and other mental health professionals. Elevated levels of psychosocial distress reported among respondents (discussed below) translate to an increased likelihood that these individuals have sought assistance from mental health professionals. Despite this probability, participants reported receiving very little information from these sources. This outcome may have been predictable given the relative paucity of formalized training provided to social work and other MH professionals in working with patients being treated with complex medical therapies (Knoepke & Johnson-Koenke, *in press*). Regardless, it represents an area that requires further attention.

More surprising was the relative popularity of some other forms of informational media. Serber and colleagues' description of group-based support preferences (2009) reported a generalized preference for direct communication with healthcare providers among defibrillator patients, especially older and female patients. Reported media use by participants in this study strengthen Serber's claims, while also illustrating patterns in media use specifically by patients cared for through UCH. For example, all but three of the informational media assessed were reported to have provided less than “some information” to patients on average. However, at least 10% of respondents reported receiving at least some information from each medium. The fact that 16.2% of respondents reported having received information from a medium not addressed in the measure buttresses the notion that the informational media questionnaire may benefit by including more informational media items (discussed below). In addition to the explicit inclusion of social media as a possible source of information, notes left by participants on paper surveys included academic journal articles and device company websites as sources of information which had provided them with some level of information about their ICDs, and should thus be included in later iterations of the measure.

Study findings revealed that the oldest quartile of participants reported receiving significantly less information from online sources than respondents from the youngest two quartiles. *Post hoc* analyses to test whether these two groups differed in the number of informational mediums through which they received treatment knowledge revealed that youngest patients reported having used more than two additional mediums on average (of 14 possible) to learn about their defibrillator (M=7.33, sd=2.76) than the oldest quartile (M=5.10, sd=2.77; t(100)=4.08, p>.001). Therefore, it is possible that differences in treatment knowledge observed between age groups may be attributable to a more broad informational acquisition process by younger ICD patients. Whether use of more and differing media is an artifact of generational comfort/familiarity with technology or a true definitional shift in what is expected of people in their roles as patients (Parsons & Fox, 1952), information acquisition behavior occurring outside the medical consultation deserves greater attention in the health communication literature.

Specific Aim 2: to assess the relationship between use of healthcare providers as the primary source of medical information and level of ICD treatment-specific knowledge. Findings from the hypothesis that patients who reported receiving greater amounts of information from healthcare providers would also score more highly on the treatment knowledge measure generate two points are of particular interest to social workers. First, while the observed correlation between these two constructs was relatively low (r=.229), it was stronger than many other observed relationships in the study. Second, the provision of knowledge by healthcare providers, while systematically complex and difficult to define, is likely more malleable than many other study constructs Implications for priorities in social work intervention research abound, especially with respect to the venues and forms in which these interventions should occur, and are discussed at greater length later in this chapter.

As mentioned above, a consistent relationship emerged between age and treatment knowledge was observed. The oldest patients in this sample - those with the highest likelihood of clinical comorbidities requiring conscientious management - scored significantly lower on the treatment knowledge measure than the youngest patients. This finding may relate to greater effort made to learn about the device through media other than the medical encounter (Knoepke & Lutfey, in review), including the use of online resources. Further, this finding elucidates a need by social work and health communication scholars to focus on the specific informational needs of older patients, despite their lack of explicit inclusion as a vulnerable population in the Common Rule (U.S. Department of Health and Human Services, 2009).

Specific Aim 3: to examine the relationship between ICD treatment-specific knowledge and QOL and mental health outcomes among study participants. To adequately assess the potential contribution of treatment knowledge to QOL in this sample, it is important to accurately characterize QOL's relationship to other variables in the dataset. With respect to elevated anxiety among ICD patients, the dominant explanatory theory in extant literature supports the idea of conditioned responses to the defibrillator shock as an adverse event. This proposition was not fully supported in the study's findings as the mean difference in HADS Anxiety subscale scores did not significantly differ between patients who had been shocked more than five times when compared to those who had been shocked less. However, it did differ between patients who had been shocked at all versus those who had not been shocked. This difference was also observed with respect to depression, and both the KCCQ's QOL subscale and Summary Score. These findings point to supporting the contribution of shock experience to QOL among ICD patients. However, they are tempered by the fact that indicators of depression in statistical models subsumed the variance in KCCQ scores -theoretically attributable to shock experience -. As discussed at greater length below, this may indicate the presence of multicollinearity in this dataset, and perhaps a need to retest these relationships with better-specified models. If additional analysis can determine whether disease severity influences the inter-relationship between QOL, experience of shocks, and mental health, it would then be possible to investigate the relative value of anxiety to

QOL, perhaps identifying opportunities for traditional social work intervention with this patient group.

Indication for ICD therapy did not significantly contribute to QOL scores in this dataset. While this finding is consistent with much of the extant literature (e.g. Sweeney, Wathen, Volosin, Abdalla, DeGroot, Otterness, & Stark, 2005) it is theoretically counter to any trauma-informed conceptualization of the development of these problems among patients. Theoretically, indication for ICD therapy should act as a functional proxy for patient experience of trauma associated with their heart disease or treatment (since patients whose ICD is indicated “secondary” have to have experienced “sudden cardiac death”, syncope, or sustained ventricular tachycardia). The fact that a similar result was not found in this study, (or for anxiety and the experience of having been shocked,) may illustrate a need to conceptualize trauma associated with ICD therapy as occurring elsewhere in the treatment trajectory. Absent the impact of life threatening cardiac events (indication), or anxiety and depression as conditioned responses to adverse therapeutic experiences (defibrillator shocks), the next logical points of universal patient trauma are either implantation surgery or the diagnosis of heart disease itself. If investigated, these points on the treatment trajectory provide excellent opportunities for social work interventions.

New Treatment Knowledge & Informational Media Measures.

Treatment Knowledge. The finding that treatment knowledge was only weakly related to QOL and mental health measures provides some context for understanding the challenges that Burns and his colleagues encountered while developing the FPAS (Burns, Serber, Keim, & Sears, 2004). By defining patient “acceptance” of device therapy both along the lines of “derivation of benefit” and “understanding of the advantages and disadvantages” of treatment, Burns attempted to concurrently assess many of the same constructs assessed in this study. The fact that subjectively assessed treatment knowledge did not reliably converge with a variety of acceptance domains in their analysis is analogous to the current study’s finding that objectively assessed knowledge was only weakly related to QOL. Additionally, while the content of the treatment knowledge items were designed through a comprehensive process that included the inclusion of knowledge points identified in earlier research as lacking among ICD patients (e.g. Stewart, Weintraub, Pratibhu, Semigran, Camuso, Brooks, ... & Stevenson, 2010; Goldstein et al., 2008; Lewis, Stacey, & Matlock, 2014), subject matter expert construction, participatory action review and revision, and preliminary testing in the pilot study, it remains possible that these items do not represent the particular points of knowledge most relevant to patient adaptation to treatment or QOL.

Informational History. Stability is an issue to consider in the new informational media measure; two-item factors were used in these analyses and more than 15% of respondents indicated that they received at least some information from a source not included in the study’s scale. To address this limitation, future investigations into informational media history should develop a number of like items to test alongside those retained in this project, with a goal of increasing each factors’ reliability coefficient to at least .80. In addition to any others which may be specific to individual treatments or disease processes (e.g. information provided to breast cancer patients by advocacy organizations such as the Susan G. Komen Foundation), one area which was likely understudied in this project was the use of social media by patients.

It seems logical that patients may request information from others in their personal, professional, and affinity-related networks, including those mediated through technology (i.e. “social networks” such as Facebook, Instagram, Twitter, LinkedIn, etc.). In these interactions, patients may receive information, support, or referrals by a combination of healthcare providers, separately knowledgeable others, or those without claims to specific knowledge. Items assessing reported levels of information acquired through these reciprocal interactions may have been prone to load with a number of factors observed in this dataset, depending on patients other information acquisition behavior. For example, if the venue for using social media to seek out information is the primary behavioral driver for doing so, and patients who use social media are also likely to look up information through other web-based resources, such items would be likely to load with the “Online Patient Information” factor. If social media simply acts as a means of accessing geographically-disperse friends and acquaintances for the purpose of information gathering, they may load (and possibly strengthen the reliability of) the “Conversations with non-Healthcare Providers” factor eliminated during the described item analysis. Identification of other such venues of information will be critical to further refining and improving the viability of the informational media questionnaire for future research.

Finally, the next logical progression in the development of any process by which to describe the media through which patients learn about treatment should include substantial emphasis on the quality of information received through these channels. A recent study investigating the channels through which new mothers received advise about various parenting issues (Eisenberg, Bair-Merritt, Colson, Heeren, Geller, & Corwin, 2015) reported findings similar to those in this project; doctors and nurses were cited as the most frequent source of parenting information, with advice received from media reports and friends and family following behind. The authors further described the consistency of advice received through these sources with current American Academy of Pediatrics guidelines, finding persistent gaps in reception of advice regarding sleep positioning, use of pacifiers, breastfeeding, and other issues. Data and procedures used in the current study rendered it impossible to parse whether accurate information had been provided to patients, or by whom. While the most important gaps in ICD treatment knowledge are less apparent than those for new parents, the development of improved informational processes relies upon a sophisticated understanding of where and how patients are likely to receive poor information just as much as where useful information resides.

Limitations

This project was limited in several methodological and practical ways. These limitations include those imposed by using a cross sectional survey design, sampling procedures, response characteristics, and issues in measurement and resultant data. While every practical effort was made to minimize threats to validity of study findings, study findings should be interpreted within the context of these limitations.

Methodological limitations. The major methodological limitation of this project is the use of a single cross-sectional study to assess, by self report, constructs which all logically change over time, across the trajectory of treatment, and may be differentially experienced by patients with newer versus older devices. With respect to the reception of information from varied sources, it is both important to consider challenges in recollecting the precise source of knowledge which may have been obtained several years prior, or the quality of information available within the same source as assessed in this study (e.g. online newsletters logically come in various quality, and the information gathered from them may vary considerably). Under-specification of regression models also limited the ability to succinctly and specifically describe relationships between study variables. Each of these issues related in some way to the project design and were chosen in light of trade-offs: resource availability with respect to model under-specification and the time necessary to recruit and observe a cohort of patients over time with respect to the selection of a cross sectional survey design. These issues should be addressed both in future projects and, in some cases, by way of subset analyses within the current dataset (requiring the inclusion of additional patient data). This author intends to use this dataset and project as a starting point from which to expand and build future empirical investigations aimed at improving care processes for ICD patients.

Response rate & characteristics. Perhaps the greatest single limitation associated with findings emanating from analysis of the primary survey is the relative inability to estimate the representativeness or power of the sample, which comes secondarily from an inability to concisely define an overall response rate within the sampling frame of UCH device patients constructed by Dr. Raphael Sung. Increasing the overall rate of response and the possibility of nonresponse bias were consistent foci in this project, and this attention served as the driver of most participant recruitment decisions. Presenting participants with the option of completing materials either online or via paper and pencil offered a maximum of flexibility while acknowledging tacit preferences for administration which are often logically tied to generational groups and access to (and comfort with) the technology necessary to complete online forms, as well as the sociodemographic correlates of these constructs, including age, educational attainment, and income. Indeed, previous investigations into the use of multimodal administration options illustrates an improved diversity of the study sample and modest increases in response rate when alternating the sequence of media through which recruitment occurs (Stern, Bilgen, & Dillman, 2014). This suggestion actually countervails earlier findings from some of the same researchers, who observed reduced rates of response associated with multimodal administration when compared to paper-only (outlined in Millar & Dillman, 2011).

While it may certainly be the case that multi-modal distribution of participant surveys improved response rate and limited the possibility of nonresponse bias, the low number of surveys returned electronically was surprising to this author. Out of the 236 total surveys received (including those with incomplete data), only 40 were returned using the web-based interface, including only eleven who returned their survey by following a link embedded into a recruitment email (during the second wave of recruitment). Thus, only 16.9% of returned surveys were completed electronically, considerably lower than the 61.7% observed in a study comparing response rates between methods and within multi-modal recruitment (Greenlaw & Brown-Welty, 2009).

While the respondents in the Greenlaw and Brown-Welty investigation (2009) tended to be educated, literate, and technologically inclined, such a stark difference in the proportion of electronic responses observed in the current study is striking. Post hoc analyses revealed that the method by which participants returned their information was significantly related to age, annual household income, and educational attainment. Previous research has also shown an effect of labor force participation on the likelihood of online survey response (de Bernardo & Curtis, 2013), although this was not assessed in this project. With respect to challenges encountered by some patients attempting to access the online form, this author received three separate pieces of feedback (twice on returned paper surveys, and one phone call from a participant), indicating that they had unsuccessfully attempted to use the link to the electronic version of the survey. In each instance, this author attempted accessing the link on his own, and was successful each time. This suggests that a degree of technological naiveté among some potential participants, including those who did not eventually respond, which may have reduced their opportunity to do so. Given that web-based survey methods are increasing in favor among researchers in a number of areas, in part due to convenience and cost savings associated with their use (Schonlau, Ronald, & Elliott, 2002), further research into differential attrition attributable to demographic variables, whether multiple modes of survey administration affect response rate, and means by which to improve response rate among various vulnerable groups needs to be completed if this trend should spread further into health services research.

The observed rate of response for the study was 38.6%. While much lower than the widely debated 60% "rule of thumb" for general acceptability for publication in medical literature (Johnson & Wislar, 2012), this calculation may have underestimated the actual rate of response in this study. The primary reason for this is that it was not possible to completely assess for disqualification of ineligible participants, the net result of which is inclusion of an unknown number of individuals in the denominator who would otherwise not have been. Further, these issues compromised the investigator's ability to meaningfully conduct power analyses of the new measures created in this project (even though it was determined that such an analysis would not be necessary following the pilot trial). Challenges to calculating a more precise rate of response included:

1. Information about individuals appearing on the recruitment list was limited, and did not allow for a comprehensive exclusionary process. For example, no information addressing languages spoken by patients was available, rendering it impossible to accurately determine how many individuals communicate primarily in Spanish, Somali, Hindi, or other non-English primary languages common to the Denver Metro Area. Individuals who do not communicate in English would have experienced significant difficulty in responding to many survey items, and would thus be likely to simply discard survey materials. Given the underwhelming response from participants identifying as Hispanic, it would not be overly

pessimistic to surmise that this dynamic may have systematically affected response rate.

2. Similar challenges existed in identifying non-responders who were unable to complete survey materials or should have been disqualified due to a lack of medical decisional capacity secondary to medical conditions. While one response was received from a patient’s caretaker reporting that she suffered from advanced dementia, and one other was determined by happenstance during chart review, the number of other patients experiencing similarly limiting cognitive and/or communication problems could not be determined without a more expansive review of nonresponders’ medical charts (which was not allowed under this project’s IRB approval).
3. While a significant number of surveys were returned to sender without forwarding information, and those individuals were removed from the response rate denominator, the USPS system managing the return of mail sent to outdated addresses is imperfect. The fact that 25 were returned in the third wave of mailings and 16 in the fourth provides support for the notion that continued recruitment would have resulted in a greater number of surveys being returned to sender (while also possibly increasing the number of returned surveys).
4. Findings from this project’s pilot trial illustrated that the means by which potential participants were identified were similarly imperfect. During the pilot trial, four participants returned their surveys reporting that they did not have an ICD, but rather were only being treated with the pacemaker function of their

device (prompting changes to the language used in recruitment materials discussed in the previous chapter). The PACEART query (one of the electronic medical record system used by UCH for cardiac device patients) conducted by Dr. Raphael Sung completed prior to beginning the pilot trial was not able to distinguish between patients for whom the defibrillator function of their devices was being utilized or the patient was only being treated with pacemaker functionality. This issue notwithstanding, following analysis of pilot data, this author and the dissertation committee determined that it was appropriate to continue using the same list of patients under the rationale that over-identification of device patients was preferable to potentially systematically missing eligible patients being treated with certain device models or for particular medical indications. The IRB-approved chart review process (and associated waiver of informed consent) limited this author's ability to review medical charts to those participants who returned survey data, negating any ability this author would otherwise have to determine which patients should be removed from the participant pool, (and therefore the return rate denominator), post-hoc. To address this uncertainty, future publication-driven analyses of this dataset should include an IRB amendment allowing for an analysis of the types of devices implanted in responders and non-responders alike.

Problems with validated study measures. A few measurement-related limitations should also be noted. First, language used in the *Kansas City Cardiomyopathy Questionnaire* (KCCQ) may have been confusing to some patients. For example, a number of respondents indicated that they do not have “heart failure” in response to questions about how their disease had impacted their well being, leading a number of participants simply not to complete these items. While there was no detectable pattern to missing data points for either the fully Summary Score or QOL Subscale (as tested using Little’s MCAR Test), it would be advisable to use alternate forms in future investigations of QOL among cardiac disease patients who may not all identify “heart failure” as an issue which affects them, accurately or not.

Next, we experienced several problems with the Self Efficacy Expectations After ICD Implantation Scale (SE-ICD: Dougherty, Johnston, & Thompson, 2007). First, pilot trial data illustrated the potential for a “ceiling effect” (Devellis, 2011) and subsequent lack of variability in scale summary scores. Following consultation with the study’s supervisory committee, however, it was decided that this measure should be retained owing to a strong theoretical foundation between self-efficacy and QOL and mental health outcomes among other client/patient populations.

Potential effects of multicollinearity in regression models. The presence of multicollinearity in this data, especially among the depression measure and in selected variables considered to be highly conceptually and theoretically related, may have contributing to the under specification of statistical models reported in the study. Future analyses should consider this limitation. In addition, future studies should also account for the presence of psychiatric comorbidities (Godemann, Butter, Lampe, Linden, Werner, & Behrens, 2004; Thomas, Friedmann, Kao, Inguito, Metcalf, Kelley, & Gottlieb, 2006), use of cardiac resynchronization therapy (CRT) and disease severity

(Chen, Yin, & Krucoff, 2012). Given their empirically established relationship with QOL in this patient group, it may be possible that including such variables would pull some of the variance in QOL scores away from depression, thereby better specifying and stabilizing the predictive models more generally.

Implications for Social Work Policy & Research

Social workers in all service venues are increasingly involved in the care of people with chronic cardiac disease, including those being treated with sophisticated medical interventions, including ICDs. Treatments like these, provide excellent opportunities for social work interventions that may include patient education, support in self-determined medical decisions, and post-hoc interventions with patients experiencing distress. Unfortunately, a number of professional and political factors have combined historically to limit the availability of these interventions. For example, a lack of social work education and scholarship in the treatment of chronic diseases has likely contributed to a general paucity of trained social work practitioners in medical settings. In addition, inadequate reimbursement policies often actively discourage the use of social work services by medical care teams and practices. Implications for practice, policy, and future research are summarized below.

Findings regarding the variability of treatment knowledge among patients highlight the importance of patient educational materials and processes, as well as that of informed consent for treatment. Any lack of knowledge on the part of the patient logically serves to increase risk of adverse psychosocial and medical outcomes. Social workers must be involved in research and practice strategies that seek to improve treatment knowledge among medical patients. Furthermore, treatment knowledge should itself be considered an important and viable investigatory endpoint. The value of increasing patients' absolute level of understanding on moral, legal, and ethical levels is implied both in the definition of informed consent for ICD therapy (Melton v. Medtronic, 2010) and in the overlapping ethical imperatives of medicine (Beauchamp and Childress, 2001) and social work (NASW Delegate Assembly, 2008).

Mental health concerns were common problems among study participants; 39.5% of patients reported clinically significant anxiety and 58.0% reported clinically significant depression in this sample. While these rates are at the upper end of published population prevalence estimates for these problems (Sears, Todaro, Lewis, Sotile, & Conti, 1999; Heller, Ormont, Lidagoster, Sciacca, & Steinberg, 1998), such estimates are typically based on data gathered using diagnostic instruments (e.g. the PHQ-12, Beck Depression Inventory, etc.) that use more strict diagnostic definitions than the continuously-constructed HADS. The HADS has also never been formally normed on a group of device patients, opening up the possibility that it may also slightly overestimate the number of cases of clinically significant distress. Additionally, given limitations in accurately calculating rate of response (discussed elsewhere), it remains possible that individuals experiencing elevated levels of distress were more likely to respond to recruitment requests, increasing the proportion of those meeting the HADS sensitive diagnositc definitions for anxiety and depression.

All of these issues notwithstanding, there remains a clear need to improve the emotional well being of many defibrillator patients. Aside from age, there were no other demographic or experiential variables significantly related to mental health outcomes. This finding suggests that mental health problems may be related to device therapy rather than other social conditions. Since social workers provide the plurality of all mental health services in the United States (Mechanic, McAlpine, & Rochefort, 2013) and between 58-70% of ICD patients experiencing psychosocial distress never access therapeutic services (Hoogwegt, Kupper, Theuns, Zijlstra, Jordaens, & Pedersen, 2012), there exists a clear gap which social work professionals are primed to fill. Improved understanding of the social-ecological mechanisms that undergird problems experienced by ICD patients may provide opportunities for social work intervention beyond those already described in present literature (Knoepke & Johnson-Koenke, in press).

The finding that conversations with healthcare providers remained the most prominent source of information for patients in both the pilot and main survey samples reiterates the need to improve care processes that occur in specific context. One of the most common refrains encountered in social work training and education is to “meet clients where they are.” This principle seems to imply that defibrillator patients, both literally and figuratively, should be most easily “met” in healthcare offices. Ways in which social work interventions can be brought to these patients should then emphasize both the literal and figurative senses of this canard. To work effectively with patients, social workers should advocate for inclusion into provider teams, either by inclusion on multidisciplinary medical teams (such as would be expected of truly “integrated” healthcare (Butler, Kane, McAlpine, Kathol, Fu, Hagedorn, & Wilt, 2008), or in some other form.

Finally, social work scholars must take a proactive role in conducting research and contributing to the literature that composes the evidentiary basis of medical interventions. It bears noting that social workers in heart disease and other specialized medical settings have – within our own professional ranks – a model to follow in oncological social work. In this context, social work scholars interested in improving care and other outcomes for patients with cancer have developed or participated in studies addressing long-term psychosocial adaptation to cancer treatment (Ell, Nishimoto, Morvay, Mantell, & Hamovich, 2006; Dolgin, Somer, Buchvald, & Zaizov, 1999), social support-based interventions (Roberts, Piper, Denny, & Cuddeback,1997), agendas for the promotion of social worker on cancer care teams (Black, 1989) and in intervention research (Glajchen, Blum, & Calder, 1993; Christ & Sormanti, 2000; Kramer, Christ, Bern-Klug, & Franceour, 2005), systems-based conceptualizations of cancer (Davis-Ali, Chesler, & Chesney, 1993), and secondary trauma among oncological social workers (Cunningham, 2003). With this body of literature, execution of an evidence-based approach to social work practice in cancer care is far easier and likely more effective than one in cardiac care or invasive therapies. The existence of the cancer literature, however, provides opportunities from which to derive investigational methods and care processes. Bearing the extant literature in mind, with scaffolding provided by what has been accomplished with respect to social work interventions in the care of patients with cancer, this author proposes continuing a social work research agenda with a focus on patients being treated (or recommended for treatment) with an ICD and other invasive and highly burdensome technologies.

Since the care venue seemingly most apropos to this patient group is the medical care visit, (and, notably, not in conversations with mental health professionals), social workers seeking to improve care for ICD patients would be wise to eschew the well-worn path of creating extramural care processes for use in informing or supporting patients – including manualized, traditional psychotherapeutic protocols. Recent efforts to refine or improve such processes, which typically include between 3 and 8 patient contacts of extended duration, have suffered from attrition problems. When considered within the context of conversations with healthcare providers as an informational medium attrition problems observed in research trials (ex. “Mental Stress Reduction in Defibrillator Patients”, Clinicaltrials.gov ID#NCT00624520, Russell & Middleton - PIs) could be indicative of a preference for receiving information and support related to device treatment during regular interactions with healthcare providers as opposed to information received during separate psychotherapeutic interventions. If traditional psychotherapies were to be deployed on a broad scale to inform patients and intervene early in the development of QOL problems, issues of attrition may only increase, attenuating the efficacy of such interventions. An alternative is to advocate for social work scholarship that seeks to improve the relational, informative, and socio-emotional aspects of contacts between patients and their healthcare providers. Such interventions would avoid problems related to patient dropout, “turf conflict” between social workers and other non-physician professionals, and physician buy-in. It may also dramatically improve the scalability of interventions.

Another puzzling finding in the present study was both the comparative predictive strength health-related depression had on QOL and the direction of the relationship observed among this patient group. While examining differences in predictive utility across regression models, it becomes apparent that other patient characteristics may have the potential to influence QOL, including income and history of shocks (which, despite the unmalleable nature of these constructs, are certainly easily quantified for the purpose of screening patients for potential referral to low-level preventive interventions). The variance in QOL scores is consumed much more dramatically by depression, albeit in a seemingly counter-intuitive fashion as increases in depression predicted increased QOL.

Whether this counterintuitive finding is indicative of collinearity with – or moderated by - other factors not assessed in this project (including disease severity, presence of comorbid conditions, device features, or others) or is an artifact of this dataset, its presence should be seen as an opportunity to further examine the role depression plays in the formation of QOL issues among device patients. Absent further analyses, with better specified models and an *a priori* theory of the relationship between depression and QOL in these multivariate models, it is difficult to devise an approach meant to improve patient well being. An improved understanding of the dynamics of these relationships would lend credibility to such interventions, and the presence of empirically-derived interventions would logically expand the role and value of social workers on care teams specific to device patients.

Finally, while beyond the scope of the present investigation, a number of qualitative stories, anecdotes, and reports were brought to the attention of this author by participants and their families. These covered a number of topics and ranged in length and depth, but certainly indicate that a desire exists among at least a subset of this patient population to share the lived experience of device therapy. Future research utilizing qualitative and mixed strategies, analyzed using a variety of sociological, anthropological, and/or spiritual theories and frameworks could lead to an improved understanding of the varied impacts device therapy has on patients and their social systems.

Chapter Summary

Despite being an effective and popular intervention for the prevention of sudden cardiac death, implantable defibrillator treatment carries considerable risks to quality of life among patients. Demographic risk factors including age, being female, being African American and experiential risk like the experience of receiving multiple shocks and previous history of life-threatening cardiac events have been noted in previous studies. Educating patients about heart disease and their device therapy is a critical goal of interventions intended to mitigate quality of life decrements among this patient group, even in the absence of empirical evidence directly linking improved treatment knowledge to these outcomes. There are a number of materials and processes which are available to help patients learn about how their device works, what to expect from treatment, what activities need to be avoided (and which ones do not), and what to do if they have problems. To this point, the relationships between the use of these different sources of patient information, the extent to which they inform patients about ICD therapy, and the quality of life experienced in light of these experiences had not been directly examined.

The current study was conducted to advance knowledge of the social-ecological process through which ICD patients learn about therapy, how well they understand their treatment, and how these constructs relate to quality of life and mental health outcomes. As part of this process, two new scales were created; the first assessed patients’ use of informational media to learn about their ICD and the second was a measure of treatment-specific knowledge. Findings revealed that understanding of treatment was not related to QOL outcomes. However, younger patients tended to understand their device better than older patients, which may be explainable by use of a wider variety of informational media, particularly online sources of information. Also, important, depression contributed to QOL among participants. Social workers in hospitals, outpatient health clinics, public assistance, private practice, and elsewhere, should be involved in efforts to increase patient understanding of treatment. Practice with this population could take on many forms, including helping patients through an informed decision-making process when deciding whether to have an ICD implanted, educating patients as part of a dedicated psychosocial intervention to alleviate emotional suffering, advocating for patients who have difficulty accessing information from healthcare providers and other sources, and designing care processes which best inform patients proactively.

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Appendices

Appendix A

Demographic, ICD Knowledge, & Informational Media History Questionnaires (as Included in Main Survey)

Demographics

Ethnicity: **o** Hispanic/Latino **o Not** Hispanic/Latino

Race: **o** White or Caucasian **o** Native American or Alaska Native **o** Black or African American

o Asian American **o** Hawaiian or Pacific Islander

o Multiethnic **o** Other

What is your approximate yearly household income(select the box you think is closest)?_$0-20,000___ $20,000-40,000___ $40,000-60,000___ $60,000-80,000___

$80,000-100,000______$100,000-150,000___ More than $150,000___

How much education have you completed? Less than high school___ High school graduate or GED___Some college___ Associates degree___Bachelors degree___ Masters or professional degree___ Doctorate___

About how many times have you been shocked by your defibrillator (if you've never been shocked, put "0")? 0___1-5___ 5-10___ More than 10___

If you were born inside the United States, in what City and State were you born? __________

If you were born outside the United States, in what City/Province and Country were you born?
____

What City and State or Province (or Country) did you spend most of your life from ages 0-10?
____

Do you have an implanted defibrillator? Yes___ No___

Do you have a pacemaker? Yes___ No___

ICD Knowledge Questionnaire

Please indicate whether you believe each of the following statements are true or false. If you don't know, please indicate that in the box provided instead.

	True	False	Don't Know
The main purpose of an ICD is to shock a patient's heart if it's having a dangerous rhythm			
In order to turn off an ICD, a doctor has to surgically remove it			
ICDs are not designed to cure heart disease			
As long as I stay at least 9 inches away from most large electrical appliances, it won't affect my ICD			
Every time an ICD shocks, it means that a person's heart was having a big problem			
If someone's ICD was turned off, they would die almost immediately			
Most people with ICDs can return to work if they want to.			
Even if a patient's doctor says it's ok, they probably shouldn't exercise.			
If someone is shocked while having sex, the shock wouldn't injure their partner.			

ICD Informational Media History

The following list contains sources where some patients may have learned about their ICD and how treatment works. Please indicate how much information you got from each source ranging from “No information” to “A lot of information.”. Please mark “No Info” for sources that you didn’t use at all.

Media	**No Info**	**A Little Info**	**Some Info**	**A Good Deal**	**A lot of Information**
Conversations with my doctor					
Conversations with my ICD nurse					
Advice from people who aren’t health care professionals (like family/friends)					
Conversations with a mental health professional (such as a social worker or a psychologist)					
Paper brochures about ICDs (from hospitals or device companies)					
Paper newsletters					
Online newsletters					
Web sites about ICDs where I couldn’t ask questions (like WebMD)					
Web sites where I could ask questions (like message boards)					

Online videos made by other patients (like YouTube videos)					
Online videos made by professionals (like doctors, hospitals, device companies)					
In-person support groups about ICDs					
In-person educational meetings about ICDs					
Other					

Appendix B

Data Abstraction Form (Approved for Chart Review)

Subject I.D. ☐☐☐☐☐

1.	Date of Chart Abstraction: ☐☐/☐☐☐/☐☐☐ dd mmm yyyy
2	Gender: Male ☐ Female ☐ Transgender ☐ Age ☐☐ years (18-99 qualify) Most recent height ☐☐ inches Most recent weight ☐☐☐ lbs
3	Indication for Device ☐ Primary Prevention If primary prevention, for what indication: ☐ CHF If Heart Failure – NYHA Class (most likely noted in dictation): ☐ I ☐ II ☐ III ☐ IV ☐ Not noted ☐ HCM ☐ LQT ☐ Brugada ☐ Secondary Prevention (i.e. a history of sudden cardiac death)
4	Month/Year of ICD Implant: ☐☐☐/☐☐☐☐ mmm yyyy
5	Type of ICD

	☐ Single Chamber Device ☐ Dual Chamber Device ☐ Biventricular Device ☐ No data
6	Most Recent Ejection fraction (EF)? ☐☐% If not numeric: ☐ Normal ☐ Mildly Reduced ☐ Moderately Reduced ☐ Severely Reduced
6	What is the EF source? ☐ Echocardiogram ☐ Cardiac Catheterization ☐ Magnetic Resonance Imaging (MRI) ☐ Nuclear Scan (Multiple Gated Acquisition or MUGA) ☐ Computerized Tomography (CT)
7	Left ventricular volume (LV)? (Likely reported in perioperative echo) ☐☐☐ mL
8	Present use of cardiac medications (no doses necessary): Beta blockers ☐ Which one(s):____ Ace inhibitors ☐ Which one(s):____ Diuretics ☐ Which one(s):____

	Spirinolactone ☐
9	Diagnosed Comorbidities: ☐ COPD ☐ Asthma ☐ Restrictive lung disease ☐ Obstructive Sleep Apnea If yes to OSA, what was the AHI ____ ☐ Other pulmonary disease If yes, please list____ ☐Renal disease

Does the patient have a history of?				
1	ICD shocks	No ☐	Yes ☐	Not Noted ☐
	If yes, specify how many	Total Number________		

11. Patient's insurance status (check all that apply):

☐ Medicare

☐ Medicaid

☐ Managed Care Plan (PPO, HMO, POS)

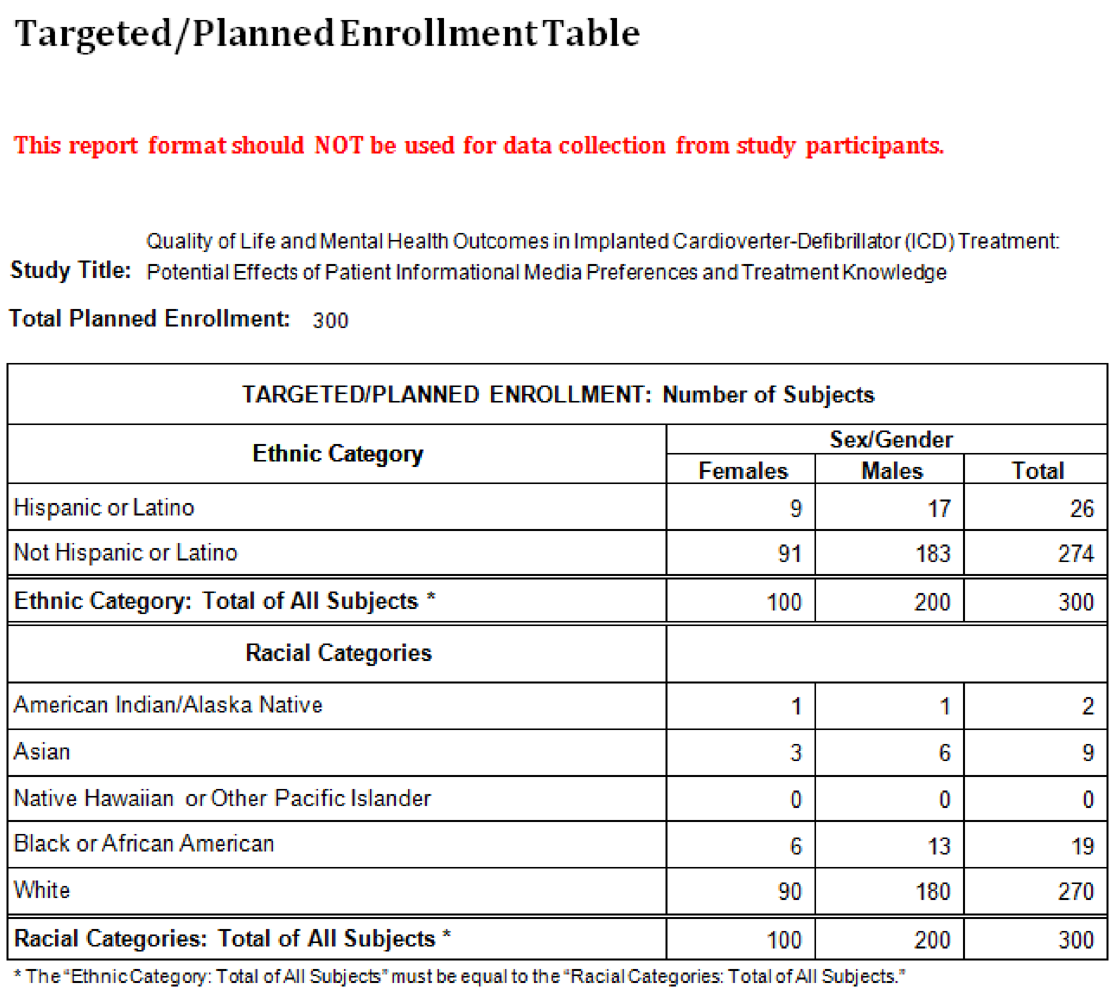
☐ Other 3rd party insurance

☐ Uninsured

☐ Other (specify):______________________________

Appendix C

Targeted/Planned Enrollment Table (NIH SF-424 Guidelines Format)



Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Quality of Life and Mental Health Outcomes in Implanted Cardioverter-Defibrillator (ICD) Treatment: Potential Effects of Patient Informational Media Preferences and Treatment Knowledge

Total Planned Enrollment: 300

TARGETED/PLANNED ENROLLMENT: Number of Subjects

Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	9	17	26
Not Hispanic or Latino	91	183	274
Ethnic Category: Total of All Subjects *	100	200	300
Racial Categories			
American Indian/Alaska Native	1	1	2
Asian	3	6	9
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	13	19
White	90	180	270
Racial Categories: Total of All Subjects *	100	200	300

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."