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A Multicenter Trial of a Shared DECision Support Intervention for Patients offered implantable Cardioverter-DEfibrillators: DECIDE-ICD Rationale, Design, Medicare Changes, and Pilot Data

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Abstract

Background: Shared decision making (SDM) facilitates delivery of medical therapies that are in alignment with patients' goals and values. Medicare national coverage decision for several interventions now includes SDM mandates, but few have been evaluated in nationwide studies. Based upon a detailed needs assessment with diverse stakeholders, we developed pamphlet and video patient decision aids (PtDA) for implantable cardioverter defibrillator (ICD) implantation, ICD replacement, and cardiac resynchronization therapy with defibrillation to help patients contemplate, forecast, and deliberate their options. These PtDA are the foundation of the Multicenter Trial of a Shared Decision Support Intervention for Patients Offered Implantable Cardioverter-Defibrillators (DECIDE-ICD), a multicenter, randomized trial sponsored by NHLBI aimed at understanding the effectiveness and implementation of a SDM support intervention for patients considering ICDs. Finalization of a Medicare coverage decision mandating the inclusion of SDM for new ICD implantation occurred shortly after trial initiation, raising novel practical and statistical considerations for evaluating study endpoints.

Methods/Design: A stepped-wedge randomized controlled trial was designed, guided by the RE-AIM planning and evaluation framework using an effectiveness-implementation hybrid type II design. Six electrophysiology programs from across the United States will participate. The primary effectiveness outcome is decision quality (defined by knowledge and values-treatment concordance). Patients with heart failure who are clinically eligible for an ICD are eligible for the study. Target enrollment is 900 participants.

Discussion: Study findings will provide a foundation for implementing decision support interventions, including PtDAs, with patients who have chronic progressive illness and are facing decisions involving invasive, preference-sensitive therapy options. **RCT#** NCT03374891

Keywords

decision aids; implantable cardioverter defibrillator; cardiac resynchronization therapy; patient-centered care; shared decision-making; implementation; RE-AIM

INTRODUCTION

Over 200,000 implantable cardioverter defibrillators (ICD) are implanted annually in the US[1] to prevent sudden cardiac death (SCD), including both new devices and replacement procedures at the end of routine battery life. In appropriately selected patients, ICDs reduce mortality from SCD resulting in roughly a 5% absolute increase in survival in the 5 years after implant.[2-5] However, a number of potential clinical and quality of life (QOL) threats exist. ICDs require surgical implantation and regular follow up. Patients have described an ICD shock as "getting kicked in the chest by a mule,"[6] leading some to have their ICDs removed for fear of repeated shocks.[7] Inappropriate shocks can occur.[8] Some studies suggest that patients with ICDs have more heart failure admissions,[9] a lower QOL - particularly if

shocked by their devices[10,11] - and an increased incidence of anxiety, depression, and post-traumatic stress disorder.[12] Furthermore, if not properly deactivated, ICDs can cause unnecessary suffering at the end of life.[13-16]

Research also suggests problems with current ICD decision making. An integrative review of patient perspectives highlighted a paternalistic approach to decision making.[6,17] Patients with ICDs frequently report never having had a conversation about periprocedural risks, expected benefits, or potential QOL problems.[6] With historical approaches to communication, patients tend to overestimate the benefits of ICDs, underestimate the risks, and are underinformed about device deactivation.[18] Recent policy changes, including a mandate in October 2018 by the Centers for Medicare and Medicaid Services requiring that "a formal shared decision making encounter must occur between the patient and an independent physician…using an evidence-based decision tool on ICDs prior to initial ICD implantation"[19] reflect the importance of this need and help address concerns regarding good shared decision making (SDM).

Patient decision aids (PtDA) have strong efficacy data. A Cochrane review of 105 randomized trials demonstrated that PtDAs improve knowledge, satisfaction, patient/provider communication, increase patient involvement in decision making, and reduce patient decisional conflict and regret.[20] Despite their established efficacy, PtDAs are not often implemented outside the research setting. A recent systematic review of PtDA implementation 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.[21]

Guided by the International Patient Decision Aid Standards (s) and following the Ottawa Decision Support Framework,[22] we developed a decision making support intervention consisting of (*a*) video and pamphlet PtDA[23] and (*b*) a clinician-directed decision support training for ICD decision making. The "Multicenter Trial of a Shared Decision Support Intervention for Patients Offered Implantable Cardioverter-Defibrillators" (DECIDE-ICD) hypothesizes that this decision support intervention will improve patient decision quality. Additionally, guided by the RE-AIM framework[24], DECIDE-ICD will explore ways to optimize implementation and increase understanding of implementation processes. This article describes the methods for this multicenter effectiveness-implementation hybrid trial.

METHODS/DESIGN

The DECIDE-ICD study will test the effectiveness and implementation of SDM support intervention for ICDs in the contexts of initial implantation, reimplantation, and CRT-D. With the goal of more rapid translation to clinical practice, this study was designed as an effectiveness-implementation hybrid type II design.[25] This allows the study team to conduct effectiveness testing traditionally done with decision-support interventions, while simultaneously assessing a real-world implementation strategy of the intervention. The dual focus will help ensure that should the intervention be effective, it can also feasibly be adopted outside of the study environment. This trial has been registered on www.clinicaltrials.gov (#NCT03374891).

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Lessons Learned from Previous Trials

ICD Decision Aid Pilot Trial—From April 2012 to March 2013, 21 participants were enrolled across 3 settings in the Denver metropolitan area to assess the acceptability and feasibility of the ICD PtDA. Participants included adult patients (>18 years of age) with systolic heart failure who were being presented with a decision to get an ICD for primary prevention. The study tested desirability of 4 different PtDA types: option grids, infographics, a video, and a website. In addition, 3 different recruitment methods were tested. Out of 3 recruitment methods, using a medical team member was the most efficient way of identifying appropriate patients. PtDA were found to be highly acceptable: 67% of those included in the study found the PtDA to be unbiased, 89% found them helpful, and 100% would recommend them to others. Patients preferred infographic and video types of decision aids compared to option grids or a website.

Decision Quality was measured as a secondary outcome in the pilot trial via the domains of knowledge and value concordance. The Pilot trial showed that knowledge remained the same between intervention and control, whereas value concordance significantly increased in the 1 month follow-up but not the 3 month follow-up. However, this trial was underpowered to make strong conclusions about these outcomes.

Some design choices in the DECIDE-ICD trial based on the results of the pilot study include: (1) having electrophysiologists as site-PIs to ensure multi-level buy-in; (2) encouraging sites to include schedulers, nurses, and others to be involved in discussions and implementation to create multidisciplinary engagement; (3) changing the timing of the baseline survey to *after* a discussion with a medical team member as identifying patients pre-discussion makes meeting recruitment targets unfeasible; (4) PtDA should be comprised of videos and paper pamphlets; and (5) have enough power with 900 subjects to show significance in Decision Quality. Additionally, our team has also learned from a similarly designed trial for patients making decisions with LVADs.[23,26]

Stepped-Wedge, Randomized, Multicenter Trial Design—A quasi-experimental multicenter trial randomized at the hospital level was chosen for a phased roll-out of the SDM support intervention.[27] This variant of the cluster trial design is termed the stepped-wedge trial (Table I): a 1-way crossover cluster trial where all programs will receive the intervention, but the time when they receive this is randomly ordered. In a stepped-wedge randomized design, each site begins in the control phase, where usual care consists of the program's current education, decision making, and informed consent process. When sites reach their randomly assigned time to transition to the intervention, the intervention is formally integrated into the existing process.

Setting and Participants—Participants are enrolled from 6 centers across the United States, including a Veteran's Affairs hospital, 2 academic medical centers, 2 private medical centers, and one combined county safety-net hospital/academic medical center, drawing both urban and rural patients from diverse settings across the country (Appendix I). Any initial differences in approach to treatment between these distinct sites will further highlight the efficacy of a more standardized approach to defibrillator education via the decision aids and may serve as a model for future implementation across cultures and countries.

Patients—A planned total of 900 patients will be enrolled across 6 sites during a 36-month enrollment period, beginning April 2018 and ending March 2021. Participants will be adult (age > 18 years) patients who have had a discussion about an ICD, ICD replacement, or CRT-D for primary prevention of heart failure. This excludes patients with subcutaneous ICDs. These discussions will take place between a patient and a member of the clinical team, which can be a cardiologist, nurse, electrophysiologist, or anyone else partaking in their care. Discussions may include risk and benefit, next steps, and other items, but can vary in length of time, content, and specificity between clinics and patients. As this is an implementation trial, there is not a specific protocol for how this discussion will be done with each patient. However, at the beginning of each implementation roll-out at each site, three talks will be given by the study team to staff who will be initiating these discussions. These meetings will include the importance and intent of SDM, teaching techniques for EPs to use SDM, and a meeting with the clinic staff where they decide the best way for their clinic to have these discussions and dissemination. The study staff will record this implementation strategy, and periodically ask and record any changes to each clinic's implementation strategy. Given that the PtDAs and study assessments are currently in English, recruitment is limited to English speakers. Study staff will identify eligible patients through clinical referrals or by screening patient charts in electronic medical records. They will look at referrals, notes, or problem lists to ascertain indications for inclusion.

Effectiveness of the Intervention—The effectiveness of the PtDA intervention will be evaluated.[23] Using a step-wedge design, after a 5-month control period for all sites, a new site will begin the intervention every 5 months and continue through the end of the trial. Paper and video PtDA will be handed out in combination to eligible patients before a discussion about a defibrillator. Both the pamphlet and the video contain information about what an ICD/CRT is, risks and benefits, and important questions about the device. The videos are 8-20 minutes long and contain patient narratives about their decision-making processes regarding getting or not getting a device (see Appendix II). These PtDA have been shown to be helpful, largely unbiased, and highly acceptable to patients.[28]

We plan for the PtDA to be adapted as new evidence arises, consistent with IPDAS.[29] Evidence will be reviewed throughout the study and changes to the PtDA made as necessary. An evidence document will be maintained and updated every 6-12 months, reviewing feedback and documenting any changes to the PtDA.

Implementation Strategy—At the time of intervention implementation, each site will participate in (1) a grand rounds-style presentation given by the principal investigator and targeting cardiologists and electrophysiologists, which explains the background to the

project, pilot work conducted for the intervention, and the objectives of implementation science; (2) a demonstration of the PtDA materials and a 30 to 60 minute coaching session for staff directly or indirectly involved in defibrillator patient education and care, which includes important aspects of SDM such as discussing approaches to tough questions faced with previous patients; and (3) a 30-60 minute coaching and strategizing session for staff directly involved in implementing defibrillator patient education and care. Along with tenets learned from the decision coaching sessions, the PtDA materials will be integrated into existing education and decision making processes at the site level for all patients undergoing defibrillator evaluation.

Data Collection

Eligible patients are identified by the study team at each site during the time that a discussion around defibrillators is initiated for the patient. These discussions will be identified through chart review notes or through clinician referrals to study staff. Patients will be recruited within 1 week after the defibrillator discussion. Baseline, 1-month, and 6-month surveys will be completed. Medical record data (e.g.: outcomes, adverse events, treatment decisions) for patients will also be collected at baseline and 6 months. Study coordinators, with the help of the clinical staff, will complete the Study Coordinator Checklist for each patient. The primary physician or staff who had the defibrillator discussion with the enrolled patient will complete the Clinician's Perceptions of Patient Appropriateness for SDM survey, reporting his/her opinion on the best therapy for the patient and an estimate of risk of unfavorable outcome. Data collection is the same during control and intervention periods.

The RE-AIM framework will be used for evaluation.[30] The RE-AIM framework assesses an intervention's potential for dissemination and public health impact using five criteria: Reach, Effectiveness, Adoption, Implementation, and Maintenance. The RE-AIM framework has been used to translate research into practice and to help plan programs and improve their chances of working in "real-world" settings.[30]. Highlighted below are the primary outcomes of the trial, and Table III provides details of all 5 criteria of the RE-AIM framework[30-33].

Reach—Reach is defined as the proportion and representativeness of the target population who participate in the intervention. While Reach is a relatively straightforward measure, defining the denominator of eligible patients can be 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 PtDA to maintain a log of intervention recipients.

Effectiveness—A variety of secondary outcomes and covariates will be measured at baseline and follow-up. A number of effectiveness measures will be collected (Table IV). Appendix III provides more detail on the effectiveness measures.

Primary outcome: The primary effectiveness outcome will be decision quality. Decision quality is an essential element of the Ottawa Decision Support Framework, defined as "the

extent to which the implemented decision reflects the considered preferences of a well-informed patient."[34] Decision quality measures consist of two domains: knowledge and value-choice concordance.

- Knowledge: Consistent with methods developed by Sepucha et al.,[34,35] we have developed a knowledge measure. We will use this measure to test knowledge at baseline, 1 month, and 6 months.
- Value-choice concordance: We will calculate concordance between patients' values and the treatment they choose according to the validated methods of Sepucha et al.[34,35] 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 six questions based on key domains of decision process as outlined in the IPDAS background document. In prior work, these questions had significant reliability (Cronbach's alpha of 0.78).[29]
- 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.[36,37]
- The Decision Conflict Scale (DCS): DCS is a 10-item instrument that measures decision quality and determines decisional uncertainty.[38] DCS reliability measures include test-retest correlation and Cronbach's alpha coefficients exceeding 0.78-0.90.[20,29] The DCS discriminates between groups who make and delay decisions.[20].
- 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).[20,29] It correlates with satisfaction, decision conflict, and QOL.[39]
- Hospital Anxiety & Depression Scale (HADS): The HADS is a 14-item measure assessing symptoms of anxiety and depression among general medical patient populations.[40].
- ICD experiences: These are 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.
- Literacy: The REALM-R is an 11-item test used to identify people with low health literacy.[41]

- Subjective Numeracy: The subjective numeracy test identifies how comfortable people are with numbers, and determine subjective comfort with numerical preferences.[42]

Adoption—RE-AIM defines adoption as the absolute number, proportion, and representativeness of settings and intervention agents (people who deliver the program) who are willing to initiate a program. For this trial, we approached 7 sites and 6 agreed to participate giving an adoption rate of 86% at the site level since all 6 programs have agreed to participate. We will also assess adoption at the clinician level, where each clinician can adopt SDM each time they see a patient. We hypothesize that physicians will be more open to SDM as patients become older and sicker. We will explore clinicians' adoption of SDM in two ways:

1. Clinician Attitudes Toward SDM: A quantitative survey will measure attitudes towards SDM at baseline and year 5.
2. Clinician's Perceptions of Patient Appropriateness for SDM: We have developed and piloted a 6 question survey, which will be asked of clinicians in regard to each patient with whom they have a defibrillator discussion. (Table V) By exploring this preference on a per-patient basis, we will begin to understand how patient characteristics influence adoption of SDM and PtDAs.

Implementation—The RE-AIM framework defines implementation as the extent to which the intervention is implemented as intended, adaptations made, and costs to deliver the program.[30] Consistency of PtDA delivery will be assessed across hospitals, providers, patient subgroups, and time through the Study Coordinator Checklist and key informant interviews. The Study Coordinator Checklist will be used to assess how the intervention was implemented for each patient, with questions regarding the types of materials, the way in which they were provided, timeline, and use. In addition, factors associated with variation in implementation, such as who provides educational materials and when, will be identified. Key informant interviews will be conducted with various clinical staff at each site at baseline, after implementation of the intervention, and after study completion. The goals of these interviews are to (1) identify issues, facilitators, or barriers in the effectiveness of the intervention from various staff perspectives; (2) identify strategies that may be useful in the refinement of subsequent roll-out phases and future dissemination; and (3) ensure regular, uniform use of the educational materials. Adaptations will be assessed from the intervention checklists to assess deviations from the protocol and reasons. In addition, we will conduct periodic interviews to assess frequency, timing, source, type and reasons for adaptations using interview guides from Rabin et al.[43]

Maintenance—The RE-AIM framework defines maintenance as the continued use of a practice after a study has ended. This will be assessed primarily by seeing whether each of the 6 sites decides at the conclusion of the study to maintain, modify, or discontinue the PtDAs.

Pragmatism of Trial—As this is designed as a pragmatic trial, the internal team scored this study via the PRagmatic Explanatory Continuum Indicator Summary (PRECIS-2)[44]

(Figure I). Most domains showed similar assessments by the team. For the domains of Organization and Primary Outcome, there were larger ranges between raters. Organization variation (range 2-5) resulted in a discussion between low pragmatism due to the use of a formal investigator-based kick-off at the beginning of intervention for each site verses the high pragmatism of each site being able to carry out the study in a user-specific way. Primary Outcome variation (range 2-5) resulted in a rich discussion contrasting the effectiveness and implementation arms of the study. Raters scored low pragmatism due to hospital procedures and detailed research questionnaires as the measures of success, but others raters scored high pragmatism based on those processes ultimately being relevant to patients. The overall high pragmatism of the trial is promising for high generalizability of the implementation methods of this trial.

Analysis

Effectiveness—The analyses of effectiveness will use a repeated-measures mixed model. This strategy allows for partially incomplete data and relaxes the missing data assumptions to missing at random conditional on observed data. Before these analyses, the participants in the 2 phases of the study will be contrasted, identifying any participant or site characteristics that are unbalanced. If more than 3 to 5 variables are identified, a propensity score for the likelihood of being in the intervention phase will be developed. Each analysis model will include an indicator variable for the intervention phase, indicators for each of the sites, and the variables identified above. We have three pre-specified subgroups that we plan to evaluate as these groups may have important differences in terms of the primary outcome: 1) Age: >=70 vs. <70; 2) Ischemic vs. Non-ischemic cardiomyopathy; 3) Type of procedure: CRT-D, reimplant, or initial ICD. Important covariates that will be explored include health literacy, education, and subjective numeracy.

Power Estimation (knowledge)—The primary outcome is decision quality. The power estimation is based on the primary subdomain knowledge. With a sample size of 900 patients and a standard deviation of 18%, the study would have a power of 0.98 to detect an improvement in knowledge by 10% (assuming intraclass correlation 0.01) and 90 for a difference of 6% (in the 2011 Cochran review knowledge improve an average of 13.8%, in our pilot 12%). Even with variance inflation for correlation within sites (assuming intraclass correlation 0.10), the power for the 6% difference remains acceptable at 0.86. This level of power will afford the ability to assess some heterogeneity of effect across vulnerable patient groups, and this size of a study will also allow for adequate assessment of secondary effectiveness measures and implementation evaluation.

Reach, adoption, implementation and maintenance will be assessed by descriptive data (percentages, means, and indices of dispersion) and univariate and bivariate analyses (e.g., regression) of the effect of patient, staff and setting factors on implementation outcomes.

Qualitative Exploration (implementation)—The process and impact of implementing PtDA into the clinical workflow will be characterized using qualitative interviews of key informant ICD-involved clinicians at each study site. Analysis of these interviews will be guided by a grounded theory approach to develop a framework for understanding the process

of implementing PtDA at each site.[45] In accordance with this process, analysis will occur as a continuous, iterative process throughout data collection and final analysis. Transcripts will be read repeatedly by multiple analysts to achieve immersion, followed by coding using an emergent approach, emphasizing interviewee perspectives rather than speculation from the research team.[46] As these data and emerging thematic maps are described, they will be contextualized according to provider type, site characteristics, and other demographic indicators to highlight qualitative comparisons between groups. We will also analyze interview data on adaptations using categories from Rabin et al.[43] All analyses will be conducted using Dedoose analytic software (V. ***8.0.35***, 2018. Los Angeles, CA: SocioCultural Research Consultants, LLC. www.dedoose.com) to facilitate data storage, team-based analysis, code organization, and visualization.

Discussion

In February of 2018, 2 months before enrollment was set to begin, The Centers for Medicare and Medicaid Services (CMS) updated their national coverage determination decision memo to require that "a formal shared decision making encounter must occur between the patient and an independent physician…using an evidence-based decision tool on ICDs prior to initial ICD implantation,"[19] The mandate referenced PtDAs created by the principal investigator, which were intended for use in the intervention phase of DECIDE-ICD. The mandate took effect October 1, 2018. While this was a major positive endorsement of the intervention, this mandate created a scientific problem for DECIDE-ICD by potentially contaminating the ICD part of the control phases of this trial. The ICD replacement and CRT-D parts of the trial were unaffected.

The study team requested a temporary exemption from this mandate for participating research sites from CMS in April 2018. This request was declined; however, representatives from CMS decided from this complication that future mandates would include exceptions for research studies. After discussions with the trial's DSMB, project officer at the NHLBI, and other site-PIs, it was determined that sites wishing to meet the CMS mandate during control phases of DECIDE-ICD could use the paper tools developed by Dr. Matlock's lab or other tools, but during intervention phases will use both paper and video tools developed by Dr. Matlock's lab. As a consequence of this mandate, the trial may have some contamination in the control phase making achieving effectiveness more challenging. However, the advantage of the mandate is there is now more pressure to implement the intervention successfully.

Conclusion

Patients making decisions about whether to pursue invasive technologies in the setting of chronic progressive illness face arguably some of the most complicated decisions in medicine. Learning how to help patients, their loved ones, and their clinicians better make high-quality decisions is an area of need. PtDAs are increasingly available; however, they have not been widely adopted because of the challenging nature of integrating them into clinical practice. With the recent CMS mandate for SDM prior to ICD implantation, understanding the effectiveness and implementation of PtDA into practice is more important

than ever. The goal of the DECIDE-ICD trial is to address this by evaluating and implementing a SDM support intervention for patients pursuing defibrillators based on previous evidence. The DECIDE-ICD study is a platform to evaluate introduction, implementation, and dissemination of PtDA with patients facing end-of-life decisions. Our findings should inform both research and practice in SDM, implementation science, and clinical care.

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Appendix I:

In an effort to increase the diversity of our study population, a 7th site of Denver Health was added to improve the diversity of our sample. Denver Health is also a safety net hospital. Below is the expected demographics chart for our trial:

TABLE:

Anticipated Gender, Ethnicity, and Racial Distribution for Participants in DECIDE-ICD

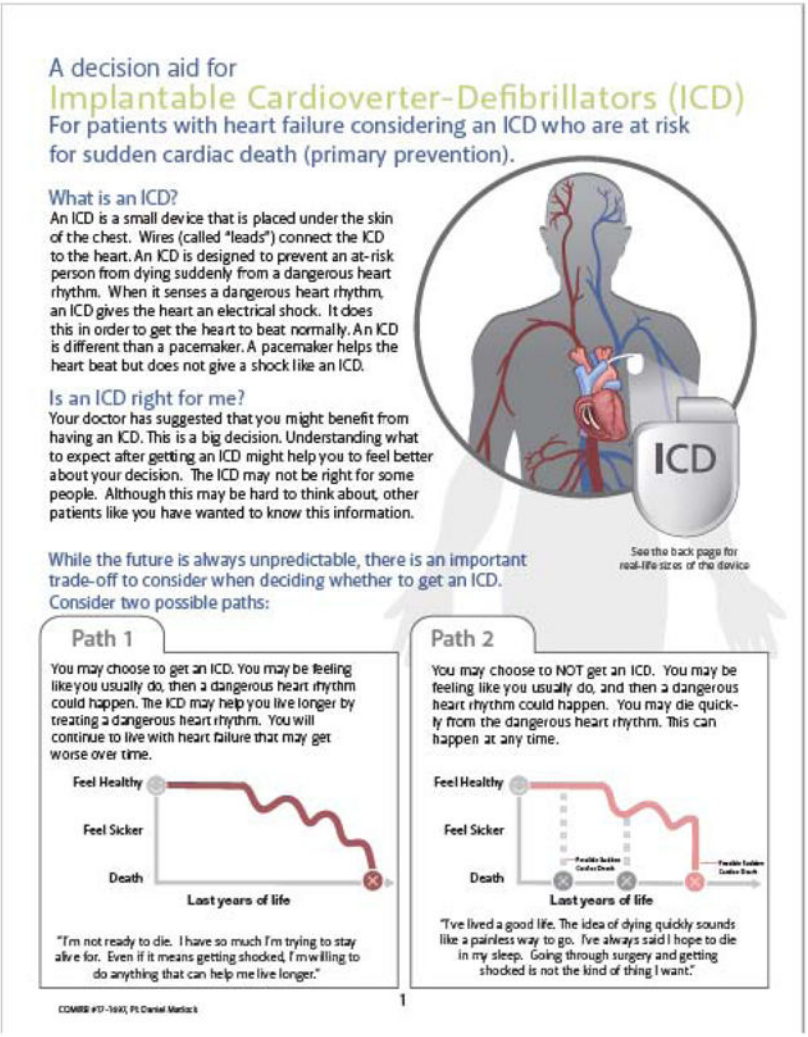
	DHMC/U. of CO		BIDMC	Providence	Baptist	DVAMC	MAHI	Total
	N=75 %	75 %	150 %	150 %	150 %	150 %	150 %	900 %
GENDER								
Female	52%	34%	27%	36%	53%	5%	40%	34%
Male	48%	66%	73%	64%	47%	95%	60%	66%
ETHNICITY								
Hispanic	28%	3%	1%	9%	5%	3%	4%	6%
Non-Hispanic	72%	97%	99%	91%	95%	97%	96%	94%
RACE								
American Indian/Alaskan Native	1%	2%	0%	1%	0%	2%	1%	1%
Asian	3%	2%	1%	7%	2%	2%	1%	3%
Black or African American	13%	10%	6%	6%	17%	10%	12%	10%
More than one race		2%	4%	5%	2%	2%	3%	3%
Native Hawaiian/other Pacific Islander	<1	<1	<1	<1	<1	<1	<1	<1%
Unknown or not reported	20%	3%	4%	4%	2%	3%	1%	4%
White	64%	81%	88%	76%	74%	81%	82%	79%

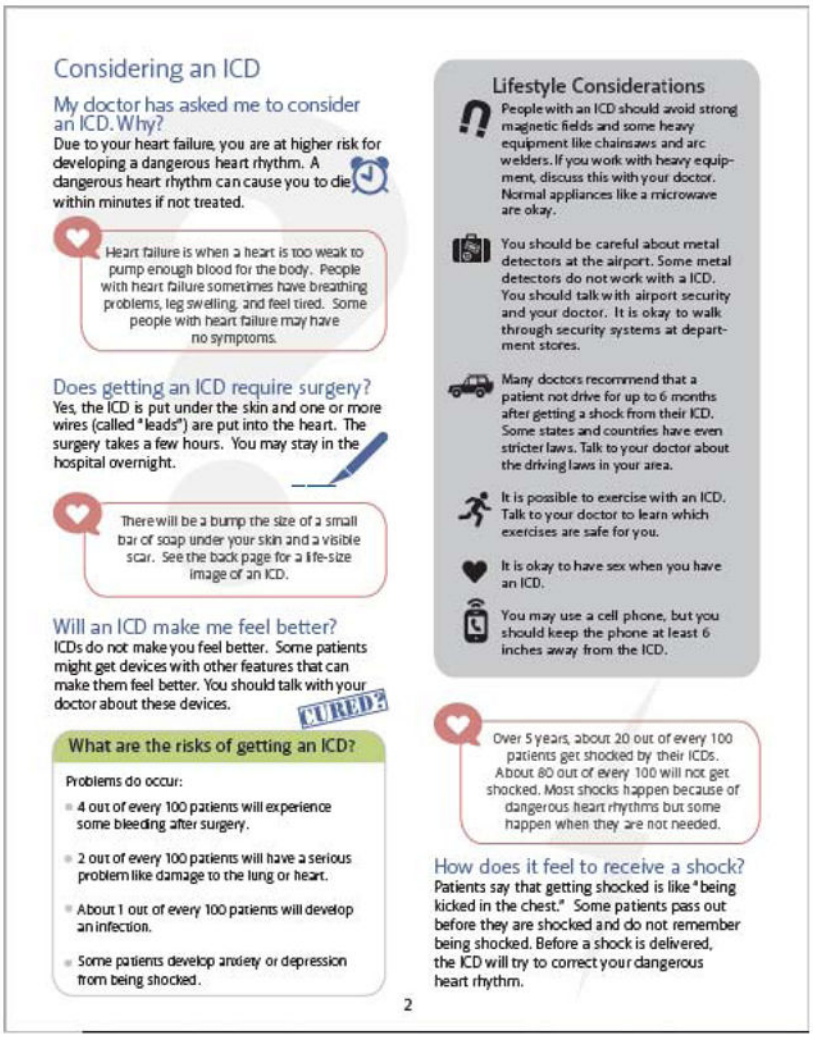
U of CO – University of Colorado; BIDMC – Beth Israel Deaconess Medical Center; DVAMC – Denver Veterans Affairs Medical Center; MAHI – Mid America Heart Institute

Appendix II:

All current versions of our patient decision aids can be found on our website at https://patientdecisionaid.org/.

Below are the current versions at the time of this submission.





Considering an ICD

My doctor has asked me to consider an ICD. Why?

Due to your heart failure, you are at higher risk for developing a dangerous heart rhythm. A dangerous heart rhythm can cause you to die within minutes if not treated.

Heart failure is when a heart is too weak to pump enough blood for the body. People with heart failure sometimes have breathing problems, leg swelling, and feel tired. Some people with heart failure may have no symptoms.

Does getting an ICD require surgery?

Yes, the ICD is put under the skin and one or more wires (called "leads") are put into the heart. The surgery takes a few hours. You may stay in the hospital overnight.

There will be a bump the size of a small bar of soap under your skin and a visible scar. See the back page for a life-size image of an ICD.

Will an ICD make me feel better?

ICDs do not make you feel better. Some patients might get devices with other features that can make them feel better. You should talk with your doctor about these devices.

CURED?

What are the risks of getting an ICD?

Problems do occur:

- 4 out of every 100 patients will experience some bleeding after surgery.
- 2 out of every 100 patients will have a serious problem like damage to the lung or heart.
- About 1 out of every 100 patients will develop an infection.
- Some patients develop anxiety or depression from being shocked.

Lifestyle Considerations

People with an ICD should avoid strong magnetic fields and some heavy equipment like chainsaws and arc welders. If you work with heavy equipment, discuss this with your doctor. Normal appliances like a microwave are okay.

You should be careful about metal detectors at the airport. Some metal detectors do not work with a ICD. You should talk with airport security and your doctor. It is okay to walk through security systems at department stores.

Many doctors recommend that a patient not drive for up to 6 months after getting a shock from their ICD. Some states and countries have even stricter laws. Talk to your doctor about the driving laws in your area.

It is possible to exercise with an ICD. Talk to your doctor to learn which exercises are safe for you.

It is okay to have sex when you have an ICD.

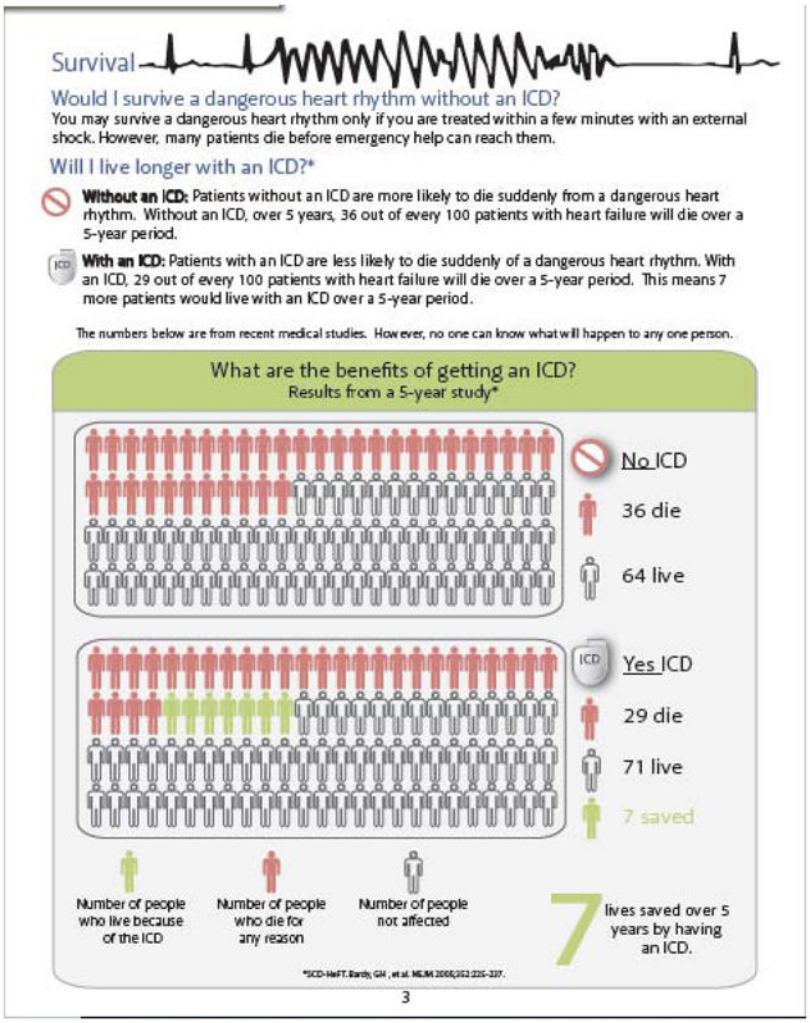
You may use a cell phone, but you should keep the phone at least 6 inches away from the ICD.

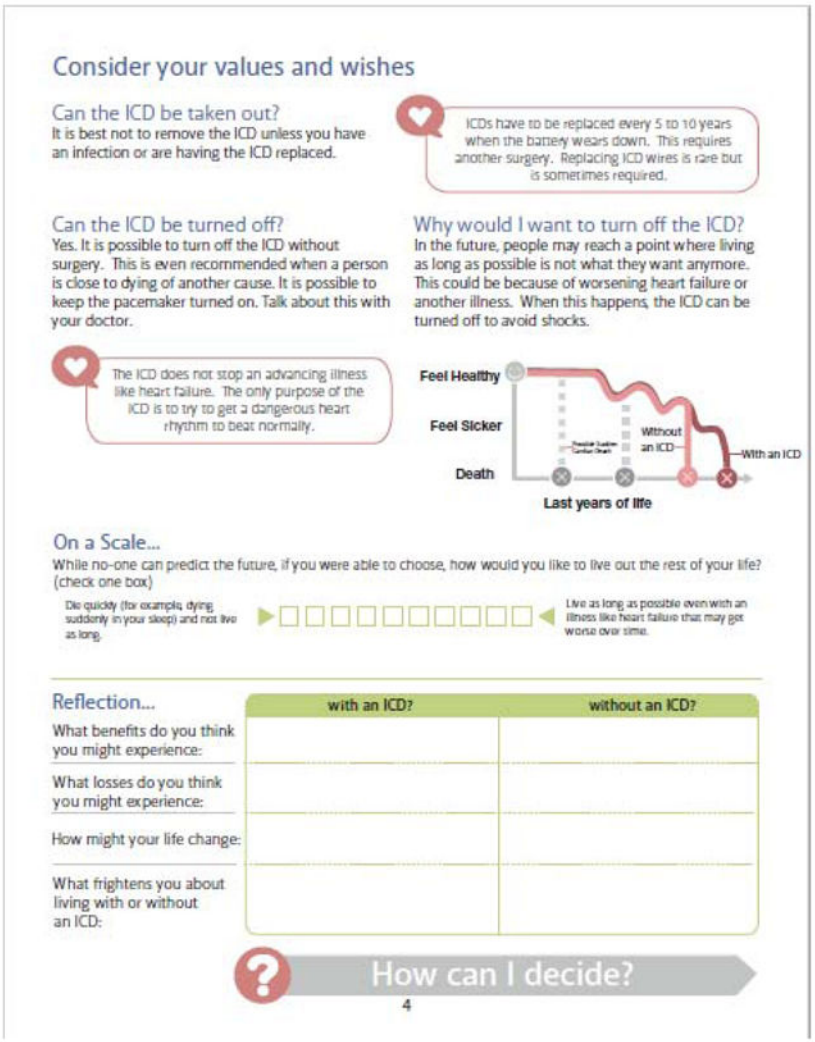
Over 5 years, about 20 out of every 100 patients get shocked by their ICDs. About 80 out of every 100 will not get shocked. Most shocks happen because of dangerous heart rhythms but some happen when they are not needed.

How does it feel to receive a shock?

Patients say that getting shocked is like "being kicked in the chest." Some patients pass out before they are shocked and do not remember being shocked. Before a shock is delivered, the ICD will try to correct your dangerous heart rhythm.

2





Consider your values and wishes

Can the ICD be taken out?

It is best not to remove the ICD unless you have an infection or are having the ICD replaced.

ICDs have to be replaced every 5 to 10 years when the battery wears down. This requires another surgery. Replacing ICD wires is rare but is sometimes required.

Can the ICD be turned off?

Yes. It is possible to turn off the ICD without surgery. This is even recommended when a person is close to dying of another cause. It is possible to keep the pacemaker turned on. Talk about this with your doctor.

Why would I want to turn off the ICD?

In the future, people may reach a point where living as long as possible is not what they want anymore. This could be because of worsening heart failure or another illness. When this happens, the ICD can be turned off to avoid shocks.

The ICD does not stop an advancing illness like heart failure. The only purpose of the ICD is to try to get a dangerous heart rhythm to beat normally.

On a Scale...

While no-one can predict the future, if you were able to choose, how would you like to live out the rest of your life? (check one box)

Die quickly (for example, dying suddenly in your sleep) and not live as long.

Live as long as possible even with an illness like heart failure that may get worse over time.

Reflection...

	with an ICD?	without an ICD?
What benefits do you think you might experience:		
What losses do you think you might experience:		
How might your life change:		
What frightens you about living with or without an ICD:		

How can I decide?

4

In Summary

FAQ	Implant an ICD	Do not implant an ICD
What does an ICD do?	An ICD may stop a dangerous heart rhythm that could cause sudden death by giving an electrical shock to the heart.	Without an ICD, you will have a higher risk of dying suddenly if a dangerous heart rhythm happens.
What is involved?	An ICD is put under the skin on your chest and wires ("leads") go into your heart. You will probably stay one night in the hospital. In about 5-10 years, when the battery runs out, the ICD will need to be replaced	You can continue to use medicine to treat your heart problem.
Will I live longer with an ICD?	Patients with an ICD are less likely to die suddenly of a dangerous heart rhythm. With an ICD, 29 out of 100 patients with heart failure will die over a 5-year period. This is 7 fewer deaths than if they did not have an ICD.	Patients without an ICD are more likely to die suddenly from a dangerous heart rhythm. Without an ICD, 36 out of 100 patients with heart failure will die over a 5-year period.
Will I get shocked by the ICD? What will that feel like?	Over 5 years, 20 out of every 100 patients who have an ICD will get a shock. 80 out of 100 patients will not get shocked.	You will not get a shock from an ICD.
What are the risks of getting an ICD?	4 out of every 100 patients will have some bleeding. 2 out of every 100 patients will have a serious problem, such as damage to the lung, a heart attack, or a stroke. 1 out of every 100 patients will get an infection, which may require removing the ICD.	You will not have the risks of placing an ICD.
Will an ICD improve my symptoms?	Having an ICD will not improve your symptoms or cure your heart problem.	Your symptoms will be influenced by your heart failure.
Are there things I cannot do?	This depends on your heart problem. Talk to your doctor about driving limitations and other activities.	Even without an ICD, talk with your doctor about driving limitations and other activities.
Can the ICD be taken out?	It is best not to remove the ICD unless it gets infected or it is time to have it replaced when the battery runs out.	Does not apply.
Can the ICD be turned off?	Yes, the ICD can be turned off without surgery. This is recommended if a person is likely to die from another illness.	Does not apply.

5

You are the expert on what is important for you.

What else do you need to help you make your decision?

Questions...

It may be helpful for you to talk with your family and friends. You may want to share the information in this decision aid with them. You should also share with your doctor your questions and concerns before making a final decision. It is important that you have all of the information you need to make a decision that is right for you. You have the right to make your own choices!

Concerns...

You know what is important to you better than anyone else. Any decision about your treatment should be based on your goals and values!

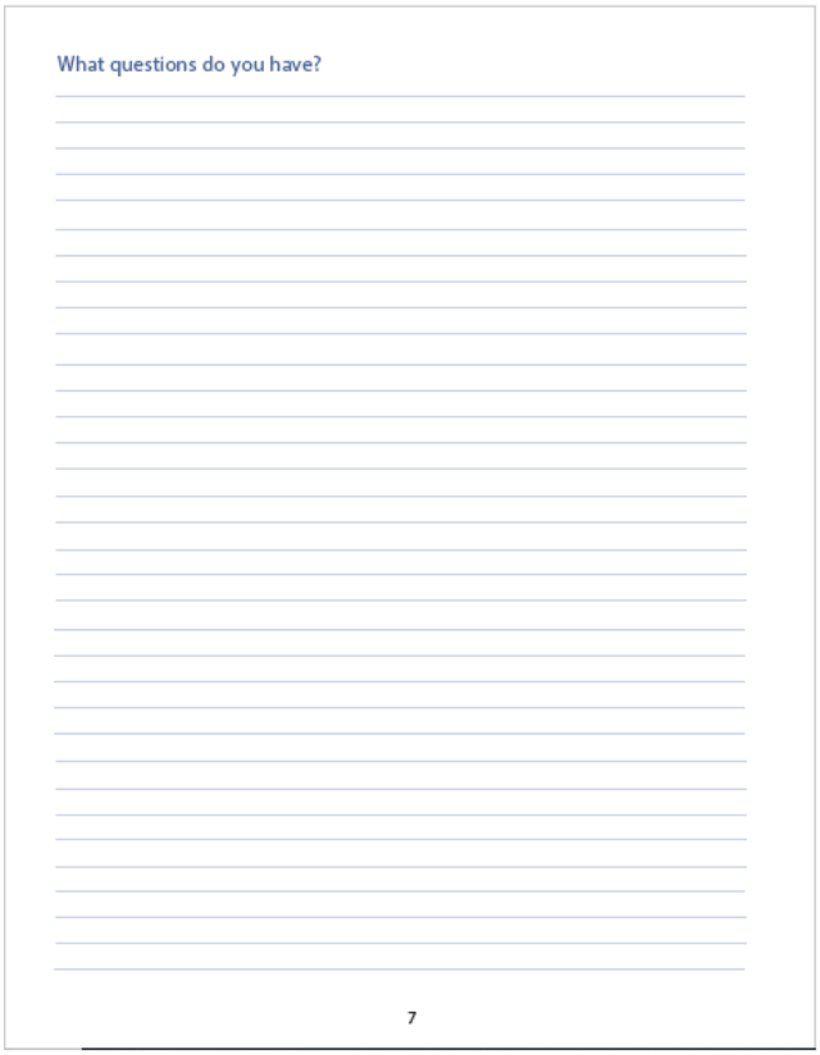
Patients' thoughts:

Jim: "The whole thing is just getting all the information from any source that you can. And take it all in, and the final decision is up to you. You have to make that decision, not your doctor. And too many patients think the doctor is God, but the doctor doesn't know your body the way you do. So, the final decision is yours."

Caroline: "First of all, I think it's a very personal choice. I think everybody needs to make their own decision. But, I think it needs to be an informed decision."

Life-size ICD images

6

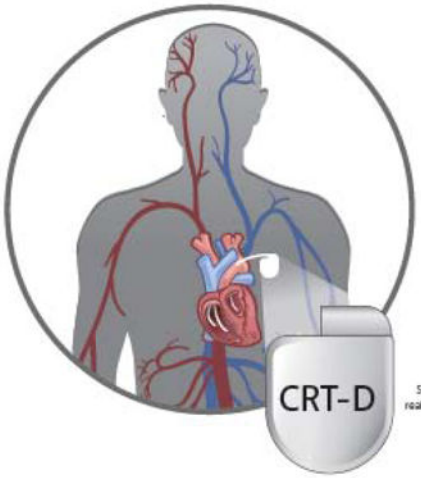



School of Medicine
Colorado Program for Patient Centered Decisions
8

A decision aid for

Cardiac Resynchronization Therapy with Defibrillation (CRT-D)

For patients with heart failure who are getting cardiac resynchronization therapy and considering defibrillation.



See the back page for real-life sizes of the device

You are being offered CRT with the option of defibrillation.

This booklet will

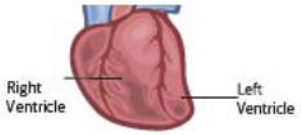
- Explain how CRT works and why your doctor is recommending it.
- Explain the option of including defibrillation to your CRT.
- Help you make your decision based on your values and wishes.

COMIRB #17-1690, PI: Daniel Matlock

1

Section 1: What is CRT?

Sometimes patients with heart failure also have a problem with their heart beating out of sync because of damage to the electrical system of the heart. CRT is a device that helps the heart beat in sync. To do this, a special pacemaker with three wires is placed in the heart to help pace it.



Heart failure is when a heart is too weak to pump enough blood for the body. People with heart failure may become tired easily, have a hard time breathing, or have swelling in their legs. Symptoms may be minor for some people. For others, they can be pretty bad.

CRT is designed to make you feel better

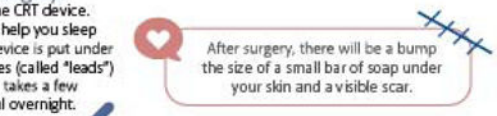
CRT helps people feel better by improving the heart's ability to get blood to the body. Some people with CRT experience less:

- shortness of breath
- leg swelling
- tiredness

Some people also notice they can walk farther with CRT. Your doctor is recommending CRT to you because she or he believes this will help lessen your overall heart failure symptoms.

Does getting CRT require surgery?

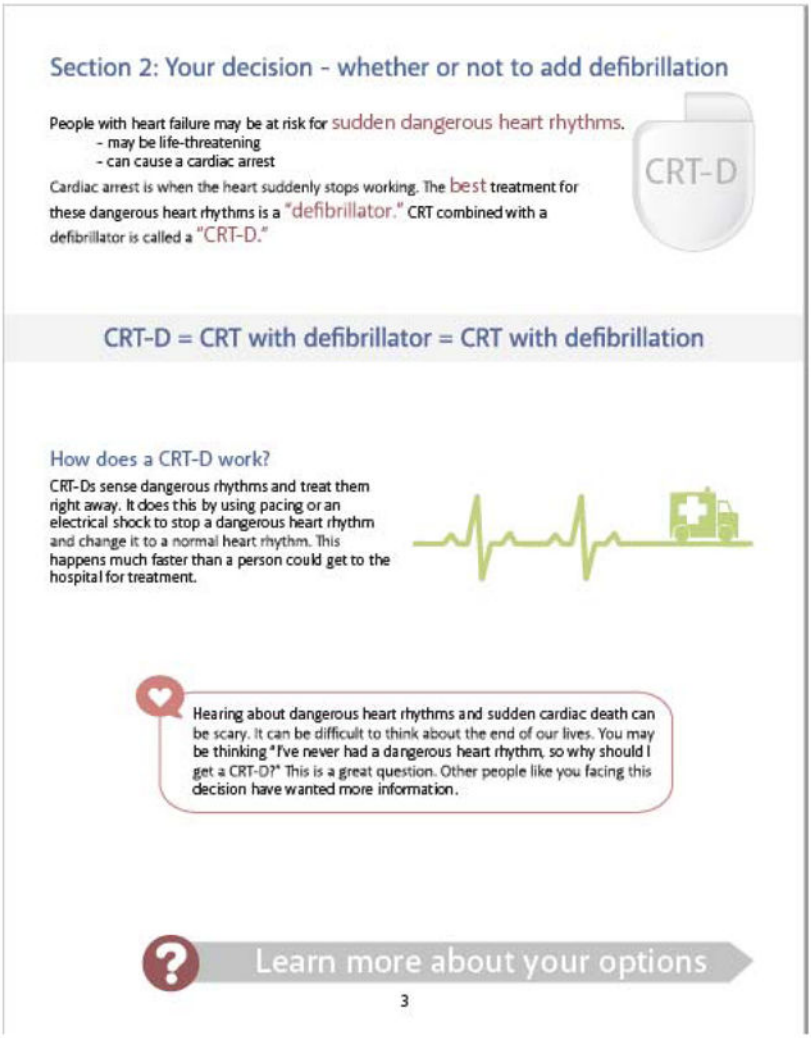
You will need surgery to implant the CRT device. You would be given medication to help you sleep lightly and control pain. The CRT device is put under the skin of the chest and three wires (called "leads") are put into the heart. The surgery takes a few hours. You may stay in the hospital overnight.

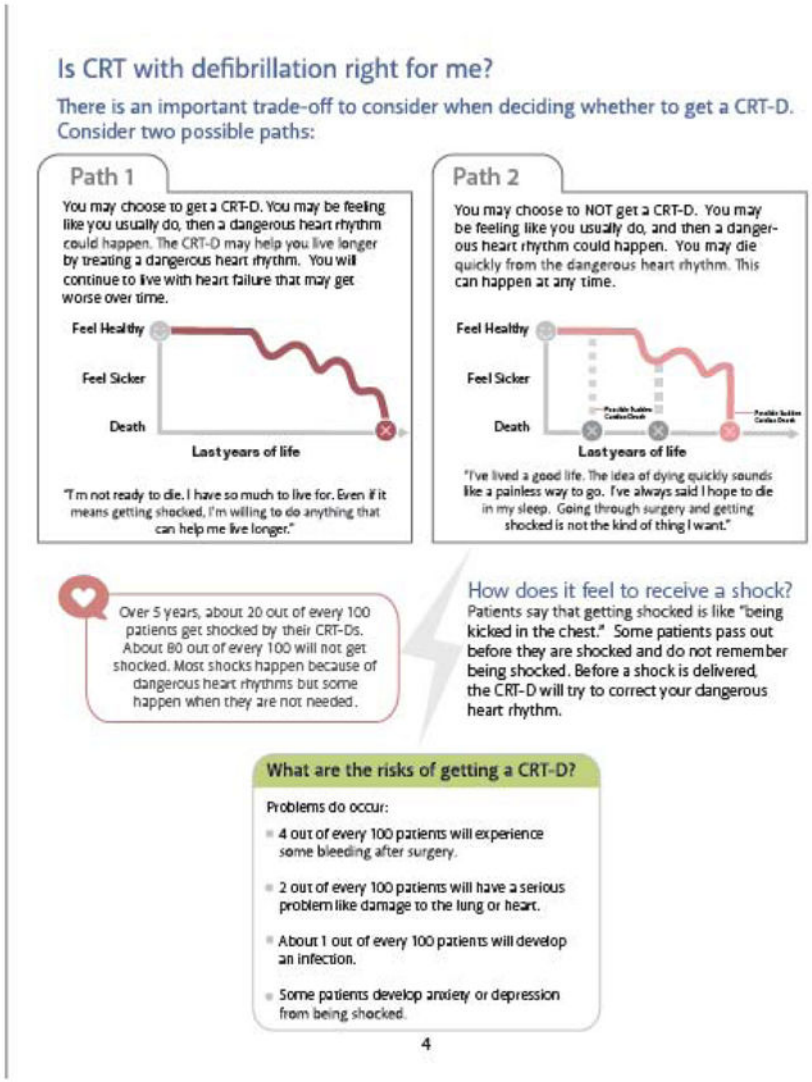


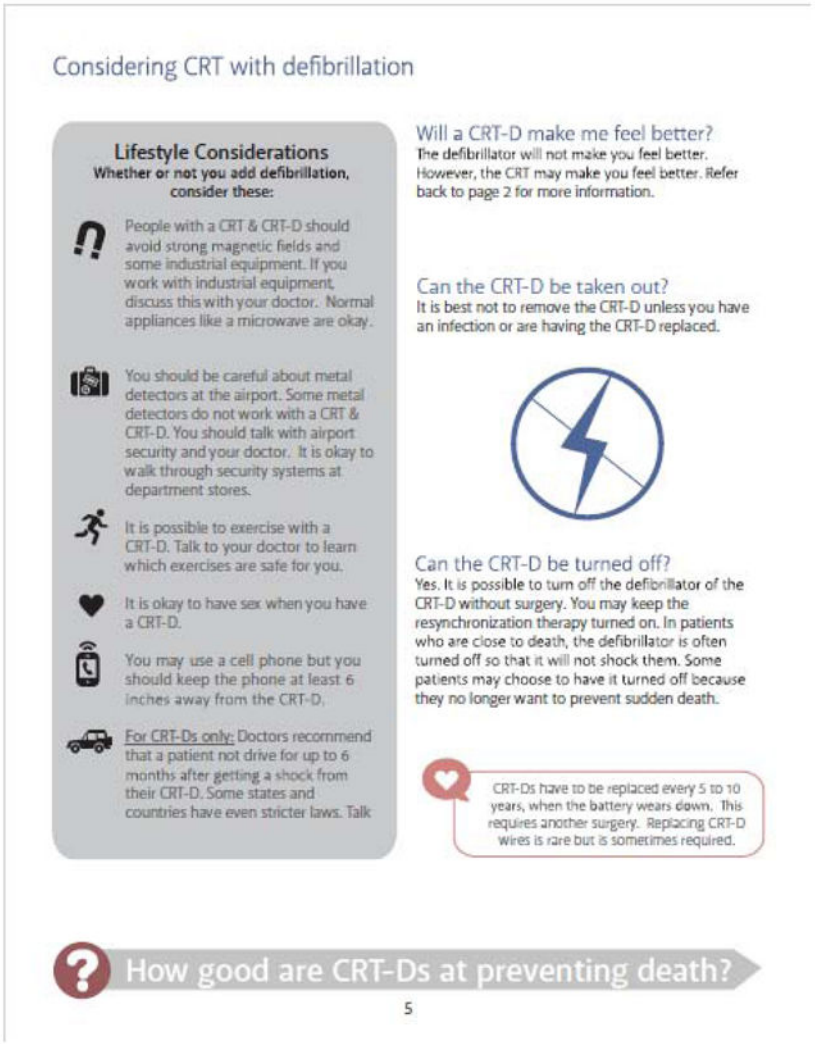
After surgery, there will be a bump the size of a small bar of soap under your skin and a visible scar.

CRT is an important therapy that can help some patients feel better. If you are not interested in getting CRT, talk to your doctor.
In the next section we are going to discuss the option of whether or not to get a CRT device that can also provide defibrillation.

2







Considering CRT with defibrillation

Lifestyle Considerations

Whether or not you add defibrillation, consider these:

People with a CRT & CRT-D should avoid strong magnetic fields and some industrial equipment. If you work with industrial equipment, discuss this with your doctor. Normal appliances like a microwave are okay.

You should be careful about metal detectors at the airport. Some metal detectors do not work with a CRT & CRT-D. You should talk with airport security and your doctor. It is okay to walk through security systems at department stores.

It is possible to exercise with a CRT-D. Talk to your doctor to learn which exercises are safe for you.

It is okay to have sex when you have a CRT-D.

You may use a cell phone but you should keep the phone at least 6 inches away from the CRT-D.

For CRT-Ds only: Doctors recommend that a patient not drive for up to 6 months after getting a shock from their CRT-D. Some states and countries have even stricter laws. Talk

Will a CRT-D make me feel better?

The defibrillator will not make you feel better. However, the CRT may make you feel better. Refer back to page 2 for more information.

Can the CRT-D be taken out?

It is best not to remove the CRT-D unless you have an infection or are having the CRT-D replaced.

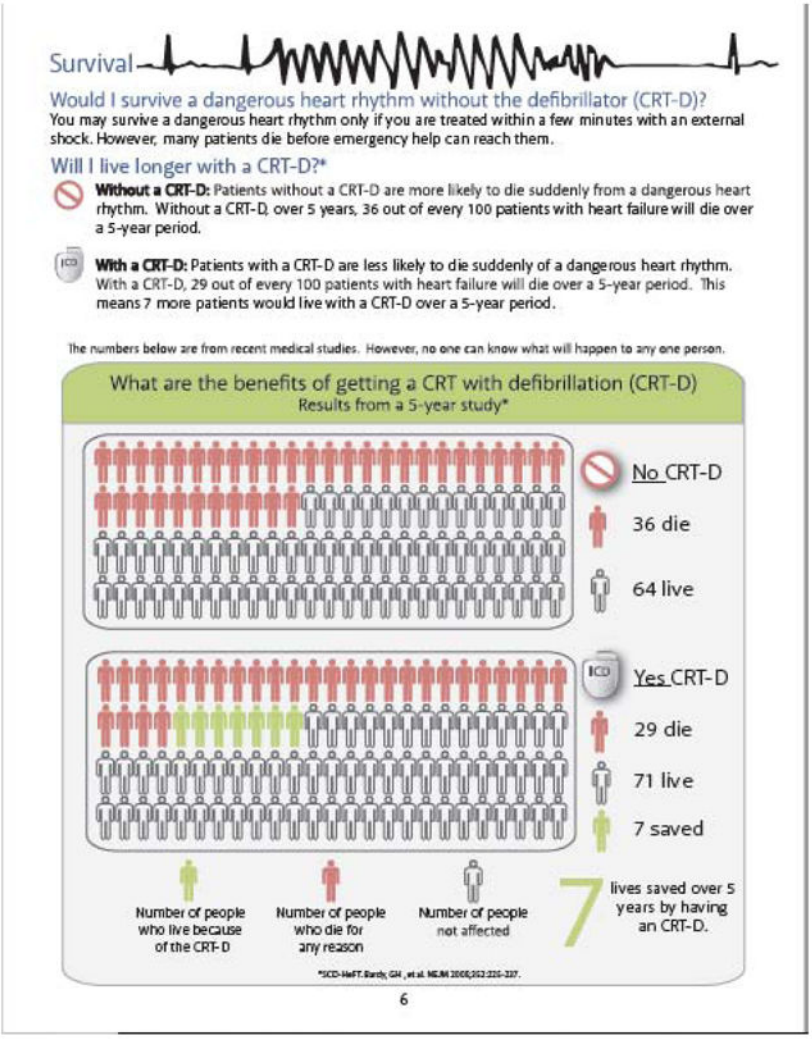
Can the CRT-D be turned off?

Yes. It is possible to turn off the defibrillator of the CRT-D without surgery. You may keep the resynchronization therapy turned on. In patients who are close to death, the defibrillator is often turned off so that it will not shock them. Some patients may choose to have it turned off because they no longer want to prevent sudden death.

CRT-Ds have to be replaced every 5 to 10 years, when the battery wears down. This requires another surgery. Replacing CRT-D wires is rare but is sometimes required.

How good are CRT-Ds at preventing death?

5



In Summary

FAQ	Implant an CRT-D	Implant CRT Only
What does a CRT-D do?	A CRT-D may stop a dangerous heart rhythm that could cause sudden death by giving an electrical shock to the heart.	Without defibrillation, you will have a higher risk of dying suddenly if a dangerous heart rhythm happens.
What is involved?	A CRT-D is put under the skin of your chest and wires ("leads") go into your heart. You will probably stay one night in the hospital. In about 5-10 years, when the battery runs out, the CRT-D will need to be replaced	The procedure to place a CRT is the same as a CRT-D.
Will I live longer with a CRT-D?	Patients with a CRT-D are less likely to die suddenly of a dangerous heart rhythm. With a CRT-D, 29 out of 100 patients with heart failure will die over a 5-year period. This is 7 fewer deaths than if they did not have a CRT-D.	Patients without a CRT-D are more likely to die suddenly from a dangerous heart rhythm. Without a CRT-D, 36 out of 100 patients with heart failure will die over a 5-year period.
Will I get shocked by the CRT-D? What will that feel like?	Over 5 years, 20 out of every 100 patients who have a CRT-D will get a shock. 80 out of 100 patients will not get shocked.	You will not get a shock from a CRT-D.
What are the risks of getting a CRT-D?	4 out of every 100 patients will have some bleeding. 2 out of every 100 patients will have a serious problem, such as damage to the lung, a heart attack, or a stroke. 1 out of every 100 patients will get an infection, which may require removing the CRT-D.	The procedure to place a CRT is the same as a CRT-D. The risks are the same.
Will a CRT-D improve my symptoms?	The defibrillator itself will not improve your heart failure symptoms.	CRT has been shown to reduce shortness of breath, leg swelling, and tiredness.
Are there things I cannot do?	This depends on your heart problem. Talk to your doctor about driving limitations and other activities.	Even without a CRT-D, talk with your doctor about driving limitations and other activities.
Can the CRT-D be taken out?	It is best not to remove the CRT-D unless it gets infected or it is time to have it replaced when the battery runs out.	It is best not to remove the CRT-D unless it gets infected or it is time to have it replaced when the battery runs out.
Can the CRT-D be turned off?	Yes, the CRT-D can be turned off without surgery. This is recommended if a person is likely to die from another illness.	It is generally not recommended to turn off CRT pacemaker since the device will not prolong your life and has no ability to shock your heart.

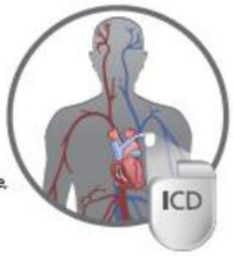
7

A decision aid for replacement of Implantable Cardioverter-Defibrillators (ICD)

For patients that already have an ICD and are considering replacement.

Refresher: What an ICD does

An ICD is designed to prevent an at-risk person from dying suddenly from a dangerous heart rhythm. When it senses a dangerous heart rhythm, an ICD gives the heart an electrical shock. It does this in order to get the heart to beat normally again.



Making a choice about ICD replacement

Your doctor has told you that it is time to replace your ICD with a new one, most likely because the battery is wearing out. For many people, this is a straight-forward decision. For others, the decision may not be so easy.

Why this might not be an easy decision

When you first got your ICD, it made sense. You were at a high risk for sudden cardiac death and you wanted to prevent that by getting an ICD. Since several years have likely passed since that discussion, it is reasonable to think again about whether you still want an ICD:

- Your overall health: you may be sicker or have other illnesses on top of your heart failure.
- You may be at a place in your life where the quality of your life is much less than it once was and preventing a sudden cardiac death isn't as important. You may be ready to accept death when it comes and are not as concerned with preventing it.
- You may have had some bad experiences with your ICD. Make sure to talk to your doctor.
- You have been shocked in the past and do not want to that experience again. Maybe you have experienced anxiety or depression because of getting the ICD and fear future shocks.
- Your risk for sudden cardiac death may not be as high as it once was.

COMRIS #07-1640, Pt. Daniel Matlock

1

Considering replacement of an ICD

Regardless of why you need to replace the ICD (battery wearing out, device malfunction, infection, etc.), you will need to have a surgery much like the one you had before.

Risks

In general, risks of this replacement procedure include pain, infection, and bleeding. Serious complications, however, are unusual. There is a slightly higher risk of complications when a wire (lead) needs to be replaced. Talk with your doctor about these complications.

Would I survive a dangerous heart rhythm without an ICD?

You may survive a dangerous heart rhythm only if you are treated within a few minutes with an external shock. However, many patients die before emergency help can reach them.

Possible benefits of having an ICD (check the ones you have experienced)

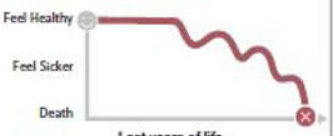
- ☐ Peace of mind
- ☐ Received shock in past
- ☐ Avoid sudden cardiac death
- ☐ Paced out of dangerous rhythm before shock
- ☐ Other:_____
- ☐ Other:_____

ICD Trade-offs

Deciding whether or not to replace your ICD can be difficult but you do have options. While the future is always unpredictable, there is an important trade-off to consider when deciding whether to get an ICD. Consider two possible paths:

Path 1

You may choose to get an ICD. You may be feeling like you usually do, then a dangerous heart rhythm could happen. The ICD may help you live longer by treating a dangerous heart rhythm. You will continue to live with heart failure that may get worse over time.

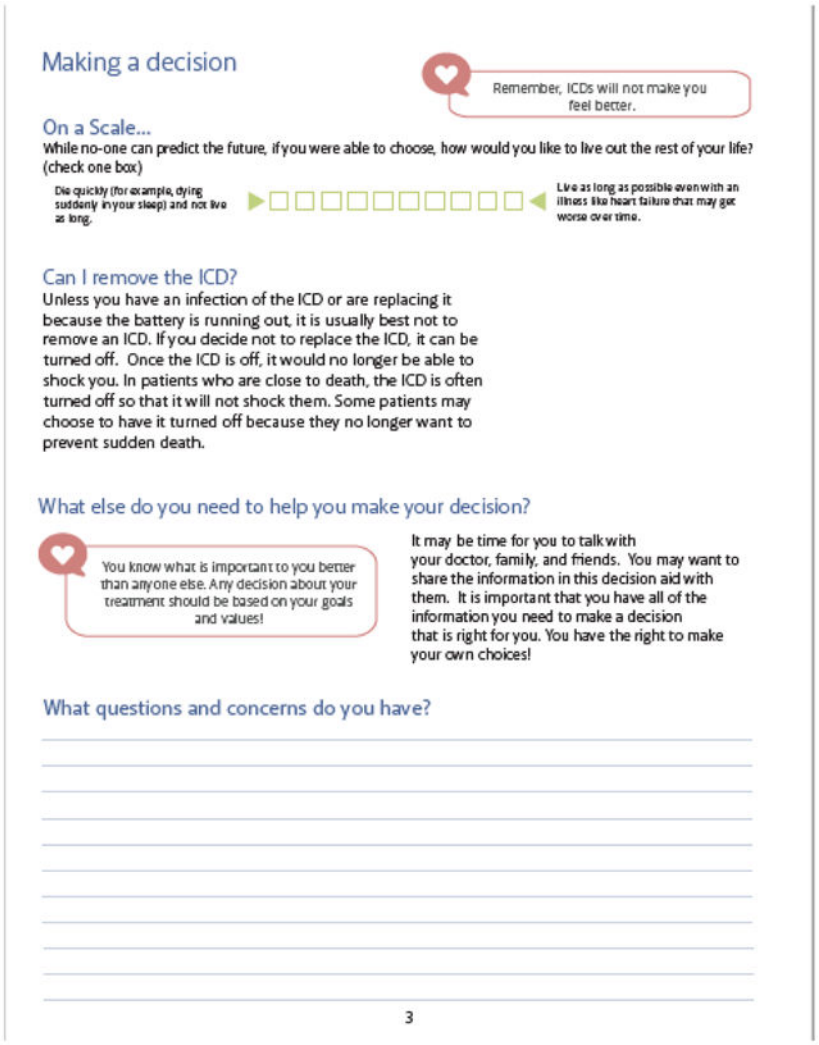


"I'm not ready to die. I have so much I'm trying to stay alive for. Even if it means getting shocked, I'm willing to do anything that can help me live longer."

Path 2

You may choose to NOT get an ICD. You may be feeling like you usually do, and then a dangerous heart rhythm could happen. You may die quickly from the dangerous heart rhythm. This can happen at any time.

"I've lived a good life. The idea of dying quickly sounds like a painless way to go. I've always said I hope to die in my sleep. Going through surgery and getting shocked is not the kind of thing I want."



Making a decision

Remember, ICDs will not make you feel better.

On a Scale...

While no-one can predict the future, if you were able to choose, how would you like to live out the rest of your life? (check one box)

Die quickly (for example, dying suddenly in your sleep) and not live as long. ▶□□□□□□□□□□◀ Live as long as possible even with an illness like heart failure that may get worse over time.

Can I remove the ICD?

Unless you have an infection of the ICD or are replacing it because the battery is running out, it is usually best not to remove an ICD. If you decide not to replace the ICD, it can be turned off. Once the ICD is off, it would no longer be able to shock you. In patients who are close to death, the ICD is often turned off so that it will not shock them. Some patients may choose to have it turned off because they no longer want to prevent sudden death.

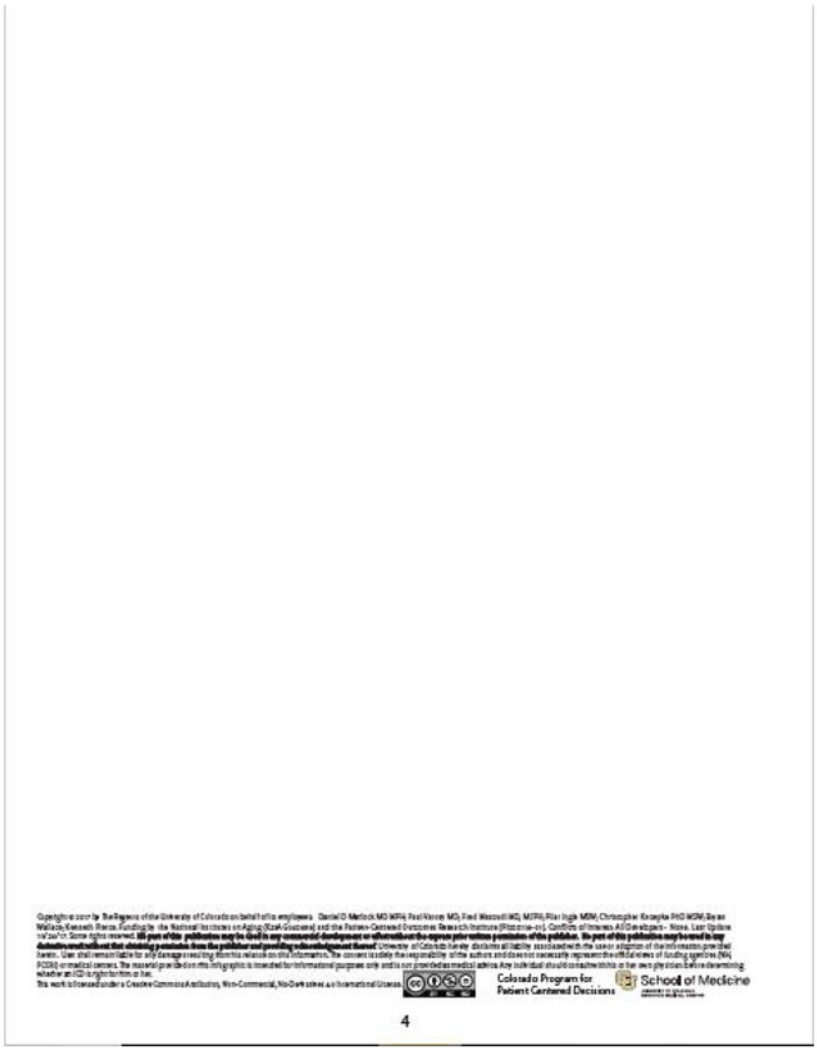
What else do you need to help you make your decision?

You know what is important to you better than anyone else. Any decision about your treatment should be based on your goals and values!

It may be time for you to talk with your doctor, family, and friends. You may want to share the information in this decision aid with them. It is important that you have all of the information you need to make a decision that is right for you. You have the right to make your own choices!

What questions and concerns do you have?

3



Appendix III:

RE-AIM is an important framework for understanding implementation science. The DECIDE-ICD trial was designed around RE-AIM, as described below:

Reach

Reach is defined as the proportion and representativeness of the target population who participate in the intervention. While Reach is a relatively straightforward measure, defining the denominator of eligible patients can be 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 PtDA to maintain a log of intervention recipients.

Effectiveness

A variety of secondary outcomes and covariates will be measured at baseline and follow-up. A number of effectiveness measures will be collected. (Table IV)

Table IV:

Effectiveness Measures

Effectiveness Measures	Baseline Pre Decision	1 Month Post Decision	6 Months Post Decision
EFFECTIVENESS OUTCOMES (see descriptions below)			
- *Decision Quality – Knowledge	X	X	X
- *Decision Quality – Value-choice concordance	X	X	X
- **Process –** 6 IPDAS-endorsed process measures	X	X	X
- **Decision choice**		X	X
- **Decision conflict**	X	X	X
- **Decision regret**		X	X
- **HADS-A** Anxiety Measure	X		X
- **ICD Experiences (+/− shock; +/− complications etc.)**		X	X
COVARIATES			
- **Demographics** (combined survey and short chart review)	X		
- **Medications, Comorbidities, Heart Failure Type/Severity**	X		
- **Literacy** (REALM-R 7 item)[41] and **Subjective Numeracy**[42]	X		

* Primary outcome measures

Primary outcome: The primary effectiveness outcome will be decision quality. Decision quality is an essential element of the Ottawa Decision Support Framework, defined as "the extent to which the implemented decision reflects the considered preferences of a well-informed patient."[34] Decision quality measures consist of two domains: knowledge and value-choice concordance.

- Knowledge: Consistent with methods developed by Sepucha et al.,[34,35] we have developed a knowledge measure. We will use this measure to test knowledge at baseline, 1 month, and 6 months.
- Value-choice concordance: We will calculate concordance between patients' values and the treatment they choose according to the validated methods of Sepucha et al.[34,35] 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 six questions based on key domains of decision process as outlined in the IPDAS background document. In prior work, these questions had significant reliability (Cronbach's alpha of 0.78).[29]
- 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.[36,37]
- The Decision Conflict Scale (DCS): DCS is a 10-item instrument that measures decision quality and determines decisional uncertainty.[38] DCS reliability measures include test-retest correlation and Cronbach's alpha coefficients exceeding 0.78-0.90.[20,29] The DCS discriminates between groups who make and delay decisions.[20].
- 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).[20,29] It correlates with satisfaction, decision conflict, and QOL.[39]
- Hospital Anxiety & Depression Scale (HADS): The HADS is a 14-item measure assessing symptoms of anxiety and depression among general medical patient populations.[40].
- ICD experiences: These are 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.
- Literacy: The REALM-R is an 11-item test used to identify people with low health literacy.[41]
- Subjective Numeracy: The subjective numeracy test identifies how comfortable people are with numbers, and determine subjective comfort with numerical preferences.[42]

Adoption

RE-AIM defines adoption as the absolute number, proportion, and representativeness of settings and intervention agents (people who deliver the program) who are willing to initiate a program. For this trial, we approached 7 sites and 6 agreed to participate giving an adoption rate of 86% at the site level since all 6 programs have agreed to participate. We will also assess adoption at the clinician level, where each clinician can adopt SDM each time they see a patient. The primary physician or staff who had the defibrillator discussion with the enrolled patient will complete the Clinician's Perceptions of Patient Appropriateness for SDM survey (see Table V), reporting his/her opinion on the best therapy for the patient and an estimate of risk of unfavorable outcome. We hypothesize that physicians will be more open to SDM as patients become older and sicker. We will explore clinicians' adoption of SDM in two ways:

3) Clinician Attitudes Toward SDM: A quantitative survey will measure attitudes towards SDM at baseline and year 5, creating pre/post results for the intervention. We have developed a way of assessing clinician attitudes towards the importance of patient preferences relative to other factors such as guidelines and mortality data. These questions were used in the preliminary data project and demonstrated wide variability in the importance clinicians place on patient preferences.[47] While this is not directly a measure of adoption, attitudes are an important predictor of adoption.

4) Clinician's Perceptions of Patient Appropriateness for SDM: We have developed and piloted a 6 question survey, which will be asked of clinicians in regard to each patient with whom they have a defibrillator discussion. The questions are related to: 1) the clinician's assessment of the 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; both scored on a Likert scale (see Table V). 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.

Table V:

Clinician's Perceptions of Patient Appropriateness for SDM (9 point Likert scale)

	LowL	MidMid	High
7) Regarding ____<<patient>>____, whom you have cared for recently, what was your recommendation regarding defibrillation?	Strongly recommended	Neither recommended for or against device	Strongly recommended against
8) How was the decision about the device made?	The majority of the final decision was made by the patient.	The patient and I decided together.	The majority of the final decision was made by me.
9) How easy did you feel the discussion(s) with this patient were?	Very easy		Very difficult
10) How well did the patient understand the device?	Not well		Very well
11) Based on this patient's clinical situation, I would say:	The downsides of the device outweigh the benefits.	The downsides and benefits of the device are about equal.	The benefits of the device outweigh the downsides.
12) Based on this patient's values & opinions, I would say:	The downsides of the device outweigh the benefits.	The downsides and benefits of the device are about equal.	The benefits of the device outweigh the downsides.

Implementation

The RE-AIM framework defines implementation as the extent to which the intervention is implemented as intended, adaptations made, and costs to deliver the program.[30] Consistency of PtDA delivery will be assessed across hospitals, providers, patient subgroups, and time through the Study Coordinator Checklist and key informant interviews. The Study Coordinator Checklist will be used to assess how the intervention was implemented for each patient, with questions regarding the types of materials, the way in which they were provided, timeline, and use. In addition, factors associated with variation in implementation, such as who provides educational materials and when, will be identified. Key informant interviews will be conducted with various clinical staff at each site at baseline, after implementation of the intervention, and after study completion. Inclusion criteria include involvement in the defibrillator decision-making process or regulatory aspects of the defibrillator program. We anticipate a total of 24 to 30 participants will be interviewed. Semi-structured interview guides were developed based on the RE-AIM framework by a decision science expert, two implementation scientists, a social worker, and a health communication expert, with input from clinical staff. These interviews will provide an understanding of the current education and decision-making process in both the control phase and post intervention implementation. The goals of these interviews are to (1) identify issues, facilitators, or barriers in the effectiveness of the intervention from various staff perspectives; (2) identify strategies that may be useful in the refinement of subsequent roll-out phases and future dissemination; and (3) ensure regular, uniform use of the educational materials. Adaptations will be assessed from the intervention checklists to assess deviations from the protocol and reasons. In addition, we will conduct periodic interviews to assess frequency, timing, source, type and reasons for adaptations using interview guides from Rabin et al.[43]

The site-principal investigator and study coordinators will identify clinical staff for the key informant interviews. Formal e-mail invitations will be sent to each identified staff member to request an interview. Interviews will be audio recorded and summarized for analysis.

Maintenance

The RE-AIM framework defines maintenance as the continued use of a practice after a study has ended. This will be assessed primarily by seeing whether each of the 6 sites decides at the conclusion of the study to maintain, modify, or discontinue the PtDAs.

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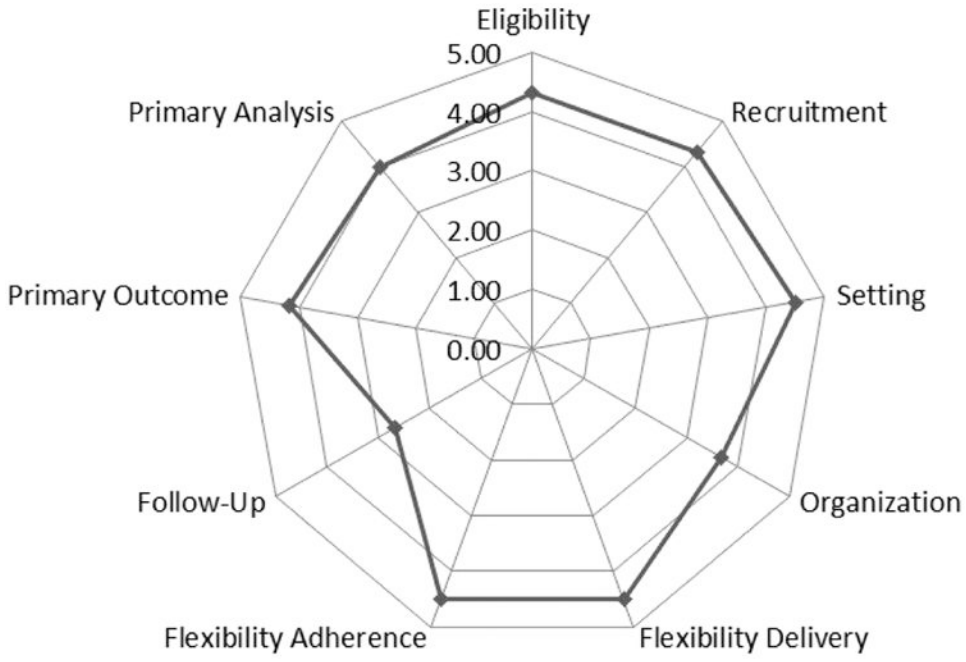

Figure I:
PRECIS-2 Diagram outlining pragmatism of proposed trial in 9 domains, compared to usual clinical care.

Table I:

Overview of the Stepped-Wedge Design

Site	Baseline (5 months)	Intervention rollout sequentially across all sites (3 years)					
Random Site 1							
Random Site 2							
Random Site 3							
Random Site 4							
Random Site 5							
Random Site 6							

Table II:

Intervention activities during implementation intervention

Implementation Action	Target Group	Components
Grand Rounds	Hospital wide – cardiology and electrophysiology	• Background to SDM • Pilot Work • Objectives of implementation and dissemination science
Focus Group	Electrophysiology Team	• NURSE listening technique • Discuss tough questions already asked by patients
Nuts and Bolts Group	Team who will be involved with implementation	• Initial strategic plan for implementation • Designation of Responsibilities • Contacts for follow-up by study team

Table III:

RE-AIM Framework

Conceptual Area	Definition	Measurement in DECIDE-ICD
Reach	Proportion and representativeness of the target population who participate in the intervention.	The number of patients who receive and remember the PtDA; over the number of patients eligible for ICD, replacement, or CRT-D. Comparison to those not participating.
Effectiveness	The impact of an intervention on important outcomes and any unanticipated outcomes.	Domains of decision quality: 1) knowledge and 2) value-choice concordance; will be measured by participant questionnaires.
Adoption	Proportion and representativeness of staff who are willing to initiate a program.	Clinician attitudes toward SDM and the intervention will be measured in pre/post interviews and a 6 question per-patient survey for each patient enrolled. Comparison to those not participating.
Implementation	How closely staff members follow the program that the developers provide, and adaptations made.	Interviews with clinicians pre-, during, and post-intervention will measure implementation of SDM with PtDA. Additionally, a study coordinator checklist for patients will measure implementation and adaptation.
Maintenance	The extent to which a program or policy becomes part of the routine organizational practices and policies.	This will be assessed primarily by seeing whether each of the 6 sites decides at the conclusion of the study to maintain, modify, or discontinue the PtDAs.

Table IV:

Effectiveness Measures

	Baseline Pre Decision	1 Month Post Decision	6 Months Post Decision
PRIMARY OUTCOMES			
- Decision Quality – Knowledge[34,35]	X	X	X
- Decision Quality – Value-choice concordance[34,35]	X	X	X
SECONDARY OUTCOMES			
- Process – 6 IPDAS-endorsed process measures[29]	X	X	X
- Decision choice[36,37]		X	X
- Decision conflict[20,29,38]	X	X	X
- Decision regret[20,29,39]		X	X
- HADS-A Anxiety Measure[40]	X		X
- ICD Experiences (+/− shock; +/− complications etc.)		X	X
COVARIATES			
- Demographics (combined survey and short chart review)	X		
- Medications, Comorbidities, Heart Failure Type/Severity	X		
- Literacy (REALM-R 7 item)[41] and **Subjective Numeracy**[42]	X		

Table V:

Clinician's Perceptions of Patient Appropriateness for SDM (9 point Likert scale)

	Low	Middle	High
1) Regarding ____<<patient>>____, whom you have cared for recently, what was your recommendation regarding defibrillation?	Strongly recommended	Neither recommended for or against device	Strongly recommended against
2) How was the decision about the device made?	The majority of the final decision was made by the patient.	The patient and I decided together.	The majority of the final decision was made by me.
3) How easy did you feel the discussion(s) with this patient were?	Very easy		Very difficult
4) How well did the patient understand the device?	Not well		Very well
5) Based on this patient's clinical situation, I would say:	The downsides of the device outweigh the benefits.	The downsides and benefits of the device are about equal.	The benefits of the device outweigh the downsides.
6) Based on this patient's values & opinions, I would say:	The downsides of the device outweigh the benefits.	The downsides and benefits of the device are about equal.	The benefits of the device outweigh the downsides.