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

Prepared for:
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, Maryland 20850

Final Report
May 23, 2012
Systematic Review of Decision Tools and their Suitability for Patient-Centered Decisionmaking Regarding Electronic Cardiac Devices

Technology Assessment Report

Project ID: CRDT0810

May 23, 2012

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None of the investigators has any affiliations or financial involvement related to the material presented in this report.
Acknowledgments

The authors wish to thank the researchers who worked on the project (Megan Jerke, Zoe Hsu, Amanda Duncan, Dr. Alex Choby, and Melisa Spaling) and those who responded to queries regarding particular studies included in this review (Dr. Cynthia Dougherty, Dr. Sandra Dunbar, Dr. Nathan Goldstein, Dr. Karin Kirchhoff, Dr. Emily Kuhl, Dr. Robert JP Lewin, and Dr. Samual Sears). We are also very thankful to the consultants for the project (Dr. James Beattie, Dr. Tiny Jaarsma, Dr. Patricia Davidson, and Dr. Patricia Strachan). We thank Jennifer Seida for copy-editing.
Peer Reviewers

We wish to acknowledge individuals listed below for their review of this report. This report has been reviewed in draft form by individuals chosen for their expertise and diverse perspectives. The purpose of the review was to provide candid, objective, and critical comments for consideration by the EPC in preparation of the final report. Synthesis of the scientific literature presented here does not necessarily represent the views of individual reviewers.

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Structured Abstract

Objectives: 1) Identify validated decision aids available for insertion, continuation, or deactivation of 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.

Patients generally have 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 wanted discussions with a range of health professionals. 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: Given the absence of well-developed tools, 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. Development of multidisciplinary support interventions around deactivation should be encouraged.
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Executive Summary

Background

Over the past three decades, electronic cardiac devices (ECDs) have been used to electronically stimulate the heart in order to regulate 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 tachyarrhythmias and other 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 shock function of the ICD to neutralize harm from the device as a patient nears the end of life.

This is challenging however because of the complexity of decisionmaking, particularly in relation to end-of-life issues which are charged with multiple uncertainties around the effects of deactivation, prognosis, and possible frequency of shocks.

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 ICDs 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.

However, over the past five years, evidence has consistently shown that health care practices around decisionmaking in the United States and elsewhere remain concerning and frequently risk compromising informed consent, particularly in relation to ICDs. Decisionmaking aids have been found to be effective in promoting shared and effective decisionmaking in various populations and health decisions. We then examine here the possible effectiveness of these aids in relation to the insertion, continuation, or cessation of ICDs.

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 generalizability 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 behavior 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 decision 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.”

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.

To assess the quality of the decision tools, we used a previously validated systematic quality assessment framework for decision aids. 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.\textsuperscript{8,9} This approach provides a new synthesis of findings to account for the phenomenon being explored\textsuperscript{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.\textsuperscript{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.\textsuperscript{9} 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.\textsuperscript{11}

For mixed methods studies on communication, we followed the same steps for quantitative studies of psychosocial outcomes.\textsuperscript{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,\textsuperscript{12} discussions prior to\textsuperscript{13} or after\textsuperscript{14} insertion, and a disease-specific end-of-life planning intervention.\textsuperscript{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\textsuperscript{16} and pacemaker\textsuperscript{17} for patients at risk from arrhythmia and for an ICD\textsuperscript{18} and pacemaker\textsuperscript{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.\textsuperscript{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 balance 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*

<table>
<thead>
<tr>
<th>Title of tool</th>
<th>Heart rate problems: Should I get an ICD?</th>
<th>Heart Rate Problems: Should I Get a Pacemaker?</th>
<th>Heart failure: Should I get an ICD?</th>
<th>Heart failure: Should I get a pacemaker (cardiac resynchronization therapy)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Condition</td>
<td>Arrhythmia</td>
<td>Arrhythmia</td>
<td>Heart Failure</td>
<td>Heart Failure</td>
</tr>
<tr>
<td>Type</td>
<td>Treatment</td>
<td>Treatment</td>
<td>Treatment</td>
<td>Treatment</td>
</tr>
<tr>
<td>Options Included</td>
<td>Get an ICD.</td>
<td>Get a pacemaker.</td>
<td>Get an ICD.</td>
<td>Get a pacemaker.</td>
</tr>
<tr>
<td></td>
<td>Don't get an ICD.</td>
<td>Don't get a pacemaker.</td>
<td>Don't get an ICD.</td>
<td>Don't get a pacemaker.</td>
</tr>
<tr>
<td>Audience</td>
<td>People with heart rate problems but do NOT have heart failure considering whether to get an ICD.</td>
<td>People with heart rate problems but NOT heart failure considering getting a pacemaker.</td>
<td>People at risk of having an abnormal heart rhythm that could cause sudden death.</td>
<td>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.</td>
</tr>
<tr>
<td>Developer</td>
<td>Healthwise</td>
<td>Healthwise</td>
<td>Healthwise</td>
<td>Healthwise</td>
</tr>
<tr>
<td>Country of development</td>
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<td>United States</td>
<td>United States</td>
<td>United States</td>
</tr>
<tr>
<td>Year of last update or review</td>
<td>2011</td>
<td>2010</td>
<td>2010</td>
<td>2010</td>
</tr>
<tr>
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<tr>
<td>Language(s)</td>
<td>English</td>
<td>English</td>
<td>English</td>
<td>English</td>
</tr>
</tbody>
</table>

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, generalizability to the Medicare population is not currently an issue.
Although current recommendations could be incorporated into high-quality decision 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.\(^{20,21}\)
- Poor communication with physicians, professionals being seen to over-impose their own values and priorities on patients.\(^{27,42,29}\)
- Widespread psychosocial disruptions across ECDs especially 3 months after device insertion, and patients with: higher shock frequency, Type D personality, and adverse social and educational status, female sex, and older age.\(^{36,44,45,46}\)
- Low patient social support for decisionmaking or psychosocial wellbeing and overly protective families and other caregivers.\(^{27,22,23}\)
- 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.\(^{27,22,23}\)
- These discussions could be in person or over the telephone with wider members of the multidisciplinary health care team.\(^{27,22,23}\)

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. 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 and practice.

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. Similarly, systematic reviews have demonstrated that untreated and unrecognized anxiety and depression are common in patients with coronary heart disease and heart failure. 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 decision 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,\(^7^1,\(^7^2\) the influence of age on patient experiences and outcomes has not been specifically examined in studies to date.

**Conclusions**

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.
References


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. These devices include:

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

Medicare coverage criteria for ICDs have been considerably broadened in the past 5 years. In the United States, 68 percent of patients with an ICD implantation are Medicare beneficiaries, and the average age at implantation is 68 years.

Professionals have expressed reservations about over-insertion of ECDs, most notably in relation to ICDs and the relative size of clinical benefits and harms of such devices. 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 (‘shocks’) may be so painful and frequent that the harms derived from an ICD can outweigh the benefits. 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. Most prominently, these issues have been expressed about ECDs in relation to informed consent and decisions to deactivate ICDs near the end of life. 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. 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; however, almost half of the U.S. physicians surveyed in 2008 were unsure of the legality of deactivating an ICD. Guidelines in the United States 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, pacemakers, and VADs. Ensuring ongoing informed consent is as important as addressing the clinical effects of insertion or deactivation in each patient. 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.

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. For decisions to be based on informed consent, they must be made voluntarily by patients who have the legal standing and sufficient capacity to make decisions. 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. Further, this information should be specific to the patient’s personal situation. 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.

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. 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.

<table>
<thead>
<tr>
<th>Table 1. Key components of informed consent</th>
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<tr>
<td>Component</td>
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<tr>
<td>Voluntary</td>
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<tr>
<td>Capacity</td>
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<tr>
<td>Legal standing</td>
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<td>Disclosure</td>
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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. 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.”

When patients do not have the capacity to make decisions, the health care team should honor an advanced directive to respect patient autonomy. 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. 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. The AMA states that surrogate decisionmakers should be accorded the same rights as patients.

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 and the U.S. Heart Rhythm Society (HRS). 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 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. This concurs with the AMA guidelines that the values of the patient should be incorporated in the decisionmaking process. Although a clinician has the right not to perform the deactivation, the clinician’s religious beliefs may not override those of the patient. However, deactivation is not incompatible with religious beliefs related to the preservation of life.

These guidelines address concerns about the ethics of deactivation and physician reservations about the legal implications of withdrawing device-related care. These have remained for some years because of a lack of legal precedents. However, there is no indication from HRS guidelines, similar European guidelines, or from the AMA that deactivation of a device could be considered an illegal physician-assisted suicide or form of euthanasia. Likewise, ethical and legal issues around resuscitation address cardiopulmonary resuscitation after a cardiac or respiratory arrest not overtly ECDs. Nor are there any legal indications that the current HRS guidelines would not apply to other devices, notably VADs, or across all U.S. states. Guidelines mention options of partial deactivation of shocks or depletion of the device generator, but do not make an ethical distinction between partial and full deactivation. 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.

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. 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. VADs may become burdensome for patients and their caregivers near the end of life due to the need to assess and monitor device function and in relation to patient anxiety.

**Ethical and Legal Care Processes**

Although past arguments questioning the ethics of deactivation now appear to be out of step with current guidelines and consensus, dismissing these concerns is inappropriate. Crucially, ensuring decisions about deactivation are legal and ethical is dependent on key processes of care associated with seeking and attaining informed consent. 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.

For ICDs while current recommendations indicate that the primary caring physician should broach deactivation initially, but if deactivation conflicts with the clinician’s conscience, the physician should attempt to identify another clinician to deactivate.35 When this is not possible an administrator or ethics board can be involved providing the physician’s relationship continues with the patient and clinicians have expressed their abstinence in a value free manner.35 It should also be recognized that other health professionals may broach discussions with health professionals or experience concern or distress around deactivation.

Communication and Consent

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 care45-47 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 guidelines35 (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>
<thead>
<tr>
<th>Aim(s)</th>
<th>Key questions for patients or surrogate decisionmakers</th>
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<tr>
<td>1. Determine what patients/families know about their illness.</td>
<td>“What do you understand about your health and what is occurring in terms of your illness?”</td>
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<tr>
<td>2. Determine what patients/families know about the role the device plays in their health both now and in the future.</td>
<td>“What do you understand about the role of the [cardiac device] in your health now?”</td>
</tr>
<tr>
<td>3. Determine what additional information patients/families want to know about their illness.</td>
<td>“What else would be helpful for you to know about your illness or the role the [cardiac device] plays in it?”</td>
</tr>
<tr>
<td>4. Correct or clarify any misunderstandings about the current illness and possible outcomes, including the role of the device.</td>
<td>“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.”</td>
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</table>
Table 2. Recommendations for Communicating about Deactivation (HRS 2010)35 (continued)

<table>
<thead>
<tr>
<th>Aim(s)</th>
<th>Key questions for patients or surrogate decisionmakers</th>
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<tr>
<td>5. Determine the patient/family’s overall goals of care and desired outcomes.</td>
<td>“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?”</td>
</tr>
<tr>
<td>6. Using the stated goals as a guide, work to tailor treatments, and in this case, management of the cardiac device to those goals.</td>
<td>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.”</td>
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Complexity

A principle reason for challenges around communication, consent, and decisionmaking in relation to devices is the complexity of decisionmaking, particularly in relation to the likelihood of future events particularly near the end of life. 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), particularly pertaining to the future likely course of the patient’s progression around 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 future potential benefits for retaining a fully functioning ICD for the specific patient.7,51 However, estimating the size of this future 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 patients42 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. Some have questioned whether health professionals, particularly cardiologists, are trained adequately to deal with such issues. 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. Although health professionals are often aware that patients have concerns about dealing with ICD shocks, some are still not comfortable discussing deactivation issues. 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 or cited as a cause of death.

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). Health professionals have also reported higher levels of discomfort in relation to deactivation of pacemakers; 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. Decisions about ECD deactivation are complex, value-laden, and deal with wide ranging probabilities and uncertainty. These decisions may involve patients and next-of-kin who may have limited understanding or unrealistic expectations of ECDs 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.

Patient decision aids have been developed to help health professionals support patients and next-of-kin in making informed decisions about health care treatments. 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.

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). 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. Indeed, these aids are more effective at ensuring higher “quality” decisions than standard forms of counseling. In a recent Cochrane systematic review of 55 trials, 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. These decision aids also: a) can be incorporated into care systems
and protocols\textsuperscript{64} (thereby addressing health professional avoidance, discomfort, and lack of timeliness of discussions); b) are systematic (thereby addressing the \textit{inconsistencies} in current discussion practices); c) take account of values relating to benefits and harms\textsuperscript{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.\textsuperscript{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 generalizability 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 Center for Medicare Management Group at the Centers for Medicare and Medicaid Services 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 behavior 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

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.” 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; 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. 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
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 studies71 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. This approach provides a new synthesis of findings to account for the phenomenon being explored 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).

Table 3. Stages of synthesis of qualitative studies

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<thead>
<tr>
<th>Synthesis Stage</th>
<th>Description</th>
<th>Output</th>
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<tbody>
<tr>
<td>1. First-order findings</td>
<td>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.</td>
<td>A detailed description of the findings of each study.</td>
</tr>
<tr>
<td>2. Second-order interpretations</td>
<td>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.</td>
<td>Interpretations of common or reoccurring concepts or those that provided explanations for help seeking.</td>
</tr>
<tr>
<td>3. Higher-order abstractions</td>
<td>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.</td>
<td>The research synthesis presented in this paper.</td>
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</table>

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. 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.

For mixed methods studies on communication, we followed the same steps for quantitative studies of psychosocial outcomes.
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. Error! Reference source not found. 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, discussions prior to or after device insertion, and a disease-specific end-of-life planning tool. 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).
Figure 1. Flow diagram of study retrieval and selection

1,499 citations retrieved from database searches

1,102 articles after removal of duplicates
51 citations from grey literature searches, hand searches, experts

1,153 articles for screening

Key Question 1–3

KQ 4 Qualitative studies on general patient experiences

Full-text articles screened for eligibility N = 49

33 included studies
- 29 ICD
- 4 other devices

4 Excluded
- 4 no relevant data

KQ 4 Quantitative studies of psychosocial outcomes

Full-text articles screened for eligibility N = 29

26 included studies

16 Excluded
- 14 not relevant
- 2 reviews

KQ 4 Mixed methods studies on communication

Full-text articles screened for eligibility N = 16

8 included studies

8 Excluded
- 7 not relevant
- 1 review

4 Included studies

Included studies
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*

<table>
<thead>
<tr>
<th>Title of tool</th>
<th>Heart rate problems: Should I get an ICD?</th>
<th>Heart Rate Problems: Should I Get a Pacemaker?</th>
<th>Heart failure: Should I get an ICD?</th>
<th>Heart failure: Should I get a pacemaker (cardiac resynchronization therapy)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Condition</td>
<td>Arrhythmia</td>
<td>Arrhythmia</td>
<td>Heart Failure</td>
<td>Heart Failure</td>
</tr>
<tr>
<td>Type</td>
<td>Treatment</td>
<td>Treatment</td>
<td>Treatment</td>
<td>Treatment</td>
</tr>
<tr>
<td>Options Included</td>
<td>Get an ICD. Don't get an ICD.</td>
<td>Get a pacemaker. Don't get a pacemaker.</td>
<td>Get an ICD. Don't get an ICD.</td>
<td>Get a pacemaker. Don't get a pacemaker.</td>
</tr>
<tr>
<td>Audience</td>
<td>People with heart rate problems but do NOT have heart failure considering whether to get an ICD.</td>
<td>People with heart rate problems but NOT heart failure considering getting a pacemaker.</td>
<td>People at risk of having an abnormal heart rhythm that could cause sudden death.</td>
<td>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.</td>
</tr>
<tr>
<td>Developer</td>
<td>Healthwise</td>
<td>Healthwise</td>
<td>Healthwise</td>
<td>Healthwise</td>
</tr>
<tr>
<td>Country of development</td>
<td>United States</td>
<td>United States</td>
<td>United States</td>
<td>United States</td>
</tr>
<tr>
<td>Year of last update or review</td>
<td>2011</td>
<td>2010</td>
<td>2010</td>
<td>2010</td>
</tr>
<tr>
<td>Format</td>
<td>Web, paper</td>
<td>Web, paper</td>
<td>Web, paper</td>
<td>Web, paper</td>
</tr>
<tr>
<td>Language(s)</td>
<td>English</td>
<td>English</td>
<td>English</td>
<td>English</td>
</tr>
</tbody>
</table>

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,\(^6^8\) 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. We rated each tool in terms of the IPDA criteria as adequate (check) or misleading (M). An element was coded as misleading if it met at least one of the following requirements: 1) wording of alternatives contained biasing language or value judgments; 2) it included only a subset of factors to consider identified in the qualitative literature on patient experiences; or 3) it overstated the likelihood of an outcome.

Tools were misleading in presentation of benefits, harms, and ability to compare positive and negative features. 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)\(^4^0\) 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**

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

| Makes it possible to compare the positive and negative features of the available options | 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, 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).1,45,58,86-89,91,93,96,97,103,105,108-112 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 decision making 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, 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. This reflects current guidelines in the United States and Europe and the nature of informed consent.

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, how the device addresses their condition, why the ICD was implanted or its function, alternative treatments to the device, overestimation of the benefits of the ICD, and the magnitude of impact on survival and quality of life.

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, resulting in the assumption that deactivation is an act of suicide. 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 decisions102 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 dismissed98,102 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 professionals102 or the sense that some questions were
not permitted. 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. 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 and addressed quality-of-life issues and emotions, such as fear.

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. In this context, patients’ preferences may depend on their perceptions of the health provider’s knowledge level and comfort in discussing sexuality. However, patients wanted to receive support around decisionmaking from a range of health professional groups, such as their primary physician and nurses. 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 or to connect in an emergency.

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, experienced coercion to accept device insertion, and were passive in patient-physician interactions. ICD recipients also wanted more information addressing a greater variety of factors on which to base decisions about implantation and therapeutic trajectory. In addition to information directly related to procedures and their risks and benefits, patients disclosed a need for more information about followup and maintenance, modification of activities of daily living, what to expect if the device fires, and how to handle malfunctions. Further, some reported that they felt their physicians understated the intensity of single or multiple shocks.

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. 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.

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 or the device’s life-extending functions. Patients themselves reflected this by expressing that they should be grateful, minimize their losses, adapt, and not complain. 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 activities97,107 and changing social roles and relationships.98,99 Many recipients lost their driver's license99,102 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 so58 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. Patients who prefer quality over quantity of life may be more likely to consider how they would like to die and initiate end-of-life and deactivation discussions with their families and health professionals.

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 or felt helpless 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. 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.

**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. Peer support groups were seen to provide more relevant information on the experience of living with an ICD than books or health professionals.

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. Barriers to being involved in support groups included aversions to “sick roles” or being reminded of their illness. There was evidence that some patients respond adversely to others in support groups who broach negative experiences related to their ICD.

**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. 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. During this time, patients appear to focus on survival and a better life after device implantation and view the ICD as the solution to their cardiac problems. 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. Nevertheless, confidence and trust in physicians and the ICD were high. Patients also expressed feeling a sense of security and the ability to plan once again for a future life. In comparison to a Swedish population, ICD patients in the United States reported greater uncertainty during this phase. For some, this period is also influenced by worries over funding the treatment.

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 especially on topics related to quality of life. 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. This information was desired both pre- and postimplantation. Although many ICD recipients did not recall formulating a deactivation preference prior to implantation, they expressed that they would have liked to discuss end-of-life issues during pre-implantation decisionmaking. 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. Nonetheless, others wanted general information about quality of life issues prior to hospital discharge, followed by specific information at routine followup visits.

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

The first three months postimplantation can be characterized by depression and anxiety, but many have adjusted to their new lives at 1 year. Patients report boredom, incision-site pain, fear of isolation, and fear of being shocked. These emotions and sensations primarily subside after experiencing the first shock. 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. Memory loss may impede end-of-life decisions at this point and rapid changes in relationships, roles, and emotions may contribute to depression. 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” and plan to live normal lives. 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. Some patients reported dressing strategically to hide the ICD or concealing symptoms, ICD shocks, and emotional concerns from family members and caregivers.

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. Although advances in biotechnology drastically reduced the size of implantable devices, ECD recipients generally express concerns over device protrusion and incision scars. ICD recipients do appear to report higher levels of anxiety and uncertainty post-implantation, 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. Similarly, driving restrictions are specific to patients living with an ICD and have a negative impact on quality of life and mental health.
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.\textsuperscript{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,\textsuperscript{85,102} and sense of self.\textsuperscript{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.\textsuperscript{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),\textsuperscript{114-126} repeated measures (n=7),\textsuperscript{127-133} and cross-sectional surveys (n=5).\textsuperscript{134-138} Only one study reported the results of a trial.\textsuperscript{139} The studies measured the effect of the following comparisons on anxiety: the experience of shock versus no shock (n=5),\textsuperscript{114,119-122} effects of device recall versus control group (n=4),\textsuperscript{115,124,132,139} and primary versus secondary prevention as an indication for ICD (n=1).\textsuperscript{T16}

The majority of the studies were conducted in the United States (n=9),\textsuperscript{118,123,124,126,128,129,136,138,139} or the Netherlands (n=6).\textsuperscript{120,121,125,131,132,135} Other countries represented in the literature included Germany (n=3),\textsuperscript{122,127,130} Canada (n=2),\textsuperscript{115,116} Denmark (n=2),\textsuperscript{134,137} Switzerland (n=1),\textsuperscript{117} and Turkey (n=1).\textsuperscript{114} One multinational study had sites in Canada, New Zealand, and the United States.\textsuperscript{119} One study did not provide a country context.\textsuperscript{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.\textsuperscript{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,\textsuperscript{135,140} The Hospital Anxiety and Depression Scale,\textsuperscript{141} and the State Trait Anxiety Inventory.\textsuperscript{142} Patients’ coping strategies were assessed using The Freiburg Questionnaires for Coping with Illness,\textsuperscript{143} and device acceptance was monitored via The Florida Patient Acceptance Survey.\textsuperscript{144} General scales such as the Short Form Health Survey\textsuperscript{145} and the Type D Scale\textsuperscript{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)\textsuperscript{114,117,118,122,124,125,127,130,133,136,139} to high (n=11);\textsuperscript{115,16,119-121,129,131,134,135,137,138} four studies were evaluated as low quality.\textsuperscript{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.\(^{156}\)

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.

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 and Canada may lack communication skills in relation to discussing deactivation of ICDs. Surveys concur that most clinicians are unaware that guidelines exist even for insertion. 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. 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; had insufficient time; forgot to discuss deactivation; or viewed discussing deactivation of devices as being different to discussing other forms of treatment withdrawal near the end of life. In addition, some professionals thought that deactivation could constitute withdrawal of life-sustaining therapy. The act of deactivation can be seen by professionals as reflecting lost hope and finality.

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 reported that almost half of respondents (46 percent) judged deactivation to be either illegal or 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. 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. Further, three-quarters of these discussions occurred in the last few days of life and one-fifth in the last few hours. In the same study, next-of-kin reported that 27 percent of patients received a shock in the last month of their life. Such shocks could also be distressing to families.

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. U.S. patients are keen to receive support from cardiologists over other
sources and the mass media. Further, patients do not appear averse to communicating about these issues with health professionals over the telephone, or for younger adults, over the internet. Female patients have expressed preferences towards participating in support groups with other patients.

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. Physician awareness of the benefits of ICDs is also high, being evident in over 95 percent of respondents in a survey. 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.

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. Having a “do not resuscitate” order was also associated with a higher likelihood of discussing deactivation.
Summary and Discussion

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, generalizability to the Medicare population is not currently an issue.

We identified four decisions aids that addressed the insertion of pacemakers and implantable cardioverter-defibrillators (ICDs) in patients with heart failure and arrhythmia. 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 for the ICD population. 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.
- Key issues around informed consent, notably uncertainty, are not currently well understood.
- 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.
These issues pertain across ECDs but are of particular relevance to ICDs.

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 devices, 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, instigated by the primary physician, early in the care trajectory and prior to insertion of the device. 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. 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 and practice.

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 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

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 disease154 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 makers82,84 and ICDs81,83 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 States35 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 aids68 and also what influences their effectiveness when used in
health care systems.

However, common and substantial barriers to the effectiveness of tools that will not be
ameliorated by the use of decision aids 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) positions37-39,156 and guidelines35
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;
• Uncertainty and how this is addressed in communication between patients, next-of-kin and health professionals, and
• The views of informed consent and reported practices of physicians around deactivation decisions compared with professional statements and relevant guidelines.

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. 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.

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; for example, U.S. guidelines now exist on specific programming strategies or pharmacotherapy to suppress arrhythmias. Systematic reviews and trials suggest that dedicated programs of cognitive behavioral therapy and psycho-education 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. Key components of these interventions include device-related education, relaxation and stress management, cognitive restructuring, social support and group discussion, and exercise. 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.

**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. Although a small number of studies indicated that age may ameliorate some of the anxiety associated with shocks, 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.
References


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### List of Abbreviations

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<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
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<td>AMA</td>
<td>American Medical Association</td>
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<td>CRT</td>
<td>Cardiac resynchronization therapy</td>
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<td>ECD</td>
<td>Electronic cardiac device</td>
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<td>HRS</td>
<td>Heart Rhythm Society</td>
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<td>ICD</td>
<td>Implantable cardioverter-defibrillator</td>
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<td>KQ</td>
<td>Key question</td>
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<tr>
<td>NRCT</td>
<td>Nonrandomized controlled trial</td>
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<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
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<tr>
<td>VAD</td>
<td>Ventricular assist device</td>
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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. |
| 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 participation$)).tw.
56. (shared adj2 decision adj2 making).tw.
57. (decision adj (support or aid* or process* or tool*)).tw.
58. (third adj party adj consent).tw.
59. (proxy or proxies).tw.
60. (informed adj1 choice).tw.
61. exp Patient Education as Topic/mt [Methods]
62. or/44-61
63. and/6,62
64. and/30,62
65. and/6,30,62
66. Health Knowledge, Attitudes, Practice/
67. Treatment refusal/es, st, td
68. Withholding treatment/
69. "Dissent and disputes"/
70. medical futility/
71. advance care planning/es, st, mt, td
72. terminal care/es, mt, px, st, td
73. ethics, medical/
74. social responsibility/
75. (ethics or ethical).tw.
76. (barriers or barrier).tw.
77. exp depression/ or (depression or depressed or depressive).tw.
78. exp anxiety/ or anxiety.tw.
79. (deactivation or deactivating or deactivate*).tw.
80. exp pain/ or pain*.tw.
81. (cultur* or customs or belief*).tw.
82. age factors/ or aged/ or (aged or elderly).tw.
83. gender/ or gender.tw.
84. or/66-83
85. and/6,84
86. and/6,30,84
87. randomized controlled trial.pt.
88. controlled clinical trial.pt.
89. random$.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$).tw.
30. (decision adj (support or aid* or process* or tool*)).tw.
31. ((informed adj1 consent) or consent*).tw.
32. (proxy or proxies).tw.
33. or/20-32
34. cooperative behavior/ or (cooperative adj behavior?).tw.
35. personal autonomy/ or (personal adj autonomy).tw.
36. Health Knowledge, Attitudes, Practice/
37. informed consent.tw.hw.
38. communication/ or (communication* or discussion* or conversation*).tw.
39. Professional-Family Relations/
40. ((patient$ 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. |
| 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. |
| 22. cardioverter-defibrillator*.mp. |
| 23. exp Cardiac Pacing, Artificial/ |
| 24. (artificial adj pacing).mp. |
| 25. ((cardiac or heart) adj resynchron?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/ |
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$)).tw.
36. (shared adj decision adj making).tw.
37. (decision adj (support or aid* or process* or tool*)).tw.
38. (informed adj1 choice).tw.
40. treatment refusal/ or (treatment adj refusal).tw.
41. withholding treatment/ or (withholding adj treatment*).tw.
42. ethics, medical/ or bioethics/ or (ethics or ethical).tw.
43. (barriers or barrier).tw.
44. anxiety/ or anxiety.tw.
45. exp pain/ or pain*.tw.
46. (cultur* or customs or belief*).tw.
47. exp depression/ or (depression or depressed or depressive).tw.
48. gender/ or gender.tw.
49. age factors/ or aged/ or (aged or elderly).tw.
50. exp distress/
51. exp caregiver burden/
52. (deactivation or deactivating or deactivate*).tw.
53. or/24-52
54. clinical trial/
55. clinical trial:.mp.
56. random:.tw.
57. placebo:.mp.
58. double-blind:.tw.
59. or/54-58
60. and/17,23,59
61. limit 60 to (human and english language and yr="1990 -Current")
62. and/17,53,59
63. (pre-test or post-test).mp.
64. quasi-experimental.tw.
65. or/63-64
66. and/17,23,65
67. and/17,53,65
68. or/66-67
69. limit 68 to (human and english language and yr="1990 -Current")
70. cohort analysis/
71. longitudinal studies/
72. follow-up studies/
73. prospective studies/
74. retrospective studies/
75. observation methods/
76. (observation$ 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>
<thead>
<tr>
<th>Table A–6. Medline focused search</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHRQ device tool project _MEDLINE - new focused search_8Feb11</td>
</tr>
<tr>
<td>MEDLINE - 8Feb11 - RCT filter and no qual filter</td>
</tr>
</tbody>
</table>

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.
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 resynchron$i?ation$).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 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.

A–10
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>
<thead>
<tr>
<th>Table A–7. EMBASE focused search</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHRQ device tool project _EMBASE - new focused search_2Feb11</td>
</tr>
<tr>
<td>EMBASE -8Feb11 - RCT filter and no qual filter</td>
</tr>
<tr>
<td>1. artificial heart pacemaker/</td>
</tr>
<tr>
<td>2. defibrillator/</td>
</tr>
<tr>
<td>3. pacemaker*.tw.</td>
</tr>
<tr>
<td>4. Heart Assist Device/</td>
</tr>
<tr>
<td>5. (artificial adj1 ventricle*).tw.</td>
</tr>
<tr>
<td>6. (implantable adj2 defibrillator*).tw.</td>
</tr>
<tr>
<td>7. (implantable adj2 device*).tw.</td>
</tr>
<tr>
<td>8. ((ICD or ICDs or CIED or CIEDs) and implantable).tw.</td>
</tr>
<tr>
<td>10. (artificial adj pacing).tw.</td>
</tr>
<tr>
<td>11. ((cardiac adj resynchroni?ation*) or (heart adj resynchroni?ation)).tw.</td>
</tr>
<tr>
<td>12. or/1-11</td>
</tr>
<tr>
<td>13. treatment refusal/</td>
</tr>
<tr>
<td>14. treatment withdrawal/</td>
</tr>
<tr>
<td>15. (withdrawal or withdrawing).tw.</td>
</tr>
<tr>
<td>16. device removal/</td>
</tr>
<tr>
<td>17. (device* adj1 remov*).tw.</td>
</tr>
<tr>
<td>18. (deactivation or deactivating or deactivate*).tw.</td>
</tr>
<tr>
<td>19. medical ethics/</td>
</tr>
<tr>
<td>20. (ethics or ethic or ethical).tw.</td>
</tr>
<tr>
<td>21. medicolegal.tw.</td>
</tr>
<tr>
<td>22. exp terminal care/</td>
</tr>
<tr>
<td>23. hospice care/</td>
</tr>
<tr>
<td>24. palliative therapy/</td>
</tr>
<tr>
<td>25. ((palliative or hospice or terminal) adj care).tw.</td>
</tr>
<tr>
<td>26. terminally ill patient/</td>
</tr>
<tr>
<td>27. exp euthanasia/</td>
</tr>
<tr>
<td>28. assisted suicide/</td>
</tr>
<tr>
<td>29. ((ICD* adj2 discharge*) and distress*).tw.</td>
</tr>
<tr>
<td>30. ((ICD* adj2 discharge*) and inappropriate).tw.</td>
</tr>
<tr>
<td>31. end-of-life.ti.</td>
</tr>
<tr>
<td>32. or/13-31</td>
</tr>
<tr>
<td>33. and/12,32</td>
</tr>
<tr>
<td>34. clinical trial/</td>
</tr>
</tbody>
</table>
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 resynchron?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

<table>
<thead>
<tr>
<th>No.</th>
<th>Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>exp &quot;Fibrillation (Heart)&quot;/</td>
</tr>
<tr>
<td>2</td>
<td>exp Artificial Pacemakers/</td>
</tr>
<tr>
<td>3</td>
<td>((artificial or cardiac) adj2 pacemaker*).mp.</td>
</tr>
<tr>
<td>4</td>
<td>pacemaker*.tw.</td>
</tr>
<tr>
<td>5</td>
<td>((heart-assist or vascular-assist or ventricular-assist) adj (device* or pump*).mp.</td>
</tr>
<tr>
<td>6</td>
<td>(implantable adj2 defibrillator*).mp.</td>
</tr>
<tr>
<td>7</td>
<td>(implantable adj2 cardiac adj2 device*).mp.</td>
</tr>
<tr>
<td>8</td>
<td>((ICD or ICDs) and implantable).tw.</td>
</tr>
<tr>
<td>9</td>
<td>((external adj2 defibrillator*) not aed).mp.</td>
</tr>
<tr>
<td>10</td>
<td>((cardiac or heart) adj resynchroni?ation$).mp.</td>
</tr>
<tr>
<td>11</td>
<td>cardioverter-defibrillator*.mp.</td>
</tr>
<tr>
<td>12</td>
<td>((biventricular or dual-chamber or single-chamber) adj1 (pacing or pacer or stimulat$)).mp.</td>
</tr>
<tr>
<td>13</td>
<td>((VAD or LVAD or CIED or ICD) and device*).tw.</td>
</tr>
<tr>
<td>14</td>
<td>or/1-13</td>
</tr>
<tr>
<td>15</td>
<td>exp Treatment Refusal/</td>
</tr>
<tr>
<td>16</td>
<td>exp Treatment Withholding/</td>
</tr>
<tr>
<td>17</td>
<td>life sustaining treatment/</td>
</tr>
<tr>
<td>18</td>
<td>(withdrawal or withdrawing).tw.</td>
</tr>
<tr>
<td>19</td>
<td>(device* adj1 remov*).tw.</td>
</tr>
<tr>
<td>20</td>
<td>(deactivation or deactivating or deactivate*).tw.</td>
</tr>
<tr>
<td>21</td>
<td>advance directives/</td>
</tr>
<tr>
<td>22</td>
<td>exp Terminally Ill Patients/</td>
</tr>
<tr>
<td>23</td>
<td>exp Hospice/</td>
</tr>
<tr>
<td>24</td>
<td>exp Palliative Care/</td>
</tr>
<tr>
<td>25</td>
<td>((palliative or hospice or terminal) adj care).tw.</td>
</tr>
<tr>
<td>26</td>
<td>((palliative or hospice or terminal) adj treatment).tw.</td>
</tr>
<tr>
<td>27</td>
<td>((palliative or hospice or terminal) adj setting).tw.</td>
</tr>
<tr>
<td>28</td>
<td>exp Bioethics/</td>
</tr>
<tr>
<td>29</td>
<td>(ethics or ethic or ethical).tw.</td>
</tr>
<tr>
<td>30</td>
<td>medicolegal.tw.</td>
</tr>
<tr>
<td>31</td>
<td>euthanasia/</td>
</tr>
<tr>
<td>32</td>
<td>exp Assisted Suicide/</td>
</tr>
<tr>
<td>33</td>
<td>exp Death Attitudes/</td>
</tr>
<tr>
<td>34</td>
<td>exp &quot;Death and Dying&quot;/</td>
</tr>
<tr>
<td>35</td>
<td>(end-of-life or &quot;end of life&quot;).tw.</td>
</tr>
<tr>
<td>36</td>
<td>((defibrillator adj2 discharge*) and (anxiety* or fear* or inappropriate or stress or distress)).tw.</td>
</tr>
<tr>
<td>37</td>
<td>((ICD adj2 discharge*) and (anxiety* or fear* or inappropriate or stress or distress)).tw.</td>
</tr>
<tr>
<td>38</td>
<td>((device adj2 discharge*) and (anxiety* or fear* or inappropriate or stress or distress)).tw.</td>
</tr>
<tr>
<td>39</td>
<td>or/15-38</td>
</tr>
<tr>
<td>40</td>
<td>and/14,39</td>
</tr>
</tbody>
</table>
# 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

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

**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
2. 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

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family/Caregivers</td>
<td></td>
</tr>
<tr>
<td>Health Professionals</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Heart Failure: Should I Get an Implantable Cardioverter-Defibrillator (ICD)?*</th>
<th>Heart Rate Problems: Should I Get an Implantable Cardioverter-Defibrillator (ICD)?†</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Section 1: Get the facts</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Your Options</strong></td>
<td><strong>Your Options</strong></td>
</tr>
<tr>
<td>• Get an ICD</td>
<td>• Get an ICD</td>
</tr>
<tr>
<td>• Don’t get an ICD</td>
<td>• Don’t get an ICD</td>
</tr>
<tr>
<td><strong>Key points to remember</strong></td>
<td><strong>Key points to remember</strong></td>
</tr>
<tr>
<td>• Your doctor suggest an ICD if you are at risk of having an abnormal heart rhythm that could cause sudden death</td>
<td>• 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</td>
</tr>
<tr>
<td>• 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.</td>
<td>• Your doctor may suggest an ICD if you are at risk of having an abnormal heart rhythm that could cause sudden death</td>
</tr>
<tr>
<td>• 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.</td>
<td>• 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</td>
</tr>
<tr>
<td>• 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.</td>
<td>• The shock from an ICD hurts briefly</td>
</tr>
<tr>
<td>• Even with an ICD, you may still need to take medicine to help prevent a deadly abnormal heart rate</td>
<td></td>
</tr>
<tr>
<td><strong>Frequently asked questions</strong></td>
<td><strong>Frequently asked questions</strong></td>
</tr>
<tr>
<td>• How can heart failure affect heart rhythm?</td>
<td>• What is an ICD?</td>
</tr>
<tr>
<td>• How can an ICD help?</td>
<td>• How is an ICD placed?</td>
</tr>
<tr>
<td>• How is the ICD placed?</td>
<td>• How does it feel to get a shock from an ICD?</td>
</tr>
<tr>
<td>• How does it feel to get a shock from an ICD?</td>
<td>• What are the benefits of an ICD?</td>
</tr>
<tr>
<td>• Who might want an ICD?</td>
<td>• What are the risks and side effects of an ICD?</td>
</tr>
<tr>
<td>• Who might not want an ICD?</td>
<td>• What followup do you need after getting an ICD?</td>
</tr>
<tr>
<td>• What are the benefits of an ICD?</td>
<td>• Why might your doctor recommend an ICD?</td>
</tr>
<tr>
<td>• What are the risks of an ICD?</td>
<td></td>
</tr>
<tr>
<td>• What followup do you need after getting an ICD?</td>
<td></td>
</tr>
</tbody>
</table>

**Section 2: Compare Options**

<table>
<thead>
<tr>
<th>Get an ICD</th>
<th>Don’t get an ICD</th>
<th>Get an ICD</th>
<th>Don’t get an ICD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What is</strong></td>
<td><strong>What is</strong></td>
<td><strong>What is</strong></td>
<td><strong>What is</strong></td>
</tr>
<tr>
<td>• Your doctor will numb the area with</td>
<td>• You keep taking heart</td>
<td>• You will have minor surgery to have the</td>
<td>• You follow a healthy</td>
</tr>
</tbody>
</table>

---

| 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 |
### Section 3: Patient Values

**What matters most to you?**

<table>
<thead>
<tr>
<th>Reasons to get an ICD</th>
<th>Reasons not to get an ICD</th>
</tr>
</thead>
<tbody>
<tr>
<td>I want to do everything I can to prevent a deadly heart rhythm</td>
<td>I would rather use only medicine to lower my chance of a deadly heart rate</td>
</tr>
<tr>
<td>1 More important</td>
<td>4 Equally important</td>
</tr>
<tr>
<td>I'm not worried that the ICD might shock me</td>
<td>I would worry all the time that the ICD might shock me</td>
</tr>
<tr>
<td>1 More important</td>
<td>4 Equally important</td>
</tr>
<tr>
<td>I don't mind having a device inside my body</td>
<td>I don't like the idea of having a device inside my body</td>
</tr>
<tr>
<td>1 More important</td>
<td>4 Equally important</td>
</tr>
<tr>
<td>I'm not worried that the ICD might shock me</td>
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</tr>
<tr>
<td>1 More important</td>
<td>4 Equally important</td>
</tr>
</tbody>
</table>

My other important reasons:

<table>
<thead>
<tr>
<th>Reasons to get an ICD</th>
<th>Reasons not to get an ICD</th>
</tr>
</thead>
<tbody>
<tr>
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My other important reasons:

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<tbody>
<tr>
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<td>1 More important</td>
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</tr>
<tr>
<td>1 More important</td>
<td>4 Equally important</td>
</tr>
<tr>
<td>I don't mind having a device inside my body</td>
<td>I don't like the idea of having a device inside my body</td>
</tr>
<tr>
<td>1 More important</td>
<td>4 Equally important</td>
</tr>
</tbody>
</table>

### Section 4: Your Decision

**Where are you leaning now?**

<table>
<thead>
<tr>
<th>Getting an ICD</th>
<th>NOT getting an ICD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leaning toward</td>
<td>1 2 3 4 Undecided 5 6 7 Leaning toward</td>
</tr>
</tbody>
</table>

### Section 5: Quiz Yourself

**Check the facts**

1. I need to have an ICD if I have heart failure
   - True
   - False
   - I’m not sure
2. I’ll feel a painful shock if an ICD fixes a heart rhythm that could cause sudden death
   - True
   - False
   - I’m not sure
3. I might need surgery again someday if the ICD breaks or if it needs a new battery
   - True
   - False
   - 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?
3. **Yes**  **No**  Do you have enough support and advice from others to make a choice?

### Certainty

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td></td>
<td></td>
<td>Somewhat sure</td>
<td></td>
<td></td>
<td>Very sure</td>
</tr>
</tbody>
</table>

2. Check what you need to do before you make this decision
   - I'm ready to take action
   - I want to discuss the options with others
   - 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.


## Decision Aid: Pacemaker

### Heart Failure: Should I Get a Pacemaker (Cardiac Resynchronization Therapy)?*

#### Section 1: Get the facts

| Your Options | | | | | |
| - | • Get a pacemaker for heart failure | • Get a pacemaker for heart failure | • Get a pacemaker for heart failure | • Get a pacemaker for heart failure |
| - | • Don’t get a pacemaker for heart failure | • Don’t get a pacemaker for heart failure | • Don’t 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.

#### 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?

### Hear Rate Problems: Should I Get a Pacemaker? †

#### Section 2: Compare Options

<table>
<thead>
<tr>
<th>Get an ICD</th>
<th>Don’t get an ICD</th>
<th>Get an ICD</th>
<th>Don’t get an ICD</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is usually involved?</td>
<td>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.</td>
<td>You take medicines for heart failure. Your doctor may change the type or dose of your medicines. You have to eat healthy</td>
<td>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.</td>
</tr>
</tbody>
</table>

---

* Heart Failure: Should I Get a Pacemaker (Cardiac Resynchronization Therapy)? Healthwise Knowledgebase 2010.
<table>
<thead>
<tr>
<th>What are the benefits?</th>
<th>The risks from surgery are usually low. But they may be different for each person. Here are some possible risks:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• A pacemaker can help you feel better so you can be more active.</td>
<td></td>
</tr>
<tr>
<td>• It can help keep you out of the hospital and help you live longer.</td>
<td></td>
</tr>
<tr>
<td>• 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.</td>
<td></td>
</tr>
<tr>
<td>• You won’t have the risk of infection or other problems from the surgery.</td>
<td></td>
</tr>
<tr>
<td>What are the risks and side effects?</td>
<td>• Your symptoms could get worse. This would limit your ability to do your daily activities.</td>
</tr>
<tr>
<td></td>
<td>• If your heart failure gets worse, you may have to go into the hospital a lot.</td>
</tr>
<tr>
<td></td>
<td>• You might not live as long as you could if you had a pacemaker.</td>
</tr>
<tr>
<td></td>
<td>• Problems can happen during or soon after the procedure. Examples include a lead tearing the heart or a lung collapsing.</td>
</tr>
<tr>
<td></td>
<td>• There might be problems with the pacemaker wires like infection or breaks.</td>
</tr>
<tr>
<td></td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• You will need surgery to replace the battery, which lasts 8 to 10 years.</td>
</tr>
<tr>
<td></td>
<td>• Your symptoms could get worse. This would limit your ability to do your daily activities</td>
</tr>
<tr>
<td></td>
<td>• You might be at risk for fainting or falling, which could be dangerous.</td>
</tr>
</tbody>
</table>
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?

<table>
<thead>
<tr>
<th>Reasons to get a pacemaker</th>
<th>Reasons not to get a pacemaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>I want to feel better so that I can do my daily activity</td>
<td>I’m not having too much trouble doing my daily activity</td>
</tr>
<tr>
<td>More important</td>
<td>Equally important</td>
</tr>
<tr>
<td>I don’t mind having a device in my chest</td>
<td>I don’t like the idea of having a device in my chest</td>
</tr>
<tr>
<td>More important</td>
<td>Equally important</td>
</tr>
<tr>
<td>My medicines aren’t controlling my symptoms anymore</td>
<td>My symptoms aren’t getting worse</td>
</tr>
<tr>
<td>More important</td>
<td>Equally important</td>
</tr>
<tr>
<td>I’m not worried about risks of surgery, because they’re small</td>
<td>I don’t want to take a chance that something could go wrong during surgery</td>
</tr>
<tr>
<td>More important</td>
<td>Equally important</td>
</tr>
<tr>
<td>My other important reasons:</td>
<td>My other important reasons:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Get a pacemaker</th>
<th>NOT get a pacemaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leaning toward</td>
<td>Undecided</td>
</tr>
</tbody>
</table>

Section 4: Your Decision
Where are you leaning now?

<table>
<thead>
<tr>
<th>Get a pacemaker</th>
<th>NOT get a pacemaker</th>
</tr>
</thead>
</table>

Section 5: Quiz Yourself
What else do you need to make your decision?

Check the facts

<table>
<thead>
<tr>
<th>1. If I get a pacemaker, I still need to follow a healthy lifestyle</th>
</tr>
</thead>
<tbody>
<tr>
<td>True</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. I don’t need a pacemaker if I don’t have any symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>True</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. A pacemaker may help symptoms caused by my heart rate problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>True</td>
</tr>
</tbody>
</table>
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.
   - I’m ready to take action
   - I want to discuss the options with others
   - 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.

Appendix D. List of Excluded Studies

Intervention Studies


Qualitative Studies


10.1186/747-5341-3-20. PMID: 18694496. (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)


Communication Studies


Psychosocial Studies


Appendix E. Evidence Tables (KQ 4)

Qualitative Studies Included on General Experiences

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Approach</th>
<th>Population</th>
<th>Device type</th>
<th>Foci</th>
<th>Sample (M/F)</th>
<th>Sample Description</th>
<th>Study Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agard et al., 2007</td>
<td>General</td>
<td>HF</td>
<td>ICD only</td>
<td>Insertion</td>
<td>25M, 6F</td>
<td>Pt perspectives on their role in initiating ICD therapy</td>
<td>M</td>
</tr>
<tr>
<td>Anderson, 2004</td>
<td>Grounded theory</td>
<td>Non–HF</td>
<td>Pacemaker</td>
<td>Living with technology</td>
<td>8M</td>
<td>War veterans with pacemakers</td>
<td>L</td>
</tr>
<tr>
<td>Andersen et al., 2008</td>
<td>Systematic text condensation (Giorgi)</td>
<td>Non–HF</td>
<td>ICD only</td>
<td>Daily life challenges</td>
<td>3M, 4F (not all had ICD)</td>
<td>Pts with a congenital disease</td>
<td>M</td>
</tr>
<tr>
<td>Beery, 1998</td>
<td>Phenomenology</td>
<td>Non–HF</td>
<td>Pacemaker</td>
<td>Living with biotechnology</td>
<td>11F</td>
<td>Female pts perspectives</td>
<td>H</td>
</tr>
<tr>
<td>Beery et al., 2002</td>
<td>Life story method (Hall)</td>
<td>Non–HF</td>
<td>Pacemaker</td>
<td>Adjustment</td>
<td>11F</td>
<td>Female pts perspectives</td>
<td>H</td>
</tr>
<tr>
<td>Berger et al., 2006</td>
<td>Survey</td>
<td>HF</td>
<td>Non–HF</td>
<td>ICD only</td>
<td>Deactivation</td>
<td>47M, 10F</td>
<td>Pts with ICD for &gt;1 month</td>
</tr>
<tr>
<td>Bolse et al., 2002</td>
<td>Longitudinal survey</td>
<td>HF</td>
<td>Non–HF</td>
<td>ICD only</td>
<td>Life situation</td>
<td>42M, 14F</td>
<td>Pre- and post-ICD implant</td>
</tr>
<tr>
<td>Bolse et al., 2005</td>
<td>Grounded theory (weak phenomenography)</td>
<td>HF</td>
<td>ICD only</td>
<td>Living with an ICD</td>
<td>8M, 6F</td>
<td>Pt perceptions of their life situation</td>
<td>L</td>
</tr>
<tr>
<td>Burke, 1995</td>
<td>Grounded theory</td>
<td>HF</td>
<td>Non–HF</td>
<td>ICD only</td>
<td>Insertion</td>
<td>14M, 10F</td>
<td>Pt perspectives on living with ICD</td>
</tr>
<tr>
<td>Dickerson, 2002</td>
<td>Phenomenology</td>
<td>Non–HF</td>
<td>ICD only</td>
<td>Living with an ICD</td>
<td>18M, 41F</td>
<td>Pt perspectives on living with ICD</td>
<td>H</td>
</tr>
<tr>
<td>Dougherty, 1994</td>
<td>Longitudinal survey</td>
<td>HF</td>
<td>ICD only</td>
<td>Insertion; adjustment</td>
<td>13M, 2F</td>
<td>Pt and family perspectives on living with an ICD</td>
<td>M</td>
</tr>
<tr>
<td>Dougherty et al., 2000</td>
<td>Grounded theory</td>
<td>Non–HF</td>
<td>ICD only</td>
<td>Insertion (1st year following)</td>
<td>13M, 2F</td>
<td>Pt and family perspectives of ICD</td>
<td>M</td>
</tr>
<tr>
<td>Dunbar et al., 1993</td>
<td>Mixed methods</td>
<td>Non–HF</td>
<td>ICD only</td>
<td>Shock discharge</td>
<td>20M, 2F</td>
<td>Pt experiences of ICD shocks</td>
<td>M</td>
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<tr>
<td>Eckert et al., 2002</td>
<td>General (weak phenomenography)</td>
<td>HF</td>
<td>ICD only</td>
<td>Daily life challenges</td>
<td>3M Cgs</td>
<td>Pt and family ICD experience</td>
<td>L</td>
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<tr>
<td>Flemme et al., 2001</td>
<td>Longitudinal survey</td>
<td>HF</td>
<td>ICD only</td>
<td>Life situation</td>
<td>42M, 14F</td>
<td>Life changes of ICD Pts over 1 year period</td>
<td>H</td>
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<tr>
<td>Fridlund et al., 2000</td>
<td>Phenomenography</td>
<td>HF</td>
<td>ICD only</td>
<td>Life conceptions</td>
<td>10M, 5F</td>
<td>Pt life conceptions</td>
<td>L</td>
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<tr>
<td>Gibson et al., 2008</td>
<td>Cohort</td>
<td>Not reported</td>
<td>ICD only</td>
<td>Malfunction</td>
<td>22M, 9F</td>
<td>Effect of device recall on Pts</td>
<td>M</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Approach</td>
<td>Population</td>
<td>Device type</td>
<td>Foci</td>
<td>Sample (M/F)</td>
<td>Sample Description</td>
<td>Study Quality</td>
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<tr>
<td>Goldstein et al., 2008&lt;sup&gt;45&lt;/sup&gt;</td>
<td>Grounded theory</td>
<td>HF</td>
<td>ICD only</td>
<td>Deactivation/End-of-life</td>
<td>10M, 5F</td>
<td>Pt attitudes towards deactivation</td>
<td>M</td>
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<tr>
<td>Kaufman et al., 2011&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Ethnography</td>
<td>HF</td>
<td>ICD only</td>
<td>Insertion, End-of-life</td>
<td>2 M</td>
<td>ICD–related ethical dilemmas for pts≥80 years</td>
<td>H</td>
</tr>
<tr>
<td>Kelley et al., 2009&lt;sup&gt;23&lt;/sup&gt;</td>
<td>Survey</td>
<td>Non–HF</td>
<td>ICD only</td>
<td>Deactivation</td>
<td>374M, 184F</td>
<td>Physician attitudes re: ICD deactivation</td>
<td>M</td>
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<tr>
<td>Lewis et al., 2006&lt;sup&gt;8&lt;/sup&gt;</td>
<td>Cohort</td>
<td>HF</td>
<td>ICD only</td>
<td>Deactivation</td>
<td>51M, 12F</td>
<td>ICD withdrawal as comfort care for terminally ill</td>
<td>M</td>
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<tr>
<td>Matlock et al., 2010&lt;sup&gt;86&lt;/sup&gt;</td>
<td>General</td>
<td>HF</td>
<td>ICD, LVAD, pacemaker</td>
<td>Insertion</td>
<td>16M, 6F</td>
<td>Pt styles of decisionmaking in relation to HF</td>
<td>M</td>
</tr>
<tr>
<td>Noyes et al., 2009&lt;sup&gt;105&lt;/sup&gt;</td>
<td>Randomized trial</td>
<td>HF</td>
<td>ICD only</td>
<td>Quality of life</td>
<td>499M, 102F</td>
<td>Pt perspectives on ICD and quality of life</td>
<td>M</td>
</tr>
<tr>
<td>Ong, 2008&lt;sup&gt;111&lt;/sup&gt;</td>
<td>Cohort</td>
<td>HF</td>
<td>ICD only</td>
<td>Daily life challenges</td>
<td>105M, 25F</td>
<td>Effects of CBT intervention</td>
<td>M</td>
</tr>
<tr>
<td>Prudente et al., 2006&lt;sup&gt;109&lt;/sup&gt;</td>
<td>Case control</td>
<td>Not reported</td>
<td>ICD only</td>
<td>Quality of life</td>
<td>59M, 16F</td>
<td>Phantom shocks in ICD pts</td>
<td>L</td>
</tr>
<tr>
<td>Sneed et al., 1992&lt;sup&gt;37&lt;/sup&gt;</td>
<td>General</td>
<td>HF</td>
<td>ICD only</td>
<td>Life adjustments</td>
<td>10M, 5F (14 Cgs)</td>
<td>ICD recipients and significant others</td>
<td>M</td>
</tr>
<tr>
<td>Sossong, 2007&lt;sup&gt;23&lt;/sup&gt;</td>
<td>Survey</td>
<td>HF</td>
<td>ICD only</td>
<td>Living with an ICD</td>
<td>79M, 11F</td>
<td>HF pts living with ICD</td>
<td>H</td>
</tr>
<tr>
<td>Steinke et al., 2005&lt;sup&gt;84&lt;/sup&gt;</td>
<td>General</td>
<td>Not reported</td>
<td>ICD only</td>
<td>General</td>
<td>10 M, 2F (4Cgs)</td>
<td>ICD pts and intimacy with partners</td>
<td>H</td>
</tr>
<tr>
<td>Stewart et al., 2010&lt;sup&gt;112&lt;/sup&gt;</td>
<td>Cohort</td>
<td>HF</td>
<td>ICD only</td>
<td>Deactivation</td>
<td>70M, 35F</td>
<td>Pt expectations of ICDs</td>
<td>M</td>
</tr>
<tr>
<td>Strachan et al., 2011&lt;sup&gt;47&lt;/sup&gt;</td>
<td>Grounded theory</td>
<td>HF</td>
<td>ICD only</td>
<td>End-of-life</td>
<td>24M, 6F</td>
<td>Pt perspectives on end-of-life care</td>
<td>H</td>
</tr>
<tr>
<td>Tagney et al., 2003&lt;sup&gt;99&lt;/sup&gt;</td>
<td>General</td>
<td>HF</td>
<td>ICD only</td>
<td>Living with an ICD</td>
<td>6M, 2F</td>
<td>Pt experiences of learning to live with ICD</td>
<td>M</td>
</tr>
<tr>
<td>Wallace et al., 2002&lt;sup&gt;34&lt;/sup&gt;</td>
<td>Survey</td>
<td>HF</td>
<td>ICD only</td>
<td>Psychosocial sequelae</td>
<td>44M, 14F</td>
<td>ICD for treatment of arrhythmias</td>
<td>H</td>
</tr>
<tr>
<td>Williams et al., 2004&lt;sup&gt;100&lt;/sup&gt;</td>
<td>General</td>
<td>HF</td>
<td>ICD only</td>
<td>Living with an ICD</td>
<td>8M, 3F (9F, 2M Cgs)</td>
<td>Pt and Cgs support group involvement</td>
<td>L</td>
</tr>
</tbody>
</table>

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
## Quantitative Studies Included on Psychosocial Outcomes

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Study Design</th>
<th>Country</th>
<th>Sample (M/F) Pts / age(years)</th>
<th>Device</th>
<th>Foci</th>
<th>Study Quality (H/M/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilge et al., 2006</td>
<td>Cohort</td>
<td>Turkey</td>
<td>91 Pts 79M, 12F Mean age: 53 yrs Range: 18–86 yrs</td>
<td>ICD</td>
<td>Shock vs. no shock</td>
<td>M</td>
</tr>
<tr>
<td>Thomas et al., 2009</td>
<td>Cohort</td>
<td>U.S., Canada, New Zealand</td>
<td>57 Pts 47M, 10F Mean age: 59.8 yrs Range: 51–69.3 yrs</td>
<td>ICD</td>
<td>Shock vs. no shock</td>
<td>H</td>
</tr>
<tr>
<td>Van den Broek et al., 2008</td>
<td>Cohort</td>
<td>The Netherlands</td>
<td>308 Pts 254M, 54F Mean age: 62.6 yrs Range: 24–79 yrs</td>
<td>ICD</td>
<td>Shock vs. no shock</td>
<td>H</td>
</tr>
<tr>
<td>Van Den Broek et al., 2009</td>
<td>Cohort</td>
<td>The Netherlands</td>
<td>205 Pts 179M, 26F Mean age: 62.1 yrs Range: 24–79 yrs</td>
<td>ICD</td>
<td>Shock vs. no shock</td>
<td>H</td>
</tr>
<tr>
<td>Pauli et al., 2001</td>
<td>Cohort</td>
<td>Germany</td>
<td>24 Pts Mean age: 53 yrs Range: 35–60 yrs</td>
<td>ICD</td>
<td>Shock vs. no shock</td>
<td>M</td>
</tr>
<tr>
<td>Undavia et al., 2008</td>
<td>Cohort</td>
<td>U.S.</td>
<td>ICD recall group: 61 Pts 43M, 18F Mean age: 67.3 yrs Control group: 43 Pts 28M 15F Mean age: 64.6 yrs</td>
<td>ICD</td>
<td>Device recall vs. control</td>
<td>M</td>
</tr>
<tr>
<td>Van Den Broek et al., 2006</td>
<td>Repeated measures</td>
<td>The Netherlands</td>
<td>33 Pts 27M, 6F Mean age: 60 yrs</td>
<td>ICD</td>
<td>Device recall vs. control</td>
<td>L</td>
</tr>
<tr>
<td>Fisher et al., 2009</td>
<td>Trial</td>
<td>U.S.</td>
<td>100 Pts 78M 22F</td>
<td>ICD</td>
<td>Device recall vs. control</td>
<td>M</td>
</tr>
<tr>
<td>Birnie et al., 2009</td>
<td>Cohort</td>
<td>Canada</td>
<td>Device recall: 86 Pts Mean age: 67.7 yrs Control: 94 Pts Mean age: 64.9 yrs</td>
<td>ICD</td>
<td>Device recall vs. control</td>
<td>H</td>
</tr>
<tr>
<td>Carroll et al., 2010</td>
<td>Cohort</td>
<td>Canada</td>
<td>Primary prevention: 15 Pts Secondary prevention: 15 Pts</td>
<td>ICD</td>
<td>Primary vs. secondary prevention</td>
<td>H</td>
</tr>
<tr>
<td>Crossmann et al., 2007</td>
<td>Repeated measures</td>
<td>Germany</td>
<td>35 Pts 30M, 5F Mean age: 57 yrs Range: 35–65 yrs</td>
<td>ICD</td>
<td>Psychosocial sequelae</td>
<td>M</td>
</tr>
<tr>
<td>Wheeler et al., 2009</td>
<td>Repeated measures</td>
<td>NR</td>
<td>33 Pts 26M, 7F Mean age: 63.4 yrs</td>
<td>ICD</td>
<td>Psychosocial sequelae</td>
<td>M</td>
</tr>
<tr>
<td>Dougherty et al., 2009</td>
<td>Repeated measures</td>
<td>U.S.</td>
<td>100 partners of ICD Pts 36M, 164F Mean age: 60.9 yrs</td>
<td>ICD</td>
<td>Psychosocial sequelae</td>
<td>H</td>
</tr>
<tr>
<td>Crow et al., 1998</td>
<td>Repeated measures</td>
<td>U.S.</td>
<td>35 Pts</td>
<td>ICD</td>
<td>Psychosocial sequelae</td>
<td>L</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Study Design</td>
<td>Country</td>
<td>Sample (M/F) Pts / age(years)</td>
<td>Device</td>
<td>Foci</td>
<td>Study Quality (H/M/L)</td>
</tr>
<tr>
<td>-------------------------</td>
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</tr>
<tr>
<td>Pedersen et al., 2009²⁵</td>
<td>Cohort</td>
<td>The Netherlands</td>
<td>446 Pts 261M, 185F Mean age: 61.6 yrs</td>
<td>ICD</td>
<td>Psychosocial sequelae</td>
<td>M</td>
</tr>
<tr>
<td>Pedersen et al., 2009²⁴</td>
<td>Cross-sectional</td>
<td>Denmark</td>
<td>557 Pts 456M, 101F Mean age: 61.9 yrs</td>
<td>ICD</td>
<td>Psychosocial sequelae</td>
<td>H</td>
</tr>
<tr>
<td>Pedersen et al., 2010²¹</td>
<td>Repeated measures</td>
<td>The Netherlands</td>
<td>348 Pts 275M, 73F Mean age: 61 yrs Range: 16–73 yrs</td>
<td>ICD</td>
<td>Psychosocial sequelae</td>
<td>H</td>
</tr>
<tr>
<td>Pedersen et al., 2005²⁵</td>
<td>Cross-sectional</td>
<td>The Netherlands</td>
<td>182 Pts 147M, 35F Mean age: 62 yrs Range: 16–84 yrs</td>
<td>ICD</td>
<td>Psychosocial sequelae</td>
<td>H</td>
</tr>
<tr>
<td>Sowell et al., 2007²⁶</td>
<td>Cross-sectional</td>
<td>U.S.</td>
<td>62 Pts 31M, 9F Mean age: 66 yrs</td>
<td>ICD</td>
<td>Psychosocial sequelae</td>
<td>M</td>
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<tr>
<td>Spindler et al., 2009²⁷</td>
<td>Cross-sectional</td>
<td>Denmark</td>
<td>535 Pts 438M, 97F Mean age: 61.5 yrs</td>
<td>ICD</td>
<td>Psychosocial sequelae</td>
<td>H</td>
</tr>
<tr>
<td>Craney et al., 1997²⁸</td>
<td>Cross-sectional</td>
<td>U.S.</td>
<td>75 Pts Mean age: 64.5 yrs Range: 21–84 yrs</td>
<td>ICD</td>
<td>Coping strategies</td>
<td>H</td>
</tr>
<tr>
<td>Fritzsche et al., 2007²⁹</td>
<td>Repeated measures</td>
<td>Germany</td>
<td>160 Pts 145M, 35F Mean age: 61 yrs Range: 16–84 yrs</td>
<td>ICD</td>
<td>Coping strategies</td>
<td>M</td>
</tr>
<tr>
<td>Petrucci et al., 1999²³</td>
<td>Cohort</td>
<td>U.S.</td>
<td>21 LVAD Pts 19M, 3F Mean age: 49.6 yrs Range: 16–66 yrs 13 VAD Pts 6M, 7F Mean age: 56.5 yrs Range: 46–73 yrs</td>
<td>LVAD and VAD</td>
<td>Psychosocial sequelae</td>
<td>L</td>
</tr>
<tr>
<td>Duru et al., 2001²⁷</td>
<td>Cohort</td>
<td>Switzerland</td>
<td>152 Pts 114M, 38F Mean age: 58 yrs Range: 40–70 yrs</td>
<td>ICD and pacemaker</td>
<td>Psychosocial sequelae</td>
<td>M</td>
</tr>
<tr>
<td>Serber et al., 2003²⁸</td>
<td>Cohort</td>
<td>U.S.</td>
<td>96 Pts 66M, 26F Mean age: 62.2 yrs</td>
<td>ICD</td>
<td>Sleep quality</td>
<td>M</td>
</tr>
</tbody>
</table>

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
## Studies Included on Communication

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Study Design</th>
<th>Country</th>
<th>Sample (M/F) Pts / age(years)</th>
<th>Device</th>
<th>Foci</th>
<th>Study Quality (H/M/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goldstein et al., 2008</td>
<td>Qualitative</td>
<td>U.S.</td>
<td>12 physicians Mean age: 36.5 yrs</td>
<td>ICD</td>
<td>Deactivation</td>
<td>H</td>
</tr>
<tr>
<td>Goldstein et al., 2004</td>
<td>Mixed method</td>
<td>U.S.</td>
<td>100 next-of-kin of ICD pts</td>
<td>ICD</td>
<td>Deactivation</td>
<td>M</td>
</tr>
<tr>
<td>Goldstein et al., 2010</td>
<td>Cross-sectional</td>
<td>U.S.</td>
<td>414 hospices</td>
<td>ICD</td>
<td>Deactivation</td>
<td>M</td>
</tr>
<tr>
<td>Cladwell et al., 2007</td>
<td>Qualitative</td>
<td>Canada</td>
<td>20 Pts 14M, 6F</td>
<td>ICD</td>
<td>Communication</td>
<td>H</td>
</tr>
<tr>
<td>Serber et al., 2009</td>
<td>Cross-sectional</td>
<td>U.S.</td>
<td>108 participants 81M, 26F</td>
<td>ICD</td>
<td>Communication</td>
<td>M</td>
</tr>
<tr>
<td>Sherazi et al., 2008</td>
<td>Cross-sectional</td>
<td>U.S.</td>
<td>87 surveys</td>
<td>ICD</td>
<td>Training</td>
<td>L</td>
</tr>
<tr>
<td>Sherazi et al., 2010</td>
<td>Cross-sectional</td>
<td>U.S.</td>
<td>110 surveys</td>
<td>ICD</td>
<td>Training</td>
<td>M</td>
</tr>
</tbody>
</table>

H = high; ICD = implantable cardioverter-defibrillator; L = low; M = medium; Pts = patients
### Appendix F: Methodological Quality of Included Studies

#### Qualitative Studies

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Study Quality (L/M/H)</th>
<th>Assessment Tool Used</th>
<th>Main Strengths</th>
<th>Main Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agard et al., 2007</td>
<td>M</td>
<td>JBI–QARI</td>
<td>Sampling rationale; congruent study design</td>
<td>Sample interview questions not provided</td>
</tr>
<tr>
<td>Andersen, 2004</td>
<td>L</td>
<td>JBI–QARI</td>
<td>Data management; ethical protection of participants</td>
<td>Interpretation of data is questionable; conclusions seem not to flow from data</td>
</tr>
<tr>
<td>Andersen et al., 2008</td>
<td>M</td>
<td>JBI–QARI</td>
<td>Detailed, rigorous procedures enhance trustworthiness</td>
<td>Low enrollment rate</td>
</tr>
<tr>
<td>Beery, 1998</td>
<td>H</td>
<td>JBI–QARI</td>
<td>Rigorous data collection and analysis methods</td>
<td>Leading interview questions</td>
</tr>
<tr>
<td>Beery et al., 2002</td>
<td>H</td>
<td>JBI–QARI</td>
<td>Rigorous data collection and analysis methods</td>
<td>Potential sampling bias</td>
</tr>
<tr>
<td>Berger et al., 2006</td>
<td>L</td>
<td>Cross-sectional Appraisal Tool*</td>
<td>High enrollment rate</td>
<td>Instrument validity/reliability measures not reported; data analysis procedures not described</td>
</tr>
<tr>
<td>Bolse et al., 2002</td>
<td>M</td>
<td>Cohort–CASP</td>
<td>Detailed sampling and instrument descriptions</td>
<td>Different end-points among the sample populations</td>
</tr>
<tr>
<td>Bolse et al., 2005</td>
<td>L</td>
<td>JBI–QARI</td>
<td>Data analysis well described</td>
<td>Potential sampling bias; methodology (phenomenography) is not convincing</td>
</tr>
<tr>
<td>Burke, 1995</td>
<td>H</td>
<td>JBI–QARI</td>
<td>Methodologically rigorous; procedures described enhance trustworthiness</td>
<td>Quotes are not tied to interview participants</td>
</tr>
<tr>
<td>Dickerson, 2002</td>
<td>H</td>
<td>JBI–QARI</td>
<td>Large sample size; appropriate methods for phenomenology</td>
<td>Quotes are not tied to interview participants</td>
</tr>
<tr>
<td>Dougherty, 1994</td>
<td>M</td>
<td>Cohort–CASP</td>
<td>Multiple methods and recruitment sites</td>
<td>Interview data not represented in findings; potential sampling bias</td>
</tr>
<tr>
<td>Dougherty, 2000</td>
<td>M</td>
<td>JBI–QARI</td>
<td>Thorough methods; discusses data saturation</td>
<td>Interview focus does not reflect research purpose</td>
</tr>
<tr>
<td>Dunbar et al., 1993</td>
<td>M</td>
<td>JBI–QARI</td>
<td>Validity and reliability reported</td>
<td>No information on data analysis</td>
</tr>
<tr>
<td>Eckert, 2002</td>
<td>L</td>
<td>JBI–QARI</td>
<td>Findings deepen nursing practice</td>
<td>Numerous data collection strategies not reported; interpretation of data is questionable</td>
</tr>
<tr>
<td>Flemme, 2001</td>
<td>H</td>
<td>Cohort–CASP</td>
<td>Thoroughly describes theoretical framework; discusses reasons for nonparticipation</td>
<td>No rationale for selection of specific time points</td>
</tr>
<tr>
<td>Fridlund et al., 2000</td>
<td>L</td>
<td>JBI–QARI</td>
<td>Diverse sample population</td>
<td>Analysis appears superficial</td>
</tr>
<tr>
<td>Gibson et al., 2008</td>
<td>M</td>
<td>Cohort–CASP</td>
<td>Large sample size; detailed description of statistical analysis</td>
<td>Validity/reliability measures not reported for one instrument</td>
</tr>
<tr>
<td>Goldstein et al., 2008</td>
<td>M</td>
<td>JBI–QARI</td>
<td>Sound methods and rationale for data collection</td>
<td>Relatively homogenous sample</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Study Quality (L/M/H)</td>
<td>Assessment Tool Used</td>
<td>Main Strengths</td>
<td>Main Weaknesses</td>
</tr>
<tr>
<td>---------------------</td>
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<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>Kaufman, 2011¹</td>
<td>H</td>
<td>JBI–QARI</td>
<td>Case studies discussed in wider ethnographic context</td>
<td>None identified</td>
</tr>
<tr>
<td>Kelley, 2009²</td>
<td>M</td>
<td>Cross–sectional Appraisal Tool</td>
<td>Survey was pilot tested</td>
<td>Greater variation in vignettes</td>
</tr>
<tr>
<td>Lewis, 2006⁶</td>
<td>M</td>
<td>Cohort–CASP</td>
<td>Detailed patient demographics table</td>
<td>Retrospective data collection; no description of data analysis</td>
</tr>
<tr>
<td>Matlock, 2010⁹⁶</td>
<td>M</td>
<td>JBI–QARI</td>
<td>Detailed description of team approach to analysis</td>
<td>Interview questions not consistent among participants</td>
</tr>
<tr>
<td>Noyes, 2009¹⁰⁸</td>
<td>M</td>
<td>RCT–CASP</td>
<td>Long followup period; account for missing data</td>
<td>Not clear how randomization was conducted</td>
</tr>
<tr>
<td>Ong, 2008¹¹¹</td>
<td>M</td>
<td>Cohort–CASP</td>
<td>Double-blind, randomly assigned intervention</td>
<td>Low participation rate</td>
</tr>
<tr>
<td>Prudente et al., 2006¹⁰⁹</td>
<td>L</td>
<td>Case control–CASP</td>
<td>Discusses recruitment and blinding</td>
<td>No baseline data established; convenience sampling from single recruitment site</td>
</tr>
<tr>
<td>Sneed et al., 1992⁹⁷</td>
<td>M</td>
<td>JBI–QARI</td>
<td>Sound data collection and analysis strategies</td>
<td>Criteria for inclusion not reported</td>
</tr>
<tr>
<td>Sossong et al., 2007⁹³</td>
<td>H</td>
<td>Cross-sectional Appraisal Tool</td>
<td>Pilot study; external validation of instrument</td>
<td>Relatively homogenous sample</td>
</tr>
<tr>
<td>Steinke et al., 2005⁹⁸</td>
<td>H</td>
<td>JBI–QARI</td>
<td>Sound data collection and analysis strategies</td>
<td>Quotations are not tied to interview participants</td>
</tr>
<tr>
<td>Stewart, 2010¹¹²</td>
<td>M</td>
<td>Cohort–CASP</td>
<td>Appropriate analysis methods</td>
<td>Survey tool not validated; did not report size of confidence intervals</td>
</tr>
<tr>
<td>Strachan et al., 2011⁴⁷</td>
<td>H</td>
<td>JBI–QARI</td>
<td>Strong grounded theory approach and methods</td>
<td>Size of eligible sample not reported</td>
</tr>
<tr>
<td>Tagney, 2003⁹⁹</td>
<td>M</td>
<td>JBI–QARI</td>
<td>Interview guide was piloted</td>
<td>Low participation rate</td>
</tr>
<tr>
<td>Wallace et al., 2002⁹⁴</td>
<td>H</td>
<td>Cross–sectional Appraisal Tool</td>
<td>Detailed description of measures</td>
<td>Sample is largely male</td>
</tr>
<tr>
<td>Williams et al., 2004¹⁰⁰</td>
<td>L</td>
<td>JBI–QARI</td>
<td>Corroboration of data findings with participants</td>
<td>Ethical approval not reported; analysis appears superficial</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Study Quality (L/M/H)</th>
<th>Assessment Tool Used</th>
<th>Main Strengths</th>
<th>Main Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilge et al., 2006&lt;sup&gt;114&lt;/sup&gt;</td>
<td>M</td>
<td>CASP</td>
<td>Questionnaires were validated; long-term followup</td>
<td>No reporting on confidence intervals or effect sizes; small number of female participants</td>
</tr>
<tr>
<td>Thomas et al., 2009&lt;sup&gt;119&lt;/sup&gt;</td>
<td>H</td>
<td>CASP</td>
<td>Long-term followup; in-depth description of statistical analysis</td>
<td>47% response rate; 42% of attrition rate</td>
</tr>
<tr>
<td>Van den Broek et al., 2008&lt;sup&gt;120&lt;/sup&gt;</td>
<td>H</td>
<td>CASP</td>
<td>84% response rate; large sample size; in-depth description of statistical analysis</td>
<td>Small number of female participants</td>
</tr>
<tr>
<td>Van Den Broek et al., 2009&lt;sup&gt;121&lt;/sup&gt;</td>
<td>H</td>
<td>CASP</td>
<td>Large sample size; in-depth description of analysis process; confounding variables were controlled</td>
<td>Small number of female participants</td>
</tr>
<tr>
<td>Pauli et al., 2001&lt;sup&gt;122&lt;/sup&gt;</td>
<td>M</td>
<td>CASP</td>
<td>In-depth description of statistical analysis; results were consistent with previous studies using the same experimental procedures</td>
<td>Small sample size; not all confounding variables were controlled</td>
</tr>
<tr>
<td>Undavia et al., 2008&lt;sup&gt;124&lt;/sup&gt;</td>
<td>M</td>
<td>CASP</td>
<td>90% response rate</td>
<td>No reporting on confidence intervals or effect sizes; validity/reliability measures not reported for one instrument</td>
</tr>
<tr>
<td>Van Den Broek et al., 2006&lt;sup&gt;126&lt;/sup&gt;</td>
<td>L</td>
<td>Cross-Sectional Appraisal Tool*</td>
<td>90% response rate</td>
<td>Small sample size; results were mostly descriptive findings</td>
</tr>
<tr>
<td>Fisher et al., 2009&lt;sup&gt;139&lt;/sup&gt;</td>
<td>M</td>
<td>CASP</td>
<td>No dropout; in-depth description of study design and statistical analysis</td>
<td>27% of response rate; number of female patients was small to determine sex differences</td>
</tr>
<tr>
<td>Birnie et al., 2009&lt;sup&gt;115&lt;/sup&gt;</td>
<td>H</td>
<td>CASP</td>
<td>In-depth description of statistical analysis; sample size was determined by power calculation; long-term followup</td>
<td>Small number of female participants</td>
</tr>
<tr>
<td>Carroll et al., 2010&lt;sup&gt;118&lt;/sup&gt;</td>
<td>H</td>
<td>CASP</td>
<td>Equal number of male and female participants in the cohorts; validity/reliability of measures were reported; in-depth description of statistical analysis</td>
<td>Small sample size; no reporting on confidence intervals or effect sizes</td>
</tr>
<tr>
<td>Crossmann et al., 2007&lt;sup&gt;127&lt;/sup&gt;</td>
<td>M</td>
<td>CASP</td>
<td>Sample size was determined by power calculation; effect sizes were reported</td>
<td>43.5% of attrition rate</td>
</tr>
<tr>
<td>Wheeler et al., 2009&lt;sup&gt;133&lt;/sup&gt;</td>
<td>M</td>
<td>CASP</td>
<td>Long-term followup</td>
<td>Small sample size; not all confounding variables were controlled</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Study Quality (L/M/H)</td>
<td>Assessment Tool Used</td>
<td>Main Strengths</td>
<td>Main Weaknesses</td>
</tr>
<tr>
<td>------------------------------</td>
<td>----------------------</td>
<td>-----------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>------------------------------------------------------</td>
</tr>
<tr>
<td>Dougherty et al., 2009</td>
<td>H</td>
<td>CASP</td>
<td>86% of response rate; 9.1% attrition rate; in-depth description of statistical analysis</td>
<td>Small number of male participants</td>
</tr>
<tr>
<td>Crow et al., 1998</td>
<td>L</td>
<td>CASP</td>
<td>Long-term followup; assessment tool used is well validated</td>
<td>No description of statistical analysis; only reported descriptive findings</td>
</tr>
<tr>
<td>Pedersen et al., 2009</td>
<td>M</td>
<td>CASP</td>
<td>Validity/reliability of measures were reported; in-depth description of statistical analysis; confounding variables were controlled</td>
<td>Only included partners of ICD patients and not CHF patients; larger sample size in the ICD cohort</td>
</tr>
<tr>
<td>Pedersen et al., 2009</td>
<td>H</td>
<td>Cross–sectional Appraisal Tool</td>
<td>Large sample size; 86% of response rate; in-depth description of statistical analysis; odds ratios with 95% confidence intervals were reported for significant findings</td>
<td>Small number of female participants</td>
</tr>
<tr>
<td>Pedersen et al., 2010</td>
<td>H</td>
<td>CASP</td>
<td>In-depth description of statistical analysis; confounding variables were accounted; odds ratios with 95% confidence intervals were reported for significant findings</td>
<td>Small number of female participants</td>
</tr>
<tr>
<td>Pedersen et al., 2005</td>
<td>H</td>
<td>Cross–sectional Appraisal Tool</td>
<td>82% of response rate; large sample size; confounding variables were accounted; odds ratios with 95% confidence intervals were reported for significant findings</td>
<td>Small number of female participants</td>
</tr>
<tr>
<td>Sowell et al., 2007</td>
<td>M</td>
<td>Cross–sectional Appraisal Tool</td>
<td>Effect size was reported</td>
<td>Small number of female participants</td>
</tr>
<tr>
<td>Spindler et al., 2009</td>
<td>H</td>
<td>Cross–sectional Appraisal Tool</td>
<td>86% of response rate; in-depth description of statistical analysis</td>
<td>Small number of female participants</td>
</tr>
<tr>
<td>Craney et al., 1997</td>
<td>H</td>
<td>Cross–sectional Appraisal Tool</td>
<td>Sample size was determined by power calculation; in-depth description of statistical analysis and data transformation</td>
<td>Small number of female participants</td>
</tr>
<tr>
<td>Fritzutsche et al., 2007</td>
<td>M</td>
<td>CASP</td>
<td>Missing data were replaced using statistical techniques</td>
<td>37% of attrition rate; small number of female participants; confounding variables were not controlled in analysis</td>
</tr>
<tr>
<td>Petrucci et al., 1999</td>
<td>L</td>
<td>CASP</td>
<td>Long-term followup</td>
<td>Small sample size; no statistical analysis; only reported descriptive findings</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Study Quality (L/M/H)</td>
<td>Assessment Tool Used</td>
<td>Main Strengths</td>
<td>Main Weaknesses</td>
</tr>
<tr>
<td>------------------------</td>
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<td>----------------------</td>
<td>-------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Chamberlain, 2008\textsuperscript{128}</td>
<td>L</td>
<td>CASP</td>
<td>No missing data</td>
<td>Small sample size; no description of statistical analysis</td>
</tr>
<tr>
<td>Duru et al., 2001\textsuperscript{117}</td>
<td>M</td>
<td>CASP</td>
<td>Large sample size</td>
<td>Validity/reliability measures not reported for one instrument; not all confounding variables were controlled</td>
</tr>
<tr>
<td>Serber et al., 2003\textsuperscript{118}</td>
<td>M</td>
<td>CASP</td>
<td>Confounding variables were accounted</td>
<td>Number of female participants was small to determine gender differences</td>
</tr>
</tbody>
</table>

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

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

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

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