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Shared Decision-Making for Implantable Cardioverter-Defibrillators: Past, Present, and Future

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Shared Decision-Making for Implantable Cardioverter-Defibrillators: Past, Present, and Future

By:

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MD, University of Illinois in Chicago 2017

Advisor: Neal Dickert, MD, PhD

An abstract of
A thesis submitted to the Faculty of the
James T. Laney School of Graduate Studies of Emory University
In partial fulfillment of the requirements for the degree of
The Master of Science in Clinical Research in Health Services Research and Health Policy

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Abstract

Shared Decision-Making for Implantable Cardioverter-Defibrillators: Past, Present, and Future

By: Birju Rao, MD

Background**:** In 2018, the Centers for Medicare and Medicaid Services (CMS) mandated that patients and physicians undergo a shared decision-making (SDM) encounter prior to receiving an implantable cardioverter-defibrillator (ICD) for primary prevention of sudden cardiac death.
Methods: To understand how this mandate has impacted care, we surveyed patients who received ICD within Emory Healthcare between 2017-2019 (pre and post SDM mandate) about their experience. Pre and post mandate responses were compared using either student's t-test or chi-squared tests. Using purposeful sampling, a subset of patients was chosen to participate in a follow up key-informant interview study. Qualitative descriptive analysis of the interviews was performed utilizing a multilevel templated coding strategy.

Results: Of 101 patients who completed the survey, 45 were in the pre-mandate period and 56 were post. There were no major differences between knowledge (55.0±19.1 vs 57.4 ±19.5, p=0.245), decisional conflict (11.89±16.25 vs 6.96±11.19, p=0.0877), values choice concordance (4.35±3.11 vs 4.82±3.82), or patient engagement (48±47.52 vs 23±51.11, p=0.701). Twenty patients completed key-informant interviews. Patients' paths to an ICD decision often involved multiple visits with multiple clinicians. However, decision aids were, almost exclusively, provided during electrophysiology clinic visits. Patients' use of numerical risk-benefit data to make their ICD decision varied.

Conclusions: Policy effects to promote SDM that solely focus on a decision-aid delivered primarily during electrophysiology clinic visits may not substantively impact patient centered care. Aligning implementation of SDM strategies with trajectories of care may improve SDM.

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Introduction

Implantable cardioverter-defibrillators (ICD) are a guideline recommended therapy for the primary prevention of sudden cardiac death in certain patients with heart failure with reduced ejection fraction (HFrEF).[1] Based on these guidelines, approximately 75,000 patients with HFrEF receive a primary prevention ICD in the United States annually.[2] However, the HFrEF population is heterogenous. Some patients' values and preferences may not align with ICD implantation even if they meet clinical criteria for an ICD. There is also evidence that patients' understanding about the purpose of ICDs and risks of implantation are poor, which result in downstream adverse outcomes.[3] For instance, a small retrospective study showed 52% of patients with active ICDs had a do-not-resuscitate order at the time of death, with some even receiving shocks in the last 24 hours of life.[4] To address these issues and advance patient-centered care, the Centers for Medicare and Medicaid Services (CMS) now require that physicians conduct a shared decision-making (SDM) interaction using a patient decision-aid (DA) with patients referred for a primary prevention ICD.[5] SDM provides an opportunity to improve patients' engagement in ICD decision-making and enhance the extent to which their values align with the prescribed treatment plan.

Despite being ethically desirable, this SDM mandate has been controversial[6] for several reasons. First, many argue that a decision with such a positive balance of benefits in terms of mortality compared to with minimal procedural risks should not even be considered in an SDM framework. ICD implantation improves mortality, is guideline-recommended, and is a relatively safe outpatient procedure. Although the rate of long-term complications may be higher,[7] procedural complications are generally rare.[8] Second, CMS did not clarify how a decision aid should be used or what the intended outcome of the mandate really was. Third, while SDM may be conceptually appropriate for enhancing patient-centered care, the data on the impact of formal SDM processes for this decision were minimal at the time of the mandate. Fourth, and most importantly, a SDM mandate that only focuses the use of a decision aid may not maximize the goals of SDM. The rise in popularity of decision aids stems from data demonstrating that these tools enhance some components of shared decision-making.[9] However, there is mounting evidence that decision aids may not be a panacea.[10] Importantly, there are a variety of different decision aids for ICDs, which prominently present different types of information, and there are a variety of ways these decision aids may be integrated into the SDM process. The only trial published to date involved a provision of multiple sources of information in advance of a visit with an electrophysiologist.[11] However, current practice in the context of the CMS mandate likely involves providing the decision aid at the time of the encounter with the electrophysiologist, instead of beforehand.

Four years after enactment of this mandate, there remain questions about its real-world impact on patients, clinicians, and decisions. We utilized the natural experiment created by the SDM mandate to better understand how mandated decision aid use has impacted relevant domains of patients' experiences and decisions. In addition, we conducted a nested qualitative study to develop a deeper understanding of patients' ICD decision-making processes beyond decision aid use and specifically, to examine the trajectories of ICD decisions, the roles different clinicians play, and how patients make ICD decisions.

Methods

Study Design and Population

Using the natural experiment created by the CMS mandate in February 2018, we surveyed and interviewed patients who underwent initial implantation of a single- or dual-chamber ICD for primary prevention of sudden cardiac death between January 1, 2017, and December 31, 2019, within the Emory Healthcare system. The pre-mandate group consisted of patients who had an ICD implanted prior to February 2018; the post-mandate group were patients with ICDs implanted after February 2018. In general, 80-90% of primary prevention ICD implantations at the participating institution are performed as scheduled, outpatient procedures. During the post-mandate period, the institutional practice for SDM involved providing patients a paper copy of the decision aid developed at the University of Colorado[12] during the pre-operative electrophysiology visit (specific use of the decision aid was at clinicians' discretion). Surveys were administered by a single individual (E.A) via telephone between September 2020 and February 2021. Subsequent, key informant interviews were conducted by a single individual (B.R.) via telephone during March 2021 and April 2021. Participants for the key informant interviews were purposefully selected based on survey responses to represent varying levels of decisional conflict, health status, and demographics. The primary objective of these in-depth, follow up interviews was to explore drivers of patients' decision-making about ICDs in greater depth and to identify potential areas where clinicians can improve the shared decision-making process. Completion of the survey and interview were voluntary, patients were compensated for their time. The study was approved by the Emory University Institutional Review Board.

Survey Sampling and Interview Recruitment

The survey instrument was adapted from instruments that have been developed and validated for use in a multicenter trial evaluating SDM for ICD implantation (ClinicalTrials.gov identifier: NCT03374891). Survey questions explored several key SDM domains: knowledge about ICDs, decision conflict[13], values choice concordance, and patients' decision engagement. Post-mandate patients were asked about their experience with the patient decision aid. Age at implantation, history of ischemic or non-ischemic cardiomyopathy, and pre-procedural left ventricular ejection fraction were obtained from medical records.

In depth, semi-structured interviews were conducted using an interview guide developed by the research team. The interview guide was designed by a multidisciplinary team with expertise in cardiology, health policy, and bioethics to explore answers to survey questions in greater depth and to provide context for how participants made decisions regarding ICD implantation. The interview guide incorporated both open and closed ended questions and allowed for interactive probing. Specific domains include patients' ICD decision-making process/trajectory, use of data in their decision, and areas where clinicians could better support their decision. Interviews were conducted by B.R. via telephone from January 2021 through April 2021 and generally lasted between 20 to 30 minutes. All interviews were audio recorded and transcribed verbatim. Sampling continued until thematic saturation was achieved.

Key informants for the interview were selected based on their responses to the prior survey and in order to represent key respondent "types." After review of initial surveys by B.R., N.D, E.A., and C.B, participants were purposively sampled based on demographic characteristics and having varying levels of decision conflict, health status, exposure to the decision-aid, view on the utility of the decision aid, and feelings that they might choose differently about having an ICD implanted, if given the opportunity. Exposure to the decision aid was determined by timing of the electrophysiology consult relative to the shared decision-making mandate enacted in February, 2018. For patients who had seen an electrophysiologist after the CMS mandate, the initial survey asked their views on whether the decision aid was useful. Participants' feelings that they would choose differently were determined by the survey question, "If you had it to do over, would you decide to have an ICD implanted again?" A matrix of participants was developed to display these characteristics, and sampling continued until all cells in the matrix were represented and informational redundancy was achieved.

Quantitative and Qualitative Data Analysis

Pre-mandate patients' survey responses were compared to post-mandate responses using quantitative methods. Comparison of continuous baseline variables was performed with the Students' t-test; categorical variables of survey questions were compared using either chi squared or Fisher's exact tests. All analysis was done using SAS 9.4 (Cary, NC).

Qualitative analysis of interviews was performed using a multilevel template coding strategy.[14] First, interviews were transcribed verbatim, corrected for errors, and imported into MAXQDA (VERBI GmbH, Berlin, Germany) for analysis. Then, all transcribed interviews were reviewed by B.R. and E.A, and the preliminary codebook was developed by the research team based on domains of the interview guide designed to explore drivers of ICD decision-making. This codebook was refined inductively as themes emerged during transcript review (constant comparison) and then finalized. Using the finalized codebook, B.R. and E.A. each coded a subset of interviews separately, and C.B. served as a secondary coder. Any discrepancies in coding noted between the primary and secondary coders were discussed and adjudicated by consensus between B.R., E.A., C.B., and N.D. The team reviewed coded segments to ensure that each code represented a coherent and discrete theme and to identify sub-themes.

Results

Survey

A total of 369 patients with primary prevention ICD implants were identified, 191 pre-mandate and 186 post-mandate (**Appendix 2**). Of these, 100 patients were excluded due to either invalid contact information (86) and death or disability (14). Of the remaining 269, 28 declined to participate, 140 did not respond, and 101 completed the survey (response rate of 38%). Forty-five patients had an ICD implanted pre-mandate, and 56 underwent implantation post-mandate (**Table 1**). Non-response rates were similar between both groups. Comparison of non-responders to responders demonstrated similar age at implant, but non-responders were more likely to be male (62% vs 39.6%, p=0.0001).

There were no significant differences observed in composite knowledge about ICDs, decision conflict, values-choice concordance, or engagement in the decision-making process pre- and post-mandate. Overall, percentage of correctly answered questions regarding basic knowledge about ICDs (**Table 2**) was low in pre- and post- mandate participants (57.4% vs 53.0%, p=0.245). Participants implanted pre-mandate were more likely to correctly identify the frequency of minor complications (66.7% vs 37.5%, p=0.012). Mean decision conflict was low in both groups (11.89 vs 6.96, p=0.0877). Individual components of the decision conflict scale (**Table 3**) were similar, though pre-mandate patients were less likely to report an understanding of the benefits of ICD (88.2% vs 94.6%, p=0.0456). Answers to questions about values and engagement in decision-making were similar (**Table 3**).

Of the 56 post-mandate patients, 39 (69.6%) remembered receiving the decision-aid. Of those who remembered the decision-aid, 36 (92.3%) reported reading the decision-aid prior to the procedure, 35 (97.2%) felt it helped them feel more comfortable with their decision, and 34 (94.4%) felt it helped improve discussions with their doctor (**Table 4**).

Key-informant Interview

Twenty interviews were conducted (response rate 77%). At the time of the interview, 2 participants had chosen not to have a primary prevention ICD implanted, and 18 had an active ICD. The sample was balanced in terms of race, sex, and health status (**Table 5**). Fourteen patients were above the age of 65. The indications for ICD implantation were predominantly HFrEF with a left ventricular ejection fraction <35% (18/20). One participant had hypertrophic cardiomyopathy and another Brugada syndrome, both with features considered high risk for sudden cardiac death and meeting criteria for primary prevention ICD implantation. Three participants reported having experienced an ICD shock since implantation, and the remaining 15 with ICDs did not report any shocks. Five participants had their ICD implanted prior to CMS's shared decision-making mandate;13 were implanted after the mandate and hence, received a decision aid.

Patients' Path to an ICD Decision - Multiple Visits with Multiple Clinicians

The decision-making process about primary prevention ICD implantation rarely occurred during a single encounter. Eighteen out of the 20 patients described a process that occurred over multiple visits, starting with learning about an ICD and its purpose and ending with a decision. After first learning about the ICD, one patient notes "I think it was about three to six months, I had a couple of visits with [general cardiologist] in that time. He told me about it more than once. The first couple of times he told me about it, like I said, I didn't like being cut open and I didn't know how—I didn't know if it would really help or not… finally, after I just sat down, looked it up, did some research and tried to think about it logically."

In addition to deciding over an extended period of time, patients generally reported receiving input about the ICD from multiple clinicians and other sources of support. Often the patients' general cardiologist or heart failure specialist would first introduce the idea of an ICD and then refer the patient to an electrophysiologist, who provided additional procedural details. Notably, some patients had multiple visits with their cardiologist before they made a decision regarding ICD implantation, and these encounters were often critical to decision-making. "Initially, it was something that was brought up by my cardiologist. He gave me a brochure about the ICD… [and] we would talk about it from time to time when I would have my regular checkups. Then, he offered to make an appointment with one of the cardiologists who was an electrophysiologist to talk more about how it worked and what the procedure would be for implanting the defibrillator… Then…circling back and talking with [cardiologist name] I think there were a couple of factors that came to making the decision…" Along with involving multiple clinicians, patients may involve friends or family members in their decision-making process. As stated by one patient "…having my wife involved and discussing it with my children and other trusted friends, I think that's important as well to get as many voices as possible as you trust…"

Electrophysiologists played a heterogenous role in these patients' ICD decisions. For some patients, the substantive portion of the decision about whether to get an ICD implanted occurred prior to seeing the electrophysiologist, during discussions with their primary cardiologist. Consultation with the electrophysiologist did little to impact these patients' decisions; the visit primarily clarified procedural details. However, other patients reported only cursory discussions about the ICD prior to meeting the electrophysiologist. In these cases, the decision-making process that occurred with the electrophysiologist was substantive, and patients described the electrophysiologist's guidance as crucial. Although some patients had functionally made their decisions prior to seeing an electrophysiologist and some stated that a general cardiologist had provided some written materials, the ICD decision aid was exclusively provided by electrophysiologists (**Table 6**).

Drivers of Patients' ICD Decisions - *Typically Not the Numbers*

Some patients engaged the numeric, probabilistic data presented in the decision aid to make decisions about device implantation. For instance, one patient reported the decision aid enhanced his understanding that the risk reduction with ICD therapy was not 100%. This patient stated his doctor said, "you're at risk of sudden cardiac death, and you need to have this. You need this protection. Then I saw the paperwork, and I was a little bit surprised… 6%…decrease in risk of death over the course of five years… that's not really that big of a change… It's nice to have some improvement, but golly, I mean, I'm left pretty bad off anyway." This interaction reveals that the patient was surprised at how high the baseline risk of death from heart failure can be.

Another patient relied on quantitative data not in the decision aid: the list price of the device. This patient found the price of ICD implantation online and surmised that "…Medicare would not have approved it if I really didn't need [it]…because it's an expensive procedure." Here the patient equated price with value. "We're offered a life-saving device at no cost... Why not?"

For most patients, numeric data did not play a role in their ICD decisions; for these individuals, trust in their clinician's recommendation drove their decision about ICD implantation. Patients had multiple reasons to trust their clinician's recommendation (**Table 7**).

First, patients cited a longitudinal nature of the relationship with their clinician (typically a general cardiologist or heart failure specialist) as an important factor. Second, patients described the clinician's communication skills as a factor which engendered trust. Patients appreciated clinicians who took the time to go "step by step to explain to me exactly what was gonna happen," and those would "listen to you about you telling them what about your body and how you feel." Of note, this type of trust was only peripherally connected to the substance of an ICD implantation decision. Third, patients trusted their clinician's recommendation because they felt the clinician had expertise due to the clinicians' years of experience, position at the institution, or the prestige of the institution at which they practice.

Importantly, some patients made their decision based on a frank misunderstanding of the purpose of ICD therapy. For instance, one patient who was exposed to the decision aid reported that "When they put in the defibrillator, I've gained that little speed, my heart sped up a little bit. It was pumping a lot better, and I could breathe. Yeah, without it, I don't think I would have made it." This patient did not have any pacing requirement, nor did he have cardiac resynchronization therapy. His decision to undergo ICD implantation was simply made with an incorrect understanding of the function of the device.

The Role of Decision aids in Patients' ICD Decisions

Reported use of the decision aid was heterogenous. Among patients who had received the decision aid, many reported it was rarely used during the encounter, though some referenced the document afterwards. Patients who reported the decision aid was used by the clinician during the encounter felt it was helpful because the clinician "actually went through it with me, where I could see it, to show you diagrams and stuff on how everything's done." Some patients wished they had the decision aid before meeting with the electrophysiologist. One patient stated, “because looking at the data and the graph was the most important thing…to decide, if I coulda had that earlier… I really would’ve liked to look over that. Then when I did sit down with [the electrophysiologist] I had everything in my head…with the expert sittin’ in front of me.” Some patients reported that they “brought it home with me and reviewed it at my leisure,” while others reported “I looked at some of it... I looked at the pictures and all the other stuff, and stuff like that…” As noted in two of these quotations, patients’ recollection of the decision aid information was sometimes more that it gave them details about the device itself rather than the numeric information regarding risk or benefit that it involves.

Patient Experiences Making an ICD Decision

Almost all patients denied feeling pressured into their decision. When asking patients to reflect on whether they felt they could say no to ICD implantation, 19/20 patients reported they did not feel pressured into their decision. The one patient who reported feeling pressured reported a scenario where the decision to implant an ICD was made as an inpatient while the patient was acutely ill. She felt she did not have sufficient time to understand the ramifications of her decision.

Some patients did struggle with the decision about ICD implantation and recommended improvements to the decision aid or to the way clinicians presented the choice. First, patients desired specific information addressing aspects of living with an ICD such as aesthetic concerns and the sensation of an ICD shock, which is not highlighted in the paper decision aid. One patient stated “it was a lot bigger than I had anticipated... it's very noticeable. It's very high up on my chest, and it sticks out quite a bit.” Second, patients recommended strategies for clinicians to improve communication during the encounter. Generally, these patients requested clinicians recognize “when you're talkin' about your heart it's very scary.” Some anxieties about ICD implantation that patients noted were related to the procedure such as fear of "being put to sleep and not" waking up" or fear of post-procedural recovery. Another patient struggled with the emotional significance of making decisions related to mortality. As this patient put it, "I felt tortured about it… it was really more the emotional difficulty than the mathematical one because the math was presented to me in the document." He struggled with balancing his fear of procedures with his risk of cardiac arrest if he deferred ICD implantation.

Discussion

The CMS mandate of shared decision-making for primary prevention ICDs formally recognizes the need to integrate patients' values and preferences into decisions for a guideline recommended therapy. However, the mandate is procedural; its only stipulation is the use of a decision aid, the impact of which likely depends on the type of decision aid used, its implementation strategy, and context in which it is used. These observational data capitalize on a natural history experiment to gain insights into the impact of CMS-mandated SDM with a DA for primary prevention ICDs. This mandate does not seem to have substantially impacted patients' knowledge about ICDs, decision conflict, values-choice concordance, or engagement in decision-making, but patients liked the DA and may feel more informed. An in-depth, qualitative analysis reveals important complexities related to ICD decision-making and ways in which an isolated DA requirement may be ill-suited to advance shared decision-making. Understanding these complexities provides insights into how a DA may be integrated into the process and how shared decision-making might be made more robust.

SDM can advance patient centered care, but this study raises concerns about policies focusing on DAs alone. First, these data demonstrate no obvious impact DA on key SDM domains. Simply mandating DA use may not substantially change the encounter. Without understanding how SDM should be conducted and how best to utilize the DA, the CMS mandate risks incentivizing perfunctory interactions. Second, SDM is context specific; effective strategies likely vary based on the nature of the decision. Although our participants liked the DA, it is unclear whether it really helped them to make this assessment.

Further, the in-depth interviews described a potential explanation for the lack of an impact of this SDM mandate. A striking finding was that many patients have substantive discussions about ICD implantation long before any interaction with an electrophysiologist involving a decision aid. ICD implantation is typically not a procedure for which information is initially presented and a decision is made in a single, discrete encounter, yet these may be the kinds of decisions for which decision aids are most easily used. Because many patients have substantive discussions about ICD implantation with a non-implanting cardiologist, their decision is made prior to any exposure to a decision aid. For these patients, a decision aid may provide confirmatory information or serve as a reference document moving forward, but it seems unlikely to impact decision-making. This finding highlights the challenge of integrating shared decision-making tools into decisions that occur over time. One potential solution may be integrating decision aids upstream from the electrophysiology consultation within the context of discussions by primary cardiologists (or heart failure specialists) who may strong therapeutic relationships with patients. Although this requires further study, widening the number of physicians involved in the shared decision-making process and the time period over which that process occurs, may pose challenges for adequately documenting the shared decision-making interaction and the provision of the decision aid for the purpose of meeting CMS coverage requirements.

These data also highlight the fact that patients make ICD decisions based on factors other than what is often highlighted in decision aids. Decision aids prominently feature probabilistic data related to benefits and risks, yet many patients rely on other types of information to make ICD decisions. This may be related to health numeracy.[15] For instance, patients with lower health numeracy may value experiential information about the feeling of shocks or aesthetic information about the device post implant as more valuable and even more reliable compared to probabilistic numerical data.[16] These patients may strongly rely on the clinician recommendation, especially if it comes from a clinician with whom patients have an existing relationship. Conversely, even patients with high health numeracy may not heavily value probabilistic data related to risks and benefits of ICDs. Though decision aids mitigate numeracy issues by utilizing infographics, some patients, either with low or high numeracy, may not strongly rely on this survival data to make their ICD decisions.

Fundamentally, the tradeoff in a decision about ICD implantation involves balancing patients' desired aggressiveness in their medical care, quantity of life, and quality of life. Patients with ICDs functionally chose to live longer and to avoid a sudden death. However, this comes at the risk of potential for ICD implant complications and for experiencing painful ICD shocks, both appropriate and inappropriate shocks. Shared decision-making provides a framework to engage patients in a discussion about aggressiveness and willingness to tolerate future complications. For some patients, aggressive escalations of medical care may result in a lower quality of life. However, few patients in our cohort seemed to truly address this tradeoff when making an ICD decision. The fact that some patients reported discomfort with discussing mortality is, in some sense, encouraging because it means that the decision aid may have prompted some appreciation for the mortality risks associated with heart failure. Difficulty communicating prognosis and patients' discomfort with it has been well documented in heart failure and continues to be a challenge when discussing heart failure treatment options.[17, 18] Although discussing mortality may be difficult for patients, ICD decisions really are predicated upon patients' understanding of the nature of their illness and the nature of the device. This is just another way in which patients' general cardiologists or heart failure specialists may play an important role to facilitate shared decision-making interactions for ICD implantation. Patients' primary cardiologists are well suited to discuss their prognosis and the trajectory of their illness, which go hand-in-hand with eliciting values regarding mortality and quality of life. However, compared to electrophysiologists, general cardiologists and heart failure specialists may be less well-equipped to discuss procedural risks and technical aspects of living with an ICD, both crucial elements for decision-making.

This study has limitations. First, this is an observational study within a single health system, but patients were seen at 3 separate hospitals. Second, the structure of the SDM interaction was not standardized, though this likely reflects real heterogeneity in practice and the broad nature of the mandate. Other components of clinical encounters likely impact the extent to which effective SDM occurs. Third, there is potential for nonresponse bias, though non-responders revealed a similar distribution of age and timing of ICD implants. Fourth, recall bias is possible though not suggested by these data; knowledge regarding short-term procedural risks, for example, was higher in the pre-mandate group. Fifth, the nested qualitative key-informant study was designed to provide deeper understanding of how patients make decisions about primary prevention ICD implantation, but it does not provide information on prevalence of particular views. Finally, the decision aid used in this study was specifically cited in the CMS mandate; however, other decision aids exist that may support SDM in different ways. For instance, a video form of a decision aid for ICDs that was provided to patients prior to their clinic visits was found to be beneficial by patients.[11] The presentation and timing of decision aid delivery may impact SDM.

SDM is appropriate for patients undergoing primary prevention ICD implantation, but a mandate focusing only on DA use may be insufficient to impact patient-centered care. This may be related to the finding that SDM interactions using DAs. primarily occurs during visits with electrophysiologists. However, if SDM for these patients is to be substantive, it needs to be effectively integrated into the real patterns and trajectories of patients' care. In particular, SDM requires patients to understand their disease prognosis and to consider their values about aggressiveness of care and quantity versus quality of life. These discussions tend to happen in the context of patients' relationships with primary cardiologists and heart failure specialists, rather than electrophysiologists. Finally, printed DA documents may have an important potential for helping patients to understand the experience of living with an ICD; this role may wind up being just as significant as, or potentially more so, than communicating probabilistic data.

	Overall (n=101) n (%)	**Pre-SDM mandate (n =45) n (%)**	**Post-SDM mandate (n=56) n (%)**	**P-value**
Age				
< 65 years	51 (50.50)	21 (46.67)	30 (53.57)	0.4903
≥ 65 years	50 (49.50)	24 (53.33)	26 (46.43)	
Gender				
Female	61 (60.40)	17 (37.78)	23 (58.93)	0.7366
Male	40 (39.60)	28 (62.22)	33 (41.07)	
Race				
Asian (East Asian or South Asian)	2 (1.98)	1 (2.22)	1 (1.79)	0.7549
Black or African American	46 (45.54)	18 (40.00)	28 (50.00)	
Hispanic/Latino(a)	1 (0.99)	0 (0)	1 (1.79)	
White/Caucasian	49 (48.51)	25 (55.56)	24 (42.86)	
Other	3 (2.97)	1 (2.22)	2 (3.57)	
Education				
Some high school	3 (2.97)	3 (6.67)	0 (0)	0.4182
Graduated from high school	22 (21.78)	8 (17.78)	14 (25.00)	
Some college	21 (20.79)	8 (17.78)	13 (23.21)	
Graduated from college	32 (31.68)	14 (31.11)	18 (32.14)	
Some graduate school	5 (4.95)	3 (6.67)	2 (3.57)	
Graduated from a graduate school	18 (17.82)	9 (20.00)	9 (16.07)	
In general, would you say your health is:				
Excellent	4 (3.96)	1 (2.22)	3 (5.36)	0.1857
Very good	19 (18.81)	10 (22.22)	9 (16.07)	
Good	37 (36.63)	15 (33.33)	22 (39.29)	
Fair	25 (24.75)	15 (33.33)	10 (17.86)	
Poor	16 (15.84)	4 (8.89)	12 (21.43)	
Left Ventricular Ejection Fraction				
≤35%	81 (80.20)	34 (75.56)	47 (83.93)	0.2939
>35%	20 (19.80)	11 (24.44)	9 (16.07)	
Etiology of cardiomyopathy				
Ischemic	37 (36.63)	16 (35.56)	21 (37.50)	0.8402
Non-ischemic	64 (63.37)	29 (64.44)	35 (62.50)	
Has your ICD ever shocked you?				
Yes	9 (8.91)	3 (6.67)	6 (10.71)	0.4779
No	92 (91.09)	42 (93.33)	50 (89.29)	

Table 1. Demographic information

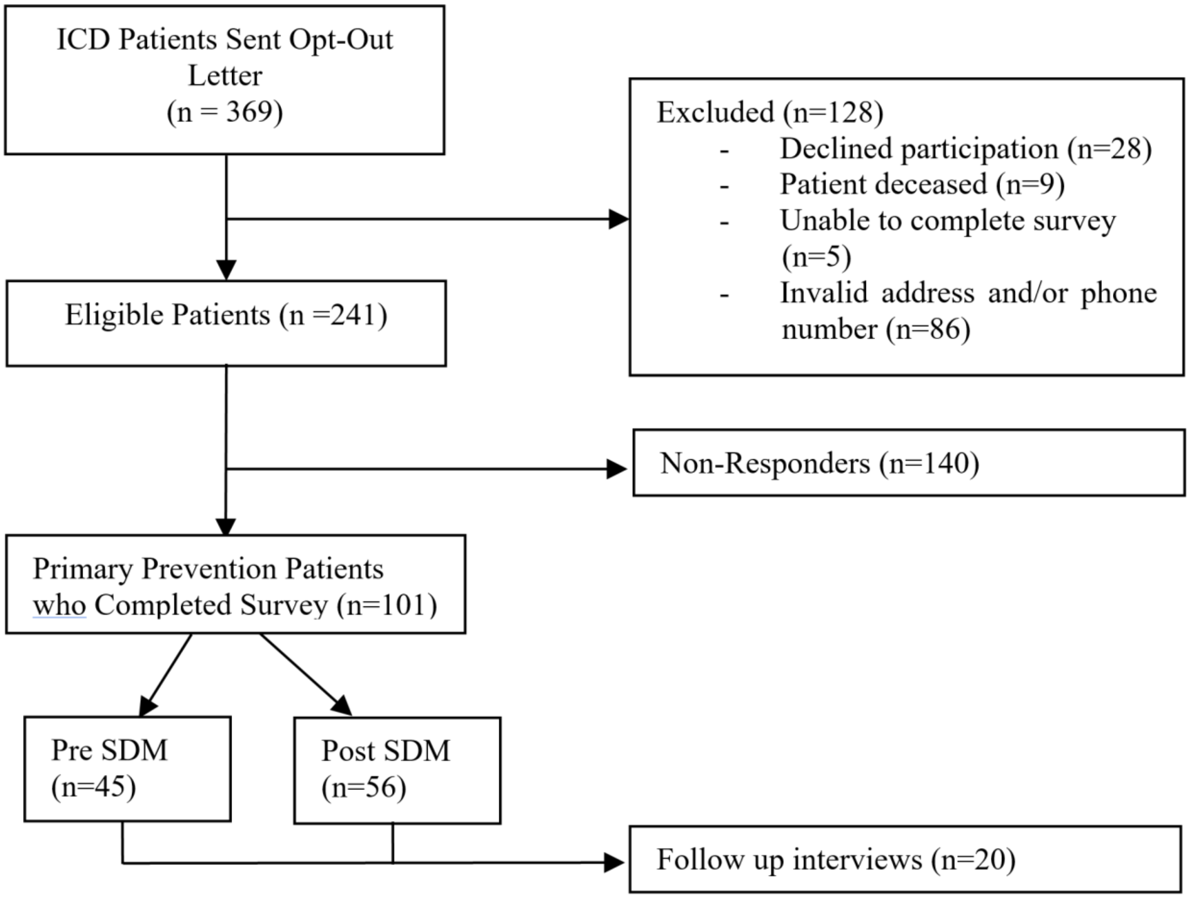

Figure 1. CONSORT Diagram

	Overall (n=101) n (%)	**Pre-SDM mandate (n =45) n (%)**	**Post-SDM mandate (n=56) n (%)**	**P-value****
What is the primary purpose of an ICD				
To prevent sudden cardiac death*	73 (72.28)	34 (75.56)	39 (69.64)	0.3402
To prevent heart failure	17 (16.83)	5 (11.11)	12 (21.43)	
To improve heart failure symptoms, such as shortness of breath and leg swelling	11 (10.89)	6 (13.33)	5 (8.93)	
How often should an ICD be checked by the doctor?				
Several times a year*	87 (86.14)	39 (86.67)	48 (85.71)	1.0000
Every 5 years	13 (12.87)	6 (13.33)	7 (12.50)	
The ICD never needs to be checked	1 (0.99)	0 (0)	1 (1.79)	
If someone decides that they no longer want their ICD on and they have it turned off, what happens next?				
They have to enroll in hospice.	2 (1.98)	0 (0)	2 (3.57)	0.5928
They will die shortly.	11 (10.89)	4 (8.89)	7 (12.50)	
Nothing needs to be done, they can continue to receive medications and other treatments for their heart failure. *	88 (87.13)	41 (91.11)	47 (83.93)	
When would it be recommended that an ICD be turned off?				
While you are asleep	4 (3.96)	3 (6.67)	1 (1.79)	0.5195
Near the end of life*	25 (24.75)	11 (24.44)	14 (25.00)	
It should never be turned off	72 (71.29)	31 (68.89)	41 (73.21)	
If 100 people have an ICD, <u>about</u> how many will have their <u>lives saved</u> by the ICD over the next 5 years? Select the answer that is closest to correct.				
0	0 (0)	0 (0)	0 (0)	0.4865
1	5 (4.95)	3 (6.67)	2 (3.57)	
7*	13 (12.87)	4 (8.89)	9 (16.07)	
28	24 (23.76)	13 (28.89)	11 (19.64)	
53	59 (58.42)	25 (55.56)	34 (60.71)	

Minor complications can happen with an ICD such as bleeding or the device becoming disconnected. If 100 people get an ICD, about how many of them will experience a minor complication as a result of their ICD surgery?				
0-1	22 (21.78)	6 (13.33)	16 (28.57)	**0.0116**
2-5*	51 (50.50)	30 (66.67)	21 (37.50)	
6-10	23 (22.77)	6 (13.33)	17 (30.36)	
More than 10	5 (4.95)	3 (6.67)	2 (3.57)	
Serious complications can happen with an ICD such as infections, lung collapse, or death. If 100 people get an ICD, how many of them will experience a serious complication as a result of their ICD surgery?				
0-1*	51 (50.50)	25 (55.56)	26 (46.43)	0.6658
2-5	33 (32.67)	14 (31.11)	19 (33.93)	
6-10	12 (11.88)	5 (11.11)	7 (12.50)	
More than 10	5 (4.95)	1 (2.22)	4 (7.14)	
The shocks from an ICD cause some patients to develop emotional problems.				
Yes*	45 (44.55)	17 (37.78)	28 (50.00)	0.2193
No	56 (55.45)	28 (62.22)	28 (50.00)	
People with an ICD will not feel it if their ICD shocks them.				
Yes	12 (11.88)	7 (15.56)	5 (8.93)	0.3063
No*	89 (88.12)	38 (84.44)	51 (91.07)	
Sometimes an ICD will *not* shock a person when a shock is needed.				
Yes*	41 (40.59)	22 (48.89)	19 (33.93)	0.1281
No	60 (59.41)	23 (51.11)	37 (66.07)	
Sometimes an ICD will shock a person when a shock is *not* needed.				
Yes*	47 (46.53)	23 (51.11)	24 (42.86)	0.4085

No	54 (53.47)	22 (48.89)	32 (57.14)	
Percent of questions correctly answered				
Mean (SD)	55.0 (19.1)	57.4 (19.5)	53.0 (18.7)	0.2452

Table 2. Patients' responses to questionnaire regarding their knowledge about ICDs

*correct answer

**p-values obtained by testing the hypothesis that there is no mean difference between pre mandate vs post mandate using a T-test or chi squared test

	Overall (n=101) n (%)	**Pre-SDM mandate (n =45) n (%)**	**Post-SDM mandate (n=56) n (%)**	**P-value***
If you were able to choose how to live the rest of your life, what number on the scale from 1 to 10 would represent where you would want to be (1 represents living as long as possible, even if symptoms from heart failure or other illnesses worsen over time and 10 represents dying quickly from any cause– for example, dying in your sleep).				
Mean (SD)	4.61 (3.52)	4.35 (3.11)	4.82 (3.82)	0.5108
Did you know which options were available to you?				
Yes	76 (75.25)	34 (75.56)	42 (75.00)	0.0706
Unsure	14 (13.86)	9 (20.00)	5 (8.93)	
No	11 (10.89)	2 (4.44)	9 (16.07)	
Did you know the benefits of each option?				
Yes	90 (89.11)	37 (82.22)	53 (94.64)	**0.0456**
Unsure	4 (3.96)	4 (8.89)	0 (0)	
No	7 (6.93)	4 (8.89)	3 (5.36)	
Did you know the risks and side effects of each option?				
Yes	81 (80.20)	32 (71.11)	49 (87.50)	0.0554
Unsure	7 (6.93)	6 (13.33)	1 (1.79)	
No	13 (12.87)	7 (15.56)	6 (10.71)	
Were you clear about which benefits mattered most to you?				
Yes	90 (89.11)	39 (86.67)	51 (91.07)	0.4821
Unsure	4 (3.96)	3 (6.67)	1 (1.79)	
No	7 (6.93)	3 (6.67)	4 (7.14)	
Were you clear about which risks and side effects mattered most to you?				
Yes	80 (79.21)	35 (77.78)	45 (80.36)	0.3204
Unsure	9 (8.91)	6 (13.33)	3 (5.36)	
No	12 (11.88)	4 (8.89)	8 (14.29)	
Did you have enough support from others to make the choice?				
Yes	88 (87.13)	38 (84.44)	50 (89.29)	0.7315
Unsure	4 (3.96)	2 (4.44)	2 (3.57)	
No	9 (8.91)	5 (11.11)	4 (7.14)	

Did you make the choice without pressure from others?				
Yes	87 (86.14)	40 (88.89)	47 (83.93)	0.7706
Unsure	2 (1.98)	1 (2.22)	1 (1.79)	
No	12 (11.88)	4 (8.89)	8 (14.29)	
Did you have enough advice to make the choice?				
Yes	96 (95.05)	43 (95.56)	53 (94.64)	0.0777
Unsure	2 (1.98)	2 (4.44)	0 (0)	
No	3 (2.97)	0 (0)	3 (5.36)	
Were you clear about the best choice for you?				
Yes	94 (93.07)	41 (91.11)	53 (94.64)	0.4911
Unsure	4 (3.96)	3 (6.67)	1 (1.79)	
No	3 (2.97)	1 (2.22)	2 (3.57)	
Did you feel sure about what to choose?				
Yes	95 (94.06)	42 (93.33)	53 (94.64)	0.2866
Unsure	2 (1.98)	2 (4.44)	0 (0)	
No	4 (3.96)	3 (2.22)	1 (5.36)	
Composite Decision Conflict Score				
Mean (SD)	9.16 (13.82)	11.89 (16.25)	6.96 (11.19)	0.0877
How much do you feel that you and your doctor shared in the decision to have an ICD implanted?				
The final decision was entirely mine	8 (7.92)	3 (6.67)	5 (8.93)	0.7010
Mostly my decision, with some input from the doctor	22 (21.78)	11 (24.44)	11 (19.64)	
My doctor and I jointly made the final decision	48 (47.52)	23 (51.11)	25 (44.64)	
Mostly my doctor’s decision, with some input from me	16 (15.84)	6 (13.33)	10 (17.86)	
The final decision was made entirely by my doctor	3 (2.97)	0 (0)	3 (5.36)	
I don’t remember	4 (3.96)	2 (4.44)	2 (3.57)	
How much did you and your doctor talk about the reasons to get an ICD?				
A lot	75 (74.26)	29 (64.44)	46 (82.14)	0.1025
A little bit	22 (21.78)	14 (31.11)	8 (14.29)	
Not at all	0 (0)	0 (0)	0 (0)	
I don’t remember	4 (3.96)	2 (4.44)	2 (3.57)	
How much did you and your doctor talk about the reasons not to get an ICD?				
A lot	25 (24.75)	13 (28.89)	12 (21.43)	0.6443
A little bit	29 (28.71)	11 (24.44)	18 (32.14)	
Not at all	32 (31.68)	13 (28.89)	19 (33.93)	

I don’t remember	15 (14.85)	8 (17.78)	7 (12.50)	
Did any of your doctors ask you if you wanted an ICD?				
Yes	69 (68.32)	31 (68.89)	38 (67.86)	0.9118
No	32 (31.68)	14 (31.11)	18 (32.14)	

Table 3. Responses to 10-item decision conflict scale and decision participation questions

*p-values obtained by testing the hypothesis that there is no mean difference between pre mandate vs post mandate using a T-test or chi-squared tests

	Overall (n=56) n (%)
1. Do you remember receiving this handout?	
Yes	39 (69.64)
No	17 (30.36)
2. Did you read the decision aid prior to the procedure?*	
Yes	36 (92.31)
No	3 (7.69)
3. If Yes, when did you read the decision aid?**	
Before meeting with the doctor	31 (86.11)
After meeting with the doctor	2 (5.56)
I don’t remember	3 (8.33)
4. The decision aid helped me feel more comfortable with the decision to have an ICD implant**	
Strongly Agree	21 (58.33)
Agree	14 (38.89)
Neutral	0 (0)
Disagree	1 (2.78)
Strongly Disagree	0 (0)
5. The decision aid helped me to know what questions to ask about the ICD when discussing the procedure with my doctor**	
Strongly Agree	18 (50.00)
Agree	16 (44.44)
Neutral	2 (5.56)
Disagree	0 (0)
Strongly Disagree	0 (0)

Table 4. Response to questions about the patient decision aid

*Of the 39 who remembered receiving the decision aid

**Of the 36 who read the decision aid prior to the procedure

Race (Gender)	**Before or After Mandated SDM**	**Decision Conflict Score**	**DA helpful?**	**Health Status**	**Do it over?**
White (F)	Before	8	N/A	'Fair'	No
White (F)	Before	28	N/A	'Good'	Yes
Black (M)	After	2	Yes	'Good'	Yes
White (M)	After	0	Yes	'Very good'	Yes
White (M)	After	0	Yes	'Good'	Yes
White (M)	After	0	Yes	'Very good'	No
White (F)	Before	0	N/A	'Very good'	Yes
Black (F)	After	6	Yes	'Fair'	Yes
White (M)	Before	12	N/A	'Fair'	Yes
Black (F)	After	4	Yes	'Good'	Yes
White (M)	After	0	Yes	'Fair'	No
Black (F)	After	0	Yes	Poor'	Yes
Black (M)	After	0	Doesn't remember	Poor'	Yes
Black (F)	Before	14	N/A	Very Good'	Yes
Black (M)	After	10	Yes	Poor'	Yes
White (M)	After	4	Doesn’t remember	Poor'	Yes
Black (M)	After	0	Yes	Good'	Yes
Black (F)	After	20	Doesn't remember	Good'	No
Black (F)	After	N/A	No	N/A	N/A
Black (M)	After	N/A	Yes	N/A	N/A

Table 5. Matrix of participant characteristics

Before	Interviewer: I see. Had you made up your mind that you were gonna go through with it before you saw the surgeon, or did you make up your mind after you saw the surgeon? Subject 73: I made up my mind before... When I talked to my heart doctor, I had already made up in my mind.
	Subject 100: …My heart failure doctor said I just needed to have it. I didn't want to, but now at that point I was just scared enough I just thought I'd just let the doctors make the decision. I didn't really pushback or anything. I hoped that I would improve and wouldn't need it. He said it was the time to get it… They sent me over to the implant doctor, and I really didn't question him. He said you're here to get a defibrillator, let's talk about it. He gave me the—well, his people gave me the paperwork to read to get oriented to what it would do and not do and some details what it would be like... Honestly, it wasn't until I was actually leaving, and I just thought, I don't know, it just kinda hit me to ask him. I said, "Is this at all optional, or is this just somethin' I just really need to do?" He was very nice. He woulda talked to me more if I'd had questions I feel sure 'cause he was an excellent doctor and very nice person. He said it's the standard of care. My heart failure doctor had been so emphatic about it that I just accepted it at that point. Then they did it, and so here I am.
After	Subject 116: Yeah. After I talked to him and after I actually met with the electrophysiologist. That's when I definitely made the decision and he explained to me more about what it was and the effect it was gonna have on me and the benefit, the pros, and the cons, he went over both of those. Gave me a little history behind the ICD itself, and the benefit and the negative about it.

Table 6. ICD decision made either before or after clinic visit with the electrophysiologist

Longitudinal relationship	Interviewer: Yeah. Which doctors' recommendation was the most meaningful? Your regular heart doctors or the electrophysiologists? Subject 116: My cardiologists. I had seen him more, so yeah, definitely my cardiologist.
Communication Skills	Interviewer: Is there anything that specifically **Dr. name** does that helped you trust his recommendation to get the defibrillator put in? Subject 80: He has the ability to talk to a nonprofessional like me in language that I can understand. If I wanna make the conversation technical and very complicated, he'll go along with that but he—ordinarily, he can address issues in layman's language. I think that's a rare talent for professionals like him.
expertise	Subject 71: No. That was probably another factor, overall, is I felt like I was in really good hands with both ***Dr. name*** ***Dr. name***, that they had had—one, they didn't recommend this to all their patients. They had had very good success in the procedure and implementation and so forth.

Table 7. Drivers of patients' trust in their clinician's recommendation

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