AHA Scientific Statement

Educational and Psychological Interventions to Improve Outcomes for Recipients of Implantable Cardioverter Defibrillators and Their Families
A Scientific Statement From the American Heart Association

Endorsed by the Heart Rhythm Society and the American Association of Critical-Care Nurses

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Abstract—Significant mortality benefits have been documented in recipients of implantable cardioverter defibrillators (ICDs); however, the psychosocial distress created by the underlying arrhythmia and its potential treatments in patients and family members may be underappreciated by clinical care teams. The disentanglement of cardiac disease and device-related concerns is difficult. The majority of ICD patients and families successfully adjust to the ICD, but optimal care pathways may require additional psychosocial attention to all ICD patients and particularly those experiencing psychosocial distress. This state-of-the-science report was developed on the basis of an analysis and critique of existing science to (1) describe the psychological and quality-of-life outcomes after receipt of an ICD and describe related factors, such as patient characteristics; (2) describe the concerns and educational/informational needs of ICD patients and their family members; (3) outline the evidence that supports interventions for improving educational and psychological outcomes for ICD patients; (4) provide recommendations for clinical approaches for improving patient outcomes; and (5) identify priorities for future research in this area. The ultimate goal of this statement is to improve the precision of identification and care of psychosocial distress in ICD patients to maximize the derived benefit of the ICD. (*Circulation.* 2012;126:2146-2172.)

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For patients who receive an implantable cardioverter defibrillator (ICD) for primary or secondary prevention of life-threatening ventricular arrhythmias, the initial experiences related to care for cardiac arrhythmias and ICD therapy are often dramatic. This is especially true if the index event is a sudden cardiac arrest (SCA). Additionally, many patients

undergoing ICD implantation for primary prevention are surprised to learn of their potentially life-threatening condition. Regardless of the indication for an ICD, patients and their family members are thrust into high-stakes medical decision making and are required to confront and cope with their uncertain health condition, consider current and potential treatment options, and then adjust to a device implanted in the body that may unexpectedly deliver a shock as therapy.[1] Fortunately, research has demonstrated significant mortality benefits and potentially desirable quality-of-life (QOL) outcomes with ICDs.[2,3] However, the underlying arrhythmia and its treatment may be accompanied by adverse psychological responses by patients and family members. These responses may be underappreciated and warrant greater attention by healthcare providers. The ICD patients' and their family members' psychological responses and need to cope are not limited to the initial index event but continue throughout the lifespan as they develop new knowledge about their condition, experience arrhythmia treatment and device-related events, return to activities of pleasure or work, and eventually confront end-of-life decisions.[4]

SCA claims nearly 300 000 lives in the United States per year, representing 65% of the total deaths that result from cardiovascular disease.[5] The number of ICDs being implanted in the United States has grown significantly in the last few years, with estimates reaching in excess of 250 000 per year in 2006,[6,7] and over the period from 1993 to 2006, ≈0.8 million patients received an ICD.[8] Because SCA accounts for ≈50% of the mortality for patients with left ventricular dysfunction with reduced ejection fraction, and the results of several primary prevention trials in patients with heart failure (HF) demonstrated absolute reductions in mortality with prophylactic implantation of the ICD,[7,9] the use of the ICD for primary prevention has been expanded. ICDs are recommended as primary prevention in the HF guidelines to reduce total mortality in patients who have class II to III HF while undergoing optimal medical therapy and who have reasonable expectation of survival for >1 year with good functional status.[10] Even though the number of ICD implantations has increased over the past few years as indications and guidelines have changed,[11,12] it is difficult to use these numbers for future projections. With up to 54% of HF patients potentially eligible,[13] the tendency is to project an aging and escalating population who will develop HF and receive an ICD. On the other hand, non–evidence-based ICD implantations have been documented at a rate of ≈22.5%.[14] A large study of a claims database found that 17% of patients eligible for an ICD who did not receive one actually had refused the device,[15] which suggests that patient preference is an important variable that may not be included in calculations of underuse or overuse. Nevertheless, the focus on optimizing psychological outcomes for those who are considering or receiving an ICD is paramount. Psychological outcomes are an important component of QOL and reflect an aspect of the cost/benefit for the patient beyond simply living longer.

The purpose of this scientific statement is to (1) present evidence regarding psychological responses to the ICD over time and (2) examine the evidence for approaches that promote improved psychological outcomes. Specifically, the statement addresses what is known about adult and pediatric patient and family responses to the ICD; educational and informational needs; factors associated with various responses; and educational, psychological, and rehabilitative interventions to promote adjustment to the ICD and prevent or reduce adverse psychological responses. The statement concludes with evidence-based recommendations for the multidisciplinary practice team, describes important gaps in the knowledge base, and identifies future directions for research.

The development of this scientific statement was challenged by the fact that the ICD patient population is very heterogeneous. Statistics used to discuss benefits of the ICD as primary prevention of SCA are derived primarily from trial populations that are not typical of the 10 000 new patients undergoing ICD implantation each month in the United States,[9] many of whom are older, have more comorbidities, and have been hospitalized recently. Additionally, more and more children and adolescents are receiving ICDs, in part because of the recent discovery of genetic markers that indicate high risk for SCA. In addition to the influence of other life-limiting comorbidities, a decreased benefit of the ICD has been observed in patients >75 to 80 years of age, those experiencing multiple HF hospitalizations or diagnosed with chronic kidney disease, and women; however, no trial to date has been adequately powered for true assessment by sex.[16,17] Such observations from meta-analyses continue to raise dialogue about who benefits from and should receive an ICD with ongoing study. Thus, examination of the evidence on psychological response reflects literature that emanates from studies of a changing and varied ICD population.

Patient Responses to the ICD

Patient understanding and attitudes about ICDs are inextricably linked to their understanding of their underlying disease and its prognosis. Patients who have already experienced cardiac arrest or sustained ventricular tachycardia have a frame of reference from which to understand the impact of potential recurrence; however, the majority of ICDs implanted in the United States are for primary prevention before any life-threatening arrhythmia in patients at risk because of low left ventricular ejection fraction or who have genetically determined diseases that put them at risk for SCA. These patients often have a limited understanding of how long they might live and of how they might die, and thus, they have difficulty placing the potential impact of the ICD into context. This is especially true for pediatric ICD recipients who have never had a symptom but have lost a sibling or other close relative to SCA and who have been identified as having a genetic marker that is associated with SCA.

Ambulatory patients with HF consistently overestimate the survival expected with their diagnosis.[18] In a survey of ambulatory HF patients with left ventricular ejection fraction <35% and symptomatic HF, two thirds expected to live >10 years and one third expected to live >20 years, considerably longer than anticipated even with optimal medical therapy.[19]

In this setting, patients overestimated the contribution of sudden death to overall mortality. A majority of patients anticipated that 50 lives per 100 would be saved during the first 5 years after implantation of an ICD.[19] This was true regardless of whether they themselves had an ICD. Of patients with an ICD already in place for primary prevention, 60% expected an ICD to save their own lives. Asked to estimate the adverse effects of ICDs (defined for the patient as the number of inappropriate ICD shocks or complications), >60% of patients without ICDs estimated ≥25 adverse events per 100 patients over 5 years, whereas patients with ICDs estimated they would occur for 20%.[19] Importantly, half of the patients surveyed indicated that they would want the ICD regardless of the frequency of adverse events. Therefore, potential ICD patients may have a tendency to believe that the device can "undo" the negative consequences of their cardiac condition, overestimate benefits, and underestimate adverse aspects. Perhaps this preference is evidence that the patient has rationally weighed the potential lifesaving benefits of the ICD as more important than inappropriate shocks, or is evidence of some type of psychological benefit that attempts to reduce threat and maximize perceived value, or it may reflect how ICD information was presented to these patients.

Psychological Responses After an ICD

Anxiety and depression are common psychosocial responses in cardiac populations, so the manifestation of these responses in those with an ICD is not unexpected but should be emphasized for its magnitude. Anxiety is a common problem in 13% to 38% of those with an ICD, and this has been documented by multiple studies.[20–23] Chronic anxiety, that is, anxiety persisting over the first year after implantation, has been observed in ≈54% of ICD patients who were considered clinically anxious at the time of implantation.[24] Over the history of the ICD, ≈10% to 46% of ICD patients have been reported to experience depression.[23,25–27] Another study in the Dutch population documented that 14% of the 386 ICD patients followed up at 3 months after implantation had persistent depression.[28]

Recently, a systematic review of literature on anxiety and depression in ICD patients that spanned 45 studies and included >5000 patients concluded that between 11% and 28% of ICD patients had a depressive disorder and between 11% and 26% had an anxiety disorder, with diagnostic interviews used as the mode of assessment.[29] Rates of self-reported anxiety and depressive disorders were much higher when questionnaires were used (8%–63% for anxiety and 5%–41% for depressive disorders). Regardless of the assessment approach, these researchers concluded that ≈20% of ICD patients have clinically significant psychological distress. These ranges and percentages are twice as high as the 9.3% and 7.9% to 17% of individuals with general cardiac and chronic medical conditions, respectively, with psychological distress.[29a] Approximately 58% to 70% of ICD patients with emotional distress receive no treatment.[29b] The psychological problems in ICD patients may be heightened

by or contribute to other symptoms such as sleep disturbances.[30] Although the majority of patients do well with their device, and positive life experiences after ICD implantation have been reported, these results suggest that systematic clinical strategies to screen and treat those who are distressed are indicated.

Exposure to a traumatic life-or-death experience is a key component of the diagnostic criteria of posttraumatic stress disorder (PTSD).[31] Given the nature of ICD patient care, this prerequisite is routinely met via an SCA or a multiple shock experience, in which the patient is placed in a context of uncertainty regarding survival.[31] Recently, Kapa et al[27] demonstrated that 21% of ICD patients reported clinically significant PTSD symptoms at implantation, and follow-up assessments at 6 and 12 months yielded 12% and 13% rates, respectively. Another investigator demonstrated that ICD patients who score in the upper quartile of a PTSD measure were more likely to have died at the 5-year follow-up assessment, even after controlling for other medical risk factors.[32] Collectively, these data suggest that PTSD symptoms in ICD patients are of concern and may be associated with increased mortality at long-term follow-up. Systematic treatment of PTSD in ICD patients has not been reported; however, a recent large-scale treatment study using cognitive behavioral therapy adapted to ICD-specific concerns demonstrated significant improvement in both PTSD and avoidance symptoms for both men and women.[33] These results are encouraging and call for increased use of tailored therapies to support recovery from specific trauma associated with SCA and ICD shock experiences.

QOL After an ICD

The patient experience of living with an ICD and the resulting QOL have been important areas of investigation with many small-scale studies and more recently with QOL data from the large trials that were powered and focused on mortality outcomes. Initial large-scale QOL research with nontransvenous lead technology (CABG [Coronary Artery Bypass Graft] Patch trial) indicated that QOL outcomes (including both emotional and physical domains) for ICD patients were significantly worse than for patients who did not receive an ICD after coronary artery bypass graft surgery.[34] Follow-up analyses suggested that the occurrence of shock accounted for these differences, because there were no differences in any QOL scores for nonshocked ICD patients versus no-ICD patients. Data for participants who survived ≥1 year from baseline in the Antiarrhythmics Versus Implantable Defibrillator (AVID) study, a study of secondary prevention, indicated no significant differences in generic QOL measures between patients randomized to antiarrhythmic drugs and ICDs[3]; however, the experience of at least 1 ICD shock was associated with reduced physical functioning and mental well-being and increased concerns among ICD recipients. The antiarrhythmic drug group also reported reduced physical functioning if adverse symptoms were experienced. A similar Canadian study with secondary prevention patients indicated that ICD therapy was associated with better QOL on 5 of 7 scales of the Nottingham Health Profile, including energy,

physical mobility, emotional reactions, sleep disturbance, and lifestyle impairment.[35] The antiarrhythmic drug group did not show any changes or reduced QOL scores; however, the QOL benefits of the ICD were not evident if ≥5 shocks were experienced. More recently, data from the primary prevention SCD-HeFT trial (Sudden Cardiac Death in Heart Failure Trial) revealed that the ICD patient group had significantly improved psychological QOL at 3 and 12 months after implantation compared with patients who were treated with medications alone, but the benefits were no longer detectable at 30-month follow-up.[2] As a result of these outcome studies, multiple reviews have generally concluded that QOL in ICD recipients is at least equal to or better than that of those taking antiarrhythmic medications.[2,3,35,36] Equivalent QOL outcomes generally have been demonstrated between primary and secondary prevention indications.[37,38] QOL outcomes remain an area of intense research, because refinement of measures including generic and disease-specific parameters, evaluation of clinically and statistically significant differences, survivor and missing data sample biases, and evolving sophistication of the technology may change our understanding of the QOL outcomes and patient experiences with ICDs over time.

Role of Shocks in QOL

A primary controversy in this area surrounds the role of ICD shock in affecting the key indicators of QOL.[39,40] As noted above, data from the AVID trial suggested that sporadic shocks and adverse symptoms were each associated with reduced physical and mental well-being.[3] A recent review and summary of the large clinical trials concluded that the relationship between shock and QOL is not straightforward and is confounded by timing of assessment and other factors in the existing empirical evidence.[39] An additional review of 3 studies indicated increased anxiety scores once the patient has had a device shock.[25,41,42] Two studies demonstrated no changes in psychological states after ICD shock therapy, whereas several studies found that >5 shocks was the threshold to impact the ICD recipient's psychological states of anxiety and depression.[35,43–46] The studies suggest that ICD patients are able to endure 1 to 5 shocks without clinically meaningful differences in QOL, but significant changes in QOL were evidenced when ≥5 shocks were experienced. More recently, the SCD-HeFT trial provided data examining the acute effects of shock on QOL subscales.[2] Specifically, a subanalysis of data from ICD patients who experienced a shock within 30 days of a previously scheduled systematic follow-up time point indicated significant decrements in multiple QOL indices compared with nonshocked ICD patients. This is particularly interesting because it provides a clinically relevant window of observation on the impact of shock in the immediate postshock period. Recent research indicates that both ICD shock history and preimplantation distress were predictors of subsequent PTSD symptoms, but the relationship varied at different times of assessment.[47] An ICD shock predicted PTSD at 3 months after implantation, but preimplantation anxiety and ICD concerns were the best predictors of PTSD at 6-month

follow-up. In summary, the experience of shock remains an aversive consequence from the patient perspective. ICD patients appear to be able to tolerate shocks up to a point (≈5 shocks). The interaction of personality, demographic, and other psychosocial factors with the experience of shocks remains an active research area with significant clinical implications.

Psychological States, Arrhythmias, and ICD Shocks

Given the destabilizing effects of mental stress on ventricular arrhythmias and the emotional precipitants of arrhythmia,[48,49] several researchers have raised the question of whether anxiety, depression, and mood disturbance served as an antecedent or cause of ICD therapy. Depression was a predictor for appropriate ICD shock in the Triggers Of Ventricular Arrhythmias (TOVA) study.[50] A prospective study demonstrated greater mood disturbance as an antecedent in ICD patients who were shocked than in those who were not shocked in the first 9 months after implantation.[51] Van den Broek and colleagues[52] found that the type D personality, described as a tendency to exhibit negative affect and social inhibition, which leads to greater distress and a low likelihood of expressing difficulties to others,[53] modulated the effect of emotional distress, as demonstrated by an increasing risk of arrhythmia in the presence of anxiety in a large prospective study of ICD patients. The authors suggest that anxious type D patients should be identified and offered greater emotional support after ICD implantation. Depression and anxiety in patients with defibrillators have been associated with autonomic nervous system dysfunction, and anger and stress have been associated with repolarization instability,[53a,53b] which suggests possible explanations for the association between psychological responses and life-threatening cardiac outcomes in vulnerable ICD patients.[53a,54] Perceived social support helps maintain adaptive hemodynamic responses to mental stress in ICD patients.[55] Furthermore, phantom shocks, that is, the patient-perceived experience of an ICD shock in the absence of an actual shock, may be observed more commonly in those with past ICD storms or a history of depression, anxiety, or substance abuse, which suggests the complexity of these relationships.[56]

QOL Summary

In summary, ICD patients can expect generally desirable QOL provided they are not exposed to excessive, unnecessary, or repeated ICD shocks. Most ICD patients derive other benefits in addition to the demonstrated mortality benefit without compromising QOL. It is important to assess and address anxiety, depression, PTSD, and mood changes after ICD implantation to potentially reduce the risk for ventricular arrhythmia and shock from the device; however, more study is needed regarding pathways that link psychosocial distress and ventricular arrhythmia leading to ICD shock. Moreover, the underlying cardiac disease, associated symptoms, and physical limitations caused by HF are important considerations in QOL outcomes.[57]

Impact of Sociodemographic and Clinical Factors on Psychological Responses

Factors associated with psychological responses that have been examined include age, sex, comorbidities, social support, personality disposition, patient knowledge and understanding of the ICD and underlying condition, coping behavior, and device events and product recalls.[4,58] Details of studies reviewed for this section, including the design, sample description and size, measures, and outcomes, can be found in online-only Data Supplement Appendix Table A.[25,27,35,36,38,41–44,46,53,55,57,59–76]

Age

A review of descriptive studies with outcomes of anxiety and depression demonstrate mixed effects for age as a factor related to psychological responses of ICD patients. Several studies identified that adult ICD recipients at a younger age are at risk for heightened anxiety at baseline or follow-up.[59,60,77,78] Other studies did not find that age affected anxiety.[25,57,79] The discrepancies related to age may be caused by the heterogeneity of the studies in terms of age ranges of participants, disease causes, and device indications, confounded by age, sensitivity of the measures of psychological responses, and analysis approaches. Nevertheless, the trend is for younger adults (<50 years of age) to experience greater concerns and negative psychosocial responses to the ICD.[20,60,77]

Sex

Among ICD patients, women acknowledge greater anxiety and depression than men, as they tend to do in general,[80] although there are some inconsistencies among studies. Importantly, many studies do not have an adequate number of women to assess for sex differences. Our review of studies that addressed sex effects in ICD patients demonstrated higher anxiety and depression in women; 1 study found no sex differences before implantation,[81] but only 1 study found no sex differences in postimplantation levels of anxiety or depression.[61] Four studies found that female ICD recipients had higher anxiety levels than men.[25,62–64] A systematic review of 18 studies with a sample size >100 found no sex effect in 80% of the outcomes in the studies, and the authors concluded that there was insufficient evidence to definitively claim that female ICD patients experienced greater psychological distress.[82] A more recent large study (n=718, 81% men) revealed no sex differences in mean anxiety of QOL scores, except women reported poorer QOL on the domains of physical functioning and vitality.[83] Sex and age may interact. Specifically, Vazquez and colleagues[60,65] identified that younger women had higher rates of shock and death anxiety and more body image concerns than middle-aged and older women with an ICD. In relation to depression, 1 study of ICD recipients identified higher levels of depression in women than in men.[25]

Comorbidities

Coping with ventricular arrhythmia and ICD treatment on top of other acute and chronic comorbidities is difficult. Studies have consistently found that symptomatic HF in ICD recipients is correlated with higher anxiety and depression scores.[24,57,68] Although an equivalent mortality benefit has been shown for ICD recipients who have high symptoms or self-care needs, including concomitant diabetes mellitus[84] and chronic obstructive pulmonary disease,[85] psychological and QOL outcomes have not been studied. As severity of illness increases and functional status decreases, a more negative mood state manifests early after ICD insertion.[66] Consideration of the complex interactions of ICDs and other chronic illnesses on psychological responses is an area of relevance for clinical and research implications.

Social Support

A number of studies measured the effects of social support on psychological outcomes after ICD implantation. Using marital status as a proxy for social support, 1 study reported that there was no difference in anxiety or depression, whereas other researchers using different measurement tools found that the lack of social support influenced levels of depression and anxiety in those not married and those who perceived a lower level of social support.[25,61] Myers and James[67] found in their sample of 150 ICD recipients that as social support and social networks increased, anxiety decreased. Sears and colleagues[36] identified that a history of depression, trait anxiety, optimism, and social support explained 39.9% of the variance on mental health outcomes in a study of 88 ICD recipients. Those who attended support groups had higher trait anxiety and were less satisfied with their social support. These results suggest that people seeking out support groups may actually be trying to improve their ability to cope because they are aware of their greater anxiety and lack of support.

Preimplantation Psychological State and Personality Disposition

Pre-ICD illness beliefs and anxiety state have been linked to worse psychological responses and QOL after implantation. Patients who have higher threat appraisals and less perceived control, as well as those with higher anxiety, have worse assessments of their QOL.[86,87] More recently, the dispositional factor of the type D personality feature, termed the *distressed personality*, has also been linked to poor psychological outcomes in ICD patients.[53,88,89] Type D personality was also an independent predictor of chronic anxiety in addition to the presence of diabetes mellitus and cardiac resynchronization therapy,[24] and when clustered with device-related concerns, it remains a predictor of distress independent of shocks.[76]

Trait optimism, or the tendency to view situations as likely to turn out positive, has been associated with better mental health and social functioning several months after ICD implantation.[36,90] Trait optimism was also found to be an important covariate in better psychological outcomes among patients receiving ICD shocks.[58] Importantly, the greater the concerns ICD recipients have about their device, the higher the anxiety and depressive symptoms, independent of shocks.[69] Collectively, these data suggest that some factors

that are associated with worse psychosocial functioning are modifiable in clinical cardiac settings (eg, ICD concerns), and others may or may not be modifiable (eg, personality features). However, researchers and clinicians should be aware of the variety of factors that influence the ultimate clinical presentation of distress in the clinical setting.

Understanding of the ICD and Underlying Condition

Knowledge about the ICD is a modifiable factor that has been the focus of preinsertion and postinsertion patient teaching. In a small study (n=30) of a computerized learning and anxiety reduction intervention for ICD patients, those randomized to treatment experienced no increase in knowledge over those receiving usual care; however, increased knowledge about the ICD accounted for a significant and moderate amount of variance in device acceptance irrespective of age, education, ejection fraction, and time since implantation.[91] There was no relationship between knowledge and device acceptance among control patients. Thus, a program that combines knowledge with efforts to reduce distress may be more beneficial than knowledge-focused approaches alone. These type of programs are referred to as psychoeducational approaches and are discussed later in the section on Interventions to Enhance Adjustment to the ICD and continue to be under investigation.[92,92a]

Coping Behaviors

Coping behaviors, defined as emotional and behavioral efforts to deal with new and stressful situations, are important in response to ICDs. Small early studies of stressors and coping strategies found that both problem-focused and emotion-focused coping were used and that denial as a coping strategy remained high over the first year after ICD insertion.[93,94] Greater psychological distress has been observed in ICD patients using avoidant or emotion-focused coping, whereas problem-focused coping is related to better emotional and functional outcomes.[66,86,95] Emotion-focused coping may not be effective in ICD patients who experience intense physical symptoms or novel stressors; thus, education and counseling approaches to promote problem-focused coping are warranted.

Device Events and Recall

Although isolated appropriate shocks can increase a patient's sense of security that the device is performing as intended, significant inappropriate shocks, electrical storms, and ICD recalls/replacements are events that that can undermine faith in perceptions of security provided by the ICD. The impact of device recall has been assessed in 6 studies. Four studies found no difference in psychological response between those with and without a device recall,[71,73–75] whereas 2 studies reported a heightened level of anxiety at the time of evaluation after a device recall.[72,75] Collectively, ICD recalls remain under study, but more recent data suggest that ICD patients can generally tolerate the specter of recall and appreciate receiving information from the physician or manufacturer[96]

but have more significant distress if that recall results in an adverse event such as a shock.[75] More clearly, ICD patients generally appear to be able to cope sufficiently with recall, but the delivery of a resulting shock, pain, or complication may mark the highest potential for resulting distress.

Summary for Factors Related to Psychological Responses

In summary, current research findings on factors that influence psychological responses to ICDs suggest that younger age in adults and being female appear to have some effect on anxiety and depression. As noted above, conclusions are drawn tentatively to aid in clinical care planning, and many of the conclusions remain the subject of current and future study. Knowledge of the ICD and illness is an important aspect of device adjustment. Similarly, initial research has indicated that unmarried or unpartnered ICD patients and those with lower perceived social support had higher levels of anxiety and depression. Type D personality is associated with greater psychosocial distress, whereas trait optimism and coping behaviors that approach living with an ICD in a problem-focused and problem-solving framework are associated with less distress. There are no reported data on the effects of race and ethnicity or health literacy on psychological responses. Some of these factors are not modifiable, yet they may help differentiate approaches to providing information and identify those who should receive greater psychological support during follow-up care. Approaches to improve coping behaviors and social support for ICD patients should remain as targeted programmatic goals for intervention.

Family Member and Intimate Partner Response to the ICD

Family and intimate partner psychological adjustment after SCA and ICD implantation is similar to that of the ICD recipients. Family member response is important, and prior research suggests that recovery from life-threatening illness occurs within a family context, in which the intimate partner's experience influences the patient's recovery.[97] A comparison of family partners of ventricular arrhythmia patients treated with ICDs versus antiarrhythmic medications found no differences in changes in partner QOL over time, with each group sharing fears about death of their family member.[98] Family members and intimate partners have reported overprotectiveness, stress, anxiety, fear, anger, depression, hopelessness, guilt, and despair after the patient has had a cardiac event and received an ICD.[98–103] Feelings of helplessness, changes in family roles and life patterns, and lack of family support are factors that strain the family system, making it difficult to sustain the demands needed for successful recovery.[99,104] Dougherty[105] reported that psychological distress and family adjustment were adversely affected in those whose loved ones received ICD shocks. Ocampo[106] suggested that although the patient eventually accepts the device and lifestyle changes, family members may have a difficult time doing so. Pycha et al[100] reported that within 17

months after ICD implantation, 81% of partners thought that the ICD was a life extender, and 66% of partners believed the ICD was a source of security. One third of spouses were concerned that expressing strong emotions might provoke an ICD shock. Even though patients and partners expressed positive perceptions about the ICD, 94% reported increased preoccupation with their heart >1 year after ICD implantation. A longer-term worry of both patients and partners was the availability of experienced providers should they travel, as well as the longevity of the ICD battery. The advent of remote monitoring and the global use of ICDs may mitigate this concern somewhat, but the relative anxiety about travel remains a common concern for ICD patients.

Research describing the impact of the ICD on intimate relationships is limited. An early investigation suggested that SCA contributed to marital strain and reduced sexual frequency between couples, with spouses of ICD patients noting increased anxiety, anger, irritability, and dependency in their mates after SCA.[107] Both spouses and patients desired more information from healthcare professionals on the details of the cardiac arrest at the time that it occurred.[108] Longitudinal investigation after SCA and ICD implantation found that family members experienced the greatest anxiety, depression, and stress at the time of hospitalization, with reactions decreasing throughout the first year.[94,108,109] Marital adjustment over the first year after ICD implantation remained within normal ranges but worsened as the year progressed. Spouses reported less marital satisfaction than ICD patients. Mood disturbances were higher in family members using an emotion-focused approach to coping,[109] and the indication or need for the ICD was another factor that contributed to spouse anxiety. Family social support was noted to be especially low throughout the first year after ICD implantation.[94] Doolittle and Sauvé[101] found differences in perceptions about ICD recovery between spouses and patients. Spouses who witnessed the cardiac arrest had a greater degree of protectiveness toward the patient, which created conflicts between the couple. In the most severe instances, spousal protectiveness led to reduced social activities for the ICD patient, altered communication between the spouse and patient, and feelings of anger and frustration toward the spouse's restrictions. Spouses who wanted to maintain a sense of independence yet experienced guilt if they left the ICD patient alone curtailed their activities and discontinued their social activities with others, which increased their own social isolation. These authors recommend that couples be assisted in communicating with each other about their perceptions, fears, and concerns to establish more realistic expectations and to reach agreement on issues that promote as normal a lifestyle as possible.[101]

Recently, the impact of ICD implantation on the sexual relationships of couples[110] has been reported. Sexual issues for patients included erectile problems (57%), overprotectiveness of partner (56%), lack of interest in sex (29%), fear of ICD shocks during sex (29%), and fear of cardiac arrest if the ICD did not work (29%). Partners also acknowledged overprotectiveness (59%), lack of interest in sex (39%), fear of cardiac arrest (32%), and fear of ICD shocks during sex (30%), although only 18% reported ICD shocks during sex over a 3.5-year period. Seventy-eight percent of individuals were sexually active before the ICD, with only 55% reporting resumption of their sexual relationship after the ICD. Sexual information was not often discussed by healthcare providers with patients after they received an ICD.[110]

For intimate partners living with a person who receives an ICD, data suggest that intimate partners can become exhausted, excessively overprotective, burdened, and anxious and suffer ill health effects. Unique experiences of intimate partners of ICD patients are the following: (1) Potential witnessing of the cardiac arrest event, and perhaps, participation in the resuscitation; (2) uncertainty about return of the patient to full social and cognitive function; (3) fear of leaving the patient alone for fear of recurrent cardiac arrest and ICD shocks; (4) the burden of fulfilling family and financial roles; (5) coping with potential driving restrictions of the ICD patient; (6) dealing with the psychological responses of the patient, as well as their own; (7) the threat of SCA and cardiopulmonary resuscitation activities; and (8) possible disturbed sexual relationships between the couple after implantation of an ICD. Furthermore, van den Broek and colleagues[111] found that ICD patients with a type D personality experience more difficulty, and this may be augmented if their family partner also exhibits poor communication and lack of emotional support in the relationship. Because it may be difficult for clinicians to evaluate the psychological profile of the partner as suggested,[111] evaluation of the ICD patient's perceived family support and family-related concerns is important to consider when providing education and support to not only the patient but also the family/partner.[111] Past research investigations have demonstrated that surviving cardiac arrest and receiving an ICD result in significant changes in the individual's physical, social, and psychological functioning over the first year. These responses impact family members and spouses as well.

Pediatric ICD Patients

Although pediatric ICD recipients constitute <1% of the total ICD population,[112] they must be included in any discussion about the educational and psychological needs of ICD recipients because of factors that distinguish them from their adult counterparts. First, in contrast to adults, the diseases that result in a need for ICD implantation in the pediatric population are much more heterogeneous. Second, clinical issues or complications associated with ICD placement in the pediatric age group are more frequent than those seen in adults, including the fact that children will have to live with their ICDs for a much longer period of time.

The ICD is used for both primary and secondary prevention of SCA in children and adolescents[113]; however, the types of disease that prompt ICD placement in pediatric patients differ from those of adults. These types generally fall into 1 of the following categories: Congenital heart disease, including but not limited to tetralogy of Fallot, transposition of the great arteries, and aortic stenosis[114]; cardiomyopathy, including dilated,[115,116] hypertrophic,[115–117] and arrhythmogenic right ventricular dysplasia[118] forms; or ion channel

abnormalities such as the congenital form of long-QT syndrome,[119] Brugada syndrome,[120] and catecholaminergic polymorphic ventricular tachycardia.[120] The diverse indications for ICD placement create a heterogeneous population with varied disease and treatment histories. The psychosocial outcomes in pediatric and adolescent ICD patients and their caregivers have not been well studied.

An examination including 9 years of data (1997–2006) from a national registry database[121] revealed a significant increase in the number of pediatric ICD implantations per year, which translated to a 3-fold increase during this time frame. Other important findings included a decrease in the number of patients receiving a device for secondary prevention and a decrease in the age of pediatric patients receiving ICDs (from 13.6 to 12.2 years). Interestingly, the percentage of children <5 years of age receiving ICDs increased, and the complication rate decreased over time. The pediatric ICD population has unique issues, including growth and development, high likelihood of prior cardiac surgery, complex cardiovascular anatomy, high incidence of supraventricular arrhythmias, and a high incidence of ICD discharges. However, research on the psychosocial needs, outcomes, and associated factors in pediatric patients with ICDs is in its infancy, and many studies have had small sample sizes.

The incidence of inappropriate shocks in pediatric patients has been reported to be in the range of 21% to 47%, and in a number of patients, the shocks were caused by supraventricular tachycardia, lead and device complications, and T-wave oversensing.[113,122,123] No difference in the incidence of device discharges in patients with single- versus dual-chamber devices was noted. Patients <12 years of age had more appropriate shocks than those 13 to 18 years old.[123] In a study of 28 patients, Celiker and colleagues[124] concluded that the high incidence of shocks, whether appropriate or inappropriate, interfered with QOL in their sample, although the measure of QOL was unclear.

Lead or device complications are not rare in the pediatric population, and the incidence of lead fractures has been found to be higher in the pediatric population than in adults, possibly because of growth-related issues, increased physical activity in children, and device location.[125,126] Lead-specific complications in the pediatric population range from 7% to 50% at a median follow-up of 2 years, with the highest incidence being in younger, smaller patients.[127,128] No studies of device recall or lead issues in relation to psychosocial outcomes in pediatric and adolescent ICD patients were found.

The limited literature about the psychosocial aspects of having an ICD in the pediatric age group has, until recently, been largely descriptive and not inclusive of QOL issues. Early exploratory studies about the effects of ICD placement in the young suggested adjustment-related difficulties,[26,77] as well as concerns about peer rejection, device explosion, depression, and suicidal ideation.[77,129] In a small qualitative pilot study of adolescents aged 12 to 19 years in 1995, when ICDs were first used as a treatment option in the pediatric age group, participants reported being anxious about the device and described life with an ICD as "being on a roller coaster."[130] Themes that emerged from this study included

the need for normalcy, parental overprotectiveness, adjustment time, and concerns about the future. In a subsequent qualitative study with 14 adolescents with ICDs (9 males and 5 females, mean age 16 years), the researchers concluded that having an ICD was described as almost normal.[131] The participants experienced social isolation, transient depression, being shocked, fear of and anxiety associated with being shocked, problems associated with activity restrictions, and trying to live a normal life in the midst of dealing with a chronic heart condition. The inability to participate in full-contact organized sports was particularly burdensome to those who had genetically determined diseases that put them at increased risk for SCA.[131] Stefanelli et al[132] reported that 3 of 27 pediatric patients who had received repeated shocks experienced anxiety that persisted for >1 month, and school phobias and PTSD requiring antidepressants, anxiolytics, and ongoing psychiatric therapy were also experienced by some.

DeMaso et al[133] sought to determine whether anxiety, depression, family functioning, and QOL were related to cardiac illness severity in children with ICDs. Patient/parent dyads (n=20) participated in this quantitative study. ICD patients aged 9 to 19 years (mean age 14.8 years) appeared to experience lower physical functioning as a component of their QOL than did their healthy peers.[133] Parents of the participants reported significantly lower physical functioning in their children than in the normative population (using the US normative sample mean). The study participants overall did not experience clinical levels of depression; however, 2 met depression criteria. Participants scored significantly lower on worry/oversensitivity and higher on the social desirability measures than the normative sample. There were no differences in any of the measures among those who had or had not received shocks. There were no correlations between illness severity (Defibrillator Severity Index) and psychosocial functioning; however, there were strong associations between QOL and feelings of anxiety and depression, as well as family functioning. Half of the participants indicated that their biggest worry was receiving a shock.[133]

In a Polish study of 45 ICD recipients aged 14 to 29 years designed to identify both clinical and psychological problems associated with living with an ICD,[134] 84.4% of the participants reported anxiety associated with ICD discharge that subsequently led to self-imposed activity restrictions, with 29% refusing to accept limitations. Other findings included difficulty accepting the ICD or the disease that necessitated its placement, nonacceptance of the ICD, negative perceptions of follow-up visits, noncompliance, refusal to accept limitations, denial of disease existence, and thoughts of having the device removed.

The largest psychosocial functioning and QOL study to date of pediatric ICD patients was a survey of patient/parent dyads (n=60) from 6 major medical centers in the United States.[135] The age of the ICD recipients ranged from 8 to 18 years, and the sample was primarily white. There were 25 girls and 35 boys, and 48.3% had experienced ≥1 shock. Parents were primarily mothers (75%). Similar to subjects in the study by DeMaso et al,[133] the ICD recipients had significantly lower scores on both psychosocial and physical

dimensions of QOL than the norms of healthy children. Compared with children with other chronic illnesses, the ICD recipients had significantly lower scores on the psychosocial health dimension but not the physical dimension. Parents also scored their children significantly lower on the psychosocial and physical dimensions of QOL than the norms of parents with healthy children and scored them lower on both dimensions than the children themselves. With respect to medical severity, those patients with greater medical severity reported significantly lower psychosocial and physical scores. There were no significant differences in any of the QOL variables based on having received a shock. Sex differences manifested in that the girls reported significantly lower QOL scores in the psychosocial and physical domains and were more likely to avoid places than boys; however, 84.7% of the entire sample reported avoidance behaviors after ICD implantation.[135] These results suggest that clinical attention for young ICD patients likely needs to include activity expectations and recommendations to prevent the common occurrence of avoidance behaviors. A recent report of 30 pediatric ICD patients in the Netherlands (mean age 16.3 years, mean duration 3.6 years) showed greater psychological problems in those who were younger and those with shocks,[136] in contrast to the study noted above.

In summary, few data are available to fully understand the psychosocial impact of the ICD on pediatric and adolescent ICD recipients, and no longitudinal studies of psychosocial response over time are available. The existing data about psychosocial functioning of young children and young adults with ICDs suggest that they encounter more physical and psychosocial challenges than same-aged peers but are quite similar to other young people with chronic disease. Collectively, these age-specific concerns, together with the typical ICD patient concerns such as both inappropriate and appropriate shocks and physical activity restrictions, remain targets of clinical and research attention. No educational or psychosocial intervention studies of pediatric and adolescent patients and their parents have been reported.

End-of-Life Considerations and the ICD

For ICD patients with HF, care is complicated by the fact that the trajectory of the disease is nonlinear and often punctuated by unpredictable exacerbations and hospitalizations. This differs from the perception that most patients and families have of chronic illness: They perceive illness as being characterized by a long period of normal function, followed by a relatively short period of losing weight, taking to bed, and dying, a trajectory based on the normal progression of cancer.[137,138] Indeed, what is often difficult for patients and their families to conceptualize is that death of HF may be sudden and unexpected. Likewise, clinicians often do not understand why families seem surprised when a patient dies who has had HF for years. Part of the reason for this is that until the terminal event, patients with HF recover from exacerbations, albeit at a level of reduced function with each episode. Few patients and their families are informed of the erratic trajectory of HF, so that they and their families

understand the complexities of the natural course of the disease and how it differs from other illnesses.

Education about ICDs is particularly important within this context, because although ICDs reduce SCA,[6,7,139,140] patients with these devices do eventually die. Although ICDs may effectively treat potentially life-threatening arrhythmias, they do not prevent exacerbations of heart disease or the gradual decrease in function associated with HF or other comorbid conditions such as dementia, cancer, chronic obstructive pulmonary disease, or renal dysfunction that may have a huge impact on the health state. Patients and families, on the other hand, may not understand this distinction.[141,141a] As the patient's disease worsens, their physiological changes (intrinsic and extrinsic to the heart) may lead to more arrhythmias and increase the frequency of shocks. Because ICD shocks can cause pain and anxiety and may not prolong a life of acceptable quality,[142–144] it is appropriate to consider ICD deactivation as a patient's clinical status worsens and death is near.[145] It has been shown, however, that clinicians and patients rarely engage in discussions about deactivating ICDs, and most devices remain active until death.[141a,146] Approximately 27% of patients receive shocks from their ICD at the end of life,[146] and this experience is painful and distressing for patients and their families. Qualitative focus groups of relatively healthy patients with ICDs have shown that patients are not aware that the benefit-burden ratio of ICDs may change as their illness progresses to a point where the burden, either from the shocks themselves or from the fear of them, outweighs the benefits of prolongation of life.[141] In fact, most patients are not even aware that deactivation of the shocking function is an option, and a large number of ICD recipients indicate they would keep the ICD on even if dying of cancer or receiving daily shocks.[19,141,147] Interviews with electrophysiologists, cardiologists, internists, and geriatricians demonstrate that although all physicians believe they should take an active role in these conversations, they admit they rarely do.[148] In terms of management of devices in hospice, a recent nationwide study of hospices showed that 44% reported that at least 1 patient had been shocked by the ICD in the last year, and only 10% of hospices reported having a written policy that addressed deactivation (that is, a policy that encouraged discussion, not a policy that required deactivation).[149]

Deactivation of an ICD is considered both legally and ethically acceptable when requested by a patient with the capacity to make such a decision (or in the case where a patient does not have capacity, when his or her surrogate decision-maker requests it).[149a–149c] Turning off the shocking function of an ICD is not physician-assisted suicide nor is it euthanasia; instead, withdrawing this therapy is akin to stopping any other treatment at the end of a patient's life (eg, stopping dialysis, removing a patient from a ventilator).[149d] While an in-depth explanation of the legal, ethical, moral, and religious aspects of deactivating an ICD is beyond the scope of this discussion, a consensus statement written by the Heart Rhythm Society (the professional society that represents electrophysiologists, nurses, and other arrhythmia care providers) has an excellent discussion that has been endorsed by both cardiology and palliative care organizations.[150] Conversations about device management are inherently complex and

involve a discussion of balancing the benefits and burdens of a particular treatment as it relates to the patient's current and potential future states of health. Some clinicians who implant devices may not be comfortable or experienced with complex conversations about goal setting and treatment alternatives.[146] For these reasons, it may be helpful to involve advanced care planning and palliative care in the trajectory of these patients' illnesses at the same time as disease-modifying therapies are offered.[151] This is particularly true at the time of ICD implantation.

Palliative care is interdisciplinary care that aims to relieve suffering and improve QOL for patients with advanced illness and their families. It is not the same as hospice or end-of-life care, and it is provided simultaneously with all other appropriate life-prolonging therapies.[152,153] The involvement of palliative care consultation around the time of implantation helps to ensure that patients and families understand the benefits and burdens of ICD implantation, and palliative care clinicians can assist with symptom management at that time or later in the course of a patient's disease. These clinicians are experts at complex conversations surrounding progressive illness and may be involved in discussions about ICDs and other implanted cardiac devices to ensure that the patient and family fully understand the nuances of these decisions and the implications for device management for the patient. Palliative care can also play a role in supporting the complex physiological needs of patients with chronic illness and their families. Although palliative care for ICD patients seems logical on the basis of these assertions, there is little research testing the best timing and optimal approaches to palliative care for ICD patients and their family members.

As a patient's underlying heart disease worsens or other chronic illnesses ensue, the role of the ICD may need to be reconsidered, especially in terms of the balance of benefit and burden of the device as it relates to the patient's overall health and goals of care. At the time of exacerbations or especially at the first office visit after a patient is released from the hospital from an exacerbation of their heart disease or a bout of dysrhythmias during which the device may have provided shocks, it is important to reevaluate the trajectory of the patient's disease, treatment goals, and symptom burden. This is an important component of palliative care that may need to be implemented without relegating it to palliative care specialists. At late stages of advanced disease, an ICD may no longer prolong a life of acceptable quality and can instead contribute to suffering and distress. When an ICD is implanted, physicians believe the device is appropriate at that particular time given the patient's clinical status and goals. But a device that is indicated at one point may become inappropriate later, and a new benefit-versus-burden calculation becomes necessary. When a patient's cardiac disease, or a new illness, worsens to a point where death is imminent, the burdens of the ICD exceed the benefits and may no longer fit into patients' overall goals for their medical care.

This is particularly true when the patient is approaching the end of life. Although prognosis in cardiac patients may be difficult to determine,[154,155] signs that patients with HF are near the end of life may include persistent, difficult to control symptoms; inability to reverse exacerbations despite maximal medical treatments; and spontaneous exacerbations without any identifiable trigger.[156,157] Conversations about the management of ICDs in patients near the end of life begin with a determination of what the patient and the family know about the advancing state of illness. The next step is to determine what the overall goals and wishes are for the patient. In this manner, the clinician is able to determine how the patient makes decisions and then tailor treatments to those goals. Then it can be determined how the ICD fits within those goals of care. For example, once a patient knows that his or her condition is advanced and not curable, he or she may want to focus only on QOL and comfort. In such patients, deactivation of the ICD may be appropriate given that they are near the end of life and that continued defibrillation will not change the outcome. Many patients, however, may not be ready to accept the fact that their illness is fatal or may have developed a psychological dependence on their device and do not wanted it deactivated.[141] Deactivation of an ICD should never be required, nor should a do-not-resuscitate order be considered tantamount to agreement to deactivation. Instead, it is important to have conversations in which the clinician specifically addresses the issue of device deactivation with patients and their families, and then have them understand that deactivation may be necessary in the future to avoid discomfort and that pacing functions may continue without the shocking component of the ICD.[158]

Taken in this manner, conversations about ICD deactivation are not one-time events but instead unfolding discussions over the course of a patient's illness trajectory. Indeed, a recent consensus statement from the Heart Rhythm Society noted that these conversations begin at the time of implantation and continue until the patient dies.[150] These conversations cannot occur once but instead unfold over the course of the patient's disease, a concept in line with palliative care and the complex and unpredictable trajectory of HF. Because exacerbations are unpredictable, these conversations begin at the time of diagnosis and ICD implantation so that patients and families can have a context for the changing nature of their illness goals of care, including possible deactivation. Then, when the patient is very near the end of life, raising the issue of deactivation is not a sudden surprise but instead a reevaluation of goals in the context of a patient's illness. In this manner, education of patients with ICDs and their families is a continuous process from the time of implantation through periods of worsening disease to the end of the patient's life. Only by communicating and educating patients in this manner can we ensure the best quality of care for patients with ICDs and their families.

ICD Patient Trajectory

For ICD patients, critical phases and events of care have been identified that may characterize their trajectory of illness and care (Figure). These phases can dramatically change a patient's perception about their well-being and their psychological response and include the short preimplantation and perioperative period during which evaluation and decisions about treatment prevail. It is important to acknowledge that
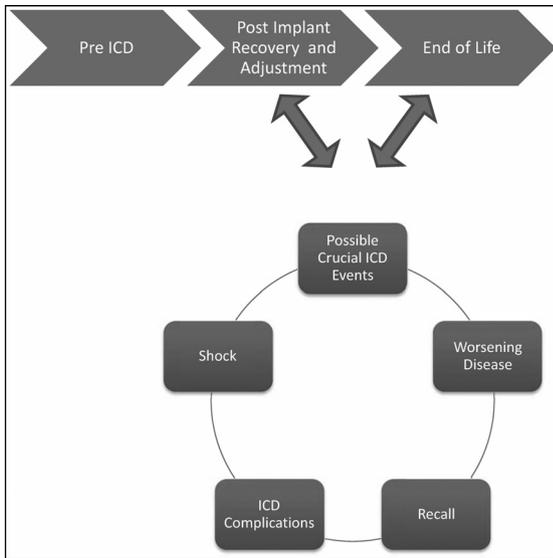
Figure. Trajectory of implantable cardioverter defibrillator (ICD) patient experiences.

this preimplantation period is embedded within the context of the patient's overall health and well-being and may be accompanied by preexisting comorbidities. Next is the postimplantation recovery phase, which may be a time of restoration of normal activities and adjustment to the ICD or may be heralded by events such as ICD shocks, complications, device and lead recall, and progressive symptoms. Critical events are clinical occurrences that may not occur in all ICD patients but, if experienced, can greatly alter the course of patient adjustment to their condition and the ICD, depending on the effectiveness of management strategies used by patients and providers. Finally, end of life ensues for all. The phases delineate points at which intentional ICD education and supportive care may need to be reinforced, intensified, or modified.

Interventions to Enhance Adjustment to the ICD

Psychological-Educational Interventions After an ICD

Over the past 2 decades, 15 studies have tested the effects of psychological or psychoeducational interventions on outcomes of anxiety, depression, ICD shocks, QOL, and symptoms in people who have an ICD (online-only Data Supplement Appendix Table B[33,159–170]). The majority of interventions directed toward improving psychosocial functioning have included patients who received an ICD for secondary prevention of SCA. In 2 studies, there was no definition of the exact patient population, and 5 studies have included both primary and secondary prevention patients; however, no differences were noted in psychosocial outcomes by ICD implantation indication. In general, the sample sizes have ranged from 8 to 246 subjects, with 8 studies having a total sample size <100. The majority of studies used a randomized trial format, with 2 using a sample of convenience[159,168]; 2 studies were cross-sectional compari-

sons,[104,171] and 1 used a crossover design.[162] The outcomes of the interventions were measured from 3 to 12 months after the intervention, with long-term benefits of psychosocial interventions noted in 5 studies at 12 months.[33,70,165,166,170] More than two thirds of the interventions tested were based on a cognitive behavioral therapy (CBT) framework. The length of CBT interventions ranged from 4 to 12 sessions, with the majority including 6 sessions. CBT interventions have demonstrated significant effects on anxiety, depression, and ICD concerns. Education and psychosocial support interventions have ranged from 2 to 8 sessions using a group or telephone mode of delivery. These interventions demonstrated significant improvements with regard to patient concerns, anxiety, and knowledge. Stress management interventions demonstrate significant effects on anxiety and have ranged from 6 to 11 hourly sessions.

Psychological and Educational Intervention Outcome Measures

Outcomes of the interventions primarily have included anxiety and depression. In the studies reported, anxiety has been measured with 3 instruments. The State-Trait Anxiety Inventory (STAI)[172] has been used in 5 studies, with statistical significance demonstrated in 2 studies. The Hospital Anxiety and Depression Scale–Anxiety (HADS-A)[173] has been used in 5 studies, with significant changes noted in 3 studies. The Hamilton Anxiety Inventory (HAM-A)[174] has been used in 1 study, with lower anxiety scores. Depression has been measured with 3 instruments: the Center for Epidemiological Studies–Depression scale (CES-D),[175] Beck Depression Inventory (BDI-I or BDI-II),[176] and Hospital Anxiety and Depression Scale–Depression (HADS-D).[173] All intervention studies that measured depression with the Center for Epidemiological Studies–Depression scale reported nonsignificant changes in depression. One study that used the Beck Depression Inventory demonstrated a significant change in depression at 9 months, although another study demonstrated no effect on depression using this instrument. Two studies used the HADS-D scale, both of which demonstrated significant improvements in response to interventions.

One study each used other instruments for assessing the effectiveness of interventions on psychological outcomes measured by the Profile of Mood States (POMS)[177] or the Psychosocial Adjustment to Illness Scale (PAIS-SR).[178] Both of these studies showed no significant change in distress as measured by these instruments. The Patient Concerns Assessment,[164] ICD Concerns Questionnaire,[179] and Florida Patient Acceptance Scale[180] were used in studies that demonstrated that interventions led to significant reductions in concerns/symptoms or significant improvements in acceptance of the ICD. Four studies used the SF-12[181] physical component score as an outcome, with only 1 study demonstrating a significant change using a cardiac rehabilitation intervention. Four studies also used the SF-12 mental component score,[181] all of which demonstrated nonsignificant changes after the intervention. One study demonstrated improvements in healthcare costs with a comprehensive cardiac rehabilitation intervention, whereas

2 telephone interventions had no effect on hospitalizations and emergency department visits.

Overview of Specific Psychological and Educational Intervention Studies

One of the first investigations tested a multicomponent intervention on the outcomes of mood and psychosocial adjustment at 4 months for cardiac arrest survivors who received an ICD.[159] The intervention consisted of a preoperative evaluation completed by a psychiatric nurse, telephone calls for 8 weeks after implantation of the ICD, and attendance at 2 support group sessions and was compared with a usual care group. The study used a convenience sample and was nonrandomized. There were no differences noted between the groups at 4 months on any scale of the Profile of Mood States or the Psychosocial Adjustment to Illness Scale. There was a nonsignificant increase in anxiety in the group that received the intervention at 4 months. In a similar approach, Carlsson et al[161] tested the effects of an intervention that consisted of a preoperative visit by a registered nurse with a follow-up telephone call at 2 weeks on health status at 1 month after receiving an ICD for secondary prevention. The authors randomized 20 patients (10 per group) to receive the intervention or usual care, which consisted of standard pre-ICD education. There were no between-group or within-group differences with the intervention according to the Nottingham Health Profile or an author-derived health profile. The number of sleep disturbances reported in the intervention group decreased with time. A pilot study by Smeulders et al[168] tested a nurse-driven self-management intervention delivered over 6 sessions in a single group (n=10) of first-time ICD recipients. Although no statistical significance was found after the intervention, anxiety, depression, and health-related QOL outcomes trended toward improvement.

Nine studies tested the effects of a CBT intervention after receipt of a first-time ICD. Kohn et al[160] tested 9 sessions of CBT in 60-minute sessions delivered over 5 months to secondary prevention patients after implantation of an ICD. The study used a randomized design with 36 patients compared with usual care. At 9 months, depression was significantly reduced in the CBT group compared with usual care. Additionally, scores reflecting psychosocial adjustment to illness and sexual adaptation were higher in the intervention group than with usual care. The greatest effects of the intervention were noted in those who received an ICD shock. There was no significant effect on the number of ICD shocks that were received. Frizelle et al,[163] using an intervention and wait-list control group design, tested the effects of 6 weekly 2-hour CBT sessions in 21 secondary prevention patients. Subjects crossed over to the other group after 6 weeks, and outcomes were compared at 12 weeks. The intervention significantly reduced anxiety, depression, and ICD concerns while improving QOL and shuttle walk distance. The sample size was small, and control condition differences were not completely reported. Chevalier et al[166] compared 6 sessions of CBT delivered over 12 weeks (reason for ICD unknown) against usual care using a randomized format. At the end of the intervention, the CBT group had higher heart rate variability, lower anxiety, and fewer ICD shocks and at 12 months continued to demonstrate higher heart rate variability and lower anxiety. There was no impact on depression or QOL noted at either time period. A limitation of this study is that >67% of patients dropped out, and only 11 patients in each group contributed data at the 12-month follow-up.

Lewin et al[169] randomized centers to intervention or usual care using 148 total patients studied in 6 centers. The intervention consisted of an ICD education plan that included 2 booklets, a diary, a relaxation tape, and 4 CBT self-help telephone calls delivered before ICD implantation and at 1, 3, and 6 weeks after implantation. Usual care centers did not receive the intervention. Outcomes were measured at 6 months, with a reported 44% dropout rate in each group. At 6 months, the intervention demonstrated significant improvements in physical health and physical limitations. The intervention had no effect on anxiety, depression, or ICD shocks. The intervention was found to be more cost-effective than usual care, with a reported reduced hospitalization rate in the intervention group. Fitchet et al[162] combined cardiac rehabilitation with a CBT intervention delivered over 12 weeks after ICD implantation, and a wait-list control group received the intervention after 12 weeks. The intervention (2 hours per week for 6 weeks) consisted of aerobic exercise combined with education, group support, and CBT self-help sessions. The primary outcome was anxiety, depression, and total exercise time. Only 11 of 16 patients completed the intervention and contributed data at the follow-up period. At 12 weeks, exercise time in the intervention group was significantly improved, whereas both anxiety and depression were significantly reduced. Conclusions are difficult to make because of the extremely small sample size (n=16) and high dropout rate.

Dunbar et al[170] tested a psychoeducational intervention delivered either in 4 group or individual telephone counseling sessions against usual care in primary and secondary prevention patients. The intervention consisted of 1 educational session delivered in the hospital, followed by posthospitalization structured coping skills training and education using the 2 CBT formats, followed by an additional booster group/telephone call at 4 to 5 months. The study group that received the intervention using the group format had lower anxiety at 3 months than patients in usual care. Participants randomized to usual care had twice the predicted probability of having depressive symptoms as those randomized to either the group or telephone intervention at 12 months. There was no significant differences or changes observed between the groups with regard to physical functioning. The usual care group reported more missed days from work at 12 months and more telephone calls to their providers at 1 and 6 months than the intervention groups. Irvine et al[33] tested an 8-session telephone and booklet intervention with relaxation exercises against usual care in patients with hypertrophic cardiomyopathy. Significant reductions in PTSD and avoidance symptoms and improvements in depression and mental health in women only were reported. There was no impact of the intervention on ICD shocks.

Two studies have tested psychoeducational interventions on psychosocial and healthcare use outcomes in those receiving a first-time ICD. Dougherty et al[164,165] tested a social cognitive theory–driven intervention with 168 secondary prevention patients over 3 and 12 months. The intervention was delivered over an 8-week period after ICD implantation and consisted of a booklet, weekly nurse coaching and education calls, and a 24-hour pager for support access. The intervention group demonstrated reduced concerns at 1 month and improved knowledge at 3 months, but there were no differences between randomized groups regarding anxiety, depression, ICD shocks, or QOL. A trend was noted in reduction in anxiety between the groups. At 12 months, there was a significant reduction in symptoms and anxiety and increased knowledge and self-efficacy in the intervention group compared with usual care. There was no significant impact on ICD shocks.

Crössmann et al[70] tested a psychological intervention to reduce anxiety at 6 months after ICD implantation in a sample of German patients receiving the device for primary and secondary prevention. Patients were randomized to usual care of 6 monthly support telephone calls plus a booklet. Support calls were semistructured and focused on living with an ICD, reducing avoidance behavior because of the ICD, exercise, and self-efficacy. Intervention patients received an average of 3.7 calls over 6 months, lasting ≈7 minutes each. Results demonstrated no significant effects of the intervention on anxiety, depression, symptoms, QOL, cardiac anxiety, or ICD attitudes. Significant improvements in anxiety, symptoms, and QOL were noted in those younger than 65 years of age. ICD shocks were associated with higher levels of depression and cardiac anxiety. The authors concluded that psychological interventions do not benefit every person in a uniform fashion.

Stress management interventions after an ICD shock were tested by Sears et al.[167] One intervention consisted of a CBT stress management intervention delivered by psychologists over 6 weeks in 90-minute sessions, for a total of 9 hours of intervention time per participant. The second intervention consisted of attending a stress management workshop delivered on 1 day for 4 hours, and no control group was included in the design. At the completion of the intervention at 2 months, anxiety was significantly reduced in the CBT group. There were no significant differences noted between the 2 interventions with regard to depression, acceptance of the ICD, physical or mental health, salivary cortisol levels, or inflammation. It was concluded that the longer intervention had a greater reduction on anxiety but that both intervention types had a significant effect in reducing physiological and psychological markers of distress.

Support Group Interventions

Three investigations tested the effects of support groups on patient outcomes after an ICD (online-only Data Supplement Appendix Table C). These studies,[171,182,183] 2 of which were conducted >2 decades ago, did not use a standardized approach to the support group delivery or a randomized design, and no studies demonstrated that attending an ICD support group significantly improved any outcome that was measured. The limitations of these studies include small sample sizes and no recording of consistent attendance or control of the content of the support group, which makes it difficult to determine what intervention was actually delivered or how to replicate it. One study demonstrated that anxiety increased in people who attended the support group compared with those who did not.

Conclusions About Psychoeducational Interventions

The 15 studies reporting effects of psychosocial interventions after an ICD have had variable results. Most have shown a stronger effect of interventions on anxiety than on depression. The sample sizes have been small, with large losses to follow-up or drop out because of deaths, declining health, and difficulty attending interventions. The effect sizes have varied widely, primarily because of large standard deviations and small sample sizes. None of the interventions tested have shown a long-term impact on ICD shocks. Although 1 study reported fewer calls to providers,[170] often hospitalizations or costs of care have not been measured. In terms of outcomes, the instruments showing the largest effect size in >1 study for anxiety and depression were the HADS-A and HADS-D. Neither the SF-12 or SF-36 was shown to be sensitive to change in any intervention study. The studies that produce the most robust results are those interventions that both enhance information and also teach skills for living successfully with an ICD. These interventions reduce psychological distress and improve QOL. There is promise for more ICD-specific instruments to be used in the future, including the assessment of patient concerns and Florida Patient Acceptance Survey (Table 1).[164,179,180,184–188] The most frequently used method was CBT, which demonstrated improvement in anxiety and depression after an average of 6 sessions. The education and support interventions improved anxiety, knowledge, and symptoms, whereas a stress management intervention demonstrated improvements in anxiety. A major limitation of this research is that the interventions have generally been provided to all participants versus using clinically significant indications for the intervention. This research strategy of treating all patients, even patients who have no elevations in distress, likely underestimates the absolute impact of the interventions for patients who manifest the clinical need for intervention.

Physical Activity and Exercise Interventions After an ICD

The physical and psychological benefits of exercise for patients with cardiovascular disease have been well established. Because physical functioning is a key component of QOL, and both physical activity and physical functioning are explicitly related to psychosocial status, the literature on cardiac rehabilitation and exercise interventions in ICD patients was evaluated (online-only Data Supplement Appendix Table D).[162,189–195] Exercise presents a challenge to ICD recipients because patients are uncertain of the level of

Table 1. ICD-Specific Assessment Measures

Measure	Authors	Construct Assessed
The Florida Shock and Anxiety Scale (FSAS)	Kuhl, Dixit, Walker, Conti, and Sears (2006)[184]	Shock anxiety
The Florida Patient Acceptance Scale (FPAS)	Burns, Serber, Keim, and Sears (2005)[180]	Device acceptance
ICD and Avoidance Survey	Lemon, Edelman, and Kirkness, 2004[185]	Behavioral avoidance
Patient Concerns Assessment (PCA)	Dougherty, Lewis, Thompson, Baer, and Kim, 2004[164]	ICD-specific patient concerns
The ICD Concerns Questionnaire (ICDC)	Frizelle, Lewin, Kaye, and Moniz-Cook, 2006[179]	ICD-specific concerns
The Implanted Device Adjustment Scale (IDAS)	Beery, Baas, and Henthorn (2007)[186]	Adjustment to device
Cognitive Appraisal of ICD Discharges	Godemann, Butter, Lampe, Linden, Werner, and Behrens, 2004[187]	Cognitive appraisal of ICD shock
Self-Efficacy Expectations After Implantable Cardioverter Defibrillator Implantation Scale (SE-ICD); Outcome Expectations After ICD Implantation Scale (OE-ICD)	Dougherty, Johnston, and Thompson, 2007[188]	Self-confidence in ICD self-care; outcome expectations after ICD implantation

ICD indicates implantable cardioverter defibrillator.

activity that is safe to perform without receiving an ICD shock. The benefits of exercise interventions for ICD recipients have been evaluated by 8 studies, with sample sizes ranging from 8 to 118 ICD recipients. All studies evaluated the safety of performing exercise after an ICD, and 7 measured the effects of exercise training on exercise outcomes. The majority of ICD recipients included in exercise trials had an ICD for primary prevention.

Before starting exercise after an ICD, most recipients had a symptom-limited exercise test to identify maximal heart rate and propensity for cardiac arrhythmias. Evaluation of ICD therapies in the 9 studies revealed there were 14 appropriate ICD therapies in the 659 subjects (2.1%) during exercise testing or training. There were 13 inappropriate ICD therapies during the study periods. One study[192] demonstrated that exercise reduced the likelihood of receiving an ICD shock in the follow-up period.

Overview of Specific Cardiac Rehabilitation and Exercise Studies

Aerobic exercise was found to significantly improve peak oxygen uptake ($\dot{V}o_2$max) in 4 studies. Six studies combined outpatient monitored exercise training with unmonitored sessions at home, with 3 having additional components of information and support. Two studies were retrospective in nature, 1 a telephone survey and 1 a chart review. In studies in which comparisons were made to a control group without an ICD, mixed results with ICD recipients were reported that showed no change in oxygen uptake in some.[189,191] Additionally, 2 samples of ICD recipients demonstrated improvements after 8 weeks of exercise training, although this was not significant.[193,194] Improvement in workload after cardiac rehabilitation was noted in an early study without a control group, with 10% reporting ICD issues and need for reprogramming.[190] When reporting metabolic equivalents, 2 studies reported significant increases after exercise compared with either a non–cardiac rehabilitation sample or matched control subjects without an ICD,[192,194] and 1 small study reported a 30% versus 37% increase in peak metabolic equivalents comparing ICD patients with matched control subjects without an ICD.[195] Exercise times were increased in

ICD recipients in 2 studies by ≥2 minutes.[162,194] One study evaluated the effect of an exercise training program on heart rate variability, noting improvements in both the time and frequency domain measures of heart rate variability.[194]

Conclusions Regarding Cardiac Rehabilitation and Exercise Interventions

Cardiac rehabilitation programs that include exercise training appear safe in those ICD recipients who are appropriately assessed by symptom-limiting exercise testing, albeit data are limited. Both inpatient and outpatient supervised programs have been evaluated, along with home exercise programs. The evaluation of psychological outcomes in exercise interventions is limited. Only 3 studies evaluated psychological or QOL outcomes, with results revealing reduced anxiety but not depression,[162] increased QOL in those with ICD–cardiac resynchronization therapy but not ICD alone,[193] and no change in physical or mental status using the SF-36.[194] Exercise intervention studies may require greater incorporation of behavioral strategies to link with desired psychosocial outcomes. Research using a comprehensive intervention with cardiac rehabilitation, education, nutrition, nursing, psychological, and behavioral strategies may help to establish the benefits of exercise and interdisciplinary approaches.

Recommendations for Clinical Practice and Directions for Future Research

Recommendations for Clinicians

On the basis of the review of existing data, it is clear that psychological responses to the ICD are varied and may range from mild to serious concerns with clinically significant anxiety and depression. Clinicians providing ICD care during the preimplantation and postrecovery periods should recognize the potential dynamic trajectory of the illness course and patient experiences and should routinely assess for patient and family member concerns, questions, and psychosocial status, including clinical assessment for changing or elevated anxiety and depression. The implementation of the recommendations will require collaboration among the members of the multidisciplinary team including electrophysiologists,

cardiologists, nurses, psychologists, and primary care providers. A summary of specific recommendations for clinical practice based on the available data to date and expert opinion is provided in Table 2.

Preimplantation

For the adult patient and their family members, preimplantation education and provision of information are key responsibilities of the clinical team, and this includes presentation of the advantages and disadvantages of the ICD for the individual patient's arrhythmia treatment, including primary prevention. The ICD recipient and a family member should be provided with direct and objective discussion about ICD benefits, limitations, general prognosis, expected trajectory of illness, battery longevity and device replacement, and modes of death in end-stage HF, if appropriate. A review of the entire medical condition of the patient before this discussion with the patient and family will inform the interdisciplinary team in order for them to consider the relative contributions of 3 competing outcomes: The likelihood of life-threatening ventricular tachyarrhythmia that will be terminated successfully by defibrillation, the likelihood that the patient will die of progressive HF, and the likelihood that the patient will die of other causes. Once considered, they should be presented to the patient. Discussion with individual patients can elicit their preferences regarding prolongation of life, prolongation of death, and the functional capacity they consider essential for meaningful QOL and survival. Presentation of information to the patient with HF should include the fact that HF is a lethal disease with progressive HF symptoms of dyspnea, fatigue, and body swelling, or other symptoms; that SCA accounts for the majority of deaths in patients who have reduced ejection fraction with few symptoms (class II) and no other life-threatening disease; and that the ICD is highly successful at preventing these deaths. The more severe HF symptoms they develop, the more likely it is that they will die sooner, with or without the ICD. Against this background of benefit, the discussion of potential impact on lifestyle and adverse effects of the ICD can be introduced. The real possibility of shocks and how they are described by ICD recipients can be presented; for example, some patients rank shock pain at approximately a level of 5 on a scale of 1 to 10, with 10 representing the worst possible pain.[102] The possibility of inadvertent shocks requires careful explanation, acknowledging the necessity of having sensitive monitoring to enhance detection of truly life-threatening arrhythmias, as does the discussion of the rate of lead complications and failures. Although patients are more aware of the possibility of recalls and advisories, which are often in the news, they should be informed that the absolute risk from these is relatively minor. If they understand the modest chances of their lives being saved by the device, it is easier to place into context the much smaller chance that their lives will be lost because of a problem with a component.

Patients should be informed at the time of implantation that inactivation of the defibrillator function can be performed easily and selectively. Explaining why this would be considered often clarifies the previous issues relating to different modes of death. There are currently no published data on this

Table 2. Recommendations for Clinical Practice to Improve Psychological Outcomes in Adult and Pediatric ICD Patients

Preimplantation

Provide the ICD recipient and family member direct discussion about ICD benefits, limitations, general prognosis, expected trajectory of illness, battery longevity and device replacement, and modes of death in end-stage HF, if appropriate.

Emphasize the protective value of the ICD against SCA but no effect on the underlying cardiac condition separate from biventricular pacing or other functions of the device, if present.

Encourage expression of patient and family preferences for therapies by weighing QOL and survival.

Review the expected impact of the ICD on usual activities, including driving, travel, sexual and physical activity, and length of time for restrictions, if any.

Provide information to address the specific concerns of women.

Provide age-specific, developmentally appropriate patient education about the device and the underlying disease, taking into account children's understanding of illness and the age and developmental level of the child.

Ask children and parents to share their thoughts and feelings regarding device placement.

Postimplantation, early recovery, adjustment

Provide instructions on wound care, medications, and pain and symptom management, and address concerns before hospital discharge.

Tailor information for age, sex, literacy, and comorbidities.

Reinforce preimplantation information on return to physical activity, work, travel, and sexual activities.

Provide a clear and succinct shock plan for what the patient and family are expected to do in the event of a shock.

Provide information to reduce assessed or expressed concerns related to body image, fear of shocks, and financial issues.

Assess ICD concerns and psychological status at follow-up visits.

Encourage patients and partners/family members to dialogue about the impact of the ICD and illness in their lives, as well as management approaches.

Provide reinforced and updated information after a routine battery/device replacement.

Promote problem solving, access to information, and ways to seek social support as problem-focused coping strategies. Consider structured support groups that focus on providing information and positive coping skills.

Provide access to information through Web resources if appropriate.

Adapt shock plan information to the developmental needs of the child.

Promote psychosocial resiliency in young people with ICDs by identifying psychosocial vulnerabilities early; be open, honest, and age-appropriate.

Provide information to parents; give parents advice about follow-up procedures, return to school, and activities.

ICD events

Prevent shocks for ventricular arrhythmias with individual and specific drug therapy, ablation procedures, and for pediatric patients, patient-specific programming of tachycardia detection criteria and termination algorithms.

Discuss the meaning of shocks with patients when they occur.

Reduce the number of inappropriate shocks in pediatric ICD recipients by optimizing the programmable parameters of the device, including advanced detection criteria; tailor sinus rate setting based on exercise stress testing.

(Continued)

Table 2.   Continued

Hold face-to-face discussions when possible with the patient and his or her family regarding the specifics of any advisory or recall.

Promote informed decision by including all potential implications of replacement, including medical, psychosocial, and burden of cost issues in the discussion.

Refer to mental health provider if indicated.

End of life

Review patient and family understanding of their disease, goals of care, and desired outcomes, as well as the relationship of the ICD to those stated goals.

Discuss the potential to deactivate the shocking component of the ICD.

Consider enhanced symptom management and palliative care.

Respect the right of the patient to request inactivation, right of the clinician to refuse inactivation, and right of the patient to request a clinician who will inactivate.

ICD indicates implantable cardioverter defibrillator; HF, heart failure; SCA, sudden cardiac arrest; and QOL, quality of life.

subject, but there is a reasonable expectation that patients and families who are informed initially of the potential for device inactivation will find it less disturbing to consider device inactivation when prognosis and comfort are limited in the future by chronic disabling disease.

Uncertainty remains a very difficult concept to present to individuals. A suggested script containing these issues for discussion has been proposed.[196] This uses the concept of "100 patients like you" to communicate the relative risks of defibrillator-preventable death, nonsudden death, inappropriate shocks, and other adverse events. The rates are based primarily on the SCD-HeFT trial,[7,197] with input from the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II).[6] The complexity of this discussion is already sufficiently daunting that it would be difficult to introduce the concept of reduced life expectancy after ICD shocks.[197] Standardized presentations of this material may need to include tailoring of information about risks and benefits, including psychological as well as mortality, in subgroups defined by female sex, age <50 or >75 years, chronic renal disease, and multiple HF hospitalizations.[198–200]

Expected trajectories of physical and psychological recovery and impact of the device on usual activities, such as driving, occupational, sexual, and physical activities, are important to address, including length of time on restrictions, if any. Information on electromagnetic interference and guidelines for travel are essential. When extended travel is anticipated, provision of the name of a cardiologist or electrophysiologist in the area is helpful. Inclusion of the family member in the discussion and clear, direct responses to questions and concerns are recommended. Written material and media presentations help reinforce the content for pre-ICD patients and their families, both of whom will have varied health literary and preferred ways of learning.

Psychosocial adjustment to an ICD for children and adolescents is best addressed before device placement. To have a baseline from which to identify those who might be at risk after ICD placement, we recommend preimplantation screening for pediatric patients who exhibit signs of anxiety or depression or have other contributing factors that may inhibit positive adjustment to the ICD. Referral to an appropriate mental health provider is mandatory when positive screens are obtained. Because many pediatric patients are receiving concomitant treatment with β-blockers, which have an adverse effect of depression, assessment and documentation of baseline psychological status can be compared with longitudinal data obtained at regular intervals. Interventions should be implemented early in the postimplantation period. In the pediatric population, before device implantation, clinicians should provide age-specific, developmentally appropriate patient education about the device and the underlying disease origin.

Positive communication strategies are recommended to emphasize the protective value of the ICD versus the risk of an SCA and to encourage children and adolescents to share their thoughts and feelings about device placement.[4,201] When providing patient and family education to pediatric ICD recipients, clinicians should focus on adhering to the model of family-centered care, taking into account children's understanding of illness and the age and developmental level of the child.[202]

Postimplantation, Early Recovery, and Adjustment

During hospitalization, at discharge after ICD implantation, and during follow-up visits, reinforcement of the information provided before implantation is essential. Provision of written information at the patient's level of health literacy is recommended. Patient education materials are available from health education companies, industry, professional societies, and institutional sources. Provision of information on wound care, pain management, arm activities and exercise on the implanted side, sleep promotion, and return to activities is recommended as noted in Table 2. Tailoring information to the needs of the ICD recipient by age, sex, other comorbidities, and their expressed concerns is key. Providers (electrophysiologists, nurses, cardiologists, and primary care physicians) who see ICD patients during follow-up visits should assess for any questions or concerns as well as evidence of clinically significant emotional distress. The questions of the Patient Health Questionnaire (PHQ-2) can be used as a short screening tool for depressive symptoms. These ask whether the patient has "over the last two weeks," been bothered by any of the following problems: (1) little interest or pleasure in doing things, and (2) feeling down, depressed, or hopeless. A yes response to either or both questions is then followed by administering the full instrument (the 9-item depression scale of the PHQ [PHQ-9]) as described in detail by the American Heart Association science advisory.[29a] The preponderance of evidence suggests that women with ICDs have higher anxiety and depressive symptoms than men, but these differences are not always statistically significant. For women, concerns about the ICD differ from men in that the ICD may take on special meaning related to family roles, concerns about childbearing and childrearing activities, body image, and issues with routine mammograms, and women may have increased pain during early recovery because of the sensitivity of breast tissue and increased use of arms for activities of daily living.[60,203] Individualized information as to whether

childbearing is safe, whether mammograms can be performed, as well as attention to implantation procedures[204] can alleviate possible concerns and promote symptom management for women.

Another recommendation for clinicians is to include a clear and succinct plan for what the patient and family are expected to do in the event of a shock. Referred to as a *shock plan*, the purpose is to provide specific guidance in the case of an ICD shock, because it has been documented that some patients do not have a clear idea of what to do in the case of device discharge.[131] Having a standardized and well-understood shock plan should be a critical component of both an adult's and a child's clinical care.[205,206] The plan should be adapted to include the specific needs of children, adolescents, and their parents, as well as adults who live alone.

Given the positive outcomes of studies using cognitive behavioral training and techniques,[160,163,166,167,169,170] clinicians are encouraged to incorporate these strategies into their communication, education, and support activities for ICD patients. Formal CBT may involve a series of 8 to 10 individual or group sessions for those who are clinically anxious and/or depressed and referred to a trained provider. However, members of the multidisciplinary team (nurses, physicians, psychologists, and social workers) can apply their behavioral skills and training to teach new coping strategies, such as use of problem solving and reframing of negative thoughts associated with the ICD when encountered. As studies have not shown significant improvements in outcome with support groups, and 1 study demonstrated an increase in anxiety, incorporation of CBT techniques into support groups may be more effective than unstructured groups.

To detect and manage early or late psychosocial issues in children and adolescents, the checklist developed by Sotile and Sears[207] has been found to be helpful by some clinicians. Known as the *Four A's checklist* for helping patients cope with ICDs, the approach addresses some of the common concerns experienced by pediatric ICD recipients. The first A is for *Ask*, which refers to assessment and clarification of patient concerns to identify specific problems. The second A is for *Advise*, which entails the anticipation of psychosocial impact and the provision of necessary interventions at the outset of patient care. The third A is for *Assist*, which includes addressing practical issues that are of importance to the patient; providing ongoing education to patients and their families about their underlying condition and the ICD; allowing patients to describe their feelings, challenges, and experiences; and using specific clinical experience to anticipate and communicate future events. The fourth and final A is for *Arrange*, which includes referral to additional resources such as social support systems outside the family or consultation with a mental health specialist.

In conjunction with this assessment, DeMaso and colleagues[208] recommend guidelines for clinicians to promote psychosocial resiliency in pediatric and adolescent patients with ICDs. Specific recommendations include the following: (1) Identify psychosocial vulnerabilities early; (2) be open, honest, and age appropriate; (3) provide information to parents; (4) give parents advice about procedures; (5) help parents provide consistency and predictability; (6) let the patient and family know that showing feelings is normal and helpful; (7) be alert for potential school fear; and (8) consider support for coping.[208]

Participation in formal cardiac rehabilitation is recommended if the patient meets the criteria for reimbursement or has other financial resources. Aerobic exercise should be encouraged using heart rate programming information from the ICD to prevent inappropriate ICD shocks during maximal physical exertion. Patients participating in supervised exercise can improve their oxygen consumption and workload, with a small risk for ICD shocks (<2%).

ICD Events

Focused efforts by healthcare providers, industry, and patients to minimize adverse events of shocks, infections, and device/lead problems are essential (Table 2). Minimization of the triggers of inappropriate shocks in adults (ie, treatment of atrial fibrillation or other supraventricular tachycardia) and prevention of shocks for ventricular arrhythmias can be optimized by use of individual and specific drug therapy and ablation procedures. Providers should recognize that ICD patients who experience events of multiple shocks and electrical storm are at high risk for PTSD, and early referral to a psychiatric or mental health professional may be beneficial. When recalls occur, direct contact with the participant and family and prompt resolution are important.

To reduce the number of inappropriate shocks in pediatric ICD recipients, several strategies are recommended. The most important is optimizing the programmable parameters of the device. Advanced detection criteria, such as rate stability and sudden onset, can be helpful, as well as higher tachycardia detection rates.[127] Because of the lack of sinus node dysfunction in many pediatric ICD recipients, exercise stress testing can be used to determine how high the sinus rate might be to program the detection rate higher than that of sinus tachycardia. Botsch and colleagues[209] reported a relatively low incidence of inappropriate shocks (only 2 of 63 shocks in 11 of 33 pediatric patients) and attributed their success to the use of individual and specific drug therapy, ablation, and patient-specific programming of tachycardia detection and termination algorithms.

With respect to manufacturer advisories or recalls, we recommend an in-depth, face-to-face discussion with the pediatric patient and their parents about the advisory or recall in order for an informed decision to be made regarding therapeutic options. In a recent report of the impact of manufacturer advisories and US Food and Drug Administration recalls of ICD generators, Mahajan and colleagues[210] identified 236 pediatric and coronary heart disease patients who had implicated devices in response to 3 advisories from ICD manufacturers. Of those, 62% were left in place and 38% were explanted. Of the 89 devices that were explanted, only 2 were found to be defective; there were 2 complications associated with device explanation, including 1 death. The decision to replace an ICD is a difficult one, even more so in children and adolescents. Any discussion should include all potential implications of replacement, including medical, psychosocial, and financial issues.

End of Life

As patients near the end of their lives, clinicians should have a conversation with the patient and his or her family about their current understanding of their disease, their overall goals of care and desired outcomes, and the relationship of the ICD to the stated goals (Table 2). For example, for a patient whose goal is to live as comfortably as possible, deactivation of the shocking function of the ICD may be appropriate. For a patient whose goal is to prolong life regardless of the ultimate state of physical function and mental awareness, keeping the shocking function of the ICD active may make sense, with the caveat that at the very end of life, the issue of deactivation may need to be raised again with the family if the patient is receiving multiple shocks from the device. Because these conversations are complex and often emotionally challenging (for patients, the family, and often the clinicians involved), it is best to have them early in care and in nonemergent situations. Previous guides to conversations with patients with advanced illness,[211,212] and in particular relating to conversations about defibrillator management,[150,213] have been published. Many of these guides include sample language to be used at each part of the discussion with patients and their families.[150,213] Deactivation of the ICD is best done by a clinician with electrophysiology expertise when possible, preferably by someone with an established relationship with the patient. If electrophysiology expertise is unavailable, allied industry personnel can aid in carrying out deactivation under direct supervision of health providers, such as a nursing facility physician or home hospice nurse. Only in extreme emergency situations, when no such clinical personnel can be arranged, should allied industry personnel be asked to perform this without supervision. At this point in the patient trajectory, respect is essential for the individual rights of the patient to request or refuse deactivation, the right of the clinician to refuse to perform deactivation, and the right of the patient to request a clinician who will deactivate the ICD.[150,214]

Recommendations for Future Research

Given the gaps in the evidence to guide information and psychological care for ICD patient, a list of recommendations for future studies can be found in Table 3. In addition to these focused research questions, the experts from the panel recommend that psychological and QOL assessments be integrated into the designs of all mortality and morbidity focused clinical trials of new devices and ICD populations and that family members be included to the degree possible. Additionally, ICD-specific measures of adjustment, concerns, and QOL that are more sensitive and standardized measures should be incorporated into clinical trials. The continued development, validation, and addition of patient-reported outcomes to clinical trials will greatly enhance the available data and understanding of the impact of the ICD on all realms of the patient's life.

Preimplantation Phase

Research demonstrating that the psychological responses to an ICD are often most pronounced around the time of

Table 3.   Recommendations for Future Research

Preimplantation
What formats of information promote the patient and family partner satisfaction with their decision making about ICDs?
What pre-ICD content and tone are essential to promote post-ICD acceptance and psychological response?
Do decision aids help patients achieve a "quality decision" about their ICD decisions and treatment?
What information about the pros and cons of ICDs is useful from a patient perspective?
Does tailored information provide better, longer-term device acceptance? What factors should be used for tailoring information, that is, sex, age, health literacy, or severity of illness?
What information do experienced patients suggest be provided, especially those undergoing routine device replacement?
What clusters of risk factors identify ICD recipients at risk for psychological distress after implantation, for both adults and pediatric patients?
Postimplantation, recovery, and adjustment
Education and psychological support
What ICD technological improvements facilitate patient and family experience, adjustment, and recovery?
Does an increase in the perceived security from the ICD promote increased physical exertion or engagement in life?
What kinds of information technology tailored for patients and their family members can improve QOL outcomes?
What interventions help family and intimate partners provide essential support to ICD patients?
What is the effect of ICD shocks on physical functioning?
What are the cost-effectiveness and QOL outcomes of various psychoeducational interventions?
Because ICD shocks are positively related to adverse psychological adjustment, interventions that can reduce the likelihood of receiving an ICD shock should be tested.
In addition to CBT, what other psychoeducational interventions are effective in reducing or preventing adverse psychological responses?
What are effective methods to translate effective psychoeducational interventions into practice?
What psychoeducational, educational, and psychological support intervention delivery methods are effective to reach as many ICD recipients as possible?
Exercise and physical activity
What interventions promote safe unmonitored exercise and physical activity interventions (home-based, walking, gym)? What are the psychosocial outcomes of these interventions? How can family members be involved in promoting physical activity interventions?
What are optimal exercise testing protocols to prescribe and promote exercise in ICD patients?
What are the optimal information, educational content, and formats regarding exercise and physical activity for standard use in clinical practice?
What other outcomes of exercise interventions can be expected in addition to oxygen consumption and oxygen uptake outcomes?
Pediatric/adolescent patients
Can risk profiles of those most likely to receive ICD shocks during exercise be identified?
What can cardiac rehabilitation add to the outcomes of QOL and patient acceptance?

(Continued)

Table 3.   Continued

Given the small number of pediatric and adolescent patients, what strategies promote engagement with other ICD patients and social support?

What level of sports participation and activity is appropriate for pediatric and adolescent ICD recipients?

What are the best practices to reduce the psychosocial and physical effects of sports/activity restrictions?

What strategies promote resiliency in pediatric and adolescent ICD patients over time?

ICD events

Post-ICD shock

What are the most salient acute shock responses for ICD patients?

How does the acute clinical management of an ICD shock affect patient recovery?

Can remote interventions via Web and cell phone technologies reduce avoidance behavior subsequent to shocks?

Does an age-specific tailored shock plan improve outcomes for pediatric and adolescent ICD patients and their parents?

Post-ICD recall and complications

What are the best approaches to managing recall messages to individual patients?

What types of media dissemination strategies create the least distress?

What are best methods to reinstill patient confidence in the technology after a recall or complication?

What are the effects of recalls and complications on pediatric/adolescent patients and their parents?

End of life

Does systematic and early discussion of EOL produce better EOL outcomes?

What are the costs and outcomes of introducing palliative care into ICD care? What is the best timing, and what approaches are needed for ICD palliative care?

When is the best time to initiate EOL discussion and to create a plan for advanced care management?

What is the best approach and timing for preparing family caregivers for EOL decision making?

What is the effect of strategies such as family conferences and decision aids focused on potential ICD deactivation at EOL on advanced care planning?

What is the impact of EOL discussions on psychological outcomes and quality of death for ICD patients and their caregivers?

What is the best way to teach clinicians, including clinicians-in-training, to improve their skills for conversations about advanced care planning for ICD patients?

ICD indicates implantable cardioverter defibrillator; QOL, quality of life; CBT, cognitive behavioral therapy; and EOL, end of life.

implantation suggests a need to study approaches to support potential ICD patients and their family members in the assimilation of a large amount of information and decision making in the midst of a health crisis. This could be informed by research that focuses on testing effects of various formats, tones, and combinations of information (eg, face-to-face discussions, video recordings of actual patient experiences, and written and Web-based materials) and decision aids. A greater understanding of the perceived pros and cons of ICDs

from patient perspectives will assist in the development of these materials. Past research has suggested that psychological response may vary by age, sex, disposition, and levels of anxiety and depression at preimplantation, and thus, studies that promote greater understanding about how to tailor information and support during preimplantation to promote optimal short- and long-term psychological outcomes would be useful. Research and clinical aids that have sensitivity to racial, cultural, and economic differences would be ideal. Finally, it is essential that approaches appropriate for pediatric and adolescent patients and their families be tested.

Because social support is an important component of positive psychosocial adjustment, greater study is needed on how to foster social support. Preimplantation support interventions, including varied support from providers, family, and/or experienced ICD patients, should be developed and tested.

Postimplantation, Early Recovery, and Adjustment

Research is needed to establish guidelines for effective approaches to reducing adverse psychological outcomes in ICD adult and pediatric patients, and studies using a randomized controlled trial design with adequate sample sizes to capture differing responses between primary and secondary implantation reasons are needed. CBT was the most widely used method for intervention development and delivery and has been shown to be effective after an average of 6 sessions. Although CBT is successful, translational studies need to be completed to make this approach more applicable clinically. Additional intervention approaches and intervention delivery methods should be tested in future studies so as to reach as many ICD recipients as possible. The impact of psychological and comprehensive cardiac rehabilitation interventions on cost and quality outcomes should be assessed. Because ICD shocks are related to adverse psychological adjustment, multifactorial interventions to reduce the likelihood of receiving an ICD shock should be developed and tested. Moreover, research examining the best approaches to recovery from shock is needed and may yield the most direct route to establishing the value of psychosocial interventions.

With support groups intuitively a candidate intervention, yet considering their low impact in prior studies, the format or content of these groups and Web-based discussion boards should be enhanced and tested. Ideally, these types of groups could even become supported by healthcare payers as evidence is developed to validate their value to ICD patients and families in terms of lifestyle and QOL outcomes. Because of the small number of pediatric ICD recipients compared with adults, it may be rare for these patients to know another individual their age who has an ICD. In addition to families, who often provide social support to their children, testing such interventions as buddy systems (both in person as well as distance/technology supported) and support groups may

help them connect with others who understand ICD-related experiences, particularly during their rapidly changing developmental stages.

Future research should also address measurement issues, and ICD-specific instruments that address specific needs of ICD recipients should be used more widely (Table 1). General measures of health status have not been found to be useful in testing intervention outcomes. For measuring psychological adjustment after an intervention in patients with an ICD, the most widely used and most reflective measures of change in anxiety and depression have been the HADS-A and HADS-D; however, the field could benefit from testing of other instruments widely used in cardiovascular research and care, such as the PHQ-9[215] and the Brief Symptom Inventory,[216] which would also allow better comparison with the ICD and cardiac populations.

Studies of exercise and comprehensive cardiac rehabilitation after ICD combined with psychoeducational interventions are recommended to promote improved physical and psychological function. Future testing of exercise and physical activity interventions using larger sample sizes and randomized controlled trial designs, greater development of exercise testing protocols, and expansion of outcomes beyond the traditional oxygen consumption and oxygen uptake outcomes for ICD patients are warranted. Unmonitored exercise interventions (home walking, gym) in people with an ICD should be developed and tested, given that cardiac rehabilitation programs are safe and associated with few ICD shocks. Exercise information and education for those with an ICD should be developed and tested so that it can ultimately be standardized for use in clinical practice to promote physical activity and reduce avoidance behavior. Risk profiles of those most likely to receive ICD shocks during exercise should be developed and tested. This area of research is very underdeveloped, may be helpful in reducing avoidance and improving multiple outcomes, and warrants careful attention for future intervention testing.

Although Pedersen and colleagues[37] concluded that there is currently no evidence that adult patients who receive ICDs for primary prevention of SCA have poorer QOL or greater distress than those receiving ICDs for secondary prevention, this may not be the case in pediatric ICD recipients. The issue is prominent for those pediatric/adolescent patients with anatomically normal hearts and genetically determined diseases that put them at risk for SCA, particularly when it comes to sports participation.[131] These individuals are generally healthy until an event or discovery of a genetic predisposition requires immediate restriction from competitive sports for functional and protective reasons secondary to ICD placement. In a Delphi study in which a sample of pediatric cardiovascular providers specializing in the care of children with rhythm disturbances were asked to identify the most common psychosocial issues seen in their ICD patients, the second-highest ranked issue was that of sports participation/activity restrictions.[201] Few data exist that indicate that sports participation is dangerous in ICD recipients, and this issue warrants further study, particularly in children

and adolescents with primary ventricular arrhythmias in the presence of anatomically normal hearts. In a recent abstract presentation, Johnson and colleagues[217] concluded that restriction from sports participation in patients with congenital long-QT syndrome may be excessively restrictive.

DeMaso and colleagues[208] provide guidelines for promoting psychosocial resiliency in pediatric patients with an ICD; however, it is currently not known what factors or to what extent certain factors contribute to resiliency in this patient population. Further research is needed to determine specific factors that enhance resiliency so that interventions that can be used to promote resiliency in all children and adolescents with ICDs can be developed and tested.

ICD Events

A number of research priorities emanate from the existing data and reports on patient and family experiences with shocks and recalls. Little is known about what is most salient about shocks for patients and families and what type of preparation will reduce short- and long-term psychological responses. Studies that develop and test readily available interventions, such as an on-call advisor available by telephone or Web- or cell phone–based applications, should be conducted for their effects on psychological outcomes and reduction of avoidance behaviors. Essential information that can be added to improve the shock plan approach for adult, pediatric, and adolescent patients and their family members should be explored and tested for effectiveness.

Great efforts are under way to minimize recalls of devices and leads, yet when these occur, examining the best approach to deliver the message to patients and their families is still required. Knowledge about the best approaches to reinstill patient confidence in technology after a recall should be developed.

Research to date has indicated the reasons children and adolescents experience inappropriate shocks; however, few aggregate data exist that demonstrate successful strategies for decreasing their incidence. By incorporating specific data reflecting strategies aimed at reducing inappropriate shocks (ie, programmable parameters) into national databases such as the Kids' Inpatient Database (KID) or the National Cardiovascular Data Registry's ICD registry, which has been recently adapted to include pediatric and congenital heart disease patients,[218] researchers could use these large data sets to determine the efficiency of certain strategies proven successful for specific disease cohorts.

Studies addressing the psychosocial effects of recalls or advisories in the adult ICD population have resulted in mixed findings[219]; however, the psychosocial impact on children and their families has not been studied to date. Because of the length of time that children and adolescents will have to live with an ICD and the likelihood of recalls and advisories in the future, research on the psychosocial impact of these issues in the pediatric population is warranted. Once these data have been obtained, appropriate interventions can be developed and tested.

End of Life

In terms of having conversations in patients with advanced illness, further research is needed to determine the most effective time and manner in which to have these conversations, as well as the ultimate impact of these discussions on psychological outcomes and satisfaction with care for patients and their caregivers. A specific study could test whether introduction of information about deactivation possibilities early in the trajectory of care makes a difference in how that information is received when broached again at the end of life. Research on ways to best teach clinicians, especially clinicians-in-training, how to improve their skills with regard to conversations about advance care planning is needed as well. Many questions remain about the role of palliative care in the overall care of ICD patients and their families, including best practices, timing, cost, and QOL outcomes, as well as satisfaction with quality of death and bereavement support outcomes. Studies of palliative care delivered through general providers versus specialized teams could test costs and outcomes.

Summary

This statement has been a comprehensive review of what is and is not known about psychological responses and psychosocial care for adult and pediatric ICD patients and their families. Recommendations for clinical practice and research are provided to promote optimal care during the interim development of greater evidence to guide practice. As clinicians become more cognizant of the need for and more skilled at providing greater psychosocial support in the preimplantation, postimplantation, and recovery periods, during times of ICD events and at the end of life, we are hopeful that ICD patient and family psychological outcomes will benefit.

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Paul Wang	Stanford University	Boston Scientific†; Medtronic*; St. Jude*	None	ACT Medical*; Bard*; Boston Scientific†; Medtronic†; St. Jude*	None	None	Impulse Diagnostics*; LifeNotch†; St. Jude*	None
Vicki L. Zeigler	Texas Women's University	None	None	None	None	None	None	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (1) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (2) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

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Dan D. Matlock	University of Colorado Denver	Principal Investigator on a grant from the Foundation for Informed Medical Decision Making, a foundation that develops decision aids*	None	None	None	None	None	None
Jennifer Peura	Medical University of South Carolina	None	None	None	None	None	None	None
Marilyn A. Prasun	Millikin University	None	None	None	None	None	None	None
Lynne Stevenson	Brigham and Women's Hospital	None	None	None	None	None	None	None

This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all reviewers are required to complete and submit. A relationship is considered to be "Significant" if (1) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (2) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "Modest" if it is less than "Significant" under the preceding definition.
*Significant.

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Educational and Psychological Interventions to Improve Outcomes for Recipients of Implantable Cardioverter Defibrillators and Their Families: A Scientific Statement From the American Heart Association

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on behalf of the American Heart Association Council on Cardiovascular Nursing, Council on Clinical Cardiology, and Council on Cardiovascular Disease in the Young

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