COMIRB Protocol

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Protocol #: 17-1697
Project Title: A Multicenter Trial of a Shared DECision Support Intervention for Patients offered implantable Cardioverter-DEfibrillators: DECIDE - ICD Trial

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Version Date:

I. **Hypotheses and Specific Aims**:
The research team proposes to assess the real-world effectiveness and implementation of patient decision aids (PtDA) for high-risk decisions using the implantable cardioverter-defibrillator (ICD) as a model.

Hypotheses
1a) Decision aids will reach over 50% of eligible patients.
1b) ICD PtDAs will be effective in improving decision quality in real-world practice.
1c) Better informed patients will have lower anxiety, higher rates of planning for the possibility of deactivation, and increased identification of a surrogate decision maker.

Specific Aims
1) Assess real-world effectiveness of PtDA for high-risk decisions using the ICD as a model.

II. **Background and Significance**:
Patient-centered care is growing in both practical and political importance. As the primary process of involving patients directly in their care, SDM is explicitly supported both by the IOM[1,2] and in the Affordable Care Act.[3] The Food and Drug Administration has recently begun the Patient Preference Initiative and is considering SDM as part of the approval process.[4] Medicare recently included requirements for SDM as a condition of reimbursement for lung cancer screening[5] and the left atrial appendage closure (WATCHMAN) device placement.[6] Our group takes a broad view of SDM as a "meeting between experts."[7] This definition from 1985 acknowledges the clinical expertise of the clinicians and the lived expertise of the patients. We reject incorrect assumptions that SDM is just presenting information to patients and asking them to choose.[8] Rather, SDM is an intimate process between patients and clinicians whereby treatment recommendations are tailored to both the best evidence and well-informed patient preferences.

Implantable cardioverter-defibrillators (ICD) are an ideal model to implement SDM. Over 200,000 ICDs are implanted annually (both new devices and replacements)[9] in an effort to prevent sudden cardiac death (SCD), a leading cause of death in the US. Once surgically implanted, the ICD monitors the patient's heart for dangerous rhythms, quickly delivering a defibrillation shock to restore a healthy rhythm. Despite their clinical utility in improving mortality from SCD, [10-12,13] a number of clinical and quality of life (QOL) threats exist. Some studies suggest that patients with ICDs have more heart failure admissions,[14] a lower quality of life— particularly if shocked[15,16]—and an increased incidence of anxiety, depression, and post-traumatic stress disorder.[17] Further, ICDs can fail,[18] shock inappropriately,[19] and, if not properly deactivated cause unnecessary suffering at the end of life.[20-23] Patients have described an ICD shock as "getting kicked in the chest by a mule"[24] leading some to have their ICDs removed for fear of repeated shocks.[25]

Patients with ICDs may face multiple preference-sensitive decisions. Patients recommended for primary prevention ICD therapy face the ICD decision in several contexts: 1) initial implantation (130,000/year); 2) re-implantation when an existing battery dies after 5-7 years (70,000/year); and 3) when considering whether to include defibrillation in cardiac resynchronization therapy (CRT) (40% of ICDs).[9] Each decision hinges on whether the patient's goals align with accepting a device in the hope of extending life, while foregoing the possibility of sudden death. Patients facing this decision may intuitively seize the opportunity to prevent sudden death, but many of the same patients also intuitively indicate that they would prefer to die peacefully in their sleep, which the ICD prevents.[26]

The current state of decision making in ICD care is poor. Even beyond drastic regional differences in rates of ICD implantation highlighted in our earlier work (see preliminary data C2.1),[27] reports frequently highlight suboptimal practice with respect to patient education and inclusion in decision making.[24,28] Patients with ICDs frequently report never having had a conversation about periprocedural risks, expected benefits, or potential QOL problems.[24] Studies of clinicians' perspectives identify guideline-based, rather than patient-preference-based decision making. Dr. Matlock led an integrative review of patient perspectives that highlighted a paternalistic approach to decision making.[24,29] It is not surprising that patients overestimate the benefits of ICDs, underestimate the risks, and are uninformed about device deactivation.[29]

PtDAs improve SDM and decision outcomes. A Cochrane review of 115 randomized trials demonstrated that PtDAs improve knowledge, satisfaction, patient/provider communication, increase patient involvement in decision making, and reduce patient decisional conflict and regret.[30] PtDAs come in many forms including paper, video,[31] interactive web sites,[32] and even telenovelas.[33] Our group has developed and piloted ICD PtDAs in multiple media formats (see preliminary data section). We have learned that most patients prefer the combination of a paper version with a video.[34] Patients did not utilize the website, and they found the shorter paper Option Grid (essentially a 1-page FAQ) to be less helpful.[35] In response, we have developed and tested paper and video PtDAs for use during: 1) initial ICD implantation; 2) ICD reimplantation (after the battery dies); and 3) ICDs in the context of cardiac resynchronization (CRT).

Despite their established efficacy, PtDAs are not implemented outside the research setting.[36] Much of the prior work on PtDA implementation has occurred in primary care settings with lower-risk interventions.[30,36,37] A recent systematic review of PtDA implementation (co-author Dr. Lewis – Co-I) identified a host of logistical barriers, including clinicians' perception of time necessary to use PtDAs, lack of reimbursement, and perceived bias inherent in the PtDAs themselves. As described above, ICDs are a higher risk treatment with significant trade-offs. Professional guidelines and proposed quality measures recommend SDM.[38,39] However, we have shown that clinician opinions vary[40] and many clinicians endorse paternalistic views which de-emphasize patient preferences out of fear that patients may "make an unwise decision and not proceed with therapy."[29]

This proposal builds on prior lessons learned. We have identified many problems in the field of SDM and PtDAs. With this innovative type II effectiveness/implementation hybrid design,[41] we will study solutions to these problems (**Table 1**). We assert that the combination of the high-risk nature of the decision, the engaged study team of clinical champions, a user-centered approach to PtDA development, a reproducible implementation strategy, and recent changes in professional guidelines will lead to implementation success.

Table 1: Problems and Solutions Addressed

Conceptual Area		Problem	Our Solution
Aim 1	1a: Reach	Unclear how to best reach eligible	A suite of 3 decisions aids and clinical

		patients	champions will assist in normalizing the new process.
	1b. Effectiveness	Lack of data regarding educational outcomes in real-world practice	Exploring effectiveness in a real-world trial rather than a tightly controlled research setting.
	1c: Downstream effects	Lack of data regarding QOL impact of SDM in real-world practice	Test the hypotheses that better informed patients have improved psychosocial outcomes.

III. **Preliminary Studies/Progress Report:**

Section 1: Strength of our infrastructure and investigators

Our transdisciplinary research team has an established record of success in a broad range of topics related to SDM development, measurement, ICDs, and implementation (**Table 2**).

Table 2: DECIDE-ICD Study Team Expertise	Core team	Expertise in SDM	Expertise in implementation	Expertise in ICDs	Analytic team
Dan Matlock, MD, MPH, Project Lead	X	X	X		X
Larry Allen, MD, MHS, Co-I	X	X	X	X	
Carmen Lewis, MD, MPH, Co-I	X	X	X		
Chris Knoepke, PhD, MSW, Co-I	X	X			X
William Sauer, MD, Site-PI – U. of CO				X	
Dan Kramer, MD, MPH, Site-PI – Beth Israel	X			X	
Sanjaya Gupta, MD, Site-PI, Mid America Heart Institute				X	
John Mandrola, MD, Site-PI – Baptist Health				X	
Paul Varosy, MD, MS, Site-PI – DVAMC	X			X	
Lucas Marzec, MD, Site-PI – Denver Health	**???**				
Pam Peterson, MD, Site-PI – Denver Health					
Scott Brancato, MD, Site-PI – Providence Health				X	
Diane Fairclough, DrPH, Lead Biostatistician	X				X

Core team experience with SDM and implementation: Drs. Allen, Matlock, and Lewis have significant collective experience in research and implementation of PtDAs. They are currently conducting the DECIDE-LVAD trial, a Patient-Centered Outcomes Research Institute (PCORI)-funded 3-year, type II effectiveness/implementation hybrid under the guidance of Russ Glasgow and the RE-AIM framework.[42] Our proposed trial is similar to the DECIDE-LVAD use of a stepped-wedge design to implement an Left Ventricular Assist Device (LVAD) PtDA at 6 sites across the United States. This trial is halfway through, and is currently overenrolling and early estimates of reach are near 100% at some sites. Dr. Matlock is leading the implementation evaluation of this project.

Dr. Lewis has extensive experience leading or participating in PtDAs and SDM implementation in primary care.[43,44,37,45-48] The challenges presented by the low-risk nature of primary care decisions and the resultant lack of clinician receptivity to SDM have informed a new scope of work with Dr. Matlock in Colorado to design PtDAs with a user-centered design approach specifically for enhanced implementation. She and Dr. Matlock are funded by the Dean to develop a program in SDM and they now co-lead the SDM Core on campus.

Electrophysiologists as site investigators: The team of site-PIs are all highly engaged clinical electrophysiologists poised to be champions of SDM implementation. Dr. Matlock has previously published with many of these site-PIs.[49,29,50] This high level of engagement will facilitate implementation within this project and dissemination after this project.

Advisors: We also have two expert advisors. John Spertus, MD (cardiologist with experience in multisite DA implementation) and Russ Glasgow, PhD (expert in implementation science).

Section 2: Prior research on ICD decision making

Through our extensive work on ICD decision making—including patterns of ICD use, qualitative interviews of patients and clinicians, and clinician and patient surveys—we have identified problems in current ICD decision-making practice, including wide practice variation, clinician paternalism, and low patient knowledge.

Wide practice variation: Using data from the Medicare-mandated ICD registry, we found significant variation (4.5 fold between the lowest and highest quintile) in the utilization of ICDs among fee-for-service Medicare beneficiaries (**Figure 1**).[51] Surprisingly, this variation was completely unrelated to the regional supply of electrophysiologists or cardiologists. We followed this study with another analysis examining the decision to receive a single or dual lead ICD at the hospital level and found that use of this therapy ranged from 0% at some hospitals to 100% at other hospitals.[52] Physician, hospital, and regional effects far outweighed patient effects, further suggesting that patients' considerations were not included in current ICD decision making practices.

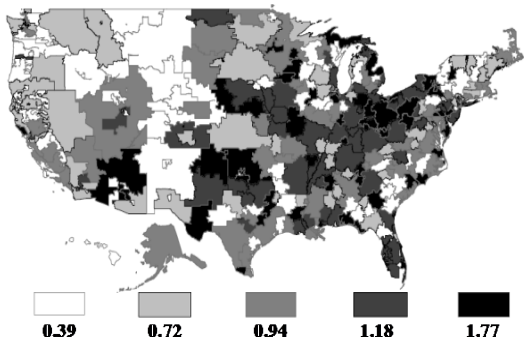

Figure 1. Rate ratio of receiving an ICD compared to the national average

National clinician survey demonstrating paternalism: Following this study, we conducted a national survey of over 1200 members of the American College of Cardiology to determine if attitudes towards ICDs varied across regions of utilization. Notably, over half of the cardiologists rated "ICD mortality data" as more important than "patient preferences" in their recommendations for ICDs.[40] Clinicians in high use regions from Figure 1 were more likely to recommend an ICD to a "frail" patient or a patient with a life expectancy of less than one year, which is discordant with guideline recommendations.[53]

Patient survey demonstrating poorly informed patients: As part of the development of a decision quality measure, we surveyed all patients with ICDs within the Kaiser Permanente Colorado (KPCO) system (n=417). We asked a host of knowledge, values, and participation questions surrounding ICD decision making. Responses raised concerns about patients' understanding surrounding their ICDs: 58% incorrectly thought that the ICD should never be turned off and 60% overestimated the lifesaving benefit of ICD therapy by 400%. Most interestingly, 61% noted that they would rather "die quickly and not live as long" than "live as long as possible and die slowly of a progressive illness," which is in diametric opposition to ICD function. Dan Kramer (site-PI, Beth Israel) found similar knowledge deficits in a recent survey where only about 15% of patients reported ever hearing from their doctors about the possibility of ICD deactivation.[54]

Qualitative studies about ICD decision making: To understand decision needs surrounding ICD decision making (for theoretical framework, see Section 3), we conducted a qualitative study of patients with ICDs, patients who had declined ICDs, and cardiologists regarding ICD decision making.[29]

- Cardiologists varied markedly in approach to ICD decision making. Most were heavily influenced by *"the guidelines."* Indeed, the guidelines seem to promote a beneficence/paternalism that impedes a frank discussion with patients: *"I think my biggest concern is if I convey the risks to them too strongly, that they will choose or make an unwise decision and not proceed with therapy."*
- Patients with ICDs indicated not being offered a choice: *"I was…told by two heart doctors I had to have it, so there you go. There ain't much thinking about it. Just get it done."* These same

patients also noted learning of the risks after implantation: *"…I don't think anything I read touched on how depressed I was going to be about it."*

- Patients declining ICDs expressed concerns that the numbers didn't apply to them and/or the benefits were not enough: *"It's like walking around with a motorcycle helmet on when you're driving your car."* One patient addressed the trade-off between dying sooner from sudden death and living longer and dying of progressive heart failure: *"Going into my decision is also the fact that I can't work because of my medical condition. I can't work at the hospital; I can't work at the church. My life is sitting here and watching TV… to take a defibrillator would just lengthen the process that I don't really want lengthened."*
- Behavioral economics were applied via a framework analysis of two sets of interviews. We found evidence of cognitive bias in decision making, including patients attributing a halo effect to a clinician, who then presents a status quo bias to perform an ICD in the context of influential framing techniques. Taken together, the biases appeared to encourage ICD treatment.(under review)

Development of a measure of decision quality: Decision quality is an essential element of the Ottawa Decision Support Framework (Figure 2) defined as "the extent to which the implemented decision reflects the considered preferences of a well-informed patient."[55] Accordingly, a decision is "a quality decision" if the treatment chosen is concordant with a knowledgeable patient's values.[55,56] Some have proposed that measures of decision quality be included in the pay for performance agenda[57] and the Affordable Care Act calls for "the development of quality measures that allow for the assessment of the experience, quality, and use of information provided to and used by patients..."[3] We developed a measure of ICD decision quality using a robust process of patient and clinician assessment to determine the key knowledge items (content validity). We then tested this measure on a large population of patients and determined test-retest reliability ($r=0.56$, $p>.01$) and internally-reliable assessment of patient knowledge ($\alpha=.61$). We demonstrated discriminant known-groups validity of the knowledge measure by showing that clinicians scored better than patients with ICDs who scored better than patients without ICDs (98% vs. 60% vs. 40% mean scores, respectively).
For values items, we found that patients would rate competing values (such as dying quickly or living as long as possible) very highly when asked as single items, leaving little variability in responses. When forced to choose on a visual analogue scale, however, we found that groups of patients would discriminate their preferences. In total, the values items included herein account for 53% of the variance in relevant patient values. This item will be used to assess value-concordance going forward.

Chris Knoepke's dissertation: In his doctoral dissertation,[58] Dr. Knoepke surveyed current defibrillator patients at the University of Colorado (with the guidance of Dr. Matlock - PI) to conceptualize relationships between how patients learned about their ICDs, how well they understand benefits and risks associated with ICD therapy, and QOL. In addition to creating new ICD knowledge and informational media history measures, the data gathered in this project highlighted group-based differences in treatment knowledge and information-seeking behavior. When compared to their younger counterparts, the oldest patients in the sample (age >71.5) both used fewer forms of media to learn about their ICD (being particularly less likely to use online information) and scored lower on a treatment knowledge measure, as did participants who did not complete high school when compared to those with at least a college degree. Significant depression and anxiety were also highly prevalent in this sample of patients (58% and 39.5%, respectively), and depression illustrated high statistical collinearity in models predicting patients' QOL. Dr. Knoepke continues to analyze whether this association indicates that depression drives QOL among ICD patients to a greater extent than previously thought, and/or the possibility that depression mediates other factors' influence on QOL.

Hartford-sponsored symposium on older adults: In 2014, Drs. Matlock and Kramer received funding from the Hartford Foundation to host a multi-disciplinary symposium of researchers to discuss the practice and research agenda for older adults considering ICDs. The proceedings from this symposium highlighted many aspects of ICD research and practice, including the importance of SDM for ICDs.[49]

In sum, not only do our preliminary data demonstrate our team's strong history of research on decision making and patient engagement, but the above studies reveal substantial gaps in decision making, including wide practice variation, a tendency towards paternalism among clinicians, and low patient understanding regarding important aspects of their ICD, clearly demonstrating the need for PtDA implementation in the real world.

Section 3: ICD PtDA theory, development, pilot, and implementation:
Theoretic foundation behind the ICD PtDAs: Normative theories of decision making, such as Expected Utility Theory, are based on an ideal—that all patients can approach decisions rationally and are able to weigh the risks and benefits of various interventions.[59] Descriptive theories of decision making, such as Prospect Theory, demonstrate that humans are subject to cognitive biases that cause decision making to deviate from the normative/rational.[59,60] The Dual-Process Theory and more recent theories such as Fuzzy Trace Theory argue that people make decisions both intuitively, drawing on past experiences and emotion, and rationally, using a reasoned analytic process.[59,61] Prescriptive frameworks attempt to define ways in which decision making can be improved.[62] The Ottawa Decision Support Framework (**Figure 2**) is the prescriptive framework we used to guide development and evaluation of the ICD PtDAs. This framework asserts that participants' decisional needs (e.g., knowledge, values, support) will affect decision quality, which then impacts subsequent outcomes such as emotions (e.g., regret, blame), behavior, and appropriate use of health services.[63] The framework asserts that decision support can improve decision quality by addressing unresolved decisional needs.[29]

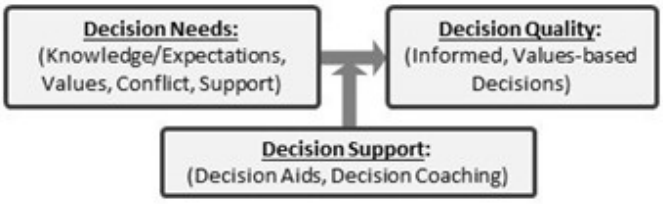

Figure 2. Ottawa Decision Support Framework

ICD PtDA development process: We have developed combined paper and video PtDAs for patients considering several aspects of implanted defibrillation: 1) Initial implantation; 2) Reimplantation; and 3) Defibrillation in the setting of CRT. Following the Ottawa Decision Support Framework and International Patient Decision Aid Standards (IPDAS), and utilizing the extensive needs assessment described above, we developed drafts of the pamphlet PtDAs. We included all components suggested in the IPDAS, including information about options, unbiased probabilities, values clarification exercises, and structured guidance on deliberation and communication.[64] We iteratively reviewed the PtDAs with **multiple stakeholders,** including 29 patients, the electrophysiology faculty at the University of Colorado, the Colorado Cardiovascular Outcomes Research Consortium, the Palliative Care research group, all the site-PIs, and an expert review panel. We performed 18 formal iterations until all stakeholders felt that the PtDAs met the criteria of accuracy, readability, and lack of bias.[65] Following completion of the paper PtDA, we developed the video PtDA and began another process of iteration. In addition to meeting all IPDAS criteria, our PtDAs incorporate a host of **innovations** that were deemed necessary based on the preliminary work.

1) Addressing intuitive and emotional aspects of decision making: The PtDA design was informed by the Dual-Process Theory,[59,60] recognizing that patients use both intuitive "automatic" and reasoned "reflective" processes in their approach to decisions. In response,

our PtDAs utilize palliative care communication techniques such as naming/addressing emotion, normalizing language, and avoiding euphemisms.[66]

2) Framing around death: Our needs assessment caused us to rethink our approach to SDM around the topic of death. Prospect Theory advises that people will be risk-seeking when faced with losses.[60] When choosing to forgo an ICD is framed as a certain loss (i.e., death), people will naturally "do anything" to avoid it. Our PtDAs frame both options as reasonable. In the videos, this is achieved with narration by Paul Varosy (Site-PI, DVAMC) and with patients describing their competing choices. This "imagined futures" exercise is a strategy move into a more cognitive space where they can make a reasoned decision while considering their values.[67]
3) Balanced and standardized patient and caregiver testimonials: We made an explicit decision to include patient narratives in our PtDAs. First, in our needs assessment, many patients stated that they wanted to hear from other patients. Second, biased narratives from industry and other sources are abundant on the internet - by including tested and controlled narratives, we were able to ensure honesty in the messages patients receive.[68] We were aware of concerns that narratives may be overly biasing.[69] To avoid this, we chose to include only process narratives (e.g., "Here is how I made my decision") and avoid outcome narratives (e.g., "This is the best/worst decision I've ever made").[70]
4) Combined pamphlet and video PtDAs: The combined format of a pamphlet and video was chosen based on our prior work and designed to fit diverse clinical contexts. Further, some data suggests that videos are better for patients with lower health literacy.[71]
5) Design for implementation: While we followed IPDAS guidelines, our iterative development process utilized a user-centered design perspective with both patients and clinicians. Consistent with user-centered design principles, feedback from users took precedence over IPDAS guidelines specifically for the purpose of facilitating future implementation.[72,73]

Pilot trial of the ICD PtDAs: 21 patients enrolled; 15 were randomized to the intervention. 67% found the PtDAs to be unbiased, 22% found them biased toward ICDs, and 11% found them biased toward not getting an ICD. Furthermore, 89% found the PtDAs helpful, and 100% would recommend them to others. The pilot was feasible at all sites; however, using clinic staff to identify eligible patients was more efficient than research assistants conducting chart review. Intervention patients had trends towards improvements in both domains of decision quality: greater knowledge about ICDs (*M*=14.0/20 vs. 11.6/20, *ns*) and increased concordance between their decision and values (71% concordant vs. 29%, *p*=0.06).[34]

High Value Health Collaborative (HVHC) implementation: Dr. Matlock's initial iteration of ICD PtDAs were adopted by the HVHC as part of a national SDM implementation project funded by the Centers for Medicare and Medicaid (CMMI). Implementation occurred across 17 health systems using a paid health coach as the agent of PtDA delivery. At the end of the grant, none of the health systems continued funding the health coaches independently and the practice came to a halt with no maintenance. As part of an additional PCORI grant, we qualitatively studied this natural implementation using an organizational systems theory approach. We interviewed health coaches, site leaders, and program leadership. A major reason the implementation was not successful was the timeline and change in scope from patient engagement to SDM imposed by CMMI halfway into the project. Limited resources hindered buy-in; for example, at many sites, health coaches were expected to do all the relationship building. Plus, health coaches were working across multiple conditions in multiple clinics, and they were not able to connect with clinic staff to normalize the process for sustainability in their absence. The most successful site achieved clinician engagement at multiple levels, and health coaches shared positive reactions to the PtDAs. One health coach told a story about how the Spanish version of the PtDA helped a suspicious patient visiting from Panama decide that the ICD would be a good choice for him. Lessons learned from observing this failed implementation heavily inform the strategy herein. Namely, use of normalization process

theory and clinical champions and staff to develop a low-cost, sustainable strategy of PtDA delivery.

IV. Research Methods

A. Outcome Measure(s):

Reach**:** Reach is defined as the proportion of the target population who participate in the intervention. While this is a straightforward measure, defining the denominator of eligible patients is surprisingly difficult. We will assess the percentage of patients that both receive and remember reviewing the PtDAs. Representativeness will be assessed by comparing participants to those who opt out on a range of available demographics and clinical indicators (e.g., age, gender, comorbidities) from chart review. As we are only enrolling a subset of patients into the trial at each site, we will ask the staff delivering the PtDAs to maintain a log of intervention recipients. We will obtain a waiver of consent to calculate aggregate reach at each site among all patients receiving ICDs.

Effectiveness:

- Primary outcome: Decision quality is an essential element of the Ottawa Decision Support Framework (Figure 2), defined as "the extent to which the implemented decision reflects the considered preferences of a well-informed patient."[55] Decision quality measures consist of two domains: knowledge and values.
  - Knowledge: Consistent with methods developed by Sepucha et al.,[55,56] we have developed a knowledge measure. We will use this measure to test knowledge at baseline and at 1 months and 6 months.
  - Value-treatment concordance: We will calculate concordance between patients' values and the treatment they choose according to the validated methods of Sepucha et al.[55,56] We will measure this in two ways: 1) we will measure the values-clarity sub-scale of the decision conflict measure (test-retest reliability and Cronbach's alpha > 0.78, correlated with knowledge, regret, and treatment discontinuance) and 2) we will explore the prevailing value trade-off between "living longer even if it means getting an invasive therapy" versus "not living as long and avoiding an invasive therapy" as this item was able to discriminate between groups.

- Secondary outcomes: Additionally, we will collect the following secondary outcomes:
  - IPDAS process measures: We will use seven questions based on key domains of decision process as outlined in the IPDAS background document. Dr. Matlock used these questions in his prior survey and they had significant reliability (Cronbach's alpha of 0.78).[74]
  - Decision choice: We will use single item measures of decision predisposition, choice, and enactment. These questions have test-retest reliability of 0.9 and correlates with values.[75,76]
  - Self-efficacy: The 'Decision Self-Efficacy Scale' measures self-confidence or belief in one's ability to make decisions, including participate in shared decision making.[77]
  - Control Preferences: This is a 2 question measure of a patient's opinion of their preferred and actual role in decision-making.[78]
  - The Decision Conflict Scale (DCS): DCS is a 10-item instrument that measures decision quality and determines decisional uncertainty.[79] The DCS quantifies personal perception of: a) uncertainty in choosing options; b) modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values, and unsupported in decision making, and c) effective decision making such as feeling the choice is informed and values-based, and expressing satisfaction with the choice. DCS reliability measures include test-retest correlation and Cronbach's alpha coefficients exceeding 0.78-0.90[30,74]. The DCS discriminates between groups who make and delay decisions.[30]

- The Decision Regret Scale: Decision regret is a 5-item scale which measures regret with the decision making. It is a commonly used measure in decision aid trials and has good reliability (Cronbach's alpha of 0.82-0.91).[30,74] It correlates with satisfaction, decision conflict, and QOL.[80]
- The Patient Health Questionnaire-2 (PHQ-2): This comprises the first 2 items of the PHQ-9, inquires about the degree to which an individual has experienced depressed mood and anhedonia over the past two weeks. [81]
- The Generalized Anxiety Disorder Scale (GAD-2): In primary care patients, the Generalized Anxiety Disorder scale (GAD-7) had high sensitivity for detecting generalized anxiety disorder and panic disorder. The GAD-2 had high sensitivity and specificity for GAD and high specificity for panic disorder, social anxiety disorder, and post-traumatic stress disorder.[82]
- ICD experiences: These will be questions developed and used previously to describe ICD-specific issues such as whether the participant has experienced a shock or complication and whether they have considered discussing their ICD in an advance directive or with a surrogate decision maker.

B. Description of Population to be Enrolled:

Inclusion Criteria:

1. The participants in the trial will be adult (age ≥18) patients who have been offered a primary prevention ICD for initial implant, reimplantation, or CRT with defibrillation. Primary prevention must be for heart failure.

Exclusion Criteria:

1. Under 18 years of age
2. Non-English speaking (decision aids and study assessments are in English only currently)
3. Unable to consent
4. Currently has a left ventricular assist device (LVAD)
5. Prisoners

Given that the PtDAs and study assessments are in English, we must limit recruitment to English speaking patient participants. However, the paper tool will also be available in Spanish and we will measure whether this facilitated implementation among this group using aggregate measures. As we do not have the resources to enroll every patient at every site, we will enroll a subset of eligible patients. Specifically, we will ask each site to enroll the first ~6 patients each month, or until at least 6 patients are enrolled per month. While not completely random, there is also no systematic reason why demography would differ. This approach allows each site-PI to meet their aim of 50 enrolled patients per year without going over and maintaining awareness if they are under-target. A lesson learned from the DECIDE-LVAD trial is that without this constriction, over-enrollment is possible. If the site researcher is not able to enroll up to 6 patients in the first week of the month, then s/he may continue to approach patients until 6 have been enrolled that month.

Setting: We propose a 7-hospital trial (**Table 3**). Each site investigator is a practicing electrophysiologist within the setting. In addition to access to patients, each has research expertise in the area of ICDs in his/her own right. This proposal has already benefitted from strong engagement by all sites in crafting the PtDA and the proposal. A multi-site design affords many advantages:

- Aim 1: Conducting the trial at multiple sites avoids biases that could confuse the results. If conducted at a single center, it would be difficult to determine which changes in the decision process were due to the PtDAs versus those that were happening regardless (secular trends). Multiple sites allow for sequential transition of hospitals to the PtDAs (stepped-wedge design, see Table 4), thereby allowing for changes to the PtDA to be teased out from changes occurring in the background.
- Aim 2: Individual programs have diverse policies, providers, and institutional cultures that reflect the

Table 3: Randomized sites and annual ICD volumes

Site	ICD Volume
University of Colorado Hospital	200
Denver Health Medical Center	70
The Denver VA Medical Center	100
Providence Health, Oregon	300
Baptist Health	87
Beth Israel	250
Mid America Heart Institute	350

hospital and surrounding community. Testing the PtDAs in multiple programs across the U.S. can help determine how well the PtDA would disseminate to other hospitals.

C. Study Design and Research Methods

Overview: We propose a type II effectiveness implementation hybrid trial[41] of our suite of ICD PtDAs. Our pragmatic design will allow us to simultaneously assess real-world effectiveness (Aim 1), and implementation (Aim 2).

Table 4: Overview of the Stepped-Wedge Design

Site	Baseline (1 year)	Intervention rollout sequentially across all sites (3 years)							Follow-up (1 year)
Random Site 1									
Random Site 2									
Random Site 3									
Random Site 4									
Random Site 5									
Random Site 6									

We will use a 6-site stepped-wedge design, with implementation guided by normalization process theory and evaluation guided by the RE-AIM framework (reach, effectiveness, adoption, implementation, and maintenance).[83-85] For the purpose of this study, and as discussed with our grant proposal team, we will include 2 hospitals as one site during randomization in order to meet demographic requirements. As such, the University of Colorado Hospital and Denver Health Medical Center will be considered 1 site. We have 7 diverse sites (3 academic, 2 private, 1 county hospital, and 1 Veteran's Affairs hospital) to allow us to explore broad contextual issues related to implementation variation. Sites all begin in the control phase, where usual care consists of the current education, decision making, and informed consent process. When sites reach their randomly assigned time to transition to the intervention, we will travel to the site to conduct the implementation. The pamphlet and video PtDAs will be formally integrated into the existing process. In both pre- and post-phases, we will enroll patients and survey them prior to their ICD decision and then again at 1 month and 6 months post-decision to determine the intervention's effect on decision quality and a host of secondary outcomes. These patient-centered outcomes will be compared before and after implementation to determine intervention effectiveness. We will also survey clinicians and staff before, during, and after implementation of the intervention. In the broad view, this study will inform the science of decision support implementation for many interventional therapies in cardiovascular disease.

Stepped-wedge multicenter trial (Table 3): We considered three potential designs for this trial. A classic patient-level randomization is not possible since programs (rather than patients) are effectively the primary targets of intervention implementation. The traditional cluster randomized trial would be disadvantaged by the small number of sites. Therefore, we propose a multicenter trial that is randomized at the clinic-level for a phased rollout of the shared decision support intervention.[42,84] A variant of the cluster trial design, the stepped-wedge trial design is a one-way crossover cluster trial where all the groups will receive the intervention, but the time of intervention is randomly ordered. It is a compelling choice of design when 1) one of the goals is to study intervention implementation, 2) the intervention is thought to be efficacious, 3) all sites wish to receive the intervention and continue its implementation after the trial if it is effective, and 4) contamination/diffusion of the intervention effects to other subjects is likely. The stepped-wedge design is more efficient in terms of statistical power when compared to the classical cluster randomized design because the impact of the intervention is estimated using both within and between cluster differences.

Table 5: Measures	Baseline Pre Decision	1 Month Post Decision	6 Months Post Decision

COVARIATES			
- Demographics (combined survey and short chart review)	X		
- Medications, Comorbidities, Heart Failure Type/Severity	X		X
- Literacy (REALM-R 7 item)[85] and **Subjective Numeracy**[84]	X		
EFFECTIVENESS OUTCOMES (see descriptions below)			
- Decision Quality – Knowledge	X	X	X
- Decision Quality – Value-concordance	X	X	X
- Decision Process		X	X
- Decision choice		X	X
- Self-Efficacy Scale	X	X	X
- Control Preferences	X	X	X
- Decision conflict	X	X	X
- Decision regret		X	X
- PHQ-2	X		X
- GAD-2	X		X
- ICD Experiences (+/- shock; +/- complications etc.)		X	X

Data collection and storage: Baseline questionnaire and case report forms can be completed as soon as is medically reasonable, ideally within 48 hours of enrollment. Patient characteristics shall include basic demographics (age, gender, educational level, health insurance status, employment), additional social support, medical history and medications, as well as health literacy[86] and numeracy.[87] Questionnaires will also be completed at 1 month and 6 months after enrollment (see Table 5).
In addition, there will be a 6-item survey asked of clinicians per patient they see. We have developed and piloted six questions related to: 1) the clinician's assessment of appropriateness of SDM for a particular patient; and 2) the clinician's assessment of how well they think this particular patient will do with an ICD. While ICD is arguably a preference-sensitive decision, clinicians tend to think about preference sensitivity while integrating other aspects of patient clinical characteristics. We expect that this has been an important barrier to adoption of SDM in clinical practice. For example, a younger, patient with a higher risk of sudden death will find a clinician strongly encouraging an ICD while an older patient with multi-morbidity will find a clinician more comfortable engaging with SDM. This is why we organized this part of the evaluation under "adoption." By exploring this preference on a per-patient basis, we will begin to understand how patient characteristics influence adoption of SDM and PtDAs.

Data will be collected electronically using RedCAP, the University of Colorado IRB-preferred system. Data forms will be programmed by our analyst at the start of the project with supervision from the PI and the Lead Statistician. Data quality checks will be performed every 6 months during periods of active data collection.

D. Description, Risks and Justification of Procedures and Data Collection Tools:
Participants: We believe that this study is minimal risk to all subjects involved. Participants are only answering surveys and interview questions and allowing for medical record review, thus there is no physical risk to them. While there is the possibility that the participants may be upset by some of the survey/interview questions because it discusses the possible futures that patients with heart failure have, studies of patients with serious illness show that patients actually are not upset by such studies and can find them helpful. Further, patients may terminate participation at any point.

The survey and decision aids talk about patients' understanding of the ICD. This includes discussions of sudden cardiac death and progressive heart failure. This may be upsetting to patients and/or they may become tearful. This is however, a normal reaction to information and not an adverse event. If a patient becomes so upset that they cannot complete the interview, this would be noted in the database. Only in cases where subjects are so distraught that they need to

be referred for emergency counseling or supportive services will this be considered an adverse event.

Given that these are all patients have heart failure, it is unlikely that any of them will be pregnant. This would be extremely rare but it is not specifically an exclusion criteria. Again the researchers may not know this, and regardless the study poses no risk to the health of a pregnant embryo/fetus.

Data Safety: Data collection and storage has been planned where it is improbable that participant confidentiality will be breached. All patients will be given a unique identification number, and study data and identifiable information will always be kept separate. REDCap, the COMIRB-preferred system, will be used to store all data, and access will be limited to study personnel only. All paper documents will be stored in a secure and locked file cabinet in a secure and locked office building – again, all study data paperwork will be stored separate from paperwork with identifiable information (i.e. signed consent forms).

E. Potential Scientific Problems:

Stepped-Wedge Trials are difficult logistically: For all of their associated advantages, stepped-wedge designs are not without challenges including logistical management of multiple sites in varying stages of implementation over time, the possibility of treatment diffusion (to patients initially seen during the control period but receiving follow-up care during the intervention), and the requirement that all sites begin and end evaluation at the same times. Fortunately, Drs. Matlock & Allen both have experience with this design in a recent trial assessing implementation and effectiveness of PtDAs for ventricular assistance device therapy.[42] Also, the baseline survey combined with the importance of getting all sites to start at the same time is why we've included a year of start-up time.

Enrolling 900 patients is overly optimistic: Each site will be expected to enroll 50 patients per year. Because we are implementing a suite of PtDAs, we expect no trouble enrolling the appropriate amount. In our pilot trial at the site with the lowest volume (the Denver VA) we enrolled 9 patients in 6 months for only the initial implant decision aid. We learned that there were many patients getting reimplantation and CRT devices whom were missing. With the suite of PtDAs available in this trial, we think we'll have no trouble enrolling the eligible amount of patients. Also, with our experience with the DECIDE-LVAD trial, we are having more trouble with over-enrollment which is only a problem in rebudgeting to reimburse sites per patient.

What if the study is not successful? If the study does not meet its primary endpoint, our formative evaluation will provide information about potential reasons that it was not successful and lead to better studies of alternative dissemination and implementation strategies for advanced progressive illness. In a pragmatic design such as this, most of the threats (e.g. low reach, low implementation) bias to the null. Indeed, this is precisely why this is a more interesting study than doing a research staff controlled efficacy trial.

How will the PtDAs stay Up-To-Date and Responsive to Perceived Needs? Given the rapid changes in ICD technology, the PtDAs must be kept current to maintain relevance. This will be accomplished via:

- Annual reviews of literature: With incorporation of important changes into the PtDAs.

Modular design: The sectional build of the PtDAs—clearly defined pages for the pamphlet and segmented video—allows for simple revision as problems are identified or information changes over time.

F. Data Analysis Plan:

Quantitative analysis (Hypotheses 1a, 1b, 1c): The analyses of the effectiveness will use a repeated measures mixed model. This strategy allows for partially incomplete data (e.g. missing follow-up or one of the collection periods) and relaxes the missing data assumptions to missing at

random conditional on observed data. Prior to these analyses, we will contrast the participants in the 2 phases of the study, identifying any patient/site characteristics that are unbalanced. If more than 3-5 variables are identified, we will develop a propensity score for the likelihood of being in the intervention phase. Each analysis model will include an indicator variable for the intervention phase, indicators for each of the sites and the variables identified above.

Sample Size and Power Calculation: This trial was designed to have diversity in implementation settings. As such, to effectively be powered to explore implementation across diverse settings, we are overpowered to test our primary quantitative outcomes (the knowledge domain of decision quality). With a sample size of 900 patients and a standard deviation of 18%, achieved power would approach 1.00 to detect a 10% improvement in knowledge (in the 2011 Cochrane Review, knowledge improved an average of 13.8%, in our pilot trial, knowledge improved 12%).[6] Even with variance inflation for correlation within sites (assuming intraclass correlation 0.01), the power remains good at 0.98. This level of power will afford the ability to assess some heterogeneity of effect across sites and vulnerable patient groups, as well as adequate assessment of secondary effectiveness measures and implementation evaluation. To test the hypothesis that better informed patients will have less anxiety (hypothesis 1c), we will correlate the knowledge score with the HADS- A. Using a using a Pearson's correlation coefficient, for a sample size of 300 (based on 1/3 illustrating significant anxiety) then the person's correlation is 0.18 for a power of 90% and an alpha of 0.05.

G. Summarize Knowledge to be Gained:

We have designed the implementation to use and leverage existing resources to implement the intervention. Further, we have designed the study as an effectiveness/implementation study with emphasis on formative evaluation. Together, it is our hope that if the intervention is successful, we will develop an implementation guide and online distribution of materials for other ICD programs and other practitioners interested in testing and disseminating effective therapies.

The lessons learned herein will apply broadly. As discussed in the Significance section, policies are changing. Patients are increasingly demanding involvement and seeking additional sources of information. The PtDA development group in Colorado has been contracted by the American College of Cardiology to develop a PtDA for patients with severe aortic stenosis considering surgical versus transcutaneous repair. The American College of Cardiology has also inquired with Colorado about developing a tool for the recently approved left atrial appendage occlusion device. Science on real-world effectiveness and implementation is essential in informing the field of PtDA delivery for high risk medical conditions.

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