Official Title: Decision Support for Adults Facing Implantable Cardioverter-Defibrillator Pulse Generator Replacement

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Protocol Title

Development and Evaluation of Decision Support for Adults Considering Implantable Cardioverter-Defibrillator Pulse Generator Replacement: A Multi-Methods Study

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Abstract

Background: The use of the implantable cardioverter-defibrillator (ICD) has increased substantially in the last 10 years due to advances in heart failure and arrhythmia management. The number of ICD generator replacements is therefore also increasing. The current widespread practice is to automatically replace the battery, despite it being non-compulsory. Shared decision-making (SDM), an approach that encourages the deliberation about the options between patients and providers, is inadequate at ICD pulse generator replacement as evidenced by more than half of patients not knowing it was a decision that could be made. A patient decision aid (PtDA) may help facilitate SDM by providing patients with accurate probabilities of the benefits and risks of each option, eliciting their preferences, and assisting them in making an informed choice.

Objective: To evaluate the feasibility and provide preliminary effectiveness data of the PtDA in adults faced with the decision to replace their ICD pulse generator.

Methods: Feasibility testing will be conducted using a pilot randomized controlled trial. Participants will be randomized into one of two arms: exposure to the decision support intervention (PtDA and decision coaching) or usual care. Primary outcomes are measures of feasibility related to study processes such as recruitment and referral rates, use of the PtDA, quantity of missing questionnaire data, and assessment of randomization procedures. Secondary outcomes include attributes of decision quality, decision-making process and acceptability and usability measures for those exposed to the intervention.

Relevance: No recommendation or decision support intervention exists to guide and support patients and providers towards making an informed decision regarding ICD pulse generator replacement. By informing patients and facilitating the exploration of their values for each option, higher quality decisions may be achieved. Otherwise, we risk inappropriately and inefficiently using a treatment modality that informed patients simply no longer want or value.

Research Problem

Implantable cardioverter defibrillators (ICDs) are battery-powered devices programmed to detect and correct life-threatening cardiac arrhythmias. They are an effective treatment modality for patients at risk of sudden cardiac death (Bardy et al., 2005; Moss et al., 2002). In the past 10 years, ICD implantation rates have dramatically increased due to expanding indications (Fishman et al., 2010; Simpson, Hoffmaster, & Dorian, 2005). The life expectancy of an ICD generator is estimated between four and seven years (Kramer et al., 2013). Given the recent increase in ICD implantation rates, the number of ICD pulse generator replacements will rise in consequence.

ICD pulse generator replacement is a preference-sensitive decision (Wennberg, 2002). In these instances, individuals may weigh the benefits and potential risks of ICD therapy differently than others (Wennberg, 2002). The decision to replace is not straightforward for a variety of reasons: the risks of the replacement procedure, changes in health status and goals since initial implantation, and the experience of living with an ICD (Kramer, Buxton, & Zimetbaum, 2012). It is well-documented that ICD therapy can detrimentally affect a patient's quality of life, including non-trivial rates of clinically significant psychological distress (Dunbar et al., 2012). In addition, the effectiveness of ICD therapy in octogenarians and those with a higher burden of comorbidities is understudied. The survival benefit of ICD therapy in these patient populations is uncertain (Goonewardene et al., 2014). Hence, the decision to replace should depend on the careful weighing of the benefits and risks from the individual and provider's perspective.

SDM is a collaborative process that occurs between provider and patient whereby a decision regarding a patient's health care is achieved jointly (Charles, Gafni, & Whelan, 1997; Makoul & Clayman, 2006). Its goal is to promote a patient centered care approach towards values-based, informed decisions (Barry & Edgman-Levitan, 2012). Currently, shared decision-making (SDM) is inadequate at this decision point (Kramer et al., 2012; Lewis, Nery, & Birnie, 2014a). There is no clear recommendation or decision support intervention for providers and patients to make an informed decision regarding ICD pulse generator replacement. Patient decision aids (PtDA) are evidence-based tools that facilitate SDM by making explicit the decision that needs to be made, providing evidence-based information about the options and outcomes, and clarifying personal values. PtDAs improve knowledge, increase patient engagement, and result in choices that are concordant with patients' values (Stacey et al., 2014). However, no PtDA exists for adults facing the decision to replace their ICD generator.

Current Practice and Proposed Solution

Practice guidelines for initial ICD implantation require clinicians to determine ICD candidacy based on the individual's risk for sudden death, including a "reasonable expectation of survival with a good functional status for more than 1 year" (Epstein et al., 2012). Yet, ICD pulse generator replacement is not usually precluded by this criteria. Discussion regarding prognosis and patient preferences for continued ICD therapy are often omitted (Kramer et al., 2012). Pulse generator replacement is an opportune time when provider and patient can review health care goals, reassess the risk for sudden cardiac death, reflect on the experience of living with a device, assess for psychological adjustment difficulties, review the benefits and risks of device therapy, and explore personal values and preferences regarding the option to replace it.

The purpose of this research is to develop and evaluate a PtDA for patients faced with the decision to replace their ICD pulse generator. The goal of this PtDA is to ensure that patients are informed of the option of replacement or non-replacement, have access to accurate probabilities of the benefits and risks of each option, and assist in the clarification of their values to promote informed choice. A novel aspect of my proposed research will be to navigate the PtDA design and development process with implementation in mind, in an attempt to overcome known PtDA implementation difficulties (Elwyn et al., 2013).

Theoretical Frameworks

Two theoretical frameworks will guide this research project. The Ottawa Decision Support Framework (ODSF) (O'Connor et al., 1998a) will support PtDA development, and the Normalization Process Theory (NPT) (May & Finch, 2009) will ensure the integration of key implementation elements. These key elements will be integrated throughout the design and development phase, to attempt to overcome the implementation and adoption difficulties that have prevented the routine usage of PtDAs in clinical practice (Elwyn et al., 2013a).

Ottawa Decision Support Framework

The ODSF (O'Connor et al., 1998a) has been extensively used as a guide for PtDA development. Its main goal is to provide patients with the best knowledge and realistic expectations of the outcomes of each option which they face while clarifying their values associated with those outcome to achieve a quality decision. A quality decision is characterized by the patient's understanding of the options and outcomes, the selection of choice that is concordant with the patient's values, and meaningful patient involvement in the decision-making process (Sepucha et al., 2013). The framework is based on the

construct of decisional conflict (Janis & Mann, 1977), and theories from general psychology (Tversky & Kahneman, 1981), social psychology (Ajzen & Fishbein, 1980), decisional analysis (Keeney & Raiffa, 1976), social support (Orem, 1995) and self-efficacy (Bandura, 1982). The ODSF asserts that patients and their support networks' decisional needs (ie: knowledge and expectations of each option, lack of value clarification and support, uncertainty) can affect decisional quality (O'Connor et al., 1998a). The quality of a person's choice depends on their level of knowledge about the options, their expectations of their most-valued outcomes, their level of confidence in the decision, and the level to which they feel supported in their choice (O'Connor et al., 1998a). Unmet needs may result in poor decision quality, delayed decisions, regret, dissatisfaction, and poor outcomes (O'Connor et al., 1998a). The ODSF acknowledges the presence and contribution of the patient, members of their support network, and members of the interprofessional team. Main limitations include a restriction to individual level factors, and a lack of acknowledgment of context, and implementation. Application of the ODSF for this research will ensure that all key elements for a quality decision are included in the PtDA. The ODSF's schematic representation can be viewed in Appendix A.

Normalization Process Theory

The NPT is a middle-range theory concerned with factors that affect the implementation, embedding, and integration of innovative and complex interventions into specific institutional settings (May & Finch, 2009). The theory is based in sociology, and focuses on what people do, what work is required, and how that work is achieved (May et al., 2009). The NPT has been successfully used as a framework to identify the factors that promote and inhibit PtDA implementation (Elwyn et al., 2008; Elwyn et al., 2013b). To achieve this theory's goal, focus is needed on the dynamic work and social processes among key players. According to the NPT, the normalization of a complex intervention can be achieved by the practices that people engage in, the manner in which they execute them, and what meaning they attribute to them, which is explained by way of four main elements (coherence, cognitive participation, collective action, and reflective monitoring) (May & Finch, 2009) (see Appendix B). Coherence refers to the meaning, or the sense-making work that people engage in individually and collectively when presented with a newly proposed practice. It asks the question *What is the work?* Cognitive participation refers to the level of commitment adopted by actors involved in the development and mobilization of the proposed practice (*Who does the work?*). Collective action requires effort put forth by all of the key players to reach the predetermined goal (*How does the work get done?*). And finally, reflexive monitoring is concerned with how end-users comprehend, understand, and appraise the utility of the new practice for themselves, and for those it is intended for (*How is the*

work understood?) (May & Finch, 2009). As the implementation of PtDAs into established workflows have proven difficult to date, the research process will be navigated by the NPT to keep clinical (micro-level) and organizational (meso-level) implementation considerations at the forefront.

Literature Review

A review of the ICD decision-making and PtDA literature was conducted and is organized using the ODSF's three main pillars: decisional needs, decision support, and decision quality as they relate to the decision of ICD generator replacement. The search was executed using electronic databases, hand searching, and by reviewing the reference list of selected articles. The following electronic databases were searched from their inception date: the Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, Medical Literature On-line (MEDLINE), PsycINFO, and the Cochrane Database of Systematic Reviews. Key words used in the search included *implantable cardioverter-defibrillator, pulse generator replacement, battery replacement, decision-making, shared decision-making, patient decision aids, decision support, and patient participation*. Inclusion criteria included both peer-reviewed and grey literature. Articles were included if related to ICD decision-making, ICD replacement surgery, and decision support interventions. Limits were not set for publication date, study design, or language.

First, the characteristics of the decision to replace an ICD pulse generator are described. Second, the literature is organized using the ODSF's three main pillars. Third, a review of patients' reported preferences for or against ICD generator replacement will be reported.

Characteristics of the Decision

In 2012, the Ministry of Health and Long-Term Care's Seniors Strategy for Ontario cited providing "Choice" as the third of five principles to encourage and promote the independence and wellness of older Ontarians. The Ministry of Health and Long-Term Care states that health providers should respect the choices of informed individuals even if it means they are choosing to live with risk (Government of Ontario, 2012).

When patients approach the need for a pulse generator replacement, it is an opportune time to revisit their decision to maintain or discontinue the ICD. . Ethical considerations regarding ICD replacement include providing patients and their families relevant and meaningful evidence-based information regarding the risks and benefits of continuation versus discontinuation of the ICD , aligning this information to their goals and values, and offering patients the opportunity to exercise their right to refuse preference sensitive treatments if they so choose.

One of the most influential factor of ICD therapy for patients is its life-saving potential (Lewis, Stacey, & Matlock, 2014b). With a burst of fast pacing or internal shock, a life-threatening arrhythmia

can be terminated. However, ICD therapy is not a benign intervention. To terminate the potential life-threatening arrhythmia, a shock – often described as a "horse kick to the chest" - can occur suddenly, and can cause physical and emotional discomfort. In addition, the risk of inappropriate shocks (Daubert et al., 2008), safety advisories (Sengupta et al., 2012), psychosocial adjustment difficulties such as anxiety, depression, and post-traumatic stress disorder (Dunbar et al., 2012), and possible temporary driving restrictions in the event of an appropriate ICD shock with loss of consciousness (Thijssen et al., 2011) are other potentially negative aspects patients must consider. Also, the pulse generator replacement surgery includes substantially greater procedural risks as compared to the initial implantation surgery, particularly as related to infection (Krahn et al., 2011; Poole et al., 2010). Finally, an ICD can lead to protracted dying experiences, due to the possibility of repeated shocks nearing death (Goldstein et al., 2007).

For most, the risk of sudden death and the desire to live prevails over the adverse consequencesof the device—unless the value trade-off between a prolonged death versus a sudden one has been carefully considered (Lewis et al., 2014b). Importantly, the non-replacement of an ICD pulse generator does not result in immediate or near immediate death. Rather, non-replacement indicates that a patient is choosing to discontinue future ICD therapy.

Decisional Needs

Concept. According to the ODSF, decisional needs represent a myriad of factors that can impact the quality of a decision. Factors include one's level of decisional conflict (uncertainty about the best course of action), the knowledge required to make an informed decision, realistic expectations of possible outcomes, the patients' values and preferences for those outcomes, and the receipt of adequate support (O'Connor et al., 1998a). These can be mediated by the patient and provider's characteristics. If decisional needs are left unresolved, decision quality can be negatively impacted**.**

Evidence. There is increasing interest in understanding patients' decisional needs and preferences in the context of ICD decision-making given the number of articles published on this topic within the last nine years (Lewis et al., 2014b). Current practice guidelines acknowledge the preference-sensitive nature of ICD therapy, recommending individualized counseling to "facilitate shared decision-making between patients, families, and the medical care team about ICDs" (Yancy et al., 2013, p. 71). An integrative review of patients' perspectives of ICDs revealed a significant degree of patient misunderstanding and inaccurate recall of information regarding ICD function (Lewis et al., 2014b). Most patients overestimated device benefits, underestimated risk, and misunderstood device function (Dodson, Fried, Van Ness, Goldstein, & Lampert, 2013; Fluur, Bolse, Stromberg, & Thylén, 2013;

Goldstein et al., 2007; Habal, Micevski, Greenwood, Delgado, & Ross, 2011; Kirkpatrick, Gottlieb, Sehgal, Patel, & Verdino, 2012; Lewis et al., 2014a; Stewart et al., 2010; Strachan, Carroll, de Laat, Schwartz, & Arthur, 2011). For some patients, the best source of understanding the ICD's impact on lifestyle was the opportunity to live with one (Matlock et al., 2011a). Prior to a decision being made to receive an ICD, it is imperative that patients are aware of the option, degree of risk and uncertainty, the seriousness of outcomes, and whether the decision is irrevocable (O'Connor et al., 1998a). Patients should be provided the opportunity to articulate their expectations, values, and goals of care. The current state of knowledge on patients' decisional needs as related to ICD replacement is presented here.

***Patients' decisional needs*.** Four studies have been published about patients' perspectives related to decision-making at ICD generator replacement (Fluur et al., 2013; Gibson, Kuntz, Levenson, & Ellenbogen, 2008; Lewis et al., 2014a; Thylén et al., 2013). Gibson et al. (2008) addressed patients' decision-making processes at the time of a manufacturer initiated device advisory. Thirty-one affected patients were sent a notification letter from their physician supplemented by an in-clinic discussion. Many patients did not recall receiving the letter. Over 33% of patients incorrectly recalled the risk of device failure and 71% overestimated the rate of failure. Lewis et al. (2014a) surveyed patients who had their ICD pulse generator replaced from 2009 to 2012. The authors found that 55/106 (51.9%) patients were unaware that it was noncompulsory. Yet, 83.0% patients placed a great importance on a discussion of risks and benefits of continued therapy before making a decision. Misunderstandings of device functions and overestimation of device benefits were commonly reported at this decision point (Fluur et al., 2013; Lewis et al., 2014a). Thylén et al. (2013) surveyed 3,067 ICD recipients to identify factors associated with patients' attitudes towards withdrawal of ICD therapy, including pulse generator replacement. Substantial ambivalence and indecisiveness about having discussions regarding ICD therapy withdrawal was reported (Thylén et al., 2013). Little is known about the role and influence of external support on the decision, and the patient's preferred role when making this decision.

Decision Support

Concept. Decision support can be used to facilitate SDM to improve decision quality by addressing decisional needs (O'Connor et al., 1998a). Depending on their professional scope of practice, providers are expected to either diagnose and/or discuss the implications of the condition, present available treatment options, and provide or refer for further decision support. Decision support involves assessing for decisional conflict, ensuring that patients are aware of their options and their risks and benefits, determining if they are leaning towards a particular option, and determining the degree of

support (or pressure) they perceive from their support network (Stacey, Taljaard, Drake, & O'Connor, 2008).

Evidence. Decision coaching and PtDAs are two effective evidence-based decision support strategies suggested to increase the adoption of SDM, particularly when they target both patients and health professionals (Légaré et al., 2014; Stacey et al., 2012; Stacey et al., 2014).

Patient decision aids. PtDAs are evidence-based tools that facilitate SDM by making explicit the decision that needs to be made, providing evidence-based and balanced information about the options and outcomes, and clarifying personal values (Stacey et al., 2014). A systematic review of 115 randomized controlled trials showed that PtDAs improve knowledge by 13%, improve patients' realistic perceptions by 82%, increase patient engagement by 39%, result in values-choice agreement by 51%, and reduce decisional conflict by 6% (Stacey et al., 2014). Using PtDAs has also demonstrated a 20% decline in elective surgeries after patients became well informed of alternative options without affecting health outcomes or patient satisfaction (Stacey et al., 2014). This is important given the elective and invasive nature of the ICD replacement procedure. Although PtDAs exist for patients facing the initial decision to receive an ICD (Carroll et al., 2013), none exists for those faced with generator replacement.

To date, the majority of decision aids have been systematically developed, and field tested with promising results. Despite their established effectiveness in research settings, PtDAs have not yet been routinely integrated in practice (Elwyn, Légaré, van der Weijden, Edwards, & May, 2008; Elwyn et al., 2013a). Elwyn and colleagues (2013a) suggested that to overcome these major implementation challenges, we must go beyond the barriers and facilitators approach, and quest to understand the driving forces behind professional and organisational resistance to their adoption and use. When developing and implementing SDM interventions, involving the entire interprofessional team - including nurses and patients - is recommended (Elwyn et al., 2013b).

PtDA development process. A systematic, step-wise process should be followed when developing PtDAs (Coulter et al., 2006; Elwyn et al., 2006). A collaboration of international researchers, healthcare providers, and stakeholders established the International Patient Decision Aid Standards (IPDAS), a set of 25 criteria across 12 core dimensions to assess the quality of PtDAs (see checklist in Appendix C) (Elwyn et al., 2006; O'Connor et al., 2005). The criteria include key elements related to the PtDA's content (14 criteria), development process (9 criteria), and effectiveness (2 criteria).

Five key elements are required to develop a PtDA (Coulter et al., 2006). To begin, scoping and design involves a systematic review of the literature with critical appraisals of the evidence to quantify the risks and benefits of each option (O'Connor & Jacobsen, 2003). Synthesized results offer users

accurate probabilities of each option. Second, an advisory committee composed of various experts in the decision (e.g.: nurses, physicians, allied health members, and experts in SDM and PtDA development) is formed to systematically create a prototypic PtDA. Third, once the draft version is complete, anticipated PtDA end-users (eg: administrators, physicians, nurses, patients, and their families) provide feedback on the prototype for comprehensibility, acceptability, and usability. Using an iterative process, the PtDA is revised according to the feedback received. Fourth, the PtDA is then evaluated for feasibility with patients and providers who are facing the decision in a "real-world real-time setting," excluding those involved in the prototypic development process. Finally, a PtDA is produced for use, and/or for larger-scaled evaluation.

Decision coaching. A decision coach is a trained and skilled professional who engages patients to be involved in their decisions while remaining neutral in the decision (Stacey et al., 2008). The primary goal of coaching is to support patients to achieve quality decisions. A systematic review of 10 trials revealed that decision coaching increases knowledge of options as compared to usual care (Stacey et al., 2012). Trained decision coaches also resulted in 20.9% fewer preference-sensitive heart surgeries (Veroff, Marr, & Wennberg, 2013). The identification of patients in decisional conflict can be challenging for providers, but interventions such as workshops and online tutorials are effective to enhance knowledge and decision support skills (Stacey, O'Connor, Graham, & Pomey, 2006).

Decision Quality

Concept. The extent to which the chosen option best matches the informed patient's values and preferences for the benefits, risks, and uncertainties of the choice refers to the quality of a decision (O'Connor et al., 1998a). A quality decision-making process is contingent on the patient's awareness that (a) a decision can be made; (b) he/she is aware of the options and its associated risks, benefits, probabilities, and uncertainties; (c) he/she understands that values can affect the decision; (d) be clear about which features of the options matter most to them; (e) he/she can discuss values with the health care team; and (f) he/she can become involved to the degree they prefer (O'Connor, 2006). Three decision quality constructs can be measured when using PtDAs: a) knowledge, b) realistic expectations, and c) values-choice agreement (Elwyn et al., 2006). No single instrument can measure all of them at once, nor do researchers have an obligation to report them all (Sepucha et al., 2013).

Evidence. In the ICD decision-making literature, the construct of knowledge has been frequently investigated with similar findings. In a recently published review, studies report patient misunderstandings about ICD function, overestimation of ICD benefits, and underestimation of risks (Lewis et al., 2014b). Otherwise, little is known about patients' realistic expectations, the agreement

between patient values and their choice, and constructs of the decision-making process. A recent Cochrane review reported that PtDAs positively impact decision quality, whereby knowledge is improved by 13%, realistic expectations improve by 82%, and the agreement between values and choice increase by 51% (Stacey et al., 2014).

Patients' preferences for or against ICD replacement

Discussions about ICD pulse generator replacement between patients and their providers occurred less than 50% of the time (Lewis et al., 2014; Thylén et al., 2013). When discussions did occur, it was unclear if the option of non-replacement was part of these discussions (Thylén et al., 2013). In a survey based study of 3,067 respondents, 79% reported that they would replace the battery, 16% could not decide, and 5% would not even if ICD therapies were not needed during the first pulse generator's life. Where patients were very old or seriously ill, the proportions changed with 10% and 11%, respectively, not wanting a replacement. Lewis et al. (2014a) surveyed patients who had their ICD battery replaced from 2009 to 2012. The authors found that 55/106 (51.9%) patients were unaware that they had a choice to not replace the ICD. If given the option, 15/106 (14.2%) stated they would have considered non-replacement (Lewis et al., 2014). No demographic or clinical variables suggested the type of patient who would consider not replacing their ICD generator. Hence, it seems important to discuss this decision with all patients.

In summary, to date, the literature revealed that patients with ICDs facing pulse generator replacement are inadequately involved in this health decision. Yet, when informed of the option, patients and providers think about ICD replacement as a key decision-making point. Substantial high quality evidence supports the use of SDM, PtDAs and decision coaching as decision support interventions for preference-sensitive decisions such as this. Yet, none have been developed for this decision. There is a clear evidence-practice gap for patient participation in this health decision.

Purpose and Objectives

This study's purpose is to evaluate the feasibility and provide preliminary effectiveness data of the PtDA in adults faced with the decision to replace their ICD pulse generator.

Specific research questions include:

1) What is the feasibility of a pilot randomized controlled trial on study processes? and;

2) What is the effect of this PtDA for patients faced with ICD pulse generator replacement on attributes of decision quality and the decision-making process?

Hypothesis

We anticipate that the pilot RCT will meet our primary feasibility outcomes including recruitment and referral rates, use of the PtDA, quantity of missing questionnaire data, and assessment of randomization procedures needed to justify a larger trial. In terms of secondary outcomes, we hypothesize that patients randomized to the decision support arm will have better knowledge, be more involved in the decision, yet may have increased decisional conflict. We anticipate that the majority of patients will favor ICD replacement, but with a 5-10% reduction in the intervention arm.

Research Design

A pilot randomized controlled trial (RCT) will be conducted. Pilot RCTs are defined as "a small study for helping to design a further confirmatory study" (Arnold et al., 2009). They usually contain all the major features designed to conduct a major study, yet no power calculation is undertaken to detect statistical significance in relation to the hypothesis (Arain, Campbell, Cooper, & Lancaster, 2010). The sample size is selected based on feasibility (yet must be sufficiently adequate) to identify the necessary parameters for a larger trial such as recruitment rates, and to test the feasibility of the randomization and data collection procedures. This is an accepted design to evaluate new PtDAs (O'Connor & Jacobsen, 2003).

Setting and participants. This study will be conducted in an ambulatory care cardiac device clinic in a Canadian tertiary care hospital. A total of eight electrophysiologists and eight nurses work in this clinic. The clinic is co-led by the director of the pacemaker and defibrillator clinic, director of the arrhythmia service, and a nursing administrator. In this clinic, leaders and staff value evidence-based practice and are committed to integrating it into its practices and policies.

An estimated 350 ICDs are implanted and 150 ICD pulse generators are replaced annually in this institution (Cardiac Care Network of Ontario, 2013). No data exists on the number of patients who refuse ICD replacement, but anecdotal evidence supports that non-replacement does occur. Every 6 months, nurses assess patients' ICDs. The physicians meet the patient to confirm normal function, or to troubleshoot and resolve concerns. Battery measurements are charted at all visits. Nearing depletion, the frequency of visits to the clinic increases until replacement is indicated based on battery voltage. Patients can thus be advised of the decision about replacement ahead of time, and can return home to

reflect and discuss with their support network. Questions regarding the replacement decision can then be addressed at the next follow-up visit.

Inclusion/Exclusion criteria. Patients prospectively facing ICD pulse generator replacement will be eligible to participate. Eligible participants will be 18 years of age or older, are approaching or have reached the indicator for elective replacement, and are able to read, write, and understand English. Those unable to understand the PtDA due to a language barrier or visual impairment will be excluded. Patients incapable of providing informed consent due to dementia or other cognitive issues will be considered for inclusion, but only with the informed consent of their substitute decision-making and/or power of attorney for personal care. Patients will be excluded if they have conduction system disease and are pacemaker dependent. Patients with CRT or those being considered for an upgrade from ICD to a CRT will also be excluded as this type of device can improve heart failure symptoms (Tang et al., 2010).

Sampling strategy. Convenience non-probabilistic sampling will be used to recruit consecutive patients who are prospectively facing the decision to replace their ICD pulse generator. Eligible patients who meet the inclusion and exclusion criteria who have consented to have their charts reviewed for research purposes will be invited to participate. Research personnel will introduce the study to eligible patients after it has been determined that their ICD pulse generator is low in voltage and will soon require replacement to remain functional (when the frequency of visits increase to monitor battery status, at elective replacement indicator, or when the treating physician deems that the patient should be referred for pulse generator replacement to ensure continued ICD function). Once an ICD reaches the elective replacement indicator, an additional three months of battery function remains. Replacement procedures are booked within four to eight weeks. There is plenty of lead time before patients reach a fully depleted ICD battery. As such, there will be no delays in clinical care due to study activities. Participants' informed consent will be obtained by research personnel. For patients who agree to participate, randomization and the baseline visit will occur upon recruitment. For patients who wish to have more time to review the information sheet and consent form, a mutually convenient time and location will be arranged for the baseline visit and randomization.

Sample size, allocation, and blinding. We will enroll 30 patients. The sample size for this pilot trial is based on the number of patients seen annually in our institution who fit inclusion criteria. Consented participants will be randomized into one of two arms: exposure to the PtDA with decision coaching or usual care for a final 1:1 distribution in each arm. A randomization system will be used, which will conceal the aleatory allocation sequence. Randomization will occur during the baseline visit. Blinding of providers will not be possible due to the nature of the intervention. To blind patients, they

will not be informed of the other intervention. Data will be collected by a research assistant. Data analysis will be conducted by KL and a statistician, both blinded to the participants' allocation.

Usual care. The usual care group will receive a standard ICD follow-up visit as provided by the interprofessional team in the ICD clinic. This includes ICD interrogation with a nurse and a consult with the physician. The amount of detail provided about ICD generator replacement is at the discretion of the providers involved in that patient's care at the moment of battery depletion. In the majority of instances, a depleted battery results in an automatic referral for ICD generator replacement.

Intervention. The intervention group will receive the PtDA with decision coaching by a trained research assistant (see Appendix D for decision coaching protocol). Upon distribution, participants will navigate the PtDA supported by a decision coach. Participants will be invited to bring the PtDA home and review with anyone they wish to include in the decision-making process. To minimize contamination, one person will act as the decision coach. Patients randomized to the intervention arm will meet with the decision coach. The decision coach will provide information on options and support their decision-making needs in preparation for discussion with the device clinic physician, who would ultimately be responsible for sharing the decision with the patient.

Procedures.

Baseline visit. At the time of the baseline visit, demographic information such as age, sex, ethnicity, education levels, work status, whether they live alone or not, quality of life and device acceptance measures will be collected. Device acceptance will be measured using the Florida Patient Acceptance Survey (FPAS), a standardized and validated device specific instrument which measures the degree to which a person has accepted their ICD (Burns, Serber, Keim, & Sears, 2005). It has good internal consistency with an overall Cronbach's alpha of 0.83. Internal consistency for each of the subscales ranged from 0.74 to 0.89. (Burns et al., 2005). Quality of life will be measured using the Medical Outcomes Trust Short Form (SF-36v2), a reliable and valid generic health related quality of life scale (HRQL) comprised of 36 items. Patients randomized to the intervention arm will be given the decision support intervention.

Follow-up visit (2-4 weeks). Two to four weeks following randomization, patients in both groups will be contacted via phone for the first follow-up. Those randomized to the intervention will have a decision coaching session with the decision coach to review the decision aid. Those randomized to usual care will be asked if they have any questions or concerns. Follow-up data will be collected from both groups (see table on p. 24 for measures to be collected). Patients who choose not to replace their ICD will be invited to return to clinic for a follow-up visit, where the patient will have the opportunity to

review their decision with the clinic's healthcare providers to answer any outstanding questions or concerns.

Follow-up visit (6 months). Six month following randomization, patients in both groups will be contacted via phone or met in person for the second follow-up (see table on p. 24 for measures to be collected).

Follow-up visit (12 months). Twelve months following randomization, patients in both groups will be contacted by phone or met in person for the third, and final follow-up (see table on p. 24 for measures to be collected).

Outcomes. Primary outcomes are concerned with measures of feasibility related to study processes which include recruitment and referral rates, patient use of the PtDA, quantity of missing questionnaire data, and assessment of randomization procedures.

Secondary outcomes are attributes of decision quality and decision-making process consistent with the ODSF and IPDAS. These outcomes include knowledge, decisional conflict, preferred option, actual choice, and perception of involvement in decision-making. Data will be collected quantitatively using valid and reliable tools. Participants randomized to the intervention will also be asked questions regarding the acceptability and usability of the PtDA and the decision coaching session.

Primary outcomes - criteria for success. Criteria for success of feasibility for a larger study will be evaluated according to the following stipulations: (a) participant recruitment rate of at least 75%; (b) successful delivery and completion of PtDA in 80% of consented patients randomized to the intervention arm; and, (c) no more than 10% of missing questionnaire data.

Secondary outcomes - evaluation measures. The timing of participant exposure to the instruments of measurement outcomes is depicted in the table below.

Acceptability and usability questionnaire (intervention group; 2-4 weeks): Only participants randomized to the intervention will be asked 4 weeks after randomization to rate their satisfaction with the PtDA using the same acceptability and usability questions used as part of Phase II. Patients' satisfaction with decision coaching will be measured using the Genetic Counseling Satisfaction Scale and perceptions of decision coach neutrality (Schwalm, Stacey, Pericak, & Natarajan, 2012; Tercyak, Johnson, Roberts, & Cruz, 2001). This scale has face validity and a reliability coefficient of alpha 0.80 to 0.90 in genetic counselling contexts with adults.

Knowledge test (both groups; 2-4 weeks). A knowledge test was developed and endorsed for validity by the PtDA development team using a standardized template in the form of true or false questions. There are six questions. This exercise is meant to assess a patient's understanding of their

heart condition, treatment options, and risks and benefits of each option. Correct answers will be summed to determine an overall score.

Decisional conflict (comfort) scale (both groups; 2-4 weeks, 6 months, 12 months). The Decisional Conflict Scale (O'Connor, 1995) will be used to measure personal perceptions of uncertainty at baseline and post PtDA exposure. Patients who experience decisional conflict are more likely to sway between options, delay the decision, regret their decision, and fail the knowledge test (O'Connor, 1995; Stacey et al., 2014). The scale's main goal is to measure patient perception on five subscales: uncertainty, informed, values clarity, support, and effective decision-making. It consists of 16 statements each rated on a five point Likert scale from 0 (strongly agree) to 4 (strongly disagree). Scores for the five subscales can also be calculated. Aggregated scores of the entire scale or of the subscales can be used in the analysis. It has an alpha coefficient of >0.78 and good predictive validity. Total scores can range from 0 to 100 where higher scores indicate greater decisional conflict.

Preferred option (both groups; baseline, 2-4 weeks, 6 months, 12 months). Preferred option will be measured by asking patients whether they prefer to have their ICD's pulse generator replaced, not replaced, or whether they are unsure. Preferred option will be further quantified using the 15-point Choice Predisposition Scale that demonstrates a patient's inclination toward a given option, with a score of 1 indicating a strong preference for option A, ICD replacement, 15 indicating a strong preference for option B, non-replacement of the ICD, and the centre of the scale indicating no preference. Reports will be reclassified as: 1-5 (A); 6-10 (unsure); 11-15 (B). This scale has a test-retest coefficient >0.90 (O'Connor et al., 1998b).

Perceptions of involvement in decision-making (both groups; 6 months, 12 months). The patient's perception of involvement in the final ICD replacement or non-replacement decision will be measured using a modified version of Strull, Lo, & Charles's (1984) role in decision-making survey. Five statements rest along the continuum of how decisions can be made between patients and providers. Patients must select the statement that best represents their perceived involvement in the final decision.

Actual choice (both groups; 6 months, 12 months): This will seek to find out what the patient's actual choice was 6 months post randomization: replaced the ICD or declined ICD replacement.

Survival (both groups; 6 months, 12 months): We will seek to determine if the participant is alive or deceased. If the participant is deceased, what was the cause of death?

Table 3. Patient Questionnaires, Outcomes Measures, and Timing of Evaluation

Survey (n items per survey)	Baseline visit @ randomization	Follow-up 1 2-4 weeks post randomization	Follow-up 2 6 months	Follow-up 3 12 months
Demographics (6)	X	no	no	no
Preferred Choice (1)	X	X	X	X
Actual Choice (1)	no	no	X (if actual choice not made post-randomization)	X (if actual choice not made at 6 months)
Perceptions of Involvement in DM (1)	no	no	X	X
iCD Acceptance - FFAS (15)	X	no	no	no
Acceptability (12) and Usability of decision support (9)	no	X (intervention only)	no	no
Decisional Comfort (16)	no	X	X	X
Knowledge (6)	no	X	no	no
Values Clarification (4)	no	X	no	no
Quality of Life – SF-36-v2 (36)	X	no	X	X
Vital Status (1) (in Case Report Form only)	no	no	X	X

Risks and benefits. While there are no direct risks associated with this study, participants may find the interviews and questionnaires upsetting or tiring if they are quite lengthy. The final decision, whether to replace or not replace the ICD, will be made with their treating physician (e.g., cardiologist, electrophysiologist). This decision support intervention is meant to help them consider their options in preparation for that consultation, thus participants randomized to the intervention arm may feel enhanced support in decision-making and may feel better informed of their options. The decision support intervention is not meant to replace the physician's recommendation. The purpose of this study is to ensure that patients are aware that ICD non-replacement is an option, NOT to promote the non-replacement of the ICD.

For patients discussing the option of ICD non-replacement, there is potential for increased uncertainty, worry or discomfort. All patients, including those randomized to the usual care group may have questions after reading the consent form. Questions and concerns will be addressed sensitively and appropriately as they arise.

Given the nature of the inherent decision, questions about the ethics of offering this option may arise. The Heart Rhythm Society's Expert Consensus Statement on the Management of ICDs in Patients Nearing End of Life or Requesting Withdrawal of Therapy (Lampert et al., 2010) clearly states that

ethically and legally, there is no difference between declining ICD therapy prior to initial implant, and declining replacement and/or requesting its withdrawal.

Data analysis. Outcomes have been selected based on feasibility studies, the ODSF, and IPDAS. Primary feasibility outcomes will be expressed as descriptive statistics. Categorical variables will be summarized using counts and percentages, and continuous variables using measures of central tendency. Secondary outcomes related to attributes of decision-making quality and process will be calculated using inferential statistics. Both arms will be compared at baseline, 1 month and 6 months post randomization. For comparison of categorical data, a chi-square test or Fisher's exact test will be used (Norman & Streiner, 2008). Differences in attributes of decision quality and decision-making process will be compared within and across groups, at all time points. The first will be within group (between baseline and follow-up visit) which will be compared using paired t-test. The second comparison will be across groups (intervention group versus usual care group) using t-test. A p value of ≤0.05 will be used to indicate statistical significance. SAS (SAS Institute Inc., Cary, NC, USA) will be used for quantitative analyses. Plans for statistical analysis will be confirmed with a statistician.

Ethical Considerations

Ethical approval will be obtained from the Ottawa Health Science Network Research Ethics. Participants' human rights will be protected using all advised steps (Canadian Institute of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada, 2010). A participant information sheet and consent form will be presented to potential participants. The consent will emphasize confidentiality, anonymity, voluntary participation, and permission to withdraw consent at any time. Participants willing to participate will provide uncoerced, informed written consent – a copy of which they will receive for their files.

All personal information about potential and enrolled participants will be stored electronically on site at the University of Ottawa Heart Institute. All data will be encrypted and protected with a password. Participants' contact data will be stored separately from the remaining research materials. All participants will be assigned a study identification number which will be used for data collection forms and other research materials (eg: recorded interviews). All study materials will be kept secured for 15 years as dictated by our institutional research ethics board. Given the nature of the inherent decision – one option being the non-replacement of a life-saving therapy – questions around the ethics of offering this option may arise. Clinical guidelines such as the *Heart Rhythm Society's Expert Consensus Statement*

on the Management of ICDs in Patients Nearing End of Life or Requesting Withdrawal of Therapy clearly state that ethically and legally, there is no difference between refusing ICD therapy prior to initial implant, and requesting its withdrawal (Lampert et al., 2010). However, there is potential for increased uncertainty, worry or discomfort for patients discussing the option of ICD non-replacement. All patients, including those randomized to the usual care group may have questions after reading the consent form. Questions and concerns will be addressed sensitively and appropriately as they arise. Participants who are exposed to the PtDA may feel enhanced support in decision-making. The main benefit of this study will be to enhance nursing and interprofessional team knowledge of patient participation at this decision point, and help patients who are faced with this decision achieve higher quality decisions.

Rigor

External validity and reliability will be established by using valid and reliable instruments to measure outcomes. To minimize sampling bias, all participants will be recruited sequentially from the same device clinic (Polit & Beck, 2012). The majority of these individuals have thus been subjected to similar clinic practices and institutional culture since the initial ICD implant. To minimize contamination, only one person will act as the decision coach. Survey studies are susceptible to response bias as respondents may be inclined to provide answers that are congruent with prevailing social values and/or to not offend or disappoint researchers (Polit & Beck, 2012). Losing recruits to follow-up is also a possibility. Recovery of missing data will be attempted by calling respondents. The statistical tests selected to analyze the quantitative measures will be appropriate and robust for the selected instruments (Norman & Streiner, 2008). Measures should be accurate and generalizable to other similarly structured Ontario and/or Canadian tertiary care facilities that assess and manage patients with ICDs. In the report, the analytical process will be sufficiently described to ensure reproducibility.

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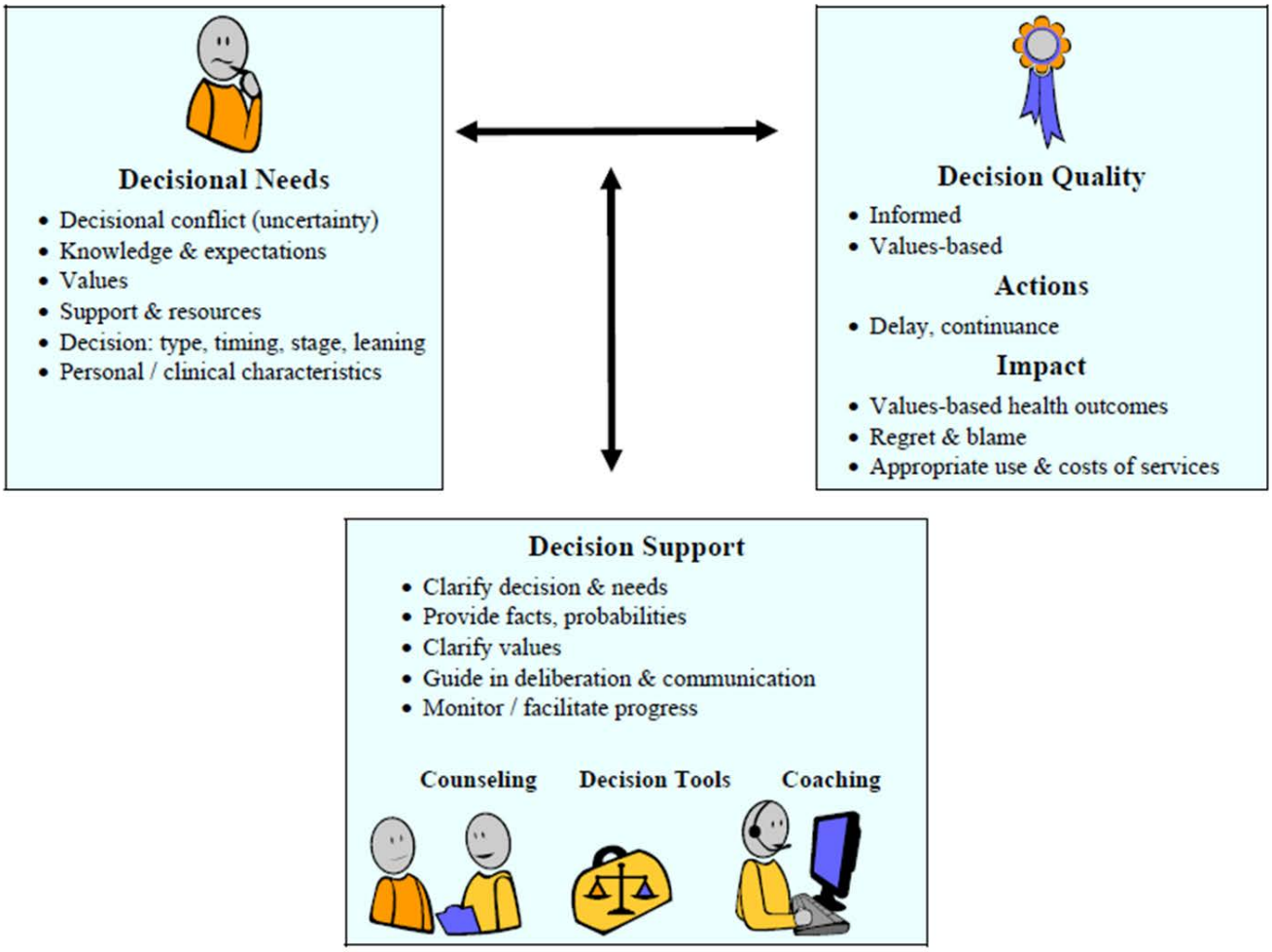
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Appendix A

Ottawa Decision Support Framework

Figure 1. Ottawa Decision Support Framework



Note. O'Connor, A. M., Tugwell, P., Wells, G. A., Elmslie, T., Jolly, E., Hollingworth, G.,...Drake, E. (1998a). A decision aid for women considering hormone therapy after menopause: Decision support framework and evaluation. *Patient Education and Counseling, 33*(3), 267-279.

Appendix B

Normalization Process Theory

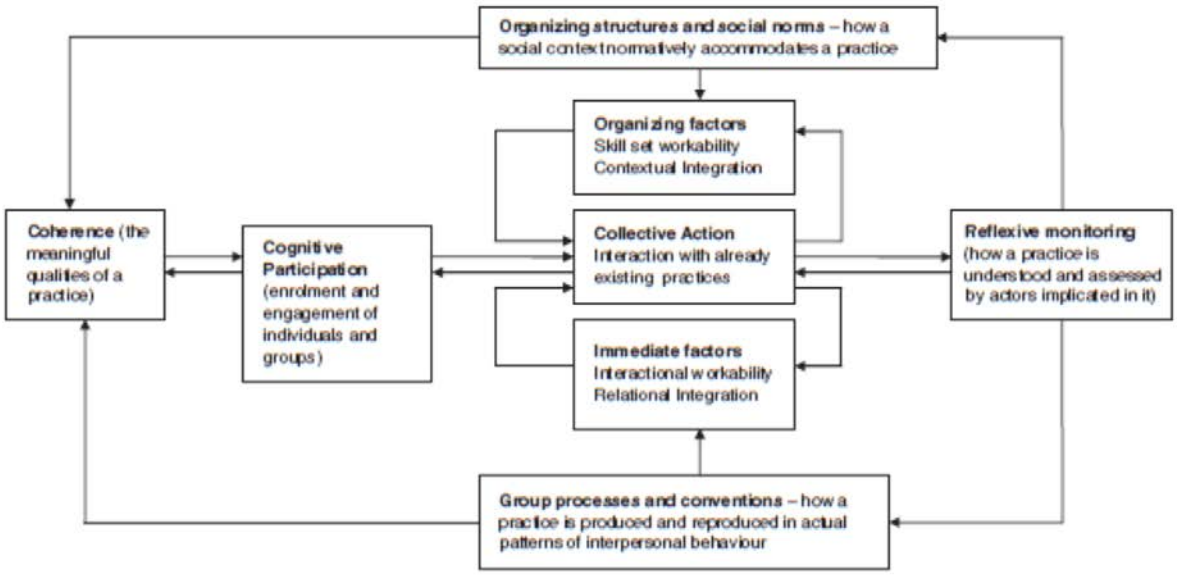


Figure 1 Model of the components of normalization process theory

Note. May, C. & Finch, T. (2009). Implementing, embedding, and integrating practices: An outline of normalization process theory. *Sociology, 43*(3), 535-554.

Appendix C

International Patient Decision Aids Standards Criteria

A. Criteria Related to Content of the Patient Decision Aid (PtDA)

The PtDA provides information about options in sufficient detail for decision making	□ describe the health condition □ list the options □ list the option of doing nothing □ describe the natural course without options □ describe procedures
If the PtDA is to provide information about tests, meets additional criteria.	□ describe what test is designed to measure □ include chances of true positive, true negative, false positive, false negative test results □ describe possible next steps based on test result □ describe positive features [benefits] □ include chances the disease is found with / without screening □ describe negative features of options [harms / side effects / disadvantages] □ include chances of positive / negative outcomes □ describe detection / treatment that would never have caused problems if one was not screened
The PtDA presents probabilities of outcomes in an unbiased and understandable way	□ use event rates specifying the population and time period □ allows the patient to select a way of viewing probabilities [words, numbers, diagrams] □ compare outcome probabilities using the same denominator, time period, scale □ describe uncertainty around probabilities □ use visual diagrams □ use multiple methods to view probabilities [words, numbers, diagrams] □ allow patient to view probabilities based on their own situation [e.g. age] □ place probabilities in context of other events □ use both positive and negative frames [e.g. showing both survival and death rates]

The PtDA includes methods for clarifying and expressing patients‟ values	□ describe the procedures and outcomes to help patients imagine what it is like to experience their physical, emotional, social effects □ ask patients to consider which positive and negative features matter most □ suggest ways for patients to share what matters most with others
The PtDA includes structured guidance in deliberation and communication	□ provide steps to make a decision □ suggest ways to talk about the decision with a health professional □ include tools [worksheet, question list] to discuss options with others

B. Criteria Related to the PtDA Development Process

The PtDA presents information in a balanced manner	□ able to compare positive / negative features of options □ shows negative / positive features with equal detail [fonts, order, display of statistics]
The PtDA has a systematic development process	□ includes developers‟ credentials / qualifications □ finds out what users [patients, practitioners] need to discuss options □ has peer review by patient / professional experts not involved in development and field testing □ is field tested with users [patients facing the decision; practitioners presenting options]. PtDA is: □ acceptable □ balanced for undecided patients □ understood by those with limited reading skills
The PtDA uses up to date scientific evidence that is cited in a reference section or technical document	□ provides references to evidence used □ report steps to find, appraise, summarizes evidence □ report date of last update

	□ report how often patient decision aid is updated □ describe quality of scientific evidence [including lack of evidence] □ uses evidence from studies of patients similar to those of target audience
The PtDA discloses conflicts of interest	□ report source of funding to develop and distribute the patient decision aid □ report whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid
The PtDA uses plain language	□ is written at a level that can be understood by the majority of patients in the target group □ is written at a grade 8 equivalent level or less according to readability score [SMOG or FRY] □ provides ways to help patients understand information other than reading [audio, video, in-person discussion]
If PtDA is internet based, meets additional criteria.	□ provide a step-by-step way to move through the web pages □ allow patients to search for key words □ provides security for personal health information entered into the decision aid □ make it easy for patients to return to the decision aid after linking to other web pages □ provide feedback on personal health information that is entered into the patient decision aid □ permit printing as a single document
If stories are used in the PtDA, meets additional criteria.	□ use stories that represent a range of positive and negative experiences □ state in an accessible document that the patient gave informed consent to use their stories □ reports if there was a financial or other reason why patients decided to share their story

C. Criteria Related to PtDA Effectiveness

The PtDA supports decision processes leading to decision quality	The DA helps patients to … □ recognize a decision needs to be made □ know options and their features

The PtDA ensures decision making is informed and values based (Decision quality)	□ understand that values affect decision □ be clear about option features that matter most □ discuss values with their practitioner □ become involved in preferred ways □ improves the match between the chosen option and the features that matter most to the informed patient

Note. Modified from "Developing a quality criteria framework for patient decision aids: online international Delphi consensus process" by G. Elwyn, A. O'Connor, D. Stacey, R. Volk, A. Edwards, A. Coulter et al., 2006. *BMJ* Data supplement, doi: 10.1136/bmj.38926.629329.AE

Appendix D
Decision Coaching Protocol

Step in PDA	Decision Coaching Element (based on the ODSF)[11]	Process	Suggested Language
Title page and **Table of Contents**	Build skills in deliberation, communication, and accessing support	Introduce and explain the PDA: "Making the decision to replace your implantable cardioverter-defibrillator pulse generator."	
Introduction	Assess/discuss decision-making needs	Clarify the decision: Ensure that the patient/family member knows exactly what decision they are facing.	Tell me about the decision you are facing. What are your reasons for making this decision?
		Assess stage of decision-making	When do you need to make a choice? How far along are you in making a choice?
Introduction/ **Step 1: Be clear about the options/** **Step 2: Weigh your options**	Assess understanding	Assess facts: options, harms, risks, and probabilities *Prompts*: Complications; shocks; effectiveness of the ICD; health status; speed of recovery of the replacement procedure; logistical issues	Tell me about your options. Tell me what you know about the reasons to choose either option. Tell me what you know about the reasons to avoid either option.
	Provide information	Reinforce facts and realign expectations	That's right. You've got it. Did you know…? The research shows…
Step 3: Consider your Preferred Option	Clarify values	Assess values/importance of outcomes of options	Rate each statement to show how much each one matters to you. Which statement do you agree with the most? Which statement do you disagree with the most?
		Clarify and facilitate communication of values	On a scale of 0 (not at all important) to 5 (extremely important), how would you rate the importance of the benefit of having the ICD? What about the harms of ICD replacement?
		Preferred option	Thinking about these ratings, which option do you prefer?
Step 4. Check your knowledge of the options	Assess/discuss level of knowledge related to the ICD and the ICD replacement procedure	Encourage patient and family members to answer questions, and clarify any misunderstandings.	Thinking about these questions, is there anything you remain unsure of? Is there anything else you would like to know about the ICD

			and/or the ICD replacement procedure.
Step 5. What Else Do You Need to Make a Choice? / **Frequently Asked Questions**	Assess/discuss decision making needs	Assess the involvement of others in the decision (opinions, support, pressure)	Who else is involved in the decision? Are you feeling pressure from anyone to choose a specific option? How could they support you?
		Assist patient/family member to develop skills/confidence in the steps of decision making and communicating their preferences to others.	Whose opinion is most important to you? Can you block out the opinions that don't matter? What role do you prefer in making the choice?
	Facilitate progress in decision-making	Facilitate development of a plan for next steps to address unresolved decisional needs.	What else do you need to make a choice? What do you think are the next steps?
If preferred decision expressed:	Screen for implementation needs	Determine what is needed to implement the preferred choice.	What do you need to carry out your preferred choice? When do you need to carry out the choice?
	Facilitate progress in decision-making	Discuss sharing his/her preference with the clinic physician. Encourage him/her to take the completed PDA to their next appointment.	Do you have questions you want to ask to the device nurse or doctor prior to making your decision? *[If yes, encourage them to write them down in Step 5 of PDA].* Is there anybody else you would like to discuss this decision with? Do you feel comfortable sharing your preferred option with the device clinic physician.
	Build skills in deliberation, communication, and accessing support.	**NOTE:** If two people are involved, highlight areas of agreement/disagreement on values, pressure and support. Make sure each person has a chance to express their responses to the questions. If one person is more vulnerable (e.g. frail elderly), then have that person respond first.	

Note. Adapted from ***CHEO Family Decision Services intervention protocol for decision coaching using the OFDG*****.** CHEO Family Decision Services © 2011 Boland, Lawson, Feenstra, Stacey, Children's Hospital of Eastern Ontario, Canada. www.cheo.on.ca/en/DecisionServices