SUPPORTING EVIDENCE FOR THE DEVELOPMENT OF ICD DECISION AIDS

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Introduction

Through extensive qualitative, quantitative, and epidemiologic research we have identified problems in the current ICD decision-making practice including low patient knowledge, wide practice variation and clinician paternalism.[1]

Patient decision aids (PtDAs) have proven to be effective at increasing patient knowledge and satisfaction while reducing decisional conflict and regret.[2] These PtDAs present an unbiased explanation of the risks and benefits for ICD therapy, and help patients consider their personal values. The primary goal of PtDAs is to help support the shared decision-making process.

We have developed multimedia PtDAs to assist patients in the ICD decision-making process:

1. Option Grid: A one-page list of frequently asked questions to aid patients in the early discussions with their providers
2. Paper Decision Aid: A graphic PtDA detailing risks and benefits, while encouraging patients to factor their values and goals into the decision- making process
3. Video: A 17-minute educational video that pairs the evidence from the infographic with patient testimonials about their decision-making experiences
4. Website: An interactive website that incorporates the content from the paper decision aid and vignettes from the video in an interactive format

These tools are designed to be supplemental information for patients to use in discussions with their clinicians.

Through our recent research we have discovered that patients making decisions regarding replacement or the combination of cardiac resynchronization therapy need separate, unique decision tools. Therefore, we have developed a paper decision aid and video specifically for these separate decisions.

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Development Process

The development of the ICD PtDAs followed the principles as outlined in the International Patient Decision Aid Standards (IPDAS) and the Ottawa Decision Support Framework.[3, 4]

Ottawa Decision Support Framework (ODSF)

The Ottawa Decision Support Framework (ODSF) is an evidence-based, practical, mid-range theory for guiding patients making health or social decisions. It uses a three-step process to: assess client and practitioner determinants of decisions to identify decision support needs; provide decision support tailored to client needs; and evaluate the decision making process and outcomes.[4]

I. Needs Assessment

As part of the needs assessment, we have performed a qualitative study,[5] a survey of physicians,[1, 6-9] and a patient survey (data not yet published). Subsequently, we reviewed the evidence from the major randomized trials and observational studies (n ≥ 1000) related to primary prevention ICDs. Additionally, we reviewed the excellent summary of psychosocial outcomes provided in the American Heart Association (AHA) Scientific Statement: Educational and psychological interventions to improve outcomes for recipients of implantable cardioverter-defibrillators and their families.[10]

Review of Evidence

The consolidation of this evidence provides the foundation for our decision tools. This document is available at www.patientdecisionaid.org (SupportingEvidence.pdf).

II. Decision Aid Development

Based on our needs assessment, we developed an initial draft of the paper tool which underwent a process of iterative testing to assure accuracy, readability and lack of bias including:

Interviews with Patients, Caregivers and Health Providers

Interviews with patients, caregivers, and clinicians; along with focus groups of ICD acceptors and decliners were conducted. Patients were recruited from two facilities, interviewed about their experience with being introduced to ICDs, details about the procedure and options, whether or not they elected to receive an ICD, and the amount of time they had to make their decision. They were then asked to review prototypes of the PtDAs and provide constructive, candid feedback along with areas for improvement. Iterative process, refer to feedback log. A log of all feedback provided by patients, caregivers and clinicians was

maintained to track the iterative process. It includes the reviewer's name and comments along with reasoning for selecting or declining the suggestions. All selections were agreed upon by the study team.

Prototype Development and Testing

- Drafting structure and content – initial content for the prototype came from consulting cardiologists and EPs. We incorporated revisions provided by the expert clinician panel and literacy expert. These early drafts were presented to patients referred for an ICD (both accepters and decliners) and caregivers during an interview to obtain their concerns and suggestions.
- Design and construction of interactive website – The infographic was used as the template for the website with the addition of patient video clips and interactive questions.
- Video production – The Development Team drafted a script that went through several iterations before filming began. We chose to have a Cardiologist be the primary narrator for the video and another member of the Development Team provided more detailed information. Consenting patients were asked a series of questions and that video footage was honed into the vignettes included in the video and on the website.
- Field testing - reviewed by expert patient panel and expert clinician panel. Once all addressable changes were incorporated and saturation of feedback was achieved, we finalized the versions of the tools.

Translation

Two independent translation services provided a forward translation (English to Spanish) of the option grid and infographic. We then asked several Spanish- speaking clinicians to compare each of the translations, and used their feedback to consolidate the translations into one document. Once the translations were collated, we asked the clinicians to review the tools a second time for readability and grammar. The final version of the option grid and infographic were presented.

Spanish subtitles have been added to the videos online. A forward translation of the paper tools for ICD, ICD replacement, and CRT have all been conducted as well.

Revision Policy

The Development Team will annually review the literature for advances and alternate treatments to incorporate into the PtDAs.

Benefit: Probability of Mortality (any cause)

Study	Year*	Subjects**	Duration	Population	Design	Results		
			(months)			Intervention	Control	P-Value
MADIT-RIT[11]	2012	N=1500	15	post-devise implant sinus rhythm at implant Age: ≥ 21 primary prevention LVEF ≤ 0.35, NYHA II, III	High-rate ICD therapy Delayed ICD therapy ICD conventional programming	5% high-rate programming, 9% delayed programmin	12% conventional programming	p-value = 0.03
IRIS[12]	2009	N=898	37	MI w/in last 30 days heart rate of ≥ 90 beats LVEF≤ 0.40, NSVT NYHA I, II, III	Conventional medical therapy Prophylactic therapy with ICD	22%	23%	p-value =0.76
SCDHeFT[13]	2005	N=2521	45.5	Stable Ischemic/non-isch CHF NYHA II, III LVEF ≤ 0.35, Age: 18+ NSVT, no indications CABG	Placebo + Conventional therapy Amiodarone + conv. therapy ICD therapy +	22%,	29% placebo 28% amiodarone,	p-value = 0.53 (amiodarone) p-value
DEFINITE[14]	2004	N=458	29	Non-Isch CMP, Hx HF Ambient arrhythmias LVEF < 0.36, NYHA I, II, III NSVT	Standard oral medical therapy ICD + oral medical therapy	12%	17%	p-value =0.08
DINAMIT[15]	2004	N=674	30	recent MI (w/i 6-40 days) LVEF ≤ 0.35 HR ≥ 80, Age: 18-80, NYHA I, II,	No ICD therapy ICD therapy	19%	17%	p-value =0.66
MADIT II[16, 17]	2002	N=1232	20	prior MI > 1 mo, LVEF ≤ 0.30 Age: ≥ 21	Conventional medical therapy Prophylactic	14%	20%	p-value = 0.016
CABG Patch[18]	1997	N=900	32	Dx=CAD scheduled CABG, abn SAECG LVEF < 0.36,	Conventional medical therapy Prophylactic therapy with ICD	23%	21%	p-value =0.64
MADIT[19]	1996	N=196	27	NYHA I, II, III prior MI, NSVT, ischemic HD LVEF ≤ 0.35, Age: 25-80 Inducible VT, no indications	Conventional medical therapy Prophylactic therapy with ICD	16%	39%	p-value =0.009
MUSTT[20]	1996	N=704	39	Hx CAD – MI or catheterization NSVT, LVEF ≤ 0.40, Age < 80	No Antiarrhythmic therapy Antiarrhythmic therapy guided by EP	22%	28%	p-value =?

* published findings, ** subjects who wererandomized

NYHA – New York Heart Association, LVEF – left ventricular ejection fraction, MI – Myocardial infarction, NSVT- non-sustainable ventricular tachycardia, CABG-coronary artery bypass graft, CMP- cardiomyopathy, SAECG-signal-averaged electrocardiogram, HD-heart disease, CAD-coronary artery disease, VT-ventricular tachycardia

Benefit: CRT Probability of Mortality (any cause)

Study	Year*	Subjects	Duration	Population	Design	Results		
		(N)				**Intervention**	**Control**	***p*-Value**
CARE-HF	2005	813	29.4 months	≥ 18 years. Ventricular fraction ≤ 35%. ORS duration ≥ 150msec or QRS duration 120-149. NYHA Class III/IV.	CRT Therapy Vs. Pharmacological Therapy	24.7% @ 3 years 32.2% @ 5 years 49.1% @ 6.5 years 54.8% @8 years	38.1% @ 3 years 43.9% @ 5 years 56.3% @ 6.5 years 61.8% @8 years	0.007
REVERSE	2008	610	12 months	NYHA Class I or II heart failure with a QRS ≥ 120ms and a LV ejection fraction of ≤ 40%.	CRT- ON Vs. CRT-Off (control)	The heart failure clinical composite response indicated that 16% worsened on CRT-ON.	The heart failure clinical composite response indicated that 21% worsened on CRZT-OFF.	0.10
CRT for Mild-to-Moderate Heart Failure	2010	1798	40 months	NYHA class II or III heart failure, a left ventricular ejection fraction of 30% or less, and an intrinsic QRS duration of 120 msec or more or a paced QRS duration of 200 msec or more.	CRT-D Vs. ICD	Death or hospitalization for heart failure 33.2%. Hospitalization for heart failure 19.5%	Death or hospitalization for heart failure 40.3%. Hospitalization for heart failure 26.1%	Death or hospitalization p-value= .001 Hospitalization for heart failure p-value= .001

		(N)				**Intervention**	**Control**	***p*-Value**
RAFT	2010	1,798	40 months	NYHA class II-III	CRT-D Vs. ICD	Mortality rate 20.8%. HF hospitalization 19.4%	Mortality rate 26.1%. HF hospitalization 26.1%	0.01 (mortality rate) 0.001 (hospitalization
Miracle ICD II	2004	186	6 months follow up	NYHA class I-II	CRT-D Vs. ICD	2% mortality rate	1.9% mortality rate	
COMPANION	2004	1520	24 months	NYHA Class III/IV- Resulting from ischemic or non-ischemic cardiomyopathy. Left ventricular ejection fraction of .35 or less. QRS of 120. PR interval of more than 120msec.	Pharmacological therapy Vs. CRT-P (with pacemaker) Vs. CRT-D (with defibrillator)	Compared with pharmacological treatment CRT-P and CRT-D were associated with a 21% and 25% reduction in all-cause mortality, 34% and 37% reduction in cardiac, and 44% and 41% reduction in heart failure hospital admissions, respectively.		0.002 (CRT-P) 0.001 (CRT-D)

MADIT-CRT	2009	1820	2.4 years plus up to 7 years for follow up	≥ 21 years. Ischemic cardio-myopathy (NYHA I/II) or non-ischemic (NYHA II). Ejection fraction of 30% or less. QRS 130msec or more.	3:2 ratio of CRT-D and ICD only, respectively	17.2% death/heart failure and 13.9% from heart failure only for CRT-D patients, which resulted in 34% reduction in the risk of death or non-fatal heart failure compared with ICD use only.	0.001
MIRACLE	2002	453	6 months follow up	NYHA class III/IV with chronic HF. All patients were on an optimal HF medical regimen that was unchanged for a minimum period of 1 month. QRS duration ≥130msec, an LV end-diastolic diameter ≥55 mm and ejection fraction ≤ 35%.	CRT Vs. MT (medical therapy)	CRT was associated with reduced end-diastolic and end-systolic volumes (both P0.001), reduced LV mass (p-value= 0.01), increased ejection fraction (p-value= 0.001), reduced MR (p-value= 0.001), and improved myocardial performance index (p-value= 0.001) compared with control.	
MIRCALE ICD	2003	369	6 months follow up	Mildly symptomatic (NYHA class II) chronic heart failure, an LV ejection fraction (LVEF) 35%, an LV end diastolic dimension 55mm, a QRS interval 130ms, and an indication for an ICD.	CRT-D Vs. ICD only	V˙ E/V˙ CO2 improved in CRT patients (p-value= 0.01). Echocardiographic assessment showed statistically significant reductions in LV end-diastolic and end-systolic volumes (p-value=0.04 and p-value= 0.01, respectively) and improvement in LVEF (p-value= 0.02) in patients receiving CRT. NYHA class also improved in patients receiving CRT (p-value= 0.05). Composite clinical response of the CRT group showed a clear improvement (p-value= 0.01) over the control group, with 58% of the CRT patients improving compared with 36% of the control patients.	

Contak CD Trial	2003	581	6 months	(NYHA) class II to IV, left ventricular ejection fraction (LVEF) ≤35%, QRS interval ≥120 ms, and conventional indications for implant of an ICD.	CRT-D Vs. ICD	Significant improvement in peak VO_2., reductions in ventricular dimensions and improvement in left ventricular ejection fraction (5.1% vs. 2.8%, p-value = 0.020). A subgroup of patients with advanced HF (NYHA class III/IV) consistently demonstrated improvement across all functional status end points.
Left Ventricular Reverse Remodeling but Not Clinical Improvement Predicts Long-Term Survival After Cardiac Resynchronizati on Therapy	2005	141	6 months	The inclusion criteria included severe symptomatic heart failure despite optimized medical therapy, LV systolic dysfunction with an LV ejection fraction (EF) 40%, and QRS duration 120 ms or more.	Patients with advanced heart failure who received CRT. Serial echocardiographic studies with tissue Doppler imaging (TDI) were performed before and 3 to 6 months after CRT to assess LV reverse remodeling.	Echocardiographic studies demonstrated LV reverse remodeling 3 to 6 months after CRT. The LVESV decreased significantly by 17.6% (p-value= .001), whereas LVEDV decreased by 11.0% (p-value= .001). LV EF increased by 6.3% (p-value=.001).

Effects of Cardiac Resynchronization Therapy on long-term quality of life. An analysis from the Cardiac Resynchronization-Heart Failure (CARE- HF) study Clevland et al.	2009	813	18 months follow up	?	CRT Vs. Medical Therapy	At 18 months mortality rate was lower in the CRT patients (p-value= .025)

Mortality Data Summary:

As this PtDA was for primary prevention among patients with heart failure, the best trial data to present in the tool would be the SCD-HeFT trial data. While more contemporary trials such as the MADIT-RIT may alter the benefit slightly, they have more of an implication on the shock rate. While patients with ischemic HF may have greater absolute benefits based on the MADIT trial, the sub-group analysis in SCD-HeFT trial which separate the ischemic and non- ischemic patients had a similar 7% absolute risk reduction. Further, the subgroup analysis from the SCD-HeFT indicated no interaction between ICD therapy and cause of CHF. Comparing ICD therapy and patients with NYHA Class III indicated no apparent reduction in risk of death (hazard ratio: 0.84 to 1.61, p=0.001).[11]

Quality of Life – CRT-D

Study	Year	Subjects	Duration	Results
MIRACLE ICD	2003	N= 369	6 months	Patients assigned to CRT had a greater improvement in median quality of life score (p-value= .02) than controls, but there were no different in the change in distance walked in 6 minutes
REVERSE	2009	N= 262	24 months	21% of patients in the CRT-ON group had a moderately or markedly improved patient global assessment and improved NYHA class….compared to the CRT-OFF group which had only 10% of patients with moderately or markedly improved patient global assessment and improved NYHA class.
Optimizing Programation of Cardiac Resynchronization Therapy Devices in Patients with Heart Failure and Left Bundle Branch Block Vidak et al.	2007	N= 100	6 months	CRT group had an increase in distance covered in 6-min walking test (p-value= .01). CRT group has an increase in LV cardiac output (p-value= .05).
Effects of Cardiac Resynchronization Therapy on long-term quality of life. An analysis from the Cardiac Resynchronization-Heart Failure (CARE-HF) study Clevland et al.	2009	N= 813	6 months follow up	CRT patients improved their EQ-5D score (p-value= .0001). Compared to the pharmacological therapy group, the CRT patients had a mean reduction in MLWHFQ score of 10.6 (p-value= .001).

Risk: Shock Rate and Inappropriate Shock

Observational Studies					
Study	**Year**	**Subjects**	**Duration** (months)	**Design**	**Results**
National Cardiovascular Data Registry (NCDR)[21] Peterson, et al.	2013	N=32,034	--	Single-chamber and dual-chamber ICDs for primary prevention, without pacing function	Unable to evaluate
Al-Khatib, et al.[22]	2008	N=8581	--	ICD recipients - CMS data	Unreported
PEOPLE	2007	N=6319	--	--	Unreported

RCT Studies				
Study	**Year**	**Subjects**	**Duration** (months)	**Result**
MADIT-RIT[11]	2012	N=1500	15	**Inappropriate therapy** 1st occurrence (# of patients): 2% high-rate (p-value = 0.12), 3% delayed (p-value = 0.28), 4% conventional Total occurrences (# of occurrences): 5% high-rate (p- value < 0.001), 10% delayed (p-value = 0.16), 20% conventional **Appropriate therapy** 1st occurrence: 4 % high-rate (p-value = 0.68), 3% delayed (p-value = 0.74), 4% conventional Total occurrences: 14% high-rate (p-value = 0.35), 14% delayed (p-value = 0.15), 11% conventional
IRIS[12]	2009	N=898	--	Unreported
SCDHeFT[13]	2005	N=2521	45.5	Overall shock rate any cause - 31% of patients; annual average appropriate shock rate – 5.1% of patients/year; annual average inappropriate shock rate – 2.4% of patients/year
DEFINITE[14]	2004	N=458	29	appropriate shock - 18% of patients inappropriate shock - 21% patients overall shock rate - 39% of patients

DINAMIT[15]	2004	N=674	30	Included with complications
MADIT II[16, 17]	2002	N=1232	20	12% inappropriate shock episodes, 31% any shock episode
CABG Patch[18]	1997	N=900	32	57% at 32 months
MADIT[19]	1996	N=196	27	60% chance of shock within 27 months. Overall appropriateness of the defibrillator discharges could not be assessed reliably since only a small number of patients had pulse generators with electrogram storage.
MUSTT[20]	1996	N=704	--	Unreported

Shock Rate and Inappropriate Shock Summary:

We chose to present a shock rate of 20/100 over 5 years. We initially presented the shock rate of 31% from SCD- HeFT but many of our expert reviewers felt that current device programming with anti-tachycardia pacing and dual chamber sensing likely lower the shock rate compared to over 10 years ago when the SCD-HeFT trial started. In the MADIT-RIT trial, the shock rate was 6% over 1.4 years. We accounted for a proportion of people who receive multiple shocks and extrapolated this out to 5 years to keep a consistent duration for the denominator throughout the PtDAs. Consequently, we chose a value of 20/100 for shocks.[11, 12]

Additionally, inappropriate shocks were identified to be very important in our pilot work as well as in our expert review.[1] However, gaining consensus on the rate of inappropriate shocks was extremely difficult. Further, there was a challenge in how consistently this data was reported: some studies did not report shock rates, some included inappropriate and appropriate together, some only measured the first occurrence, some reported percentages based on number of occurrences while others reported based on percentage of patients who experienced shock.

Consequently, we chose to handle the topic of inappropriate shocks qualitatively: 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.

Supporting Evidence For The Development of ICD Decision Aids

CRT-D Implantation Complications

Study	Year	Subjects	Duration	Results
CARE-HF	2005	N= 409	6 months	95.4% implantation success rate Peri-implantation death rate .49% Mechanical complications 5.9% Lead problems 5.9% Infection .7%
REVERSE	2008	N= 642		96.7% implantation success rate Peri-implantation death rate N/R Mechanical complications 2% Lead problems 10.3% Infection N/R
COMPANION	2004	N= 1294		89.5% implantation success rate Peri-implantation death rate .39% Mechanical complications 1.82% Lead problems N/R Infection N/R
RAFT	2010	N= 894		94% implantation success rate Mechanical complications 1.6% Lead problems 4.5% Infection 2.1%
Higgins et al.	2003	N= 501		100% implantation success rate Peri-implantation death rate .004% Mechanical complications 4.9% Lead problems 6.9% Infection 1.1%
MADIT-CRT	2009	N= 1820		98.4% implantation success rate Peri-implantation death rate .1% Mechanical complications 1.7% Lead problems 2.4% Infection .9%

Re-Implantation Implantation Complications

Study	Year	Subjects	Duration	Results
Characteristics and Outcomes of Patients Receiving New and Replacement Implantable Cardioverter-Defibrillators Results From the NCDR Kramer et al.	2012	N= 103,985		Patients receiving replacement ICDs had lower rates of index admission complications (0.9% versus 3.2%; P<0.001) but greater risk for death compared receiving patients receiving new ICDs. Patients receiving replacement ICDs were older (70.7 versus 67.5 years of age) and more likely to have atrial fibrillation (41.8% versus 31.4%; P<0.001) and ventricular tachycardia (60.5% versus 33.9%; P<0.001) compared with patients receiving new ICDs.
Complication Rates Associated With Pacemaker or Implantable Cardioverter-Defibrillator Generator Replacements and Upgrade Procedures Results From the REPLACE Registry Poole et al.	2009	N= 1,744		(Cohort 1) those without and (Cohort 2) those with a planned transvenous lead addition for replacement or upgrade to a device capable of additional therapies. In cohort 1, 0.2% experienced a periprocedural complication (hemodynamic instability requiring intervention with vasoactive medications in both). All other complications were identified subsequently. The most common complication was the need for reoperation resulting from lead dislodgement or lead malfunction in 10 patients (1.0%).Seven patients (0.7%) developed hematomas requiring evacuation. In cohort 2, Periprocedural complications included cardiac perforation in 5 patients (0.7%), a pneumothorax or hemothorax in 6 patients (0.8%), and cardiac arrest in 2 patients (0.3%). The most common subsequent complication was the need to reoperate in 56 patients (7.9%) because of a lead dislodgment or lead malfunction. Complications were highest (18.7%) in patients who had an upgrade to or a revised cardiac resynchronization therapy device.

Risk: Bleeding/Hematoma

Study	Year	Duration (months)	Result
NCDR[21]	2013	36	30 days post implant: Overall - 0.2% Single-chamber – 0.2% Dual-chamber – 0.3%
MADIT-RIT[11]	2012	--	Unreported
IRIS[12]	2009	--	Unreported
SCDHeFT[13]	2008	--	Index hematoma 3% 30-day hematoma 5%
DEFINITE[14]	2005	--	Unreported
DINAMIT[15]	2004	--	Unreported
MADIT II[16,17]	2004	--	Unreported
CABG Patch[18]	2002	--	Unreported
MADIT[19]	1997	32	5% treated w/surgery
MUSTT[20]	1996	27	1%
PEOPLE[23]	2007	--	All occurrences - 5.3%, those requiring intervention - 0.4%

Bleeding/Hematoma Summary:

There was little mention of bleeding risk specifically in the trials we reviewed. We chose to present 4% based on results found by Al-Khatib, et al.[22] Using 4 years of Medicare data on ICD recipients aged 65 and older (n = 8,581), the study found that across four years 4.6% of patients experienced hematoma, within 30 days of implantation. As this was the only real- world assessment of bleeding rate in a large cohort, we suspect that this was the most accurate bleeding rate to report to patients. We acknowledge that a large range exists in terms of the severity of bleeding.

Risk: Infection

Study	Year	Duration (months)	Result
NCDR[21]	2013	36	Single-chamber – 0.6% at 3 months Dual-chamber – 0.7 at 3 months
MADIT-RIT[11]	2012	--	Unreported
IRIS[12]	2009	--	Unreported
Al-Khatib, et al.[22]	2008	--	Index infection 0.7% 30-day infection 1.6% 90-day infection 2.2%
SCDHeFT[13]	2005	--	Unreported
DEFINITE[14]	2004	29	0.4% infection rate at wound or catheter site no p-value reported
DINAMIT[15]	2004	--	Unreported
MADIT II[16, 17]	2002	20	0.7% requiring surgical intervention
CABG Patch[18]	1997	32	4% requiring ICD removal, 12% at wound or catheter site, 6% other infection
MADIT[19]	1996	27	2%
MUSTT[20]	1996	39	0.6% at 18 months
PEOPLE[23]	2007	--	Incidence rate of 0.68% per 100 pts over 12 months

Infection Summary:

The rate of infection ranges between 0.4% and 2%. We chose to ignore the CABG Patch infection rate as these patients were post-operative from a bypass surgery and do not adequately represent patients receiving ICDs. We present 1% in the PtDA.[16, 20]

Risk: Serious problem, such as damage to the lung or heart (excluding bleeding and infection)

Study	Year	Duration (months)	Result	Definition of Serious Problem
NCDR[21]	2013	36	Single-chamber – 1.1% at 1 month Dual-chamber – 1.7% at 1 month	Pneumothorax requiring chest tube, hematoma requiring transfusion or evacuation, cardiac tamponade
MADIT-RIT[11]	2012	--	Unreported	
IRIS[12]	2009	37	15.7% no p-value reported	Requiring hospitalization, surgical correction, IV drug administration, including lead-related problems
SCDHeFT[13]	2005	45.5	5% peri-implant 9% post-implant	clinical events requiring surgical correction, hospitalization, or new and otherwise unanticipated drug therapy no p-value reported
Al-Khatib, et a.[22]	2008	--	Unreported	
PEOPLE[23]	2007	--	Unreported	
DEFINITE[14]	2004	29	1.3% peri-implant 4.4% post-implant	Hemothorax, pneumothorax, cardiac tamponade, lead dislodgement or fracture, venous thrombosis no p-value reported
DINAMIT[15]	2004	30	8% peri-implant Unreported post-implant	lead dislodgement, pneumothorax, inappropriate shocks no p-value reported
MADIT II[16,17]	2002	20	22%	Lead problems requiring surgical intervention, new or worsened heart failure

CABG Patch[18]	1997	32	Post-operative complications were reported commingled with adverse events, so unable to extrapolate	
MADIT[19]	1996	27	17% intervention 12% control	including: hypotension, syncope, hypothyroidism, sinus bradycardia, pulmonary fibrosis, pulmonary embolism, atrial fibrillation, pneumothorax, venous thrombosis, lead/generator malfunction
MUSTT[20]	1996	--	Unreported	

Summary of serious problems:

The rate of serious complications was one of the most difficult aspects in reviewing the literature on ICD complications. Specifically, there was wide variance in the definition of short-term vs. long-term follow up, major vs. minor events and severe complications. Other challenges encountered included:

- The variability of patient populations and risk factors across studies
- Some numbers reported were extrapolated over 5 years, some were actual numbers within the follow-up timeframe
- Some data came from randomized trials while other data came from observational studies.

We chose to present 2% which is on the low end of the data reported in the studies because these risks have been reduced from the rates seen in the RCTs as both the technology advances and as people who implant ICDs gain more experience.[23]

We elected not to report data about lead or device malfunction for the following reasons:

- The highly controversial nature of the subject
- Most reports are company specific (ie., Medtronic, St Jude)
- Often these data are contained within rates of serious complications
- Management of lead removal is very complicated
- Providers have a wide range of ways in which they choose to explain these to patients

Risk: Quality of life after ICD implant (anxiety, depression, PTSD)

Study	Year	Duration (months)	Result
NCDR[21]	2013	--	Unreported
AHA Scientific Statement[10] (Dunbar, et al.)	2012	--	13-38% anxiety 10-46% depression 12-21% PTSD
Johansen, et al. (as reported in Dunbar, et al.)[10]	2008		12.6% depression 19% anxiety Using HADS
MADIT-RIT[11]	2012	--	Unreported
IRIS[12]	2009	--	Unreported
Al-Khatib, et al.[22]	2008		Unreported
PEOPLE[23]	2007	--	Unreported
SCDHeFT[13]	2005	--	Unreported
DEFINITE[14]	2004	--	Unreported
DINAMIT[15]	2004	--	Unreported
MADIT II[16,17]	2002	--	Unreported
CABG Patch[18]	1997	--	Unreported
MADIT[19]	1996	--	Unreported
MUSTT[20]	1996	--	Unreported

Quality of Life Summary:

While there was virtually no mention of psychosocial outcomes such as quality of life, depression, anxiety or PTSD in the clinical trials, we chose to include them because there is a large body of anecdotal and observational literature suggesting that ICDs can cause these problems in many patients. This topic was the subject of an extensive review recently

summarized in an AHA Scientific Statement.[10] Notably, this was something most of the patients we interviewed would have liked to know prior to making their decision.[1]

Most studies included in the AHA Statement 10 had less the 100 participants. Because these small studies also lacked a control group of patients without ICDS, we were unable to differentiate the cause of depression and anxiety as being due to ICD implantation or to the experience of living with heart failure itself.

The AHA Statement reviewed 45 studies, including more than 5,000 patients in total, concluded that between 11 and 28% patients had a depressive disorder, 11 and 26% had anxiety disorder, and between 12 and 21% had PTSD.[10] Case in point regarding how difficult it is to attribute psychosocial outcomes to the ICD was reported by Johansen, et al. in a 2008 study of 610 ICD recipients, demonstrating a 12.6% rate of depression and 19% rate of anxiety.

Specifically when trying to compare QOL and psychosocial risks, the baseline prior to implantation was not recorded so no comparison could be made that would indicate these risks were directly related to the ICD implantation. As such, we have chosen to present the psychosocial outcomes of ICD therapy qualitatively as well. “Some patients develop anxiety or depression from being shocked.”

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Appendix I: Expert Clinician Panel PtDA Review

Comments/Suggestions	Author Response	Text Changes
ICD for Primary Prevention/ Introduction to patient		
Near the top of the first page, it states "For patients with heart failure considering an ICD for primary prevention". Obviously this is meant to inform providers who this tool is intended for. For patients, however, they may not understand what primary prevention means. Should it instead read "For patients with heart failure considering an ICD to prevent initial serious complications from a life threatening heart rhythm"?	Include red text, but with less complicated wording: Change Subtitle: For Patients at risk for heart failure… (primary prevention)	Pg 1, subtitle: For patients at risk for, but have not experienced, heart failure (primary prevention) and considering an ICD. An ICD is a small device that is placed under the skin of the chest. Wires (called “leads”) connect the ICD to the heart. An ICD is designed to prevent an at-risk person from dying suddenly from a dangerous heart rhythm.
Brief description of scenario for sudden death prevention because of condition	Declined – would get complicated to list different conditions and their definitions; might cause worry in some patients?	
Not all sudden deaths are due to a rhythm that can’t be treated	We agree, but feel this would be too complicated to explain in our tool	
Soften initial description as ATP probably prevents some sudden deaths. SCDs also prevented by backup pacing function	Agree, wording change on Pg 2.	Pg 2. 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 whether these devices are right for you. Moved from last paragraph to 2nd paragraph on page.
At the beginning of the tool you mentioned "primary prevention ICD", but you do not provide a definition for this term. I would either take it out or define it in a way that patients could understand.	This is now explained in the subtitle.	Pg 1, subtitle: For patients at risk for, but have not experienced, heart failure (primary prevention) and considering an ICD.
At the very top, the decision aid is noted to be intended for ‘patients with heart failure considering an ICD for primary prevention.’ - Two issues: not all patients who are candidates for primary prevention ICD have HF. Some have LVD with NYHA I symptoms.	Progression Add red text, put primary prevention in parentheses	Pg 1, subtitle: For patients at risk for, but have not experienced, heart failure (primary prevention) and considering an ICD

I would leave out the description of the patient and simply say, “For patients considering and ICD.” - Second, patients won’t know what primary prevention is. If you want to differentiate this from a tool for those patients who have had VT or SCD, you could say ‘for patients who are at risk for, but have not experienced, serious heart rhythm problems.’		
CHF patients differ. Patients with Class II CHF will have a higher risk of SCD than worsening CHF. Variables which would predict a more likely chance of worsening CHF should be used in the tool to personalize the tool. Thus, the patient would be asked questions initially to determine their CHF class. Then, the statistics would be altered to account for this.	Declined – unable to tailor paper and video tools. The website contains tailoring features.	
It says it is for patients with heart failure. Could that be expanded so that it could be shown to patients with asymptomatic ischemic cardiomyopathy, those without heart failure? ISCM without HF are a large class of PP ICDs.	Incorporate asymptomatic; will also include as we develop other tools	Pg 1, subtitle: For patients at risk for, but have not experienced, heart failure (primary prevention) and considering an ICD
What is an ICD		
Near the top of the first page under "What is an Implantable Cardioverter-Defibrillator (ICD)?", for the 2nd sentence, I would change "...to prevent a person from dying . . ." to "...to prevent an at-risk person from dying ..."	Reworded	Pg 1, 1st Paragraph: An ICD is a small device that is placed under the skin of the chest. Wires (called “leads”) connect the ICD to the heart. 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.
and for the last sentence, I would change "It does this by ..."to "It can do this in part by..."	Reworded	See above
Near the middle of the first page in the first Heart Box, for the second sentence, I would change "... to try to get a dangerous heart	Declined because it would alter the literacy level	

rhythm to beat normally." to "...to try and correct a dangerous heart rhythm."		
An ICD is not placed under the skin, the generator is. Suggest you change to: 'An ICD is a system made up of a battery that is placed under the skin of the chest and wires, or 'leads' that connect the battery to the heart.'	Declined – based on patient feedback. They know the device as "ICD"; could confuse patients to refer to it as a battery.	
Appropriateness for Patient		
Some patients with heart failure may have conditions that dissuade their doctors from considering an ICD (e.g., reduced survival [e.g. cancer], a LV EF that isn't low enough, advanced age, etc.). For patients with these conditions that inquire about an ICD, this tool could provide a resource to help answer why an ICD may not be appropriate for them. Would it be appropriate to have a separate box or section with the following? "Some patients with heart failure may not be appropriate for an ICD. Some reasons include: X"	Declined – this would over- complicate the tool – better as discussion between patient and doctor. We plan to develop tools specifically for LVAD, CRT and ATP	
Near the top of the first page under "Is an ICD right for me?" for the last sentence, I would change "...you have wanted to know this information." to"...you have wanted and should have this information."	Declined – too prescriptive	
You are facing a decision that might make some people feel uncomfortable. Understanding what to expect after getting an ICD might help you to feel better about your decision. Although this may be hard to think about, other patients like you have wanted to know this information. I would favor: 'Your doctor has suggested that you might benefit from having an ICD. This is a big decision." Instead of the first line.	Accepted – included red text	Your doctor has suggested that you might benefit from having an ICD. This is a big decision. Understanding what to expect …
Trade-off/Paths Text		
Near the bottom of the first page in Path 1, for the first sentence, I would change "...you	Declined - over-complicates paragraph; literacy	

normally do then a dangerous . . ." to "...you normally do. Because of your heart failure, a dangerous . . ."		
Near the bottom of the first page in Path 2, I would consider capitalizing the italicized "not" to read "You may choose to NOT get an ICD."	Accepted – agree need to emphasize 'Not'	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. ~~Some people are okay with this~~. 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. ~~Some people are okay with this.~~
Near the bottom of the first page in Path 2, for the first sentence, I would change "...you normally do and then a dangerous . . ." to "...you normally do. Because of your heart failure, a dangerous ..."	Declined – as in the first bullet	
High likelihood of dying from something else than heart failure (especially older adults)	Declined – team reworded this section based on recent focus group feedback	
On the path graphics, indicate possibility of turning off device if they feel worse	Good suggestion, we address this later. Here we want to focus on the tradeoff.	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. In these situations it is recommended that the ICD be turned off to avoid shocks.
For path 1, I don't like 'even if it means getting shocked.' The emphasis on pain here is too great. Some people, though not the majority, have shocks they aren't aware of. I would leave this phrase out.	Accepted – rephrased sentence to end with living longer	"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."
For both Path 1 and Path 2: You may be feeling like you ~~normally~~ usually do…	Accepted – better for literacy	You may choose to get an ICD. You may be feeling like you usually do, then a dangerous heart rhythm could happen. You may choose to NOT get an ICD. You may be feeling like you usually do and then a dangerous heart rhythm could happen.

Graph – Time with Heart Failure – Should the X axis on the graph be labeled in months. Bottom of slide (end point) is death	Declined – we want to emphasize the trade-off	We changed the labels on the Y axis to indicate disease progression.
Page 1 – the two paths – I don't love the last line "Some people are okay with this" - it feels both unnecessary and a little patronizing	Accepted – phrase removed in both Path 1 and Path 2	You may choose to get an ICD. … ~~Some people are okay with this.~~ You may choose to NOT get an ICD. … ~~Some people are okay with this~~.
Two different paths? Paths to what? Why not say paths towards inevitable death. You have said death is not a choice; the choice is death sooner or later.	Declined – based on patient feedback – they didn't like the bluntness of the word 'death', felt it was too negative	
How good is the ICD? Staci does not like the smiley faces on the faces of the plot. But the plot is a good idea.	Declined – too negative and de-personalizes tool	
How do I decide? Would it be possible to add the concern over loss of independence? The Aid doesn't really hit on the negatives of prolonged living with co- morbidity. It's not free to just keep going with chronic illness. Of course, I realize this is a Mandrola bias.	We agree but worry about palatability from other clinicians	
Trade-off/Paths - Chart		
I think the figures that show the paths are good, but it is not clear to me where "Feel Sick" should appear. As it is, it appears very close to when patients die, and may give the impression that prior to that, patients are feeling fine.	Agree – changed to "feel sicker" and added "death" to Y axis to give a sense of illness progression	
I like the graphics for path 1 and path 2. However, I would change 'Last years of life' to "Years of living." Path2 is great.	Declined - don't think patients would understand this phrasing	
Chart on page 3: I wonder if there were some way to display the ICD pts who do NOT receive a shock over their lifetime to reflect possible unnecessary surgery but also possible improved quality of life thru reassurance by having the ICD	Declined – too much nuance to explain	
I have a minor concern about the way that path 1 & 2 are presented. It is subtle but I think it needs to be emphasized that in both paths there is likely continued deterioration in	Declined – handled in existing statement "You will continue to live with heart failure that may get worse over time."	

health and functional status and that the ICD by prolonging life could add years of lower quality of life and similarly a death without the ICD could occur prior to any deterioration in quality of life. I might add something like the following to path 1, ”As a result it is possible that some of the years of life added by the ICD may occur at a time when you have significantly worse heart failure symptoms than you do now”. Similarly I might add something like this to path 2, “This death could occur before your symptoms of heart failure have become worse and you could lose years of life with a quality similar to what you have now”.		
I tend to think that in the written aid that the contrast between path 1 & 2 should be presented after the basic information that is on page 2. I think it might be harder to understand the distinction without the background. I, however, am open to the idea that presenting it first gives people a question in their mind when they read the background information. If this is the case, perhaps the same strategy should be used in the video	Agreed – added phrase “while the future is always unpredictable…” to the introduction of the charts	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:
Unpredictable nature of sudden death. May happen tomorrow, maybe in 10 years. In Path 2, the sudden death could occur very early or very late. It should be explained that the point where this death occurs is unpredictable.	Declined - chose the 5-year cut-off based on the SCD HeFT. To show the 1-year mortality rate would be too scary for patients	
Graph on path 1 and 2 should not just say “feeling sick” it should say death. I never realized how difficult this was when death is the outcome. Basically, everyone dies*eventually. If you use 5 years as the cutoff, a large number of patients die. If you die at 1 year suddenly, you count as much as if you die of HF at 5 years. You have lost 4 years of life. I have no idea how to convey the concept of area under the curve to patients.		

Why Consider ICD		
Due to your abnormal heart function ~~heart failure~~, your doctor believes you are at higher risk for developing a dangerous heart rhythm. Why this? The patient is at risk poor the tool shouldn't be used. I favor, 'you are at risk.'	Accepted - removed "your doctor believes"	Pg 2, 1st paragraph: Due to your heart failure, your doctor believes you are at higher risk for developing a dangerous heart rhythm.
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. Delete this. It is not needed and confuses the issue.	Ask P/F, include phrase "some may have no symptoms…"	Call out box: Some people with heart failure may have no symptoms.
"My doctor has asked me to consider an ICD. Why?" Feels like this should be at the very top of page 1 – it is the first question to answer for people.	Declined – version one was organized that way and changed because of patient feedback	
ICD Surgery		
On the 2nd page on the left side, between the "Does getting an ICD require surgery?" and the Heart Box below it that starts "There will be a bump . . .", I would insert a section that reads "Are there risks to having an ICD placed?". I would then create a Heart Box with the risks of ICD implantation included in it. In other words, I would consider moving the "What are the risks of getting an ICD" Box from the 3rd page to this location.	Declined except for last sentence; accepted – moved risk information to same page as benefits	
Does getting an ICD require surgery? Yes. The ICD battery is put under the skin and one or more wires (called "leads") are put into the heart (see the cover picture).	Declined – patients are used to the device being referred to as an ICD	
The surgery takes a few hours. You would probably may stay in the hospital overnight.	Accepted	Pg 2, 2nd paragraph: … You ~~would probably~~ may stay in the hospital overnight
Use of Sling		
I am not comfortable with the statement that patients may need to use a sling after the procedure. We tell patients to only use them at night, as using them all the time even for a week or 2 may lead to frozen shoulders so this is something that people do not advise	Accepted - removed language re: sling from video and paper tools	

FWIW we don't discharge people with slings or immobilize the arm after the first night. I tend to sell the procedure itself and subsequent wound care and recovery as pretty low-key to help focus on the decision-making on the lived experience of having the device and its role in someone's overall health care goals.	Accepted - removed language re: sling from video and paper tools	In video script changed “there will be a small bump and a scar”
I do not use slings and most patients we implant go home the same day.	Accepted - removed language re: sling from video and paper tools	
ICD Removal		
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~~. Once it is placed, the battery is only removed if it has to be replaced after several years of use or if it becomes infected	Declined	
It is best not to remove the ICD unless you have an infection or are having the ICD replaced. Consider “need to have the ICD replaced”	Accepted	It is best not to remove the ICD unless you have an infection or ~~are having the~~ need to have the ICD replaced.
ICD Turn off (can & why)		
Can the ICD be turned off? Yes. It is possible to turn off the ICD at any time ~~without surgery. This is even recommended when a person is close to dying of another cause.~~	Accepted	Can the ICD be turned off? Yes, the ICD can be turned off at any time without surgery. This means you would not receive a shock when the heart goes into a dangerous rhythm. 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. In these situations it is recommended that the ICD be turned off to avoid shocks.
This is even recommended when a person is close to dying of another cause? consider deleting "of another cause"	Accepted	Yes, the ICD can be turned off at any time without surgery. This means you would not receive a shock when the heart goes into a dangerous rhythm. 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. In these situations it is recommended that the ICD be turned off to avoid shocks.
Deactivation discussion is good.		
ICD Battery Change		
ICDs batteries have to be replaced every 5 to 10 years, when they ~~battery~~ wears down. This requires another surgery. Replacing ICD wires is rare but is sometimes required.	Declined – patients are more familiar with the device being called an ICD	
Shock		
On the 2nd page on the left side near the bottom, in the Heart Box that starts "Over 5 years, about 20 ...", I would change the last sentence to "...happen accidentally." to "...happen accidentally or because of other heart rhythms that aren't as dangerous."	Discuss w/ P _/F _	
The paper tool should discuss inappropriate shocks.	Agree	Most shocks happen because of dangerous heart rhythms but some happen ~~accidentally~~ when they are not needed.
Will I receive a shock? Good. Video: Shock discussion: The patient was good. This is really important. Do not ever remove that discussion.		
ICD Feel Better		
On the 2nd page on the left side near the bottom under "Will an ICD make me feel better?", I would insert the word "specialized" after "Some patients might get . . ." to read, "Some patients might get specialized devices."	Declined based on prior feedback from patients	Some patients might get devices with other features that can make them feel better.
On the 2nd page on the left side near the bottom under "Will an ICD make me feel better?", I would insert the word "additional" after "...device with" to read, "...device with additional features that can make them feel better."	Accepted with change of “additional” to “other” for literacy	See Author response
Will an ICD make me feel better? ICDs do not make you feel better. Some patients might get devices with features that	Declined – have reworked this paragraph	Yes, the ICD can be turned off at any time without surgery. This means you would not

can make them feel better. You should talk with your doctor about whether these devices are right for you. Comment [MNW5]: I would stay away from CRT discussion here as it will confuse the issue. This aid should not be used by CRT candidates. I would say: “ICDs do not make you fell better. They do not change any of the symptoms that you may be having. However, some patients experience a sense of security in having an ICD.’		receive a shock when the heart goes into a dangerous rhythm. 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. In these situations it is recommended that the ICD be turned off to avoid shocks.
Will an ICD make me feel better?: This will in all likelihood trigger a conversation for CRT. May be good for pts to know but they may be disappointed to learn that they are not candidates. May also be irritating for MDs.	Agreed	Some patients might get devices with other features that can make them feel better.
Will I live longer with an ICD?: I wonder if you should reorder with w/o an ICD first	Agreed	Re-arranged pictograph – without an ICD in left column
"Will an ICD make me feel better" - ask your doctor is the appropriate thing to say here, but every patient is going to ask their patient for a CRT that will make them feel better – I don't know is you need to change that but some electrophysiologists may push back against that because now everyone is going to ask for advice to make them feel better – just be aware of that	We are aware of this, will address in CRT decision aid to be developed	See Author response
“The ICD does not stop an advancing illness like heart failure.” This is a really important statement. I would consider making it more bold.	Accepted, moved to second paragraph on 2nd page	See Author response
Pictograph – SCD-HEFTData		
The use of risk stratification tools, either derived from SCD-HeFT or extrapolated from other studies (if someone did an EP study to look for inducible VT, say) could change those numbers a lot. Some might say that MADIT-RIT makes it hard to give precise numbers to a "SCD-HeFT" patient now as we would program the devices differently than they did	For now we are going to stay with the SCD-HeFT data until a new efficacy trial is done. We are using MADIT-RIT shock rate numbers and that is cited in the evidence document	

and (evidently, though I can't explain why) this change not only reduces therapies but mortality.		
what citations did you use for the statistics provided under "Will I live longer with an ICD"? On page 3 under "what are the risks of getting an ICD" I would add perforation of the heart as although it is rare, it is one of the most serious complications. You may want to also add to that list device and mostly lead issues that may arise in follow up (fracture et.).	Agreed – will add asterisk to SCD-HeFT citation to this heading.	Will I live longer with an ICD?* With an ICD: Patients with an ICD are less likely to die suddenly of a dangerous heart rhythm. With an ICD, 29 out of every 100 patients with heart failure will die over a 5 year period. This is 7 fewer patients than would die without an ICD. *SCD-HeFT. Bardy, GH , et al. NEJM 2005;352:225-237.
The time scale on the graph is not clear. The pictogram shows outcomes at 5 years, but the graph shows an unclear time frame for when I might die or realize benefit.	Declined – would detract patient focus from the trade-off to be considered	
A second subtle point I would like to make is though I think that the survival visual is quite effective at showing the 5 year survival in a way that is easier to understand than a survival curve, I think this presentation misses the fact that there are patients with the ICD that die before year five but still gain years of life from the ICD that could be significant. I think it would be reasonable to state on the video or add to the handout a statement something like, “This representation may somewhat underestimate the benefit of the ICD because there will be some patients with an ICD who have died by the 5 year anniversary of their implant but nevertheless ended up living longer than they would have if they had not had an ICD”. Perhaps this could be shown on the figure by having a third icon for patients who gained a year or more of life but still died by 5 years.	Declined - might overcomplicate the pictograph, confuse patients. Covered by “Individual situations may vary. You should discuss this with your doctor.”	
Not sure smiles are the best. Some patients with HF are not smiling but frowning. We have just used dots.	Declined – makes the tool too impersonal	
Will I Live Longer w/ ICD		

Will I live longer with an ICD?: I wonder if you should reorder Without an ICD first	Agreed	Re-arranged pictograph – without an ICD in left column
Survive Dangerous Heart Rhythm w/o ICD		
On the 3rd page on the left side at the top under "Would I survive a dangerous . . .", I would change "You can survive a dangerous . . ." to "Most commonly, you can survive a dangerous . . ."	Accepted with variation for literacy	You ~~can~~ may survive a dangerous heart rhythm only if you are treated within a few minutes with an external shock
Risks		
Where'd you get the complication data from? PTX, bleeding etc happen but stroke and MI almost unheard of as far as I know.	Agreed – removed stroke, changed heart attack to heart	2 out of every 100 patients will have a serious problem like damage to the lung, or the heart
I am most concerned about the presentation of risks and benefits. My concerns are twofold: - Are you basing the aid on solely on SCDHeFT? Each patient who uses this tool has a bit of a different risk, so lumping all together in a pictograph is tough. In fact, the statement that, “individual situations may vary. You should talk to your doctor’ makes the tool kind of useless. - The risks and benefits are presented late.	Declined – pilot work indicates that it’s more about the values, than the actual numbers Agreed – moved to second page	
The consequences and complications of the ICD needs to be expanded. It is one thing to say that 1/100 will have an infection – but what does that mean? If you say 1/100 stroke or death, then patients understand that. If you say 1/100 have to stop a medication due to side effects, then patients understand that. But what does an ICD infection mean to me? What does bleeding, serious problem, or frequent shocks mean to me? These are the reasons that patients should consider not getting an ICD, and you do not provide enough clarity. For example, the 1% infection means that the patient will need to be hospitalized for 4 weeks of antibiotics, needs to have the device removed with potential complications, etc…	This is a good comment, we have had experience with prior decision aids where patients felt the presentation of the risks made the benefit seem too minimal. The argument was that the benefit is improved “survival” and the risks are not “death.”	

Risks: Should you use the adjective “minor” surgery? That’s not how I see ICD surgery? What’s the saying about minor surgery? It’s only minor if it’s not being done on you…?	Agreed, changed in video	Agreed, changed in video but used “short” instead of “minor” – don’t want to trivialize patients’ emotions about procedure
Anything Else I should Know?		
Page 3- on the right side in the box "Is there anything else I should know?", I would insert a section that reads something like "The ICD will need to be checked intermittently. This may be performed in your doctor's clinic or at home. If the ICD needs to be programmed differently, it will require an in person visit."	Declined – we kept this out because of the moving target that is home monitoring and forthcoming advances. Don’t feel this would keep people from making a decision	
Page 3 - "Is it okay to have sex?" - so I was doing some research on this for this AHA talk I had to give – this is actually a huge question for people and they get no information at all. While obviously not the point – you can do a huge good here if there is another sentence or two. Something like "Having sex will not increase the risk that you will be shocked." Just a thought	Accepted	It is okay to have sex when you have an ICD. Having sex will not increase the risk that you will be shocked
MRIs are likely to be safe. That thought is changing with the MAGNA Safe registry.	Agreed, but will wait for publication of trial findings	
On a Scale		
On a Scale…: Although the example of dying in your sleep is quite helpful, I wonder if the word "quickly" is too close to "not live as long", that is, dying sooner. I wonder if some consideration needs to be provided about overtreatment where you get an ICD but it does not help you live longer, e.g., the group w/o shocks. As worded and illustrated seems as though not living as long is certain.	Agreed	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)?
What Else is Needed to Make a Decision		
On the 4th page at the top under "What else do you need to help you make your decision?", I would change "You should also ask your doctor your questions and concerns before making a final decision." to "You	Accepted	You should also ~~ask~~ share with your doctor your questions and concerns before making a final decision.

should also share your questions and concerns with your doctor before making a final decision."		
Video-Specific Feedback Format/Layout		
One thing to keep in mind is that both should be 100% in agreement with each other – for example the specific benefits are laid out in both based on SCD-HeFT data, but the paper instrument (correctly) notes that "Individual situations may vary. You should discuss this with your doctor." Unless I missed it that qualifier was missing in the video but is important.	Check script, change narrator's voice recording	
Some people might object to use of SCA vs SCD as too loose in the video -- ICDs treat the former and can prevent the latter, but at least once I think I heard Masoudi say the ICD would treat SCD, which is getting into Princess Bride territory. Dead people stay dead, but those arresting can be saved.	Will check script and discuss w/ P /F	
Have narrator remove stethoscope	Declined	
Why are you explain heart failure to patients with heart failure	Considering	
Found the bad heart rhythm scary	Declined	
Mention the grey circles to avoid problems with the denominator – most people receiving an ICD are not at risk of benefitting	Add 64/71 live – TV	
Not sure about the way the harms were presented –why not use icon arrays	AJ to look into	
Power point of lists is dull, maybe some illustrations to catch attention	Declined	
One-item tradeoff demo seems to me to be too directive as to how one should think	AJ to look into	
Offer a summary at the end before credits	The 2 paper tools serve as summaries for the video	
Do patients have a form with the questions of this video ("Would I Receive a Shock?") for them to write their thoughts as they occur		

when reviewing the video? Perhaps the summary of issues could be in that form.		
At 1 min and 58 seconds, the snapshot you show has a typo: "dangerous" should be changed to "dangerous".	Fixed	
I do not agree with the statement that if an ICD gets infected, it "may" need to be removed". If an ICD gets infected, it HAS to be removed	Discuss w/ P /F	
In the video there is no mention that a cell phone has to be used on the opposite side to that of the ICD, or that the type and level of exercise needs to be discussed with the doctor. I thought Ed and Jim (2 of the patients) were too soft spoken and one could not hear everything they said.	AJ will amplify voices	
At about 2 minutes into the video, dangerous is misspelled. I am sure you have caught this by now.	Fixed	
I am a little concerned about the patient who declines an ICD. In my experience, she looks atypical. Generally, very young and healthy looking patients don't Declined ICDs. More typically, patients who are ill do. Now that may sound like I want you to show someone who is near death declining an ICD, but in a 17 minute video, you can't explain all the concepts very well and this patient is not typical.	Discuss w/ P /F	
Love that it is AJ's voice. Well done, comes across very professional.	No change necessary	
It feels a bit slow. That may be just the fast talking New Yorker in me. I wonder if transitions between segments can go a little faster. Feels like those are easy edits without you having to reshoot anything.	No changes necessary	
The portion with the sliding bars showing the tradeoff - "What is important to you?" - why is the text so small? It is hard to read and the	Adjusting font size of slider graphic	

only part of the video that is visually unappealing.		
There is a lot of patient empowerment in the video that is not in the print version (I am especially impressed with the patients at the end). Is there any way to get MORE of that in the paper version? The video feels like it is going to be a more effective intervention in terms of those patients who want to say no.	Will incorporate patient quotes from video into paper document – last page - Patient clip – “take the fight” - Pt clip – “God” - Pt clip – “ personal/ informed choice”	
“Dangerous” is misspelled	Fixed	
Video: Can we show an EKG rhythm strip with the shocking of the ICD.	Will ask TV	
J felt that we underemphasized the value of an early shock. That is late shocks lead to brain damage. We say that the early shock is good but we don’t say enough as to why?	Declined – might confuse patients; over complicate tool	
Framing: with the pictograph, we only present the loss frame. We should present the gain and loss frame “XX many live, XX many die” Also, emphasize that the majority live regardless.	Will ask TV to incorporate in graphic for video	
Biggest criticism: We don’t handle inappropriate shocks. We should give a number of some kind.	Discuss w/ P /F	
The narrator. He is speaking a bit fast (sounds normal to us but probably not to a CHFer; compare how Ed talks -- the patient -- to FM...worlds apart!). His eye movements following the teleprompter are noticeable (this is totally ok, but if you were to reshoot, think about placing the teleprompter closer to him with larger font). Also, if you reshoot, change the camera angle so that FM’s face is not so distorted...have the tripod higher...Also encourage FM not to change his facial expressions so much...otherwise, he did a nice job for a nonactor!	Declined	
The elctrophysiologist does a SUPERB job!	No change necessary	
Length: it is a bit long. Ten minutes is the sweet spot	Declined	

Content: less is more. I guess you will find this out when you test it with CHFers but its a lot of info to absorb	Accepted	
Powerpoint aspects: less is more. Fewer bullet points with larger fonts. Like the blue background but maybe a tad darker...makes the white lettering more pronounced.	Accepted	
Graphics: may wish to just pick a few...they look great! But information overload...We go back and forth with our video work about including graphs and face charts as well...I think one is fine...but more than one is tough for patients...Again, your study will determine what they absorb...The last graphic what is important to me, the font is way small...	Don't want to eliminate any of the graphics; will increase font on last graphic	
Closed captioning: definitely include this. It is a standard requirement for most aids...	Accepted	
RISKS AND NUMBERS: you are a brave soul to put numbers in the risks categories!!! We have eschewed these because most people don't get them. We have preferred using words like very few, etc.	No change necessary	
The ICD generator is made to look as small as a key. It's bigger than that. The pictures do not accurately reflect size in the video. On the paper aid, they do.	AJ to check size and thickness of key – TV to adjust	
The depiction of the shock look likes nothing. Just a bright light and then the heart is in rhythm. It's rarely like that in the real world. Patients shake and often holler. You address that later so it's probably ok.	Declined – will discuss later	
P is good. The patient examples are good. Really important stuff in that section.	No change necessary	
The graphic depiction of life's paths do better on the video. I think the drop in QAL after a shock is depicted especially well with the video. (Would it be worth a qualifying sentence to explain the x and y axes of the plots?	Declined – overcomplicates the graphic.	
Infographic Specific Feedback Format/Layout		

On the 2nd page on the left side, I would consider moving the Heart Box that starts "ICDs have to be replaced . . ." to be between the sections "Can the ICD be taken out?" and "Can the ICD be turned off?"	Accepted	
I anticipate many providers printing out this tool in the hospital or from their office. I printed out the tool from home in black and white. Because most office/hospital printers print in grey scale, some font color choices should be changed.	Great comment – will rework color scheme for grey scale printing	
On the 2nd page on the right side, the font color for the box that starts "What are the benefits of getting an ICD?" needs to be made darker.	Accepted - will lighten background color so text is more prominent	
On the 3rd page on the left side, assuming that you leave in the box that starts "What are the risks of getting an ICD?" (see my comments in #11 above), the font color for this text needs to be made darker.	Accepted	
On the 3rd page at the bottom, the font color for the box to the right of "Reflection . . ." needs to be made darker.	Accepted	
I think the format is not very easy to follow. A couple of the pages are too crowded (especially page # 2). On page 2, it is not clear why the information provided in the boxes is separate from the responses to the questions. I personally think the boxes can be removed and the information you provide in them could be combined with the responses. This will make the text flow better (as it is, it feels too segregated).	Accepted - working on reformat	We have moved some of the paragraphs around to improve the flow of the document and will work on visual flow and crowding.
It would be good to provide the COI information for all developers; not just yours.	Accepted	COI for all authors has been added to the final page
Overall, it is too wordy and too much text. It felt more like a patient education pamphlet, rather than a decision aid to be used in the clinical encounter. If I were a clinician, then I would question if I can cover all the	Declined – this decision aid was not explicitly designed to be an “in the clinical encounter” tool – rather, it was designed to be used before the clinical encounter.	

information and discussion, questions in 20 minutes given its length.		
Who is primary audience for DA? If primary audience is patient, then why would your reference the Bardy NJEM study since most patients would not be able to read it or understand it.	Citation included for clinicians	
-Page 3- two trajectories on one graph – while well done in the video – it is out of place and context here. It needs a little set up so people get it.	Declined – summarizes trade-off to help patients answer "On a Scale…" section	
Small font.	Accepted	
Too much info!	Declined	
Very typical paper aid that is a good control to compare for the video!!!!	No changes	
The circle plot looks more powerful (negative) on the paper aid. Perhaps it is the taller aspects of it. You scroll down and just see plain circles before getting to the 7 green ones.	AJ to discuss with graphic team.	
Concerns about Way Information is Presented		
The information is presented in a balanced way. I do not have any concerns beyond the ones I listed above.	Concerns addressed above	
As a geriatrician and pall care doc I think its great. My concern for you as a colleague is the pushback from HF and electrophysiologists. Especially at your own institution. This will need a lot of framing when you roll it out.	Agreed	
Allow Patients to See Decision Aids Before Getting an ICD? Why/Why Not?		
I would be willing to let my patients use these tools after they are revised. Yes. I think the adjustments I describe above are important. I think that I would emphasize a lot that not all patients are the same and that this tool should absolutely be used in conjunction with a discussion with the doctor.	We received a lot of feedback on this and why we declined M's statement – because of B's reasoning	
Other Things We Should Consider		

For the more educated patients: providing a few references might be helpful.	We will have an evidence document available for those interested	
As a geriatrician and pall care doc I think its great. My concern for you as a colleague is the pushback from HF and electrophysiologists. Especially at your own institution. This will need a lot of framing when you roll it out. I think you do a nice job of balancing pros and cons, but I can see a doc who implants these or recommends them coming at this with a bias thinking it will be slanted against and that making them feel it is too pro against. "C" the patient seems very young to me to have refused an ICD – so they are going to harp on that as well. "Why would a woman like that refuse?" This doesn't mean you have to change anything in the aids, but realize that selling docs on the aid will also be a hurdle – having a great aid like this won't be enough. I think that's my comments/concern for you from a research perspective.	May re-order clips	
A random point that came up here at AHA – have you thought about a study where patients choose one or the other? The idea is to let patients choose the intervention – will be more powerful if there is an element of choice for them. We have found in WISDOM that some patients don't have internet access. Not 100% of older population is plugged in.	Agreed	
I think the piece on trying to adjust for CHF class is a lot of work but necessary.	Declined – overcomplicates tool	
General/Overall Comments		
The video is fantastic. I thought length of presentation, videography, and patient interviews were all fantastic. I really have no recommendations about how to make video better.		
Overall I liked the paper instrument more than the video, though both provide a lot of useful information		

I really like both aids together. They are complementary not mutually exclusive.		
My main concern is the length of the video. It's long. Not saying I saw a lot to cut. It's just long		
Yes, I would want my patients to see them I would go so far as to say they could be mandated. (Shhh that's progressive.)		
First, they are both fantastic! I can tell a ton of work went into both. Very impressive!		
Paper Tool: "Great"		
I like both of the decision aids and I would certainly be willing to have my patients see them. I tend to think the video will be more effective because people are more likely to skip over parts of the written text and are more likely to hear the whole presentation on the video. I also think that hearing the points of views of other patients in their own words will be very effective. I have long wanted a video like this that I could show my patients.		
Overall, OUTSTANDING! A nice balance of seeing a real person, animation, and powerpoint. Really well done! OVERALL, this is ground breaking stuff and you should feel VERY PROUD!!!! THIS IS AWESOME AND WILL CHANGE LIVES!!!!		

Appendix II. PtDA Development Logs

ICD Option Grid Log

Date recd	Reviewer	Suggestions	Reasoning behind changes
12/9/11	Internal team or team member	1. Accept: replaced description of procedure w/graphic of ICD in chest - kept: length of hospital stay Decline: removed mention of heart transplant 2. changed 'may be a bump and possibly have scar' to 'will be a bump and likely have scar' 5. Accept: changed 'increases chances of living longer' to 'it is likely that you will live longer'. 9. Decline: added 'You may have an abnormal heart rhythm that could cause sudden cardiac death.'	
12/15/11	Internal team or team member	Added: 'This option grid is for patients with heart failure who have never had a cardiac arrest (primary prevention). 1. Decline: changed 'You and your clinician may discuss treatment alternatives such as medications, lifestyle changes, or other procedures' to 'Even if you decline an ICD, you and your clinician can still use medications to treat the symptoms of your heart failure' 3. Added bleeding to risk section 4. 'Will' changed to 'can' 5. Add to text pictograph of statistics 6. Removed question about dying quickly in sleep 7. Changed 'Will I always have the ICD' to 'Can the ICD be taken out?' 8. Accept: added 'some patients with ICDs experience worsening heart failure' Decline: deleted 'Your clinician may prescribe you medications which may improve your heart failure.'	
12/16/11	Internal team or team member	8. Add comment to Decline column: 'Will my heart failure ever improve?'	
12/16/11	Internal team or team member	Retitled, reformatted graphics and reorganized questions suggestion to add 'common concerns' -- activities can't do	
12/19/11	Internal team or team member	New rows: Will I have to limit exercise and sexual activity; can I drive with an ICD?	
12/21/11	Internal team or team member	added legend to pictograph; added citation for pictograph. additional text at bottom of page: 'Other common concerns: 1) Exercise: It is possible to exercise with an ICD; however, we	

		recommend that you receive specific training. 2) Sexual Activity: ICDs should not limit one's Sexual activity and therefore should not discourage someone from engaging in intimate activities with his or her partner. Furthermore, if a shock should be delivered during intimate activities, your partner is NOT in danger of also receiving a shock. 3) Driving: Driving post implantation differs from country-to-country. You will most likely have to restrict driving after you have received a shock; however, the timeline differs from country-to-country. 4) Pacemaking: We recommend you speak further with your physician regarding additional device functions to the ICD function such as pacemaking.'	
2/6/12	External advisory group or member Patient or family member	Rewording of questions along with short, simpler language. changed ICD Risks: 'From surgery: You may develop an infection or bleeding at the sight of the implant. Longer-term: Some patients may develop anxiety, depression, and posttraumatic stress disorder (PTSD) from being shocked by their ICD. More study is needed to fully understand the impact of an ICD on one's quality of life. Added: 'shock feels like getting kicked by a mule' version w and w/o graphics	
6/18/12	Patient or family member	Tailored risks - What are my risks of these things happening and how can I improve my odds of a successful surgery? Can I get a sample shock? Use of color to highlight critical spots (not red) Discuss surgery procedure more (and the testing of the ICD where they stop your heart) A picture of the device or having a device present would be helpful	Tailored risks will be on website, not feasible in paper formats. Sample shock: not able to incorporate, space decided to stay with colored rows and bolded text where necessary
6/25/12	External advisory group or member	Image of ICD removed	Added device picture
7/5/12	Internal team or team member	The word "defibrillator" is a big one. I would suggest we just use ICD throughout. For another project I work on, I had several of the big name health literacy researchers review some materials for me. One of their comments was that patients often don't understand terms like "provider" or "clinician." I suggest replacing "clinician" with "doctor," although I know it may not always be the doctor engaged in this discussion. Those health literacy experts also indicated they patients don't understand words like "monitor" and understand "medicine" better than "medication." I changed that terminology throughout.	I made changes throughout the document to increase active voice, reduce sentence length, and use simpler/smaller words. That brought the grade level down (from 6.3 to 4.4) and sentence length down from 11.2 to 9.6. I was really shooting for sentence length of about 8 words, but did not quite get there. I'm happy to take another stab on a revised draft. - I would remove the "not applicable" text. That would be consistent with the option grids I am seeing

		I would remove the “not applicable” text. That would be consistent with the option grids I am seeing on the website and excludes unnecessary text. It’s important to avoid using too many font styles (italics, bold, etc.), so I removed a lot of that formatting. Likewise, I changed anything in all caps, which is more difficult to read than title case or lower case. Can we increase the font size? 12 point font is recommended. Also, serif fonts are recommended (the fonts that have little feet, like Times).	on the website and excludes unnecessary text. It’s important to avoid using too many font styles (italics, bold, etc.), so I removed a lot of that formatting. Likewise, I changed anything in all caps, which is more difficult to read than title case or lower case.
7/11/12	External advisory group or member	Description: input on language, content, and layout. Strong input to simplify the values clarification exercise extensively.	
7/13/12	External advisory group or member	try adding an image of the ICD	Agreed
7/28/12	Internal team or team member	added SCD HeFT citation	
7/31/12	Internal team or team member	1. Need to add end of live care/planning; psychological adverse effects; Lead or ICD replacement 2. Add balanced risk presentation 3. Medication will provide some degree of protection 4. Possibility of shock storm 5. Infection rates; lead failure/breaks. psychological risks (depression, anxiety, PTSD). Generator change. I think this underestimates the risk of ICD implantation see Lee et al J Am Coll Cardiol. 2010 Feb 23;55(8):774-82. Major 4%, minor 5%. Remote monitoring reduces visits, and is the standard. 6. But a CRT-D will, and about half ICDs now have CRT capability. To balance risk information, perhaps add something on benefits of ICD for peace of mind and improved quality of life? E.g. Mark 2008. I know this is tough given the mixed evidence on QoL. 7.& 8. Show defibrillator at actual size 9. What does “after talking to your doctor “mean?. Some people don’t want to talk sex with their doctor. This depends on the patient’s heart failure rather than his ICD. My ICD patients cannot all exercise. 10. "Restrict driving" is vague term 11.They are taken out, eg for infection, but there are risks associated with this.	tradeoff verbage: w/ ICD not likely to die quickly, unlikely to die in sleep

7/31/12	External advisory group or member	Q4. possibility of shock storm Q5. do you want to include psychological risks (depression, anxiety, PTSD). Q6. To balance risk information, perhaps add something on benefits of ICD for peace of mind and improved quality of life? E.g. Mark 2008. I know this is tough given the mixed evidence on QoL.	
7/31/12	External advisory group or member	1. I would say sometimes with a shock rather than often with a shock. I think otherwise the sentence implies that the patient will receive shocks often. 2. Is it worth giving an estimate of the mean extra lifespan (surprisingly short I think). Is it worth saying that the absolute benefit is less if you are older. 5. I think these figures are wrong - for UK data anyway - presumably they come from SCD Heft? Anyway the risk of MI and stroke peri implant is very small, but the risk of pneumothorax may be higher. The very important risk of infection should be mentioned and the fact that this would mean extraction. 5.5 I would have a separate section for long term risks which include infection, lead and device failure with inappropriate shock. and the fact that some people ask to have the device switched off. 8. Good to show a picture, but I would at least blank out the makers name. I'd also show it in profile so the thickness can be seen. 9. I'd leave out the bit about talking to the doctor (or put it in both sides). 10. I'd replace restrict with stop for a while. Restrict gives the impression that they might be able to drive short distances during the day etc....	Short and long term risks: Takes up too much space
7/31/12	External advisory group or member	Generator change. I think this underestimates the risk of ICD implantation see Lee et al J Am Coll Cardiol. 2010 Feb 23;55(8):774-82. Major 4%, minor 5%. Remote monitoring reduces visits, and is the standard. 6. But a CRT-D will, and about half ICDs now have CRT capability. 7. & 8. show defibrillator at actual size 9. This depends on the patient's heart failure rather than his ICD. My ICD patients cannot all exercise.	

		11. They are taken out, eg for infection, but there are risks associated with this	
8/5/12	External advisory group or member	1. Need to add end of live care/planning; psychological adverse effects; Lead or ICD replacement 2. Add balanced risk presentation 3. Medication will provide some degree of protection 5. Infection rates; lead failure/breaks. 9. What does “after talking to your doctor “mean?. Some people don’t want to talk sex with their doctor. 10. "Restrict driving" is vague term	We felt advance care planning should be left as a separate discussion
8/7/12	Internal team or team member	Q4. I've avoided storm to avoid biasing the decision support tools in the other direction. Q5. I’ve never found these data. As far as I know, these were never really compared between control and intervention groups. The high rates of anxiety and depression in observational studies are not much different than the high rates of depression and anxiety among patients with heart failure – so I’ve chosen to handle this qualitatively under #4: “some patients find it upsetting”. Q6. I think CRT is really a separate decision despite the fact this it is combined here. I try to handle this with the statement: “Some patients can get special ICDs that may improve symptoms”	
8/16/12	Patient or family member	This is a good preliminary piece of info but definitely needs to be given by the doctor. Would like if you could fold (like the infographic) so I could put it in my purse. Something that tells patient it’s okay to research and it’s okay to ask questions. Visually, nice/interesting to see the ICD HOWEVER, it’s a distraction where it is; disrupts the text; perhaps put it at the bottom of the page? Not in the cell. Almost a little biased toward getting ICD. stats seem high to me and deters me from wanting to get it	Move picture to better fit with text. add sentence at bottom of page?: Your opinion matters, or What questions do you have. Started incorporating patient reviews of option grid along with CCOR and PtDA Team
9/5/12	Internal team or team	More text adjustments to lower literacy rate	use bold, not italics or underline to call attention to words, phrases
9/5/12	External advisory group or member	Feedback: not fair to say that the ICD requires frequent visits to the doctor in the era of remote monitoring. Note: When we get a generic picture from TV, I would like to use that separately.	Conclusion: Deleted: "The ICD requires frequent visits with your doctor – typically every 3 months"
9/5/12	External advisory group or member	Feedback: CRT: Still ongoing feedback about CRT improving symptoms	Conclusion: Still trying to avoid CRT - kept the statement

			"Some patients have reasons to get special ICDs that may improve symptoms. You should discuss this with your doctor"
9/5/12	External advisory group or member	Feedback: Asked by EPs in the UK to single out infection as a complication.	Conclusion: Added the statement "About 1 out of every 100 patients will get an infection requiring the ICD to be taken out" based on the meta-analysis in 2007
9/5/12	External advisory group or member	Feedback: Discuss the possibility of shock storm.	Conclusion: I'm pretty sure that shock storm would bias the decision aid away form ICDs and I've made a decision early on to avoid that discussion. One of my main goals is to develop a decision aid that someone will actually use.
9/5/12	External advisory group or member	Feedback: Discuss the psychological harms of ICDs.	Conclusion: AJ reviewed this evidence extensively and it is very difficult to make quantitative conclusions. As far as I know, these were never really compared between control and intervention groups. The high rates of anxiety and depression in observational studies are not much different than the high rates of depression and anxiety among patients with heart failure – so I've chosen to handle this qualitatively under #4: "some patients find it upsetting."
9/5/12	External advisory group or member	Feedback: I should discuss inappropriate shocks separately. This echoed feedback from the qualitative study I did previously.	Conclusions: Added "but some happen accidentally" to the phrase in #4: Most happen because of bad heart rhythms [but some happen accidentally].
9/5/12	External advisory group or member	Feedback: Received feedback that the risk rates were too low (2/100 for minor; 1/100 for major). Risks: Had a long discussion at CCOR on 9/5/2012 about risks. The risk data is all over the map with the meta- analysis from 2007 showing relatively low rates to the Medicare population study (Al-Kahtib, Circ-EP 2010) showing very high rates.	We agreed that 2/100 for minor and 1/100 for major were indeed low. However, it would be very easy to get too specific with all the risks and bias the decision aid away from ICDs. Also, we suspect that much of the effect of the decision aid will be to recalibrate the benefits.
9/5/12	Internal team or team member	Enlarge graphic of device to actual size add proactive statement at end: "your opinion matters. What questions do you have for your doctor."	

9/5/12	Patient or family member	Mention that people can have very different experiences with shocks; more information on why someone would want the ICD turned off or removed.	No changes
9/6/12	Patient or family member	3. When talking about heart rhythm, people need to be aware what causes rhythm to be off - maybe prompt pt to talk with doctor more. 4. Should we indicate that some won't feel shock 5. Stats seem high; upsetting to pt., provide reference for stat. 6. Pt didn't understand about ICD not improving condition - why else would get it? 11. Pt. told ICD could be removed in 5 yrs (perhaps for battery change), didn't realize leads had to stay in. -Other: include row for questions to ask your doctor - encourage pt to research and ask questions -a little biased toward getting ICD	Conclusion: provided statistics re: getting shocked. Other points are good suggestions, but there isn't room on the tool for them.
9/11/12	Patient or family member	Would have loved to have had this in the hospital; I'm a textual learner (not verbal); ID card/bracelet provided indicating ICD for MRI and airport security. Likes the actual numbers rather than percentages. Highlight that ICD is "full term" [think he means that it won't be completely removed]. Thought it helpful in providing more knowledge so could make decision easier.	Tool presents both numbers and percentages. Added row: Can the ICD be taken out.
10/2/12	Internal team or team member	Add to bottom of page: You're opinion matters or What questions do you have.	Added "Finally, your opinion matters! What questions do you have? Make ICD actual size
10/18/12	External advisory group or member	Strong feedback to remove picture make columns more similar in width.	Agreed with both suggestions
10/19/12	Internal team or team member	Literacy changes - formal readability assessment separated last question into two: can ICD be taken out? Can ICD be turned off?	Conclusion: simplified language further; separated last question into two: Can ICD be taken out? Can ICD be turned off?
10/30/12	External advisory group or member, Internal team or team member	Incorporation of 10/18, 10/19, 10/20 suggestions	See above
11/5/12	Patient or family member	Seems biased against getting ICD. Good for doctor to give to patient after initial discussion about needing and ICD, not beforehand. Good material for patient to take home and think over.	No changes

11/5/12	Patient or family member	Felt it was biased towards not getting ICD; didn't learn anything new; no suggestions for improvement	No changes
11/5/12	Patient or family member	Finds it scary - "dwelling on having it and still a lot of people dying;" it has a very sad message. Line about ICD not improving heart symptoms confusing - include w/ proper medication; discuss option to have pacer along w/ICD, the process is scary, but not as scary as facing heart attack and possibly death. replacement vs. battery change	Included: Some patients may get other devices to improve symptoms. You should check with your doctor.
11/15/12	Patient or family member	The statistics scared the patient; hadn't heard them before, thought they were high.	No changes
12/10/12	Patient or family member	Felt it was biased towards getting an ICD; thought information on symptoms was important and overlooked by doctors.	No changes
12/13/12	Patient or family member	Helpful for family members who haven't been to the clinic visits. Does the doctor go through all this w/pts? Skeptical re: statistics.	No changes
12/19/12	Patient or family member	Maybe move 'avoid sudden death' to beginning of sentence on Will I live longer with an ICD?	No changes
12/27/12	Patient or family member	Felt that 'bump under skin' and driving very important.	No changes
1/7/13	Patient or family member	Explain more about types of infections that would cause the ICD to have to come out. He didn't know if this meant any kind of infection or if it just mean infections related to the implant.	No changes
1/15/13	Patient or family member	Clarify difference between battery change and device removal.	No changes
1/9/13	Patient or family member	No suggestions for improvements/changes.	No changes
1/9/13	Patient or family member	Include something about what it will feel like on a daily basis to have an ICD; what it's like during normal living? For example: Will it feel like a lump that hurts? Will I feel the electricity? Will I feel pain? Will I feel it beating or thumping? What will it do to my everyday life? What if it goes off all the time – what should I do then?	No changes
1/16/13	Patient or family member	Thought it might be good to include what things can cause a person to need an ICD	No changes
1/17/13	Patient or family member	Liked the statistics, increase font, provide more stats for "do not implant" column, more content for "do not implant" , how did 36 people w/ICD die, heart or other problem--if don't specify patients could read that as the ICD isn't working in those 36 people.	No changes
1/18/13	External advisory group or	Make multiple OG for primary vs. secondary HF and the ICD combined with pacing; need to specifically differentiate between	No changes

	member, Internal team or team member	stand-alone ICD and biventricular ICD; discussion of deactivation separate line.	
4/4/13	Internal team or team member	Mainly, I shortened sentences, used simpler (and shorter) words, and tried to eliminate unnecessary words. I redid the numeracy section again. I struggled a bit with the sentence about a shock being uncomfortable and worrying. See my comments about and revision to this. I am hopeful that we can revise this to be more direct and to use shorter words (e.g., “some people feel scared and upset when the get shocked”).	No changes
4/9/13	External advisory group or member	1) add more to the "without an ICD" column 2) Add language re: driving 3) make sure that people know that the deactivation is non-surgical	Beefed up w/o an ICD column for consistency.
6/6/13	Internal team or team member	Another literacy level check	Modified row labels to fit with the content in both columns.
8/2/13	Translation agency 1	Forward translation 1st agency	
8/13/13	External advisory group or member	Just FYI- Did you talk to DS about the ICD decision aid tool? He mentioned that often patients say that they had no idea that having an ICD placed would entail a 3 month f/u visit for life. He thought this would be a good thing to maybe add to the tool.	
8/15/13	Patient or family member	Pt said it sounded like the ICD replaced the medication put information on living with ICD on grid. Several didn't know that the ICD could be turned off w/o surgery. Really like hearing from patients who went through decision making process already. what should the family know about taking care of pt after surgery	
8/19/13	Internal team or team member, External advisory group or member	Translation guidelines	
8/22/13	Translation agency 2	Forward translation 2nd agency	
9/26/13	translated into Spanish	Modified Bombardier Method: 2 forward translations, 4 clinician Reviews.	

ICD Paper Pamphlet Log

Date recd	Reviewer	Suggestions	Reasoning/action behind changes
Original Version	Internal team or team member		
4/27/12	Internal team or team member	draft compared to IPDAS checklist	
9/7/12	Internal team or team member	**Change text: What is primary prevention?** Some patients get an ICD because they were lucky enough to survive a dangerous heart rhythm – this is called “secondary prevention.” “Primary prevention” is a different because you have never actually had a bad heart rhythm but for some reason, your doctors think you are at higher risk for a bad heart rhythm. The most common reason to get a primary prevention ICD is heart failure. • Heart failure is a term used to describe a heart that is too weak to pump enough blood for the body. People with heart failure sometimes experience breathing problems, leg swelling, and fatigue. Heart Failure can happen for many different reasons including a heart attack or high blood pressure. **What are the risks of ICD therapy?** About 4 out of every 100 patients will have a minor problem, such as bleeding. About 2 out of every 100 patients will have a serious problem, such as lung puncture, heart attack, or stroke. About 1 out of every 100 patients will get an infection requiring the ICD to be taken out. • Some patients develop emotional problems such as anxiety or depression from being shocked by their ICD.	
9/17/12	Patient or family member	Very comprehensive, no changes suggested	
9/27/12	Patient or family member	Line the description of the pictograph up with the graphic rather than to the side "right to make own choices" unnecessary, obvious.	
10/11/12	Patient or family member	Wording around without an ICD have higher quality of life is confusing, implys that with ICD immediate decline in health.	
12/17/12	External advisory group or member	Summary of changes from meetings with people over 3 months: 1) - Move the values discussion earlier - based on that it is biased towards ICDs, GE felt that changing the order would make it more like a decision aid and less like an information pamphlet. 2) - Problems with the icon array. No titles, no legend. Need to fix that. 3) - Literacy and readability.	

1/3/13	Internal team or team member	DV redesign based on 12/17/12 feedback.	
1/18/13	Patient or family member	Better explains pros and cons of getting ICD; expanded patient reflection piece; revised graphics.	
3/18/13	Internal team or team member	KP patient interview feedback summary.	
3/18/13	Internal team or team member	Text errors: 1. What is an Implantable Cardioverter Defibrillator (ICD)? • Last sentence: If your rhythm is not normal, the ICD would try to restore a normal rhythm or an electrical shock. o Should be "…restore a normal rhythm with an electrical shock. 2. Is an ICD right for me? • 3rd paragraph: "One one hand,…" Should be "On one hand…" 3. Consider two possible paths: • Since the text describes living with an ICD as Path 1, the graph should depict that. Path 2 should be living without an ICD since that is the order of the text. • There are 2 periods in Path 2's last sentence. • There is no period in Path 1's last sentence.	
3/30/13	Internal team or team member	Trimmed text, made graphics more prominent, expanded risk section to be comparable to benefits section	
4/7/13	Internal team or team member	Revised format, layout and content based on discussion with PRAs	
4/8/13	Internal team or team member	1. "There is an important trade off..." I wonder if this sentence should be in a larger font or helped visually to stand out in some way. Perhaps ended with a "..." or maybe that's too cheesy. 2. Did we talk about changing the term "function" in the 2 paths to "health," healthy/not healthy," or "QOL?" - I really like the quotes at the bottom of the graphs! 3. My doctor has asked me to consider an ICD. - Does the "asked" part of this have a loadedness to it? Like my dr. asked me to do this and i said no vs. my dr. suggested or something else? Maybe not, just thinking out loud... 4. In the box of 'anything else?' do you want to move the cell phone between the luggage and car? I think it's a better flow that way... 5. Okay, I looked through 2x and didn't see anything about deactivation...?	

4/9/13	Internal team or team member	**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 **Will I live longer with an ICD?** With an ICD: Patients are less likely to die suddenly of a dangerous heart rhythm if they have an ICD. With and ICD, 29 out of 100 patients with heart failure will die over a 5 year period. This is 7 fewer patients than would die without an ICD. Without an ICD: Patients without an ICD are more likely to die suddenly from a bad heart rhythm. Without an ICD, over 5 years, 36 out of every 100 patients with heart failure will die.	
5/30/13	Internal team or team member	Some language change to lower reading level: change healthy/ not healthy to feel healthy/feel sick.	
8/15/13	Patient or family member	More discussion on what it's like to be shocked.	
8/20/13	Translation agency 1	Forward translation - 1st agency 8/14/13 version.	
9/26/13	Patient or family member	Pts had difficulty with pictograph - got hung up on 5 yr timeline -- "what happens after 5 years - death?" Need to be clearer that this is based on a study and that many pts live longer that 5 years post implant. need to present a more positive outlook -- express the possibility of living > 5 years. Clarification on airport check-in procedures, using cell phone in opposite ear, keep tablet/devices 9-10 " from chest. tool slanted toward getting an ICD.	
10/28/13	Internal team or team member	email volley re: "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."	
11/17/13	External advisory group or member	1. Some patients with heart failure may have conditions that dissuade their doctors from considering an ICD (e.g., reduced survival [e.g. cancer], a LV EF that isn't low enough, advanced age, etc.). For patients with these conditions that inquire about an ICD, this tool could provide a resource to help answer why an ICD may not be appropriate for them. Would it be appropriate to have a separate box or section with the following? "Some patients with heart failure may not be appropriate for an ICD. Some reasons include:" 2. Near the top of the first page, it states "For patients with heart failure considering an ICD for primary prevention". Obviously this is meant to inform providers who this tool is intended for. For patients, however, they may not understand what primary prevention means. Should it instead read "For patients with heart	

		failure considering an ICD to prevent initial serious complications from a life threatening heart rhythm"? 3. Near the top of the first page under "What is an Implantable Cardioverter-Defibrillator (ICD)?", for the 2nd sentence, I would change ". . . to prevent a person from dying . . ." to ". . . to prevent an at-risk person from dying . . ." 4. Near the top of the first page under "What is an Implantable Cardioverter-Defibrillator (ICD)?", for the last sentence, I would change "It does this by . . ." to "It can do this in part by . . ." 5. Near the top of the first page under "Is an ICD right for me?" for the last sentence, I would change ". . . you have wanted to know this information." to ". . . you have wanted and should have this information." 6. Near the middle of the first page in the first Heart Box, for the second sentence, I would change ". . . to try to get a dangerous heart rhythm to beat normally." to ". . .to try and correct a dangerous heart rhythm." 7. Near the bottom of the first page in Path 1, for the first sentence, I would change ". . . you normally do then a dangerous . . ." to ". . . you normally do. Because of your heart failure, a dangerous . . ." 8. Near the bottom of the first page in Path 2, I would consider capitalizing the italicized "not" to read "You may choose to NOT get an ICD." 9. Near the bottom of the first page in Path 2, for the first sentence, I would change ". . . you normally do and then a dangerous . . ." to ". . . you normally do. Because of your heart failure, a dangerous . . ." 10. On the 2nd page on the left side, between the "Does getting an ICD require surgery?" and the Heart Box below it that starts "There will be a bump . . .", I would insert a section that reads "Are there risks to having an ICD placed?". I would then create a Heart Box with the risks of ICD implantation included in it. In other words, I would consider moving the "What are the risks of getting an ICD" Box from the 3rd page to this location. 11. On the 2nd page on the left side, I would consider moving the Heart Box that starts "ICDs have to be replaced . . ." to be between the sections "Can the ICD be taken out?" and "Can the ICD be turned off?"	

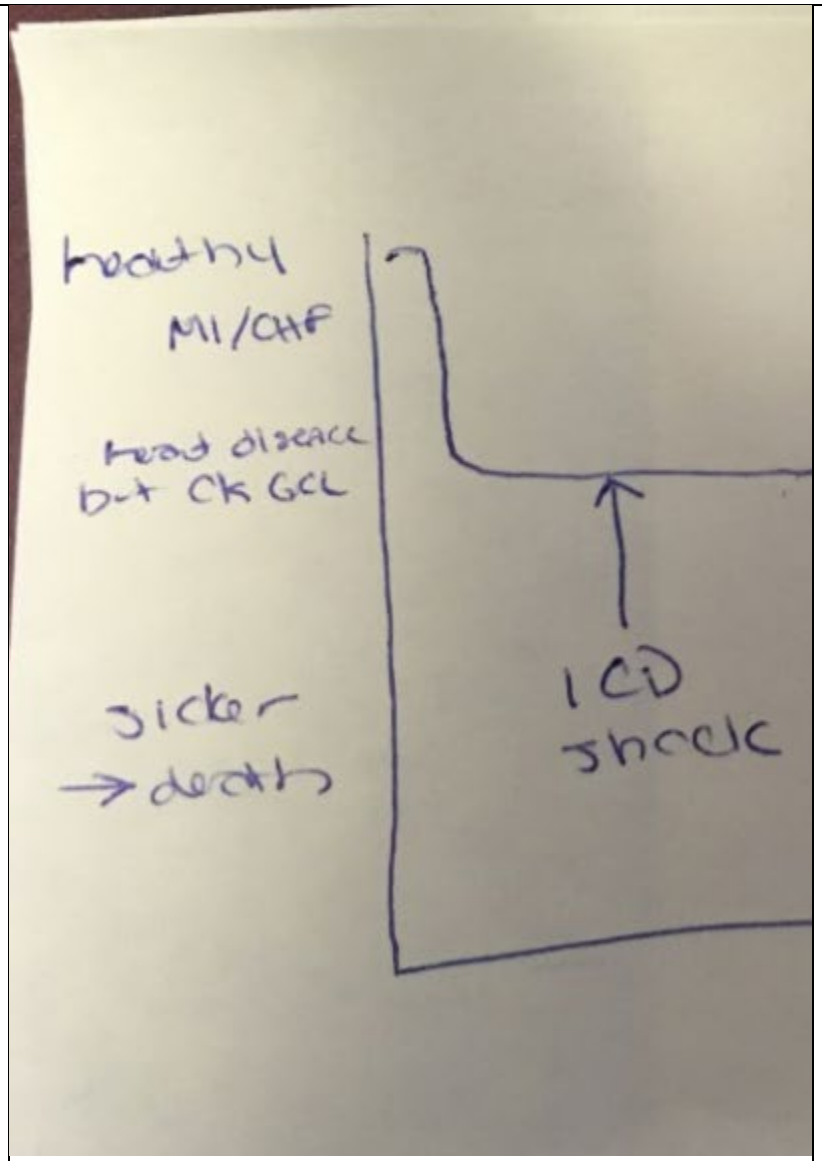
		12. On the 2nd page on the left side near the bottom, in the Heart Box that starts "Over 5 years, about 20 . . .", I would change the last sentence to ". . . happen accidentally." to ". . . happen accidentally or because of other heart rhythms that aren't as dangerous." 13. On the 2nd page on the left side near the bottom under "Will an ICD make me feel better?", I would insert the word "specialized" after "Some patients might get . . ." to read, "Some patients might get specialized devices . . ." 14. On the 2nd page on the left side near the bottom under "Will an ICD make me feel better?", I would insert the word "additional" after ". . . device with" to read, ". . . device with additional features that can make them feel better." 15. I anticipate many providers printing out this tool in the hospital or from their office. I printed out the tool from home in black and white. Because most office/hospital printers print in grey scale, some font color choices should be changed. 16. On the 2nd page on the right side, the font color for the box that starts "What are the benefits of getting an ICD?" needs to be made darker. 17. On the 3rd page on the left side, assuming that you leave in the box that starts "What are the risks of getting an ICD?" (see my comments in #11 above), the font color for this text needs to be made darker. 18. On the 3rd page on the left side at the top under "Would I survive a dangerous . . .", I would change "You can survive a dangerous . . ." to "Most commonly, you can survive a dangerous . . ." 19. On the 3rd page on the right side in the box "Is there anything else I should know?", I would insert a section that reads something like "The ICD will need to be checked intermittently. This may be performed in your doctor's clinic or at home. If the ICD needs to be programmed differently, it will require an in-person visit." 20. On the 3rd page at the bottom, the font color for the box to the right of "Reflection . . ." needs to be made darker. 21. On the 4th page at the top under "What else do you need to help you make your decision?", I would change "You should also ask your doctor your questions and concerns before making a	

		final decision." to "You should also share your questions and concerns with your doctor before making a final decision."	
4/4/14	External advisory group or member	E and I talked after our call with you yesterday. I drew this graph to try to capture her point about some heart failure patients having a relatively stable course before they enter the slow decline phase. She thought this captured that reasonably well. With a modified graph like this, a clinician could potentially tailor the info in the decision aid by helping the patient understand whether they are on the relatively flat part of the graph or the down-sloping part.	No changes made, because development team felt nuance would be lost on patients.
11/30/17	External advisory member	One of the most common questions I get about ICDs is what is the difference between and ICD and a pacemaker. I would address this simply in the beginning of the handout. I usually explain it as this: "a pacemaker is a small device that delivers a small amount of electricity into the heart and is used to treat a slow heart rate and bring it up to a normal level. A defibrillator is a slightly larger device that delivers a larger amount of electricity into the heart and is used to treat an unstable heart rhythm and shock it back into a normal rhythm. A defibrillator also has a backup pacemaker built into it, but a regular pacemaker does not have a defibrillator function."	Accepted
11/30/17	External advisory member	I have some questions/concerns about the contraindication. You list large magnetic fields and industrial equipment that patients should avoid. I think this is going to lead to a lot of confusion. The main contraindications are the use of chainsaws and arc welders. Most equipment is actually okay to be around and the devices are pretty well shielded. In fact, most new ICDs are even MRI conditional, meaning that they can safely have an MRI if the device is programmed in the right way. I have a lot of patients who work in and around industrial equipment and I tell them that they are fine to continue to do this, they just can't be directly holding any piece of equipment that has a large current going through it (arc welder) or causes vibration of both arms simultaneously (chainsaw) as it could lead to an inappropriate shock. Most other types of equipment such as lawnmowers, weed eaters, tractors/motorcycles are fine to continue to use.	Accepted
11/30/17	External advisory member	The other question/concern is about the metal detectors at the airport. The newer full body Advanced Imaging Technology (AIT) scanners that use millimeter waves to look under clothes are actually safe to use with a pacemaker and defibrillator. The old	Accepted

		fashioned metal detectors that look like a doorway are the ones that should be avoided. These are less common at airports now, but are still used at sporting events and concerts. We tell our patients to just show their pacemaker or ICD card to security and they wil direct them what to do. If the only security option is an old fashioned scanner, they should request to be hand-scanned and should put their hand over their device to remind the security personnel to not wave the scanner over their device.	
1/16/2018	External advisory group or member	In either the FAQs or elsewhere, drawing distinction between ICDs and pacemakers might be useful. Many MDs don't know the difference. The table 1 in Dr. Kramer's JAGS paper (with terminology adapted for lay audience, less technical etc) might be adaptable for this purpose, or a graphical version.	"An ICD is different than a pacemaker. A pacemaker helps the heart beat but does not give a shock like an ICD" was added to the What is an ICD section.
1/16/2018	External advisory group or member	Two of the 3 tools use the SCD-HefT data – I'm sure this will be something we discuss as a group, but I wonder if this is problematic, particularly for the CRT patients. Do we need to acknowledge both the unknown treatment heterogeneity, but also the known differences in survival advantage of the ICD depending on ischemic vs non-ischemic etiology, SCD-HEFT vs MADIT-II vs MUSTT indications? In the non-device arm (or both, really), do we need some allusion to Seattle or other models predicting medium-term death from heart failure? Embedded some other thoughts on way I might talk about the risks with fewer #s (but including the risk of device malfunction). (I know, all electrophysiologists protest about the risk seeming too scary.)	This is a good point. We hope in future work to develop tailored models to individual patients. We felt SCD-HeFT was better than other options for a single tool.
1/19/18	External advisory group or member	Maybe simplify benefits and risks to numbers? When I talk to patients about risks, I usually talk about aggregate risk rather than risk on a year-to-year basis. I usually talk about risks in percentages to patients.	In Pilot studies for PtDA, we found people like pictures to represent the numbers, although electrophysiologists prefer the risks to be shown as numbers since they look less threatening that way.
1/19/18	External advisory group or member	We should include a discussion about battery failure (2 centers had recalls or warnings for batteries in devices). Devices can be reactivated through natural occurrences (light on planes, scanning devices). Some devices become uninterrogable (can't shut off during a shock or shock-storm).	We do discuss battery failure and device removal briefly. Ideally, these tool are meant to support a conversation rather than be comprehensive.

1/19/18	External advisory group or member	We should take a look at LVAD handouts and re-emphasize on ICD handouts that each patient is different, and a PtDA does not replace a discussion with your doctor about your choices.	Accepted. It is emphasized several times in each decision aid to discuss your specific situation with your doctor, or that a decision aid is not a replacement for a conversation with a doctor.
1/19/18	External advisory group or member	In the Paper Pamphlets, we should be sure to distinguish between defibrillator and pacemaker.	"An ICD is different than a pacemaker. A pacemaker helps the heart beat but does not give a shock like an ICD" was added to the What is an ICD section.
1/19/18	External advisory group or member	CRT handout should be re-organized to better match clinical flow.	Accepted
1/19/18	External advisory group or member	On the CRT PtDAs, I'm not excited about using SCD-HeFT data, but I don't know what is better to use.	No changes necessary
2/22/18	External advisory group or member	We have been discussing the CMS coverage policy for ICD's now incorporating shared decision-making. It's great to see value being put on this concept. Your decision-aids, the pdf and website and video, are great. Much of the verbiage leaves me saying, "Yes! That's exactly what I like to say!" There are a few aspects however, that I am concerned will lead to biasing against ICD implantation, that may ultimately lead to lives lost to SCA unnecessarily. Several of these have to do with the apparent assumption that all patients in the primary-prevention-ICD eligibility population, will move rapidly toward progression of their disease. Too many patients do have repeated CHF hospitalizations after a primary prevention ICD implant, but the majority do well for a period of time. There are a number of studies which show QOL after ICD implant is good. This is mainly apparent in the pair of graphs. While we are all unfortunately heading inevitably toward death, when I look at these graphs, it looks like the sole purpose of an ICD is to prolong misery. I wouldn't buy a green banana after looking at these, let alone get an ICD implanted. I think these misrepresent the course	We are planning to do another round of edits this summer before we begin our implementation roll-out for our RO1. We're consolidating input now so any and all input is great. In regards to the paths, we've heard this concern before. We've struggled in finding the best way to specifically not frame the trade-off as quality vs. quantity of life but rather as sudden death vs. progressive illness. It was through a pretty long process with lots of patient input that we came up with those two paths. I think we've moved towards the flattening out on our CRT tool that we're developing and certainly might need to for the ICD. I don't think it changes it qualitatively. In regards to bias, I'm quite a bit less concerned about this. Achieving balance in a decision aid is perhaps the single hardest aspect of the development. Patients who see this tool and these videos tell us they are biased towards getting the ICD. They do say that they are better than the industry materials in they don't feel they are being sold on the ICD but rather that they just think the data is

		of many if not most patients, which I would see represented by the graphs below. (very sketchy obviously) The two people in the video on the website somewhat similarly I think misrepresent what life is like with an ICD. The man describes living with progression of his disease, which, again, while ultimately CHF will progress, may not happen for some number of years. The woman talks about trading quantity of life for quality of life, implying that getting the ICD will impair QOL. For some yes, but the studies show for most, QOL impact is not high. I'm wondering, if you will be revising this at any time, and if so, if you would consider including as one of the outcome pathways, the course as described in the graphs below—eg, put in two pairs of graphs, the one you have and one along the lines of the below. The text would say, along lines of, "…there are several ways things go after an ICD…many people feel well for a period of time, although eventually many will have progression of their heart disease…" and similarly, include one person in a video, among several, saying, "I got my ICD and am back to work and enjoying being with my grandkids etc"	very supportive of getting an ICD. Maine had one patient who spoke only Spanish then saw the Spanish paper tool and decided to get an ICD based on the decision aid so perhaps not as scary for patients as clinicians think. However, clinicians frequently share the concerns you have.

			
2/24/18	External advisory group or	We are going to get a lot of exposure because of the new CMS requirements. Looking over the site, I think that we should probably	Thanks, I think the data do include MADIT-RIT and ADVANCE III, but both of them were

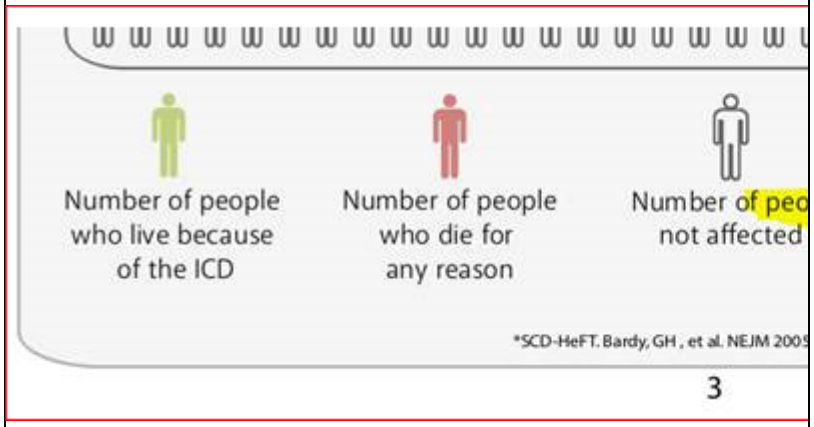
	member	clarify the 20% shock rate. Does this number include MADIT-RIT and ADVANCE III programming? Seems high to me. Perhaps we should put a footnote for clinicians watching this with their patients. Over 5 years, about 20 out of 100 patients get shocked by their ICDs. About 80 out of every 100 will not get shocked. Most shocks happen because of dangerous heart rhythms but some happen when they are not needed.	relatively short term studies - it used to be that 5-20% of patients received shocks *in the first year*, but with ADVANCE III and MADIT-RIT, it's much lower in the short term. It is absolutely worth reviewing all of it, which I think is part of the plan (please correct me, if I'm wrong, Dan) as part of the beginning phases of DECIDE-ICD.
2/24/18	External advisory group or member	I have already been contacted by several EP directors being harassed by their hospital administration. We have already been asked about how we are going to handle the new requirement. My input, after looking over the site and watching the patient videos, is that there appears to be a little bit of bias against ICD implantation. I understand that we are obligated to provide a balanced view, but I think that there is the assumption that an ICD implant as surgery is dangerous and living with an ICD may significantly impair an individual's quality of life. I also think that the examples for the disease progression does not apply to everyone. There is also an implication that an ICD shock will accelerate disease progression. I don't think that this is always the case and it is unclear whether it is causative or mereley associated with worsening heart failure.	It's been through several iterations including some that were perceived by the patient focus groups as biased in favor of ICDs, and that feedback contributed to the current iteration. It's difficult to strike the right tone and message, which is why we need the input of even more people from the EP community. The reality is that based on increasing demands from payors and patient groups, SDM is here, and we can either choose to lead, or it will be inflicted upon us in a very negative way - witness the LAAO SDM requirement for a "SDM interaction with an independent noninterventional physician" - CMS wasn't asking for shared decision making for WATCHMAN; they were mandating that we, the proceduralists need noninterventional chaperones. The huge win for us and for our patients is that while the ICD draft coverage memo was going to ask for this SDM interaction for ICDs to be conducted by an "independent" physician - but, thanks to lobbying by HRS and ACC, an effort to which several of helped to craft the language, they removed the word "independent" for the final coverage decision, effectively hearing our concern that we, the EP community need to do this if they want SDM to be mandated. So now, we really do need to make it work.

			Yes, there is going to be a lot of exposure about this issue, and it just makes it even more important for us to get things as right as we can. Lori and I are doing a webinar with David Slotwiner, Minnow Walsh and George van Hare next week for ACC and HRS to jointly address the issue of the new ICD coverage policy and the shared decision making requirement. The single hardest piece of making these things is getting them balanced. With most of the tools (both ICD and LVAD) we usually end up in a spot where the docs feel like it is slightly biased against and the patients feel it is slightly biased towards. We will be doing a round of updates soon. We had an experience in the CMMI implementation work with Dartmouth where a Spanish speaking patient at the Maine medical center didn't want an ICD until he read the Spanish version of our tool. Then he elected the ICD. There is huge underuse of ICDs in African Americans (some data as low as 30%) with a theme related to trust (or lack there of keeping them away). We have heard qualitatively that African Americans trust our tool more than the industry materials so may increase use there. Also, lots of data that docs strongly encourage the ICDs (in a very well-meaning way) with language that isn't quite consistent with the data. The goal is an honest presentation AND the tools never replace a discussion with docs so docs can still frame things for individual patients. One of the secondary hypotheses we're testing in our trial is the appropriateness of shared decision making for individuals. A 50 yo, ischemic MADIT 1 type patient is very different than an 80 you non-ischemic

			DANISH type patient. We hypothesize the physicians will be much more amenable to SDM with the latter. Also, shared decision making doesn't mean not making recommendations.
3/5/2018	External advisory group or member	I've seen a few more questions about the ICD policy and SDM start to trickle in. One that I think you may be able to help me answer is how to approach the fact that your infographic is copyrighted. I suspect a lot of people may simply use it without thinking about that. Is that a problem? Also, do you have a mechanism to grant permission to those who do take that into consideration and want to formally obtain it? Or, is there some other solution for this sort of thing of which I'm not aware?	Yes, the tools (all of them, not just the infographic; the video and interactive website are as well) are all copyrighted, but not because we want to restrict their use. To be completely clear, anyone is welcome to use an/all of them as they are, anywhere, anytime. I know that Dan Matlock (and the whole team) developed them with the hope that they would be used and would be useful in general. I'm pretty sure that the copyright is there primarily to protect the intellectual property in terms of modification and the content - not as a barrier to the tools' use. Given all the care that goes into development, vetting by physician and patient focus groups, filtering through patient literacy experts, etc., we do not want to give free reign to allow folks to modify the tools, especially not without talking with Dan first. Anyone with specific concerns should reach out to him directly, and I'm also more than happy to serve as a connection to others; since the coverage policy was announced, I've heard from several people around the country already, and I suspect that there will be others who reach out to us.
3/5/2018	External advisory group or member	I do wonder whether people will be satisfied with me telling them that the copyright is not meant to prohibit use, but to prohibit changes. Is there some way to indicate that on your website or the infographic itself?	This is a good question. I had that same concern. We really want them to be freely shared. We've been around with the University lawyers for multiple iterations. The purpose of the creative commons is precisely from our desire to share and not have them taken. We had to add the copyright when one of the tools

			was taken. We can revisit with the lawyers at the next version to see if they can give us language that may make it more clear.
4/2/18	External advisory group or member	Our facility would like to use the decision aid for ICD implantation since it was mentioned in the recent CMS Decision Memo. In reviewing the decision aid, multiple typos were discovered and our team would like to see if they could be cleaned up so we could begin using this aid with our patients. Below are a few examples, would it be possible to have these corrected? Thank you for your help.	Accepted.

FAQ	Implant an ICD	Do
What does an ICD do?	An ICD may stop a dangerous heart rhythm that could cause sudden death by giving an electical shock to the heart.	Witho higher adang happe
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 ca medic proble
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.	Patien likely t dange an ICD heart f 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 wi an ICD
What are the risks of getting an ICD?	4 our of every 100 patrients will have some bleeding. 2 out of every 100 patients will have a serious probelm, 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 wi placin
Will an ICD improve my symptoms?	Having an ICD will not improve your symptoms or cure your heart problem.	Your s by you
Are there things I cannot do?	This depends on your heart problem. Talk to your doctor about driving limitations and other activities.	Even v yourd limitat
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
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

			
8/24/18	Internal team or team member	The Flesh-Kincaid score for the ICD infographic is 5.4.	No changes necessary.
10/10/18	Internal team or team member	In order to match requirements for printing decision aids for implementation, decision aids need to be multiples of 4 pages.	Accepted and changed. Some formatting changes were needed, possibly including adding a page for notes or moving around images of devices. All content remained the same.
11/15/18	External advisory group or member	Several EPs now want a shortened 1-2 page decision aid that can be used in clinic with patients that covers the highlights of the larger decision aids, but is briefer to use in clinc.	Accepted and in development. A separate evidence document will be created for this, as not all edits or responses to this decision aid will reflect edits/responses to the DA short, and vice-versa.
2/15/21	Internal team or team member	Add I-DECIDE logo to heading, move graphics and copyright to fit. Also make sure pamphlet matches 4/8/12 pages for printing options.	Accepted and changed.
2/15/21	Internal team or team member	Remove “COMIRB# 17-1697” as this is not considered solely study materials.	Accepted and changed.

ICD Video Log

Date recd	Reviewer	Suggestions	Reasoning/action behind changes
March/April 2012	Internal team or team member	1st draft	
8/14/13	External advisory group or member	Didn't feel like there were any decliners in there – I was wanting to hear a real person who said no – I like the suggestion "You are going to hear from a few people who went through this process, some of whom accepted and some who declined". The early discussion of heart failure felt odd (although later, when you talk about quality v. quantity, it makes more sense). I know there is a balance between simplicity and detail, but may need to make it more clear this video is ONLY for primary prevention ICD for CHF. Might be better to say "people with a variety of underlying heart problems can have life- threatening abnormal rhythms." OR better have the narrator mention that "ICDs can be used for a variety of scenarios but in your case (this video) is for people with HF/weak hearts at risk for dangerous rhythms, who haven't had one". Also, something kind of feels missing is that the MAJORITY of patients will neither have complication nor a shock – they just have a piece of metal in their chest. That seems missed in all the discussion of shocks, death, etc. ATP comment and MADIT-RIT incorporation seems relevant. D.K.'s comment about "avoiding shocks through trying non-shock therapies first" (or something like that) seemed good. "Accidental" shocks felt odd. Literature uses "inappropriate".	Narrative was added to introduce each segment of the video. We decided not to change the rate of speech. Changed accidental to inappropriate.
9/26/13	Patient or family member	Pts expressed concern about 5-year study -- does that mean we all die after 5 years? Airport says going through security screening is fine, don't need to request the wand, this differs from	The wording was changed and the statement "Individual situations may vary.

		what doctors tell pts. Need to revise DA every time there's a new technology -- i.e. tablets need to be kept ~10 inches from implant; cell phone use on opposite side from implant.	You should discuss this with your doctor." was added.
10/23/13	External advisory group or member	1. Repeat ICD and implantable defib so good defining 2. Font on HF sx graphic is too small. Too technical a. TV illustrate? 3. HF font is too small 4. ATP vs. shocks – bring it up? Some say no 5. Inappropriate shocks not addressed a. Put it in complications section? (during clip of rarely do leads need to be b. Rarely are pts shocked for a non-deadly heart rhythm c. Is this in the video? 6. Immobilization of arm – be more vague a. Dr will ask you to wear a sling for a few days and there may be some restrictions on what you can do with your arm for a while. 7. Pictograph – missed over 5 year period – put it on the slide. a. The drop is better 8. Will I receive a shock – we don't really answer the question. Ask 2 questions (will and what) 9. Then what does a shock feel like? 10. HF def and causes – don't mention "the other" causes. 11. DM: Outstanding, fabulous, 100% better. But at end, where refilm narrator where there is an awkward transition - AJ has a fix for this. 12. Right balance between Dr talking and patients talking. 13. DB: Great video- very much improved. 14. Quality vs. quantity of life: person spoke it very clearly. DM - impact of quality of life is visible. For others - eg iCD gets infected - quality of life is severely affected some of these things can hold until you make your next iteration. we have a focus group on Thursday - small tweaks are OK. I know that people in the collaborative are hungry to get their hands on this. Let's let them use this even tho there will be a revised one. circles with green and red. I missed the initial where they say it's a 5 year window. Over 5 years or something. Need more testing with patients? We will have had 3 focus groups and we will bring a few patients back for a 1:1 with the	CHECK THE SCRIPT AGAINST THE VIDEO Font size was increased throughout the video and the beating heart graphic revised. We chose not to include ATP in the decision aids because that was one of the factors that was not consistent across the studies used as evidence support. Discussion of inappropriate shocks added to script. Eliminated the discussion about wearing a sling, as most patients aren't being asked to use them currently. Description of what a shock might feel like was added. - AJ has a fix for this.

		website. Patients have liked it so far. Def of HF and causes - Coronary and hypertension. But we put ICDs in a lot of non-ischemic patients. Sometimes don't know exact reason pt don't have weak heard muscle. AJ can fix this with voice over. Length: about 15 minutes.	
10/28/13	Internal team or team member	1. The Effects Clip (the pictograph with red and green circles) a. Please have the green circles pop up when I say "this means that 7 more patients with an ICD…" b. Please make the green a little more vibrant. Some have said it doesn't "pop" enough. c. At the top of the clip (above the two columns) can you please write "Results from a 5 year study" 2. ICD Part 1 Clip (What is an ICD) a. At time marker 0:38 there is a white fadeout… could you please just hold the heart beating shot and crossfade until 0:43? Some patients though the whiteout meant that someone was dying and seeing the "white light." 3. I found this picture (see attached) that helps describe symptoms of heart failure. No one likes it… and I don't blame them J I was wondering, if you have time, could you please help us brainstorm a way to visually help describe symptoms and how we might better present this information in this clip? I'm also attaching the clip so you can see it in context.	Accepted
10/23/13	Internal team or team member	1. The procedure length comments of "2-3 hours" is a little long for a garden variety ICD. Recognizing that there is a range of procedure time depending on operator volume, training requirements (if fellows are involved), etc., and also incorporating that we want the information to be accurate for ICD recipients who will also be undergoing CRT device implantation, I'd say something like this: "The surgery usually takes less than two hours, but more complex surgeries may be longer." 2. The comments on post-op restrictions should be a little more flexible to allow for variations in practice patterns and physician preferences. I don't think we'd want anything that would potentially conflict with instructions that physicians may be giving their patients. A good example is the comments about the sling. Rather than describing a specific number, I would keep it simpler, saying something like the following: "After the surgery, your doctor will probably ask you to wear a sling for a few days	Accepted

		and to restrict some movements of your arm for up to a few weeks." 3. In the spectrum of EP physicians, I think I'm pretty open to the ideas of patient decision making and the concept of the "imagined futures" that you've helped me to understand in the context of decision science. That said, it even made me bristle a little to hear the female patient who chose not to undergo ICD placement because she wanted "quality of life and not quantity of life." I understand the sentiment, but at the same time, I think that her comments are somewhat simplistic and the actual issues are somewhat more nuanced. It is true that the goal of an ICD is increasing quantity of life by averting death from a lethal arrhythmia, and that at a certain level this does require undergoing a surgical procedure with risks and dealing with the follow-up issues inherent to ICD therapy, which could be viewed as a potential threat to quality of life. On the other hand, I think that while one alternative to dying suddenly is to have progressive heart failure, another is to continue living at the same functional status, which a substantial number of patients do after ICD placement. So in a sense, getting an ICD may reduce the risk of sudden death to allow for going on living at whatever functional status trajectory the patient was on, which may, or importantly, may not necessarily include worsening quality of life. I bring this up not necessarily to try to get you to remove it, but to bring up that this may be something to which at least some of my colleagues may react strongly. I don't have a good solution, but I just wanted to bring it up for your consideration.	
10/28/13	Internal team or team member	This looks fantastic! You all have done a wonderful job revising this. It is terrific! AJ's voice over is a great addition on the intro screen and throughout! Love the intro music. During AJ's section about heart failure, can you simplify the wording on the graphic of the person? Love the graphic during narrator's section on bad heart rhythms. It is so great that you were able to match the video and narrative so perfectly. PV – I love that you slowed this down and simplified the language. I really like that you introduced the videos so that people can anticipate what is coming.	Accepted

		Love the talk through of the icon array! I love that the video is broken into lots of short clips now. Various places throughout the video (e.g., narrator's section on turning off the ICD), the video and audio were not well synced. I am not sure what that means. Will I Receive a Shock – this header comes before a section on what a shock feels like. Can we tweak the header to be "What does a shock feel like?" Seems like a section on will I be shocked would be important though	
10/29/13	Internal team or team member/ External advisory group or member	Permission to use graphic of man with swollen legs - NHLBI declined changing the text.	Accepted
10/29/13	Internal team or team member	Yes, I think it would be better. You might also shorten this to "your doctor will probably ask you to wear a sling for a few days and may also ask you to limit the movement ~~restrict some movements~~ of your arm for ~~up to~~ a few weeks"	Accepted
11/1/13	Internal team or team member	Version 4 of video -- pared down patient clips, minor edits on the text and graphics	Accepted
1/1/14	Internal team or team member	Final version	Accepted
12/04/2017	External advisory group or member	16-20 minutes may be beyond some patients' attention span for this kind of information. Have you received any feedback from patients about the videos?	Patients in our focus groups and pilot trial didn't mind the time at all. We didn't even force the patients to watch the video and most of them did anyway. I have a colleague who tried to study a video for colon cancer screening and no one watch it. It was like 20 minutes. Our LVAD video was 26 minutes and one patient said "I wish it was longer with more patients." My current thinking on this is as decisions span the spectrum from low stakes (colon ca screening) to high stakes (LVAD), patients tolerate a longer pause. I think ICDs are somewhere in the middle. We will measure this as part of the trial.
8/13/2018	Internal team or team member	ICD Video: https://vimeo.com/284768867	Accepted

		-Replace “What is ICD” animation; replace Fred voiceover to add statement about pacemaker -Replace two paths animation to reflect longer lines before graphs curve -Change mortality graphics animation from smiley faces to people figures -Insert new voiceover about turning ICD off to after Danny statement (added on-screen text to accompany voiceover) -Other considerations: changed on-screen text and audio for changes in “Other considerations” to reflect changes on paper tool about airport security, machine equipment, etc.	
8/15/18	Internal team or team member	ICD : No notes, I still like the updated graphics and I think the voiceover changes were integrated nicely. The look and feel of this is just like our other DA videos, and that’s a great thing	No changes necessary

ICD Website Log

Date recd	Reviewer	Suggestions	Reasoning/action behind changes
8/2/12	Internal team or team member	Flowchart development based on infographic.	Accepted
2/21/13	Internal team or team member	Breakdown of site sections.	Accepted
5/10/13	Internal team or team member	Prototype launch.	Accepted
5/23/13	Internal team or team member	AJ drafted "values," "next steps," and "life with an ICD" sections.	Accepted
7/8/13	Internal team or team member	Independent audience testing - 5 people.	Accepted
10/29/13	Internal team or team member	•Can we (do we want to) add a feature for user to change font size? •"This site is for…" add at end: "Use the "Ask" button (show icon) at left of page to record any questions you think of as you go	Accepted

		through this site. Along the way, there are also questions for you to consider. You can print a report containing your questions and decisions, once you have completed all the steps. You will be able to go back to previous pages, but your first responses are what will be recorded." •Should we let them know that if they re-enter the site 24 hours after initial visit, they're answers will not be saved? Tab 3 •Doesn't save patient input in textboxes, if advance page, then return •" These questions are a way of …" change "checking" to "confirming" or "reinforcing" •Do we want to add a popup reminder upon advancing to next page if user skips a question? •"What losses do you…" change "losses" to "dangers" Tab 4 •"Are you clear about which benefits and side effects…" change "side effects" to "risks" for consistency across pages •Under "test your understanding" remind user that can print report at completion (Will the answer they chose be highlighted along with correct answer when different?) Tab 5 •Have three blue buttons? 1) Complete and print report 2) Complete without printing 3) Return to step 1	
9/11/13	Internal team or team member	Prototype url: http://sproutlogic.com/patient/.	Accepted
10/31/13	Internal team or team member	The website has a great look to it—incredibly sleek design. I thought that you might consider making the "radio buttons" check black rather than light blue because when you hover over a selection it becomes light blue as well and it isn't completely clear that you've checked that option. For some reason, it seemed a bit odd to have the 4th tab on next steps before the 5th tab (life with an ICD)—seems like the issues around life with an ICD are important to informing decisions around next steps. The "check your answer" function wasn't currently functional (my guess is that you already knew	Accepted

		this). I assume that at the end, when one prints the “print” button that it will print up something that has any questions or notations embedded in the printed document—presuming this is the case, I think it is a terrific idea. Great work!	
10/28/13	Internal team or team member	We've added color to the sliders and separated the content for the video http://patientdecisionaid.org/sliders.php Some additional updates to the site: 1. new portal page (in progress) example: http://patientdecisionaid.org/new-index.html 2. sliders (color, work on tablets) 3. Added color and artwork to form selections 4. Updated footer (evidence link) 5. Privacy statement on thank you page In progress: popup on every page, passing in dr. questions values, print/email format	Accepted
10/10/13	External advisory	2nd independent testing - 5 people	No changes necessary
10/28/13	Internal team or team member	We've added color to the sliders and separated the content for the video http://patientdecisionaid.org/sliders.php Some additional updates to the site: 1. New portal page (in progress) example: http://patientdecisionaid.org/new-index.html 2. Sliders (color, work on tablets) 3. Added color and artwork to form selections 4. Updated footer (evidence link) 5. Privacy statement on thank you page In progress: popup on every page, passing in dr. questions values, print/email format	Accepted
10/28/13	Internal team or team member	This looks very good. I have a handful of comments, mainly on functionality. When you click on the Next button, you have to input your id or enter as guest again. Let’s have that only happen on first entry to the overall site. On the first screen, I notice that it presumes someone has heart failure. Is that appropriate for people who may arrive as guests at the website? What happens when a guest enters information into the reflection fields? Can it print something out for them? On the Values screen, if won’t allow you to move on to the next screen if you don’t answer these questions. May want to allow flexibility here. Oh, actually, it may be that the Next button just does not work.	Accepted

		I like the wording related to the radio buttons on the Values page. I think that really gets at the issue succinctly! The check your answer buttons don't work. Maybe these questions should be on a different tab focused on Checking Your Knowledge rather than the Next Steps tab. Or maybe this Tab needs to be renamed, it's not really about next steps. The quiz seems a little out of place to me, although I like the idea. Maybe this should be step 3, so you know they have the knowledge before the go on to the values section. The Next button on the Next steps screen does not work. Is it possible to make people's selections more obvious? The distinction between the grey and the blue is pretty subtle. When I click complete on the last screen, I get told "you have recorded 3 notes for your doctor" and then there is a list of 5 items – seemingly written in Latin – which I am pretty sure I did not enter! Where did this come from. I think it would be nice if what they got at the end was a print out that has their entries from the values screen and add to that screen a place they can jot down their questions, which could go on the print out too. Maybe you could offer the option of printing the infographic as well. Can you provide a link to the video as well? Are you trying to keep them separate?	
10/31/13	Internal team or team member	A few bits of feedback from my visit earlier this week to the DA website. Overall it looks GREAT! I can't believe how much progress you all have made with this! For the "What is important to you" section, seems like it needs anchors at either end of the slider bar (less important on one end, more important on the other end). I really like the slider concept!! Instead of "Test your understanding," how about "Check your understanding." The word "test" can be loaded. On my computer, certain words (e.g. security, cell) appeared in red with double- underlining. When I hovered over these words, a pop-up appeared with a link to buy cell phones, or security systems. Under "If you decided not, please explain why." Instead of "explain why," which can put people on the defensive, how about "please write down your reasons." I agree with FM--I thought "Living with an ICD" (Tab#5) would work better as #4 rather than last. The "notes for the doctor" on my screen were in Latin—I'm sure this is just	Accepted

		dummy script for now? Is it possible to add more color? Great job, website team!	
Unknown	Patient or Family member	**General:** "I don't think I'd ever use that." "I like that you don't time out of the site." **2 paths**: "So my choices are 1)die in my sleep or 2)die really sick in a hospital?" When presented with the 2 paths graph again on page 3: "I've already seen this graph. Why is it here again?" **Benefits** (#'s and Pictograph): "The numbers confuse me." "I don't think the picture (pictograph) is helpful. It's not visually impactful and it takes up a lot of space." **Reflection and user questions**: "I like that you say there are no right or wrong answers." "I like that I can check the answers to each of the questions (immediate feedback)." "I don't like the interactive bar because I see the pros and cons to both (living long/dying in your sleep). But I suppose someone who is sicker than me would probably like this bar." "I know it's weird but I think you can never really know enough but still make a decision." **Videos**: "I like that you don't have a time ticker at the bottom of the clips." "I like all the points of view. I could even do with more of them." "My favorite part is the patient clips (she said this numerous times)." "Some of the shorter clips aren't as good. I like the story ones." "I wish you had another clip of a decliner." – when I explained that Jim was a decliner she asked if there was another clip we could put in there where he talks about his doctor's reaction to him declining. We do have a clip like this and could swap out one of the shorter clips**. Picture:** In E's clip that shows his ICD bump and scar: "It took a minute to know what I was looking at. Then I saw his chin and understood. Can you unzoom it a bit?" I looked into that picture and ..] **Questionnaires**: "the site is pretty balanced but it's a little skewed toward getting an ICD because more people in the videos got the ICD." "I feel like most people don't decline the ICD."	Accepted
4/10/14	Patient or family member	Background: this patient was a decliner when we filmed her but has now been implanted with an ICD (Jan 2014). **General:** hard to find info on the surgery itself anywhere. More than get from any other source. **Ask questions/reflect**: liked it--anytime you can engage people, it's better. If we can interact with something, it causes people to be more engaged ... Thinking about vs. responding to it are 2 different things. **Decisions**: I'm a visual learner, so don't talk stats with me. Videos: **Video**s covered questions from patients' viewpoint. **Surgery**: wanted	Accepted

		more info about it but then realized every hospital does things a bit differently so this is probably sufficient. **Benefits**: I'm a visual person, worked for me. As pts we care about what it's going to do for me individually. Liked honesty about ICD not making you feel better. **Values**: When watched videos, almost felt like everybody else was [saying]: I'd rather live a long life, [it] made me feel wimpy [and that I should] suck it up, it's not just about you. It's really hard, does come down to Qual vs Quant. Not a light decision for me, some of these sounded almost flippant. If I was first time patient, watching these videos, I'd be more inclined to have it done vs. not. **Reflection**: some people will use, engages kinetic learning style. **Option**: give you basis on which to talk with physician, makes it more concrete. **Tests:** liked those, helps you see if you really understand. **Other**: Medical bracelet or necklace: several friends who are EMTs told her she should get a bracelet indicating that she has an ICD. Thought we should let people know. Conflicting info: cell phones? going through airport? Can we make this clearer? She had several trips recently and learned that actually the scanners are OK, but metal detectors are not. Wants people to know they can go through the scan where you raise your arms, so can avoid a pat down. Might be helpful to add a link to more information about different types of ICDs: she was offered a new one with wire that wraps around the heart. Add a statement like: don't be afraid to discuss your lifestyle and preferences with your physician. Add info about the remote unit: not explained well by her doctor (purpose, what it does and doesn't do, etc.)	
4/10/14	Patient or family member	Background: this patient has had an ICD for almost 10 years, has received shock. Also, this patient is not comfortable/knowledgeable about using computers and the internet. She like the overall look and content. She didn't understand the slider bar and thought there should be some instructions here. She thought we need to explain what the shock feels like better ("It leaves you rattled") and it can happen at anytime, anywhere. Also could be more reassuring about life after an ICD -- yes there will be adjustments, but there is still a lot you can do.	Accepted
4/23/14	Internal team or team member	"Go live" date of website with data collection capabilities.	No changes necessary

ICD Replacement Paper Pamphlet Log

Date recd	Reviewer	Suggestions	Reasoning behind changes
December 2015	CCOR	P1: disclaimer to exclude CRT-D?	Declined for now
December 2015	CCOR	Why replace: Implied that this is recommended/indicated	Agree will change wording
December 2015	CCOR	P2 Heart failure description blob: seems random	Removed
December 2015	CCOR	Path 1: add shock into picture to show shock saves life on path 1	The paths are really meant to display a concept. We have changed the paths based on lots of feedback.
December 2015	CCOR	Path 1 & 2: Where am I on the path? Have patients indicate where they are or ask physician. A few QOL questions for patients to complete and give examples of QOL	The paths are really meant to display a concept. We have changed the paths based on lots of feedback.
December 2015	CCOR	Risk: list them (higher in re-implant) infection, bleeding, pain	Accepted
December 2015	CCOR	Path 2: how likely is this to happen? The last few years can vary widely	Declined – the 2 paths has been accepted for ICD for Primary Prevention; trying to keep it the same.
December 2015	CCOR	Heart blob: Remember, ICDs will not make you feel better. Some ICDs have features that may make you feel better. Talk with your doctor about what kind of device may be right for you.	Reworded bubble to just say “Remember, ICDs will not make you feel better.”
3/22/16	External advisory group or member	P1 title: "REPLACEMENT"? Better, and maybe make all caps or another color to call this one out?	Accepted: changed “Reimplantation” to “Replacement.”
3/22/16	External advisory group or member	Try to make the whole thing shorter	We aim to make tool shorter.
3/22/16	External advisory group or member	Change “for patients that already have an ICD but need to have it replaced.” To “For patients who have an ICD and are considering replacement.”	Accepted

3/22/16	External advisory group or member	Reasons to replace: This probably covers 90% of the reasons, though 89% of that is the "end of battery life" indication. Maybe this could be "Your doctor may have recommended replacing your ICD because the battery is wearing out or the device is not working properly." Infections I think are different animals, clinically.	Declined for paper but changed tone on script for video decision aid to (end of battery life).

3/22/16	External advisory group or member	Why consider: This is the key transition as for most people the idea that this is a "choice" at all will be novel...What about being more directed with the heading: "You have a choice"? Or the more bland "Making a choice about ICD replacement"?	Changed title to making a choice about ICD replacement.
3/22/16	External advisory group or member	For some easy: This is tricky since a large chunk of ICD recipients don't have heart failure...We should discuss how to make this applicable to those people.	Changed to heart condition
3/22/16	External advisory group or member	Paths pic: I thought this was funny but maybe too subtle for people not inclined to think about this in such Frostian terms...?	Left photo for now
3/22/16	External advisory group or member	Why not easy: What about including phrasing like "Things you might want to discuss with your doctor include...:" Also, I would move this section after the "What does replacement mean" section	Left phrasing as is for now
3/22/16	External advisory group or member	P2: what does replacement mean: change to "minor surgery"	Left it as is for now b/c some people don't ever see surgery as minor
3/22/16	External advisory group or member	Explaining ICD: repetitive from first page	Kept as is for now
3/22/16	External advisory group or member	Would I survive w/o: probably repetitive from 1st page	Removed bubble
3/22/16	External advisory group or member	Benefits: Interesting - we should discuss - is this helpful or burdensome to include?	Thinking of how to best incorporate
3/22/16	External advisory group or member	Risks: I take it this is a placeholder...I think that after a succinct description of the procedure (can include all of this on the 1st page with the introductory stuff about why this is a decision at all". I think some rough #s here about infection, bleeding, pain, etc. are worth including.	Kept for now
3/22/16	External advisory group or member	P3 tradeoffs: This page is from your prim prevention aid I think...Tricky because more of the patients at gen change will be considered "secondary" prevention, and the "paths" are more specific to heart failure patients...	Kept b/c visualization is helpful
3/22/16	External advisory group or member	What if I change my mind: This is good stuff	No change necessary
11/9/16	Patient feedback	5. Found the benefits piece confusing (pg2) kind of after the fact. Maybe reword to "Now that you've had your ICD…"	Accepted

11/30/17	External advisory group or member	The ICD replacement handout is also great- I think that in some patients, particularly those with CRT-D, the option of downgrading to a pacemaker should be presented. We have this discussion frequently and we have several patients who had a CRT-D and benefitted from this, but when it came time for a gen change, elected to downgrade to a CRT-pacemaker. I would recommend that you state this option somewhere, perhaps in a way like this: "if your defibrillator also functions as a pacemaker, you may want to consider replacing the pacemaker/defibrillator with just a pacemaker."	CRT D vs. P is handled separately. The replacement tool is meant to generate a conversation.
1/16/2018	External advisory group or member	The pacemaker point is particular important for the replacement tool since "downgrading" is a real option here that will be relevant for some patients. Could just put that in a box or something but worth thinking about.	The replacement tool is really to generate a conversation.
1/16/2018	External advisory group or member	One specific comment on the replacement tool – I don't think it is correct that a non-replacement strategy can include just letting the battery go out on its own. I spoke to 2 of the 3 major vendors about this. The issue is that even if you turn it off, as the battery dwindles the devices become more (but unreliably) susceptible to power on reset events, which restores tachy-therapy to nominal settings. As battery life drains even farther, the device can actually lose its ability to be interrogated, which is obviously problematic. I think it would be safer to say that non-replacement, unless someone is imminently dying, requires removal of the generator	This has been corrected.
8/24/18	Internal team or team member	The Flesh-Kincaid score for the ICD replacement is 7.1.	No changes necessary.
10/10/18	Internal team or team member	In order to match requirements for printing decision aids for implementation, decision aids need to be multiples of 4 pages.	Accepted and changed. Some formatting changes were needed, possibly including adding a page for notes or moving around images of devices. All content remained the same.
11/15/18	External advisory group or member	Several EPs now want a shortened 1-2 page decision aid that can be used in clinic with patients that covers the highlights of the larger decision aids, but is briefer to use in clinc.	Accepted and in development. A separate evidence document will be created for this, as not all edits or responses to this decision aid will reflect edits/responses to the DA short, and vice-versa.
2/15/21	Internal team or team member	Add I-DECIDE logo to heading, move graphics and copyright to fit. Also make sure pamphlet matches 4/8/12 pages for	Accepted and changed.

		printing options.	
2/15/21	Internal team or team member	Remove “COMIRB# 17-1697” as this is not considered solely study materials.	Accepted and changed.

ICD Replacement Video Log

Date recd	Reviewer	Suggestions	Reasoning behind changes
4/25/16	External advisory group or member	Intro: Would it be simpler to restrict the study sample and related materials to the "routine" replacements? This is the majority of them, and I wonder if the major factors are different for patients being evaluated for other reasons like infections or malfunction.	
4/25/16	Internal team or team member	Dangerous heart rhythm here: Just maybe want to vary the language a bit here: "Like you see here" or "watch what this looks like" etc.	Declined suggestion b/c clip is already filmed/timed
4/25/16	External advisory group or member	Move the "why this might not be an easy decision" section to above the "what are my choices section."	Accepted
4/25/16	External advisory group or member	3 options: I think this starts to get too complicated…These lines seem to be aiming at CRT upgrades, or adding an atrial lead for someone with new SN dysfunction or something – these are really different sorts of patients than the "routine" ERI replacements…	Accepted
4/25/16	External advisory group or member	<<risk is lower>>Maybe your risk for sudden cardiac death is not as high as it once was: This is an interesting bullet, and while there are several papers looking at this, the upshot generally is that we do not have great predictors of people who are "low enough" risk now to use that much clinically to make non-replacement decisions. So I might move that bullet lower, thinking about them in a hierarchy of usefulness…the next 2 bullets seem more germane to me.	Accepted, moved reasons down to the bottom.
4/25/16	Internal team or team member	Which do you prefer? The bullets up top or EP discussion? Or writing it somehow to include both?	Decided to meld the two: So now we have the 1) the reasons why this decision might be difficult and 2) keeping the EP section
4/25/16	External advisory group or member	Removing ICD: I get why this is here but it feels a little redundant. Maybe keep with a pause so we can cut if necessary? -Dan I agree, the point's been made already. – Kramer	Accepted
4/25/16	External advisory group or member	Pacing options: Do we want to lead in with some simple gist overarching statement: "all of your options are still on	Declined

		the table…" you can have both, one or the other, or neither. I know that having an ICD without a PM in a bradycardic patient wouldn't make much sense, but that's something a patient's doc would explain, right?	
4/25/16	External advisory group or member	Risks: Just my take…While not insignificant, I generally downplay the acute procedural stuff when I talk to patients about replacements. Bleeding maybe I discuss in more depth for patients on triple-therapy but otherwise, not much goes wrong here…The index admission complication rate in my study was <1%, and really serious complications << than that.	Accepted
4/25/16	External advisory group or member	Die quickly vs. live longer: I thought this was redundant, but maybe that's because I had the other tools in mind. I think the stuff up front does get to this though. I like the final paragraph below – I think the real point for ICD replacement has always been to get people to believe it actually involves a choice. I suspect the vast majority of people will still elect for replacement, but just knowing that it is a choice should be empowering.	Accepted
11/2/16	Internal team or team member	Slide on why this might not be an easy decision seems critical. 1. "Risk is lower" is actually the main reason in my mind, and I think that needs more, perhaps with some data on how expected benefits are lower for people who haven't had VT, particularly with recovered LVEF. 2. "Sicker" is also important, and I think that should be addressed more explicitly. Out of sensitivity you have kept it vague, but I'd argue to be more explicit. 3. I think having testimonials from people who turned down replacement for various reasons would be powerful and ground this.	We agree that videos of people who turned down replacement are important. We've had significant challenges finding those people.
11/9/16	Patient feedback	Didn't think the video was dynamic. Seemed like a classroom preso. I asked if we should improve upon it by switching up the setting he said "no," if the info is presented clearly, which it is, I think that's the more important thing.	Declined for now

8/13/18	Internal team or team member	ICD Replacement: https://vimeo.com/284784783 -Replace ICD animation (as above) - ~4:26 change voiceover, remove “let battery run out”	Accepted
8/15/18	Internal team or team member	Replacement: Also looks great. New audio and graphics work perfectly.	No changes necessary.
11/9/16	Patient Feedback	Suggestion – it would be great to provide a phone # or website you could call to get more info.	Accepted

CRT-D Paper Pamphlet Log

Date recd	Reviewer	Suggestions	Reasoning behind changes
3/22/16	External advisory group or member	I would set this up as "...aid for Cardiac Resynchronization Therapy or Biventricular Pacing" at the top level. First half page is explaining what CRT does as a CHF treatment - I have other graphics we can use...	Declined
3/22/16	External advisory group or member	The section defining desynchronization: This is good start but might confuse some patients who associate "irregular" with AF. I might phrase as something like: "What is CRT? Patients may experience "heart failure" because of prior heart attacks, genetics, or other reasons. Heart failure means that the heart cannot pump blood effectively enough to prevent fluid build-up in the lungs, or to meet the needs of the body. In some cases, the poor pumping function is due to a lack of coordination between different areas of heart muscle. Cardiac resynchronization, or CRT, tries to fix this by pacing the heart muscle in such a way that the pumping function is brought back into sync." Or something like that.	Changed wording to make it less confusing.
3/22/16	External advisory group or member	What is defibrillation: I would take the material from here to bottom of page and put AFTER a box highlighting the choice with a graphic that shows the wires connected either to a PACEMAKER or a DEFIBRILLATOR....	Moved information to a new section title "Decision section."
3/22/16	External advisory group or member	CRT vs. CRT-D section: This good - can move this up a bit and have graphic below illustrate that the wires for the pacing are the same either way, but that patients and their doctors together may choose to have a CRT-Pacemaker or CRT-Defibrillator...	Addressed decision of defibrillation on pg1 in bolded box titled "Your decision."
3/22/16	External advisory group or member	Considering CRT with D section: This and the next wee section can go up to Page 1 where the basics of the procedure are outlined along with some procedural risks. These are essentially the same with or without the ICD so can cover quickly.	Took out section and covered elsewhere. Addressed for both Defibrillation and CRT
3/22/16	External advisory group or member	Size of bump/scar: Since we aren't asking patients to choose device/no-device, would just turf this point.	Kept for information regardless. And added a scar and bump present for either.

3/22/16	External advisory group or member	Receiving a shock: This is important and well said.	No change required.
3/22/16	External advisory group or member	Live longer w/ ICD: You've probably collected real data on this, but I wonder if this is too much math for patients, who are looking for something more qualitative or more like ranges of benefit?	Tested with patient panel, and patients approved level of math on decision aids.
3/22/16	External advisory group or member	Consider values/wishes: I think we can summarize this more succinctly in a "Things to consider when choosing CRT-Pacemaker or CRT-Defibrillator" section...	Accepted. Shortened to avoid redundancy.
3/22/16	External advisory group or member	Summary: I really like the idea of a summary comparison page...	No change necessary
3/22/16	External advisory group or member	What questions do you have: Probably would delete this page for space	Declined.
11/30/17	External advisory group or member	The CRT handout is great – I don't have specific changes. There are two places where you have indicated that you need text. One is the risks of implanting a CRT pacemaker. The procedure is virtually identical to that of a CRT-D, just putting in a defibrillator lead in the RV, instead of a pacemaker lead. I would quote the same level of risk. Regarding turning off the CRT-P, I would state that it is generally not recommended to turn off the CRT pacemaker, since this device will not prolong your life and has no ability to shock your heart. This device will continue to improve the quality of your life but not extend the length of your life.	Accepted
1/16/2018	External advisory group or member	For the CRT tool, I suggest a slight re-ordering of content to set up more clearly what CRT does and then lay out the decision +/- ICD…There are a few other options for presenting the additional sudden death risk/benefit here which I imagine the group will discuss in Denver…	Accepted
8/24/18	Internal team or team member	The Flesh-Kincaid score for the CRT-D is 6.1.	No changes necessary.
2/15/21	Internal team or team member	Add I-DECIDE logo to heading, move graphics and copyright to fit. Also make sure pamphlet matches 4/8/12 pages for printing options.	Accepted and changed.
2/15/21	Internal team or team member	Remove "COMIRB# 17-1697" as this is not considered solely study materials.	Accepted and changed.

CRT-D Video Log

Date recd	Reviewer	Suggestions	Reasoning behind changes
3/28/16	External advisory group or member	What about a little more transitional phrasing like this? "This video will help explain how CRT works. In addition, there are choices you can make when deciding to have CRT implanted. This video will help walk you through those decisions." It felt a little quick to me to jump right to "CRT-D" considering most MDs don't' know what that means… I think the CRT stuff can go first and then the P v D comes in….	Accepted Kramer's suggestions by adding his transition phrasing and removing too much detail regarding CRT- D.
3/28/16	Internal team or team member	You may have never heard of CRT or CRT-D before. We are here to help you understand what a CRT is. Then we hope to help you decide whether getting CRT with or without defibrillation may be right for you. Other patients like you have gone through this process. Some decided to get a CRT-D. Others decided to get CRT only, without defibrillation. As you watch this video, we encourage you to take notes and write down your questions so that you may talk about this decision with your doctor and loved ones. We hope by the end of this video that you will have a better understanding of how you might feel about getting a CRT-D your decision.	Changed the bolded wording – I think writing it this way leaves it open if we are able to get clips but doesn't shoot us in the foot if we aren't.
3/28/16	External advisory group or member	"Sometimes the heart pumps poorly. In other words, the heart beats out of sync." I think some patients may confuse this phrasing with atrial fibrillation	Left the wording the same for now; wanted to test with patients first.
3/28/16	External advisory group or member	"Cardiac resynchronization therapy, or CRT, helps the heart beat pump normally by synchronizing the ventricles to help the right and left parts of the heart pump together." Just thinking about literacy here.	Accepted the change.
3/28/16	External advisory group or member	This device helps the body get more blood. A CRT-D is a similar device that combines CRT with defibrillation. To understand the difference between CRT only and CRT-D, let's talk a little more about heart failure. To do this,	Removed and reworded to "To do this, special wires are placed in the heart to pace the heart muscle in a specific way

		special wires are placed in the heart to pace the heart muscle in a specific way that improves the pumping function of the heart.	that improves the pumping function of the heart."
3/28/16	External advisory group or member	"We are not sure what these symptoms will be like for you. Some people with heart failure are also at a higher risk for dangerous heart rhythms, which can be treated with a CRT-D." Delete section Add this instead: "Your doctor has recommended CRT to help improve or prevent symptoms of heart failure."	Accepted his deletion and addition.
3/28/16	External advisory group or member	I think there needs to be a more explicit call-out to what, exactly, we are hoping to engage patients in here. I think nearly everyone who is offered CRT agrees to have it so the real focus is on the ICD – some suggested phrasing: "Patients with heart failure may be at risk for sudden dangerous heart rhythms. These heart rhythm abnormalities may be life-threatening, and in some cases can cause a cardiac arrest. The best treatment for these dangerous heart rhythms is a "defibrillator". This is a device that can sense these heart rhythms and deliver a shock to your heart if you need it. CRT can be combined with a defibrillator. This combination is sometimes abbreviated "CRT-D""	Accepted edits.
3/28/16	External advisory group or member	The section of "How well do CRT-Ds work": We should discuss this – seems like too much math for the patients to me…Also not sure where these numbers came from – SCD-HeFT doesn't exactly translate here…And the numbers vary a lot depending on the COMPANION vs MADIT-CRT vs RAFT populations…	Declined
3/28/16	External advisory group or member	How about "A small number of patients will experience bleeding, infections, or damage to the heart or lungs. It is also possible that the wires put into the heart will move, and this may require a second procedure to place them again. In general, serious complications are unusual."	Added: "But, in general, serious complications are unusual."

3/28/16	External advisory group or member	Patients getting shocked: Could hedge a little and say something like: "Each year, a small number of patients (around 5%) with CRT-D devices receive a shock" Or something like that….	Changed first sentence to: "Each year a small number of patients, about 5 out of 100, will be shocked by their CRT-Ds."
7/5/16	CCOR	Unable to understand if the decision is about CRT-D vs CRT or CRT-P vs. CRT-D.	Made major changes to make it more clear. Chapter 1 and Chapter 2.
11/2/16	Internal team or team member	Benefits of CRT do not seem comprehensive. You only say CRT makes you feel better and then show a graphic that you can walk further. CRT causes positive remodeling in the majority of patients which improves cardiac function, thus reducing symptoms, improving exercise capacity, lowering hospitalization, and reducing death. In RAFT, death was 21% v. 26%. Hospitalization and death was 33% v. 40%. This is somewhat proportional to severity of LBBB.	This data is controversial. We do feel very comfortable saying that CRT helps you feel better.
11/2/16	Internal team or team member	Risks of CRT – consider presenting the 100 face option grid as you later do with ICD benefits (rather than just text "1/100").	Declined we have found this to be too confusing for patients
11/2/16	Internal team or team member	Text sometimes seems unnecessarily small. There are times where I also think the PPT bullet format is overly sterile	Accepted changes to make font larger
11/2/16	Internal team or team member	Video showing the heart beating out of sync is not particularly obvious. Maybe use water balloon analogy?	Travis made a side-by-side animation to depict difference more readily.
11/2/16	Internal team or team member	Is the decision at the end right? Declining CRT-D v. accepting CRT-D? Shouldn't the more appropriate decision be CRT-P versus CRT-D? Fred actually finishes with the sentence "ask questions . . . so that you can decide if adding a defibrillator to your CRT is right for you."	Accepted
11/9/16	Internal team or team member	For the desynchronized heart, we should do a cross section where you can see the chambers beating out of sync rather than a closed heart. It'll be more obvious	Declined, see above.
11/9/16	Internal team or team member	Scar picture: place arrows indicating that's the CRT device and that's the scar.	Declined we thought this was overkill.

11/9/16	Internal team or team member	Should this be a decision about CRT-P vs. CRT-D?	We have made some changes to the script to include CRT-P vs. CRT-D.
11/9/16	Internal team or team member	Caroline mentions “ICD” which could be confusing	We will try to replace that clip with a CRT- D clip.
11/9/16	Internal team or team member	Pictograph needs to be resynched; Also says “ICD” at the bottom	Accepted. We will ask Travis to fix this.
11/30/16	Internal team or team member	Music at beginning sounds a lot louder than voice audio.	Accepted.
11/30/16	Internal team or team member	On CRT benefits the person walks further, but you never say this directly or quantify?	Addressed on page 2.
11/30/16	Internal team or team member	On the graph with the different paths, I wonder if there are 3 paths. First is without CRT: A) faster decline and then possible SCD, B) CRT-P with slower decline but then SCD, and C) CRT-D slower decline to later death of pump failure.	The paths would be too complicated. These are really to display a point.
11/30/16	Internal team or team member	I wonder if you say “This decision is complicated and different people make different choices. Most people in the US get CRT-D, whereas in Europe most get CRT-P. Ultimately only you can decide what is right for you.”	The CRT tool is complicated and dense. Not included due to space.
11/30/16	Internal team or team member	When you show the 100 faces, Amy says “individual situations may vary” - I didn’t hear “These are averages for groups of patients. What will happen to you as a single person is unknown.”	We have kept this on the paper tool.
11/30/16	CCOR	When you say “help get blood to the body” ppl may think that the heart creates blood	This wasn’t a concern in our patient testing.
11/30/16	CCOR	2 paths: some people may be okay with this – too leading?	Patients have been okay with this presentation.
11/30/16	CCOR	Should you use smiley faces? They’re alive but feeling crappy maybe?	Changed to persons.
11/30/16	CCOR	The walking guy doesn’t tie into what’s being said about symptom improvement	Tied into video by adding benefits of CRT.
11/30/17	External advisory group or member	I just finished watching the CRT-D video and noted an issue with the audio and video right at about 4 min.	Changed to remove anomalies
8/13/18	Internal team or team member	CRT-D Video: https://vimeo.com/284783377 -Replace two paths animation -Replaced funky audio around ~4:10	Accepted

		-Insert Fred voiceover around ~15:52 about turning battery off -Changed on-screen text and audio for changes in “Other considerations” to reflect changes on paper tool about airport security, machine equipment, etc.	
8/15/18	Internal team or team member	CRT : I hadn’t thought about it before, but the slide underneath the new audio where Fred talks about device deactivation (~16:10) is really nice. It calls out the deactivation discussion specifically, and sets patients up to be thinking about it early on.	No changes necessary

Appendix III. Option Grid Evidence Document

What does an ICD do?

- Editorial consensus.

How would I like the rest of my life to be?

- Allen LA, Stevenson LW, Grady KL, et al. Decision Making in Advanced Heart Failure: A Scientific Statement From the American Heart Association. Circulation. 2012. 17;125(15):1928-1952.
- Matlock DD, Nowels CT, Masoudi FA, et al. Patient and cardiologist perceptions on decision making for implantable cardioverter-defibrillators: a qualitative study. Pacing and Clinical Electrophysiology. 2011;34(12):1634-44.

What is involved?

- Editorial consensus.

Will I live longer with an ICD?

- Bardy GH, Lee KL, Mark DB, et al. Amiodorone or an implantable cardioverter defibrillator for congestive heart failure. The New England Journal of Medicine. 2005;352(3):225-237.
- Buxton AE, Lee KL, Fisher JD, Josephson ME, Prystowsky EN, Hafley G. A randomized study of the prevention of sudden death in patints with coronary artery disease. The New England Journal of Medicine. 1999;341(25):1882-1890.
- Moss AJ, Zabera W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infaction and reduced ejection fraction. The New England Journal of Medicine. 2002;346(12):877-883.
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Will I get shocked by the ICD? What will that feel like?

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- Dunbar SB, Dougherty CM, Sears SF, et al. Educational and psychological interventions to imrpove outcomes for recipeients of implantable cardioverter defibrillators and their families: a scientific statement from the American Heart Association. Circulation. 2012;126(17):2146-2172.

What are the risks of getting an ICD?

- Al-Khatib SM, Anstrom KJ, Eisenstein EL, et al. Clinical and Economic Implications of the Multicenter Automatic Defibrillator Implantation Trial-II. Annals of Internal Medicine. 2005;142:593-600.
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- Moss AJ, Zabera W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infaction and reduced ejection fraction. The New England Journal of Medicine. 2002;346(12):877-883.
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Will an ICD improve my symptoms?

- Goldenberg I, Moss AJ, Hall WJ, et al. Causes and consequences of heart failure after prophylactic implantation of a defibrillator in the Multicenter Automatic Defibrillator Implantation Trial II. Circulation. 2006;113(24):2810-2817.

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Are there things I cannot do?

- Davids JS, McPherson CA, Earley C, Batsford WP, Lampert R. Benefits of cardiac rehabilitation in patients with implantable cardioverter-defibrillators: A patient survey. Archives Physical Medicine Rehabilitation. 2005;86(10):1924-1928.
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Can the ICD be taken out?

- Editorial consensus.

Can the ICD be turned off?

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