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Decision-Making Experiences of Patients with Implantable Cardioverter-Defibrillators

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Abstract

Background—When patients are not adequately engaged in decision making, they may be at risk of decision regret. Our objective was to explore patients' perceptions of their decision-making experiences related to implantable cardioverter-defibrillators (ICD).

Methods—Cross-sectional, mailed survey of 412 patients who received an ICD without cardiac resynchronization therapy (CRT) for any indication between 2006–2009. Patients were asked about decision participation and decision regret.

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Author contributions

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Results—295 patients with ICDs responded (72% response rate). Overall, 79% reported that they were as involved in the decision as they wanted. However, 28% reported that they were not told of the option of not getting an ICD and 37% did not remember being asked if they wanted an ICD. In total, 19% reported not wanting their ICD at the time of implantation. Those who did not want the ICD were younger (<65 years; 74% vs. 43%, $p<.001$), had higher decision regret (31/100 vs. 11/100, $p<.001$), and reported less participation in decision making (the doctor “totally” made the decision, 9% vs. 3%; $p<.001$).

Conclusions—A considerable number of ICD recipients recalled not wanting their ICD at the time of implantation. While these findings may be prone to recall bias, they likely identify opportunities to improve ICD decision making.

Keywords

ICDs; decision making; shared decision making; decision regret

Introduction

Implantable cardioverter-defibrillators (ICDs) have become a cornerstone of therapy for selected patients at risk of sudden cardiac death. Once used only for patients who had survived cardiac arrest (secondary prevention), ICDs are now broadly indicated to reduce mortality in patients at risk for lethal ventricular arrhythmias (primary prevention, as defined by class II–III heart failure and an ejection fraction of 35% or less).¹ More than 110,000 ICDs are implanted in the United States each year,² and a significant portion of the estimated 5 million patients in the United States with systolic heart failure may benefit from the devices to reduce their risk of sudden cardiac death.³

Despite survival benefits in appropriately selected patients, ICDs exemplify the complexities of decision making surrounding use of medical technologies to extend life. ICDs are a prophylactic therapy with potential harms: procedural complications, device malfunctions, inappropriate shocks, reduced quality of life, psychological distress, an increase in hospitalizations, and futile shocks that increase discomfort at the end of life.^{4–6} There is a pressing need to ensure that decision making regarding the devices is informed and consistent with patient preferences. Recognizing this need, the 2013 guidelines of the American College of Cardiology (ACC) and American Heart Association (AHA) recommend that physicians engage in shared decision making with patients and families surrounding ICD implantation. These guidelines specify that discussions should include the potential for sudden cardiac death as well as non-sudden death from other conditions.⁷ In addition, the ACC, AHA and American Medical Association have proposed a new health care quality metric that addresses “counseling about the potential benefits of ICDs.”⁸

Previous research has shown that patients overestimate the survival benefits associated with ICDs, and that their decisions regarding ICD implantation may be based on these assumptions.⁹ Cardiologists tend to minimize the potential harms of ICDs and instead emphasize potential survival benefits.^{10–13} Yet patients and families may make different healthcare decisions if fully informed and given the opportunity to engage in shared decision making.^{14–16} While there are many indications for ICDs and patients can receive ICDs for

primary or secondary prevention, the objective of this study was to explore patients' perceptions of their decision-making experiences related to their ICD, regardless of indication.

Methods

Design Overview

This was a cross-sectional study of patients from a large integrated delivery system in Colorado who had ICDs for either primary or secondary prevention. Patients completed a mailed survey regarding their experiences at the time of ICD implantation and thereafter.

Setting and Participants

Eligible patients were identified from a registry of ICD recipients developed for the Longitudinal Study of ICDs, a cohort established to understand a broad range of outcomes in patients receiving ICDs outside of the context of randomized controlled trials.¹⁷ All patients were enrolled in a nonprofit health plan with an integrated delivery system. Patients were included in the registry if they were 18 years of age or older, English speaking, and had received an ICD between 2006 and 2009. The survey was administered in 2011. Receipt of an ICD was determined based on the presence of an inpatient or outpatient procedure code for insertion or ongoing evaluation of a single or dual-chamber ICD (33240, 33245, 33246, 33249, 93282, 93283).

Survey Development

The survey was originally developed to test the psychometric properties of an instrument to measure the quality of ICD decision making, which was designed using previously-described methods.¹⁸ Briefly, decision quality involves a process of identifying key knowledge and values relating to the decision in question. The development of the ICD-specific decision quality measure (the ICD Decision Quality Instrument), including the identification and psychometric properties related to these knowledge and values items, will be reported in a separate report. The 75-question survey included a section on decision participation, which included 10 items. Six of these items were based on decision processes identified as being important by the International Patient Decision Aids Standards committee.¹⁹ These 6 items had good reliability estimates, with a Cronbach's alpha of 0.80. The remaining four participation items asked: "*Did you want an ICD?*", "*Who made the final decision about your ICD?*", "*How much were you involved in making the decision about your ICD?*" and an open ended response asking them to identify the "main reason" they got the ICD.

The survey also included the Decision Regret Scale, a validated tool for measuring regret after health care decisions (scored 0–100).²⁰ The scale includes five short statements such as, "*I regret the choice that was made,*" and "*I would go for the same choice if I had it to do over again.*" Participants are then asked to indicate the extent to which they agree or disagree with the statements by choosing a number from 1 ("*Strongly Agree*") to 5 ("*Strongly Disagree*"). Decision regret has a Cronbach's alpha of 0.81–0.92, and has been correlated with satisfaction, decision conflict, and quality of life. Additionally, the survey collected

information on patient demographics, self-reported health status and comorbidities, subjective memory complaints, knowledge of ICD function, risks and benefits, and history of ICD shocks since implantation.²¹ Comorbidities were assessed by asking, “*Has a doctor ever told you that you have any of the following [conditions]?*” Health literacy was assessed using an established 3-item screening tool that has been shown to have c-statistics of 0.74 and 0.84²² when compared to longer health literacy assessments and has been validated in patients with heart failure by demonstrating its association with poorer outcomes.^{23, 24} The full survey can be found in Appendix 1. No data were collected from the registry.

Consenting and Data Collection Procedures

Eligible patients from the registry were sent a letter about the survey with an opt-out postcard. Those who did not opt out were mailed the survey, and non-responders received another mailing. Patients who did not respond to any of the mailings were called up to nine times to ask them to complete the survey via telephone.^{24, 25} The opt-out approach was used to increase response rate and because it may reduce bias by eliminating barriers to participation, especially for functionally-impaired individuals or those in poor health.²⁶ It is possible (though unlikely) that some non-responders had died after being identified as eligible and before the initial mailing. The opt-out approach does not seem to be associated with increased distress among bereaved relatives as compared with an opt-in approach that requires potential participants to request the questionnaire by returning a reply slip.²⁶ The study was approved by the Institutional Review Board of the Kaiser Institute for Health Research.

Analysis

Participants were stratified by demographic characteristics (gender, age, race/ethnicity, education, marital status), the presence or absence of 12 comorbidities, subjective memory complaints, years since ICD implantation, participation in ICD decision making, values around living as long as possible vs. dying quickly, experience living with their ICDs, health literacy, and basic understanding of ICD function, risks and benefits. Those responding “Yes” or “No” to the question about wanting an ICD were compared using Pearson’s Chi-squared test for dichotomous outcomes and *t*-tests for continuous outcomes. P-values <0.05 were considered significant. Analyses were performed using Stata Version 12.0 software (Stata Corporation, College Station, TX).

Responses to the open-ended items were categorized using a simple card-sort methodology where like responses were grouped into categories using Microsoft Word.²⁷ Two investigators (DM and AJ) independently reviewed the transcripts to identify themes and met to develop consensus regarding which themes were represented by the quotes and how these themes could be categorized. The categories were developed using a mixed inductive and deductive approach.²⁸ The investigators then iteratively modified the initial categories as they reviewed subsequent transcripts.

Results

Sample Characteristics

A total of 295 patients with ICDs responded to the survey (response rate 72%). Demographic characteristics of respondents are reported in Table 1. Overall, 50% of study participants were aged ≥ 65 years, most were male and white. Patients had a high burden of comorbid illness: for example, 61% of respondents had congestive heart failure, 27% had diabetes, 16% had cancer (either current or past), 23% had depression, 21% had anxiety, 92% had more than one comorbidity, and 14% said their memory was a problem or a serious problem. Among respondents, 63% had an ICD for 4 or more years, and 43% had received an ICD shock since implantation, with 32% reporting multiple shocks.

Decision-Making Experiences

Overall, the majority of patients (79%) reported that they were involved in the decision making as much as they wanted (Table 2). However, 28% reported that they were not told that they had the option of not getting an ICD and 37% reported that they did not remember being asked if they wanted an ICD. The majority (93%) of patients reported that they had talked with their doctor about the reasons to get the ICD, while a considerably smaller percentage (61%) reported that they had talked with their doctor about reasons *not* to get an ICD (Table 3). In the only open-ended question asking patients their reasons for getting an ICD (Table 4), the most commonly identified reasons were that they got the ICD to improve health/heart failure/quality of life (29%) or to prolong life/avoid cardiac arrest (23%). A considerable proportion of patients reported that their major reason was that the doctor knows best (16%) or that they had no choice (17%).

Of the 263 respondents who answered the question about whether they wanted their ICD at the time of implantation, 19% reported that they did not want it. Those who stated that they did not want their ICD were younger (<65 years old; 74% vs. 43%, $p<0.001$) and reported higher decision regret (31/100 vs. 11/100, $p<0.001$). Survey respondents who indicated that they did not want their ICD recalled less participation in their decision making (Table 5). For example, they were less likely to feel that doctors had explained the option of *not* getting an ICD (58% vs. 80%, $p<0.002$) and were less likely to feel that doctors had discussed how they would feel if their heart failure continued to get worse. Overall, those who said they did not want their ICD were more likely to feel that the doctor made the final decision about whether or not they should get an ICD (the doctor “totally” made the decision, 9% vs. 3%; $p<0.001$).

There were no significant differences between those who did and did not want their ICD with respect to sex, race, education, marital status, or number of comorbidities. Also, patients wanting and not wanting their ICD were equally likely to have experienced a shock (41% vs. 53%, $p=.19$) and equally likely to value dying quickly over living as long as possible (6.76 vs. 6.14 out of 9, $p=.14$).

Discussion

In our survey of patients with ICDs, we found a broad range of decision-making experiences. The majority of patients reported approval of their decision-making process and participation. Notably, some patients reported less participation than they would have liked and regret. A fair number indicated that they did not want their ICD. These findings may be prone to recall bias, in which patients express disappointment with experiences occurring after the device was implanted. Yet, these results also identify areas where the decision-making process can be improved.

Nearly 1 in 5 patients who consented to have an ICD indicated that they did not want the device at the time of implantation. While recall bias may contribute to these findings, we must also entertain additional possibilities. Patients may have been properly informed and believed that the potential lifesaving benefits of ICD therapy outweighed the risks. Or, they may have been hesitant to question the doctor. We do not know if they expressed their doubts to their physician prior to implantation, or if there were there factors that convinced them to accept the device despite not wanting it. It is also possible that they came to regret their decision after their lived experiences with the device and its trade-offs.

Our results are consistent with findings described by others. For example, a recent focus group study found that 80% of patients with ICDs could not recall having a discussion with their cardiologist about risks associated with ICD implantation or potential long-term complications.¹² Two other qualitative studies of ICD recipients found that patients relied on doctors to decide whether an ICD was best for them, and doctors often emphasized the benefits and minimized the potential harms.^{10, 29} Indeed, a recent review of 25 studies exploring the patients perspectives in decision making demonstrated a common theme that patients faced with ICD-related decisions often misunderstood the functionality of their ICD, or overestimated its benefit.¹¹ Although the ACC and AHA recommend shared decision making surrounding the use of technologies such as ICDs in patients with heart failure, there are substantial challenges to implementing these guidelines.^{7, 30} Discussions with patients about the tradeoffs of pursuing treatment with invasive technologies are complex and time-consuming. Cardiology has historically focused on prolonging life, and cardiologists may feel that they are doing patients a disservice if they emphasize the potential downsides of ICD therapy.³¹ In addition, physician quality metrics, fragmentation of care, and the incentive structure of the existing fee-for-service health care system are impediments to high-quality, shared decision making.^{10, 32}

We found that patients who reported not wanting their ICDs were more likely to be younger. Older patients may be more aware of their own mortality and thus more willing to accept the burdens of ICD therapy in exchange for the possibility of life extension.³³ Older adults are also more likely to have low health literacy, cognitive impairment and sensory deficits that make it difficult for them to communicate effectively with their doctors and may make them more likely to follow a doctor's advice without question.^{34, 35} However, the survival benefit of ICDs may be diminished in older adults and those with certain types of cancer due to their high burden of coexisting illnesses, and the potential harms are magnified.^{2, 36, 37} Thus, it is particularly important that older adults and patients with serious, life-limiting comorbidities

are informed about the uncertainties of ICD therapy and given an opportunity to participate in shared decision making.

The major limitation of our study is recall bias. The majority of participants had had their ICDs for more than 4 years, and patients' perceptions may be affected by experiences occurring after the ICD was implanted. The fact that patients who reported wanting and not wanting their ICD were equally likely to have experienced shocks lessens this concern to some extent, however it does not eliminate the possibility of recall bias.

Participants were relatively well-educated, English-speaking and had health insurance. On the one hand, these characteristics limit generalizability. However, they also underscore the need for improved shared decision-making, since even in this population, there were issues with high-quality patient-physician communication and decision making. We did not collect information on the indication for the ICD, and were unable to distinguish between patients who received their ICDs for primary or secondary indications. This is a limitation, as patients who have already experienced an episode of sudden death may have very different perceptions than those who receive ICDs for primary prevention. Survivorship bias is another potential limitation, though it is not clear which way this would influence our results. In addition, we did not have data on complications related to the ICD or on appropriate vs. inappropriate shocks. Both of these may influence how a patient looks back on the decision-making experience. Finally, we do not know the content of the conversations that took place, if patients' recollections were accurate, or if they would have made different decisions in other circumstances.

Our findings provide insight into the patients' perceptions of their decision-making experiences surrounding ICD implantation, and identify opportunities for improvement in this process. The decision to implant an ICD is highly preference-sensitive because of the considerable tradeoffs involved. This is particularly true for primary prophylaxis ICDs in patients with serious competing health risks, in whom the benefits of the ICD are uncertain and the potential harms may be magnified. Shared decision making in patients with ICDs is an ongoing process, beginning with the first discussion about implantation to subsequent decisions about battery replacement and deactivation. At each decision point, the patient should be provided with complete information about the risks and benefits of the device, the clinical uncertainties associated with ICD therapy, and the alternatives. Practitioners should elicit and respect patient preferences in the context of the patient's overall health status. Patient decision aids, evidence-based tools that can help patients clarify their values, are a potential solution to improve patient involvement in the ICD decision process.^{14, 38, 39}

With the rapid pace of medical advances, physicians need to engage with patients in thoughtful consideration of the potential benefits – as well as the difficult trade-offs – of using medical technologies to extend life. Future research should develop and evaluate interventions designed to improve physician-patient discussions of such trade-offs. In addition, it will be important to assess implementation of the ACC/AHA clinical practice guidelines that seek to promote shared decision making.

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References

1. Epstein AE, DiMarco JP, Ellenbogen KA, Estes NA 3rd, Freedman RA, Gettes LS, Gillinov AM, Gregoratos G, Hammill SC, Hayes DL, Hlatky MA, Newby LK, Page RL, Schoenfeld MH, Silka MJ, Stevenson LW, Sweeney MO, Smith SC Jr, Jacobs AK, Adams CD, Anderson JL, Buller CE, Creager MA, Ettinger SM, Faxon DP, Halperin JL, Hiratzka LF, Hunt SA, Krumholz HM, Kushner FG, Lytle BW, Nishimura RA, Ornato JP, Page RL, Riegel B, Tarkington LG, Yancy CW. American College of Cardiology/American Heart Association Task Force on Practice G, American Association for Thoracic S, Society of Thoracic S. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices) developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. *Journal of the American College of Cardiology*. 2008; 51:e1–62. [PubMed: 18498951]
2. Cutro R, Rich MW, Hauptman PJ. Device therapy in patients with heart failure and advanced age: too much too late? *International journal of cardiology*. 2012; 155:52–5. [PubMed: 21342708]
3. Turakhia M, Tseng ZH. Sudden cardiac death: epidemiology, mechanisms, and therapy. *Curr Probl Cardiol*. 2007; 32:501–46. [PubMed: 17723906]
4. Al-Khatib SM, Greiner MA, Peterson ED, Hernandez AF, Schulman KA, Curtis LH. Patient and implanting physician factors associated with mortality and complications after implantable cardioverter-defibrillator implantation, 2002–2005. *Circulation Arrhythmia and electrophysiology*. 2008; 1:240–9. [PubMed: 19169382]
5. Tung R, Zimetbaum P, Josephson ME. A critical appraisal of implantable cardioverter-defibrillator therapy for the prevention of sudden cardiac death. *Journal of the American College of Cardiology*. 2008; 52:1111–21. [PubMed: 18804736]
6. Goldstein N, Carlson M, Livote E, Kutner JS. Brief communication: Management of implantable cardioverter-defibrillators in hospice: A nationwide survey. *Annals of internal medicine*. 2010; 152:296–9. [PubMed: 20194235]
7. Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Drazner MH, Fonarow GC, Geraci SA, Horwich T, Januzzi JL, Johnson MR, Kasper EK, Levy WC, Masoudi FA, McBride PE, McMurray JJ, Mitchell JE, Peterson PN, Riegel B, Sam F, Stevenson LW, Tang WH, Tsai EJ, Wilkoff BL. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of

Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Journal of the American College of Cardiology*. 2013; 62:e147–239. [PubMed: 23747642]

8. Bonow RO, Ganiats TG, Beam CT, Blake K, Casey DE Jr, Goodlin SJ, Grady KL, Hundley RF, Jessup M, Lynn TE, Masoudi FA, Nilasena D, Pina IL, Rockswold PD, Sadwin LB, Sikkema JD, Sincak CA, Spertus J, Torcson PJ, Torres E, Williams MV, Wong JB. ACCF/AHA/AMA-PCPI 2011 performance measures for adults with heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures and the American Medical Association-Physician Consortium for Performance Improvement. *Circulation*. 2012; 125:2382–401. [PubMed: 22528524]
9. Stewart GC, Weintraub JR, Pratibhu PP, Semigran MJ, Camuso JM, Brooks K, Tsang SW, Anello MS, Nguyen VT, Lewis EF, Nohria A, Desai AS, Givertz MM, Stevenson LW. Patient expectations from implantable defibrillators to prevent death in heart failure. *Journal of cardiac failure*. 2010; 16:106–13. [PubMed: 20142021]
10. Matlock DD, Nowels CT, Masoudi FA, Sauer WH, Bekelman DB, Main DS, Kutner JS. Patient and cardiologist perceptions on decision making for implantable cardioverter-defibrillators: a qualitative study. *Pacing and clinical electrophysiology : PACE*. 2011; 34:1634–44. [PubMed: 21972983]
11. Lewis KB, Stacey D, Matlock DD. Making decisions about implantable cardioverter-defibrillators from implantation to end of life: an integrative review of patients' perspectives. *Patient*. 2014; 7:243–60. [PubMed: 24668214]
12. Hauptman PJ, Chibnall JT, Guild C, Armbrrecht ES. Patient perceptions, physician communication, and the implantable cardioverter-defibrillator. *JAMA internal medicine*. 2013; 173:571–7. [PubMed: 23420455]
13. Caverly TJ, Al-Khatib SM, Kutner JS, Masoudi FA, Matlock DD. Patient preference in the decision to place implantable cardioverter-defibrillators. *Archives of internal medicine*. 2012; 172:1104–5. [PubMed: 22688654]
14. Stacey D, Legare F, Col NF, Bennett CL, Barry MJ, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Thomson R, Trevena L, Wu JH. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2014; 1:CD001431. [PubMed: 24470076]
15. Dodson JA, Fried TR, Van Ness PH, Goldstein NE, Lampert R. Patient preferences for deactivation of implantable cardioverter-defibrillators. *JAMA internal medicine*. 2013; 173:377–9. [PubMed: 23358714]
16. Torke AM, Schwartz PH, Holtz LR, Montz K, Sachs GA. Caregiver perspectives on cancer screening for persons with dementia: “why put them through it?”. *Journal of the American Geriatrics Society*. 2013; 61:1309–14. [PubMed: 23865814]
17. Masoudi FA, Go AS, Magid DJ, Cassidy-Bushrow AE, Doris JM, Fiocchi F, Garcia-Montilla R, Glenn KA, Goldberg RJ, Gupta N, Gurwitz JH, Hammill SC, Hayes JJ, Jackson N, Kadish A, Lauer M, Miller AW, Multerer D, Peterson PN, Reifler LM, Reynolds K, Saczynski JS, Schuger C, Sharma PP, Smith DH, Suits M, Sung SH, Varosy PD, Vidaillet HJ, Greenlee RT. Longitudinal study of implantable cardioverter-defibrillators: methods and clinical characteristics of patients receiving implantable cardioverter-defibrillators for primary prevention in contemporary practice. *Circulation Cardiovascular quality and outcomes*. 2012; 5:e78–85. [PubMed: 23170006]
18. Sepucha KR, Levin CA, Uzogara EE, Barry MJ, O'Connor AM, Mulley AG. Developing instruments to measure the quality of decisions: early results for a set of symptom-driven decisions. *Patient education and counseling*. 2008; 73:504–10. [PubMed: 18718734]
19. Sepucha KR, Borkhoff CM, Lally J, Levin CA, Matlock DD, Ng CJ, Ropka ME, Stacey D, Joseph-Williams N, Wills CE, Thomson R. Establishing the effectiveness of patient decision aids: key constructs and measurement instruments. *BMC medical informatics and decision making*. 2013; 13(Suppl 2):S12. [PubMed: 24625035]
20. Brehaut JC, O'Connor AM, Wood TJ, Hack TF, Siminoff L, Gordon E, Feldman-Stewart D. Validation of a decision regret scale. *Medical decision making : an international journal of the Society for Medical Decision Making*. 2003; 23:281–92. [PubMed: 12926578]

21. Goldstein NE, Lampert R, Bradley E, Lynn J, Krumholz HM. Management of implantable cardioverter defibrillators in end-of-life care. *Annals of internal medicine*. 2004; 141:835–8. [PubMed: 15583224]
22. Chew LD, Griffin JM, Partin MR, Noorbaloochi S, Grill JP, Snyder A, Bradley KA, Nugent SM, Baines AD, Vanryn M. Validation of screening questions for limited health literacy in a large VA outpatient population. *Journal of general internal medicine*. 2008; 23:561–6. [PubMed: 18335281]
23. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. *Family medicine*. 2004; 36:588–94. [PubMed: 15343421]
24. Peterson PN, Shetterly SM, Clarke CL, Bekelman DB, Chan PS, Allen LA, Matlock DD, Magid DJ, Masoudi FA. Health literacy and outcomes among patients with heart failure. *Jama*. 2011; 305:1695–701. [PubMed: 21521851]
25. Dillman, D. *Mail and telephone surveys: The total design method*. New York: John Wiley & Sons; 1978.
26. Hunt KJ, Shlomo N, Addington-Hall J. Participant recruitment in sensitive surveys: a comparative trial of ‘opt in’ versus ‘opt out’ approaches. *BMC Med Res Methodol*. 2013; 13:3. [PubMed: 23311340]
27. *The SAGE Handbook of Qualitative Research*. 4. United States of America: SAGE Publications, Inc; 2011.
28. Sbaraini A, Carter SM, Evans RW, Blinkhorn A. How to do a grounded theory study: a worked example of a study of dental practices. *BMC Med Res Methodol*. 2011; 11:128. [PubMed: 21902844]
29. Agard A, Lofmark R, Edvardsson N, Ekman I. Views of patients with heart failure about their role in the decision to start implantable cardioverter defibrillator treatment: prescription rather than participation. *J Med Ethics*. 2007; 33:514–8. [PubMed: 17761818]
30. Allen LA, Stevenson LW, Grady KL, Goldstein NE, Matlock DD, Arnold RM, Cook NR, Felker GM, Francis GS, Hauptman PJ, Havranek EP, Krumholz HM, Mancini D, Riegel B, Spertus JA, American Heart A, Council on Quality of C, Outcomes R, Council on Cardiovascular N, Council on Clinical C, Council on Cardiovascular R, Intervention Council on Cardiovascular S and Anesthesia. Decision making in advanced heart failure: a scientific statement from the American Heart Association. *Circulation*. 2012; 125:1928–52. [PubMed: 22392529]
31. Butler K, Puri S. Deathbed shock: causes and cures. *JAMA internal medicine*. 2014; 174:88–9. [PubMed: 24276576]
32. Lin GA, Matlock DD. Less patient-centered care: an unintended consequence of guidelines? *JAMA internal medicine*. 2013; 173:578–9. [PubMed: 23420530]
33. Finucane TE. How gravely ill becomes dying: a key to end-of-life care. *Jama*. 1999; 282:1670–2. [PubMed: 10553796]
34. Wolff JL, Roter DL, Barron J, Boyd CM, Leff B, Finucane TE, Gallo JJ, Rabins PV, Roth DL, Gitlin LN. A tool to strengthen the older patient-companion partnership in primary care: results from a pilot study. *Journal of the American Geriatrics Society*. 2014; 62:312–9. [PubMed: 24417565]
35. Say R, Murtagh M, Thomson R. Patients’ preference for involvement in medical decision making: a narrative review. *Patient education and counseling*. 2006; 60:102–14. [PubMed: 16442453]
36. Swindle JP, Rich MW, McCann P, Burroughs TE, Hauptman PJ. Implantable cardiac device procedures in older patients: use and in-hospital outcomes. *Archives of internal medicine*. 2010; 170:631–7. [PubMed: 20386008]
37. Epstein AE, Kay GN, Plumb VJ, McElderry HT, Doppalapudi H, Yamada T, Shafiroff J, Syed ZA, Shkurovich S. Implantable cardioverter-defibrillator prescription in the elderly. *Heart rhythm : the official journal of the Heart Rhythm Society*. 2009; 6:1136–43. [PubMed: 19539542]
38. Healthwise. *Heart Failure: Should I get an implantable cardioverter-defibrillator?*. 2013
39. Carroll SL, McGillion M, Stacey D, Healey JS, Browne G, Arthur HM, Thabane L. Development and feasibility testing of decision support for patients who are candidates for a prophylactic implantable defibrillator: a study protocol for a pilot randomized controlled trial. *Trials*. 2013; 14:346. [PubMed: 24148851]

Table 1

Baseline characteristics of survey respondents

	N	% ^a
Gender		
Male	229	77.6
Age (at time of survey; n=292)		
< 55	59	20.0
55–64	85	28.8
65–74	73	24.7
75–84	67	22.7
85 +	8	2.7
Race/Ethnicity (N=292)		
American Indian or Alaskan Native	12	4.1
Black or African American	13	4.4
White	250	85.6
Hispanic/Latino	17	5.9
Education (N=292)		
Less than 9 th grade	1	0.3
Some high school	26	8.9
High school graduate or equivalency degree	63	21.6
Some college, 4-year college graduate or more than 4-year degree	202	69.2
Marital Status (N = 289)		
Married	206	71.3
Comorbidities		
Anxiety (n = 287)	61	21.3
Cancer (n = 286)	45	15.7
Chronic obstructive pulmonary disease (COPD) (n = 282)	34	12.1
Congestive heart failure (n = 291)	178	61.2
Dementia (n = 285)	5	1.8
Depression (n = 288)	67	23.3
Diabetes (type I or II) (n = 285)	78	27.4
Coronary artery disease (blocked arteries, heart attack, stents, bypass surgery) (n = 290)	165	56.9
Hypertension (n = 288)	108	37.5
Kidney Failure (n = 286)	16	5.6
Liver Disease (n = 286)	11	3.8
Stroke (n = 289)	26	9.0
Subjective Memory Complaints (n = 283)		
“A problem” or “a serious problem”	39	13.8
Duration of ICD Implantation (N=293)		

	N	% ^a
Less than 2 years	49	16.7
2–4 years	61	20.8
More than 4 years	183	62.5

^aTotals may not equal 295 because of item non-response.

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Table 2

Decision participation

	Yes n (%) ^a	No n (%)
Did the doctors explain that you had the option of not getting an ICD?	202 (71.9)	79 (28.1)
Did any of your doctors ask <u>you</u> if you wanted an ICD?	180 (62.7)	107 (37.3)
Who made the final decision about your ICD	n = 289	%
Totally you	50	17.3
Mostly you	39	13.5
Both you and your doctor equally	126	43.6
Mostly your doctor	57	19.7
Totally your doctor	17	5.9
How much were you involved in the decision about your ICD	n = 279	
Much less than you wanted	18	6.5
A little less than you wanted	30	10.8
About as much as you wanted	221	79.2
A little more than you wanted	6	2.2
Much more than you wanted	4	1.4

^aTotals may not equal 295 because of item non-response.

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Table 3

Recall of experiences talking with doctors and other health care professionals about ICDs

	A Lot n (%)^a	Some n (%)	A Little n (%)	Not at All n (%)
How much did you and your doctors talk about the reasons to get an ICD? (n = 288)	129 (44.8)	103 (35.8)	37 (12.8)	19 (6.6)
How much did you and your doctors talk about he reasons <u>not</u> to get an ICD? (n = 287)	41 (14.3)	77 (26.8)	57 (19.9)	112 (39.0)
How much did you and your doctors talk about how <u>you</u> felt about getting an ICD? (n = 289)	72 (24.9)	98 (33.9)	59 (20.4)	60 (20.8)
How much did you and your doctors talk about how <u>you felt</u> about the possibility that your heart failure would continue to get worse? (n = 288)	76 (26.4)	97 (33.7)	48 (16.7)	67 (22.3)

^aTotals may not equal 295 because of item non-response.

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Table 4

Responses to “What was the main reason that you got an ICD?”

Theme	% ^a (n)	Representative Quotes
Improve Health/Heart Failure/ Quality of Life	29.1% (83)	“I felt it was the best way to give me quality of life and a prolonged life with my heart problem.”
Prolong Life/Avoid Arrest	22.8% (65)	“I was 50 yrs old and have a 13 yr old daughter, she was 9 at the time in 2007. I am a single dad and want to see her grow up.”
Dr. Thought/Knows Best	16% (47)	“After open heart surgery, my doctor had a meeting with other doctors and they thought an ICD was a good choice.”
Had no choice/needed it/afraid not to	16.5% (46)	“Scared of another heart attack – talked into it by others.” “The uncertainty/I felt I was being held hostage in the hospital until I agreed.” “The doctor said he could not sign me out without a defibrillator.”
Peace of Mind/Insurance	12.7% (36)	“Even though I was merely a borderline case for getting an ICD, I chose it as a type of ‘insurance’ against a problem.”
Joint Decision	1.1% (3)	“A good discussion of possible risks/benefits with the doctors for my particular condition and outdoor lifestyle was positive.”
Other	1.8% (5)	
No response	3.5% (10)	

^aPercentage is calculated as percentage of respondents (n=285)

Table 5

Comparisons between patients who did and did not want their ICD on measures of decision regret

	Did you want an ICD? ^a		P-value (χ^2)
	Yes (n = 214)	No (n = 49)	
I would go for the same choice			
Strongly Agree (n=158)	68.4%	28.3%	
Agree (n=68)	25.0%	32.6%	
Neither Agree/Disagree (n=18)	5.2%	15.2%	<i>p</i> < .001
Disagree (n=11)	0.9%	19.6%	
Strongly Disagree (n=3)	0.5%	4.3%	
The choice did me a lot of harm			
Strongly Disagree (n=156)	66.8%	32.6%	
Disagree (n=65)	25.1%	26.1%	
Neither Agree/Disagree (n=24)	4.3%	32.6%	<i>p</i> < .001
Agree (n=11)	3.3%	8.7%	
Strongly Agree (n=1)	0.5%	0%	
Who made the final decision about your ICD?			
Totally the patient (n = 49)	18.8%	19.1%	
Mostly the patient (n = 39)	16.0%	10.6%	
The doctor and patient equally (n = 118)	50.2%	23.4%	<i>p</i> < .001
Mostly the doctor (n = 43)	11.7%	38.3%	
Totally the doctor (n = 11)	3.3%	8.5%	
How much did you and your doctors talk about how you felt about the possibility that your heart failure would continue to get worse?			
A lot (n = 75)	30.8%	20.8%	
Some (n = 91)	37.0%	27.1%	<i>p</i> < .001
A little (n = 41)	17.1%	10.4%	
Not at all (n = 52)	15.2%	41.7%	
Did your doctors explain that you had the option of not getting an ICD?			
Yes (n = 192)	79.8%	57.8%	<i>p</i> < .002
No (n = 61)	20.2%	42.2%	

^aTotals may not equal 295 because of item non-response.