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Experiences implementing a suite of decision aids for implantable cardioverter defibrillators: Qualitative insights from the DECIDE-ICD Trial

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Abstract

Background—Shared decision making (SDM) is gaining importance in cardiology, including CMS reimbursement policies requiring documented SDM for patients considering primary prevention implantable cardioverter defibrillators (ICD). The DECIDE-ICD Trial assessed the implementation and effectiveness of patient decision aids (DAs) using a stepped-wedge design at seven sites. The purpose of this sub-analysis was to qualitatively describe electrophysiology (EP) clinicians' experience implementing and using the DAs.

Methods—Semi-structured individual interviews with electrophysiology clinicians at participating sites across the U.S., at least six months following conversion into the

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implementation phase of the trial (June 2020-Feb 2022). The interview guide was structured according to the RE-AIM framework, assessing clinician experiences which can impact implementation domains, and was qualitatively assessed using a mixed inductive/deductive method.

Results—We completed 22 interviews post-implementation across all seven sites. Participants included both physicians (n= 16) and other clinicians who counsel patients regarding treatment options (n=6). While perception of SDM and the DA were positive, participants highlighted reasons for uneven delivery of DAs to appropriate patients. The CMS mandate for SDM was not universally viewed as associating with patients receiving DA's, but rather 1) logistics of DA delivery, 2) perceived effectiveness in improving patient decision-making, 3) match of DA content to current patient populations. Remaining tensions include the specific trial data used in DAs and reconciling timing of delivery with when patients are actively making decisions.

Conclusions—Clinicians charged with delivering DAs to patients considering primary prevention ICDs were generally supportive of the tenets of SDM, and of the DA tools themselves, but noted several opportunities to improve the reach and continued use of them in routine care.

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Background:

Shared decision making (SDM), use of patient decision aids (DAs) in particular, continues to garner political support and evidence as a set of practices which promote patient-centered care[1–3]. A Cochrane Review of DAs found that they routinely illustrate improvements in patient knowledge, satisfaction, self-efficacy, decision regret, involvement in decision making, and communication with healthcare providers when compared to standard care[4]. Despite these advantages, DAs are not routinely used in patient education and support. Reasons for failure to implement DAs involve complex logistical and perception-based barriers, including clinician perception that DAs are biased against device therapy, that they will extend the amount of time spent in consultation with patients, and that the time spent is not reimbursable[5,6].

With these barriers to patient-centered care as context, CMS has begun requiring documented use of DAs as a condition for reimbursement, including the decision of whether to accept implantable cardioverter defibrillator (ICD) placement for primary prevention of sudden cardiac death[5,7,8]. However, despite the political acceptability of SDM and explicit policy support from the Centers for Medicare & Medicaid Services (CMS) for using decision aids with these patients, documented use of DAs (or other educational efforts) with those considering ICDs is poor[9] resulting in an unclear relationship between these mandates and actualized improvements in the patient-centered qualities of care[10]. Additionally, recent investigations into implementation of shared decision making in cardiology have either not explicitly focused on the use of decision aids,[11] were conducted largely in the inpatient or critical care setting[12], did not include CMS documentation requirements[7,8], or some combination of the three. As such, little Is known about the practical experience of attempting to implement DAs into the clinical workflow of outpatient specialty cardiology

settings. Accordingly, the goal of this project was to describe experiences implementing patient decision aids into routine care for patients considering ICD placement, with a particular focus on experiences and intervention aspects which help or hinder use of the DA in real-world care.

Methods

Setting and overview

All data upon which these analyses are based are available upon reasonable request to the project leadership. The DECision Support Intervention for Patients offered implantable Cardioverter-Defibrillators (DECIDE-ICD) Trial was a pragmatic, type 2 implementation-effectiveness hybrid, stepped-wedge randomized controlled trial, conducted at seven sites across the United States, the design of which has been reported elsewhere[13]. Briefly, the primary goal of DECIDE-ICD was to simultaneously assess effectiveness and implementation of a suite of DAs meant for patients considering primary prevention ICD placement. Effectiveness outcomes were related to patient-centric decisions. The DAs themselves were in multiple formats (brochure and video) and clinical contexts (initial ICD implantation, cardiac resynchronization therapy (deciding between pacemaker-only or pacemaker plus ICD), and reimplant at battery depletion). The DA's were developed using iterative user-centric design methods, were seen as unbiased and acceptable among patients participating in a pilot trial, and are publicly available[14,15]. Notably, the trial coincided with the advent of the CMS reimbursement mandate (in 2018) and the COVID-19 pandemic (affecting the last two years of recruitment and site implementation), both of which logically influenced trial procedures, clinical incentives, and implementation outcomes. All activities described here were approved by the University of Colorado's IRB (COMIRB).

Sample and method

Potential interview participants were approached on a site-by-site basis, such that interviews occurred between six and twelve months after the intervention period had begun at their centers. First, site investigators were asked to participate in interviews, then to identify other members of their clinical electrophysiology teams who have responsibility for providing education and decision support for patients being considered for primary prevention ICD placement. Additionally, we utilized a secondary snowball method whereby we asked participants who had been identified by site-PIs to identify other clinicians at their site who may be knowledgeable about how patient decision support occurs at their center. Interviews followed a semi-structured interview guide (SUPPLEMENT 1) which was designed to assess RE-AIM domains and was modelled from a guide used in a previous investigation of decision aid implementation for patients considering left ventricular assist device implantation[16]. The semi-structured guide organizes thematic domains assessed while allowing for attention and description to be responsive to participant reports and narrative[17]. Interviews were conducted by members of the primary analytic team (BW, CEK), who met weekly over the course of interviewing and analysis to ensure consistency of approach and characterize emergent patterns emanating from participants' descriptions. Each was conducted using Zoom videoconferencing software, and all participants received a $50 gift card as compensation for their time.

Theoretic framework: The DECIDE-ICD project is guided by the Practical, Robust Implementation and Sustainability Model (PRISM)[18]. PRISM is used to understand how an intervention, the external environment, the implementation and sustainability infrastructure, and recipients interact to influence adoption, implementation, maintenance, reach, and effectiveness. The framework includes elements important to improve program implementation in diverse settings, including addressing perspectives of the organization and staff by facilitating internal (across team) and external (patient and payer) work. The outcomes evaluations are guided by the RE-AIM framework (the precursor to PRISM)[19,20] which assesses an intervention's potential for dissemination and population impact using five criteria: reach, effectiveness, adoption, implementation, and maintenance (of which we included all but adoption – the number of centers agreeing to participate over the number approached – which has been previously described[13].

Analysis

Interviews were analyzed using a team-based mixed inductive/deductive method similar to that used previously by members of our group[16,21–24]. This approach includes a mix of analytic methods, including constant comparative, grounded theory, and content analysis methods[25]. Coding was conducted by the interviewers (BW, CEK) who have masters and doctoral level training in qualitative research methods. A codebook was developed *a priori* addressing the primary research questions organized according to the modified PRISM and RE-AIM frameworks but also allowed for the inductive recognition of concepts emerging within our data In this analysis[26]. Analyses were conducted using Dedoose analytic software (v 9.0.17: SocioCultural Research Consultants, Los Angeles, CA). Six interview transcripts were coded by both coders, who met weekly over the course of analysis with the Principle Investigator (DDM) to discuss emerging concepts, codes and thematic structure as well as ensure consistent application of the codebook.

Results

Semi-structured interviews were completed with 22 clinicians at all seven participating sites between June 2020 and February 2022. Participants included 16 physicians and six other clinicians (including three registered nurses, two nurse practitioners, and one physician assistant) identified by site-PIs as being responsible for counseling patients regarding the option of whether to accept primary prevention ICD placement, with 2–5 interviewees per site (TABLE 1). Interviews ranged in duration from 17 to 49 minutes. Dominant themes within each implementation evaluation domain are described in detail below, with additional representative quotes for each subtheme appearing in TABLE 2.

Experiences Using DA

Reach

Practical and logistic issues featured prominently in interviewees' discussion of what determines whether decision aids are successfully delivered to appropriate patients. Having paper DAs available in clinic spaces facilitated reach both by being physically present when conversations were occurring and by reminding nurses and EPs to actually use them. As

one nurse stated, "*I think visibility helps, because you go into clinic and you're not always on your radar to grab something…if you see it in front of you, then you're like, oh yeah, I should just grab one of those*." [S7P5-MD]. Concurrently, some sites used a variety of technological methods to deliver DAs to patients prior to their EP visit, which became a critical delivery mechanism during COVID-imposed virtual visits: "*Then of course there's the whole COVID situation, which threw wrenches into everything. I mean, we had the links, the URLs, so if somebody was a phone visit, they could get that*" [S6P1-MD].

A few interviewees highlighted that adoption at the site level did not necessarily translate to universal uptake among clinicians within each site, influencing whether an individual patient received a DA or not. While all sites had adopted the DA intervention and had developed strategies for embedding the DAs into the clinical workflow, a minority of clinicians elected either not to use the tool or substituted other methods of discussing ICD placement in a manner which they felt met the CMS reimbursement mandate. As one described "*I think it varies by the provider. I think that here we have – there's three implanters and I think two of us use the folders pretty extensively. And I don't think the other one uses it very much*." [S4P2-MD]

Effectiveness

Decision quality: When asked to comment on whether they perceived DAs to be effective, clinicians consistently emphasized that DAs helped patients make more informed decisions. Conversations between patients and clinicians appeared to start with a better understanding of SCD risk and what the ICD does: "*I think the patients are more aware of what they're getting themselves into. There's certainly a better understanding of what the device is intended to do on their part. It certainly decreases the amount of questions that you need to answer*." [S3P1-MD].

Additionally, there was a widespread sense that using the DA, and the conversations it started, led patients to feel more secure in their decisions and less likely to express regret later on. One remarked that the DA *"just helped them feel more comfortable with whatever choice they made*." [S4P1-MD] and another said, "*I definitely feel like I see less regret in my practice. For the people who chose to move forward they kind of said, 'Oh yeah, we talked about this. I knew this was coming*." [S2P1-MD]. These improvements may be more pronounced among patients with lower health literacy, as one participant described *"it's got great visual aids; it's got different ways to introduce the data. And I think any education level would find they were able to understand the decision-making process in that packet*." [S6P4-RN]

Effective Use of Clinicians' Time: When asked to comment on how using the DA affected the amount of time spent with patients, experiences varied between clinicians and sites. Some participants indicated that using the DA extended the conversation during their consult. One participant tied this increase specifically to the notion that the DA potentiated new conversations about patient preferences in addition to well-rehearsed risk and benefit statistics typically discussed. One electrophysiologist posited *"I think that's also why a lot of clinicians stay in the knowledge sharing. That's a place where, 'I know these facts. I can*

tell you about benefits. I can tell about risks, and that's a realm I'm very comfortable in. But if we're gonna get into your individual preferences in life and death' that's a whole 'nother muddy waters a person may or may not feel very comfortable going into." [S6P1-MD]

Conversely, some participants noted an overall decrease in the total amount of time spent providing education to patients. While consultation time in clinic was described as either slightly longer or the same duration as without the DA, some described a scenario in which fewer patients had questions after the clinic visit, resulting in fewer follow-up contacts prior to deciding whether to proceed with ICD placement. As one nurse practitioner noted: *"in a way I think it's helped because I've watched people finally decide, 'Oh well, yeah, I think this is a good thing. I think I need to do it,' that have been putting it off for a long period of time*." [S1P3-NP]. Another clinician reflected that the suite of DA reduced follow-up visits with family members: *"(Prior to using the DA) it was not infrequent to have a second visit …somebody requires like a phone call or some sort of follow-up from there. I can't remember the last time I've had to do that…Now, that (DA) has effectively replaced that." [S1P1-MD]*. When asked to quantify the time saved, the same interviewee estimated that eliminating these extra consultations saved between 1.5–2 hours per month.

Treatment Decisions: Responses were mixed as to whether using the DA affected the number of patients who decided to receive an ICD. Some clinicians believed the DA increased the proportion of patients who accepted ICD placement by reducing the number of patients who might delay or otherwise avoid the decision. As one put it: "*I haven't had any patients call back and have tons of questions after going home and reading through it. I think some of them just call in and say, 'Hey, yeah, we do want to go ahead and proceed with it' if they didn't decide at the appointment*" [S1P3-NP]. Others sensed that the DA increased the number of patients who decline but felt as if this was an appropriate response to patients' values and preferences: "*I think there are more who choose not. I don't think a lot more but I think it's more common that people will reflect on the information and say, "Well, I think maybe not." I think that's okay, right? That should be completely okay*." [S1P4-MD].

Implementation

External environment—The 2018 CMS reimbursement policy requiring documented use of SDM tools with patients considering ICDs (using this DA as an explicit example) would seem to serve as strong external support for implementing these tools into routine practice. In some cases, the policy provided support for a top-down method of emphasizing the importance of consistent DA delivery to support staff: "*Doctor (X) …the director of our group – (has) been pretty proactive also about making sure that the right patients get included in the study. So, I think that's been helpful, too, kind of coming from the top to make sure that we're capturing all the patients we need to*" [S5P6-NP]. In contrast, a nurse at another site noted that inconsistent communication made implementation difficult: "*I don't know that it was ever formally presented to the providers, and so it's sort of a hit-and-miss thing now*." [S6P4-RN].

However, even with the added support provided to trial sites, implementation was uneven. One EP lamented *"(the CMS policy) seems not to be enough of an incentive, which is*

surprising to me. This was brought to the attention of our group, even independent of our participation in the study. I'm not sure I have a good answer for why it's not observed as religiously as it ought to be."[S7P1-MD].

Implementation infrastructure—Participants frequently cited the presence of local implementation "champions" as critical to successful implementation, especially by explaining the DA to other clinicians and staff. One EP nurse simply said "*it had good buy-in from both of our providers, that it was a helpful thing. So I think that [the transition] was pretty seamless*" [S2P3-RN].

This "spreading" of the DA between providers sometimes occurred organically, rather than through formal processes. Recalling a time after they were asked to cover for a colleague who was off of work, one EP said "*Then my partner comes back from vacation and he's like, "Suddenly everybody is talking about you in this office." They're like, "I go for like one week and suddenly it's like, 'Oh, Dr. (X) had this really great tool. He gave all this stuff. Oh my gosh, the patients are so impressed and stuff like that.'" He's like, "Now, I've got to do this thing. I can't stop hearing about this tool that you have" [S1P1-MD].*

Intervention characteristics—Participants who had used the DAs frequently commented on specific characteristics of the tools themselves, inferring that clinician-perceived advantages or weaknesses would drive their willingness to use them with patients. First, many participants felt that the DAs could be improved by tailoring the risk/benefit statistics at the patient level. One clinician said, "*if there were a tool that could take patient-specific variables and come up with a slightly more specific estimate of their likelihood of benefitting from the device or their likelihood of experiencing certain outcomes like appropriate or inappropriate shocks, infections, procedural complications, that sort of thing*", while noting that "*the most complex version would be actually trying to put numbers on it the way the Seattle model does.*" [S7P1-MD].

Similarly, several interviewees were critical of the specific risk/benefit data cited. SCD-HeFT data[27], in the opinion of these clinicians, are dated, with one saying specifically that they were troubled by the fact that the DA "*statistically draws on data that are 20 years old*" [S7P1-MD]. Moreover, these data are seen as limited by the designs of the trials themselves, as they do not accurately represent risk among patient subpopulations seen in their practice: "*It's not all Joe Smith is 60 years old with ischemic cardiomyopathy and he's on four meds and his (ejection fraction) is still 25. You know, those patients are infrequent at our place because they already have an ICD. So there's just not a lot of super straightforward patients*" [S4P1-MD].

Other basic suggestions to improve the DA's ability to be implemented included shortening the brochure version of the DA. Advantages to shorter tools included matching the brevity of the clinic visit, with one saying "*if we can continue to simplify and make the material succinct, that's going to help people. Attention spans are the lowest they've ever been*" [S2P2-MD], and because shorter tools could be more easily integrated into EMR-created resources already provided to patients: "*I haven't been able to put the PDF of that Colorado model – that discussion – into my After Visit Summary, so, sometimes, I'll have to print it,*

but that's kind of one of the limiting factors." [S7P6-MD]. Similarly, and with the additional advantages of streaming the documentation process for the purpose of the CMS mandate and availability to the minority of primary prevention patents seen in the inpatient setting, integration into EMR for direct delivery was seen as an area of potential: "*it would be something to incorporate into the system as a whole. Because if we could somehow put the decision aid into Epic, where it'd be available to inpatients as well, that might be a beneficial path*." [S6P4-RN]

Recipients/Patients—Patient characteristics featured prominently in interviewees' descriptions of challenges to universal delivery and effectiveness of these tools. There was a broad perception that a substantial proportion of patients seen in outpatient settings are not interested in reviewing any materials prior to appointments, including the DAs. As one indicated "*some people who just, for various reasons, are just not going to look at it…I think the hospital patients are a captive audience that's there. But again, it's sort of like doing the homework ahead of class…Sometimes their personality is just, 'Nah, I'll just go to the doctor and I'll just see what they've got to say. I'll just show up.'" [S1P1-MD]*.

Participants theorized that many of these patients had actually decided to pursue ICD placement prior to meeting with the EP team, perhaps following conversations with referring general cardiologists or after seeking out other information. One participant posited that the proportion of patients for whom this was true was *"probably about a third…So, a third come in with a real interest in it and having looked into it a bit or talked to their referring, and they're leaning towards it and they really just sort of want to come and get the sort of stamp of approval and meet me and go forward…(another) third hear about it, and they lean towards it during the course of the visit, and they're sort of – they'll often tell you they're ready to sign off on it by the time they leave, but they'll just go home and sleep on it. And then, the last third are not sure, and they just want to go home and think about it and talk to their family."* [S5P1-MD]. Several participants felt this variability strengthened the value of delivering the decision aid upstream of patients' conversation with the EP group, at least ahead of their clinic visit. As one remarked "*I think it would just be helpful to receive that before the conversation, so that it's not coming out of left field when they're first hearing about the surgery or whatever*" [S6P2-MD].

Maintenance

Participants tied their predictions about whether their sites would continue to use the DAs to a number of factors. One such factor was individual clinicians' perceptions of the DAs effectiveness - the sense being that since they had experienced improved conversations with patients, the tools would maintain as a standard component of the patient education process. As one noted "*Yeah. I do. I think that – I think this is among the more nuanced discussions that we have with patients and so, I think that having something that helps that discussion start or continue is very helpful, and I find it especially helpful among people who haven't really thought about this before – haven't heard about it and maybe don't have particularly good health literacy. I think it's been very helpful*" [S7P4-MD].

Many saw the continued use of the DAs as a straightforward way to meet the CMS mandate. When asked whether they would continue, one doctor mused "I don't see a reason not to. I mean it's expected by CMS, right? And it's helpful for patients, I think. So, I expect we'll just keep doing it" [S1P4-MD].

These desired improvements and developments notwithstanding, EP centers generally felt this suite of DA had a positive impact on patient conversations and plan to continue using these DA tools or something similar. As one clinician stated: "*I'm happy with how my discussions go. So I'll probably continue to use this tool or something similar and have similar kind of points of emphasis*" [S4P2-MD], and another said, "*I don't think we'd ever go back to not using it*." [S2P1-MD].

Discussion

The implementation context and subsequent clinical experience of the DECIDE-ICD Trial is unique as it occurred alongside a then-new CMS reimbursement requirement for documented DA use in the ICD decision context. The embedded qualitative project described here, including the use of RE-AIM evaluative implementation framework, was critical to understanding both how sites experienced implementation of patient DAs for those considering primary prevention ICD placement and use of the DAs themselves. As a practical matter, these experiences are likely to mirror those for outpatient advanced cardiology practices as they attempt to simultaneously meet CMS reimbursement guidelines and maintain the effectiveness and efficiency of their clinical workflow.

Despite widespread conceptual support for shared decision making among our participants, we observed clear challenges in implementing DAs into routine practice. These include many previously-described clinician concerns about adding time to patient visits, a sense that DAs are a covert cost-control mechanism (by reducing utilization of expensive therapies), clinical workflow inertia, and others[5,28,29]. The unique nature of delivering DAs in specialty outpatient cardiology settings came through in participant narratives. These stories highlighted a number of intersecting challenges which affected Reach (whether patients who should have gotten DAs ultimately did), perceptions of Effectiveness (how clinicians' subjectively evaluated whether DAs were helpful to patients or not), and Implementation (with particular focus on characteristics of the DAs making them usable, helpful, and appropriate).

First, whether a DA ultimately reached a patient who was supposed to receive one was primarily a function of many logistical, personal, and patient-centric factors. The most common factor was availability and prompting, as brochure DAs were viewed by many as critical both for facilitating easy access in the course of a conversation and as a physical reminder for clinicians. Another factor was variability in clinician-level uptake of the DA within practices, where a proportion of clinicians charged with supporting patients in their decision making had elected not to use versions of the DA. Finally, patient factors, such as difficulty accessing these materials or explicit preferences to talk with clinicians about their options, contributed to variability in DA uptake. Notably, clinicians charged with delivering DAs to patients did not mention a number of commonly-cited factors contributing to

"reach", including the presence/quality of clinician-focused training in SDM[28] or concerns about the DA "challenging" their authority with patients[30]. While these differences may be partially due to the fast-paced nature of specialty cardiology practice, they may indicate that interventions meant to improve whether appropriate patients actually get DAs should focus on the basic logistics of getting tools and patients in the same physical location.

Second, how clinicians subjectively evaluated whether the DAs were effective or not varied considerably. In SDM, "decision quality" is defined as a combination of patient knowledge and value-choice concordance[31–33], and measures constructed along these lines have been developed for patients considering an ICD[34]. In determining the efficacy of the DA, our participants emphasized two separate facets of decision quality: 1) their perception of whether the DAs could be delivered efficiently within their workflow; and 2) whether they sensed that patients were making different treatment decisions than they would have otherwise. These perceptions are crucial, as they inform clinicians' sense of whether DAs would be used after the trial was completed, which is the realistic goal of implementation efforts.

Third, clinicians highlighted characteristics about the tools which affect their willingness to implement them into routine care, including in certain subgroups of patients. How clinicians perceive these tools concurrently supports and challenges the user-centered design process through which the DAs were developed[14]. Clinicians, who our user-centered design process conceived of as the "users" of the DAs, want them to be shorter and include updated and tailored risk/benefit data. One participant conscientiously chooses to discuss Seattle Risk Model[35] estimates with their patients rather than the DA for these reasons, although the viability of this approach in terms of meeting the CMS mandate is unknown[29]. Nonetheless, these comments underscore the importance of thinking about patient DAs as living artifacts, which require continual updating and adaptation[28]. Creating ways to support this process is critical to the long-term success of policies forcing the use of these tools, such as CMS reimbursement policies[8,36].

Limitations:

Our qualitative findings should be considered in light of several limitations. First, sites involved in our study were selected to be approached based on a combination of enthusiasm for the content area (patient-centered care in specialty cardiology), diversity of settings, and historical connection to the research team. Each had highly-engaged site champions, who served both as communications liaisons for trial purposes and as a local resource to develop implementation strategies and troubleshoot problems. Our findings may not be representative of EP clinicians in other settings, particularly in smaller and/or private practices. Second, the pool from which we were able to draw participants included only clinicians who participate in patient education and decision support related to ICDs at trial sites. While we conducted as many interviews as possible, with professionally-diverse participants, within the pre-determined timeframe following sites' crossover into the intervention period, we were not able to continue interviewing new participants in order to establish thematic saturation. As such, it may be possible that additional factors affecting reach, implementation, and perceived effectiveness of DAs in this population exist but were

not represented in our sample. Third, the team chose to operationalize implementation and reach according to whether clinicians delivered a DA to a patient, rather than whether the patient themselves engaged with the DA. Patient's ability and willingness to engage with these tools varies, logically impacting the extent to which the tool can improve patient-centered outcomes[37].

Also, the CMS mandate itself provided both a scientific challenge (in maintaining an untreated control group) and a financial impetus for sites to implement effectively. This policy context, and the community-level support for shared decision making the policy evidences, may have affected how clinicians described their personal enthusiasm for the DAs. Finally, while the CMS mandate requiring DA use with this patient group specifically requires that the DA be discussed with a member of the EP team, the optimal timing for delivering it has not been defined. It may be possible that patients would experience greater benefit from exposure to the DA if it were delivered earlier in the decision process (e.g. by the referring general cardiologist or heart failure specialist). If so, and these improved patient experiences were noted by clinicians, it may influence their enthusiasm for the DA more generally.

Conclusions

Our efforts to implement a patient decision aid for primary prevention ICD care into routine practice met mixed results. Successes in implementation include a general sense that DAs improve clinicians' perceived quality of conversations with patients, resulting in better understanding of their option, improved value-choice concordance, and possible saving of clinician time over the course of the EP teams' interaction with a patient and their care partners. Challenges persist, including developing versions of the DA in diverse enough formats as to facilitate EHR delivery to patients, tailoring risk and benefit statistics to specific patients in a scalable way, defining the optimal point in the referral process to provide patients with DAs, and standardizing delivery not just across sites but across clinicians within each site. These challenges pose important questions for future CMS reimbursement policies meant to improve shared decision making, as variability in practice persists in spite of their seeming influence, including variability in something as simple as whether decision aids reach the patients they are intended for.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Acronyms used:

SDM	Shared decision making
DA	Decision aid
ICD	Implantable cardioverter defibrillator
CMS	Centers for Medicare & Medicaid Services
DECIDE-ICD	The DECision Support Intervention for Patients offered implantable Cardioverter-Defibrillators Trial
PRISM	Practical, Robust Implementation and Sustainability Model
RE-AIM	Reach, Effectiveness, Adoption, Implementation & Maintenance (implementation evaluation model)
EP	electrophysiology
EMR	Electronic medical record

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What is known:

Decision aids can help improve patient decision making, and use of them is required by CMS for patients considering primary prevention ICD placement

What the study adds:

Whether clinicians actually present decision aids to patients still varies, according to several practical and design factors

Table 1:

Description of Programs and Participants Involved in the DECIDE-ICD Trial

Site	Hospital Type	Total Patients Enrolled in Trial	Post-intervention Study Interviews Conducted
Site 1	Private, academically-affiliated	238	Electrophysiologists: 2 Nurse practitioner: 1
Site 2	VA	53	Electrophysiologists: 2 Registered nurse: 1
Site 3	Private, non-profit	150	Electrophysiologists: 1 Nurse practitioner: 1
Site 4	Private, for-profit	114	Electrophysiologists: 2 Other clinician: 0
Site 5	Academic medical center	70	Electrophysiologists: 2 Nurse practitioner: 1
Site 6	County safety-net	40	Electrophysiologists: 1 General cardiologists: 1 Physician assistant: 1 Registered Nurse: 1
Site 7	Academic medical center	95	Electrophysiologists: 4 Heart failure physician: 1 Other clinician: 0

VA=Veterans Administration

Table 2:

Additional Selected Representative Quotes, by RE-AIM Domain and Subtheme

RE-AIM Domain	Subtheme	Representative Quote
Reach	**Logistics**	I think having hard copies for whatever resource material, for ICDs or not ICDs, just from general EP care, is probably what will work best for our clinic setup…I think having some sort of decision information tool or packet or thing in the patient room is helpful. S6P2-MD
		I think just having them [DA] physically there (improves reach). S5P3-MD
		I think location physically, because they're right in front of you, and if you see them, I mean, I see them, like, I sit in this one spot for clinic, and I, like, see them right in front of me, so it's, like, a good reminder. And I remember one time somebody, a patient left, and I was like, oh, I should have given it, so I grabbed one. S7P5-MD
	Uneven Uptake Among Clinicians	Yeah, I mean, we use it, but that being said, I mean, we don't have like a ton of providers back here, but as far as I know, our electrophysiology group is using it and the rest of our general cardiology providers are using it as well. So, I've never asked them, but I was under the assumption that they were. S6P5-PA
Effectiveness	Decision Quality	Interviewer: You told us a bit about how you try to get the decision aids to people. Have you changed the way that you talk with patients or have you noticed a change in the conversation that you have with patients after you started using the packet? Interviewee: I think that maybe we try to maybe make it more towards them making a decision about it. S1P3-NP
		This [decision aid/study] has just really like opened the door to what the discussion should be, which is, "Here's your potential for benefit. Here are the risks. Here's your likelihood of benefit over four years. Here's how many of people like you who get this procedure, get this device implanted actually derive benefit from the device during those four years. Here's the number who don't." Then patients can make a better decision about it. S1P4-MD
		So what I would definitely say is, relative to before implementing the ideas of shared decision making in our practice more generally I do feel like we have more effective communication with patients. I definitely feel like I have a more mindful and concrete understanding of what patients want specifically. S2P1-MD
		My personal opinion is I think that folks are more sure of what they want. They feel like it either is the right thing for them or not. And I benefit from it because to me it's important that they understand what the purpose of this is. And I'm always surprised by what – how different interpretations of what we said can be. Often when physicians, I think in particular, are saying something, they think, "Boy, I could not have said that any clearer." And then you assess what people heard, and you're kind of surprised. You're like "Oh, that's what you took out of what I said?" S2P2-MD
Implementation	**External Environment**	I think obviously the CMS mandate, the guidelines, and the mandate I think have made the process a little bit different. S6P1-MD
	Implementation Infrastructure	Our staff, meaning our medical assistants and schedulers, are instructed to provide them with materials for shared decision making so they get printed materials and they get a link to your website with the shared decision making videos…It's been going pretty well. Ideally we'd be at 100 percent, but we're not at 100 percent so we're trying to figure out ways we can increase our reach to make sure that patients have reviewed everything before they show up. S3P1-MD
		the director of our group – (they've) been pretty proactive also about making sure that the right patients get included in the study. So, I think that's been helpful, too, kind of coming from the top to make sure that we're capturing all the patients we need to. S5P6-NP
	Intervention Characteristics	one is making them shorter. But the – I feel this way about informed consent forms, too. Anything over a page, you've probably lost your audience. I see by actually having one of these things be one page, or at most two, like a front and back because you can laminate it, reuse it. Post-COVID you can start reusing things again. There's a simplicity to that one to two-page max that I think would be actually valuable. S7P1-MD
		how likely people are to respond by their different conditions or what may or may not be appropriate. Like if you have like in my opinion if you have an 80 year old nonischemic with a huge left bundle there's good evidence that probably you do a CRT pacemaker. But a defibrillator may not be the right option. And sometimes people kind of struggle with that concept. S4P2-MD
		we've had a couple people comment about they love the videos and it really helped them. S4P1-MD
	Recipients/ Patients	I think before the packets are introduced in the clinics and inpatient settings, I think it needs to be presented at a provider meeting, just so everybody knows what's out there and it's not a surprise.

RE-AIM Domain	Subtheme	Representative Quote
		Where we had not done that here, so it's a constant upgrade to the attendings when they come into clinic. And so it's sort of the fellows and the nursing staff know about it, but sometimes the attendings don't. They haven't been in clinic for a while. S6P4-RN
Maintenance	**Perceived Effectiveness**	this should just be part of the standard of care. S5PP3-MD

RE-AIM = Reach, Effectiveness, Adoption, Implementation, Maintenance; ICD=Implanted cardioverter defibrillator; EP=electrophysiologist/electrophysiology; DA=Decision aid; CMS=Centers for Medicare & Medicaid Services; MD=Physician; PA=physician assistant; RN=Registered nurse