Technology Assessment

Technology Assessment Program

Systematic Review of Decision Tools and their Suitability for Patient-Centered Decisionmaking regarding Electronic Cardiac Devices

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Systematic Review of Decision Tools and their Suitability for Patient-centered Decisionmaking regarding Electronic Cardiac Devices

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Structured Abstract

Objectives: 1) Identify validated decision aids available for electronic cardiac devices (ECDs); 2) Review evidence on the effectiveness of decision aids for promoting informed decisionmaking and their relevance to the Medicare population; 3) Identify barriers to use of decision aids.

Data Sources: We systematically searched six electronic databases up to February 2011. We searched extensively for grey literature and contacted experts in the field.

Methods: Two reviewers independently selected studies and assessed quality. One reviewer extracted data, and a second reviewer checked data. We assessed quality of tools using recognized criteria and synthesized findings using meta-ethnographic and integrative approaches.

Results: We identified four decisionmaking tools for insertion of implantable cardioverter-defibrillators (ICDs) and pacemakers in patients with heart failure or with or at risk for arrhythmia. No trials evaluating these tools were available. The tools contained adequate information for technical comprehensiveness, but were weak in addressing patient quality of life and presenting neutral information about devices. Deactivation was not addressed in any of the tools. No tools existed for deactivation of any device.

We identified 67 studies on barriers to the use of decisions aids in ECD populations: patient experiences (n=33), psychosocial outcomes (n=26), and communication (n=8). Studies focused predominantly on ICDs. Overall study quality was moderate.

The decisionmaking process is shaped by factors that are inherent and contextual. Inherent factors relate to the complexity of decisions and included ambiguities: about prognosis, likelihood and frequency of shocks, prognosis, and size of risks and benefits of decisions to deactivate an ECD. Decision-making occurs in contexts characterized by a relatively new clinician-patient relationships, clinician reticence, and lack of institutional support for the decisional process. Patients generally had poor knowledge of key aspects of deactivation, the role of the device, and the impact of deactivating the device on their health. Communication with physicians was often poor, with professionals viewed as over-imposing their own values and priorities. Patients often felt that they lacked control of these discussions in terms of agenda and values. Patients wanted discussions with a wider range of health professionals. Patients expressed a willingness to harness peer groups as a source of information and support; caregivers and family may play a role in the decisionmaking process and may have different agendas that will impact the patient. Threats to informed consent were patient passivity, lack of information on the implications of deactivation, and the psychosocial disruption caused by devices, notably the shocks from ICDs. Limited social support was reported around decisionmaking or psychosocial wellbeing. Both quantitative and qualitative studies showed anxiety in many patients. The main factors associated with anxiety were: shock frequency, Type D (distressed) personality, social and educational status, and age.

Communication-related factors that influenced psychosocial outcomes and quality of decisionmaking were the presence or absence of organizational policies around deactivation, lack of training and comfort among health professionals in instigating and maintaining dialogue with patients about deactivation, and discussions that were too near patients' end of life.

Conclusions: Decision tools are urgently needed to address deactivation of ECDs. These should address gaps in patient knowledge and issues related to anxiety, social support, and fear of shocks. Decision tools that address insertion should also address the possibility of future deactivation. The information should be accurate, balanced, and address both technical and quality-of-life dimensions. Further, clinicians need guidance in how to effectively implement tools in their setting. The nature of communication will depend on implementing tools at appropriate junctures before the end of life, addressing and responding to patients, and including the appropriate significant others in decisions, such as partners and families. Development of multidisciplinary support interventions around deactivation should be encouraged, as well as institutional policies around deactivation.

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Contents

Executive Summary ES-1
Evidence Report 1
Introduction 1
Ethical and Legal Considerations 1
Informed Consent 1
Principles to Guide Decisionmaking 2
Ethical and Legal Care Processes 3
Decisionmaking Tools: A Potential Solution? 6
Objectives and Key Questions 7
Methods 9
Literature Search 9
Study Selection 10
KQs 1 to 3: Decision Aids and Tools 10
KQ 4: Barriers to Decision Aids and Tools 10
Methodological Quality 10
KQs 1 to 3: Decision Aids and Tools 10
KQ 4: Barriers to Decision Aids and Tools 11
Data Extraction 11
KQ 1 to 3: Decision Aids and Tools 11
KQ 4: Barriers to Decision Aids and Tools 11
Data Synthesis 11
KQ 1 to 3: Decision Aids and Tools 12
KQ 4: Barriers to Decision Aids and Tools 12
Results 13
Literature Search 13
Key Questions 1 to 3: Decision Aids and Tools 15
Description of Included Studies 15
Quality of Tools 16
Summary 17
Key Question 4: Barriers to Use of Decision Tools 18
Qualitative Studies of General Patient Experiences 18
Quantitative Studies of Psychosocial Outcomes 25
Studies in Communication 26
Summary and Discussion 29
Future Research 31
Applicability 32
Conclusions 33
References 34
List of Abbreviations 44

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Tables

Table 1. Key components of informed consent 2
Table 2. Recommendations for Communicating about Deactivation (HRS 2010) 4
Table 3. Stages of synthesis of qualitative studies 12
Table 4. Tools for electronic cardiac devices identified by the review 15
Table 5. Decision tools: Quality of content for insertion of electronic cardiac devices 16

Figure

Figure 1. Flow diagram of study retrieval and selection 14

Appendixes

Appendix A. Search Strategies
Appendix B. Data Extraction Form
Appendix C. Decision Tools Included in Review
Appendix D. List of Excluded Studies
Appendix E. Evidence Tables (KQ 4)
Appendix F. Methodological Quality of Included Studies

Executive Summary

Background

Over the past three decades, electronic cardiac devices (ECDs) have been used to electronically stimulate the heart in order to regulate and replicate heart function. ECDs include implantable cardioverter-defibrillators (ICDs; with or without cardiac resynchronization therapy [CRT] function), pacemakers, and ventricular assist devices (VADs).

Patients with ECDs may develop terminal illnesses due to worsening of their underlying heart condition or other chronic disease. Terminally-ill patients are at greater risk for developing arrhythmias, thereby increasing the frequency of ICD shocks. ICD discharges may be so painful and frequent that the harms derived from an ICD can outweigh the benefits.[1] Therefore, it is reasonable to consider deactivating the ICD to neutralize harm from the device as a patient nears the end of life.

High-quality decisionmaking, with associated aspects such as informed consent, effective communication, and patient involvement, has emerged as an important area for the insertion and deactivation of ECDs. Recently, the Health Rhythm Society in the United States has addressed important ethical and legal concerns regarding deactivating ICDs and published guidelines on how to promote effective and ethical decisionmaking. These and other recent European guidelines view deactivation of devices as being similar in ethical and legal terms as the withdrawal of any other form of health care or medical treatment. Current opinion is that deactivation of ECDs cannot be considered legally or ethically synonymous with any form of assisted suicide, euthanasia, or cardiopulmonary resuscitation.

For practice to be ethical, informed consent must guide decisionmaking on the withdrawal of devices. Specific recommendations exist for ICDs, with current guidelines stating that deactivation issues should be discussed prior to insertion. Further, decisions should be made wherever possible by patients following extensive dialogue with appropriate physician(s) and should be based on personalized, balanced, and comprehensive information of choices. Sufficient time should be provided for patients to make decisions and when possible, discussions should occur prior to the end-of-life stages of the underlying disease.

Recently, evidence has consistently shown that health care practices around decisionmaking in the United States and elsewhere are typified by unbalanced communication, partial information, and inappropriate timing, particularly in relation to ICDs. These practices reflect differences in knowledge and priorities as well as the inherent complexity of decisions, and risk compromising informed consent.

Decision aids are tools designed to help patients participate in decisionmaking about health care options; the tools provide information on these options to help patients clarify and communicate the personal value they associate with different features of the options. The usefulness of aids is supported by large high quality systematic reviews and randomized control trials. However, the use of such tools has not been explored in relation to ECD deactivation.

Objectives and Key Questions

The objectives of this report were to: identify and synthesize the available evidence regarding decisionmaking aids and similar tools for ECDs; determine the generalizabililty of these tools to Medicare populations; and identify the main barriers to the use of such tools.

The key questions (KQs) were as follows: For patients undergoing insertion, continuation, or deactivation of ECDs (including pacemakers, ICDs and CRT–ICDs, and VADs) and their next-of-kin:

1. Are there validated decision aids and tools available for ECDs?
2. How effective are these decision aids and similar tools for promoting informed decisionmaking?
3. Is the Medicare population sufficiently represented in the published studies? If not, are the conclusions of the studies generalizable to the Medicare population?
4. What are the main barriers to the use of decision aids?

Methods

Literature Search

The research librarian, in collaboration with the research team, developed search strategies designed to identify evidence relevant to the KQs. Our search for the published literature included structured searches in the following bibliographic databases: MEDLINE® (1948–2011), EMBASE (1980–2011), CINAHL (1980–2011), Cochrane Central Register of Controlled Trials, SCOPUS, and PsycINFO (1903–2011). The searches were performed between December 8, 2010 and February 8, 2011. We identified search terms through consultation with research team members, reviewing search strategies from systematic reviews on similar topics, and examining how relevant studies had been indexed in various databases. A combination of subject headings and text words was adapted for each database.

We completed two sets of searches for published literature (Appendix A). First, we conducted a broad search using a combination of the following terms: (pacemaker* OR heart-assist device* OR ICD or CIED OR implantable defibrillator*) AND ((decision making or choice behavio?r OR patient preference* OR communication* OR consent* OR proxy OR decision aid* OR decision tool* OR decision support* OR gender OR health knowledge OR patient attitude* OR treatment refusal OR treatment withdrawal OR device removal OR deactivation OR palliative care OR hospice care OR terminal care OR end-of-life). We restricted searches to English language studies published after 1989. We applied study design filters to capture experimental and qualitative studies.

This search was supplemented by a second search in order to elicit additional articles published after the first search or articles that may have been missed (Appendix A). The second search focused on the concepts of ECDs and end-of-life; the qualitative design filter was not applied. Search terms included: (pacemaker* OR heart-assist device* OR ICD or CIED OR implantable defibrillator*) AND (treatment refusal OR treatment withdrawal OR device removal OR deactivation OR palliative care OR hospice care OR terminal care OR end-of-life).

To locate grey literature, we searched Google using combinations of keyword terms for ECDs and end-of-life decisionmaking. Results from these searches were stored and categorized in a bookmarking web software called Delicious (www.delicious.com) and were evaluated by the research team for potential relevancy to KQ 1 to 4. In addition to searching online resources, we hand searched reference lists from relevant publications and included studies, consulted with content experts, and searched citations.

Study Selection

We developed a priori eligibility criteria for each KQ, which are described below. Two reviewers independently screened the titles and abstracts of the search results using broad criteria. We classified each study as "include," "exclude," or "unsure." We retrieved the full text articles for all studies that were rated "include" or "unsure." Two reviewers independently reviewed the full text of potentially relevant studies using a standard form that was pretested on a sample of studies. We resolved disagreements through consensus or third-party arbitration.

KQs 1 to 3: Decision Aids and Tools

We sought to identify research evaluating decisions aids or similar tools to guide decisionmaking with patients or their next-of-kin pertaining to insertion, continuation, or cessation of ECDs. ECDs included ICDs, CRT–ICDs, pacemakers, and VADs. Decisionmaking tools were defined according to the *International Patient Decision Aid Standards Collaboration* as: "…tools designed to help people participate in decisionmaking about health care options. They provide information on the options and help patients clarify and communicate the personal value they associate with different features of the options."[2]

We initially searched for randomized controlled trials (RCTs), cluster RCTs, nonrandomized controlled trials (NRCT), pragmatic trials, and quasi-experimental pre-post test studies. Our population of interest was adult patients with or needing an ECD, regardless of age or condition. We did not prespecify outcomes.

Our initial searches did not identify any tools that had been evaluated in trials or other comparative studies. Therefore, we made a post hoc decision to search for studies of tools that had been evaluated using other methods based on the second set of searches (i.e., published and grey literature of nontrial designs).

KQ 4: Barriers to Decision Aids and Tools

For this question, we included studies with primary data that could be reasonably interpreted as pertaining to barriers (or conversely facilitators) to the use of decision tools or similar aids in relation to ECDs in eligible patients. We did not prespecify methodological criteria. As such, studies could use qualitative, survey, or other observational methods or include data that were reported as an adjunct to other methods, such as mixed methods studies.

Methodological Quality

KQs 1 to 3: Decision Aids and Tools

To assess the methodological quality of RCTs and NRCTs, we planned to use the Cochrane Risk of Bias tool.[3]

To assess the quality of the decision tools, we used a previously validated systematic quality assessment framework for decision aids.[4] This framework assesses quality in all stages of decision tools (that is, from development to content) and multiple facets of a tool, including the following domains: systematizing the development process; information about treatment options; presenting probabilities; clarifying and expressing values; using patient stories; guiding and coaching; disclosing conflicts of interest; providing internet access; balancing presentation of options; using plain language; basing information on up-to-date evidence; and establishing

effectiveness. Two reviewers independently appraised the decision aids, and there were no discrepancies in their assessments.

KQ 4: Barriers to Decision Aids and Tools

We used different tools to assess the quality of studies depending on study design. For qualitative studies, we used the Critical Appraisal Skills Program tool for assessing qualitative research.[5] For observational studies, we used either a tool for cohort studies[6] or a tool for descriptive cross-sectional studies.[7] We categorized studies as high, medium, or low quality.

One reviewer applied the tools, and a second reviewer independently checked the scores. We resolved differences in assessments by consensus.

Data Extraction

KQs 1 to 3: Decision Aids and Tools

One reviewer extracted data from individual studies using standardized templates; a second reviewer independently verified the accuracy of data extraction. We used different templates for qualitative and quantitative studies.

KQ 4: Barriers to Decision Aids and Tools

We classified studies into three categories: qualitative studies describing general experiences with ECDs; quantitative studies addressing psychosocial outcomes; and mixed methods studies relating to communication.

For qualitative and mixed method studies, we extracted publication details (year, author, study title, journal, main focus of paper), methodological details (principle approach, data collection methods, sampling methods), and population characteristics (sex, age, recruitment criteria, country of study, device type). We noted if the participants were patients, health professionals, or caregivers. When possible, we recorded details regarding indication for ECD (primary or secondary prevention), New York Heart Association functional class, left ventricular ejection fraction, and disease (heart failure or non-heart failure). We also recorded the focus of the study in relation to ECD insertion, malfunction, deactivation, or end-of-life.

For quantitative studies focusing on psychosocial outcomes, we similarly extracted publication details, population characteristics, and the indication for ECD (primary or secondary prevention). We noted if the participants were patients, spouses, or other primary caregivers. We recorded which instruments were used to measure specific outcomes. For each outcome, we extracted baseline, followup, and change from baseline data, including information on the effect size and statistical significance, if available.

Data Synthesis

KQs 1 to 3: Decision Aids and Tools

We present a narrative summary of the studies that provided data to address this question.

KQ 4: Barriers to Decision Aids and Tools

For qualitative studies on general experience with ECDs, we used the meta-ethnographic approach to synthesise findings.[8 9] This approach provides a new synthesis of findings to account for the phenomenon being explored[9] and involves a three-stage process including first-order findings, second-order interpretations, and higher-order abstractions. Through this process, studies are re-analyzed and compared in light of each other to produce new theory or knowledge.[9 10]

For quantitative studies with psychosocial outcomes, we used an integrative approach to synthesis. We chose this approach because, although the selected studies were the same topic, there were differences in methods and outcomes which precluded pooling of results.[11] For the integrative review, we examined the findings of comparable studies in relation to each other, taking account of the methodological quality and differences in populations.[11]

For mixed methods studies on communication, we followed the same steps for quantitative studies of psychosocial outcomes.[11]

Results

Literature Search

We identified 1449 citations in our literature. After removal of duplicates, 1102 studies remained. Through the grey literature search, we identified 43 additional web citations containing potentially relevant content.

Description of Included Studies (KQs 1 to 3)

We identified four studies that may have contained data relating to decision aids for insertion or deactivation. These included interventions for ECD populations using telephone counseling,[12] discussions prior to[13] or after[14] insertion, and a disease-specific end-of-life planning intervention.[15] Based on followup with authors via email, we determined that none of these interventions included a discussion of aspects of insertion, malfunction, or deactivation of ECDs.

Based on our search of the grey literature, we identified four patient decision aids for insertion of an ICD[16] and pacemaker[17] for patients at risk from arrhythmia and for an ICD[18] and pacemaker[19] for patients with heart failure (Table ES–1). These aids have not been evaluated using any formal research methodology (e.g., RCT) but have been independently validated as meeting quality criteria for decision aids.[4] Given the lack of other studies evaluating decisions tools around deactivation, these four tools could be considered the “best available evidence.”

KQ 1: Are there validated decision aids and tools available for electronic cardiac devices?

We identified four decisions aids that addressed insertion of pacemakers and ICDs in patients with heart failure and arrhythmia (Table ES–1). We found no validated decision aids or tools that adequately address the deactivation of ECDs. The tools focusing on insertion included comprehensive content on technical aspects of insertion, but made limited references to implications for quality of life and generally lacked neutrality in terms of how the decision to insert was presented.

KQ 2: How effective are these decision aids and similar tools for promoting informed decisionmaking?

In contrast with current recommendations, these aids do not address deactivation in discussions about insertion. No aids were identified that addressed deactivation of ICDs, pacemakers, or VADs for any patient populations. Insertion was partially addressed by the tools, and quality was reduced by the lack of focus in discussion around insertion prior to deactivation. Indeed, deactivation was not addressed in any of the tools relating to insertion of either a pacemaker or ICD.

KQ 3: Is the Medicare population sufficiently represented in the published studies? If not, are the conclusions of the studies generalizable to the Medicare population?

Due to the lack of tools examining deactivation, the representation of the Medicare population is not currently an issue.

Table ES–1. Tools for ECDs Identified by Review*

Title	Heart rate problems: Should I get an ICD?	Heart Rate Problems: Should I Get a Pacemaker?	Heart failure: Should I get an ICD?	Heart failure: Should I get a pacemaker (cardiac resynchronization therapy)?
Health Condition	Arrhythmia	Arrhythmia	Heart Failure	Heart Failure
Type	Treatment	Treatment	Treatment	Treatment
Options Included	Get an ICD. Don't get an ICD.	Get a pacemaker. Don't get a pacemaker.	Get an ICD. Don't get an ICD.	Get a pacemaker. Don't get a pacemaker.
Audience	People with heart rate problems but do NOT have heart failure considering whether to get an ICD.	People with heart rate problems but NOT heart failure considering getting a pacemaker.	People at risk of having an abnormal heart rhythm that could cause sudden death.	People with class III or class IV heart failure, symptoms not controlled with medication, an ejection fraction of 35% or less and tests showing the heart's ventricles are not beating at the right time.
Developer	Healthwise	Healthwise	Healthwise	Healthwise
Country of development	United States	United States	United States	United States
Year of last update or review	2011	2010	2010	2010
Format	Web, paper	Web, paper	Web, paper	Web, paper
Language(s)	English	English	English	English

ICD = implantable cardiac defibrillator; OHRI = Ottawa Hospital Research Institute
*See Appendix C for copies of the tools and URLs for further information on the tools and their validation.

Description of Included Studies (KQ 4)

Literature Search and Screening

The search for barriers to use of tools in the ECD populations identified a total of 97 potentially relevant studies of which 67 met the inclusion criteria. Included studies fell into the following three categories: a) 33 qualitative studies that contained data on patient experiences related to decisionmaking; b) 26 quantitative studies of psychosocial outcomes, all of which

examined anxiety issues in patients with ECDs; and, c) 8 studies using mixed methods designs addressing communication issues. We present the results below according to these three categories.

Qualitative Studies of General Experiences

Qualitative research into patients' experiences consistently showed that patients often have poor knowledge of key aspects related to deactivation, including the role of the device and how their health would be affected by deactivation of the device. Communication with physicians was often poor, with professionals viewed as over-imposing their own values and priorities on patients. Patients reported wanting more discussions with a wider range of health professionals.

The most common threats to informed consent were patient passivity, lack of information on the implications of deactivation for daily living activities, and the psychosocial disruption caused by devices, notably the shocks from ICDs. Patient experiences appeared to change over time, with 3 months after insertion being notable for a higher need for more information and psychosocial support. Social support for patients around decisionmaking or psychosocial wellbeing was limited over time. Families and other caregivers were the main source of support provided, but were often seen to be overly protective.

Psychosocial disruptions were common across ECDs. However, research suggests that psychosocial disruptions were highest for ICDs due to the frequency and intensity of shocks.

Although current research presented limited sex- and age-based analyses, women appear to be prone to greater psychosocial sequelae from ICDs, and older adults may be more prone to lower social support.

Quantitative Studies of Psychosocial Outcomes

The quantitative studies of psychosocial outcomes corroborate the qualitative findings. The main factors influencing anxiety and depression were: shock frequency, Type D (distressed) personality, social and educational status, and age.

Studies of Communication

Communication-related factors that influenced psychosocial outcomes and quality of decisionmaking were: the presence or absence of organizational policies around deactivation; the lack of training and comfort among health professionals in initiative and maintaining dialogue with patients around deactivation; and poorly-timed discussions that were too near patients' end of life.

Patients reported that they would welcome more discussion with health professionals around deactivation and would be comfortable having these discussions in person or over the telephone with wider members of the multidisciplinary health care team.

Discussion

Four decisions aids were identified that addressed insertion of pacemakers and ICDs in patients with heart failure and arrhythmia. No existing tools addressed the deactivation of ECDs. In contrast to guidelines, current tools do not address deactivation in discussions prior to insertion. Due to the lack of tools examining deactivation, generalizabililty to the Medicare population is not currently an issue.

Although current recommendations could be incorporated into high-quality decisions aids for each type of ECD, there are consistent indications that other barriers exist to high-quality decisionmaking and effective use of decision aids. These barriers include:

- Low patient knowledge of key aspects of deactivation, the role of the device, and how health could be affected by deactivation of the device.
- Poor communication with physicians; professionals being seen to over-impose their own values and priorities on patients.
- Widespread psychosocial disruptions across ECDs especially3 months after device insertion, and patients with: higher shock frequency, Type D personality, and adverse social and educational status, female sex, and older age.
- Low patient social support for decisionmaking or psychosocial wellbeing and overly protective families and other caregivers.
- Decisionmaking could be improved via: implementation of organizational policies around deactivation, better training of health professionals in instigating and maintaining dialogue with patients around deactivation, and instigating discussions earlier with a wider range of health professionals, markedly before the patients' end of life.
- These discussions could be in person or over the telephone with wider members of the multidisciplinary health care team.

This review identified that common barriers to attaining and maintaining informed consent are: gaps in basic knowledge about ECDs, disparities in values with health professionals, and patient anxiety. More positively, patients do appear to want to be involved more, know more, and receive support from different professional groups.

Deactivation of an ECD is an important aspect of health care that should be discussed openly and early in the care trajectory prior to insertion of the ECD. However, there is consistent evidence that physicians are not well trained to instigate and maintain this dialogue, that when it does occur the values and priorities of patients and professionals can be incongruent, and that patients often lack basic knowledge that will allow them to make choices about deactivation in an informed manner. Moreover, there was limited evidence that caregivers and family provide support that patients perceive as useful around deactivation decisions. Decisions about deactivation are likely to be complex due to the prevalence and negative effects of shocks on psychosocial wellbeing, particularly during the first year after insertion. Nevertheless, patients have voiced both a need and desire for more comprehensive information about the implications of deactivation and for support from other health professionals.

Health professionals have expressed different opinions over the legality and ethics of deactivation of ECDs. Clinicians have markedly different levels of comfort in addressing deactivation decisions, different views of their role and of the ethics and legality of these decisions. Generalizability is restricted as research has been based on relatively small, qualitative studies and surveys that have been mostly local and/or had relatively low response rates. Further, ECD deactivation emerged as a new and contentious issue only in recent years.

This review has identified research on patient perspectives regarding decisionmaking around ECDs. Though the overall quality of the qualitative, quantitative, and mixed methods studies

included in the review was moderate, most research focused on aspects of insertion decisions. Even when deactivation was addressed, seldom was this done from the perspective of end-of-life care. Also, there was very little existing evidence on decisionmaking about ECDs by surrogate decisionmakers.

It is not necessarily surprising that there are no existing decision tools that adequately address deactivation either prior to insertion as part of the decision to insert the ECD or after insertion as a discrete decision. Clear guidance on the most contentious issues around deactivation relating to ICDs was only published in 2010.[20] Many of the concerning patterns identified in this review around informed consent related to the deactivation of ICDs predate this guidance, and there was a lack of consensus prior to this around the ethics and legality of deactivation evident in both argument[21-24] and practice.[25]

These guidelines may in time influence organizational policies and health care practice in relation to deactivation of ICDs and other ECDs, for which the same ethical and legal principles apply. High-quality decisionmaking that supports the principles and practices of informed consent and patient involvement in decisions is the best means to ensure care is legal and ethical.

Based on patient accounts of discussions about insertion and deactivation, the ability of practitioners to attain and maintain informed consent is likely to be constrained by basic gaps in knowledge and understanding. These gaps include aspects of device function, efficacy, and implications of deactivation, as well as basic knowledge of underlying health conditions. Though it may be surprising that such gaps exist even after years of treatment, similar gaps in basic knowledge are relatively common in people with advanced heart failure.[26-28] Similarly, systematic reviews have demonstrated that untreated and unrecognized anxiety and depression are common in patients with coronary heart disease[29] and heart failure.[30] As such, many of the psychosocio-educational challenges in maintaining informed consent in people with ECDs occur in patients with other cardiac conditions and may be amenable to similar solutions.

Future Research

Research is needed to develop discrete, high-quality decisions aids or similar tools to support deactivation of ECDs in eligible patient groups. Further, large-scale surveys are needed to establish the prevalence of organizational policies around deactivation in appropriate care providers and identify physician attitudes and practices to deactivation following publication of guidelines from the Heart Rhythm Society in 2010.

Trials and meta-analyses are needed to determine the effectiveness of multidisciplinary psychosocio-educational interventions to support patient knowledge, receptiveness, and psychosocial wellbeing. Early results of trials are promising, but telehealth and electronic interventions should be developed for rural populations.

Interventions are needed to support physicians and other health professionals to instigate and maintain dialogue with patients and maintain informed consent around insertion and deactivation. These interventions should offer assistance in how to provide noncoercive, balanced, and understandable support that is responsive to the needs and values of patients and/or surrogate decisionmakers.

Research should be focused on examining how surrogate decisionmakers make decisions about ECD deactivation and their perceived role and satisfaction with informed consent and support from health professionals.

Applicability

The applicability of the trends identified in this review to the Medicare population is constrained by the relatively young mean age of participants in most studies and a lack of incorporation of age into analyses. Though a small number of studies do indicate that age may ameliorate some of the anxiety associated with shocks,[31 32] the influence of age on patient experiences and outcomes has not been specifically examined in studies to date.

Conclusions

There is a pressing need for high-quality decision-making around deactivation of ICDs. Although deactivation is cognizant with ethical standards and guidelines exist to govern practice, there are no valid tools to facilitate case-by-case decision-making. Persistent large gaps in communication undermine truly informed decision-making. Clinicians focus on technical aspects of implantation and do not address quality of life issues. We identified four decision aids that address insertion of pacemakers and ICDs in patients. However, these tools were of low quality and did not address deactivation prior to or, as a discrete decision, after insertion. In addition to the development of tools to inform and support decisions to insert or deactivate different types of ECDs, a number of common individual and contextual factors exist to reduce the quality of care and decision-making in ECD populations. Older age, female sex, and higher shock frequency in ICDs were all associated with higher psychosocial disruption that may further inhibit patients' ability to make decisions.

In addition to the development of separate tools that address deactivation of ECDs before and after insertion, healthcare can be improved via organizational policies that promote discussions markedly prior to the end of life, more widespread training of health professionals to discuss and counsel patients around insertion and deactivation decisions, and better utilization of multidisciplinary health care teams.

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Evidence Report

Introduction

Emerging technologies raise new challenges in health care and for health care professionals. Over the past three decades, electronic cardiac devices (ECDs) have been used to electronically stimulate the heart in order to regulate and replicate heart function. These devices include:

- Implantable cardioverter-defibrillators (ICDs), including those with cardiac resynchronization therapy functions (CRT–ICDs);
- Pacemakers; and
- Ventricular assist devices (VADs).

ECDs are considered the treatment of choice for patients who have ventricular arrhythmias or weakened heart function and are at risk of sudden cardiac death. Medicare coverage criteria for ICDs have been considerably broadened in the past 5 years.[1] In the United States, 68 percent of patients with an ICD implantation are Medicare beneficiaries, and the average age at implantation is 68 years.[2]

Professionals have expressed reservations about over-insertion of ECDs, most notably in relation to ICDs[3-5] and the relative size of clinical benefits and harms of such devices.[6 7] Patients with ICDs may develop terminal illnesses as a result of worsening of their underlying heart condition or other chronic disease. Terminally-ill patients are at greater risk for developing hypoxia, sepsis, heart failure, and electrolyte imbalance, which predisposes them to arrhythmias and thereby increases the frequency of ICD shocks. The ICD discharges may be so painful and frequent that the harms derived from an ICD can outweigh the benefits.[8] Therefore, it is reasonable to consider deactivating the ICD to neutralize the harm from the device as a patient nears the end of life.

Ethical and Legal Considerations

In the United States, mainstream media has raised concerns over the lack of patient involvement in health care decisions near the end of life.[9-11] Most prominently, these issues have been expressed about ECDs in relation to informed consent and decisions to deactivate ICDs near the end of life.[1] Indeed, a series of papers published before 2006 expressed concerns that withdrawal of ICDs and other ECDs may be unethical or even illegal in some circumstances.[12-14] A recent survey of legal and medical professionals and patients indicated that the majority believe it is lawful to withdraw device therapy at the end of life in response to a patient's request;[15] however, almost half of the U.S. physicians surveyed in 2008 were unsure of the legality of deactivating an ICD.[16] Guidelines in the United States[17] recommend that it can be appropriate to reprogram the device, deactivating the patient's ICD, near the end of life.

Informed Consent

Concerns about the quality of informed consent have been raised regarding ICDs,[18-20] pacemakers,[21] and VADs.[22-24] Ensuring ongoing informed consent is as important as addressing the clinical effects of insertion or deactivation in each patient.[25] Health care decisions should address the likely benefits, harms, and costs of an intervention for the particular patient, but also its ethical and legal appropriateness and congruence with the patient's values and preferences.[25-27]

Informed consent is recognized internationally as being essential to health care and is based on the key ethical and legal principles highlighted in Table 1.[28 29] For decisions to be based on

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informed consent, they must be made voluntarily by patients who have the legal standing and sufficient capacity to make decisions.[30] Decisions should be based on the provision of sufficient accurate information for patients to understand the choices being made, the likely benefits, and any common and serious potential harms of an alternative course of action.[30] Further, this information should be specific to the patient's personal situation.[30] These principles serve to respect patient autonomy, protect the patient from fraud, misinformation, and coercion under duress, and promote self-reflection and rational decisionmaking by health professionals.[31]

Informed consent also addresses the legal authority upon which decisions are made: whether or not those involved in making a decision are legally entitled to participate.[30] Operational issues include what documentation should be used to provide information and record consent, when consent should be sought, and who should seek consent from patients or surrogate decisionmakers.[32]

Table 1. Key components of informed consent[31]

Component	Explanation
Voluntary	Decisions are made without coercion, inducement, or persuasion
Capacity	The deciding party(s) has the facets to make the decision
Legal standing	The deciding party(s) is legally the individual appropriate to make the decision
Disclosure	Provision of the right information to understand the proposed course of action and possible alternatives

The American Medical Association (AMA) mandates that care should be based on informed consent and should incorporate the "clinical impression" of clinicians regarding consequences of treatment, alternatives, and recommendations for all procedures.[33] The current AMA policy states that "full disclosure (is) appropriate in all cases, except in rare situations in which such information would, in the opinion of the health care professional, cause serious harm to the patient."[34]

When patients do not have the capacity to make decisions, the health care team should honor an advanced directive to respect patient autonomy.[34] When an advanced directive is not available, reasonable efforts should be taken to identify a prior written expression of values such as a pertinent living will or a health care proxy.[34] When such materials are unavailable and there are no state laws identifying appropriate surrogate decisionmakers or a process to identify them, the patient's family, domestic partner, or close friend should become the surrogate decisionmaker.[34] The AMA states that surrogate decisionmakers should be accorded the same rights as patients.[34]

Principles to Guide Decisionmaking

Advice to support decisions around ICD deactivation for patients nearing the end of life or requesting withdrawal of therapy were recently addressed by the European Heart Rhythm Association[8] and the U.S. Heart Rhythm Society (HRS).[35] These guidelines do not view decisions about devices as different from other decisions pertaining to consent for the withdrawal or initiation of health care treatments or interventions. Hence, normal procedures associated with legal and ethical consent should be followed. Decisions about whether to insert or deactivate an ECD, like other decisions to initiate or withdraw treatment, have clear legal and ethical dimensions and require informed consent.

The HRS guidelines[35] are based on the following key ethical, legal, and religious principles and precedents:

- A patient with decisionmaking capacity has the legal right to refuse or request the withdrawal of any medical treatment or intervention regardless of whether he or she is terminally ill, and regardless of whether the treatment prolongs life and its withdrawal results in death.
- When a patient lacks capacity, his or her legally-defined surrogate has the same right to refuse or request withdrawal.
- Ethically and legally, there are no differences between refusing ICD therapy and requesting a withdrawal of ICD therapy.
- Advanced directives should be encouraged for all patients with ICDs.
- Legally and ethically carrying out a request to withdraw life-sustaining treatment is neither physician-assisted suicide nor euthanasia.
- A health professional cannot be compelled to carry out ICD deactivation that he or she views is in conflict with their own personal values, but should involve a colleague who is willing to carry out the procedure.

The HRS guidelines also make clear that decisions may have spiritual and religious dimensions for the patient and health professionals involved in the decision.[35] This concurs with the AMA guidelines that the values of the patient should be incorporated in the decisionmaking process.[34] Although a clinician has the right not to perform the deactivation, the clinician's religious beliefs may not override those of the patient.[35] However, deactivation is not incompatible with religious beliefs related to the preservation of life.[36]

These guidelines address concerns about the ethics of deactivation[12-14] and physician reservations about the legal implications of withdrawing device-related care.[18-20] These have remained for some years because of a lack of legal precedents.[15 19] However, there is no indication from HRS guidelines,[35] similar European guidelines,[8] or from the AMA that deactivation of a device could be considered an illegal physician-assisted suicide or form of euthanasia.[37 38] Likewise, ethical and legal issues around resuscitation are relevant only to cardiopulmonary resuscitation after a cardiac or respiratory arrest, not to ECDs.[39] Nor are there any legal indications that the current HRS guidelines would not apply to other devices, notably VADs,[22] or across all U.S. states.[35] Advanced directives, either in the form of a power of attorney to specify a surrogate decisionmaker or a list of health care preferences, values, or religious beliefs in a living will, are recognized across 50 states.[35]

The same ethical and legal principles related to ICD deactivation apply to the insertion and deactivation of other ECDs. Discussions about deactivating any ECD should follow best practices of informed consent, but are not subject to any distinctive legal or ethical requirements.[23] Issues in relation to pacemakers near the end of life may be less likely to arise because these devices rarely cause harmful or painful shocks compared to ICDs and do not lengthen life.[19] VADs may become burdensome for patients and their caregivers near the end of life due to the need to assess and monitor device function[23] and in relation to patient anxiety.[22] Nevertheless, like ICDs, neither VADs nor pacemakers are viewed as being life support devices.[8 23]

Ethical and Legal Care Processes

Although past arguments questioning the ethics of deactivation[12-14] now appear to be out of step with current guidelines and consensus, dismissing these concerns is inappropriate.[40] Crucially, ensuring decisions about deactivation are legal and ethical is dependent on key

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processes of care associated with seeking and attaining informed consent.[12-14 41] Concerns about the ethical and legal aspects of deactivation appear well placed when current practices around patient-professional communication, the complexity of care, and aspects of organizational context are taken into account.

Communication

Evidence shows that communication between patients, surrogate decisionmakers, and health professionals regarding the deactivation of ICDs is often poor. In a telephone survey, the next-of-kin of dying patients reported that physicians discussed deactivating the ICD in only 27 percent of cases.[42] A recent survey of 47 European care centers showed that only 4 percent reported routinely discussing deactivation with patients at or before insertion, and 4 percent provided patients and surrogate decisionmakers with information on deactivation.[43] Communication around deactivation often takes place only days or even hours before the patient's death.[42] Only 33 percent of internists and 45 percent of cardiologists thought their patients were aware that ICDs could be deactivated.[44] Ambulant patients with ICDs reported that discussions about deactivation rarely occurred during the course of their care[45-47] and expressed a desire for these discussions to take place earlier.[47] A systematic review showed that patients are anxious about future shocks and have limited knowledge of ICDs.[48]

The HRS guidelines[35] (Table 2) emphasize the importance of initiating dialogue prior to ICD insertion and continuing dialogue throughout the care trajectory. Discussions should be timely,[29 49] occur before the end-of-life phase,[29 49] and address misconceptions that deactivation may result in immediate death.[50] Patients should receive information about the option to deactivate an ICD prior to potential loss of functional capacity; when anti-arrhythmic drug therapy is withdrawn; when a patient's heart failure status changes; and at refractory end-stage heart failure.[17,49] For the Medicare population, physicians should discuss the impact of decisions on comorbidities and general health status and recommend specialist geriatric consultations to maximize patient involvement.[35]

Table 2. Recommendations for Communicating about Deactivation (HRS 2010)[35]

Aim(s)	Key questions for patients or surrogate decisionmakers
1. Determine what patients/families know about their illness.	"What do you understand about your health and what is occurring in terms of your illness?"
2. Determine what patients/families know about the role the device plays in their health both now and in the future.	"What do you understand about the role of the [cardiac device] in your health now?"
3. Determine what additional information patients/families want to know about their illness.	"What else would be helpful for you to know about your illness or the role the [cardiac device] plays in it?"
4. Correct or clarify any misunderstandings about the current illness and possible outcomes, including the role of the device.	"I think you have a pretty good understanding of what is happening in terms of your health, but there are a few things I would like to clarify with you."
5. Determine the patient/family's overall goals of care and desired outcomes.	"Given what we've discussed about your health and the potential outcomes of your illness, tell me what you want from your health care at this point." For patients or families needing more guidance: "At this point some patients tell me they want to live as long as possible, regardless of the outcome whereas other patients tell me that the goal is to be as comfortable as long as possible while also being able to interact with their family. Do you have a sense of what you want at this point?"

Table 2. Recommendations for Communicating about Deactivation (HRS 2010)[35] (continued)

Aim(s)	Key questions for patients or surrogate decisionmakers
6. Using the stated goals as a guide, work to tailor treatments, and in this case, management of the cardiac device to those goals. Phrases to be used here depend on the goals as set by the patient and family.	1) For a patient who states that her desired goal is to live as comfortably as possible for whatever remaining time she has left: "Given what you've said about assuring that you are as comfortable as possible, it might make sense to deactivate the shocking function of your ICD. What do you think about that?" OR 2) For a patient who states s/he wants all life-sustaining treatments to be continued, an appropriate response might be, "In that case, perhaps leaving the anti-arrhythmia function of the device active would be most in line with your goals. However, you should understand that this may cause you and your family discomfort at the end of life. We can make a decision at a future point in time about if/when to deactivate."

Complexity

A principle reason for challenges around communication and decisionmaking in relation to devices is the complexity of decisionmaking, particularly in relation to end-of-life issues. Although the decision to deactivate an ECD can be viewed in some respects as the same as other decisions about treatment withdrawal or intervention,[35] additional uncertainties exist related to deactivation (versus retaining the fully functioning ICD in place), the patient's prognosis, and the likelihood of shocks near the end of life should the patient not choose deactivation.

As with the decision to insert a device, health professionals must also use clinical judgment to assess the evidence concerning the size of the potential benefits for retaining a fully functioning ICD for the specific patient.[7 51] However, estimating the size of this benefit from existing trials is challenging because data on risk reduction are derived from trials with broad enrollment criteria and patients who are not near the end of life.[52] For some groups of patients, the actual benefit of retaining the ICD in place may be much smaller than current trials suggest and might be borderline at best for some clinical subpopulations.[7] Compounding this, even during the end-of-life stage, the patient's anticipated life expectancy is also very difficult to predict,[24 42 47 53] and most sudden cardiac deaths still occur in patients who are assessed as being at low or medium levels of risk.[54 55] Furthermore, current tools to assess the risk of sudden cardiac death have limited predictive power.[56 57] As such, decisions relating to deactivation near the end of life are subject to multiple ambiguities that extend far beyond "uncertainties."

Context

The ethics and legality of informed consent are also compounded by a lack of institutional support for care and a lack of adequate training in clinicians. Discussions about deactivation are complex for health professionals because of multiple uncertainties related to expected prognosis in cardiac patients[42] and the anticipated frequency of shocks (whether necessary or unnecessary) a patient will receive.[44] Moreover, this dialogue often occurs when the health professional has had little prior relationship with the patient.[46] Some have questioned whether health professionals, particularly cardiologists, are trained adequately to deal with such issues.[21] Health professionals who have had problematic prior experiences discussing deactivation with patients are less likely to broach the topic in subsequent discussions with other patients.[58] Although health professionals are often aware that patients have concerns about dealing with ICD shocks, some are still not comfortable discussing deactivation issues.[59] Health professionals may also be wary of instigating discussions about deactivation with patients because of legal concerns around

whether deactivation of an ICD could be interpreted as a withdrawal of treatment[19] or cited as a cause of death.[60]

Health professionals may be concerned about a lack of institutional support and advice around deactivation. A recent survey of 900 U.S. hospices indicated that although 97 percent had admitted patients with ICDs (58 percent reported that patients had received shocks, and 42 percent reported deactivation of devices in the past), only 10 percent had policies on deactivation (95% CI, 37 percent to 48 percent).[61] Health professionals have also reported higher levels of discomfort in relation to deactivation of pacemakers;[60 62] around one-third of those surveyed in the United States reported being comfortable deactivating a pacemaker in a terminally-ill patient compared with over 56 percent in relation to ICDs ($p<0.001$).

Decisionmaking Tools: A Potential Solution?

Guidelines are essential tools for promoting evidenced-based care. In the case of ECDs, they provide an important means to ensure that care is ethical and legal. As with other health care decisions, there is no inherent "best choice" around whether to deactivate an ECD.[63] Decisions about ECD deactivation are complex, value-laden, and deal with wide ranging probabilities and uncertainty.[64] These decisions may involve patients and next-of-kin who may have limited understanding or unrealistic expectations of ECDs[65] and health professionals who may not understand the knowledge levels, values, and aspirations of the patient and next-of-kin and may struggle to translate population-based risks to individuals.[65]

Patient decision aids have been developed to help health professionals support patients and next-of-kin in making informed decisions about health care treatments.[64] Patient decision aids support decision quality and reduce unwanted variations in practice by:

- Providing factual information about the patient's condition, options, outcomes, and probabilities;
- Detailing patients' evaluations of the outcomes that matter most to them; and
- Guiding patients in the steps of deliberation and communication so the choice taken best accords with their values.[65]

The aids can be administered to groups of patients or on an individual basis and via face-to-face, print, or electronic means (e.g., web, video, or App).[65] Decision aids facilitate understanding of the decision and better ensure decisions that are in accord with the values, preferences, and circumstances of patients and next-of-kin.[64] Indeed, these aids are more effective at ensuring higher "quality" decisions than standard forms of counseling.[65] In a recent Cochrane systematic review of 55 trials,[63] decision aids were found to significantly improve knowledge, lower decisional conflict related to feeling uninformed or unclear about personal values, and reduce the proportion of people who were passive in decisionmaking or remained undecided post-intervention.[63] These decision aids also: a) can be incorporated into care systems and protocols[64] (thereby addressing health professional avoidance, discomfort, and lack of timeliness of discussions); b) are systematic (thereby addressing the *inconsistencies* in current discussion practices); c) take account of values relating to benefits and harms[64] (thereby addressing some key elements of deactivation decisions); and, d) address patient and next-of-kin understanding and knowledge levels (thereby addressing common knowledge limitations).

Decisions aids do not constitute clinical guidelines for health care around specific decisions, but can incorporate the recommendations from guidelines more systematically into the dialogue,

discussions, and decisions necessary for informed consent. Given the evidence suggesting that discussion around deactivation of devices is often poorly addressed in health care practice, decision aids appear to offer potential to support effective, ethical, and legal decisionmaking around the deactivation of ECDs. That said, effect sizes tend to vary widely across studies and populations, and there is limited application to patients with heart disease.[63]

Objectives and Key Questions

The objectives of this report are to identify and synthesize the available evidence regarding decisionmaking aids and similar tools for ECDs, determine the generalizabililty of these tools to the Medicare population, and identify the main barriers to the use of such tools in the future to patient populations.

We examined the following key questions (KQs) for patients undergoing insertion, continuation, or deactivation of ECDs (including pacemakers, ICDs and CRT–ICDs, and VADs) and their next-of-kin:

1. Are there validated decision aids and tools available for ECDs?
2. How effective are these decision aids and similar tools for promoting informed decisionmaking?
3. Is the Medicare population sufficiently represented in the published studies? If not, are the conclusions of the studies generalizable to the Medicare population?
4. What are the main barriers to the use of decision aids?

Methods

The Centers for Medicare and Medicaid Services (CMS) Coverage and Analysis Group requested this report from the Technology Assessment Program at the Agency for Healthcare Research and Quality (AHRQ). AHRQ assigned this report to the University of Alberta Evidence-based Practice Center.

This chapter describes the prospectively designed methods that the University of Alberta Evidence-based Practice Center used to identify, assess, and synthesize the evidence on electronic cardiac devices (ECDs) in relation to the key questions (KQs). We outline the literature search strategy and our approach to selecting relevant articles, extracting data from eligible studies, assessing the methodological quality of individual studies and rating the overall body of evidence, and analyzing and synthesizing the data.

Literature Search

The research librarian, in collaboration with the research team, developed search strategies designed to identify evidence relevant to the KQs. Our search for the published literature included structured searches in the following bibliographic databases: MEDLINE® (1948–2011), EMBASE (1980–2011), CINAHL (1980–2011), Cochrane Central Register of Controlled Trials, SCOPUS, and PsycINFO (1903–2011). The searches were performed between December 8, 2010 and Feb 8, 2011. Search terms were identified through consultation with research team members, reviewing search strategies from systematic reviews on similar topics, and examining how relevant studies had been indexed in various databases. A combination of subject headings and text words was adapted for each database.

We completed two sets of searches for published literature (Appendix A). First, we conducted a broad search using a combination of the following terms: (pacemaker* OR heart-assist device* OR ICD or CIED OR implantable defibrillator*) AND ((decision making or choice behavio?r OR patient preference* OR communication* OR consent* OR proxy OR decision aid* OR decision tool* OR decision support* OR gender OR health knowledge OR patient attitude* OR treatment refusal OR treatment withdrawal OR device removal OR deactivation OR palliative care OR hospice care OR terminal care OR end-of-life). We restricted searches to English language studies published after 1989. We applied study design filters to capture experimental and qualitative studies.

This search was supplemented by a second search in order to elicit additional articles published after the first search or articles that may have been missed (Appendix A). The second search focused on the concepts of ECDs and end-of-life; the qualitative design filter was not applied. Search terms included: (pacemaker* OR heart-assist device* OR ICD or CIED OR implantable defibrillator*) AND (treatment refusal OR treatment withdrawal OR device removal OR deactivation OR palliative care OR hospice care OR terminal care OR end-of-life).

To locate grey literature, we searched Google using combinations of keyword terms for ECDs and end-of-life decisionmaking. Results from these searches were stored and categorized in a bookmarking web software called Delicious (www.delicious.com) and were evaluated by the by the research team for potential relevancy to KQ 1 to 4. In addition to searching online resources, we hand searched reference lists from relevant publications and included studies, consulted with content experts, and searched citations.

Study Selection

We developed a priori eligibility criteria for each KQ, which are described below. Two reviewers independently screened the titles and abstracts of the search results using broad criteria. We classified each study as "include," "exclude," or "unsure." We retrieved the full text articles for all studies that were rated "include" or "unsure." Two reviewers independently reviewed the full text of potentially relevant studies using a standard form that was pretested on a sample of studies. We resolved disagreements through consensus or third-party arbitration.

KQs 1 to 3: Decision Aids and Tools

To be eligible for inclusion for KQ 1–3, studies must have examined any decision aid or tool in adult patients with or needing an ECD, regardless of age or condition. ECDs included implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy plus ICDs (CRT–ICDs), pacemakers, and ventricular assist devices (VADs). We defined decisionmaking tools according to the *International Patient Decision Aid Standards Collaboration* definition as: "…tools designed to help people participate in decisionmaking about health care options. They provide information on the options and help patients clarify and communicate the personal value they associate with different features of the options."[66] We did not prespecify outcomes.

Initially, we included only comparative studies, such as randomized controlled trials (RCTs), cluster RCTs, nonrandomized controlled trial (NRCT), pragmatic trials (e.g., trials comparing tools), and quasi-experimental pre-post test studies. However, our initial searches did not identify any tools that had been evaluated in trials or other comparative studies. Therefore, we made a post hoc decision to include qualitative and uncontrolled studies.

KQ 4: Barriers to Decision Aids and Tools

To be included in KQ4, studies had to contain primary data that could be reasonably interpreted as pertaining to barriers (or conversely, facilitators) to the use of decision tools or similar aids in relation to ECDs in eligible patients. We did not prespecify methodological criteria. As such, studies could use qualitative, survey, other observational methods, or mixed methods.

Methodological Quality

We assessed the methodological quality of the included studies and decision aids using a variety of tools, depending on the KQ being addressed and study design.

KQs 1 to 3: Decision Aids and Tools

We planned to use the Cochrane Risk of Bias tool to assess RCTs and NRCTs;[67] however, we did not identify any eligible trials.

To assess the quality of the decision tools, we used a previously validated, systematic assessment framework for decision aids.[68] This framework assesses quality in all stages of tool development (including: processes of refinement and final content) and multiple facets of a tool, including the following domains: systematizing the development process; providing information about treatment options; presenting probabilities; clarifying and expressing values; using patient stories; guiding and coaching; disclosing conflicts of interest; providing internet access; balancing presentation of options; using plain language; basing information on up-to-date

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evidence; and establishing effectiveness. Two reviewers independently appraised the decision aids, and there were no discrepancies in their assessments.

KQ 4: Barriers to Decision Aids and Tools

We used different tools to assess the methodological quality of studies depending on study design. For qualitative studies, we used the Critical Appraisal Skills Program tool for assessing qualitative research.[69] This narrative-based tool can be used for different qualitative methods and has been previously validated in large qualitative systematic reviews.[70] For observational studies, we used a tool for cohort studies[71] and for descriptive cross-sectional studies.[72] We categorized studies as being of high, medium, or low quality.

One reviewer applied the tools, and a second reviewer independently checked the appraisal. We resolved differences in quality assessments by consensus.

Data Extraction

One reviewer extracted data from individual studies using standardized templates; a second reviewer independently verified the data for accuracy and completeness.

KQ 1 to 3: Decision Aids and Tools

We extracted information on the content of each tool and its development using the content of the tools and the fields of the systematic assessment framework for decision aids.[68](Appendix C)

KQ 4: Barriers to Decision Aids and Tools

We classified studies into three categories: a) qualitative studies describing general experiences with ECDs; b) quantitative studies addressing psychosocial outcomes; and c) mixed method studies relating to communication.

We used different data extraction forms for studies using qualitative and quantitative designs, which are available in Appendix B. Data were extracted on elements of tools. For qualitative and mixed method studies, we extracted publication details (year, author, study title, journal, main focus of paper), methodological details (principle approach, data collection methods, sampling methods), and population characteristics (sex, age, recruitment criteria, country of study, device type). We noted if the participants were patients, health professionals, or caregivers. When possible, we recorded details regarding indication for ECD (primary or secondary prevention), New York Heart Association functional class, left ventricular ejection fraction, and disease (heart failure or non-heart failure). We also recorded the focus of the study in relation to ECD insertion, malfunction, deactivation, or end-of-life.

For quantitative studies focusing on psychosocial outcomes, we similarly extracted publication details, population characteristics, and the indication for ECD (primary or secondary prevention). We noted if the participants were patients, spouses, or other primary caregivers. We recorded which instruments were used to measure specific outcomes. For each outcome, we extracted baseline, followup, and change from baseline data, including information on the effect size and statistical significance, if available.

Data Synthesis

KQ 1 to 3: Decision Aids and Tools

We present a narrative summary of the studies that provided data to address this question.

KQ 4: Barriers to Decision Aids and Tools

For qualitative studies on general experiences with ECDs, we used a meta-ethnographic approach to synthesise findings.[73 74] This approach provides a new synthesis of findings to account for the phenomenon being explored[74] and involves a three-stage process including first-order findings, second-order interpretations, and higher-order abstractions. Through this process, studies are re-analyzed and compared in light of each other to produce new theory or knowledge (Table 3).[74 75]

Table 3. Stages of synthesis of qualitative studies

Synthesis Stage	Description	Output
1. First-order findings	Each primary reviewer read each study to identify, based on the team's definition of help seeking, the main concepts in each study linked to help seeking decisions and experiences. First-order findings were recorded in a matrix with study details and methodological quality results.	A detailed description of the findings of each study.
2. Second-order interpretations	Each primary reviewer independently examined the nature and relationships between concepts identified in Stage 1. Views of main themes across studies were discussed at length. Common or reoccurring concepts or those that provided explanations for help seeking were sought and interpreted in the context of study quality and setting. Main concepts identified at this stage were: the problematic nature of cardiac heart failure, the ambiguity of body sensations, links with wider self-care, help seeking processes, and coping.	Interpretations of common or reoccurring concepts or those that provided explanations for help seeking.
3. Higher-order abstractions	The main concepts identified during Stage 2 were re-interpreted in the light of the findings on help seeking from each paper. A line of argument or explanatory interpretation was developed in an iterative process to identify and question key barriers and facilitators of help-seeking.	The research synthesis presented in this paper.

We used an integrative approach to synthesis for the quantitative studies related to psychosocial barriers to tool use in the ECD population. We chose this approach because, although the selected studies were on the same topic, there were differences in methods and outcomes which precluded pooling of results.[76] For the integrative review, we examined the findings of comparable studies in relation to each other, taking account of the methodological quality and differences in populations.[76]

For mixed methods studies on communication, we followed the same steps for quantitative studies of psychosocial outcomes.[76]

Results

This chapter reports on the results of our literature review and synthesis. First, we present the results for Key Questions (KQs) 1 to 3 on existing decision aids and their effectiveness. We then present results for KQ 4 on barriers to the use of decision aids. Several appendixes provide supporting information to the findings presented in this section. Appendix C provides details on the decision tools that were identified for KQs 1 to 3. Appendix D provides a list of citations for the excluded studies. Appendix E and F provide a description of the included studies and detailed quality assessments, respectively.

Literature Search

The literature search identified 1,449 citations; after the removal of duplicates, 1,102 studies remained. We identified an additional 51 citations from grey literature searches, hand searches, and from contacting experts. In total, we screened 1,153 studies. Figure 1 describes the flow of studies through the selection process.

For KQs 1 to 3, we identified eight potentially relevant studies. Four studies appeared to contain data relating to decision aids for insertion or deactivation. The studies examined interventions for electronic cardiac device (ECD) populations using telephone counseling,[77] discussions prior to[78] or after[79] device insertion, and a disease-specific end-of-life planning tool.[80] However, based on followup with authors over email, we determined that none of these interventions included a discussion of aspects of insertion, malfunction, or deactivation of ECDs; therefore, these studies were excluded. We identified four patient decision aids that were included in our review.

We identified a total of 97 potentially relevant studies addressing barriers to the use of tools in the ECD population (KQ 4). Of these, 67 met the inclusion criteria. Included studies fell into the following three categories: a) 33 qualitative studies that contained data on patient experiences related to decisionmaking; b) 26 quantitative studies of psychosocial outcomes; and, c) 8 studies using mixed methods designs addressing communication issues. The remaining studies were excluded because: they were not relevant to the topic (n=21), they were reviews (n=5), or were not published in English (n=1).

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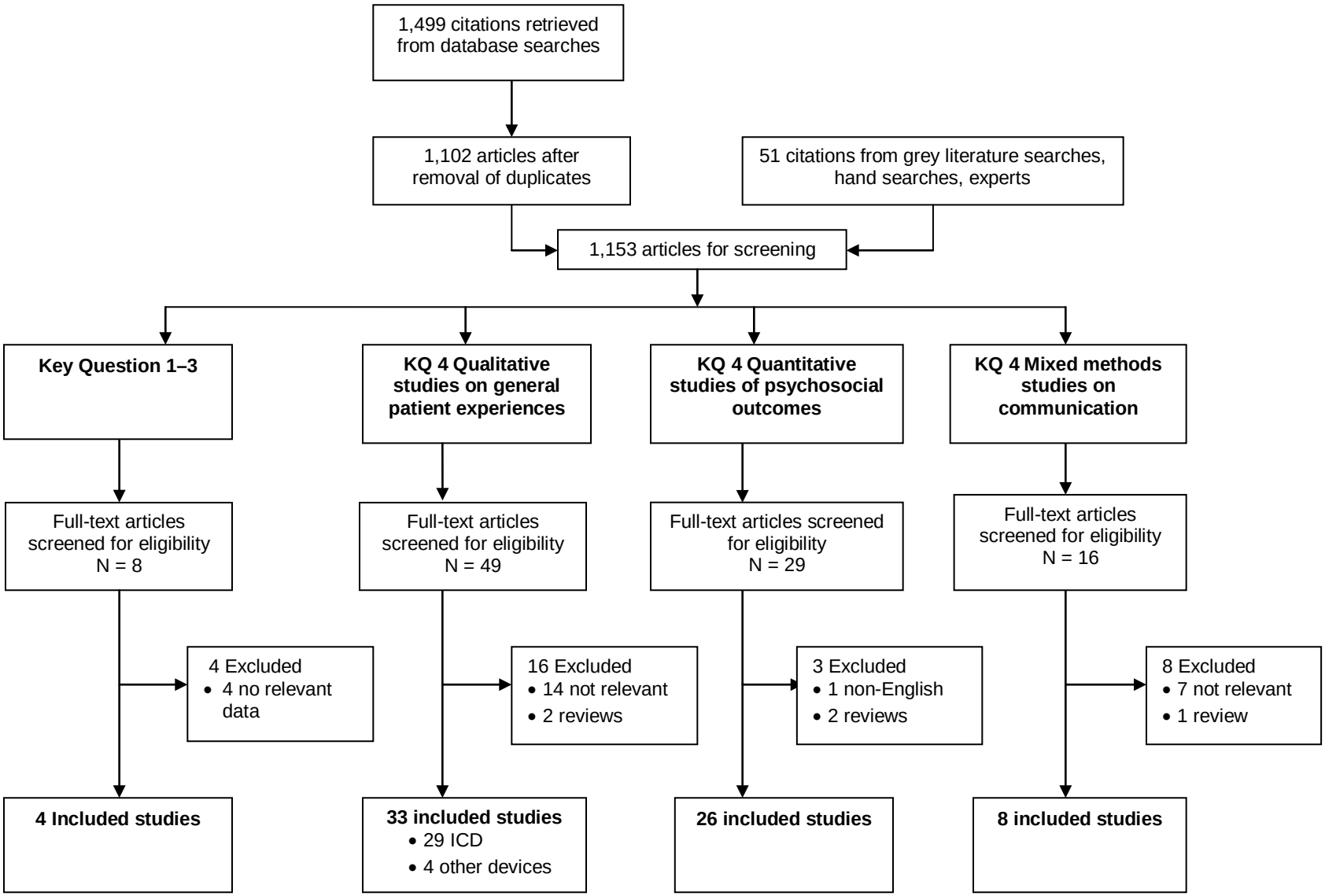
Figure 1. Flow diagram of study retrieval and selection



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Key Questions 1 to 3: Decision Aids and Tools

Description of Included Studies

We identified four patient decision aids for inserting an implantable cardioverter-defibrillator (ICD)[81] and pacemaker[82] for patients at risk from arrhythmia and an ICD[83] and pacemaker[84] for patients with heart failure (Table 4 and Table 5; full copies of tools are available in Appendix C). These aids have not been evaluated using any formal research methodology (e.g., randomized controlled trial [RCT]), but have been independently validated as meeting quality criteria for decision aids by the Ottawa Hospital Research Institute.[68] Given the lack of other studies evaluating decisions tools around deactivation, these four tools could be considered the "best available evidence."

All of the tools focused on the decision of whether or not to have an ECD implanted. We did not identify any tools that focused on deactivation decisions. Separate tools were available for patients with heart failure versus heart rate problems in relation to ICDs versus pacemakers.

The tools were all developed by Healthwise, a nonprofit organization based in the United States (http://www.healthwise.org/) that develops proprietary health content, patient education tools and solutions for health plans, care management companies, hospitals, and consumer health portals. They are available in English in both electronic and paper format. Although these tools are fully available via the internet, they remain proprietary products of this company, and Healthwise retains copyright for their use and distribution. Healthwise has no formal links to device manufacturers and has developed decision tools in over 160 health-related decisions areas. We requested information on the method of development and evaluation for these tools; however, Healthwise did not provide this information.

Table 4. Tools for electronic cardiac devices identified by the review*

Title	Heart rate problems: Should I get an ICD?	Heart Rate Problems: Should I Get a Pacemaker?	Heart failure: Should I get an ICD?	Heart failure: Should I get a pacemaker (cardiac resynchronization therapy)?
Health Condition	Arrhythmia	Arrhythmia	Heart Failure	Heart Failure
Type	Treatment	Treatment	Treatment	Treatment
Options Included	Get an ICD. Don't get an ICD.	Get a pacemaker. Don't get a pacemaker.	Get an ICD. Don't get an ICD.	Get a pacemaker. Don't get a pacemaker.
Audience	People with heart rate problems but do NOT have heart failure considering whether to get an ICD.	People with heart rate problems but NOT heart failure considering getting a pacemaker.	People at risk of having an abnormal heart rhythm that could cause sudden death.	People with class III or class IV heart failure, symptoms not controlled with medication, an ejection fraction of 35% or less and tests showing the heart's ventricles are not beating at the right time.
Developer	Healthwise	Healthwise	Healthwise	Healthwise
Country of developme nt	United States	United States	United States	United States
Year of last update or review	2011	2010	2010	2010
Format	Web, paper	Web, paper	Web, paper	Web, paper
Language(s)	English	English	English	English

ICD = implantable cardiac defibrillator; OHRI = Ottawa Hospital Research Institute

*See Appendix C for copies of the tools and URLs for further information on the tools and their validation.

Quality of Tools

We evaluated the quality of the tools against the International Patient Decision Aid Standards,[68] which assesses content, tool development, and effectiveness. For this review, we only evaluated elements related to the tool content and effectiveness. Although we requested information on tool development via email, the developer did not make this information available to us, precluding our ability to assess items related to tool development.

In terms of quality of content, the tools focused almost exclusively on technical aspects of implantation with very little related to quality-of-life issues (Table 5, Appendix C). Risks and benefits of not having the procedures were simply presented as the quantitative inverse of the risks and benefits of getting the procedure. Only one tool specifically identified harms to quality of life (Tool 1–Heart Failure: Should I get an ICD?); however, the information was limited with the only issues listed being "falling out of bed" and "worry about shocks." Although other aspects of content did acknowledge the existence of unnecessary shocks, there was no information presented on the likelihood of pain and other implications of shocks. Rather, the tools sought to normalize these shocks by presenting them as acceptable because shocks are "a sign that the ICD is working."

Though the tools adequately addressed aspects of insertion, none of the tools addressed the topic of deactivation of the ECD, either in relation to discussing the future prospect of deactivation with patients prior to insertion (as recommended by guidelines)[40] or as a separate decision after insertion before or near the end of life.

Table 5. Decision tools: Quality of content for insertion of electronic cardiac devices

Assessment Criteria ***Decision Aid:*** **Topics covered:**	**T1**		**T2**		**T3**		**T4**	
	I	**D**	**I**	**D**	**I**	**D**	**I**	**D**
Describes condition (health/other) related to the decision	✓	–	✓	–	✓	–	✓	–
Describes the decision that needs to be considered	✓	–	✓	–	✓	–	✓	–
Lists the options (health care or other)	✓	–	✓	–	✓	–	✓	–
Describes natural course of condition if no action is taken	P	–	P	–	P	–	P	–
Describes procedures involved (before/during/after)	✓	–	✓	–	✓	–	✓	–
Gives information on benefits/advantages	M	–	M	–	M	–	M	–
Gives information on harms/side effects/disadvantages	M	–	M	–	M	–	M	–
Information about outcomes of options (positive and negative) includes the chances they may happen	P	–	–		P	–	–	
Gives information on what test is designed to measure	NA		NA		NA		NA	
Describes possible next steps based on the test results	NA		NA		NA		NA	
Describes odds of finding disease with/without screening	NA		NA		NA		NA	
Gives information on detection/treatment of disease that would have never been identified without screening	NA		NA		NA		NA	
Gives probabilities using event rates in a defined group of people for a specified time.	–		–		–		–	
Compares chances of a disease, benefit, harm, or side effect of options using the same denominator	✓	–	–		✓	–	–	
Compares probabilities of options over the same period of time	–		–		–		–	
Uses the same scales in diagrams comparing options	NA		NA		NA		NA	
asks people to think about which positive and negative features of the options matter most to them	✓	–	✓	–	✓	–	✓	–
Makes it possible to compare the positive and negative features of the available options	M	–	M	–	M	–	M	–
Shows the negative and positive features of the options with equal detail	–	–	–	–	–	–	–	–

✓ = adequate; – = inadequate; D = Deactivation; I = Insertion; M = misleading information; P = partial information; T1 = Heart Failure: "Should I get an Implantable Cardioverter-Defibrillator?"; T2 = Heart Rate Problems: "Should I get an Implantable

Cardioverter-Defibrillator?"; T3 = Heart Failure: "Should I Get a Pacemaker?"; T4 = Heart Rate Problems: "Should I Get a Pacemaker?"

KQ 1 to 3: Decision Aids and Tools: Summary

Existing decisions tools address only insertion of ICDs and pacemakers in relation to heart failure and arrhythmia populations. The overall quality of the tools in terms of content was mixed. The tools contained comprehensive information on technical elements of the underlying health condition, nature of devices and implantation process and maintenance. However, limited information was presented on quality-of-life implications, and the tools appeared to lack neutrality in relation to the choice to implant the device.

Therefore, there are no existing validated decision aids or tools that adequately address deactivation either prior to or after implantation of an ECD. In light of guideline recommendations to discuss deactivation prior to insertion,[40] current aids are ineffective at promoting informed decisionmaking about insertion or deactivation. Also, existing tools addressing insertion appeared to lack balance in the presentation of information. Due to the lack of research evidence, the generalizeability of decision tools for deactivation of ECDs to the Medicare population is unclear.

Key Question 4: Barriers to Use of Decision Tools

For KQ 4, we classified studies into three categories: qualitative studies that contained data on patient experiences related to decisionmaking (n=33); quantitative studies of psychosocial outcomes, all of which examined anxiety issues in patients with ECDs (n=26); and studies using mixed methods designs addressing communication issues (n=8). We present a description of the studies and a synthesis of the results separately for each of these categories.

Qualitative Studies of General Patient Experiences

Description of Studies

The main designs used in these studies were: grounded theory (n=6),[45 47 85-88] surveys with a qualitative dimension (n=7),[58 89-94] or general qualitative methods (n=7).[95-101] Other studies used systematic text condensation (n=1),[102] phenomenology (n=2),[103 104] life story method (n=1),[105] ethnography (n=1),[1] mixed methods (n=1),[106] and phenomenography (n=1).[107] Designs that are traditionally quantitative were included in this qualitative group if narratives of patient experiences were reported in the study. Therefore, other designs were RCT (n=1),[108] case-control study (n=1),[109] and cohort studies (n=4).[12 110-112] Most (n=29)[1 12 45 47 58 86-95 97-102 104 106-112] of the studies centered solely on ICDs, with several (n=4)[85 96 103 105] studies exploring issues related to pacemakers and VADs. Irrespective of device, the majority (n=20)[85 86 90 92-95 97-100 102-109 111] of the literature focused on quality-of-life topics, such as adjusting to life with an ECD. Additionally, six studies focused on deactivation or end of life,[12 45 47 58 89 112] six reported on insertion,[1 87 88 91 96 101] and one addressed malfunction.[110]

Of the 28 studies that reported study setting, most were conducted in the United States (n=17).[1 45 58 86-89 91 93 96 97 103 105 108-110 112] Other settings were: Australia (n=3),[85 95 100] Sweden (n=3),[92 101 107] Canada (n=2),[47 111] Norway (n=1),[102] and the United Kingdom (n=1).[99] One comparative study evaluated the experiences of American and Swedish ICD recipients.[90] Sampling methods were largely convenience-based, with participants routinely recruited from a single university hospital or outpatient clinic in an urban center.

Although the studies rarely reported heart failure diagnosis, we could draw some conclusions about disease characteristics based on several indicators presented in demographic tables (e.g., New York Heart Association functional class, left ventricular ejection fraction, and cardiac disease). Less than half (n=15) of the studies recruited patients with heart failure, whereas eight studies included populations without heart failure (e.g., diagnoses of cardiomyopathy, coronary artery disease). Heart failure status was unclear in three studies, and the remaining seven studies recruited patients both with and without heart failure.

The typical patient in the study population was white, American, male, an ICD recipient, and near 62 years of age. The sample populations were almost exclusively patients (n=27) or patients and their caregivers (n=4). One study exclusively sampled health professionals,[58] whereas another included family members, patients, and health professionals using a case study design.[1]

The mean age was 62 years across 23 reporting studies; a range of 18 to 90 years illustrates the breadth in sample populations across the body of literature. Although few studies reported data on ethnicity or race, the demographic data that was reported highlights the overrepresentation of white patients. Likewise, the populations in 27 studies were predominantly male, and 1 study was exclusively male.[85] The proportion of women was greater than the proportion of men in only two studies;[102 104] however, two additional studies intentionally recruited a female-only population.[103 105] The remaining article used a case study design and did not report participant demographics.[1] Overall, these trends indicate the potential for future

research with specific ECD subpopulations, including different ethnic or racial groups and women.

Half of the studies were appraised as moderate quality (n=16). The remaining studies were assessed as high (n=10) and low (n=7) quality. The detailed results of the quality assessment are presented in Appendix F. The most common weaknesses were: over-reliance on convenience sampling, low representation of older adults and superficial analyses of themes.

Synthesis of Results

This question addresses the important issue of what must be in place for decision tool(s) for insertion and deactivation of ECDs to be successful. Although no such tools currently exist for deactivation currently, it is nevertheless important to consider current evidence on the main barriers to the use of such tools in future and to use existing research to inform tool design and wider health care practices.

It is assumed in doing this that it is possible for decisionmaking tools to be developed specifically for deactivation of the different kinds of ECDs. Indeed, recognizing from guidelines that decisions around deactivation of ECDs are not ethically or legally different than decisions to commence or withdraw other treatments in the United States,[35] there are no ethical, legal, or practical barriers to the development of tools for decisions about the deactivation of ECDs. As with current tools for insertion of ECDs, different tools will be needed for patients with heart failure versus those at risk of arrhythmia and for different devices.

Decisionmaking tools support high-quality decisionmaking, ensuring, for example, informed consent and that all appropriate elements of a decision are covered at the right junctures and in the right ways. Nevertheless, such tools must be used effectively, that is: based on the right knowledge, at the right time, in the right ways, and with the appropriate people. Based on our review of the literature, we identified individual barriers, that is, factors existing in people that could act to reduce decisionmaking quality and could constrain the use or effectiveness of tools for decisionmaking. These included poor patient background knowledge, poor communication, issues with informed consent, and psychosocial sequelae. We also identified contextual barriers, including organizational factors, family and other caregiver networks, and patient support groups.

Individual Barrier: Poor Patient Background Knowledge

Decisions about ECDs, whether related to insertion or deactivation, should be informed by the relative benefits and harms associated with different choices open to the patient or surrogate decisionmaker.[35] This reflects current guidelines in the United States[35] and Europe[8] and the nature of informed consent.[33 113]

However, the evidence shows that patients with ECDs frequently have misconceptions regarding basic elements of ECDs. This is most evident for ICDs. Even in patients fitted with an ICD, gaps in knowledge exist about the purpose of the device,[45 92] how the device addresses their condition,[92] why the ICD was implanted or its function,[45] alternative treatments to the device,[86 95] overestimation of the benefits of the ICD,[45 86 88 97 101] and the magnitude of impact on survival and quality of life.[47 89 112]

Misconceptions can relate to the likelihood and severity of the consequences of deactivation. For example, there is a widespread belief that deactivation of an ICD will result in rapid death,[1 45 86 95 99 112] resulting in the assumption that deactivation is an act of suicide.[45] Hence, in some

cases, patients felt they were presented with no choice because their physician equated not getting the device with choosing to die.[1 104]

Individual Barrier: Poor Communication

Ensuring that patients or surrogate decisionmakers are provided with personalized, fair, balanced, and comprehensive information to make decisions about deactivation is central to establishing and maintaining informed consent.[35] Current guidelines encourage long-term dialogue between health professionals and patients about the prospect of deactivation so that the topic is not first broached at or near the end of life.[35] However, current practices around communication suggest that there are significant barriers to effective communication around deactivation in people with ECDs.

One study reported that nearly one-third of patients preferred deactivation when asked, but reported that no one had raised the topic with them previously.[89] Patients generally believe that health professionals should initiate the discussion of issues around insertion and deactivation with them proactively, rather than depending on the patient to raise the issue.[88 91 102] However, some patients perceived that physicians had not even discussed ICD deactivation with them or only address deactivation after implantation.[89] Only 61 percent of patients with devices recalled being informed by their physicians that the device could be deactivated.[110]

Some patients reported receiving inconsistent information from different health care providers;[58 88 102] for example, they noted conflicting information about driving restrictions from family physicians and cardiologists.[99] Misinformation or conflicting information could affect care decisions[102] or lead to concerns over remuneration for implantation, maintenance, and possible replacement of the device.[99]

The goals of patients and health professionals around ECD insertion and deactivation frequently conflict. Patients commonly perceive a number of key differences between the priorities of physicians and their own concerns, and in turn, these differences reflect and shape how patients and professionals perceive one another. Patients felt that clinicians were overly concerned with technical aspects of device function.[88 98 99 102] Moreover, patients expressed a desire for physicians to take a more holistic approach to their health, for example, by addressing all of their (cardiac) symptoms in the context of other medical conditions and concerns.[102] Indeed, one study found that patients were more likely to be dissatisfied with their care when experiencing more disease symptoms.[102] Patients reported that physicians dismissed[98 102] or disrespected their concerns.[102]

Physicians' presentation of risks to patients may reflect the presumption that death should always be avoided or delayed if possible.[1 86 87] For example, patients reported that their physician began a discussion about implantation by emphasizing the chance of death from a cardiac event over the chance of a nonrecurrence.[87] On other occasions, patients felt that their physician presented the device only in positive terms or subtly indicated that it was assumed that the patient would choose to have the device implanted.[104]

Patients reported wanting their physicians to personalize the information they were given, not only to their specific health history, but also to their values about quality of life, lifestyle, and habits.[98 102] Such factors could in turn adversely affect how the patient communicated with the health professional. Indeed, patients perceived that physicians often lacked communication skills about device effects, particularly in relation to the impact of ICDs on sexuality,[47] end-of-life issues,[47] or more generally.[98]

Weaknesses around communication were also evident to patients in the tone and manner of information delivery provided by health professionals[102] or the sense that some questions were

not permitted.[88] These negative aspects of communication could adversely affect the dialogue between patient and professionals by reducing the likelihood of patients identifying key issues of concern to health professionals. For example, patients may choose to report only more intense shocks to their physicians and omit milder symptoms relevant to device function.[93 99] This may be a trade-off that patients make given the limited timeframe for consultations; they may only report the most direct technical issues in order to reserve some time to raise other concerns. Alternatively, patients reported feeling more positively about communication when physicians spent time with them[88] and addressed quality-of-life issues[98] and emotions, such as fear.[88]

Patients reported valuing dialogue with some types of clinicians, specifically cardiologists, general practitioners, nurse practitioners, and physician assistants, regarding sensitive and personal concerns, such as sexual intimacy.[98] In this context, patients' preferences may depend on their perceptions of the health provider's knowledge level and comfort in discussing sexuality.[86 98] However, patients wanted to receive support around decisionmaking from a range of health professional groups, such as their primary physician[88] and nurses.[86 95] The inclusion of nurses in followup care practices could increase access to support, which was identified as another prominent issue for patients who reported physicians' responsiveness. Some patients wanted better access to their physician, especially with regards to time to discuss health concerns[88] or to connect in an emergency.[88]

Individual Barrier: Issues with Informed Consent

Some issues identified in the studies related specifically to informed consent. Importantly, these issues were raised about insertion, but may have important implications for discussions of consent around deactivation.

Patients with ECDs frequently reported encounters with health professionals in which they felt they relinquished control of the decisionmaking process,[85 101 105] experienced coercion to accept device insertion,[1 103] and were passive in patient-physician interactions.[85 96]

ICD recipients also wanted more information addressing a greater variety of factors on which to base decisions about implantation and therapeutic trajectory.[1] In addition to information directly related to procedures and their risks and benefits, patients disclosed a need for more information about followup and maintenance,[102] modification of activities of daily living,[86 99] what to expect if the device fires,[106] and how to handle malfunctions.[106] Further, some reported that they felt their physicians understated the intensity of single or multiple shocks.[106]

These factors can clearly reduce the degree to which consent around decisions is informed and incorporates the patients' or surrogate decisionmakers' values. Moreover, reactions to poor communication could compound this by increasing anxiety and/or reducing involvement in decisionmaking. For example, recognizing the large gaps that exist in their knowledge about ICDs, patients can report feeling overwhelmed by the need to educate themselves about their condition and frustrated when trying to access information and advice from health professionals.[88] In the absence of a clear understanding of the device, some patients with ICDs totally abdicated the responsibility of making decisions to their clinician, including choices about deactivation.[102]

Patients can also experience pressure in health-related decisions from other sources. For instance, patients disclosed that family members corrected them if they discussed negative aspects of the ICD and reoriented them to think and talk only about its positive aspects[45 47 87] or the device's life-extending functions.[86 87] Patients themselves reflected this by expressing that they should be grateful, minimize their losses, adapt, and not complain.[45 86 87 107] Some patients had difficulty coming to terms with the idea that death is a possible outcome and reiterated that

cardiac transplant was the only "cure" for their heart condition and the single circumstance under which they would opt for permanent deactivation.[45]

Individual Barrier: Psychosocial Sequelae

Patients do not see ECDs as neutral technical devices, but link device function to anxiety and fear related to anticipation of shocks. There is some evidence that ICD recipients experience reduced fear after their first shock.[93] Patients who had not previously experienced a shock reported higher anxiety,[93 111] more uncertainty, and poorer quality of life.[93] However, shock frequency is also important to anxiety levels. Although anxiety dissipates following the first shock, it rises for those who experience five or more shocks.[111] Further, occasional shocks were less anxiety provoking than several shocks in succession.[111] Patients may lose confidence in the effectiveness of the ICD after multiple shocks.[106]

Additionally, a subgroup of ICD recipients have phantom shocks (i.e., they feel shocked when the device has not actually fired). These patients tend to have higher baseline levels of anxiety and depression than patients who do not report phantom shocks.[109] Irrespective of whether they had received shocks, patients wanted more information about what to do following a shock.[45] Additionally, patients who had never been shocked wanted information about shock intensity and how to avoid triggering a shock.[45]

Negative psychosocial sequelae of ECDs occur irrespective of time and include a range of negative emotions arising from shocks. As this review demonstrates elsewhere, patient anxiety over ECDs is common and damaging. ICD recipients experience greater levels of anxiety, depression, and worry than nonrecipients.[93 109 111] Twenty-one percent of this population is above the normal adult threshold for anxiety and five percent is above the normal adult threshold for depression,[94] indicating that anxiety is a greater concern than depression for ICD patients.[111]

ICD recipients may forgo trigger activities or move at a slower pace to avoid being shocked.[95] Patients may also become hypervigilant in their efforts to control and avoid ICD shocks.[104] Hence, for ICD patients, the fear of shocks may affect patterns of daily life as much as, if not more, than actual shocks.

Negative emotions may arise from loss of activities[97 107] and changing social roles and relationships.[98 99] Many recipients lost their driver's license[99 102] and reported that their caregivers were overprotective.[99] As a result of these factors, either singly or in combination, recipients may feel a loss of control,[97 99] independence,[99 102] and self-confidence,[99] or experience boredom,[99] loneliness,[107] or isolation.[100]

Contextual Barriers: Organizational Factors

Although patients reported valuing input from multidisciplinary teams, they can also be confused by team-based approaches to care. They reported confusion over which physician was in charge of their care, wanted more information from, and contact with, their cardiologist as opposed to interns or residents, and wanted a more stable relationship with one provider.[88]

Evidence suggests that physicians may be more comfortable discussing ICD deactivation when their facility has a policy or protocol to do so[58] or if the patient has a terminal illness (e.g., cancer).[12 58] Physicians have been found to be more likely to raise the issue of advanced directives with patients than ICD deactivation.[58]

Contextual Barriers: Family and Caregiver Networks

Several studies show that patients who have more supportive social networks are more proactive, report better quality of life,[94] have better communication with physicians,[107] and lower

levels of depression and loneliness.[107] Patients who prefer quality over quantity of life may be more likely to consider how they would like to die[47] and initiate end-of-life and deactivation discussions with their families and health professionals.[47 98]

Caregivers experienced challenges with a number of issues related to caring for a person with an ICD. In relation to ICD shocks, they were unsure how to respond[106] or felt helpless[106] and wanted to stay physically close to the patient to protect them and other members of the public should the patient experience a shock in a public vicinity.[95] Caregivers themselves reported reduced coping resources over time as they perceived patients were losing the capacity for some roles and responsibilities due to memory loss or reductions in function, such as the inability to drive.[88]

Contextual Barriers: Patient Support Groups

The studies also reported alternative sources of patient support, particularly support groups that involved lay peers (i.e., other people with devices). Patients reported that these groups were an important and useful source of social support and information, which facilitated a shared sense of identity and community. These served to reduce isolation and loneliness.[100] Peer support groups were seen to provide more relevant information on the experience of living with an ICD than books or health professionals.[100 104]

However, patients also enumerated a number of barriers to participation in support groups. Group composition in terms of gender and age can affect participation because patients may feel that they cannot relate to the experiences of other group members.[86 100] Barriers to being involved in support groups included aversions to "sick roles" or being reminded of their illness.[100] There was evidence that some patients respond adversely to others in support groups who broach negative experiences related to their ICD.[86]

Reactions to ECDs over Time

The challenges patients experience in relation to ECDs appear to change over time. Patients with an ICD share a set of experiences and move through a number of identifiable stages that should be taken into account in designing a tool to facilitate deactivation conversations. The stages include pre-implantation, postimplantation, normalization or adjustment (first year after implantation), and worsening health. Implant recipients may be more receptive or able to engage in deactivation discussions at some stages than others. Patients reported that their attitudes and preferences towards living and dying changed over time, but these changes are complex, non-linear, and sometimes contradictory.[47] Of key importance, many patients retrospectively identify a need for more information at pre-implantation.

In the pre-implantation stage, patients report experiencing a crisis in which they come to terms with the fact that death is imminent and their previous life cannot continue without an ICD.[86] During this time, patients appear to focus on survival and a better life after device implantation[86 102] and view the ICD as the solution to their cardiac problems.[102] Common reactions during this stage also include feeling a loss of control due to the belief that their physician assumed they would ultimately opt for implantation.[87 104] Nevertheless, confidence and trust in physicians and the ICD were high.[45 86 97] Patients also expressed feeling a sense of security and the ability to plan once again for a future life.[86] In comparison to a Swedish population, ICD patients in the United States reported greater uncertainty during this phase.[86 90] For some, this period is also influenced by worries over funding the treatment.[99]

The postimplantation phase includes hospitalization and the first three months of recovery. Notably, after device implantation many patients said they would have liked more information

prior to implantation[47 102] especially on topics related to quality of life.[98 99] In retrospect, patients identified wanting more information on activities associated with higher risk of triggering a shock, particularly in the context of preparing for life after hospital discharge.[99] This information was desired both pre- and postimplantation.[99] Although many ICD recipients did not recall formulating a deactivation preference prior to implantation,[102] they expressed that they would have liked to discuss end-of-life issues during pre-implantation decisionmaking.[47] However, some patients pointed out that hospitalization is an exceedingly poor time to try to impart new information given the limited timeframe and problems with memory.[86,101] Nonetheless, others wanted general information about quality of life issues prior to hospital discharge, followed by specific information at routine followup visits.[98]

In the first year after insertion, ICD recipients are likely to experience important changes to social relationships,[98 99] communication,[107] and identity.[85 102] Although appropriate social support is integral to ICD adaptation and quality of life,[94] both family coping and quality of life diminish over time.[88]

The first three months postimplantation can be characterized by depression and anxiety,[92] but many have adjusted to their new lives at 1 year. Patients report boredom, incision-site pain, fear of isolation,[99] and fear of being shocked.[97 99] These emotions and sensations primarily subside after experiencing the first shock.[97] The first three months are also a stressful period for caregivers; both spouses and patients report high levels of anger postimplantation, which also subsides over the course of the first year.[109] Memory loss may impede end-of-life decisions at this point and rapid changes in relationships, roles, and emotions may contribute to depression.[103 105] Consequently, this is not an ideal time for end-of-life decisionmaking.

ICD recipients may struggle to maintain a sense of normalcy in the face of profound changes to their activities, relationships, and sense of self. Although many report various losses, others state that they "feel normal"[107] and plan to live normal lives.[102] One obstacle that many encounter is their changed appearance and the impact of that on how others perceive them. Both males and females can feel embarrassed and different as a result of the visible implant and report coming to terms with a new body image.[99 102] Some patients reported dressing strategically to hide the ICD[97] or concealing symptoms, ICD shocks, and emotional concerns from family members and caregivers.[99]

Differences across Populations in the Qualitative Studies

We examined population differences in the qualitative studies for devices, gender, and age.

Evidence from the qualitative studies reviewed consistently suggest that issues related to informed consent are *not* markedly varied among recipients of different cardiac devices, despite differences in the purpose and function of ICDs and other ECDs. In both cases, the data illustrates problematic areas of the consent process, namely voluntariness and disclosure.

Similarly, recipients express high increases of self-confidence ("omnipotence") in physical ability after device implantation.[45 85 88 105] Although advances in biotechnology drastically reduced the size of implantable devices, ECD recipients generally express concerns over device protrusion and incision scars.[99 102 105]

ICD recipients do appear to report higher levels of anxiety and uncertainty post-implantation,[108 109 111] which is understandable given the higher number of shocks delivered by ICDs. Consequently, ICD patients' concerns may vary slightly from those of other ECD recipients in their preference to discuss wider, health-related quality-of-life issues with their physicians.[102] Similarly, driving restrictions are specific to patients living with an ICD and have a negative impact on quality of life and mental health.[99 102]

Lack of representation of both sexes in the samples of the qualitative studies (a consistent oversampling of men) reduced the ability of the studies to shed light into sex differences and the influence of gender. There were preliminary findings that women are more likely to select deactivation of an ECD near the end of life than men.[89]

Although none of the studies focused on the effects of age or compared people over 65 to younger patients, some of the factors identified in the qualitative studies are likely to be influenced by age. For most patients, the first year is a time of adjustment to the device, as well as to changing roles,[98 99] and sense of self.[85 102] The data show that adjustment is particularly difficult for younger patients. Indeed, younger patients may report higher anxiety, uncertainty, and lower quality of life than older patients.[93]

Quantitative Studies of Psychosocial Outcomes

Description of Studies

The populations studied were patients with ICD only (n=19 studies), VAD only (n=1), ICD and pacemaker in combination (n=2), and other devices (n=4).

The most common study designs and methods of data collection were cohort studies (n=13),[114-126] repeated measures (n=7),[127-133] and cross-sectional surveys (n=5).[134-138] Only one study reported the results of a trial.[139] The studies measured the effect of the following comparisons on anxiety: the experience of shock versus no shock (n=5),[114 119-122] effects of device recall versus control group (n=4),[115 124 132 139] and primary versus secondary prevention as an indication for ICD (n=1).[116]

The majority of the studies were conducted in the United States (n=9),[118 123 124 126 128 129 136 138 139] or the Netherlands (n=6).[120 121 125 131 132 135] Other countries represented in the literature included Germany (n=3),[122 127 130] Canada (n=2),[115 116] Denmark (n=2),[134 137] Switzerland (n=1),[117] and Turkey (n=1).[114] One multinational study had sites in Canada, New Zealand, and the United States.[119] One study did not provide a country context.[133]

Over two-thirds of the studies (n=18) reported on patient assessments completed more than 12 months postimplantation. Although two studies did not provide any data on time since implantation, six studies reported data on patient assessments within 1 year of ICD implantation. Four of these six studies established pre-implantation baseline data.

The mean age of patients was 61 years (range 16–90 years). In 22 studies, the majority of the subjects were male; female proportions remained low at 13 to 23 percent of the sample population. Additionally, one study included only males.[126]

The instruments used to collect data were consistent across the quantitative studies. The questionnaires that were used in almost every study included the *ICD Patient Concerns (ICDC) Questionnaire,*[135 140] *The Hospital Anxiety and Depression Scale,*[141] and the *State Trait Anxiety Inventory.*[142] Patients' coping strategies were assessed using *The Freiburg Questionnaires for Coping with Illness,*[143] and device acceptance was monitored via *The Florida Patient Acceptance Survey.*[144] General scales such as the *Short Form Health Survey*[145] and the *Type D Scale*[146] were used to measure health-related quality of life and the distressed (Type D) personality, respectively.

Study quality was critically appraised as moderate (n=11)[114 117 118 122 124 125 127 130 133 136 139] to high (n=11);[115 116 119-121 129 131 134 135 137 138] four studies were evaluated as low quality.[123 126 128 132] Studies ranked as low quality frequently did not comment on statistical analysis procedures.

Main factors affecting quality were a reliance on convenience sampling, superficial analyses, and lack of diversity in patient samples.

Synthesis of Results

Up to one-third of patients with an ECD experience anxiety or depression.[135] There is some evidence from a moderate-quality study that partners' anxiety about the possibility of shocks can be even higher than patients' anxiety.[136]

There was consistent evidence of moderate to high quality that the frequency of ICD shocks was associated with higher risk of concerns,[121] anxiety,[114 120] and long-term depression (> 2 years).[119]

The effects of these shocks on psychosocial outcomes was moderated by a wide range of factors, the most common of which were: previous frequency of shocks;[114 121 122 131] and sex, with females being up to 58 percent more likely to be anxious (OR = 1.58, 95% CI, 0.62 to 6.91; p=0.019,).[114 130 136 139] Women were also more likely to have concerns about shocks,[136 137] be more likely to fear death,[136] and use emotional-focused coping,[138] all of which are linked to higher anxiety.[130 135]

Other factors that were found to moderate psychosocial outcomes were: Type D personality;[120 125 131 134] social and educational status;[121 134] coping style;[130 138] the presence of concerns;[135] social support;[131] previous psychosocial distress;[128] age;[115 120] expectancy bias;[122] and sleep.[118]

Although patients with VADs also fear death, shocks, and disability,[123] compared to those with pacemakers, there was a small amount of evidence of low to moderate quality that ICDs are more likely to instigate depression and anxiety[126] and a need for psychosocial support.[117]

In relation to the factors that affected psychosocial outcomes, there was consistent moderate-quality evidence that anxiety and depression tended to improve significantly over time, for example, 12 months[129 131 133] to 2 years[127] after implantation. There was inconsistent evidence that anxiety was affected by recalls or advisories, with studies indicating both no change[124] and negative effects.[120] Some evidence from small and moderate-quality trials showed that counselling interventions could reduce anxiety for both women and men.[139]

Studies of Communication

Description of Included Studies

In the eight relevant studies, the foci were communication on deactivation,[42 46 61] patient preferences for communication,[147-149] and training around communication.[16 150]

Study designs included surveys (n=4),[16 61 148 150] qualitative studies (n=2),[46 147] mixed methods studies (n=1),[42] and other methods (n=1).[149] Seven studies were conducted in the United States,[16 42 46 61 148-150] and one study was conducted in Canada.[147] Sample populations included physicians (n=3),[16 46 150] hospices (n=1),[61] next-of-kin (n=1),[42] and patients (n=3).[147-149] Subjects were between 33 and 93 years of age; however, only 3 studies reported mean and range of ages.[46 148 149] Across four studies, the majority of the subjects were male;[147-150] sex was not reported in the four remaining studies.

Study quality was appraised as high (n=2),[46 147] moderate (n=5),[42 61 148-150] and low (n=1).[16] The study ranked as low quality did not validate survey instruments and had a low response rate.

Synthesis of Results

The results are presented according to four themes that emerged from the studies: lack of skills, prioritization, and ethical barriers; perceptions of legal and ethical issues around communication; problems arising from poor communication; and improving communication.

Lack of Skills, Prioritization, and Ethical Barriers

Small qualitative studies on communication have identified that clinicians in the United States[46] and Canada[147] may lack communication skills in relation to discussing deactivation of ICDs. Surveys concur that most clinicians are unaware that guidelines exist even for insertion.[150]

Indeed, qualitative studies indicate that, even when health professionals view deactivation as being important to discuss, this often does not translate into actual dialogue with the patient. Frequently, this is because the professional lacks the comfort or skill in instigating and undertaking these discussions.[46 147] In 2008, prior to publication of guidelines around deactivation, there was evidence of a common perception that discussions did not take place. Reasons for this included that professionals: had poor rapport with patients;[46] had insufficient time;[46] forgot to discuss deactivation;[46] or viewed discussing deactivation of devices as being different to discussing other forms of treatment withdrawal near the end of life.[46] In addition, some professionals thought that deactivation could constitute withdrawal of life-sustaining therapy.[46] The act of deactivation can be seen by professionals as reflecting lost hope[61] and finality.[61]

Perceptions of Legal and Ethical Issues around Communication

The transferability of these findings is unclear, and there is mixed evidence as to what degree the findings from these relatively small, though good-quality, qualitative studies are mirrored elsewhere. Some survey findings corroborate these more negative patterns, but this is by no means consistent. For example, a survey of 87 physicians in the United States in 2007[16] reported that almost half of respondents (46 percent) judged deactivation to be either illegal or were unsure whether it was legal to withdraw ICD therapy in terminally-ill patients. Incorrectly, 63.2 percent of physicians considered deactivation of an ICD to be ethically the same as a “do not resuscitate” order.[16] Further, 4.6 percent of physicians considered deactivation of an ICD equivalent to physician-assisted suicide or euthanasia, and 88.5 percent considered this not to be the case.

Problems Arising from Poor Communication

The effects of poor communication do appear to negatively impact the quality of decisionmaking and compromise the care recommended by guidelines. This is exemplified in a U.S. study in which only 27 percent of patients’ next-of-kin reported that deactivation of ICDs was discussed with them.[42] Further, three-quarters of these discussions occurred in the last few days of life[42] and one-fifth in the last few hours.[42] In the same study, next-of-kin reported that 27 percent of patients received a shock in the last month of their life.[42] Such shocks could also be distressing to families.[42]

Improving Communication

There appears to be significant scope for health professionals to address these communication issues. Patients have reported that they want to know more about treatment options, even when these may involve making difficult decisions regarding uncertainties and potential harms.[147] U.S. patients are keen to receive support from cardiologists[148 149] over other sources and the mass media. Further, patients do not appear averse to communicating about these

issues with health professionals over the telephone,[148] or for younger adults, over the internet.[148] Female patients have expressed preferences towards participating in support groups with other patients.[148]

One survey identified that 78 percent of physicians are somewhat comfortable or comfortable with accepting the deactivation of an ICD, whereas less than 5 percent reported being uncomfortable with the deactivation.[16] Physician awareness of the benefits of ICDs is also high, being evident in over 95 percent of respondents in a survey.[150] However, in the same survey, physicians believe that only 76 percent of patients older than 70 years, and 49 percent of those older than 80 years, would benefit from an ICD.[150]

Contextual factors, such as organizational policies, appear to have promise for contributing positively to communication around deactivation. A high-quality national survey of 414 U.S. hospices identified that 97 percent of hospices had admitted patients with active ICDs, but 10 percent had a deactivation policy.[61] Having a “do not resuscitate” order was also associated with a higher likelihood of discussing deactivation.[42]

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Summary and Discussion

We identified four decisions aids that addressed the insertion of pacemakers and implantable cardioverter-defibrillators (ICDs) in patients with heart failure and arrhythmia. Currently, there are no validated decision aids or tools that adequately address the deactivation of electronic cardiac devices (ECDs). In contrast with current recommendations, existing decision aids do not address deactivation in discussions about insertion. Due to the lack of tools examining deactivation, generalizabililty to the Medicare population is not currently an issue.

Although it remains feasible that current recommendations could be incorporated into high-quality decisions aids for each type of ECD, there are consistent indications that other aspects of health care constitute barriers to high-quality decisionmaking and effective use of decision aids. These barriers include the following:

- Patients often have poor knowledge of key aspects related to deactivation, the role of the device, and how their health would be affected by deactivation of the device.
- Communication with physicians is often poor, and professionals are viewed as over-imposing their own values and priorities on patients.
- Patients reported wanting more discussions with a wider range of health professionals.
- The most common threats to informed consent were patient passivity, lack of information on the implications of deactivation for daily living activities, and the psychosocial disruption caused by devices, notably the shocks from ICDs.
- Patient experiences appeared to change over time. At 3 months after device insertion, there was a notably higher need for more information and psychosocial support.
- Limited social support existed for patients around decisionmaking or psychosocial wellbeing. Families and other caregivers were the main source of support, but were often seen to be overly protective.
- Psychosocial disruptions were common across ECDs. Studies reported that psychosocial disruptions were highest in patients with an ICD due to the frequency and intensity of shocks.
- Although current research presented limited sex- and age-based analyses, women appear to be prone to greater psychosocial sequelae from ICDs, and older adults may be more prone to lower social support.
- The main factors influencing anxiety and depression were: shock frequency, Type D personality, and social and educational status, and age.
- Communication-related factors that influenced psychosocial outcomes and quality of decisionmaking were the presence or absence of organizational policies around deactivation, the lack of training and comfort among health professionals in instigating and maintaining dialogue with patients around deactivation, and poorly-timed discussions that were too near to the end of the patient’s life.
- Patients reported that they would welcome more discussion with health professionals around deactivation and would be comfortable having these discussions in person or over the telephone with wider members of the multidisciplinary health care team.

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Patient accounts of and satisfaction with decisionmaking around deactivation and insertion are an important part of ensuring informed consent. This review identified that common barriers to attaining and maintaining this consent are: gaps in basic knowledge about ECDs, disparities in values between patients and health professionals, and patient anxiety. More positively, patients do appear to want to be more involved, be more informed, and receive support from different professional groups.

Deactivation of an ECD is an important aspect of health care that should be discussed openly and early in the care trajectory prior to insertion of the ECD. However, there is consistent evidence that physicians are not well trained to initiate and maintain this dialogue, that values and priorities of patients and professionals can be incongruent, and that patients often lack basic knowledge that will allow them to make choices about deactivation in an informed manner. Moreover, there was limited evidence that caregivers and family provide support that patients perceive as useful around deactivation decisions. Decisions about deactivation are likely to be complex due to the prevalence and negative effects of shocks on psychosocial wellbeing, particularly during the first year after insertion. Nevertheless, patients have voiced both a need and desire for more comprehensive information about the implications of deactivation and for support from other health professionals.

Health professionals have expressed different opinions over the legality and ethics of deactivation of ECDs. Clinicians have markedly different levels of comfort in addressing deactivation decisions, and different views of their role and of the ethics and legality of these decisions. The ability to generalize from these studies to the United States is constrained because current research has been based on relatively small qualitative studies and surveys that have been mostly local and/or had relatively low response rates. Further, ECD deactivation emerged as a new and contentious issue only in recent years and has thus far been characterized by a lack of consensus and guidance around practice, policy, and legal and ethical aspects.

This review identified research on patient perspectives regarding decisionmaking around ECDs. Although the overall quality of the qualitative, quantitative, and mixed method studies included in the review was moderate, most research has focused on aspects of insertion decisions. Even when deactivation was addressed, this was seldom done from the perspective of end-of-life care. Also, there was very little existing evidence on decisionmaking about ECDs by surrogate decisionmakers. The prevalence and quality of decisions about ECD deactivation made by surrogate decisionmakers is therefore unknown. Similarly, how family members are involved and their own satisfaction with decisionmaking about ECD deactivation is not well understood.

It is not necessarily surprising that there are no existing decision tools that adequately address deactivation either prior to insertion as part of the decision to insert the ECD or after insertion as a discrete decision. Clear guidance on the most contentious issues around deactivation relating to ICDs was only published in 2010.[35] Many of the concerning patterns identified in this review around informed consent for the deactivation of ICDs predate this guidance, and there was a lack of consensus prior to this around the ethics and legality of deactivation evident in both argument[12-15] and practice.[16]

These guidelines may in time influence organizational policies and health care practice in relation to deactivation of ICDs and other ECDs, for which the same ethical and legal principles apply. That said, the recognition that deactivation of an ICD does not constitute an act of euthanasia or assisted suicide[37 38] and has the same legal and ethical status as withdrawal of any treatment does not guarantee that care is legal and ethical. Rather, high-quality decisionmaking

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that supports the principles and practices of informed consent and patient involvement in decisions is the best means to ensure care is legal and ethical.

Practitioners' ability to attain and maintain informed consent may be constrained by the wide prevalence in patients of basic knowledge gaps that exist not only in device function, efficacy, and implications of deactivation, but also in knowledge of underlying health conditions. Although it may be surprising that such knowledge gaps exist even after years of treatment, similar gaps are relatively common in patients with advanced heart failure.[151-153] Systematic reviews have demonstrated that untreated and unrecognized anxiety and depression are common in patients with all forms of coronary heart disease[154] and heart failure.[155] As such, many of the psychosocio-educational challenges in maintaining informed consent in people with ECDs occur in patients with other cardiac conditions and may be amenable to similar solutions.

Future Research

To support legal and ethical decisionmaking around ECDs, decision tools should be developed for insertion that incorporate issues of deactivation. Due to differences in device purpose and underlying conditions, different tools will be required for different types of ECDs (i.e., ICD, including cardiac resynchronization therapy [CRT] and non-CRT, pacemaker, and ventricular assist device [VAD]) and different patient populations. Current tools to inform decisions about insertion of pace makers[82 84] and ICDs[81 83] should incorporate a discussion of deactivation, not only because this is recommended by guidelines,[35] but because such discussions are integral to ensuring adequate informed consent prior to insertion. In all instances, further research is needed to ensure that each tool is of high quality; this can be assessed using recognized quality criteria.[68]

In the light of current guidelines in the United States[35] and elsewhere,[8] high-quality decision tools focusing on deactivation of ECDs are urgently needed. These tools should follow a systematic development process, provide information on options, explain the probabilities involved in clear and numerical ways, and provide guidance on how to communicate with health professionals.[68] Further, the aids should be based on the latest scientific evidence, use plain language, and present information in a balanced manner.[68] As with insertion, separate tools around deactivation are needed for different patient populations and ECDs. Research should focus on the quality of these aids[68] and also what influences their effectiveness when used in health care systems.

Possible barriers to the effectiveness of tools relate to the wider communication and consent processes. There is an urgent need for a U.S. national survey of relevant care settings to determine what proportion have policies in place related to deactivation of ECDs, particularly of ICDs in patients with heart failure or arrhythmia. This survey is an important extension to a recent national survey of hospice policy.[61]

Physician attitudes and practices around deactivation of ICDs should be reassessed in key clinical groups in the light of recent guidelines on key processes of care and consent.[35] The perceived congruence between the legal and ethical acceptability of ICDs from the perspective of practitioners to current American Medical Association (AMA) positions[37-39 156] and guidelines[35] should be ascertained. Other topics that merit further exploration via surveys include:

- Physician readiness to involve other professional groups in patient support and discussions around deactivation;

- The degree and nature of collaboration that exists between cardiology and palliative care teams in deactivation decisions; and
- The views of informed consent and reported practices of physicians around deactivation decisions compared with professional statements[33 113] and relevant guidelines.[35]

Future interventions to support patient wellbeing and high-quality decisions should focus on training clinicians in communication and decisionmaking and promoting patient involvement, receptivity to discussions, and psychosocial wellbeing.

Further training of health professionals involved in deactivation decisions should be evaluated prior to implementation. The effectiveness of training could be evaluated using randomized control trials (RCTs) with patient-centered outcomes to determine adequacy of consent, such as patient knowledge, content, involvement, and timing of discussions. Interventions to support training of health professionals should address the different roles that physicians and other professional groups may have in deactivation discussions and should incorporate recommendations from guidelines.[35] In addition, they should address the receptiveness of patients or surrogate decisionmakers to these discussions in the light of their values and preferences, adverse psychosocial factors, and gaps in basic knowledge about ECDs. Training resources have been developed in other countries that may be transferable to the United States. Since 2007, the British Heart Foundation has adopted a policy of advanced communication skills training as integral to their heart failure nurse training curriculum.[157]

Most adverse psychosocial outcomes occur in patients after ICD insertion. Women are particularly vulnerable to anxiety. Patient anxiety can be addressed by reducing the risk of inappropriate shocks;[158] for example, U.S. guidelines now exist on specific programming strategies or pharmacotherapy to suppress arrhythmias.[159] Systematic reviews and trials suggest that dedicated programs of cognitive behavioral therapy[78 160] and psycho-education[79 161] may also have positive effects on anxiety in ICD patients. A narrative review showed that interventions tailored to individual needs can address a wide range of ICD-related anxieties, including device acceptance, shock anxiety, and death anxiety. These interventions can be specifically targeted to women, young patients, and next-of-kin.[162] Key components of these interventions include device-related education, relaxation and stress management, cognitive restructuring, social support and group discussion, and exercise.[162] The development and testing of electronic or telehealth interventions to promote access to hard-to-reach populations, such as patients from rural communities, are important and have been shown to be effective in for other cardiac conditions.[163-166]

Applicability

The applicability of the findings to the Medicare population is constrained by the relatively young mean age of participants in most studies and a lack of incorporating age into analyses. The expansion of Medicare reimbursement of ICDs, and the resultant increasing prevalence of ICDs in the Medicare population, point to the need to improve practice and outcomes in this large and potentially vulnerable population.[1] Although a small number of studies indicated that age may ameliorate some of the anxiety associated with shocks,[115 120] the influence of age on patient experiences and outcomes has not been specifically examined in studies to date. Future studies should specifically examine the degree to which age moderates key elements of care, including attitudes to involvement in decisionmaking, factors considered and weight given to these factor, and the roles of other family members.

Similarly, surrogate decisionmakers remain absent from existing research, despite having a potentially pivotal involvement in making decisions for patients who do not have capacity to understand choices around deactivation and/or make decisions about deactivation.[35]

Conclusions

We identified four decision aids that addressed insertion of pacemakers and ICDs in patients with heart failure and arrhythmia. There are no existing validated decision aids or tools that adequately address the deactivation of ECDs.

In contrast with current recommendations, none of the aids for ICDs, pacemakers, or left ventricular assist devices addressed deactivation in discussions about insertion. Insertion was partially addressed by the tools, with quality reduced by the lack of focus in discussions prior to insertion of deactivation. Due to the lack of tools examining deactivation, the representation of the Medicare population is not currently an issue.

Although current recommendations could be incorporated into high-quality decisions aids for each type of ECD, there are consistent indications that other aspects of health care constitute barriers to high-quality decisionmaking and effective use of decision aids. There was consistent evidence from the qualitative research that patients often have poor knowledge of basic elements related to deactivation, including the role of the device and how their health would be affected by its deactivation. Communication with physicians was often poor, and patients perceived that professionals over-imposed their own values and priorities. Patients reported wanting more discussions with a wider range of health professionals. The most common threats to informed consent were patient passivity, lack of information on the implications of deactivation for daily living activities, and the psychosocial disruption caused by devices, notably the shocks from ICDs. Patient experiences appeared to change over time. The need for more information and psychosocial support was highest at 3 months after insertion. Continued social support for patients around decisionmaking or psychosocial wellbeing was limited. When support was provided, families and other caregivers were the main source, but were often seen to be overly protective.

Psychosocial disruptions were common across all ECDs, but were greater for ICDs due to the frequency and intensity of shocks. Although current research presented limited sex- and age-based analyses, women appeared to be prone to greater psychosocial sequelae from ICDs, and older adults may be more prone to lower social support.

The quantitative studies of psychosocial outcomes corroborated the qualitative findings. The main factors influencing anxiety and depression were shock frequency, Type D personality, social and educational status, and age.

Communication-related factors that influenced psychosocial outcomes and quality of decisionmaking were: the presence or absence of organizational policies around deactivation, the lack of training and comfort among health professionals in initiating and maintaining dialogue, and poorly timed discussions that were too near patients' end of life. Patients reported that they would welcome more discussion with health professionals around deactivation and would be comfortable having these discussions in person or over the telephone with wider members of the multidisciplinary health care team.

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List of Abbreviations

AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
CRT	Cardiac resynchronization therapy
ECD	Electronic cardiac device
HRS	Heart Rhythm Society
ICD	Implantable cardioverter-defibrillator
KQ	Key question
NRCT	Nonrandomized controlled trial
RCT	Randomized controlled trial
VAD	Ventricular assist device

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Appendixes

Appendix A. Search Strategies

Appendix B. Data Extraction Form

Appendix C. Decision Tools Included in Review

Appendix D. List of Excluded Studies

Appendix E. Evidence Tables

Appendix F. Methodological Quality of Included Studies

Appendix A. Search Strategies

Table A–1. MEDLINE–OVID Version

Limits: trials, observational/qualitative studies; English only, 1990 – present **Date searched:** 6Dec10 **Results:** 395 trials; 3952 observational/qualitative studies
1. heart failure/th 2. heart diseases/th 3. Arrhythmias, cardiac/th 4. Myocardial ischemia/th 5. Ventricular dysfunction, left/th 6. or/1-5 7. exp Pacemaker, Artificial/ 8. ((artificial or cardiac) adj2 pacemaker*).mp. 9. pacemaker*.tw. 10. (PPM and pacemaker*).tw. 11. exp Heart-Assist Devices/ 12. heart conduction system/ 13. ((heart-assist or vascular-assist or ventricular-assist) adj (device* or pump*)).mp. 14. (device adj therapy).tw. 15. (ventricular adj2 device*).tw. 16. ((VAD or LVAD) and device*).tw. 17. (artificial adj1 ventricle*).mp. 18. exp Defibrillators, Implantable/ 19. ((ICD or ICDs) and implantable).tw. 20. (implantable adj2 defibrillator*).mp. 21. (internal adj2 defibrillator*).mp. 22. ((external adj2 defibrillator*) not aed).mp. 23. (implantable adj1 cardiac adj1 device*).mp. 24. cardioverter-defibrillator*.mp. 25. exp Cardiac Pacing, Artificial/ 26. (artificial adj pacing).mp. 27. ((cardiac or heart) adj resynchroni?ation$).mp. 28. ((biventricular or dual-chamber or single-chamber) adj1 (pacing or pacer or stimulat$)).mp. 29. ((mechanical adj circulatory adj support adj system*) or MCSS).tw. 30. or/7-29 31. choice behavior/ 32. decisionmaking/ 33. decision support techniques/ 34. decision support systems, clinical/ 35. patient preference/ 36. informed consent/ 37. ((informed adj1 consent) or consent*).tw. 38. (decision adj (support or aid* or process* or tool*)).tw. 39. proxy/ 40. (proxy or proxies).tw. 41. or/31-40 42. and/6,41 43. and/30,41 44. patient participation/ 45. personal autonomy/ 46. cooperative behavior/ 47. communication/ or (communication* or discussion* or conversation*).tw. 48. educational technology/ 49. (decision$ or choice$ or choose or preference$).tw.

50. exp health education/
51. Health Knowledge, Attitudes, Practice/
52. Professional-Family Relations/
53. ((patient$ or consumer$) adj2 (decision$ or choice$ or preference$ or participation)).tw.
54. ((women or men) adj2 (decision$ or choice$ or preference$ or participation)).tw.
55. ((personal or interpersonal or individual$) adj2 (decision$ or choice$ or preference$ or participat$)).tw.
56. (shared adj2 decision adj2 making).tw.
57. (decision adj (support or aid* or process* or tool*)).tw.
58. (third adj party adj consent).tw.
59. (proxy or proxies).tw.
60. (informed adj1 choice).tw.
61. exp Patient Education as Topic/mt [Methods]
62. or/44-61
63. and/6,62
64. and/30,62
65. and/6,30,62
66. Health Knowledge, Attitudes, Practice/
67. Treatment refusal/es, st, td
68. Withholding treatment/
69. "Dissent and disputes"/
70. medical futility/
71. advance care planning/es, st, mt, td
72. terminal care/es, mt, px, st, td
73. ethics, medical/
74. social responsibility/
75. (ethics or ethical).tw.
76. (barriers or barrier).tw.
77. exp depression/ or (depression or depressed or depressive).tw.
78. exp anxiety/ or anxiety.tw.
79. (deactivation or deactivating or deactivate*).tw.
80. exp pain/ or pain*.tw.
81. (cultur* or customs or belief*).tw.
82. age factors/ or aged/ or (aged or elderly).tw.
83. gender/ or gender.tw.
84. or/66-83
85. and/6,84
86. and/6,30,84
87. randomized controlled trial.pt.
88. controlled clinical trial.pt.
89. random$.ab.
90. trial.tw.
91. or/87-90
92. (humans or human or adult or adults).hw,sh.
93. and/91-92
94. and/42,93
95. and/43,93
96. quasi-experimental.tw.
97. (pre-test or post-test).mp.
98. or/96-97
99. and/42,98
100. and/43,98
101. or/94-95,99-100
102. cohort studies/
103. longitudinal studies/
104. prospective studies/
105. retrospective studies/

106. comparative study.pt. 107. (observation$ or prospectiv$ or retrospectiv$ or cohort$ or control$ or volunteer$ or evaluat$ or compar$ or longitudinal or long term or long-term or longterm or followup or follow up or follow-up).mp. and (study or studies or trial$).tw,sh,pt. 108. exp Evaluation Studies/ 109. (survey* or questionnaire* or pre-test* or post-test*).mp. 110. (observation adj stud*).mp. 111. or/102-110 112. (humans or human or adult or adults).hw,sh. 113. and/111-112 114. and/63,113 115. and/64,113 116. and/65,113 117. and/85,113 118. and/86,113 119. and/63,93 120. and/64,93 121. and/65,93 122. or/119-121 123. or/101,122 124. limit 123 to (english language and yr="1990 -Current") 125. or/114-118 126. limit 125 to (english language and yr="1990 -Current") 127. limit 126 to humans

Table A–2. EMBASE–Ovid Version

Limits: trials, observational/qualitative studies; English only, 1990 – present **Date searched:** 7Dec10 **Results:** 370 trials; 2997 observational/qualitative studies
1. exp Pacemaker, Artificial/ 2. ((artificial or cardiac) adj2 pacemaker*).mp. 3. pacemaker*.tw. 4. exp Heart-Assist Devices/ 5. ((heart-assist or vascular-assist or ventricular-assist) adj (device* or pump*)).mp. 6. (artificial adj1 ventricle*).mp. 7. exp Defibrillators, Implantable/ 8. (implantable adj2 defibrillator*).mp. 9. (implantable adj1 cardiac adj1 device*).mp. 10. ((ICD or ICDs) and implantable).tw. 11. ((external adj2 defibrillator*) not aed).mp. 12. cardioverter-defibrillator*.mp. 13. exp Cardiac Pacing, Artificial/ 14. (artificial adj pacing).mp. 15. ((cardiac or heart) adj resynchroni?ation$).mp. 16. ((biventricular or dual-chamber or single-chamber) adj1 (pacing or pacer or stimulat$)).mp. 17. ((mechanical adj circulatory adj support adj system*) or MCSS).tw. 18. ((VAD or LVAD) and device*).tw. 19. or/1-18 20. choice behavior/ 21. decisionmaking/ 22. decision theory/ 23. decision support techniques/ 24. decision support systems, clinical/ 25. patient preference/ 26. patient attitude/

27. patient participation/
28. educational technology/
29. (decision$ or choice$ or choose or preference$).tw.
30. (decision adj (support or aid* or process* or tool*)).tw.
31. ((informed adj1 consent) or consent*).tw.
32. (proxy or proxies).tw.
33. or/20-32
34. cooperative behavior/ or (cooperative adj behavio?r).tw.
35. personal autonomy/ or (personal adj autonomy).tw.
36. Health Knowledge, Attitudes, Practice/
37. informed consent.tw,hw.
38. communication/ or (communication* or discussion* or conversation*).tw.
39. Professional-Family Relations/
40. ((patient$ or consumer$) adj1 (decision$ or choice or preference or participation)).tw.
41. ((women or men) adj1 (decision$ or choice or preference or participation)).tw.
42. ((personal or interpersonal or individual) adj (decision$ or choice or preference$ or participat$)).tw.
43. (shared adj decision adj making).tw.
44. (decision adj (support or aid* or process* or tool*)).tw.
45. (informed adj1 choice).tw.
46. Patient Education/ or (patient adj education).mp.
47. treatment refusal/ or (treatment adj refusal).tw.
48. withholding treatment/ or (withholding adj treatment*).tw.
49. "Dissent and disputes"/
50. medical futility/
51. ethics, medical/ or (ethics or ethical).tw.
52. (barriers or barrier).tw.
53. (deactivation or deactivating or deactivate*).tw.
54. exp anxiety/ or anxiety.tw.
55. exp pain/ or pain*.tw.
56. (cultur* or customs or belief*).tw.
57. exp depression/ or (depression or depressed or depressive).tw.
58. gender/ or gender.tw.
59. age factors/ or aged/ or (aged or elderly).tw.
60. or/34-59
61. clinical trial/
62. clinical trial:.mp.
63. random:.tw.
64. placebo:.mp.
65. double-blind:.tw.
66. or/61-65
67. and/19,33,66
68. limit 67 to (human and english language and yr="1990 -Current")
69. and/19,60,66
70. (pre-test or post-test).mp.
71. quasi-experimental.tw.
72. or/70-71
73. and/19,33,72
74. and/19,60,72
75. or/73-74
76. limit 75 to (human and english language and yr="1990 -Current")
77. cohort analysis/
78. longitudinal study/
79. follow-up/
80. prospective study/
81. retrospective study/
82. (observation$ or prospectiv$ or retrospectiv$ or cohort$ or control$ or volunteer$ or evaluat$ or compar$ or

longitudinal or long term or long-term or longterm or followup or follow up or follow-up).mp. and (study or studies or trial$).tw,sh. 83. exp Evaluation Studies/ 84. (pre-test or post-test).mp. 85. (observation adj stud*).mp. 86. or/77-85 87. and/19,60,86 88. and/19,33,86 89. or/87-88 90. limit 89 to (human and english language and yr="1990 -Current") 91. or/67,76 92. and/19,33,60,86 93. 88 or 92 94. or/1,7-8 95. 87 and 94 96. limit 95 to (human and english language and yr="1990 -Current")

Table A–3. CENTRAL

Limits: 1990 – present. Trials only **Date Searched:** 08Dec10 **Results:** 158 trials
1. Heart Failure/th 2. heart diseases/th 3. Arrhythmias, Cardiac/th 4. Myocardial ischemia/th 5. Ventricular Dysfunction, Left/th 6. or/1-5 7. exp Pacemaker, Artificial/ 8. ((artificial or cardiac) adj2 pacemaker*).mp. 9. pacemaker*.tw. 10. exp Heart-Assist Devices/ 11. heart conduction system/ 12. ((heart-assist or vascular-assist or ventricular-assist) adj (device* or pump*)).mp. 13. (artificial adj1 ventricle*).mp. 14. (device adj therapy).tw. 15. (ventricular adj2 device*).tw. 16. ((VAD or LVAD) and device*).tw. 17. exp Defibrillators, Implantable/ 18. (implantable adj2 defibrillator*).mp. 19. (implantable adj1 cardiac adj1 device*).mp. 20. ((ICD or ICDs) and implantable).tw. 21. ((external adj2 defibrillator*) not aed).mp. 22. cardioverter-defibrillator*.mp. 23. exp Cardiac Pacing, Artificial/ 24. (artificial adj pacing).mp. 25. ((cardiac or heart) adj resynchroni?ation$).mp. 26. ((biventricular or dual-chamber or single-chamber) adj1 (pacing or pacer or stimulat$)).mp. 27. ((mechanical adj circulatory adj support adj system*) or MCSS).tw. 28. or/7-27 29. or/6,28 30. choice behavior/ 31. decisionmaking/ 32. decision support techniques/ 33. decision support systems, clinical/ 34. patient preference/

35. informed consent/ 36. Third-Party consent/ 37. ((informed adj1 consent) or consent*).tw. 38. proxy/ 39. (proxy or proxies).tw. 40. patient participation/ 41. personal autonomy/ 42. cooperative behavior/ 43. communication/ or (communication* or discussion* or conversation*).tw. 44. educational technology/ 45. (decision$ or choice$ or choose or preference$).tw. 46. (decision adj (support or aid* or process* or tool*)).tw. 47. or/30-46 48. Health Knowledge, Attitudes, Practice/ 49. Professional-Family Relations/ 50. ((patient$ or consumer$) adj2 (decision$ or choice$ or preference$ or participation)).tw. 51. ((women or men) adj2 (decision$ or choice$ or preference$ or participation)).tw. 52. ((personal or interpersonal or individual) adj2 (decision$ or choice$ or preference$ or participat$)).tw. 53. (shared adj2 decision adj2 making).tw. 54. ((decision adj2 (support or aid* or process* or tool*)) or decision*).tw. 55. (third adj party adj consent).tw. 56. (proxy or proxies).tw. 57. (informed adj2 (choice* or consent*)).tw. 58. exp Patient Education as Topic/ or (patient adj education).tw. 59. treatment refusal/ or (treatment adj refusal).tw. 60. withholding treatment/ or (withholding adj treatment*).tw. 61. "Dissent and disputes"/ 62. medical futility/ 63. ethics, medical/ or (ethics or ethical).tw. 64. (barriers or barrier).tw. 65. (deactivation or deactivating or deactivate*).tw. 66. or/48-65 67. and/29,47 68. and/29,66 69. or/67-68 70. limit 69 to yr="1990 -Current"

Table A–4. PsycINFO

Limits: 1990 – present. **Date searched:** 9Dec10 **Results:** 9 trials; 112 qualitative results
1. exp "Fibrillation (Heart)"/ 2. exp Artificial Pacemakers/ 3. ((artificial or cardiac) adj2 pacemaker*).mp. 4. pacemaker*.tw. 5. ((heart-assist or vascular-assist or ventricular-assist) adj (device* or pump*)).mp. 6. (artificial adj1 ventricle*).mp. 7. (implantable adj2 defibrillator*).mp. 8. (implantable adj1 cardiac adj1 device*).mp. 9. ((ICD or ICDs) and implantable).tw. 10. ((external adj2 defibrillator*) not aed).mp. 11. cardioverter-defibrillator*.mp. 12. (artificial adj pacing).mp. 13. ((cardiac or heart) adj resynchroni?ation$).mp. 14. ((biventricular or dual-chamber or single-chamber) adj1 (pacing or pacer or stimulat$)).mp.

15. ((mechanical adj circulatory adj support adj system*) or MCSS).tw.
16. ((VAD or LVAD) and device*).tw.
17. or/1-16
18. (decision$ or choice$ or choose or preference$).tw.
19. (decision adj (support or aid* or process* or tool*)).tw.
20. ((informed adj1 consent) or consent*).tw.
21. (proxy or proxies).tw.
22. computer assisted instruction/
23. or/18-22
24. cooperative behavior/ or (cooperative adj behavio?r).tw.
25. health knowledge/
26. client education/
27. exp social support/
28. exp psychological needs/
29. exp psychological effects/
30. personal autonomy/ or (personal adj autonomy).tw.
31. informed consent.tw,hw.
32. communication/ or (communication* or discussion* or conversation*).tw.
33. ((patient$ or consumer$) adj1 (decision$ or choice or preference or participation)).tw.
34. ((women or men) adj1 (decision$ or choice or preference or participation)).tw.
35. ((personal or interpersonal or individual) adj (decision$ or choice or preference$ or participat$)).tw.
36. (shared adj decision adj making).tw.
37. (decision adj (support or aid* or process* or tool*)).tw.
38. (informed adj1 choice).tw.
39. Patient Education/ or (patient adj education).mp.
40. treatment refusal/ or (treatment adj refusal).tw.
41. withholding treatment/ or (withholding adj treatment*).tw.
42. ethics, medical/ or bioethics/ or (ethics or ethical).tw.
43. (barriers or barrier).tw.
44. anxiety/ or anxiety.tw.
45. exp pain/ or pain*.tw.
46. (cultur* or customs or belief*).tw.
47. exp depression/ or (depression or depressed or depressive).tw.
48. gender/ or gender.tw.
49. age factors/ or aged/ or (aged or elderly).tw.
50. exp distress/
51. exp caregiver burden/
52. (deactivation or deactivating or deactivate*).tw.
53. or/24-52
54. clinical trial/
55. clinical trial:.mp.
56. random:.tw.
57. placebo:.mp.
58. double-blind:.tw.
59. or/54-58
60. and/17,23,59
61. limit 60 to (human and english language and yr="1990 -Current")
62. and/17,53,59
63. (pre-test or post-test).mp.
64. quasi-experimental.tw.
65. or/63-64
66. and/17,23,65
67. and/17,53,65
68. or/66-67
69. limit 68 to (human and english language and yr="1990 -Current")
70. cohort analysis/

71. longitudinal studies/ 72. follow-up studies/ 73. prospective studies/ 74. retrospective studies/ 75. observation methods/ 76. (observation$ or prospectiv$ or retrospectiv$ or cohort$ or control$ or volunteer$ or evaluat$ or compar$ or longitudinal or long term or long-term or longterm or followup or follow up or follow-up).mp. and (study or studies or trial$).tw,sh. 77. (pre-test or post-test).mp. 78. (observation adj stud*).mp. 79. or/70-78 80. and/17,53,79 81. and/17,23,79 82. or/80-81 83. limit 82 to (human and english language and yr="1990 -Current")

Table A–5. CINAHL

Limits: 1990 – present. **Date searched:** 13Dec10 **Results:** 403 trials; 1628 qualitative results
S37 S26 and S36 S36 (MH "Clinical Trials+") S35 S26 and S34 S34 S27 or S28 or S29 or S30 or S31 or S32 or S33 S33 TX observational study or TX observational studies S32 (MH "Retrospective Panel Studies") OR retrospective study S31 TX comparative study or TX comparative studies S30 (MH "Nonexperimental Studies") S29 TX pre-test Or post-test S28 (MH "Evaluation Research") S27 (MH "Prospective Studies+") OR (MH "Concurrent Prospective Studies") S26 S10 and S25 S25 S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 S24 (MH "Patient Education+") and TX (decision* or choice* pr preference*) S23 (MH "Decision Support Systems, Management") OR (MH "Decision Support Systems, Clinical") OR Decision support system S22 TX shared decisionmaking S21 TX (patient preference* or patient choice* or patient participation or patient decision*) or TX (consumer decision* or consumer choice* or consumer preference* or consumer participation*) S20 (MH "Decisionmaking, Family") OR (MH "Decisionmaking, Ethical") OR (MH "Decisionmaking, Patient+") S19 TX third party consent or TX Proxy or TX proxies S18 TX informed consent or TX consent S17 (MH "Consumer Participation") S16 (MH "Consent") S15 (MH "Educational Technology") S14 TX (choice* or decision$ or choose or preference*) S13 (MH "Help Seeking Behavior") S12 (MH "Information Seeking Behavior") S11 (MH "Decisionmaking+") S10 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 S9 (MH "Heart Assist Devices") S8 TX cardiac resynchronization or TX cardiac resynchronisation or TX heart resynchronization or TX heart resynchronisation S7 (MH "Cardiac Pacing, Artificial") S6 TX cardioverter-defibrillator

S5 implantable defibrillator* or implantable cardiac device*
S4 (MH "Defibrillators, Implantable")
S3 TX (heart-assist device* or heart-assist pump*) or (cardiac-assist device* or cardiac-assist pump*) or (ventricular-assist device* OR ventricular-assist pump*)
S2 TX pacemaker*
S1 (MH "Pacemaker, Artificial")

Table A–6. Medline focused search

AHRQ device tool project _MEDLINE - new focused search_8Feb11
MEDLINE - 8Feb11 - RCT filter and no qual filter

1. heart failure/th
2. heart diseases/th
3. Arrhythmias, cardiac/th
4. Myocardial ischemia/th
5. Ventricular dysfunction, left/th
6. or/1-5
7. exp Pacemaker, Artificial/
8. ((artificial or cardiac) adj2 pacemaker*).mp.
9. pacemaker*.tw.
10. (PPM and pacemaker*).tw.
11. exp Heart-Assist Devices/
12. heart conduction system/
13. ((heart-assist or vascular-assist or ventricular-assist) adj (device* or pump*)).mp.
14. (device adj therapy).tw.
15. (ventricular adj2 device*).tw.
16. ((VAD or LVAD or CIED) and device*).tw.
17. (artificial adj1 ventricle*).mp.
18. exp Defibrillators, Implantable/
19. ((ICD or ICDs or CIED or CIEDs) and implantable).tw.
20. (implantable adj2 defibrillator*).mp.
21. (internal adj2 defibrillator*).mp.
22. ((external adj2 defibrillator*) not aed).mp.
23. ((implantable adj3 cardiac adj3 device*) or (implantable adj3 cardiovascular adj3 device*)).mp.
24. cardioverter-defibrillator*.mp.
25. exp Cardiac Pacing, Artificial/
26. (artificial adj pacing).mp.
27. ((cardiac or heart) adj resynchroni?ation$).mp.
28. ((biventricular or dual-chamber or single-chamber) adj1 (pacing or pacer or stimulat$)).mp.
29. ((mechanical adj circulatory adj support adj system*) or MCSS).tw.
30. or/7-29
31. Treatment refusal/
32. Withholding treatment/
33. (withdrawal or withdrawing).tw.
34. exp device removal/
35. (device* adj1 remov*).tw.
36. (deactivation or deactivating or deactivate*).tw.
37. medical futility/
38. advance care planning/
39. terminal care/
40. hospice care/
41. palliative care/
42. ((palliative or hospice or terminal) adj care).tw.
43. terminally ill/
44. ethics, medical/
45. (ethics or ethic or ethical).tw.

46. medicolegal.tw.
47. exp euthanasia/
48. suicide, assisted/
49. (end-of-life or "end of life").tw.
50. ((ICD adj2 discharge*) and distress*).tw.
51. or/31-50
52. and/30,51
53. randomized controlled trial.pt.
54. controlled clinical trial.pt.
55. random$.ab.
56. trial.tw.
57. or/53-56
58. (humans or human or adult or adults).hw,sh.
59. and/57-58
60. and/30,51,59
61. 52 not 60

Table A–7. EMBASE focused search

AHRQ device tool project _EMBASE - new focused search_2Feb11
EMBASE -8Feb11 - RCT filter and no qual filter

1. artificial heart pacemaker/
2. defibrillator/
3. pacemaker*.tw.
4. Heart Assist Device/
5. (artificial adj1 ventricle*).tw.
6. (implantable adj2 defibrillator*).tw.
7. (implantable adj2 device*).tw.
8. ((ICD or ICDs or CIED or CIEDs) and implantable).tw.
9. cardioverter-defibrillator*.tw.
10. (artificial adj pacing).tw.
11. ((cardiac adj resynchroni?ation*) or (heart adj resynchroni?ation)).tw.
12. or/1-11
13. treatment refusal/
14. treatment withdrawal/
15. (withdrawal or withdrawing).tw.
16. device removal/
17. (device* adj1 remov*).tw.
18. (deactivation or deactivating or deactivate*).tw.
19. medical ethics/
20. (ethics or ethic or ethical).tw.
21. medicolegal.tw.
22. exp terminal care/
23. hospice care/
24. palliative therapy/
25. ((palliative or hospice or terminal) adj care).tw.
26. terminally ill patient/
27. exp euthanasia/
28. assisted suicide/
29. ((ICD* adj2 discharge*) and distress*).tw.
30. ((ICD* adj2 discharge*) and inappropriate).tw.
31. end-of-life.ti.
32. or/13-31
33. and/12,32
34. clinical trial/

35. clinical trial:.mp.
36. random:.tw.
37. placebo:.mp.
38. double-blind:.tw.
39. or/34-38
40. and/12,32,39
41. 33 not 40

Table A–8. CENTRAL focused search

AHRQ device tool project _CENTRAL - new focused search_3Feb11
CENTRAL - 3Feb11 - drafted secondary focused search - devices AND end of life

1. exp Pacemaker, Artificial/
2. ((artificial or cardiac) adj2 pacemaker*).mp.
3. pacemaker*.tw.
4. exp Heart-Assist Devices/
5. Heart Conduction System/
6. ((heart-assist or vascular-assist or ventricular-assist) adj (device* or pump*)).mp.
7. (device adj therap*).tw.
8. (ventricular adj2 device*).tw.
9. ((VAD or LVAD or CIED) and device*).tw.
10. (artificial adj1 ventricle*).mp.
11. Defibrillators, Implantable/
12. ((ICD or ICDs or CIED or CIEDs) and implantable).tw.
13. (implantable adj2 defibrillator*).mp.
14. (internal adj2 defibrillator*).mp.
15. ((external adj2 defibrillator*) not AED).tw.
16. ((implantable adj3 cardiac adj3 device) or (implantable adj3 cardiovascular adj3 device*)).mp.
17. cardioverter-defibrillator*.mp.
18. exp Cardiac Pacing, Artificial/
19. ((cardiac or heart) adj resynchroni?ation*).mp.
20. ((biventricular or dual-chamber or single-chamber) adj1 (pacing or pacer or stimulat$)).mp.
21. or/1-20
22. exp Treatment Refusal/
23. exp Withholding Treatment/
24. Device Removal/
25. (device* adj1 remov*).tw.
26. (withdrawal or withdrawing).tw.
27. (deactivation or deactivating or deactivate*).tw.
28. Medical Futility/
29. exp Advance Care Planning/
30. Terminal Care/
31. hospice care/
32. terminally ill/
33. Ethics, Medical/
34. (ethics or ethic or ethical).tw.
35. medicolegal.tw.
36. exp euthanasia/
37. (end-of-life or "end of life").tw.
38. ((ICD adj2 discharge*) and distress*).tw.
39. or/22-38
40. and/21,39

Table A–9. PsycINFO focused search

AHRQ device tool project _PsycINFO - new focused search_3Feb11
PsycINFO - 3Feb11 - drafted secondary focused search - devices AND end of life

1. exp "Fibrillation (Heart)"/
2. exp Artificial Pacemakers/
3. ((artificial or cardiac) adj2 pacemaker*).mp.
4. pacemaker*.tw.
5. ((heart-assist or vascular-assist or ventricular-assist) adj (device* or pump*)).mp.
6. (implantable adj2 defibrillator*).mp.
7. (implantable adj2 cardiac adj2 device*).mp.
8. ((ICD or ICDs) and implantable).tw.
9. ((external adj2 defibrillator*) not aed).mp.
10. ((cardiac or heart) adj resynchroni?ation$).mp.
11. cardioverter-defibrillator*.mp.
12. ((biventricular or dual-chamber or single-chamber) adj1 (pacing or pacer or stimulat$)).mp.
13. ((VAD or LVAD or CIED or ICD) and device*).tw.
14. or/1-13
15. exp Treatment Refusal/
16. exp Treatment Withholding/
17. life sustaining treatment/
18. (withdrawal or withdrawing).tw.
19. (device* adj1 remov*).tw.
20. (deactivation or deactivating or deactivate*).tw.
21. advance directives/
22. exp Terminally Ill Patients/
23. exp Hospice/
24. exp Palliative Care/
25. ((palliative or hospice or terminal) adj care).tw.
26. ((palliative or hospice or terminal) adj treatment).tw.
27. ((palliative or hospice or terminal) adj setting).tw.
28. exp Bioethics/
29. (ethics or ethic or ethical).tw.
30. medicolegal.tw.
31. euthanasia/
32. exp Assisted Suicide/
33. exp Death Attitudes/
34. exp "Death and Dying"/
35. (end-of-life or "end of life").tw.
36. ((defibrillator adj2 discharge*) and (anxiety* or fear* or inappropriate or stress or distress)).tw.
37. ((ICD adj2 discharge*) and (anxiety* or fear* or inappropriate or stress or distress)).tw.
38. ((device adj2 discharge*) and (anxiety* or fear* or inappropriate or stress or distress)).tw.
39. or/15-38
40. and/14,39

Appendix B. Data Extraction Form

QUALITY

Study Characteristics

Devices Barrier Synthesis:

First Author (Year):

Study Title:

Journal:

Reviewer: ZH ☐ MS ☐ ACh ☐ AMC ☐

Main Focus of paper:

Methodological Quality

Criteria	Yes	No	Unclear
1) There is congruity between the stated philosophical perspective and the research methodology.			
2) There is congruity between the research methodology and the research question or objectives.			
3) There is congruity between the research methodology and the methods used to collect data.			
4) There is congruity between the research methodology and the representation and analysis of data.			
5) There is congruity between the research methodology and the interpretation of results.			
6) There is a statement locating the researcher culturally or theoretically.			
7) The influence of the researcher on the research, and vice-versa, is addressed.			
8) Participants, and their voices, are adequately represented.			
9) The research is ethical according to current criteria or, for recent studies, there is evidence of ethical approval by an appropriate body.			
10) Conclusions drawn in the research report do appear to flow from the analysis, or interpretation, of the data.			
TOTAL			

Summary of appraisal

1. Main strengths:
2. Main concerns:

Overall quality rating: High ☐ Medium ☐ Low ☐

FIELDS OF EXTRACTION

Methods

Approach (principle only)

☐ Grounded theory ☐ Ethnography
☐ General ☐ Critical theory
☐ Mixed methods ☐ Phenomenology
☐ Other: _____

Data collection

1. ☐ Face-to-face ☐ Telephone

2. ☐ Interview: unstructured
☐ Interview: semi-structured
☐ Interview: structured
☐ Focus group
☐ Other (specify):_____

Context: _____

Setting: _____

Culture: _____

Population

Disease

☐ Heart failure ☐ Non-Heart failure

Device type

☐ ICD only ☐ ICD and CRT ☐ Pacemaker
☐ LVAD ☐ Other

Foci

☐ Insertion ☐ Deactivation ☐ Malfunction
☐ End of life

Group (*Check all applicable*)

☐ Patients ☐ Health Professionals
☐ Family / Caregivers
☐ Other (specify):_____

Sample

☐ Men only ☐ Women only ☐ Mixed

Type

☐ Convenience ☐ Purposive ☐ Theoretical

☐ Other: _____

Sample Size

	Number	**%**
Males		
Females		
Total		

	Number
Family/Caregivers	
Health Professionals	

If patients:

Mean Age: _____ Range: _____to _____ years

If professionals:

Type (s):_____

Results

Definition of Barrier: "Factors or processes that act singularly or in combination with other factors or processes to reduce the likelihood, quality, or ethical appropriateness of discussions and/or decisionmaking around insertion, malfunction, or deactivation of electronic heart devices between health professionals, patients with devices, and, where appropriate, surrogate decisionmakers"

Definition of Facilitator: "Factors or processes that act singularly or in combination with other factors or processes to increase the likelihood, quality, or ethical appropriateness of discussions and/or decisionmaking around insertion, malfunction, or deactivation of electronic heart devices between health professionals, patients with devices, and, where appropriate, surrogate decisionmakers"

Findings (Verbatim)

Second reviewer has checked ☐

Appendix C. Decisions Tools Included in Review

(Tools Copyright: Healthwise)

Decision Aid: Implantable Cardioverter-Defibrillator[a]

	Heart Failure: Should I Get an Implantable Cardioverter-Defibrillator (ICD)?*		Heart Rate Problems: Should I Get an Implantable Cardioverter-Defibrillator (ICD)?†	
Section 1: Get the facts				
Your Options	• Get an ICD • Don't get an ICD		• Get an ICD • Don't get an ICD	
Key points to remember	• Your doctor suggest an ICD if you are at risk of having an abnormal heart rhythm that could cause sudden death • Many medical facts play a role in whether you should get an ICD. For example, the amount of blood your heart pumps (ejection fraction) helps your doctor decide if an ICD is right for you. Your doctor will consider other health problems you may have. • The shock from an ICD hurts briefly. It's been described as feeling like a punch in the chest. But the shock is a sign that the ICD is doing its job to keep your heart beating. The ICD also can use painless electrical pulses to fix a heart rate that is too fast or too slow. • Your doctor may also advise you to take medicine to reduce your chance of having a deadly abnormal heart rhythm. Also, some abnormal heart rhythms may be fixed with a procedure called catheter ablation. It destroys some of the heart tissue where the abnormal rhythm starts.		• An ICD constantly checks your heartbeat for an abnormal rate. If it senses a dangerous rate, it gives the heart an electrical shock to restore a normal rate. An ICD also can fix a heart rate that is too fast or too slow • Your doctor may suggest an ICD if you are at risk of having an abnormal heart rhythm that could cause sudden death • Your doctor also will consider other health problems you may have to see how high your risk is for a deadly heart rate and whether an ICD could prevent it • The shock from an ICD hurts briefly • Even with an ICD, you may still need to take medicine to help prevent a deadly abnormal heart rate	
Frequently asked questions	• How can heart failure affect heart rhythm? • How can an ICD help? • How is the ICD placed? • How does it feel to get a shock from an ICD? • Who might want an ICD? • Who might not want an ICD? • What are the benefits of an ICD? • What are the risks of an ICD? • What followup do you need after getting an ICD?		• What is an ICD? • How is an ICD placed? • How does it feel to get a shock from an ICD? • What are the benefits of an ICD? • What are the risks and side effects of an ICD? • What followup do you need after getting an ICD? • Why might your doctor recommend an ICD?	
Section 2: Compare Options				
	Get an ICD	**Don't get an ICD**	**Get an ICD**	**Don't get an ICD**
What is	• Your doctor will numb the area with	• You keep taking heart	• You will have minor surgery to have the	• You follow a healthy

[a] Heart Failure: Should I Get an Implantable Cardioverter-Defibrillator (ICD)? Healthwise Knowledgebase 2010. Heart Rate Problems: Should I Get an Implantable Cardioverter-Defibrillator (ICD)? Healthwise Knowledgebase 2011.

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usually involved?	local anaesthesia • You may spend the night in the hospital • You would need to have minor surgery to replace the battery after 5 to 8 years • You keep taking your heart failure medicine and following a healthy lifestyle	failure medicine and following a healthy lifestyle • In some cases, you may be able to have catheter ablation to fix an abnormal heart rhythm • You may take a rhythm-control medicine to prevent abnormal heart rhythms	ICD put in. Your doctor will numb the area with local anaesthesia • You may spend the night in the hospital • You will need to have minor surgery to replace the battery after 5 to 8 years • You keep taking heart failure medicine following a healthy lifestyle	lifestyle • In some cases, you may be able to have catheter ablation to fix an abnormal heart rate • You may take a rhythm-control medicine to prevent abnormal heart rates
What are the benefits?	• An ICD may lower the risk of sudden death in people who have heart failure • An ICD can fix a heart rate that is too fast or too slow without using a shock • You may have peace of mind that a dangerous heart rhythm could be fixed right away	• You avoid the risks of surgery • You won't worry about when the ICD might shock you	• An ICD can prevent sudden death from an abnormal heart rate • An ICD can fix a heart rate that is too fast or too slow without using a shock • You may have peace of mind that a dangerous heart rhythm could be fixed right away	• You avoid the risks of surgery • You won't worry about when the ICD might shock you
What are the risks and side effects?	The risks of surgery usually are low. But they are different for each person. Here are some of them: • You could get an infection where the ICD is placed • The leads that attach to the heart may break or stop working right. Then you would need more surgery • Serious bleeding could occur after placement of the ICD • A lung could collapse from a buildup of air in the space between the lung and the chest wall • The manufacturer could recall an ICD for a problem. If this were to happen, you might need surgery to take out the ICD and leads • The shock from an ICD hurts briefly • You might worry about when the ICD might shock you • An ICD shock could be strong enough to throw you off a chair or out of bed. You could get hurt from a fall • If the ICD gives you too many shocks, you also may need to take a rhythm-control medicine or have catheter ablation	• You could have an abnormal heart rhythm that could cause sudden death	• Problems can happen during or soon after the procedure to place the ICD. Examples include a lead tearing the heart or a lung collapsing • The manufacturer could recall an ICD for a problem. If this were to happen, you might need surgery to take out the ICD and leads • The shock from an ICD hurts briefly • If the ICD gives you too many shocks, you also may need to take a rhythm-control medicine or have catheter ablation	• You could have an abnormal heart rhythm that could cause sudden death

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Personal stories	Are you interested in what others decided to do? Many people have faced this decision. These personal stories may help you decide.

Section 3: Patient Values

What matters most to you?

Reasons to get an ICD				Reasons not to get an ICD		
I want to do everything I can to prevent a deadly heart rhythm				I would rather use only medicine to lower my chance of a deadly heart rate		
1 More important	2	3	4 Equally important	5	6	7 More important
I'm not worried that the ICD might shock me				I would worry all the time that the ICD might shock me		
1 More important	2	3	4 Equally important	5	6	7 More important
I don't mind having a device inside my body				I don't like the idea of having a device inside my body		
1 More important	2	3	4 Equally important	5	6	7 More important
I'm not worried that the ICD might shock me				I would worry all the time that the ICD might shock me		
1 More important	2	3	4 Equally important	5	6	7 More important
My other important reasons:				My other important reasons:		
1 More important	2	3	4 Equally important	5	6	7 More important

Section 4: Your Decision

Where are you leaning now?

Getting an ICD						**NOT getting an ICD**
1 Leaning toward	2	3	4 Undecided	5	6	7 Leaning toward

Section 5: Quiz Yourself

Check the facts	1. I need to have an ICD if I have heart failure o True o False o I'm not sure 2. I'll feel a painful shock if an ICD fixes a heart rhythm that could cause sudden death o True o False o I'm not sure 3. I might need surgery again someday if the ICD breaks or if it needs a new battery o True o False o I'm not sure
Decide what's next	1. Yes No Do you understand the options available to you? 2. Yes No Are you clear about which benefits and side effects matter most to you?

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	3. Yes No Do you have enough support and advice from others to make a choice?						
Certainty	1. How sure do you feel right now about your decision?						
	1 Not at all	2	3	4 Somewhat sure	5	6	7 Very sure
	2. Check what you need to do before you make this decision o I'm ready to take action o I want to discuss the options with others o I want to learn more about my options						
	3. Use the following space to list questions, concerns, and next steps.						
Section 6: Your summary Here's a record of your answers. You can use it to talk with your doctor or loved ones about your decision.							

* Details available at: http://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=uf9848; information on validation available at: http://decisionaid.ohri.ca/AZsumm.php?ID=1310

† Details available at: http://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=abk4103; information on validation available at: http://decisionaid.ohri.ca/AZsumm.php?ID=1328

Decision Aid: Pacemaker[b]

	Heart Failure: Should I Get a Pacemaker (Cardiac Resynchronization Therapy)?*		Hear Rate Problems: Should I Get a Pacemaker? †	
Section 1: Get the facts				
Your Options	• Get a pacemaker for heart failure • Don't get a pacemaker for heart failure		• Get a pacemaker for heart failure • Don't get a pacemaker for heart failure	
Key points to remember	• A pacemaker for heart failure, also called cardiac resynchronization therapy or CRT, can help you feel better so you can do your daily activities. It also may help keep you out of the hospital and help you live longer. • If you get a pacemaker, you still need to take medicines for heart failure. You'll also need to follow a healthy lifestyle to help treat heart failure. This may include watching how much fluid you drink, eating healthy foods that are low in salt, and not smoking. • Heart experts have guidelines about who might need a pacemaker. A pacemaker may be a good choice if you have moderate or severe heart failure and your heart's ventricles don't pump at the same time. • A pacemaker sends electrical pulses to your heart to help it work better. You can't feel the pulses. • There can be problems from having a pacemaker placed in your chest. The wires (called leads) that connect the pacemaker to your heart can move from the spot where they were placed. You could get an infection where the pacemaker was placed. Or the pacemaker or leads might not work.		• A pacemaker can help you feel better so you can return to your daily activities. • A pacemaker sends electrical pulses to your heart to help it work better. You can't feel the pulses. • If you get a pacemaker, you may still need to take medicines. You'll also need to follow a healthy lifestyle to help your heart. Eat heart-healthy foods, and don't smoke. • Heart experts have guidelines about who might need a pacemaker. A pacemaker may be a good choice if your heart rate is very slow and you have symptoms like dizziness or fainting. • There can be problems from having a pacemaker placed in your chest. The wires (called leads) that connect the pacemaker to your heart can move from the spot where they were placed. You could get an infection where the pacemaker was placed. Or the pacemaker or leads might not work.	
Frequently asked questions	• How can a pacemaker help heart failure? • How is the pacemaker placed? • Who can have a pacemaker for heart failure? • What are the benefits of having a pacemaker for heart failure? • What are the risks of having a pacemaker for heart failure? • Why might your doctor recommend a pacemaker for heart failure?		• What is a pacemaker? • What heart rate problems can a pacemaker help? • How is a pacemaker placed? • What are the risks and side effects? • Why might your doctor recommend a pacemaker for a heart rate problem?	
Section 2: Compare Options				
	Get an ICD	**Don't get an ICD**	**Get an ICD**	**Don't get an ICD**
What is usually involved?	• Your doctor will numb the area so you won't feel pain. (This is not open-chest surgery). • It can take up to 2 to 3 hours to place the pacemaker.	• You take medicines for heart failure. Your doctor may change the type or dose of your medicines. • You have to eat healthy	• You will have minor surgery to have the pacemaker put in. The doctor will numb the area so you won't feel pain. • It can take up to 2 to 3 hours to place the pacemaker.	• You take medicines for whatever disease is causing your heart rate problem. • You eat healthy foods,

[b] Heart Failure: Should I Get a Pacemaker (Cardiac Resynchronization Therapy)? Healthwise Knowledgebase 2010.
Heart Rate Problems: Should I Get a Pacemaker? Healthwise Knowledgebase 2011.

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	• You may spend the night in the hospital • You will need regular checkups to make sure that the pacemaker is working and to adjust the pacing, if needed. • You still need to take medicines for heart failure. • You still have to eat healthy foods and exercise as your doctor advises. You also may need to limit salt and fluids.	foods and exercise as your doctor advises. You also may need to limit salt and fluids. • You may have to see your doctor often to check your symptoms and how your medicine is working.	• You may spend the night in the hospital to make sure that the device is working and that there are no problems. • You will need regular checkups to make sure that the pacemaker is working and to adjust the pacing, if needed. • You may still need to take medicines for your heart rate problem. • You still have to eat healthy foods and to exercise as your doctor advises.	and you exercise as your doctor advises. • You see your doctor regularly to check your symptoms and how your medicine is working.
What are the benefits?	• A pacemaker can help you feel better so you can be more active. • It can help keep you out of the hospital and help you live longer. • It can help your heart pump better by changing the shape of your heart. In heart failure, the left ventricle often gets too big as it tries to make up for not pumping well.	• You won't have the risk of infection or other problems from the surgery.	• A pacemaker can help you feel better so you can be more active. • If your risk for getting a heartbeat problem is high, a pacemaker can help prevent that from happening. • If your heart rate problems are due to heart block, a pacemaker may help you live longer.	• You won't have the risk of infection or other problems from the surgery. • You won't have to think about safety around devices that could stop your pacemaker from working.
What are the risks and side effects?	The risks from surgery are usually low. But they may be different for each person. Here are some possible risks: • A lead could treat the heart. • A lung could collapse from a build-up of air in the space between the lung and the chest wall. • You could get an infection in the chest. • The doctor might not be able to place the pacemaker. For example, a vein could be too small to place a lead. After surgery, you may have some other risks: • You will need surgery to replace the battery, which lasts 8 to 10 years. • If a lead breaks or the pacemaker stops working, you may need another surgery to fix the problem. • Some devices with strong magnetic or electrical fields could stop the pacemaker from working. You need to avoid MRI machines, battery-powered cordless power tools, and CB or ham radios. But most everyday appliances	• Your symptoms could get worse. This would limit your ability to do your daily activities. • If your heart failure gets worse, you may have to go into the hospital a lot. • You might not live as long as you could if you had a pacemaker.	• Problems can happen during or soon after the procedure. Examples include a lead tearing the heart or a lung collapsing. • There might be problems with the pacemaker wires like infection or breaks. • Some devices with strong magnetic or electrical fields could stop the pacemaker from working. You need to avoid MRI machines, battery-powered cordless power tools, and CB or ham radios. But most everyday appliances and electric devices are safe. • You will need surgery to replace the battery, which lasts 8 to 10 years.	• Your symptoms could get worse. This would limit your ability to do your daily activities • You might be at risk for fainting or falling, which could be dangerous.

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	and electric devices are safe.			
Personal stories	Are you interested in what others decided to do? Many people have faced this decision. These personal stories may help you decide.			

Section 3: Patient Values

What matters most to you?

Reasons to get a pacemaker				Reasons not to get a pacemaker		
I want to feel better so that I can do my daily activity						I'm not having too much trouble doing my daily activity
1 More important	2	3	4 Equally important	5	6	7 More important
I don't mind having a device in my chest						I don't like the idea of having a device in my chest
1 More important	2	3	4 Equally important	5	6	7 More important
My medicines aren't controlling my symptoms anymore						My symptoms aren't getting worse
1 More important	2	3	4 Equally important	5	6	7 More important
I'm not worried about risks of surgery, because they're small						I don't want to take a chance that something could go wrong during surgery
1 More important	2	3	4 Equally important	5	6	7 More important
My other important reasons:						My other important reasons:
1 More important	2	3	4 Equally important	5	6	7 More important

Section 4: Your Decision

Where are you leaning now?

Getting a pacemaker						**NOT getting a pacemaker**
1 Leaning toward	2	3	4 Undecided	5	6	7 Leaning toward

Section 5: Quiz Yourself

What else do you need to make your decision?

Check the facts

4. I don't need a pacemaker if I have mild heart failure and can still do my daily activities
   - o True
   - o False
   - o I'm not sure
2. A pacemaker could help me stay out of the hospital and live longer
   - o True
   - o False
   - o I'm not sure
3. If I get a pacemaker, I still need to take medicines for heart failure and follow a healthy lifestyle
   - o True
   - o False
   - o I'm not sure

1. If I get a pacemaker, I still need to follow a healthy lifestyle
   - o True
   - o False
   - o I'm not sure
2. I don't need a pacemaker if I don't have any symptoms
   - o True
   - o False
   - o I'm not sure
3. A pacemaker may help symptoms caused by my heart rate problem
   - o True
   - o False
   - o I'm not sure

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Decide what's next	1. Yes No Do you understand the options available to you? 2. Yes No Are you clear about which benefits and side effects matter most to you? 3. Yes No Do you have enough support and advice from others to make a choice?
Certainty	1. How sure do you feel right now about your decision? 1 Not at all | 2 | 3 | 4 Somewhat sure | 5 | 6 | 7 Very sure
	2. Check what you need to do before you make this decision. o I'm ready to take action o I want to discuss the options with others o I want to learn more about my options
	3. Use the following space to list questions, concerns, and next steps.
Section 6: Your summary Here's a record of your answers. You can use it to talk with your doctor or loved ones about your decision.	

* Details available at: http://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=uf9843; information on validation available at: http://decisionaid.ohri.ca/AZsumm.php?ID=1328

† Details available at: http://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=abk4063; information on validation available at: http://decisionaid.ohri.ca/AZsumm.php?ID=1419

Appendix D. List of Excluded Studies

Intervention Studies

1. Dougherty CM, Lewis FM, Thompson EA, et al. Short-term efficacy of a telephone intervention by expert nurses after an implantable cardioverter defibrillator. Pacing Clin Electrophysiol 2004;27(12):1594-602. PMID: 15613121. (No relevant data)

2. Dunbar SB, Langberg JJ, Reilly CM, et al. Effect of a psychoeducational intervention on depression, anxiety, and health resource use in implantable cardioverter defibrillator patients. Pacing Clin Electrophysiol 2009;32(10):1259-71. PMID: 19796343. (No relevant data)

3. Lewin RJ, Coulton S, Frizelle DJ, et al. A brief cognitive behavioural preimplantation and rehabilitation programme for patients receiving an implantable cardioverter-defibrillator improves physical health and reduces psychological morbidity and unplanned readmissions. Heart 2009;95:63-69. PMID: 18070951. (No relevant data)

4. Kirchhoff KT, Hammes BJ, Kehl KA, et al. Effect of a disease-specific planning intervention on surrogate understanding of patient goals for future medical treatment. J Am Geriatr Soc 2010;58(7):1233-40. PMID: 20649686. (No relevant data)

Qualitative Studies

1. Bostwick JM, Sola CL. An updated review of implantable cardioverter/defibrillators, induced anxiety, and quality of life. Psychiatr Clin North Am 2007;30(4):677-88. PMID: 21109213. (Review)

2. Edelman S, Lemon J, Kirkness A. Educational intervention for patients with automatic implantable cardioverter defibrillators. Aust J Adv Nurs 2007;24(3):26-32. PMID: 17518162. (No relevant data)

3. Hall P, Sanford JT, Demi AS. Patterns of decision making by wives of patients with life-threatening cardiac disease. J Fam Nurs 2008;14(3):347-62. PMID: 18780888. (No relevant data)

4. Kobza R, Erne P. End-of-life decisions in ICD patients with malignant tumors. Pacing Clin Electrophysiol 2007;30(7):845-9. PMID: 17584265. (No relevant data)

5. Marinskis G, van Erven L, EHRA Scientific Initiatives Committee. Deactivation of implanted cardioverter-defibrillators at the end of life: Results of the EHRA Survey. Europace 2010;12:1176-77. PMID: 20663788. (No relevant data)

6. Mueller PS, Hook CC, Hayes D. Ethical analysis of withdrawal of pacemaker or implantable cardioverter-defibrillator support at the end of life. Mayo Clin Proc 2003;7:959-63. PMID: 12911044. (No relevant data)

7. Mueller PS, Swetz KM, Freeman MR, et al. Ethical analysis of withdrawing ventricular assist device support. Mayo Clin Proc 2010;85(9):791-7. PMID: 20584919. (No relevant data)

8. Pedersen SS, Van Den Broek KC, Sears Jr SF. Psychological intervention following implantation of an implantable defibrillator: A review and future recommendations. Pacing Clin Electrophysiol 2007;30(12):1546-54. PMID: 18070312. (Review)

9. Rahmoeller G, Moss AJ. Comments on ethical issues with implantable defibrillators by F. James Brennan. Pacing Clin Electrophysiol 2004;27(7):899-900. PMID: 15271006. (No relevant data)

10. Rizzieri AG, Verheijde JL, Rady MY, et al. Ethical challenges with the left ventricular assist devices as a destination therapy. Philos Ethics Humanit Med 2008;3(20):doi:

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10.1186/747-5341-3-20. PMID: 18694496. (No relevant data)

11. Schoenfeld MH. Contemporary pacemaker and defibrillator device therapy: Challenges confronting the general cardiologist. Circulation 2007;115(5):638-53. PMID: 17283279. (No relevant data)

12. Simpson CS, Gillis AM. The pacemaker and implantable cardioverter defibrillator recall issue - A Canadian perspective. Can J Cardiol 2006;22(6):467-71. PMID: 16685309. (No relevant data)

13. Strachan PH, Ross H, Rocker GM, et al. Canadian Researchers at the End of Life Network (CARENET). Mind the gap: Opportunities for improving end-of-life care for patients with advanced heart failure. Can J Cardiol 2009;25(11):635-40. PMID: 19898695. (No relevant data)

14. Tagney J. A literature review comparing the experiences and emergent needs of adult patients with permanent pacemakers (PPMs) and implantable cardioverter defibrillators (ICDs). J Clin Nurs 2010;19:2081-89. PMID: 20477907. (No relevant data)

15. Vazquez LD, Conti JB, Sears SF. Female-specific education, management, and lifestyle enhancement for implantable cardioverter defibrillator patients: The FEMALE-ICD study. Pacing Clin Electrophysiol 2010;33(9):1131-40. PMID:20487354. (No relevant data)

16. V itale MB, Funk M. Quality of life in younger persons with an implantable cardioverter defibrillator. Dimens Crit Care Nurs 1995;14(2):100-11. PMID: 7889798. (No relevant data)

Communication Studies

1. Cosgriff JA, Pisani M, Bradley EH, et al. The association between treatment preferences and trajectories of care at the end-of-life. J Gen Intern Med 2007;22(11):1566-71. PMID: 17874168. (No relevant data)

2. Duru F. Telephone calls from nurses can improve symptoms, anxiety, and knowledge among ICD recipients. Evid Based Cardiovasc Med 2005;9(2):136-37. PMID: 16380012. (No relevant data)

3. Field ME, Sweeney MO. Socio-economic analysis of cardiac resynchronization therapy. J Interv Card Electrophysiol 2006;17(3):225-36. PMID: 17372813. (No relevant data)

4. Geist M, Newman D, Greene M, et al. Permanent explantation of implantable cardioverter defibrillators. Pacing Clin Electrophysiol 2000;23(12):2024-9. PMID: 11202242. (No relevant data)

5. Goldstein N, Bradley E, Zeidman J, et al. Barriers to conversations about deactivation of implantable defibrillators in seriously ill patients. J Am Coll Cardiol 2009;54(4):371-4. PMID: 19608038. (No relevant data)

6. Powell-Cope GM, Luther S, Neugaard B, et al. Provider-perceived barriers and facilitators for ischaemic heart disease (IHD) guideline adherence. J Eval Clin Pract 2004;10(2):227-39. PMID: 15189389. (No relevant data)

7. Rodriguez KL, Appelt CJ, Switzer GE, et al. Veterans' decision-making preferences and perceived involvement in care for chronic heart failure. Heart Lung 2008;37(6):440-8. PMID: 18992627. (No relevant data)

8. Sears SF, Todaro JF, Lewis TS, et al. Examining the psychosocial impact of implantable cardioverter defibrillators: A literature review. Clin Cardiol 1999;22(7):481-89. PMID: 10410293. (Review)

Psychosocial Studies

1. Burke JL, Hallas CN, Clark-Carter D, et al. The psychosocial impact of the implantable cardioverter defibrillator: A meta-analytic review. Br J Health Psychol 2003;8(Pt 2):165-78. PMID: 12804331. (Review)

2. Wójcicka M, Lewandowski M, Smolis-Bak E, et al. Psychological and clinical problems in young adults with implantable cardioverter-defibrillators. Kardiol Pol 2008;66(10):1050-60. PMID: 19006026. (Not English)

3. Zayac S, Finch N. Recipients' of implanted cardioverter-defibrillators actual and perceived adaptation: A review of the literature. J Am Acad Nurse Pract 2009;21:549-56. PMID: 19796289. (Review)

Appendix E. Evidence Tables (KQ 4)

Qualitative Studies Included on General Experiences

Author(s)	Approach	Population	Device type	Foci	Sample (M/F)	Sample Description	Study Quality (H/M/L)
Agard et al., 2007[101]	General	HF	ICD only	Insertion	25M, 6F	Pt perspectives on their role in initiating ICD therapy	M
Anderson, 2004[85]	Grounded theory	Non–HF	Pacemaker	Living with technology	8M	War veterans with pacemakers	L
Andersen et al., 2008[102]	Systematic text condensation (Giorgi)	Non–HF	ICD only	Daily life challenges	3M, 4F (not all had ICD)	Pts with a congenital disease	M
Beery, 1998[103]	Phenomenology	Non–HF	Pacemaker	Living with biotechnology	11F	Female pts perspectives	H
Beery et al., 2002[105]	Life story method (Hall)	Non–HF	Pacemaker	Adjustment	11F	Female pts perspectives	H
Berger et al., 2006[89]	Survey	HF Non–HF	ICD only	Deactivation	47M, 10F	Pts with ICD for >1 month	L
Bolse et al., 2002[90]	Longitudinal survey	HF Non–HF	ICD only	Life situation	42M, 14F	Pre- and post-ICD implant	M
Bolse et al., 2005[86]	Grounded theory (weak phenomeno-graphy)	HF	ICD only	Living with an ICD	8M, 6F	Pt perceptions of their life situation	L
Burke, 1995[87]	Grounded theory	HF Non–HF	ICD only	Insertion	14M, 10F	Pt perspectives on living with ICD	H
Dickerson, 2002[104]	Phenomenology	Non–HF	ICD only	Living with an ICD	18M, 41F	Pt perspectives on living with ICD	H
Dougherty, 1994[91]	Longitudinal survey	HF	ICD only	Insertion; adjustment	13M, 2F	Pt and family perspectives on living with an ICD	M
Dougherty et al., 2000[88]	Grounded theory	Non–HF	ICD only	Insertion (1st year following)	13M, 2F	Pt and family experiences of ICD	M
Dunbar et al., 1993[106]	Mixed methods	Non–HF	ICD only	Shock discharge	20M, 2F	Pt experiences of ICD shocks	M
Eckert et al., 2002[95]	General (weak phenomenology)	HF	ICD only	Daily life challenges	3M Cgs	Pt and family ICD experience	L
Flemme et al., 2001[92]	Longitudinal survey	HF	ICD only	Life situation	42M, 14F	Life changes of ICD Pts over 1 year period	H
Fridlund et al., 2000[107]	Phenomeno-graphy	HF	ICD only	Life conceptions	10M, 5F	Pt life conceptions	L
Gibson et al., 2008[110]	Cohort	Not reported	ICD only	Malfunction	22M, 9F	Effect of device recall on Pts	M

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Author(s)	Approach	Population	Device type	Foci	Sample (M/F)	Sample Description	Study Quality (H/M/L)
Goldstein et al., 2008[45]	Grounded theory	HF	ICD only	Deactivation/ End-of-life	10M, 5F	Pt attitudes towards deactivation	M
Kaufman et al., 2011[1]	Ethnography	HF	ICD only	Insertion, End-of-life	2 M	ICD–related ethical dilemmas for pts≥80 years	H
Kelley et al., 2009[58]	Survey	Non–HF	ICD only	Deactivation	374M, 184F HP	Physician attitudes re: ICD deactivation	M
Lewis et al., 2006[12]	Cohort	HF Non–HF	ICD only	Deactivation	51M, 12F	ICD withdrawal as comfort care for terminally ill	M
Matlock et al., 2010[96]	General	HF	ICD, LVAD, pacemaker	Insertion	16M, 6F	Pt styles of decisionmaking in relation to HF	M
Noyes et al., 2009[108]	Randomized trial	HF	ICD only	Quality of life	499M, 102F	Pt perspectives on ICD and quality of life	M
Ong, 2008[111]	Cohort	HF Non–HF	ICD only	Daily life challenges	105M, 25F	Effects of CBT intervention	M
Prudente et al., 2006[109]	Case control	Not reported	ICD only	Quality of life	59M, 16F	Phantom shocks in ICD pts	L
Sneed et al., 1992[97]	General	HF	ICD only	Life adjustments	10M, 5F (14 Cgs)	ICD recipients and significant others	M
Sossong, 2007[93]	Survey	HF	ICD only	Living with an ICD	79M, 11F	HF pts living with ICD	H
Steinke et al., 2005[98]	General	Not reported	ICD only	General	10 M, 2F (4Cgs)	ICD pts and intimacy with partners	H
Stewart et al., 2010[112]	Cohort	HF	ICD only	Deactivation	70M, 35F	Pt expectations of ICDs	M
Strachan et al., 2011[47]	Grounded theory	HF Non–HF	ICD only	End-of-life	24M, 6F	Pt perspectives on end-of-life care	H
Tagney et al., 2003[99]	General	HF	ICD only	Living with an ICD	6M, 2F	Pt experiences of learning to live with ICD	M
Wallace et al., 2002[94]	Survey	HF Non–HF	ICD only	Psychosocial sequelae	44M, 14F	ICD for treatment of arrhythmias	H
Williams et al., 2004[100]	General	HF	ICD only	Living with an ICD	8M, 3F (9F, 2M Cgs)	Pt and Cgs support group involvement	L

CBT = cognitive behavioral therapy; Cgs = caregivers; F = female; H = high; HF = heart failure; HP = health professionals; ICD = implantable cardioverter-defibrillator; L = low; LVAD = left ventricular assist device; M = male; M = medium; pt = patient

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Quantitative Studies Included on Psychosocial Outcomes

Author(s)	Study Design	Country	Sample (M/F) Pts / age(years)	Device	Foci	Study Quality (H/M/L)
Bilge et al., 2006[114]	Cohort	Turkey	91 Pts 79M, 12F Mean age: 53 yrs Range: 18–86 yrs	ICD	Shock vs. no shock	M
Thomas et al., 2009[119]	Cohort	U.S., Canada, New Zealand	57 Pts 47M, 10F Mean age: 59.8 yrs Range: 51–69.3 yrs	ICD	Shock vs. no shock	H
Van den Broek et al., 2008[120]	Cohort	The Netherlands	308 Pts 254M, 54F Mean age: 62.6 yrs Range: 24–79 yrs	ICD	Shock vs. no shock	H
Van Den Broek et al., 2009[121]	Cohort	The Netherlands	205 Pts 179M, 26F Mean age: 62.1 yrs Range: 24–79 yrs	ICD	Shock vs. no shock	H
Pauli et al., 2001[122]	Cohort	Germany	24 Pts Mean age: 53 yrs Range: 35–60 yrs	ICD	Shock vs. no shock	M
Undavia et al., 2008[124]	Cohort	U.S.	ICD recall group: 61 Pts 43M, 18F Mean age: 67.3 yrs Control group: 43 Pts 28M 15F Mean age: 64.6 yrs	ICD	Device recall vs. control	M
Van Den Broek et al., 2006[132]	Repeated measures	The Netherlands	33 Pts 27M, 6F Mean age: 60 yrs	ICD	Device recall vs. control	L
Fisher et al., 2009[139]	Trial	U.S.	100 Pts 78M 22F	ICD	Device recall vs. control	M
Birnie et al., 2009[115]	Cohort	Canada	Device recall: 86 Pts Mean age: 67.7 yrs Control: 94 Pts Mean age: 64.9 yrs	ICD	Device recall vs. control	H
Carroll et al., 2010[116]	Cohort	Canada	Primary prevention: 15 Pts Secondary prevention: 15 Pts	ICD	Primary vs. secondary prevention	H
Crossmann et al., 2007[127]	Repeated measures	Germany	35 Pts 30M, 5F Mean age: 57 yrs Range: 35–65 yrs	ICD	Psychosocial sequelae	M
Wheeler et al., 2009[133]	Repeated measures	NR	33 Pts 26M, 7F Mean age: 63.4 yrs	ICD	Psychosocial sequelae	M
Dougherty et al., 2009[129]	Repeated measures	U.S.	100 partners of ICD Pts 36M, 164F Mean age: 60.9 yrs	ICD	Psychosocial sequelae	H
Crow et al., 1998[128]	Repeated measures	U.S.	35 Pts	ICD	Psychosocial sequelae	L

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Author(s)	Study Design	Country	Sample (M/F) Pts / age(years)	Device	Foci	Study Quality (H/M/L)
Pedersen et al., 2009[125]	Cohort	The Netherlands	446 Pts 261M, 185F Mean age: 61.6 yrs	ICD	Psychosocial sequelae	M
Pedersen et al., 2009[134]	Cross-sectional	Denmark	557 Pts 456M, 101F Mean age: 61.9 yrs	ICD	Psychosocial sequelae	H
Pedersen et al., 2010[131]	Repeated measures	The Netherlands	348 Pts 275M, 73F	ICD	Psychosocial sequelae	H
Pedersen et al., 2005[135]	Cross-sectional	The Netherlands	182 Pts 147M, 35F Mean age: 62 yrs Range: 16–84 yrs	ICD	Psychosocial sequelae	H
Sowell et al., 2007[136]	Cross-sectional	U.S.	62 Pts 31M, 9F Mean age: 66 yrs	ICD	Psychosocial sequelae	M
Spindler et al., 2009[137]	Cross-sectional	Denmark	535 Pts 438M, 97F Mean age: 61.5 yrs	ICD	Psychosocial sequelae	H
Craney et al., 1997[138]	Cross-sectional	U.S.	75 Pts Mean age: 64.5 yrs Range: 21–84 yrs	ICD	Coping strategies	H
Fritzsche et al., 2007[130]	Repeated measures	Germany	180 Pts 145M, 35F	ICD	Coping strategies	M
Petrucci et al., 1999[123]	Cohort	U.S.	21 LVAD Pts 18M, 3F Mean age: 49.6 yrs Range:16–66 yrs 13 VAD Pts 6M, 7F Mean age: 56.5 yrs Range: 46–73 yrs	LVAD and VAD	Psychosocial sequelae	L
Chamberlain (2008)[126]	Cohort	U.S.	36 Pts 36 M Range: 46–90 yrs	ICD and pacemaker	Psychosocial sequelae	L
Duru et al., 2001[117]	Cohort	Switzerland	152 Pts 114M, 38F Mean age: 58 yrs Range: 40–70 yrs	ICD and pacemaker	Psychosocial sequelae	M
Serber et al., 2003[118]	Cohort	U.S.	96 Pts 66M, 26F Mean age: 62.2 yrs	ICD	Sleep quality	M

F = female; H = high; ICD = implantable cardioverter-defibrillator; L = low; LVAD = left ventricular assist device; M = male; M = medium; NR = not reported; pts = patients; VAD = ventricular assist device; yrs = years

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Studies Included on Communication

Author(s)	Study Design	Country	Sample (M/F) Pts / age(years)	Device	Foci	Study Quality (H/M/L)
Goldstein et al., 2008 [46]	Qualitative	U.S.	12 physicians Mean age: 36.5 yrs Range: 33–61 yrs	ICD	Deactivation	H
Goldstein et al., 2004 [42]	Mixed method	U.S.	100 next-of-kin of ICD pts	ICD	Deactivation	M
Goldstein et al., 2010[61]	Cross-sectional	U.S.	414 hospices	ICD	Deactivation	M
Cladwell et al., 2007[147]	Qualitative	Canada	20 Pts 14M, 6F	ICD	Communication	H
Serber et al., 2009[148]	Cross-sectional	U.S.	108 participants 81M, 26F	ICD	Communication	M
Stutts et al., 2007[149]	Cross-sectional	U.S.	66 Pts Mean age: 61 yrs Range: 33–93 yrs	ICD	Communication	M
Sherazi et al., 2008[16]	Cross-sectional	U.S.	87 surveys	ICD	Training	L
Sherazi et al., 2010[150]	Cross-sectional	U.S.	110 surveys	ICD	Training	M

H = high; ICD = implantable cardioverter-defibrillator; L = low; M = medium; Pts = patients

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Appendix F: Methodological Quality of Included Studies

Qualitative Studies

Author(s)	Study Quality (L/M/H)	Assessment Tool Used	Main Strengths	Main Weaknesses
Agard et al., 2007[101]	M	JBI–QARI	Sampling rationale; congruent study design	Sample interview questions not provided
Anderson, 2004[85]	L	JBI–QARI	Data management; ethical protection of participants	Interpretation of data is questionable; conclusions seem not to flow from data
Andersen et al., 2008[102]	M	JBI–QARI	Detailed, rigorous procedures enhance trustworthiness	Low enrollment rate
Beery, 1998[103]	H	JBI–QARI	Rigorous data collection and analysis methods	Leading interview questions
Beery et al., 2002[105]	H	JBI–QARI	Rigorous data collection and analysis methods	Potential sampling bias
Berger et al., 2006[89]	L	Cross-sectional Appraisal Tool*	High enrollment rate	Instrument validity/reliability measures not reported; data analysis procedures not described
Bolse et al., 2002[90]	M	Cohort–CASP	Detailed sampling and instrument descriptions	Different end-points among the sample populations
Bolse et al., 2005[86]	L	JBI–QARI	Data analysis well described	Potential sampling bias; methodology (phenomenography) is not convincing
Burke, 1995[87]	H	JBI–QARI	Methodologically rigorous; procedures described enhance trustworthiness	Quotes are not tied to interview participants
Dickerson, 2002[104]	H	JBI–QARI	Large sample size; appropriate methods for phenomenology	Quotes are not tied to interview participants
Dougherty, 1994[91]	M	Cohort–CASP	Multiple methods and recruitment sites	Interview data not represented in findings; potential sampling bias
Dougherty, 2000[88]	M	JBI–QARI	Thorough methods; discusses data saturation	Interview focus does not reflect research purpose
Dunbar et al., 1993[106]	M	JBI–QARI	Validity and reliability reported	No information on data analysis
Eckert, 2002[95]	L	JBI–QARI	Findings deepen nursing practice	Numerous data collection strategies not reported; interpretation of data is questionable
Flemme, 2001[92]	H	Cohort–CASP	Thoroughly describes theoretical framework; discusses reasons for nonparticipation	No rationale for selection of specific time points
Fridlund et al., 2000[107]	L	JBI–QARI	Diverse sample population	Analysis appears superficial
Gibson et al., 2008[110]	M	Cohort–CASP	Large sample size; detailed description of statistical analysis	Validity/reliability measures not reported for one instrument
Goldstein et al., 2008[45]	M	JBI–QARI	Sound methods and rationale for data collection	Relatively homogenous sample

Author(s)	Study Quality (L/M/H)	Assessment Tool Used	Main Strengths	Main Weaknesses
Kaufman, 2011[1]	H	JBI–QARI	Case studies discussed in wider ethnographic context	None identified
Kelley, 2009[58]	M	Cross–sectional Appraisal Tool	Survey was pilot tested	Greater variation in vignettes
Lewis, 2006[12]	M	Cohort–CASP	Detailed patient demographics table	Retrospective data collection; no description of data analysis
Matlock, 2010[96]	M	JBI–QARI	Detailed description of team approach to analysis	Interview questions not consistent among participants
Noyes, 2009[108]	M	RCT–CASP	Long followup period; account for missing data	Not clear how randomization was conducted
Ong, 2008[111]	M	Cohort–CASP	Double-blind, randomly assigned intervention	Low participation rate
Prudente et al., 2006[109]	L	Case control–CASP	Discusses recruitment and blinding	No baseline data established; convenience sampling from single recruitment site
Sneed et al., 1992[97]	M	JBI–QARI	Sound data collection and analysis strategies	Criteria for inclusion not reported
Sossong et al., 2007[93]	H	Cross-sectional Appraisal Tool	Pilot study; external validation of instrument	Relatively homogenous sample
Steinke et al., 2005[98]	H	JBI–QARI	Sound data collection and analysis strategies	Quotations are not tied to interview participants
Stewart, 2010[112]	M	Cohort–CASP	Appropriate analysis methods	Survey tool not validated; did not report size of confidence intervals
Strachan et al., 2011[47]	H	JBI–QARI	Strong grounded theory approach and methods	Size of eligible sample not reported
Tagney, 2003[99]	M	JBI–QARI	Interview guide was piloted	Low participation rate
Wallace et al., 2002[94]	H	Cross–sectional Appraisal Tool	Detailed description of measures	Sample is largely male
Williams et al., 2004[100]	L	JBI–QARI	Corroboration of data findings with participants	Ethical approval not reported; analysis appears superficial

CASP = Critical Appraisal Skills Programme, Oxford; H = high; JBI–QARI=Joanna Briggs Institute–Qualitative Assessment and Review Instrument; L = low; M = medium; RCT = randomized controlled trial
*Albert Einstein College of Medicine

Quantitative Studies

Author(s)	Study Quality (L/M/H)	Assessment Tool Used	Main Strengths	Main Weaknesses
Bilge et al., 2006[114]	M	CASP	Questionnaires were validated; long-term followup	No reporting on confidence intervals or effect sizes; small number of female participants
Thomas et al., 2009[119]	H	CASP	Long-term followup; in-depth description of statistical analysis	47% response rate; 42% of attrition rate
Van den Broek et al., 2008[120]	H	CASP	84% response rate; large sample size; in-depth description of statistical analysis	Small number of female participants
Van Den Broek et al., 2009[121]	H	CASP	Large sample size; in-depth description of analysis process; confounding variables were controlled	Small number of female participants
Pauli et al., 2001[122]	M	CASP	In-depth description of statistical analysis; results were consistent with previous studies using the same experimental procedures	Small sample size; not all confounding variables were controlled
Undavia et al., 2008[124]	M	CASP	90% response rate	No reporting on confidence intervals or effect sizes; validity/reliability measures not reported for one instrument
Van Den Broek et al., 2006[132]	L	Cross–Sectional Appraisal Tool*	90% response rate	Small sample size; results were mostly descriptive findings
Fisher et al., 2009[139]	M	CASP	No dropout; in-depth description of study design and statistical analysis	27% of response rate; number of female patients was small to determine sex differences
Birnie et al., 2009[115]	H	CASP	In-depth description of statistical analysis; sample size was determined by power calculation; long-term followup	Small number of female participants
Carroll et al., 2010[116]	H	CASP	Equal number of male and female participants in the cohorts; validity/reliability of measures were reported; in-depth description of statistical analysis	Small sample size; no reporting on confidence intervals or effect sizes
Crossmann et al., 2007[127]	M	CASP	Sample size was determined by power calculation; effect sizes were reported	43.5% of attrition rate
Wheeler et al., 2009[133]	M	CASP	Long-term followup	Small sample size; not all confounding variables were controlled

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Author(s)	Study Quality (L/M/H)	Assessment Tool Used	Main Strengths	Main Weaknesses
Dougherty et al., 2009[129]	H	CASP	86% of response rate; 9.1% attrition rate; in-depth description of statistical analysis	Small number of male participants
Crow et al., 1998[128]	L	CASP	Long-term followup; assessment tool used is well validated	No description of statistical analysis; only reported descriptive findings
Pedersen et al., 2009[125]	M	CASP	Validity/reliability of measures were reported; in-depth description of statistical analysis; confounding variables were controlled	Only included partners of ICD patients and not CHF patients; larger sample size in the ICD cohort
Pedersen et al., 2009[134]	H	Cross–sectional Appraisal Tool	Large sample size; 86% of response rate; in-depth description of statistical analysis; odds ratios with 95% confidence intervals were reported for significant findings	Small number of female participants
Pedersen et al., 2010[131]	H	CASP	In-depth description of statistical analysis; confounding variables were accounted; odds ratios with 95% confidence intervals were reported for significant findings	Small number of female participants
Pedersen et al., 2005[135]	H	Cross–sectional Appraisal Tool	82% of response rate; large sample size; confounding variables were accounted; odds ratios with 95% confidence intervals were reported for significant findings	Small number of female participants
Sowell et al., 2007[136]	M	Cross–sectional Appraisal Tool	Effect size was reported	Small number of female participants
Spindler et al., 2009[137]	H	Cross–sectional Appraisal Tool	86% of response rate; in-depth description of statistical analysis	Small number of female participants
Craney et al., 1997[138]	H	Cross–sectional Appraisal Tool	Sample size was determined by power calculation; in-depth description of statistical analysis and data transformation	Small number of female participants
Fritzsche et al., 2007[130]	M	CASP	Missing data were replaced using statistical techniques	37% of attrition rate; small number of female participants; confounding variables were not controlled in analysis
Petrucci et al., 1999[123]	L	CASP	Long-term followup	Small sample size; no statistical analysis; only reported descriptive findings

Author(s)	Study Quality (L/M/H)	Assessment Tool Used	Main Strengths	Main Weaknesses
Chamberlain, 2008[126]	L	CASP	No missing data	Small sample size; no description of statistical analysis
Duru et al., 2001[117]	M	CASP	Large sample size	Validity/reliability measures not reported for one instrument ; not all confounding variables were controlled
Serber et al., 2003[118]	M	CASP	Confounding variables were accounted	Number of female participants was small to determine gender differences

CASP = Critical Appraisal Skills Programme, Oxford; CHF = congestive heart failure; H = high; ICD = implantable cardioverter-defibrillator; L = low; M=medium,
*Albert Einstein College of Medicine

Mixed Method Studies

Author(s)	Study Quality (L/M/H)	Assessment Tool Used	Main Strengths	Main Weaknesses
Goldstein et al., 2008[46]	H	JBI–QARI	Rigorous data collection and analysis methods	Not identified
Goldstein et al., 2004[42]	M	JBI–QARI	74% response rate; large sample size	Sample interview questions not provided
Goldstein et al., 2010[61]	M	Cross–sectional Appraisal Tool*	Reported results of sensitivity analysis	50% response rate; instrument validity/ reliability measures not reported
Cladwell et al., 2007[147]	H	JBI–QARI	71% response rate; rigorous data collection and analysis methods	Sample is largely male
Serber et al., 2009[148]	M	Cross–sectional Appraisal Tool	Large sample size; detailed description of statistical analysis	Relatively homogenous sample; instrument validity/reliability measures not reported
Stutts et al., 2007[149]	M	Cross–sectional Appraisal Tool	84% response rate; detailed description of statistical analysis	Relatively homogenous sample
Sherazi et al., 2008[16]	L	Cross–sectional Appraisal Tool	Detailed participant demographics table	43% response rate; instrument validity/ reliability measures not reported
Sherazi et al., 2010[150]	M	Cross–sectional Appraisal Tool	Detailed description of statistical analysis	33% response rate; instrument validity/ reliability measures not reported

H = high; JBI–QARI = Joanna Briggs Institute–Qualitative Assessment and Review Instrument; L = low; M = medium
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