

**Development and Preliminary Evaluation of Decision Support for Patients to
Accept or Decline Implantable Cardioverter-Defibrillator Replacement at the
Time of Battery Depletion**

Krystina B. Lewis RN, MN, CCN(C)

A thesis submitted in partial fulfillment of the requirements for the
Doctorate in Philosophy degree in Nursing

School of Nursing
Faculty of Health Sciences
University of Ottawa

© Krystina B. Lewis, Ottawa, Canada, 2018

Dedicated to my family, which grew by one in the midst of this research:

Pablo, Marcus, Mom & Dad

Dissertation Abstract

Purpose. To systematically develop and conduct preliminary evaluation of a decision support intervention to engage patients and their families about whether to accept or decline implantable cardioverter-defibrillator (ICD) pulse generator replacement.

Methods. A series of studies using multi-methods and guided by the Ottawa Decision Support Framework and the Normalization Process Theory: 1) an integrative review of patients' perspectives on ICD decision-making; 2) a systematic review of the risks and benefits of ICD replacement; 3) an embedded mixed methods study to iteratively develop a patient decision aid (PDA) and simultaneously plan for its implementation; and 4) a feasibility pilot randomized controlled trial to evaluate ease of recruitment, decision support intervention delivery and data collection.

Findings. The integrative review of 25 articles reported that ICD decision-making was difficult and the majority of patients misunderstood ICD therapy. The systematic review of 17 nonrandomized studies reported that complication rates are higher at replacement as compared to initial implant, mortality benefit post ICD replacement is unclear, and patients' clinical profile can affect ICD's effectiveness. Findings from both studies were used to draft a PDA. Interviews with 18 end-users (clinicians, patients, spouses) revealed that the current ICD replacement process is automated and needs to elicit patient preferences. The PDA was considered the optimal tool to initiate the discussion of options. In a feasibility trial, 30 patients were randomized to the decision support intervention (PDA + decision coaching) (n=15) or usual care (n=15). The intervention was used as intended, users found the PDA acceptable but acceptability of decision coaching was variable. Patients exposed to the intervention had better knowledge scores compared to controls.

Conclusion. The Ottawa Decision Support Framework and Normalization Process Theory were complementary frameworks to ensure that the decision support intervention has the potential for implementation. To determine whether this approach was successful, future research is required to evaluate and implement the intervention in clinical practice. Findings from the feasibility study will be used to design an effectiveness trial.

Acknowledgements

I am indebted to many individuals and teams for making this work possible.

The willing participation of University of Ottawa Heart Institute patients with implantable cardioverter-defibrillators and their families, and my colleagues and nurse manager in the Pacemaker and Defibrillator Clinic who helped challenge the status quo by being open to these ideas and welcoming this research alongside their clinical practice. Thank you to Carolynne Brousseau-Whaley who was a well-suited decision coach and competent research assistant. It is my hope that this research will help promote a steady shift towards patient engagement in ICD decision-making so that it is more patient-centered and reflective of personal preferences.

My deepest appreciation to my supervisor, Dawn Stacey. From the very beginning, her commitment and support towards my research and professional development were unwavering. She is a true model of professionalism and integrity who has ignited the academic in me by facilitating countless opportunities to build knowledge and research capacity well beyond this dissertation. It is her enthusiasm and excellence in nursing research and education that has inspired me to pursue the next phase of my nursing career in academia. To my committee members, David Birnie and Sandra Carroll, whose expertise in the patient population and research process was invaluable every step of the way. Your mentorship by way of wise advice and the sharing of personal anecdotes were always timely, invigorating, and deeply appreciated. I believe whole-heartedly that our composition made the best of teams. The collaborations must not end here.

I am privileged to have received funding from a Canadian Institutes of Health Research Fellowship, Ontario Graduate Scholarships, Academic and Excellence Scholarships from the University of Ottawa, the Hebert and Corinne Zagerman Nursing Research Scholarship Award at the Ottawa Hospital, and a research award from the Canadian Council of Cardiovascular Nurses - all of which were indispensable to the funding of this research.

To my friends - you know who you are - whom I have relied on for distraction, merriment, and the sharing of life's joys, sorrows, and opportunities. I am so grateful for your friendship, and for the beautiful fact that we take care of one another.

Finally, my deepest love and gratitude to my family who has never ceased to believe in me and my endeavors. Pablo, my husband, my rock. Your dedication to your family, to your professional calling, and to the person that you are, are immense sources of inspiration to me. Marcus, whose entry into our lives in 2016 has taught me more about love, selflessness, and life's purpose than any experience has ever before. And, to my parents, who always insisted in my early formative years that schooling only ever ended after university. Clearly, you were heard. While the formal schooling officially ends, learning never does.

Table of Contents

Dissertation Abstract.....	iii
Acknowledgements.....	iv
Table of Contents.....	vi
List of Tables.....	ix
List of Figures.....	x
Abbreviations.....	xi
Chapter 1: Introduction.....	1
1.1 Research Problem.....	1
1.2 Guiding Theoretical Frameworks.....	6
1.3 Purpose of the Dissertation.....	8
1.4 References.....	13
Chapter 2: Making Decisions about Implantable Cardioverter-Defibrillators from Implantation to End-of-Life: An Integrative Review of Patients' Perspectives.....	17
2.1 Introduction.....	19
2.2 Methods.....	20
2.3 Findings.....	21
2.4 Discussion.....	28
2.5 Limitations.....	31
2.6 Future Directions.....	31
2.7 Conclusion.....	32
2.8 References.....	48
Chapter 3: Estimating the Risks and Benefits of Implantable Cardioverter Defibrillator Generator Replacement: A Systematic Review.....	53
3.1 Background.....	55
3.2 Methods.....	56
3.3 Results.....	58
3.4 Discussion.....	61
3.5 Limitations and Strengths.....	65
3.6 Conclusions.....	65
3.7 References.....	76

Chapter 4: User-Centered Development of a Decision Aid for Patients Facing Implantable Cardioverter-Defibrillator Replacement: A Mixed-Methods Study	81
4.1 Introduction.....	84
4.2 Methods.....	84
4.3 Results.....	87
4.4 Discussion	91
4.5 Strengths and Limitations	92
4.6 Conclusions and Future Directions	92
4.7 References.....	108
Chapter 5: A Feasibility Randomized Trial of a Decision Support Intervention for Patients Facing Implantable Cardioverter-Defibrillator Replacement	111
5.1 Introduction.....	113
5.2 Methods.....	114
5.3 Results.....	119
5.4 Discussion	122
5.5 Strengths and Limitations	124
5.6 Future Implications	124
5.7 Conclusions.....	125
5.8 References.....	132
Chapter 6: Incorporating Patients' Preference Diagnosis in Implantable Cardioverter-Defibrillator Decision-Making: A Review of Recent Literature	136
6.1 Introduction.....	138
6.2 Recent Challenges and Advances with ICD Decision Making.....	138
6.3 Shared Decision-Making.....	141
6.4 Implications for Future Research and Practice	143
6.5 Conclusions.....	144
6.6 References.....	150
Chapter 7: Integrated Discussion	157
7.1 Summary of Dissertation Findings	157
7.2 Dissertation Findings in the Context of Evolving Literature	159
7.3 Implications for Nursing	167
7.4 Conclusions.....	173
7.5 References.....	175
Chapter 8: Contribution of Collaborators	182

8.1 Primary Researcher and Thesis Committee	182
8.2 Other Collaborators and Acknowledgements	183
8.3 References	186
Appendix A - Additional Search Strategies for Systematic Review	190
Appendix B - Title and Abstract Screening Criteria.....	192
Appendix C - Full Text Screening Criteria.....	193
Appendix D - Ottawa Health Science Network Research Ethics Board Initial Approval for Mixed Methods Study	195
Appendix E - Participant Informed Consent Form for Mixed Methods Study.....	196
Appendix F - Semi-Structured Interview Guide for Patients, Families and Clinicians.....	201
Appendix G - Ottawa Health Science Network Research Ethics Board Initial Approval, Amendment Approval, and Annual Renewal for Feasibility Trial.....	207
Appendix H - Participant Informed Consent Form for Feasibility Trial	212
Appendix I - Patient Decision Aid As Used in the Feasibility Trial	218
Appendix J - ICD Survival Benefit Probabilities “Sticker” by Age and ICD Indication	230
Appendix K - Decision Coaching Protocol	235
Appendix L - Baseline Questionnaire – Feasibility Trial	237
Appendix M - 2-4 Week Questionnaire – Feasibility Trial	246
Appendix N - 2-4 Week Questionnaire – Supplemental for Intervention Group Only	249
Appendix O - 6 Month Questionnaire – Feasibility Trial.....	254

List of Tables

Table 1.1 Attributes of ICD Generator Replacement and Indications For SDM.....	3
Table 1.2 Manuscript-based Dissertation Structure and Content	10
Table 2.1 Characteristics of Included Studies.....	33
Table 3.1 Eligibility Criteria	68
Table 3.2 Medline Search Strategy	69
Table 3.3 Characteristics of Included Studies.....	70
Table 3.4 Total and Frequently Reported Major Complications	73
Table 3.5 Incidence of Appropriate ICD therapies from Replacement Date in Defined Subgroups	75
Table 4.1 Patient Decision Aid Content	95
Table 4.2 Demographic Characteristics of Participants.....	97
Table 4.3 Themes – From Current ICD Replacement Approach to PDA Implementation.....	98
Table 4.4 Patient Decision Aid Acceptability and Usability per Iteration	103
Table 4.5 Revisions to Patient Decision Aid Content.....	104
Table 5.1 Baseline Patient Demographics	126
Table 5.2 Acceptability of the Patient Decision Aid	128
Table 5.3 Acceptability of the Decision Coaching	129
Table 5.4 Preliminary Effectiveness Outcomes.....	131
Table 6.1 Sources of Evidence.....	145
Table 6.2 Nine Essential Elements to Shared Decision-Making	145
Table 6.3 Format for ICD Replacement and Deactivation Discussions	146
Table 6.4 “Ask-3 Questions” to Facilitate Patient Involvement.....	147
Table 6.5 Preference-sensitive Attributes of ICD Therapy	148
Table 7.1 Use of NPT in Decision Support Development and Preliminary Evaluation.....	165
Table 8.1 Contribution of Collaborators For Published Articles and Prepared Manuscripts	187

List of Figures

Figure 1.1 The Ottawa Decision Support Framework	7
Figure 2.1 Number of Articles Published Per Decision-Making Point on the Patients' Perspective in ICD Decision-Making from 2004-2013	47
Figure 3.1 Literature Flow Diagram	67
Figure 3.2 Sensitivity Analysis for Total Major Complications.....	74
Figure 4.1 Flow Chart of PDA Development and Field-Testing Process.....	95
Figure 5.1 CONSORT Flowchart	127

Abbreviations

ATP	Anti-tachycardia Pacing
CASP	Critical Appraisal Skills Program
CENTRAL	Cochrane Central Register of Controlled Trials
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CONSORT	CONsolidated Standards of Reporting Trials
CRT-D	Cardiac Resynchronization Therapy Defibrillator
DARE	Database of Abstracts of Reviews of Effects
DCS	Decisional Conflict Scale
DFT	Defibrillation Threshold Testing
EMI	Electromagnetic Interference
ICD	Implantable Cardioverter Defibrillator
ICM	Ischemic Cardiomyopathy
iKT	Integrated Knowledge Translation
IPDAS	International Patient Decision Aids Standards
LVEF	Left Ventricular Ejection Fraction
MAPPIN' SDM	Multifocal Approach to the Sharing in Shared Decision-Making
MEDLINE	Ovid MEDLINE, National Library of Medicine
MMAT	Mixed Methods Appraisal Tool
NCDR	National Cardiovascular Data Registry
NPT	Normalization Process Theory
NYHA	New York Heart Association
ODSF	Ottawa Decision Support Framework
OPTION	Observing Patient Involvement in Decision-Making
PDA	Patient Decision Aid
PICO	Population, Intervention, Comparator, and Outcomes
PPM	Permanent Pacemaker

PROSPERO	International Prospective Register of Systematic Reviews
RCT	Randomized Controlled Trial
RA	Research Assistant
RN	Registered Nurse
RNAO	Registered Nurses Association of Ontario
SCD	Sudden Cardiac Death
SDM	Shared Decision-Making
SIGN-50	Scottish Intercollegiate Guidelines Network 50
SUNDAE	Standards for UNiversal reporting of patient Decision Aid Evaluation

Chapter 1 : Introduction

The purpose of this dissertation was to develop and conduct preliminary evaluation of a decision support intervention for adult patients faced with implantable cardioverter-defibrillator (ICD) replacement to enhance patient awareness of the options and involvement in this increasingly common and complex decision point. This first chapter orients the reader to the research problem, the two theoretical frameworks guiding this multi-methods research, the study objectives, and the structure for this manuscript-based dissertation.

1.1 Research Problem

ICDs are battery-powered devices programmed to detect and correct life-threatening cardiac arrhythmias by delivering a 30-35 joules internal shock. This shock is uncomfortable, often painful for patients, but is an effective treatment modality for appropriately selected patients at risk of sudden cardiac death (Bardy et al., 2005; Moss et al., 2002). It is estimated that 85,000 to 92,000 Canadians are eligible for an ICD, with numbers increasing by the thousands every year 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; Manolis, Maounis, Koulouris, & Vassilikos, 2017; Zanon et al., 2016). Given the recent increase in ICD implantation rates, the number of ICD pulse generator replacements is rising in consequence, with an estimated 25% of all device procedures being due to battery depletion (Kramer, Buxton, & Zimetbaum, 2012).

The decision to initiate and continue with ICD therapy involves a subjective trade-off between potential mortality benefit and potential consequences. Factors that influence the decision may be based on: (a) potential risks associated with ICD therapy and/or the replacement procedure, (b) personal experience with the ICD, (c) change in health status, and/or (d) no longer meeting the eligibility criteria. First, risks associated with ICD therapy include inappropriate shocks, device malfunction, device/lead advisories, potential driving restrictions, and the incremental risks (e.g., infection) of subsequent surgical procedures on the same device pocket. Second, patients facing ICD replacement now have the experience of living with an ICD. It is

well-documented that ICD therapy can potentially be detrimental to a patient's quality of life, and can lead to diagnoses of anxiety, depression and post-traumatic stress disorder in some patients (including younger patients) (Dunbar et al., 2012). Third, worsened heart function, and new onset competing non-cardiac comorbidities may alter a patient's goals of care. Should a patient's goals of care shift from prioritizing quantity of life to preserving quality of life, the ICD may be interfering with their preferred mode of death. Other patients may have developed competing comorbidities and/or have become frail. Little is known about the ICD's effectiveness in this population (Goonewardene et al., 2015). Hence, the risks of the replacement might outweigh the benefits of continued therapy. For these reasons, this decision is considered preference-sensitive as personal preferences and values for or against these attributes can differ among the target population (Wennberg, 2002). Four, recent studies have suggested that patients who no longer meet initial implantation indications at the time of ICD generator replacement may no longer require an ICD (Madeira et al., 2017; Weng et al., 2017). Specifically, patients with ischemic and non-ischemic cardiomyopathy who present at ICD replacement with improved left ventricular ejection fraction (LVEF) above 31%, and those with an ICD for primary prevention who have never received an appropriate therapy may be at lower risk of sustained ventricular arrhythmias.

No current clinical practice guidelines specifically address how these clinical characteristics should inform decision-making at ICD replacement (i.e. decisional algorithm), yet a companion article to the 2016 Canadian Cardiovascular Society/Canadian Heart Rhythm Society ICD guidelines (Bennett et al., 2017) introduces these elements and suggests how a clinician may consider the options (Philippon et al., 2017).

My Masters of Nursing research published in *JAMA Internal Medicine* revealed that more than half of patients who have faced ICD replacement did not know it was non-compulsory (Lewis, Nery, & Birnie, 2014), 27% of which would consider not replacing their ICD. In the context of older age or serious illness, 5-14% of patients would not replace the ICD, and 16% were undecided (Thylén et al., 2013). In these studies, no demographic or clinical variables suggested the type of patient who would consider not replacing their ICD generator; hence, it seems important to discuss the options with all patients. What is known is that certain demographic and clinical variables can influence patient participation in ICD decision-making

such as age, education level, health status, quality of life, experience with shocks and clinician recommendation – all of which can change over time and circumstance (Green et al., 2016; MacIver, Tibbles, Billia, & Ross, 2016; Standing et al., 2016; Lewis, Stacey, & Matlock, 2014).

The consequences of patients and family not knowing their options at the time of ICD replacement were poignantly captured in a perspective piece published in *JAMA Internal Medicine* (Diaconis, 2016). With such patients in mind, Kramer, Buxton & Zimetbaum (2012) argued in the *New England Journal of Medicine* to make ICD replacement a more deliberative process. They stated that “*a change to a more patient-centered approach will promote the individualization of a highly personal process and thereby improve patient care*” (p. 293).

To promote this patient centered approach towards values-based care and informed decision-making based on patient preferences and values, shared decision-making (SDM) can be utilized. SDM is a collaborative process that occurs between provider(s) and a patient whereby a decision regarding a patient’s health care is achieved jointly (Charles, Gafni, & Whelan, 1997; Makoul & Clayman, 2006). Friesen-Storms, Bours, van der Weijden, & Beurskensbe (2015) identified six attributes of health care interventions that influence the degree to which SDM is indicated for nursing practice. These attributes include: (a) the level of research evidence quality and certainty for the intervention, (b) the number of available options for the individual considering the decision, (c) the burden of side effects associated with the intervention, (d) impact on an individual’s lifestyle, (e) the spectrum of patient group values for the outcomes of the options, and (f) impact on resources. When considering these attributes as related to ICD therapy and/or replacement and its associated outcomes, the case for patient involvement and SDM at the point of ICD battery depletion is high (Table 1.1).

Table 1.1 Attributes of ICD Generator Replacement and Indications For SDM

Attributes	Application of Attributes to ICD therapy and/or ICD replacement	Indications for SDM (High vs Low)
1. Level of research evidence	- Strong recommendation for those who continue to meet initial implantation guidelines e.g. Primary prevention: Ischemic and non-ischemic cardiomyopathy LVEF $\leq 30\%$. Secondary prevention: cardiac arrest, sustained	Low for patients who continue to meet initial implantation indications as per clinical practice guidelines;

	VT in the presence of significant structural heart disease - Weak recommendation for those who no longer meet initial implantation indications: e.g. Ischemic and non-ischemic cardiomyopathy with improved LVEF >31% since initial ICD implantation. In patients with ICD for primary prevention, no appropriate therapies since initial implantation. Patients who are frail, who have significant comorbidities, and/or with limited life expectancy.	High for patients who no longer meet initial implantation indications.
2. Number of available options	Two: to accept or decline ICD replacement	Lower
3. Burden of side effects (undesirable consequences)	- Surgical risks - Risks associated with device - Device advisories and/or malfunctions - Shocks (appropriate or inappropriate)	High due to potential burden of side effects, which need to be weighed against benefit.
4. Impact on lifestyle	1. Physical effects - Scar and/or prominence of device generator - Impact on body image - Impact on intimacy/sex 2. Emotional effects - Psychological/psychiatric sequelae 3. Social effects - Driving restrictions	High due to potential for negative impact on lifestyle, which need to be weighed against benefit.

	- Limiting physical activity - Avoiding electromagnetic interference - Shock avoidance behaviours	
5. Patient group values	There is considerable variability in values for or against ICD therapy across patient groups. There can be considerable variability in values for ICD within an individual patient over time throughout the ICD pathway.	High, due to need to assess individual values for outcomes of options
6. Impact on healthcare system resources	Initial surgical implantation procedure with subsequent replacements as needed (Each ICD generator can cost up to \$20K). Semi-annual follow-ups. Potential for surgical complications, device infection, device and/or lead advisories or malfunctions.	High, due to significant costs associated with the procedure and follow-up

Evidence-based interventions such as patient decision aids (PDAs) and decision coaching can facilitate SDM by making explicit the decision that needs to be made, providing evidence-based information about the risks and benefits of each option and outcomes, and clarifying personal values (Légaré et al., 2014). PDAs improve knowledge, increase patient engagement, and result in choices that are concordant with patients' values (Stacey et al., 2017). However, no decision support intervention exists for adults facing ICD generator replacement. To fill this gap, a novel PDA was developed and field-tested in a feasibility trial according to International Patient Decision Aid Standards (Elwyn et al., 2006).

1.2 Guiding Theoretical Frameworks

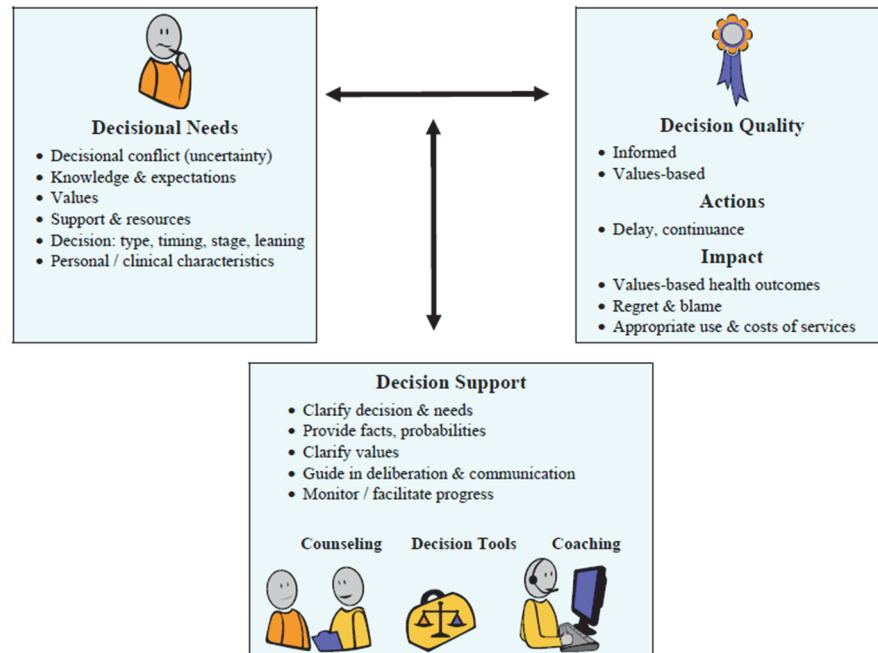
Two theoretical frameworks guided this research. The Ottawa Decision Support Framework (ODSF) (O'Connor et al., 1998) supported PDA development, and the Normalization Process Theory (NPT) (May & Finch, 2009) was used to integrate key elements of implementation throughout the design and development of the PDA in an attempt to overcome the implementation and adoption difficulties that have prevented the routine usage of PDAs in clinical practice (Elwyn et al., 2013a).

1.2.1 Ottawa Decision Support Framework

The ODSF (O'Connor et al., 1998) has been extensively used as a guide for PDA development (Durand, Stiel, Boivin, & Elwyn, 2008) (Figure 1.1). Its main goal is for patients to achieve quality decisions, defined as the extent to which the selected option matches their informed values for the benefits, risks and uncertainties for that option (O'Connor et al., 1998). The framework is based on a nursing diagnosis of decisional conflict (Janis & Mann, 1977; NANDA International, 2005), 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 when patients and their support networks have unresolved decisional needs (e.g. inadequate knowledge, unrealistic expectations, unclear values, and inadequate support) decisional quality can depreciate (O'Connor et al., 1998). Characteristics associated with the decision (e.g timing) and associated with the patient (e.g. cognitive limitations, education level, health literacy level) can also adversely impact decisional quality. Unresolved decisional needs may result in delayed decisions, feelings of regret and dissatisfaction, and in the event of poor outcomes, blame towards the clinician (O'Connor et al., 1998). Decision support interventions such as clinical counseling, PDAs and/or decision coaching can improve decision quality. The ODSF acknowledges the presence and contribution of the patient, members of their support network, and the interprofessional healthcare team in decision-making. The framework's main limitations include a restriction to individual level factors and a lack of acknowledgment of context, and implementation of the proposed decision support. The use of the ODSF for this dissertation

ensured that the essential elements needed to achieve a quality decision were included in the PDA.

Figure 1.1 The Ottawa Decision Support Framework



Note. From “Ottawa Decision Support Framework to Address Decisional Conflict” by O'Connor A.M. Reprinted with permission.

1.2.2 Normalization Process Theory

The NPT is a middle-range theory focused on 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 PDA implementation (Elwyn, Légaré, Edwards, van der Weijden, T., & May, 2008; 2013b). To achieve this theory’s goal, focus is needed on the dynamic work and social processes among key players. According to May and Finch (2009), the NPT is based on three main postulates:

1. Material practices become routinely embedded in social contexts as the result of people working, individually and collectively, to implement them.

2. The work of implementation is operationalized through four generative mechanisms (coherence, cognitive participation, collective action, reflexive monitoring).
3. The production and reproduction of a material practice requires continuous investment by agents in ensembles of action that carry forward in time and space. (p. 540)

The normalization of a complex intervention can be achieved by the practices that people engage in, the manner in which the people execute them, and what meaning the people attribute to them, which are operationalized through the four mechanisms listed above (May & Finch, 2009). 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). The implementation of PDAs into established workflows has proven difficult to date (Elwyn et al., 2013a; 2013b). In attempt to overcome these difficulties, this dissertation was navigated with the NPT to keep implementation considerations at the forefront.

1.3 Purpose of the Dissertation

The purpose of this research was to develop and conduct a feasibility trial with preliminary evaluation of a decision support intervention for patients faced with ICD replacement. The goal of this PDA was to ensure that patients are informed of the option to accept or decline ICD generator replacement, have access to probabilities of the benefits and risks of each option, and are assisted in the clarification of their values to promote a high quality choice. A novel aspect of this decision support development research was to navigate the PDA design and development process with implementation in mind, in an attempt to overcome known challenges to PDA implementation (Elwyn et al., 2013a). This multi-methods research dissertation aimed at addressing the following objectives:

Objective 1. Synthesize the evidence on patients' experience with ICD decision-making throughout the ICD pathway at implantation, replacement, and deactivation nearing end-of-life.

Objective 2. Synthesize the evidence on the risks and benefits of ICD pulse generator replacement.

Objective 3. Iteratively develop a PDA with patients, family member(s), and health professionals using synthesized evidence and prepare for its implementation in routine clinical practice.

Objective 4. Conduct a feasibility trial with preliminary effectiveness evaluation of the decision support intervention with adults facing ICD replacement.

Objective 5. Update the literature review to discuss recent challenges and advances in integrating patients' preference and values with their clinical status when making decisions about ICDs.

The content and structure for this manuscript-based dissertation is outlined in Table 1.2. To begin, an integrative review of patients' perspectives with ICD decision-making at all decision points (implantation, generator replacement, deactivation) was conducted with the aims of understanding the decisional needs of this patient population, and identifying the gaps in the literature (Objective 1). A systematic review of the risks and benefits specifically at the point of ICD generator replacement followed, for the purposes of populating the eventual PDA with synthesized and up-to-date probabilities on outcomes of the options (Objective 2). Next, a PDA was iteratively developed using an integrated knowledge translation approach (Objective 3). As part of the PDA development process, semi-structured interviews were conducted with potential end-users to obtain feedback on its acceptability and usability, and uncover ways in which it could be implemented into the established clinical workflow. Next, the PDA was field-tested in a pilot randomized controlled trial to determine the feasibility of conducting a definitive trial (Objective 4). The feasibility outcomes were ease of recruitment, intervention use, and completeness of data collection. Preliminary effectiveness data of the decision support intervention were measured on attributes of decision quality and decision-making process. Finally, the literature review was updated to determine and discuss the evolution of the state of the evidence on ICD decision-making from the time this research project was launched three and a half years ago (Objective 5).

Table 1.2 Manuscript-based Dissertation Structure and Content

Chapter	Chapter Title	Objectives	Study Design	Manuscript (with citation if applicable)
1	Introduction	To describe the research problem, research objectives, guiding theoretical frameworks, and the structure for this manuscript-based dissertation.	-	-
2	Making Decisions About Implantable Cardioverter-Defibrillators from Implantation to End of Life: An Integrative Review of Patients' Perspectives	To explore patients' decision-making experiences regarding ICDs from the decision to implant to the consideration of deactivation at end of life.	Integrative Review	Published. Lewis, K.B., Stacey, D., & Matlock, D. (2014). Making decisions about implantable cardioverter-defibrillators from implantation to end of life: An integrative review of patients' perspectives. <i>The Patient: Patient-Centered Outcomes Research</i> . 7(3), 243-260. doi: 10.1007/s40271-014-0055-2.
3	Estimating the Risks and Benefits of Implantable Cardioverter Defibrillator Generator Replacement: A Systematic Review	To synthesize the risks, benefits, and cost outcomes related to ICD pulse generator replacement.	Systematic Review	Published. Lewis, K.B., Stacey, D., Carroll, S.L., Boland, L., Sikora, L., & Birnie, D. (2016). Estimating the risks and benefits of implantable cardioverter-defibrillator generator replacement: A systematic review. <i>Pacing and Clinical Electrophysiology</i> , 39(7), 709-722. doi: 10.1111/pace.12850

4	User-centered development of a patient decision aid for implantable cardioverter-defibrillator replacement: A mixed-methods study	To develop a patient decision aid for patients facing ICD replacement and plan for its implementation.	Embedded Mixed Methods	Accepted for publication. Lewis, K.B., Birnie, D., Carroll, S.L., Clark, L., Kelly, F., Gibson, P., Rockburn, L., Rockburn, L., & Stacey, D. (in press). User-centered development and implementation planning of a patient decision aid for implantable cardioverter-defibrillator replacement: A mixed-methods study. <i>Journal of Cardiovascular Nursing</i> .
5	Feasibility of a Randomised Trial of a Decision Support Intervention for Patients Facing Implantable Cardioverter-Defibrillator Replacement	To evaluate the feasibility of conducting a future definitive trial, and obtain preliminary effectiveness of the decision support intervention on attributes of decision quality and decision-making process.	Feasibility randomized controlled trial	Manuscript prepared for submission to Circulation: Cardiovascular Quality and Outcomes.
6	Incorporating Patients' Preference Diagnosis in Implantable Cardioverter-Defibrillator Decision-Making: A Review of Recent Literature	To review recent challenges and advances with ICD decision-making in adults and to discuss shared decision-making and effective interventions as a solution to mitigate these challenges.	Narrative Review	Published. Lewis, K.B., Carroll, S.L., Birnie, D., Stacey, D., & Matlock, D.D. (2018) Incorporating Patients' Preference Diagnosis in Implantable Cardioverter-Defibrillator Decision-Making: A Review of Recent Literature. <i>Current Opinion in Cardiology</i> . 33(1), 42-49. doi: 10.1097/HCO.0000000000000464.
7	Integrated Discussion	To integrate the dissertation findings and identify implications for nursing	-	-

		practice, education, leadership, and research.		
8	Contribution of Collaborators	To describe the role of manuscript co-authors	-	-

1.4 References

- Ajzen, I. & Fishbein, M. (1980). *Understanding attitudes and predicting social behaviour*. Englewood Cliffs: Prentice Hall.
- Bandura, A. (1982). Self-efficacy mechanism in human agency. *American Psychologist*, 37, 122-147.
- Bardy, G. H., Lee, K. L., Mark, D. B., Poole, J. E., Packer, D. L., Boineau, R.,...Ip, J. H. (2005). Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *New England Journal of Medicine*, 352, 225-237.
- Bennett, M., Parkash, R., Nery, P. B., Senechal, M., Mondesert, B., Birnie, D.,...Talajic, M. (2017). Canadian Cardiovascular Society/Canadian Heart Rhythm Society 2016 Implantable Cardioverter-Defibrillator Guidelines. *The Canadian Journal of Cardiology*, 33, 174-188. doi: 10.1016/j.cjca.2016.09.009
- Charles, C., Gafni, A., & Whelan, T. (1997). Shared decision-making in the medical encounter: what does it mean? (Or it takes at least two to tango). *Social Science and Medicine*, 44, 681-692.
- Diaconis, P. (2016). I wish someone had told us the risks and benefits of replacing my father's defibrillator. *JAMA Internal Medicine*, 176(7), 885. doi:10.1001/jamainternmed.2016.1926
- Dunbar, S. B., Dougherty, C. M., Sears, S. F., Carroll, D. L., Goldstein, N. E., Mark, D. B.,...Zeigler, V. L. (2012). Implantable cardioverter defibrillators and their families: A scientific statement from educational and psychological interventions to improve outcomes for recipients of the American Heart Association. *Circulation*, 126, 2146-2172. doi: 10.1161/CIR.0b013e31825d59fd
- Durand, M. A., Stiel, M., Boivin, J., & Elwyn, G. (2008). Where is the theory? Evaluating the theoretical frameworks described in decision support technologies. *Patient Education & Counseling*, 71(1), 125-135. doi: 10.1016/j.pec.2007.12.004.
- Elwyn, G., Grande, S. W., Hoffer Gittel, J. H., Godfrey, M. M., & Collins Vidal, D. (2013b). *Are we there yet? Case studies of implementing decision support for patients*. New Hampshire: The Dartmouth Institute.
- Elwyn, G., Légaré, F., Edwards, A., van der Weijden, T., & May, C. (2008). Arduous implementation: Does the normalization process model explain why it's so difficult to embed decision support technologies in routine clinical practice. *Implementation Science*, 3, 57. doi: 10.1186/1748-5908-3-57
- Elwyn, G., O'Connor, A., Stacey, D., Volk, R., Edwards, A., Coulter, A.,...Whelan, T. (2006). Developing a quality criteria framework for patient decision aids: online international Delphi consensus process, *BMJ*, 333(7565), 417.

- Elwyn, G., Scholl, I., Tietbohl, C., Mann, M., Edwards, A., Clay, K.,... Frosch, D. (2013a). "Many miles to go...": A systematic review of the implementation of patient decision support interventions into routine clinical practice. *BMC Medical Informatics and Decision Making*, 13(Suppl 2), S14. doi: 10.1186/1472-6947-13-S2-S14
- Fishman, G. I., Chugh, S. S., Dimarco, J. P., Albert, C. M., Anderson, M. E., Bonow, R. O.,...Zheng, Z. J. (2010). Sudden cardiac death prediction and prevention: report from a national heart, lung, and blood institute and Heart Rhythm Society workshop. *Circulation*, 122, 2335-2348. doi: 10.1161/CIRCULATIONAHA.110.976092.
- Friesen-Storms, J. H. H. M., Bours, G. J. J. W., van der Weijden, T., & Beurskensbe, A. J. H. M. (2015). Shared decision making in chronic care in the context of evidence based practice in nursing. *International Journal of Nursing Studies*, 52, 393-402. doi: 10.1016/j.ijnurstu.2014.06.012
- Goonewardene, M., Barra, S., Heck, P., Begley, D., Fynn, S., Virdee, M.,...Agarwal, S. (2015). Cardioverter-defibrillator implantation and generator replacement in the octogenarian. *Europace*, 17(3), 409-416. doi: 10.1093/europace/euu248.
- Green, A. R., Jenkins, A., Masoudi, F. A., Magid, D. J., Kutner, J. S., Leff, B., & Matlock, D. D. (2016). Decision-making experiences of patients with implantable cardioverter defibrillators. *Pacing and Clinical Electrophysiology*, 39, 1061-1069. doi: 10.1111/pace.12943
- Janis, I. L. & Mann, L. (1977). *Decision making*. New York: The Free Press.
- Keeney, R. L. & Raiffa, H. (1976). *Decisions with multiple objectives: Preferences and value tradeoffs*. New York: John Wiley and Sons.
- Kramer, D. B., Buxton, A. E., & Zimetbaum, P. J. (2012). Time for a change - a new approach to ICD replacement. *New England Journal of Medicine*, 366(4), 291-293. doi: 10.1056/NEJMp1111467
- Kramer, D. B., Kennedy, K. F., Noseworthy, P. A., Buxton, A. E., Josephson, M. E., Normand, S. L.,... Mitchell, L. S. (2013). Characteristics and outcomes of patients receiving new and replacement implantable cardioverter-defibrillators: results from the NCDR. *Circulation: Cardiovascular Quality and Outcomes*, 6(4), 488-497. doi: 10.1161/CIRCOUTCOMES.111.000054
- Légaré, F., Stacey, D., Turcotte, S., Cossi, M. J., Kryworuchko, J., Graham, I. D.,...Donner-Banzhoff, N. (2014). Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database Systematic Reviews*, 15(9), CD006732. doi: 10.1002/14651858.CD006732.pub3
- Lewis, K. B., Nery, P. B., & Birnie, D. H. (2014). Decision-making at the time of ICD generator change: patients' perspectives. *JAMA Internal Medicine*, 174(9), 1508-1511. doi:10.1001/jamainternmed.2014.3435

- Lewis, K. B., Stacey, D., & Matlock, D. D. (2014). Making decisions about implantable cardioverter-defibrillators from implantation to end of life: An integrative review of patients' perspectives. *The Patient – Patient Centered Outcomes*, 7(3), 243-260. doi: 10.1007/s40271-014-0055-2
- MacIver, J., Tibbles, A., Billia, F., & Ross, H. (2016). Patient perceptions of implantable cardioverter-defibrillator deactivation discussions: A qualitative study. *SAGE Open Medicine*, 4, 1-8. doi: 10.1177/2050312116642693
- Madeira, M., António, N., Milner, J., Ventura, M., Cristóvão, J., Costa, M.,...Mariano Pego, G. (2017). Who still remains at risk of arrhythmic death at time of implantable cardioverter defibrillator generator replacement? *Pacing and Clinical Electrophysiology*. Epub ahead of publication: Available online 27 Aug 2017. doi: 10.1111/pace.13163.
- Makoul, G., & Clayman, M. L. (2006). An integrative model of shared decision making in medical encounters. *Patient Education and Counselling*, 60, 301-312.
- Manolis, A. S., Maounis, T., Koulouris, S., & Vassilikos, V. (2017). "Real life" longevity of implantable cardioverter-defibrillator devices. *Clinical Cardiology*, 40(9), 759-764. doi: 10.1002/clc.22729
- May, C. & Finch, T. (2009). Implementing, embedding, and integrating practices: An outline of normalization process theory. *Sociology*, 43(3), 535-554. doi: 10.1177/0038038509103208
- May, C. R., Mair, F., Finch, T., MacFarlane, A., Dowrick, C., Treweek, S.,...Montori, V. (2009). Development of a theory of implementation and integration: Normalization process theory. *Implementation Science*, 4, 29. doi:10.1186/1748-5908-4-29
- Moss, A. J., Zareba, W., Hall, W. J., Klein, H., Wilber, D. J., Cannom, D. S.,...Andrews, M. L. (2002). Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *New England Journal of Medicine*, 346(12), 877-883.
- NANDA International. (2005). *NANDA Nursing diagnoses: Definitions & classification 2005-2006*. Philadelphia: Author
- O'Connor, A. M., Tugwell, P., Wells, G. A., Elmslie, T., Jolly, E., Hollingworth, G.,...Drake, E. (1998). A decision aid for women considering hormone therapy after menopause: Decision support framework and evaluation. *Patient Education and Counseling*, 33(3), 267-279.
- Orem, D. E. (1995). *Nursing: Concepts of practice*. 5th ed. Toronto Mosby.
- Philippon, F., Sterns, L. D., Nery, P. B., Parkash, R., Birnie, D., Rinne, C.,...Bennett, M. (2017). Management of implantable cardioverter defibrillator recipients: Care beyond guidelines. *Canadian Journal of Cardiology*, 33, 977-990. doi: 10.1016/j.cjca.2017.05.012
- Simpson, C. S., Hoffmaster, B., & Dorian, P. (2005). Downward delegation of implantable cardioverter defibrillator decision-making in a restricted-resource environment: the pitfalls of bedside rationing. *Canadian Journal of Cardiology*, 21, 595-599.

- Stacey, D., Légaré, F., Lewis, K., Barry, M. J., Bennett, C. L., Eden, K. B., ...Trevena, L. (2017). Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews*, 12(4), CD001431. doi: 10.1002/14651858.CD001431.pub5
- Standing, H., Exley, C., Flynn, D., Hughes, J., Joyce, K., Lobban, T., ...Thomson, R. G. (2016). A qualitative study of decision-making about the implantation of cardioverter defibrillators and deactivation during end-of-life care. *Health Services and Delivery Research*, 4, 32.
- Thylén, I., Moser, D. K., Chung, M. L., Miller, J., Fluor, C., & Stromberg, A. (2013). Are ICD recipients able to foresee if they want to withdraw therapy or deactivate defibrillator shocks? *IJC Heart & Vessels*, 1, 22-31. doi: 10.1016/j.ijchv.2013.11.001
- Tversky, A., & Kahneman, D. (1981). The framing of decisions and the psychology of choice. *Science*, 211, 453-458.
- Weng, W., Sapp, J., Doucette, S., MacIntyre, C., Gray, C., Gardner, M., ...Parkash, R. (2017). Benefit of Implantable Cardioverter-Defibrillator Generator Replacement in a Primary Prevention Population-Based Cohort. *JACC: Clinical Electrophysiology*. Epub ahead of print: Available online 31 May 2017. doi: 10.1016/j.jacep.2017.03.004
- Wennberg, J. E. (2002). Unwarranted variations in healthcare delivery: implications for academic medical centres. *British Medical Journal*, 325(7370), 961-964.
- Zanon, F., Martignani, C., Ammendola, E., Menardi, E., Narducci, M. L., Filippo, P., ...Biffi, M. (2016). Device longevity in a contemporary cohort of ICD/CRT-D patients undergoing device replacement. *Journal of Cardiovascular Electrophysiology*, 27(7), 840-845. doi: 10.1111/jce.12990

Chapter 2 : Making Decisions about Implantable Cardioverter-Defibrillators from Implantation to End-of-Life: An Integrative Review of Patients' Perspectives

Published: Lewis, K.B., Stacey, D., & Matlock, D. (2014). Making decisions about implantable cardioverter-defibrillators from implantation to end of life: An integrative review of patients' perspectives. *The Patient: Patient-Centered Outcomes Research*. 7(3), 243-260. doi: 10.1007/s40271-014-0055-2.

Abstract

Implantable cardioverter-defibrillators (ICD) are used for patients at risk of sudden cardiac death. Patients considering ICD therapy are faced with several preference-sensitive decisions. Our aim was to explore patients' ICD decision-making experiences from the decision to implant to the consideration of deactivation at end-of-life. We conducted an integrative review using Whittemore and Knafl's five steps. Medline, CINAHL, PubMed, PsycINFO, and the Cochrane library were searched from 2000 to 2013. Eligible studies focused on the patient response regarding ICD decision-making. Key themes were identified and used as a framework to discuss findings through the chronological course of decisions faced by these patients. Of 354 potential citations, 25 articles were included. The trajectory of key decision points were whether or not to initiate ICD therapy, replace the battery, and deactivate at end-of-life. Three common themes from patients' perspectives were: the influence of the patient-practitioner consultation on knowledge uptake, patients' decision-making preference, and their desire to live. Patients faced with ICD-related decisions often misunderstood the functionality of their ICD, or overestimated its benefit. They also expressed mixed preferences for desire to be involved in decisions. The decisions around ICDs are particularly difficult for patients given the life and death trade off. Clinicians involved in the care of these patients could better support them by verifying their understanding and eliciting their preferences. Using a shared decision-making approach has the potential to achieve improved patient outcomes.

Key Points for Decision Makers

- When a patient is identified as a potential candidate for an implantable cardioverter-defibrillator (ICD), they embark upon a decision-making trajectory for the tenure of their implanted device.
- To achieve informed consent, patients need to understand their options (including the option to deactivate the device) and the benefits and harms of ICD therapy.
- Given the chronic nature of the condition, patients will need to revisit their decision to maintain ICD therapy with battery changes and/or as their health state changes.
- Clinicians could better support patients facing these decisions by using a shared decision-making approach.

2.1 Introduction

Clinical evidence supports the use of implantable cardioverter-defibrillators (ICD) for patients at risk of sustained ventricular arrhythmias and sudden cardiac death.(1-3) ICD therapy used for patients who have survived a cardiac arrest or a sustained ventricular arrhythmia is referred to as a secondary prevention indication.(4) Primary prevention ICDs are indicated in patients who have been identified as high risk for sudden cardiac death based on their underlying cardiac condition, but who have not yet had a sustained ventricular arrhythmia.(4) Along with its life-saving potential, ICDs are associated with procedural risks,(5-7) inappropriate shocks,(8) psychological risks(9, 10) and the potential for harm and suffering at end-of-life.(11-13) ICD therapy is considered a preference-sensitive treatment choice as an individual can value its benefits and burdens differently than others.(14) Moreover, a person's value for their life-saving device may diminish as their health and contextual circumstances change.(15) The goal for preference-sensitive decisions is to achieve a higher quality decision based on current scientific evidence and consistent with patients' informed values and preferences.(16, 17)

Patients with ICDs are faced with a series of decisions including the initial implantation, battery replacement, and deactivation. Each ICD decision point warrants careful consideration to verify that patients understand their treatment options, and to ensure that their preferences are actively elicited and honoured. This can be achieved by adopting a shared decision-making approach where clinicians and patients share the best available evidence when faced with health-related decisions, and where patients are supported to consider options to achieve informed preferences.(18) Shared decision making supports the tenets of patient centered care.(19-21) Health care professionals' ethical and legal responsibilities of informing patients prior to medical interventions are explicitly clear. To achieve informed consent a patient must have received all relevant information about a treatment, including the treatment's nature, benefits, risks, and alternatives, and have their related queries answered prior to making a decision.(22) However, engaging informed patients in their personal medical decisions and honouring their preferences is more challenging. An increasing number of patients have shifted from being passive bystanders to active participants in the clinical decision-making process. Yet many patients feel uncertain about the best course of action and need support to be engaged in decisions about their health.(23)

The aim of our integrative review was to explore patients' decision making experiences regarding ICDs from the decision to implant to the consideration of deactivation at end-of-life, in the interest of helping health care professionals enhance the care and support they provide.

2.2 Methods

We conducted an integrative review using Whittemore and Knalf's five-step approach.(24) The five steps include the identification of a problem, literature review, data evaluation, data analysis, and the dissemination of findings. The Ottawa Decision Support Framework was used as a theoretical framework, which asserts that patients and their support networks' unresolved decisional needs affect decisional quality.(25)

A search strategy was designed with a reference librarian and conducted using Medline, CINAHL, PubMed, PsycINFO, and the Cochrane library from January 2000 to November 2013. We restricted the search to the last 13 years given the dramatic increase in ICD utilization in the early 2000s; particularly when ICDs for primary prevention became indicated. The following terms were searched: implantable defibrillators, ventricular arrhythmia, cardiac arrhythmia, patient preference, decision-making, choice behaviour, patient participation, deactivation, and end-of-life. We included original quantitative and qualitative research articles that directly studied the patient response regarding ICD decision-making. Patients had to be 18 years of age or older and ICD eligibility could be for either primary or secondary prevention. Exclusion criteria were articles that did not incorporate the patient's perspective, if they solely focused on living with or adjusting to the ICD, or if they only included other implantable devices such as pacemakers and cardiac resynchronization therapy. Case studies, reviews, discussion papers, and those not published in English were excluded. Reference lists of included articles were reviewed.

Titles and abstracts were screened for inclusion. Full-texts were reviewed for eligible articles by KL and article inclusion was verified with DDM. Study appraisal was conducted by KL using the Mixed Methods Appraisal Tool,(26, 27) which evaluates the methodological quality of each study on criteria specific to its design. For each criteria met, one point is allocated for a maximum of four points. Scores are divided by four then multiplied by 100 to get a percentage score. For mixed methods studies, the overall quality score cannot exceed the score of its weakest component. As this review was an attempt to capture a comprehensive account of

patient preferences, the tool was not used to exclude studies but rather to appraise their methodological quality.

To identify themes, qualitative data analysis was approached using a constant comparative method. Data reduction involved the extraction, coding, and grouping of data into systematic categories. Using an iterative process, data were compared to identify patterns, relationships, and themes. These were used to interpret the data, and the final themes were verified with the original articles for accuracy and confirmability.

2.3 Findings

2.3.1 Study demographics

A total of 354 articles were identified. Of 68 studies reviewed as full-text, 50 were excluded as they did not directly relate to the patient's decision-making experience. Hand searching of reference lists of included articles revealed six articles. A more recent article meeting inclusion criteria was identified during the peer review process, resulting in a total of 25 included studies.

Details of the 25 included studies which addressed the patients' perspectives surrounding ICD decision-making are described in Table 2.1. The number of patients with ICDs per study ranged from 8 to 3,067 patients and totalled 5,321 across all studies. There were 1,205 women, and 3,788 men. Two studies did not report sex of participants. Studies either included patients with primary prevention ICDs (n=7), secondary prevention (n=1), both (n=6), or did not report (n=11). Across studies there were various cardiac etiologies, length of time with the ICD, and total shocks received. Perspectives of family members and support systems were only sought in one retrospective study assessing end-of-life experiences for deceased patients as remembered by their next of kin.

We identified three common decision points: the decision to implant the ICD (n=8 studies), replace the battery (n=1), deactivate ICD therapies (n=14), and both ICD replacement and deactivation (n=2) (see Table 2.1).

2.3.2 Themes

Three key themes emerged from this analysis: the influence of the patient-practitioner consultation on knowledge uptake, patients' decision-making preference, and their desire to live. Each category influenced the other, and were all mediated by factors such as the patient's health status, social influence, and trust in their physician. These themes will be explored through the chronological course of decisions faced by patients with ICDs.

2.3.2.1 The decision to implant the ICD (n=8 studies)

The decision to implant an ICD was studied by the authors of eight studies, three of which included the perspective of patients who declined the ICD. Aside from these patients, all others had already accepted or received their ICD. None of these studies captured the process while the patient was contemplating the decision. Six studies utilized qualitative methodologies, including semi-structured interviews (n=3), grounded theory (n=2), and the combination of focus groups and individualized interviews (n=1). There was one mixed methods study, and one non-experimental survey study.

2.3.2.1.1 The influence of the patient-practitioner consultation. Hauptman et al. asserted that patient-physician communication is characterized by the omission of information.(28) Several studies have supported this belief. Some patients could not recall discussions regarding treatment alternatives to the ICD,(29, 30) operative complications,(31) ICD recalls,(28) psychological risks,(28) or prognosis.(29) The overestimation of device benefits and misunderstanding of device function were also frequently reported.(32-38) For some patients, the best source of understanding the ICD's impact on lifestyle, was the opportunity to personally experience its benefits and burdens.(28, 39, 40) In one study, some patients' inability to recall was attributed to altered cognition, as the initial consultation occurred in the hospital, mere days or weeks following a cardiac arrest.(29) Alternatively, in a cohort of 75 patients, 79% believed they had received sufficient information prior to implantation. In that same cohort, 83% claimed to understand the reason for ICD implantation, yet when a subgroup of 25 were asked to describe, no patient suggested the termination of potentially life-threatening arrhythmia.(31)

The length of time used to deliberate about the ICD when first offered differed amongst patients. The entire process took only minutes for some, and up to two years for others.(30) In

particular, patients who were actively involved in decision-making required more time to reflect.(41) Whereas another study reported that all decisions were made quickly - particularly for those in hospital - as very few subjects were offered time to contemplate the decision. (28) Some patients accepted the ICD, after reconsideration of their initial refusal.(30) This suggests that preferences can fluctuate within the same individual over time.(30)

2.3.2.1.2 Types of decision-making preferences. Patients faced with the decision to accept or decline an ICD approached their decision-making either actively or passively.(30, 31, 39, 42) ICD uptake or refusal did not appear to correlate with a person's degree of involvement.(30) Active decision-makers were engaged, sought multiple opinions and information from various sources, and assumed control.(30, 39) They carefully considered their health state, balanced their risk for sudden cardiac death against the benefits of the device, and contemplated the impact of their potential sudden death on their family.(30, 42) Despite this perceived independence, active decision-makers sought reassurance from both their practitioners and family members.(42) Passive decision-makers showed signs of indifference, and deferred decision-making control to others.(28, 30, 31, 39, 42) In three studies, this was actually the preferred decision-making style.(29-31) Due to the perceived complexity of the information, some patients did not believe they were adequately prepared to make the decision.(29, 30, 41) Some did not even see the decision as theirs to make.(30, 42) Reasons for this include the fact that their life had been threatened and living was the only option,(29, 42) trust in God,(39) and trust in their physician's recommendation.(29, 30, 39, 41)

Those who declined the ICD could also be distinguished as active or passive decision-makers.(30, 39, 40) Passive decision-makers either minimized their risk of sudden cardiac death,(30, 39, 40) were disinterested,(30) or perceived the ICD to be a purely elective option.(40) Decliners who adopted an active decision-making style carefully balanced the benefits and harms, and determined that the burdens outweighed the benefits.(30, 39) Others reported that they were pleased with the current status of their lives and preferred to avoid invasive life-prolonging procedures.(30, 40) One patient considered the benefit of a sudden death against other modes of death.(39)

2.3.2.1.3 The will to live. When patients were first informed of their risk for sudden cardiac death, fear and uncertainty about the future characterized many of their responses.(28, 30, 31) The risk of sudden death and the chance for survival are powerful incentives for patients to accept an ICD. For the majority of patients faced with this reality, living was the only option.(30, 39) For many, the inconveniences of the device were worth the possibility that life could be saved. Accepting the ICD was a means to control fear and achieve a sense of security.(28, 31, 42)

Four studies included patients who declined the ICD.(30, 38-40) One patient understood that an ICD would deny him the "luxury of a sudden death."(p. 9)(38) Another patient weighed quality versus quantity of life and preferred to live out the former. Some patients expressed that accepting the ICD equated with acceptance of their risk for sudden death, which they would rather ignore.(30) It is impossible to know the distribution of patients who accepted versus declined an ICD; however, for those with ICDs, satisfaction rates ranged from 93% to 100%.(29, 31)

2.3.2.2 The decision to replace the battery (n=3 studies)

Three studies included in this review considered patient preferences at ICD battery replacement. One survey study was concerned with the decision to replace the battery when an ICD had been recalled by the manufacturer. A semi-structured interview-based study considered patients' opinions and their hypothetical choice between replacement and non-replacement for a depleted battery. In a third survey study, ICD patients were asked about their preferences for battery replacement at end-of-service indicator.

2.3.2.2.1 The influence of the patient-practitioner consultation. Gibson et al. focused on patients' decision-making processes when an ICD had been recalled by the manufacturer.(43) All 31 patients were sent a notification letter from their physician yet only 61% of patients remembered receiving it. The letter was supplemented by an in-clinic discussion. Although, patients did not have to think back to the initial consultation to remember the implications of a recall, over 33% of patients incorrectly recalled the risk of device failure and 71% overestimated the rate of failure. Nineteen percent of patients chose to remove and replace their recalled device, 16% were undecided, and 65% chose not to replace it. The option of removal and non-

replacement was not discussed. Fluor et al. conducted semi-structured interviews and focused on patients' knowledge of the ICD, and their thoughts on the battery replacement process.(33) This study revealed similar misunderstandings of device functions and overestimation of device benefits. Some patients could not think of an occurrence when the ICD could cause harm, which could explain why the majority had never reflected on any other option but to replace the battery. In Thylén et al.'s survey study, 25% of their sample had undergone battery replacement in the past.(44) The remaining 75% answered the survey's battery replacement questions hypothetically. Discussions about battery replacement occurred 43% of the time, but it was unclear if the option of non-replacement was part of their discussions. Even if ICD therapies were not needed during the first generator's life, 79% said they would replace the battery, 16% could not decide, and 5% would not. Younger patients, those with lower education levels, and depressive symptoms were more likely to not want replacement. If very old or seriously ill, the proportions changed slightly to 63% and 55% wanting replacement, 27% and 34% were unsure, and 10% and 11%, respectively, did not want the battery replaced in these circumstances.(44)

2.3.2.2.2 Types of decision-making preferences. Little information was provided about patients' preferred level of involvement in decision-making in these three studies. For patients affected by the recall, there was no information as to how or why that decision was made.(43) Fluor et al. identified this replacement decision as "standing at crossroads," whereby some individuals could choose an option without question, while others deliberately reflected.(33) Active decision-makers deliberately reflected about the future and their prognosis. Some reported they "had already lived on overtime" (p. 205)(33) and therefore considered the battery replacement non-imperative. Others deferred the decision to their trusted physician, reflecting a passive decision-making style.(33) These patients ignored their illness trajectory, and rather, lived one day at a time.(33)

2.3.2.2.3 The will to live. At this decision point, patients described the ICD objectively, rather than in existential terms. Replacement of the ICD was considered a necessity, "like an auxiliary engine that required regular service."(p. 205)(33) Others would not live without it because they considered it their lifesaver from all causes of death.(33) Some patients understood that their health status was poor and their heart condition would continue to deteriorate, and thus deliberated replacement. Regardless of shock history, the vast majority stated they would replace

the battery.(33) In some cases, patients had been advised by their physician not to replace the battery, but nevertheless proceeded with the change.

2.3.2.3 The decision to deactivate ICD therapies (n=16 studies)

Of 16 articles which explored patients' preferences regarding the decision to deactivate their ICD, 13 measured patients' preferences in hypothetical scenarios (such as terminal illness and decreased quality of life) and three reviewed the decisions and expressed preferences of deceased patients - or their next of kin - in the last moments before their death. There was a combination of qualitative methodologies, such as focus groups (n=1), interviews (n=1), and grounded theory (n=1), and nonexperimental survey studies (n=11) and chart reviews (n=2).

2.3.2.3.1 The influence of the patient-practitioner consultation. Inaccuracies prevailed when patients were questioned about ICD deactivation. Raphael et al.(45) identified two barriers to deactivation discussions: the patient's understanding of the device, and the physician's willingness to broach the subject. Patients in four studies believed that deactivation would cause immediate death and was akin to euthanasia or assisted suicide.(33, 36, 46, 47) One of these studies found that 57% of their patient cohort questioned the legality of ICD deactivation. (47) In five studies, the majority of participants had never discussed the possibility of deactivation with their physician, and therefore were unaware of the option.(33-36, 38, 44) Whereas in two recently published articles, Raphael et al.(45) and Pederson et al.,(48) reported that 38% and 68% of patients respectively knew that device deactivation was possible. Knowing when to broach this topic of discussion with patients has been debated. Fear of reducing hope or causing distress has often delayed this conversation. Yet, according to findings from an interview based study, none of the 54 subjects found the topic distressing.(45) In fact, those who had previously received shocks, were more likely to think deactivation should be discussed.(44, 45) Of surveyed patients, 49 to 52% of patients believed that device deactivation should be addressed prior to insertion.(44, 45, 48) Others preferred to discuss it when life expectancy decreased and when end-of-life neared.(33, 44, 45, 48) Thylén et al. reported that 40% of patients never wanted the physician to initiate a discussion, with 85% stating that they would prefer to broach the topic on their own terms.(44)

The studies concerned with patients' preferences for deactivation at end-of-life revealed variations in preferred course of action. In one study of patients with malignant tumors, ICD deactivation was extensively discussed with 6 of 8 patients.(49) None wished to abandon ICD therapy. Lewis et al. conducted a post-mortem chart review designed to assess the efficacy of a comprehensive care approach for 20 terminally ill patients with ICDs.(50) All 20 patients requested deactivation of therapies, and therefore, did not experience shocks at end-of-life. These patients were compared to another group of deceased patients, who were never classified as terminally ill. None had their shock therapy disabled, and 21% received shocks within 30 days of their death, significantly closer to their time of death as compared with the other group ($p=0.04$). Goldstein et al. reported that having a 'do not resuscitate' status and a higher Charlston comorbidity score was statistically significant with having a discussion about ICD deactivation.(34) Yet, there was no association between having a living will or health care proxy.(34) Of their 100 patient cohort, 27 next of kin recalled a discussion regarding ICD deactivation, six of which occurred in the last hours, and one in the last minutes prior to death.

2.3.2.3.2 Types of decision-making preferences. In regards to deactivation decisions, some patients preferred that the physician make the decision,(34, 45) while others wanted to be involved.(45, 49) For example, in a study of deceased patients with malignant tumors, all patients were relieved that they were given the option to decide for themselves.(49) However, in a focus group study, the 15 patients would only discuss hypothetical deactivation in terms of their preferred role in decision-making.(34) Patient quotes were indicative of passive decision-making styles, and expressed that the physician should make the decision. For patients who thought deactivation should not be routinely discussed, they feared that the information may be too confusing, that deactivation may prematurely end life, and therefore concluded it was a decision best left to the physician.(45)

2.3.2.3.3 The will to live. At initial implant, only 7-12% of patients identified a time when they would consider the abandonment of ICD therapies.(28, 51) When ICD recipients were asked about deactivation in hypothetical terms, the majority showed great reluctance in turning off their device, even in the setting of multiple shocks,(33, 37) if they were given a 1 month prognosis,(37) or if dyspneic at rest.(37) Others expressed a desire to deactivate in the setting of terminal illness,(32, 33, 35-37, 45, 51) impaired quality of life,(32, 48, 51) and to avoid shock-

related pain.(45, 48) Thylén et al. reported considerable indecisiveness, particularly from women, those with depressive symptoms, and those with worse ICD experiences, about engaging in deactivation discussions and expressing preferences.(44)

The authors of the one study that reported the highest number of patients who would choose deactivation (71%), had presented them with hypothetical scenarios representing various functional and cognitive limitations.(32) Another study reported that 47% of patients with ICDs would deactivate it should their condition deteriorate.(35) Incidentally, these two groups selected their deactivation preferences immediately following an informational script of the benefits and burdens of ICD therapy, suggesting that a review of the ICD's function preceding these discussions may be useful to enhance understanding.

When asked about deactivation at end-of-life, some patients chose deactivation while others did not. In a retrospective chart study of eight deceased patients with malignant tumours, none wished to abandon therapies,(49) whereas another study identified that all 20 patients with terminal illness requested deactivation.(50) In a third study, out of 100 patients, there were 27 device deactivation discussions for which 21 deactivations were requested and performed in the days, hours, or minutes before death.(11) The reduction of unwanted shocks is a benefit of device deactivation at end-of-life, as indicated by patients who preferred ICD deactivation to be able to have a quick and natural death.(33, 45, 48)

2.4 Discussion

The purpose of this integrative review was to explore patients' perceptions or concerns about their decision-making experiences around ICDs in the interest of helping health care professionals enhance the care and support they provide. We also sought to reveal patients' perspectives and preferences regarding ICD decision-making, and what factors influence their decision-making. The three main themes that appeared to influence patients' decisions across studies were the influence of the patient-practitioner consultation on knowledge uptake, patients' decision-making preferences, and a patient's desire to live. The main findings of this review revealed a significant degree of misunderstanding and inaccurate recall of information regarding ICD function at all decision points. In terms of deactivation decisions, the majority of patients were not aware of this option. Furthermore, when they are informed, their preferences for

deactivation need to be considered in the context of their health status. What a patient might opt to do when presented with a hypothetical scenario, versus what they may actually do when faced with terminal illness may differ. Finally, our findings suggest that for the majority of patients, their desire to live overrules the inconveniences of the device - unless they have considered the value trade-off between a prolonged death versus a sudden one.

Patients' perceptions and misunderstandings of the functionality of ICDs impede ICD management particularly in discussions about decisions. In contrast to our findings, 93% of surveyed cardiologists believe patients understand the intricacies of device functioning.(52) These rates of misunderstanding do not solely reflect patient-practitioner communication problems, but also suggest that patients have difficulty with information uptake and assimilation. This may be explained by numerous factors as outlined here. There may be significant practice variations amongst clinicians or organizational cultures which may result in patients being offered different amounts, types, or sources of information.(53) Also, patients' decision-making preference, whether active or passive, and their health literacy levels may affect their ability to understand information. Comprehension is fundamental to informed consent.(22) Strategies are needed to verify patients' understanding of information. Patient decision aids are effective interventions that can help patients participate in these decisions. Patient decision aids are evidence-based tools that make explicit the decision to be made, provide information on options, benefits, and harms, and help patients clarify their values in association with the options.(54) Evidence from 115 randomized controlled trials show they improve patients' knowledge, expectations of outcomes, participation in decision making, and improve the values-choice concordance.(54) Although decision aids are effective, none of the articles included in this review evaluated patient decision aids for patients facing decisions about ICDs. Patient decision aids for the initial decision to implant an ICD exist.(55, 56) The development and feasibility testing of a patient decision aid for primary prevention ICDs is ongoing.(57)

Many patients and next of kin are unaware of the possibility to deactivate the ICD. Our findings suggest that many of these discussions only occur when the practitioner chooses to introduce the subject - if they do at all. In many cases, this introduction occurs when end-of-life is near, limiting a patient and their family the time to reflect upon this complex decision. If too late, patients may be subjected to unwanted shocks. By sharing this information earlier in the

trajectory, patients are granted a degree of control to re-initiate the discussion when they are prepared. The majority (84%) of over 3,000 surveyed patients with ICDs reported that broaching the topic themselves is their preference.(44) This information will also grant them the knowledge required to establish advanced directives. Few patients with ICDs have advanced directives, but those who do are more likely to express preferences for deactivation. (51) Amongst them, however, only 0 to 8% included their preference for the ICD in their advanced directives.(35, 47, 51) The use of advanced directives has been cautioned as some individuals may dramatically revise what they want and accept as treatment when faced with the alternative of death.(58) With this in mind, when eliciting patients' preferences for deactivation, their responses need to be considered in the context of their health status. What remains unclear is when healthy patients express their preferences for deactivation in certain scenarios, do these same preferences hold when they are terminally ill? Contextual influences are unpredictable and powerful, and so it is difficult to foresee how one may act when faced with decline and impending death.

For the most part, patients' desire to live trumped the inconveniences of the ICD. The ICD can be described in terms of a "one-value trade off" with death. In an existential sense, the ICD is meant to save a life of quality, but when considered from a different person's perspective or by the same person at a different time, it can be viewed with potential for undue suffering and harm. The wide range of deactivation rates amongst the studies at end-of-life highlight the preference-sensitive nature of this decision. Increasingly, patients want control over their end-of-life experiences, and for ICD patients, discussing deactivation is an important and justifiable way to achieve this. The multidisciplinary comprehensive counselling approach adopted in Lewis et al. may have helped terminally ill patients and their families understand and contextualize the trade-off more clearly.(50) Practitioners need to be clear about the potential for pain and suffering from repeated firings at end-of-life, and that for some, a sudden death may be a better mode of dying.

There appears to be increasing interest in understanding how to integrate patient preferences into ICD decision-making particularly given the number of articles published on this topic within the last nine years (Figure 2.1). Consideration for patient preferences emphasizes a patient centered care approach, which is axiomatic to the delivery of quality care. Rather than idolize an increasing rate of implantation and productivity, we should begin to measure and

improve the rate and quality of discussions that occur over the device's lifetime to ensure that patients' initial and subsequent decisions are informed, and reflective of their preferences.(59)

2.5 Limitations

Our findings are limited by the fact that various methodologies have been included, which do not lend themselves easily to a collective analysis. However, the five-step integrative review framework(24) we have utilized facilitates such combinations, and common themes were clearly revealed. Second, given the uniqueness of ICD therapy, these findings are not transferable to other forms of implantable devices. Third, there was little emphasis on the presence of family members and support persons during consultations. Their presence is an important component of patient centered care(60), and they can adopt an influential role in information recall and decision-making. Some limitations were inherent to the studies included in the review. Many of the studies were from single centres and retrospective in nature. A high degree of recall bias may exist as subjects may not clearly remember the details of past discussions. Only two studies provided a clear blueprint of the consent procedures, making it difficult to know which factors contributed to better understanding and recall.

2.6 Future Directions

The legal and ethical imperative of informed consent binds clinicians to a comprehensive discussion prior to the initial implantation. Yet, this discussion should not be limited to that sole decision-making point. Nurses, physicians, and all other health care professionals involved in the care of these patients need to consider ICD therapy as a trajectory of dynamic decisions; decisions that are subject to review. The decision-making points highlighted in this review are three of plenty opportune moments to reiterate the benefits and burdens, confirm understanding, and present options in a balanced and transparent manner. Strategies are needed to bridge the gap in comprehension, such as confirmation of understanding, the use of support tools, and the presence of support persons. A patient's non-cardiac medical history should also be actively monitored to initiate timely deactivation discussion and allow adequate time for reflection and deliberation.

Future research should consider investigating the effect of patient decision-making styles and practitioners' consultation approach on patients' understanding and uptake of information. It

remains unclear if a patient's mood or mental health state has any effect on ICD decision-making, and if so, how these factors may influence the decision. Future multicentre research could be designed to dilute the effect of practice and institutional variations. Longitudinal studies could follow patients through this decision-making journey, and assess whether initial patient perceptions can predict future decision-making. Finally, there is a paucity of information regarding decision-making processes at battery replacement. More research is required to know how best to advocate for patients and their support persons at this increasingly common decision-making point.

2.7 Conclusion

The decisions around ICDs are particularly difficult for patients given the life and death trade off. Whether or not patients want to make decisions related to their ICDs, informed consent requires that patients understand the benefits and harms of ICDs and are aware of alternative options. By helping patients explore their preferences, they can be better supported to participate in several elements of a shared decision-making process and achieve higher quality decisions. Otherwise, we risk inappropriately using a treatment modality that informed patients simply do not want, or when standing at life's crossroads, may no longer value.

Table 2.1 Characteristics of Included Studies

IMPLANTATION				
Author (Year) Country	Purpose and Method	Participants	Main findings	Critical Appraisal with Mixed Methods Appraisal Tool (MMAT) score
Agard et al. (2007) Sweden	To explore how patients referred for secondary prevention ICD experience the consent procedure and view their role in the decision-making process. Qualitative, semi-structured interviews with content analysis.	n=31 19% women; mean age 65 years; 61% ICM; Mean implant time 40 months; 39% prior shocks.	None were informed of alternatives to ICD therapy. None were informed of their prognosis by their physician. Participants did not perceive a lack of information or a lack of participation in the decision-making process. Patients were content with adopting a passive role in decision-making. None regretted the decision of having an ICD implanted.	MMAT Score: 75% Limitations: No provided details regarding the interview guide development. Not all interviews were transcribed and analyzed in their entirety No mention of reflexivity or bracketing Short interviews, thus limited engagement Limited generalizability as only secondary prevention patients were included

Carroll et al. (2011) Canada	To explore patients' decision-making process to reach the decision to accept or decline an ICD for primary prevention. Qualitative, Grounded theory with constant comparative method.	n=44 34 accepted the ICD; 10 declined the ICD; 25% women; Mean age 65 years; 64% ICM; 52% with post-secondary education or higher.	Patients adopted decision-making approaches which fall along an active to passive continuum. Three major factors influenced patients' decision making: trust, social influences and health state. The majority of patients preferred that physicians made the final treatment choice. Patients could not recall alternatives to ICD therapy.	MMAT Score: 100% Limitations: Limited to primary prevention patients. Recall bias. Strengths: Multi-center recruitment (3) Data sources triangulated. Member checking Interview guide was revised over the course of the data collection period. Data saturation achieved. Patients' voices represented by direct quotes.
Groarke et al. (2012) Ireland	To examine the understanding and perspectives of patients with primary and secondary prevention ICDs on various aspects of ICD therapy. Non-experimental, cross-sectional survey via telephone interviews.	n=75 17% women; Median age at time of implant 64 years; Mean implant time 36 months 85% primary prevention.	Patients' understanding of the risks, benefits, and functions of ICD therapy is poor. Patients overestimate the benefits of ICD therapy. 83% of patients claimed to understand the reason for ICD implantation, yet no patient suggested the termination of life-threatening arrhythmia when asked to describe.	MMAT Score: 100% Limitations: Retrospective design Small sample size Study specific survey Strengths: Multi-center recruitment (2) Random sampling

			53% preferred that the doctor make the decision. 47% want to receive all necessary information before making their decision. 93% are satisfied with their decision to accept ICD therapy. 12% will want to deactivate therapies in the setting of terminal illness.	
Hauptman et al. (2013). United States	To examine patient-physician communication at the time the decision is made to implant a primary prevention ICD. Qualitative, focus groups, and separate standardized patient interviews.	n=41 51% women; Mean age 61 years;	Patient-physician communication about ICDs is unclear and omits important information about periprocedural risks, psychological implications, quality of life, and potential long-term complications. The degree to which patients felt informed before the implant procedure was 5.7 out of 10. Decisions were made quickly, particularly with admitted patients. Many older participants deferred the decision to family members.	MMAT Score: 50% Limitations: Study not powered to analyze the effects of key demographic variables on communication Strength(s): Multi-center recruitment (3)
Kantor et al. (2012) United States	To determine which factors are most influential when a patient is making a decision regarding ICD implantation? Does demographic or geographic location affect influencing factors?	n=191. 27% women; 71% Caucasian; mean implant time 65 months; 61% without prior shocks.	Reasons for deciding for ICD implantation was categorized into two themes: contributing factors (physical, psychological, social, and no decision) and their relation with their physician.	MMAT Score: 50% Limitations: 40.5% response rate Cultural bias Recall bias Strengths:

	Mixed methods. Telephone interviews		Active vs passive decision-making was interwoven in the identified themes. Substantial differences among regions and gender were found for contributing factors towards the decision.	Subjects recruited from three different regions of the United States Inter-rater reliability
Matlock et al. (2010) United States	To reveal what patients with heart failure identify as difficult decisions, and to describe features associated with those decisions. Qualitative, in-depth, semi-structured interviews using descriptive theme analysis	n=22 n=12 with ICDs Of the 22 subjects: 27% women; Mean age 69 years.	Patients were classified as either active or passive decision-makers. Accepting the ICD was classified as a difficult decision by 4 active and 1 passive decision makers. The active decision makers weighed concerns for side effects, family and quality of life. They required time for reflection and wanted second opinions. Passive decision-makers placed importance on trust in God, trust in the physician and power of the physician.	MMAT Score: 75% Strengths: Bracketing and reflexivity Inter-rater reliability
Matlock et al. (2011) United States	To understand cardiologists and patients' perspectives about decision making surrounding ICD implantation for primary prevention, specifically exploring how benefits and risks were discussed.	n=20 patients, 14 accepted the ICD 6 declined the ICD 40% women; 65% Caucasian;	Shared decision-making does not occur when patient and physicians are considering ICD implantation. For those who accepted the ICD, three themes emerged: 1) Desire to avoid death 2) Desire to follow doctor's advice	MMAT Score: 100% Limitations: Data saturation not achieved in patients who declined an ICD Strengths: Bracketing and reflexivity

	Qualitative, semi structured, in-depth interviews using a constant comparative analysis method.	mean age 59 years.	3) Discovery of the risks after implantation For those who declined the ICD, many believed it was unnecessary, the risks related to sudden cardiac death did not apply to them, and that the burdens outweigh the benefits. One patient weighed the trade-off between a prolonged death vs. SCD.	Member checking Triangulation of data sources
Yuhas et al. (2012) United States	To explore patients' attitudes and perceptions of ICDs to better understand patient-related barriers to primary prevention implantation. Qualitative, Grounded theory. Semi-structured, open-ended telephone interviews with constant comparative analysis.	n=25 12 accepted the ICD 13 declined the ICD 28% women; 100% Caucasian; mean age 69 years.	Five themes emerged. Those who declined the ICD: 1) lacked insight into their own risk potential for SCD 2) did not perceive like it was strongly recommended 3) were not interested in lengthening their life through invasive interventions Amongst those who accepted and declined: 4) Concerns about recall, malfunction and surgical risk were common 5) Inaccurate perceptions of ICD-related risks and lifestyle changes were clarified with the acceptors but not discussed with the decliners.	MMAT Score: 100% Limitations: Cultural bias Response rate/Rate of participation Strengths: Triangulation of data sources (3 sites) Inter-rater reliability Patients' voices represented by direct quotes Interviews occurred prior to implantation, shortly after the consultation with their physician

BATTERY REPLACEMENT				
Gibson et al. (2008) United States	To assess patients' decision-making process related to device replacement vs. maintenance when affected by a device recall. Non-experimental, comparative survey study with quantitative analysis.	n=81. 31 were affected by a recall. mean age 63 years; 68% Caucasian; 80% with secondary education and higher.	The majority of patients affected by the recall kept their original device. Six patients decided to replace, and five were undecided. Most patients accurately estimated the risk of device failure, but the majority overestimated the odds of device failure.	MMAT Score: 50% Limitations: Selection bias Sample size may be too small to capture variations in responses to device recalls. Single centre
BATTERY REPLACEMENT AND DEACTIVATION - Deactivation in hypothetical terms				
Fluur et al. (2013) Sweden <i>* Addresses battery replacement and deactivation</i>	To describe patients' experiences regarding complex decisions such as battery replacement and deactivation of the ICD. Qualitative, semi-structured, in-depth interviews using content analysis.	n=37 38% women; median age 64 years; 43% ICM; 43% NICM; median implant time 54 months.	Identified a major theme: "Being a part of an uncertain illness trajectory" Analysis revealed 2 categories: 1)"Standing at crossroads" when deliberating battery replacement 2) "Progressing from one phase to another" when thinking about the option to deactivate at end-of-life. Discussions about end-of-life issues with clinicians were rare. When asked, the majority stated they would not choose to deactivate the ICD.	MMAT Score: 75% Limitations: Patients in the end-stage of a terminal illness were excluded. Strengths: Triangulation of data sources and investigators Quota sampling Patient voice represented by direct quotes

			No definitive answer on the right timing for these discussions.	
Thylén et al. (2013) Sweden <i>* Addresses battery replacement and deactivation</i>	To identify the factors associated with patients' experiences of end-of-life discussions, attitudes towards such end-of-life discussions, and attitudes towards withdrawal of therapy. Non-experimental, correlational study with survey.	n=3,067; 20% women; mean age 66 years; mean implant time 4.7 years; prior shocks 35%; 66.8% secondary education and higher.	Regarding battery replacement: The majority of patients (79%) would replace their battery when it has reached end-of-service even if no shocks had been delivered, 16% were undecided, and 5% would not replace. Younger patients, those with lower levels of education, and those with depressive symptoms were more likely to state that they did not want the battery replaced. At a "very advanced age," 63% would replace, 27% did not know, and 10% would not. If seriously ill, 55% would replace, 34% did not know, and 11% would not. Regarding deactivation: The majority (86%) had not discussed deactivation with their physician. Most thought it would be best at end-of-life (69%), yet 50% also said they would like it discussed at implantation. Forty percent said that they would never want to discuss it. Many patients were unable to foresee what they would do if terminally ill.	MMAT Score: 75% Limitations: 55% response rate Eligibility criteria unclear Unclear if those with CRT-D were asked to consider deactivation/withdrawal of shocking therapy only or all functions of their device. Strengths: Large sample size Details regarding patients' psychological morbidity
DEACTIVATION - Deactivation in hypothetical terms				

Berger et al. (2006) United States	To assess whether ICD recipients have considered preferences for disabling the ICD at time of implant, and at time of survey. To assess whether ICD recipients have advanced directive and whether they address ICD use. Non-experimental, exploratory study with self-administered survey with open and closed-ended questions.	n=57 17% women; 91% Caucasian; mean implant time 25 months; 79% secondary education and higher.	At implant, 53/57 did not have preferences for disabling. Two of which had wanted disabling for cardiac function improvement. At time of survey, 36/57 did not have preferences for disabling. 21/57 described situations in which they would want deactivation. Advanced directives were prepared by 35/57 subjects, yet none of them addressed the use of their ICD. People with advanced directives were more likely to express preferences for deactivation than those without them.	MMAT Score: 75% Limitations: Cultural bias Retrospective Selection bias
Dodson et al. (2013). United States	To assess patients' understanding of the benefits and harms of the ICD. To examine preferences for ICD deactivation in the context of five key domains of health including functional, cognitive and medical illness. Non-experimental, descriptive, cohort telephone survey.	n=95. 28% women; 81% Caucasian; mean age 71 years; mean implant time 48 months; 29% with prior shock(s).	31/95 (33%) patients reported unknown or no benefits to the ICD. Following an informational script regarding the benefits and harms of ICD therapy, 67/95 (71%) subjects wanted ICD deactivation in 1 or more scenarios.	MMAT Score: 100% Limitations: Single centre Selection bias Strengths: ICD (mis)information was clarified prior to patients making a decision regarding deactivation.

Goldstein et al. (2008) United States	To identify barriers to ICD deactivation discussions in patients with advanced illness. Qualitative focus groups.	n=15 2 - >1 year with ICD, no shock; 8 - >1 year with ICD, shock; 5 - <1 year with ICD, no shock; 33% women; median age 69 years; 27% secondary preventions; 87% secondary education and higher.	No participant had ever discussed deactivation with their physician, nor knew that deactivation was an option. All patients believed that the ICD was exclusively beneficial. Some subjects expressed that the physician should make the decision.	MMAT Score: 100% Limitations: Single centre Small sample size Recall bias
Habal et al. (2011) Canada	To determine heart failure patients' awareness, comprehension and utilization of advanced care directives To assess patients' knowledge of the process of cardiopulmonary resuscitation and their current resuscitation preferences. Non-experimental, descriptive, semi-structured survey study	n=41 total patients n=19 with ICD * demographics unknown for subset of patients with ICDs	* <i>Focused on subset of patients with ICDs</i> Two/19 (11%) reported discussing the possibility of ICD deactivation with their physician. Following clarification, 9/19 (47%) stated they would want their ICD turned off should their condition deteriorate. Five/19 (26%) would not want it deactivated.	MMAT Score: 75% Limitations: Convenience sampling Single centre Small sample size

Kapa et al. (2010). United States	To determine patients, medical professionals, and legal professionals' opinions regarding the withdrawal of ICDs at end-of-life. Non-experimental, descriptive, survey.	N=246 patients 54% women 60% >50 years old	Opinions regarding the appropriateness and legality of therapy withdrawal varies widely. 85% of patients agreed or strongly agreed that an ICD can be turned off at end-of-life. Significantly more patients disagreed with turning off the ICD than medical professionals ($p=0.001$). Twenty percent of patients thought that turning off the ICD could be considered akin to physician-assisted suicide or euthanasia. Fifty-three percent of patients agreed that it was legal turning off an ICD in a patient who no longer wanted shocks.	MMAT Score: 50% Limitations: Response rate (12%) Unclear what patient population was surveyed Unclear what percentage of patients surveyed had an ICD.
Kirkpatrick et al. (2012) United States	To determine whether patients with ICDs have advanced directives and whether they address the handling of their ICD at the end-of-life. To explore patients' preferences for ICD deactivation in the setting of a do not resuscitate order and/or admission to hospice.	n=278 30% women; 85% Caucasian; median age 61 years; mean implant time 61 months; 100% secondary education and higher;	140 subjects either had a living will or a power of attorney. Those with advanced directives were significantly older ($P<0.0001$). Only 3 (2%) of these subjects included a plan for their ICD. 96% had never discussed what to do with their ICD at end-of-life with a medical professional. When asked if they would deactivate their ICD in an end of life situation, 42% said it would depend on the	MMAT Score: 75% Limitations: Study objectives not explicitly stated Single centre Cultural bias Strengths: Triangulation of data collection time points.

	Non-experimental, descriptive, telephone survey.	38% with prior shock(s); mean number of shocks 4.69.	situation, 28% said they would want it deactivated and 11% said they would leave it turned on.	
Kramer et al. (2011) United States	To identify the ethical beliefs and legal knowledge of patients with hypertrophic cardiomyopathy relating to end-of-life care and the withdrawal of implantable cardiac device therapy. Non-experimental, descriptive, online survey.	n=546 57% with an ICD; 47% women; 92.5% Caucasian; mean age 49 years; 76% secondary education and higher.	Widespread uncertainty and confusion regarding the legal status on implantable cardiac device deactivation was found. 57% were unsure if ICD deactivation was legal. 198 patients with an ICD had advanced directives, and only 15 (8%) specifically addressed their ICD.	MMAT Score: 100% Limitations: Study specific survey Cultural bias Limited generalizability Unclear if 43% of respondents without ICDs were informed about and understood the device, its treatment, and the implications of deactivation.
Pederson et al. (2013) Netherlands	To examine patients' perspective on: 1) their knowledge and wishes for information about deactivation of the ICD toward the end-of-life, and 2) the prevalence of patients in favour of deactivation and the correlates of a favourable attitude. Considers both ICDs for primary and secondary prevention. Nonexperimental, descriptive survey study.	n=294 28% women; mean age 59 years; 28% secondary prevention; 87% secondary education and higher; 12% with prior shock(s).	68% knew that the ICD could be deactivated at end of life. 95% of patients believed that recipients should be informed about the possibility of turning off the ICD. A favourable attitude toward deactivation was related to the avoidance of shock-related pain, anxiety, poor quality of life, and the wish for a worthy death.	MMAT Score: 100% Limitations: Positively worded vignettes Strengths: Details regarding patients' psychological morbidity

Raphael et al. (2011) United Kingdom	To explore patients' recollection of the consent procedure prior to ICD implantation (for both primary and secondary prevention). To determine the degree to which patients want to discuss device deactivation and in what circumstances. Qualitative, comparative, structured interviews.	n=54 20% women; mean age 72 years; 80% ICM; 48% primary prevention; mean implant time 37 months.	38% of patients knew that the device could be deactivated. 84% of patients want to be involved in deactivation decisions. Most patients would consider deactivation if they were unwell, rather than if receiving shocks. Mode of death appears important to patients. Two barriers to end-of-life discussions: Patient's understanding of the device, and physician willingness to broach the subject.	MMAT Score: 50% Limitations: Recall bias Single center Questionnaire not validated with no details about its origin No details regarding the qualitative analysis
Stewart et al. (2010) United States	To examine patients' expectations from their primary prevention ICD. Non-experimental, descriptive, written survey.	n=105 65% with ICDs. 30% women; mean age 58 years; 40% New York Heart Association Class III-IV.	HF patients anticipate long survival, overestimate survival benefits from their ICD and are reluctant to deactivate their ICD.	MMAT Score: 50% Limitations: Study specific survey Limited generalizability Unclear if 35% of respondents without ICDs were informed about and understood the device, its treatment, and the implications of deactivation
Strachan et al. (2011) Canada	To explore patients' perspectives of end-of-life issues in relation to the ICD at the time of their initial decision to either accept or decline a primary prevention ICD.	n=30 24 accepted the ICD 6 declined the ICD	Three themes emerged: 1) quality vs quantity of life 2) preferred mode of death	MMAT Score: 100% Limitations Interviews were conducted shortly after the device was implanted. Would

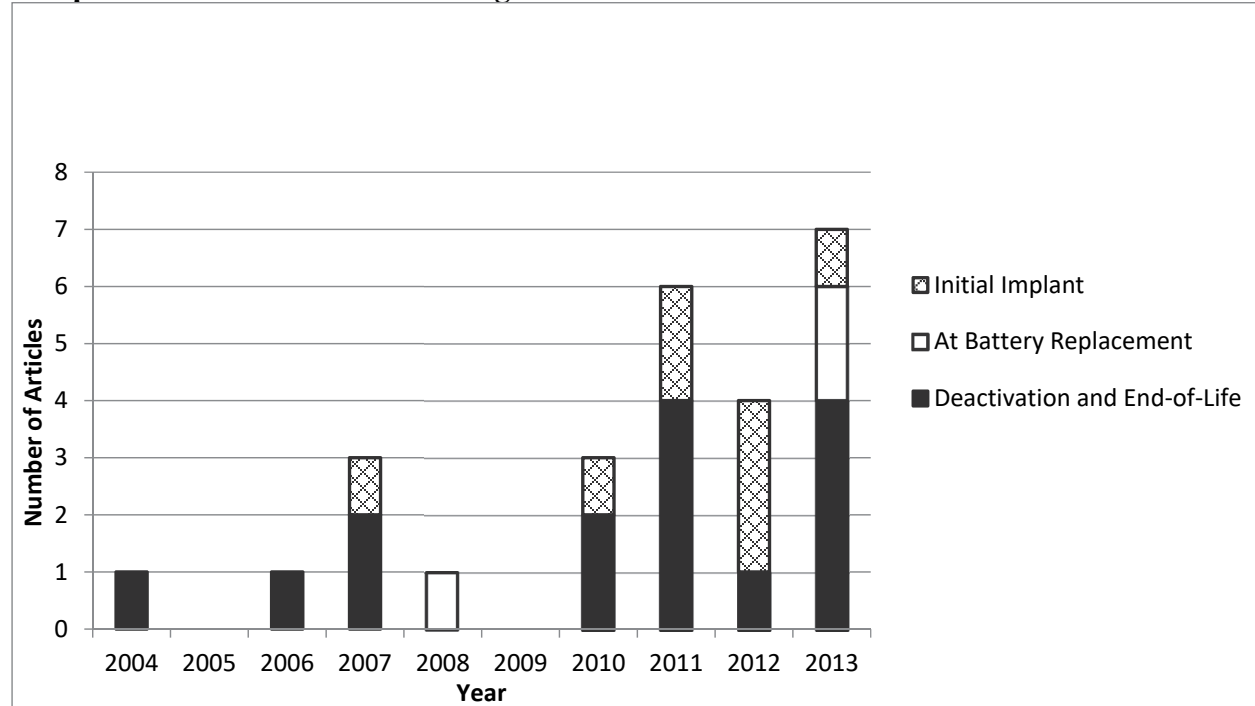
	Qualitative, grounded theory with a constant comparative approach.	20% women	3) technical realities of the ICD Most subjects focused on the prevention of sudden cardiac death, and not death by any other cause. Most patients had not considered that a time would come when they would want to have to device turned off or removed, but agreed that it was an important discussion to have.	knowing this information earlier have impacted their decision to implant? Strengths Member checking sent to all subjects, and completed and returned by half. Went beyond the point of data saturation Patients' voice represented by direct quotes
DEACTIVATION - Deactivation at end-of-life				
Goldstein et al. (2004) United States	To describe the frequency, timing, and correlates of ICD deactivation discussions Nonexperimental descriptive study. Telephone survey of the next-of-kin of deceased patients.	n=100 <u>Deceased patients:</u> median age 76 years at death; 27% women; median implant time 27 months. <u>Interviewed next-of-kin:</u> median age 67; majority were spouses.	27% of next of kin recalled a discussion regarding deactivation of the ICD with their clinician. 21% chose to deactivate. These discussions all took place in the last few days or hours of the patient's life. 27 patients received shocks in the last month of life, 8 patients received a shock from their ICD in the minutes before death. Having a do not resuscitate order and a higher Charlson comorbidity score was statistically significant with having a discussion about deactivation.	MMAT Score: 100% Limitations Relied on reports from the next-of-kin Recall bias (interviews occurred a median of 2.3 years after patient death) Single centre Strengths Inter-rater reliability

Kobza et al. (2007) Switzerland	To evaluate whether deceased patients with a primary or secondary ICD and a malignant tumor desired deactivation of their ICD prior to the end-of-life. Nonexperimental, chart review with descriptive quantitative analysis.	n=8 13% women; Median implant time 58 months; 38% primary prevention; 88% prior shocks.	In 6 of 8 patients, the option of disabling the device was discussed extensively, and none wished to abandon therapies.	MMAT Score: 75% Limitations Retrospective design No mention of a standard protocol for deactivation discussion Small sample size
Lewis et al. (2006) United States	To review the impact of a multidisciplinary strategy used to identify terminally ill patients and initiate withdrawal of ICD shock therapy as part of a comprehensive comfort care approach. Nonexperimental, chart review with descriptive quantitative analysis.	n= 63 Two groups of deceased patients emerged: n= 20 whose ICD was turned off because a terminal illness was identified n= 43 not identified as terminally ill with ICD therapies on.	Of those whose terminal illness was identified in the clinic, 20/20 (100%) had their shock therapy turned off before death. None of the 43 patients not identified as terminally ill had their shock therapy disabled prior to death. They received shocks significantly closer to their time of death compared with the other group (p=0.04)	MMAT Score: 75% Limitations Randomization of patients could have been considered. No mention if a standardized protocol for deactivation discussion was developed and used.

CRT-D: cardiac resynchronization therapy defibrillator; ICD: implantable cardioverter-defibrillator; ICM: ischemic cardiomyopathy; MMAT: mixed methods

appraisal tool^(26, 27)

Figure 2.1 Number of Articles Published Per Decision-Making Point on the Patients' Perspective in ICD Decision-Making from 2004-2013



This figure highlights the increase in the number of articles that have been published on the patients' perspective on ICD decision-making in the last 10 years.

2.8 References

1. Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med* 2005;352:225-37.
2. Moss AJ, Zareba W, Hall WJ, Klein H, Wilber DJ, Cannom DS, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med* 2002;346:877-83.
3. Connolly SJ, Hallstrom AP, Cappato R, Schron EB, Kuck KH, Zipes DP, et al. Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials. AVID, CASH and CIDS studies. Antiarrhythmics vs Implantable Defibrillator study. Cardiac Arrest Study Hamburg . Canadian Implantable Defibrillator Study. *Eur Heart J* 2000;21:2071-8.
4. Epstein AE, Dimarco JP, Ellenbogen KA, Estes NA, III, Freedman RA, Gettes LS, et al. ACC/AHA/HRS 2008 Guidelines for device-based therapy of cardiac rhythm abnormalities. *Heart Rhythm* 2008;5:e1-62.
5. Krahn AD, Lee DS, Birnie D, Healey JS, Crystal E, Dorian P, et al. Predictors of short-term complications after implantable cardioverter-defibrillator replacement: results from the Ontario ICD Database. *Circ Arrhythm Electrophysiol* 2011;4:136-42.
6. Nery PB, Fernandes R, Nair GM, Sumner GL, Ribas CS, Menon SM, et al. Device-related infection among patients with pacemakers and implantable defibrillators: incidence, risk factors, and consequences. *J Cardiovasc Electrophysiol* 2010;21:786-90.
7. Poole JE, Gleva MJ, Mela T, Chung MK, Uslan DZ, Borge R, et al. Complication rates associated with pacemaker or implantable cardioverter-defibrillator generator replacements and upgrade procedures: results from the REPLACE registry. *Circulation* 2010;122:1553-61.
8. Daubert JP, Zareba W, Cannom DS, McNitt S, Rosero SZ, Wang P, et al. Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. *J Am Coll Cardiol* 2008;51:1357-65.
9. Kapa S, Rotondi-Trevisan D, Mariano Z, Aves T, Irvine J, Dorian P, et al. Psychopathology in patients with ICDs over time: results of a prospective study. *Pacing Clin Electrophysiol* 2010;33:198-208.
10. Sears SF, Jr., Conti JB, Curtis AB, Saia TL, Foote R, Wen F. Affective distress and implantable cardioverter defibrillators: cases for psychological and behavioral interventions. *Pacing Clin Electrophysiol* 1999;22:1831-4.
11. Goldstein NE, Lampert R, Bradley E, Lynn J, Krumholz HM. Management of implantable cardioverter defibrillators in end-of-life care. *Ann Intern Med* 2004;141:835-8.
12. Nambisan V, Chao D. Dying and defibrillation: a shocking experience. *Palliat Med* 2004;18:482-3.

13. Sherazi S, McNitt S, Aktas MK, Polonsky B, Shah AH, Moss AJ, et al. End-of-life care in patients with implantable cardioverter defibrillators: a MADIT-II substudy. *Pacing Clin Electrophysiol* 2013;36:1273-9.
14. O'Connor AM, Wennberg JE, Légaré F, Llewellyn-Thomas HA, Moulton BW, Sepucha KR, et al. Toward the 'tipping point': decision aids and informed patient choice. *Health Aff (Millwood)* 2007;26:716-25.
15. Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE, Jr., Drazner MH, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation* 2013;128:e240-e319.
16. Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ* 2006;333:417.
17. Ratliff A, Angell M, Dow RW, Kuppermann M, Nease RF, Jr., Fisher R, et al. What is a good decision? *Eff Clin Pract* 1999;2:185-97.
18. Elwyn G, Laitner S, Coulter A, Walker E, Watson P, Thomson R. Implementing shared decision making in the NHS. *BMJ* 2010;341:c5146.
19. Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). *Soc Sci Med* 1997;44:681-92.
20. Charles C, Gafni A, Whelan T. Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model. *Soc Sci Med* 1999;49:651-61.
21. Laine C, Davidoff F. Patient-centered medicine. A professional evolution. *JAMA* 1996;275:152-6.
22. Government of Ontario. Health Care Consent Act. In: S.O.1996 ed, 1996:c.2-Sched. A.
23. O'Connor AM, Drake ER, Wells GA, Tugwell P, Laupacis A, Elmslie T. A survey of the decision-making needs of Canadians faced with complex health decisions. *Health Expect* 2003;6:97-109.
24. Whittemore R, Knafl K. The integrative review: updated methodology. *J Adv Nurs* 2005;52:546-53.
25. O'Connor AM, Tugwell P, Wells GA, Elmslie T, Jolly E, Hollingworth G, et al. A decision aid for women considering hormone therapy after menopause: decision support framework and evaluation. *Patient Educ Couns* 1998;33:267-79.
26. Pace R, Pluye P, Bartlett G, Macaulay AC, Salsberg J, Jagosh J, et al. Testing the reliability and efficiency of the pilot Mixed Methods Appraisal Tool (MMAT) for systematic mixed studies review. *Int J Nurs Stud* 2012;49:47-53.

27. Pluye P, Gagnon MP, Griffiths F, Johnson-Lafleur J. A scoring system for appraising mixed methods research, and concomitantly appraising qualitative, quantitative and mixed methods primary studies in Mixed Studies Reviews. *Int J Nurs Stud* 2009;46:529-46.
28. Hauptman PJ, Chibnall JT, Guild C, Ambrecht ES. Patient perceptions, physician communication, and the implantable cardioverter-defibrillator. *JAMA Intern Med* 2013;173:571-7.
29. Agard A, Lofmark R, Edvardsson N, Ekman I. Views of patients with heart failure about their role in the decision to start implantable cardioverter defibrillator treatment: prescription rather than participation. *J Med Ethics* 2007;33:514-8.
30. Carroll SL, Strachan PH, de Laat S, Schwartz L, Arthur HM. Patients' decision making to accept or decline an implantable cardioverter defibrillator for primary prevention of sudden cardiac death. *Health Expect* 2013;16:69-79.
31. Groarke J, Beirne A, Buckley U, O'Dwyer E, Sugrue D, Keelan T, et al. Deficiencies in patients' comprehension of implantable cardioverter defibrillator therapy. *Pacing Clin Electrophysiol* 2012;35:1097-102.
32. Dodson JA, Fried TR, Van Ness PH, Goldstein NE, Lampert R. Patient preferences for deactivation of implantable cardioverter-defibrillators. *JAMA Intern Med* 2013;173:377-9.
33. Fluor C, Bolse K, Stromberg A, Thylén I. Patients' experiences of the implantable cardioverter defibrillator (ICD); with a focus on battery replacement and end-of-life issues. *Heart Lung* 2013;42:202-7.
34. Goldstein NE, Mehta D, Siddiqui S, Teitelbaum E, Zeidman J, Singson M, et al. "That's like an act of suicide" Patients' attitudes toward deactivation of implantable defibrillators. *Journal of General Internal Medicine* 2007;23:7-12.
35. Habal MV, Micevski V, Greenwood S, Delgado DH, Ross HJ. How aware of advanced care directives are heart failure patients, and are they using them? *Can J Cardiol* 2011;27:376-81.
36. Kirkpatrick JN, Gottlieb M, Sehgal P, Patel R, Verdino RJ. Deactivation of implantable cardioverter defibrillators in terminal illness and end of life care. *Am J Cardiol* 2012;109:91-4.
37. Stewart GC, Weintraub JR, Pratibhu PP, Semigran MJ, Camuso JM, Brooks K, et al. Patient expectations from implantable defibrillators to prevent death in heart failure. *J Card Fail* 2010;16:106-13.
38. Strachan PH, Carroll SL, de LS, Schwartz L, Arthur HM. Patients' perspectives on end-of-life issues and implantable cardioverter defibrillators. *J Palliat Care* 2011;27:6-11.
39. Matlock DD, Nowels CT, Masoudi FA, Sauer WH, Bekelman DB, Main DS, et al. Patient and cardiologist perceptions on decision making for implantable cardioverter-defibrillators: a qualitative study. *Pacing Clin Electrophysiol* 2011;34:1634-44.
40. Yuhas J, Mattocks K, Gravelin L, Remetz M, Foley J, Fazio R, et al. Patients' attitudes and perceptions of implantable cardioverter-defibrillators: potential barriers to appropriate primary prophylaxis. *Pacing Clin Electrophysiol* 2012;35:1179-87.

41. Matlock DD, Nowels CT, Bekelman DB. Patient perspectives on decision making in heart failure. *J Card Fail* 2010;16:823-6.
42. Kantor PB, Bullinger JM, Gal CS. Patient decision-making modes and causes: A preliminary investigation. *Journal of the American Society for Information Science and Technology* 2012;63:1339-49.
43. Gibson DP, Kuntz KK, Levenson JL, Ellenbogen KA. Decision-making, emotional distress, and quality of life in patients affected by the recall of their implantable cardioverter defibrillator. *Europace* 2008;10:540-4.
44. Thylén I, Moser DK, Chung ML, Miller J, Fluor C, Stromberg A. Are ICD recipients able to foresee if they want to withdraw therapy or deactivate defibrillator shocks? *IJC Heart & Vessels* 2013;1:22-31.
45. Raphael CE, Koa-Wing M, Stain N, Wright I, Francis DP, Kanagaratnam P. Implantable cardioverter-defibrillator recipient attitudes towards device deactivation: how much do patients want to know? *Pacing Clin Electrophysiol* 2011;34:1628-33.
46. Kapa S, Mueller PS, Hayes DL, Asirvatham SJ. Perspectives on withdrawing pacemaker and implantable cardioverter-defibrillator therapies at end of life: results of a survey of medical and legal professionals and patients. *Mayo Clin Proc* 2010;85:981-90.
47. Kramer DB, Kesselheim AS, Salberg L, Brock DW, Maisel WH. Ethical and legal views regarding deactivation of cardiac implantable electrical devices in patients with hypertrophic cardiomyopathy. *Am J Cardiol* 2011;107:1071-5.
48. Pederson SS, Chaiting R, Szili-Torok T, Jordaens L, Theuns D. Patients' perspectives on deactivation of the implantable cardioverter-defibrillator near the end of life. *The American Journal of Cardiology* 2013;111:1443-7.
49. Kobza R, Erne P. End-of-life decisions in ICD patients with malignant tumors. *Pacing Clin Electrophysiol* 2007;30:845-9.
50. Lewis WR, Luebke DL, Johnson NJ, Harrington MD, Costantini O, Aulisio MP. Withdrawing implantable defibrillator shock therapy in terminally ill patients. *Am J Med* 2006;119:892-6.
51. Berger JT, Gorski M, Cohen T. Advance health planning and treatment preferences among recipients of implantable cardioverter defibrillators: an exploratory study. *J Clin Ethics* 2006;17:72-8.
52. Goldstein N, Bradley E, Zeidman J, Mehta D, Morrison RS. Barriers to conversations about deactivation of implantable defibrillators in seriously ill patients: results of a nationwide survey comparing cardiology specialists to primary care physicians. *J Am Coll Cardiol* 2009;54:371-3.
53. Matlock DD, Peterson PN, Heidenreich PA, Lucas FL, Malenka DJ, Wang Y, et al. Regional variation in the use of implantable cardioverter-defibrillators for primary prevention: results from the National Cardiovascular Data Registry. *Circ Cardiovasc Qual Outcomes* 2011;4:114-21.

54. Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2014;CD001431.
55. Healthwise. Heart rhythm problems: Should I get an implantable cardioverter-defibrillator (ICD)? Available from: <https://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=abk4103>
56. Healthwise. Heart Failure: Should I get an implantable cardioverter-defibrillator? In: 2013. Available from: <https://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=uf9848>
57. Carroll SL, McGillion M, Stacey D, Healey JS, Browne G, Arthur HM, et al. Development and feasibility testing of decision support for patients who are candidates for an implantable defibrillator: a study protocol for a pilot randomized controlled trial. *Trials* 2013;14:346.
58. Fagerlin A, Schneider CE. Enough: The failure of living will. *Hastings Cent Rep* 2004;34:30-42.
59. Bonow RO, Ganiats TG, Beam CT, Blake K, Casey DE, Jr., Goodlin SJ, et al. ACCF/AHA/AMA-PCPI 2011 performance measures for adults with heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures and the American Medical Association-Physician Consortium for Performance Improvement. *Circulation* 2012;125:2382-401.
60. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. National Academy Press 2001;6.

Chapter 3 : Estimating the Risks and Benefits of Implantable Cardioverter Defibrillator Generator Replacement: A Systematic Review

Published: Lewis, K.B., Stacey, D., Carroll, S.L., Boland, L., Sikora, L., Birnie, D. (2016). Estimating the risks and benefits of implantable cardioverter-defibrillator generator replacement: A systematic review. *Pacing and Clinical Electrophysiology*. 39(7), 709-722. doi: 10.1111/pace.12850

Abstract

Background: Every four to seven years an implantable cardioverter-defibrillator (ICD) pulse generator must be replaced surgically. This procedure is not without risk. In some cases, the risk versus benefit ratio may be against replacement. We aimed to synthesize the evidence on risks, benefits, and costs related to ICD replacement.

Methods: A systematic review was conducted using electronic databases from 2000 onwards. Literature screening, quality appraisal, and data extraction were independently conducted by two reviewers. Outcomes included major and minor complications, ICD therapies, and costs, which were synthesized descriptively.

Results: Of 1,483 citations, 17 non-randomized studies met criteria. Median rate of major complications was 4.05% (range 0.55%-7.37%) and minor complications was 3.50% (range 0.36%-7.37%). Without non-ICD control groups, the true risk reduction provided by the ICD following replacement is unknown. Following ICD replacement, annualized rates of appropriate ICD therapy was 10.52% (range 2.42%-75.00%). Of these, patients without therapies during their first generator life and those no longer meeting ICD criteria received appropriate therapies at non-trivial rates.

Conclusion: Rates of complications associated with ICD replacement are substantial. No study had non-replacement groups, hence the true risk reduction provided by the ICD following replacement is unknown. Our analysis did not identify a subgroup at low risk of therapies following replacement. Shared discussions should occur with patients about the evidence, healthcare goals, risk tolerances, and feelings about life and death trade-offs to enable high quality decisions about ICD replacement.

Systematic review registration: PROSPERO CRD 42015017275

(url:http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42015017275#.VX8mvUafjC4)

Key words: implantable cardioverter-defibrillator, systematic review, complication, benefit, cost

3.1 Background

Implantable cardioverter-defibrillators (ICD) are an effective treatment modality in the prevention of sudden cardiac death.¹⁻³ Yet, every four to seven years, an ICD pulse generator battery will deplete and must be surgically replaced to ensure uninterrupted function.⁴ Replacement of an ICD pulse generator is not a benign procedure. Studies report important rates of procedural risks associated with ICD replacement. Furthermore the risk of device infection has been shown to be higher following replacement as compared to initial implantation.⁵⁻⁷ In elderly and/or frail individuals, these risks may be particularly important to consider if the benefit of continued ICD therapy is less clear. Also some patients develop important psychological distress with an ICD.⁸

Currently, discussions with patients about prognosis and patient preferences in association with continued ICD therapy do not routinely occur at the time of ICD replacement.⁹ ¹⁰ In a recent *New England Journal of Medicine* opinion article, Kramer et al suggested that “patients and clinicians must move beyond the view of ICD therapy as a lifelong treatment committing patients to obtaining replacement devices for years or decades after implantation.”⁹ There are various reasons why individuals may elect not to replace their ICD: the risks of the replacement procedure, competing morbidities, age, improved clinical status, changes in treatment goals since initial implantation, and a poor experience of living with an ICD.⁹ At an individual level, clinicians and patients should jointly and deliberately weigh the potential risks and burdens against the ICD’s benefit. At a systems level, the decision to replace an ICD should be deemed valuable and of highest quality to justify its associated immediate and downstream costs.¹¹

To achieve values-based informed decisions with patients, a shared decision-making (SDM) process should be utilized. To achieve SDM, the most current evidence associated with the options must be paired with patients’ values and preferences for the options. Individual studies report risks and benefits of ICD replacement but to our knowledge, this data has not been synthesized. The purpose of this study was to synthesize the risks, benefits, and cost outcomes related to ICD pulse generator replacement in order to inform patients and clinicians. We also

sought to explore whether there are subgroups of patients with lower risk of therapies following generator replacement.

3.2 Methods

This systematic review was conducted using a protocol developed *a priori* guided by the Cochrane Handbook for Systematic Review of Interventions.¹² Inclusion and exclusion criteria according to PICO (participants, intervention, comparator, and outcomes) are listed in Table 3.1. Articles reporting a combination of various types of cardiac implantable electronic devices without lead involvement were included. However every effort was made to extract the ICD data only. Peer-reviewed publications of quantitative or observational studies reporting original data were eligible, with or without comparator groups. Articles were excluded if the majority of patients had a lead addition/replacement or system upgrade, or if replacement data could not be extracted from initial implantation data. We searched from 2000 to July 2014. There were no language restrictions.

3.2.1 Search Strategy

The search strategy was designed using the PICO criteria and executed with an academic librarian (LS). The following databases were accessed: Cochrane Database of Systematic Reviews, DARE (Database of Abstracts of Reviews of Effects), Cochrane Central Register of Controlled Trials (CENTRAL), Medline and Medline in Process (via OVID), Embase (via OVID), PsycINFO (via OVID) and the Cumulative Index to Nursing and Allied Health Literature (CINAHL). A search strategy was developed for Medline, which was then adapted for all other databases (Table 3.2). Reference lists of included articles and review articles were scanned. <https://clinicaltrials.gov/> was consulted for information regarding ongoing trials.

3.2.2 Screening

Duplicates were removed and citations were uploaded onto a web-based screening application designed by our research team's computer systems analyst (AS). Articles were screened for inclusion by two independent reviewers (KL, LB) using a three-staged screening process: title, abstract, and full-text. First, all citations were randomly assigned to reviewers. Titles were screened for general relevance. If a title was excluded by one reviewer, it was sent to

the other for screening. Only titles excluded by both reviewers were discarded. Abstract and full-texts were screened using the PICO eligibility criteria. Any disagreements were addressed through consensus. If consensus could not be reached, a third reviewer (DS, DB) acted as an arbitrator.

3.2.3 Data Extraction and Quality Appraisal

A structured data extraction form was developed by the authors and piloted with two studies by both reviewers (KL, LB). The form was revised according to reviewers' comments and results of the pilot test. Two data extractors independently extracted the data from included articles. In our *a priori* protocol, the Scottish Intercollegiate Guidelines Network 50 (SIGN-50) was to be used to appraise included studies (SIGN Network, 2014). However, according to the SIGN-50 "Algorithm of classifying study design for questions of effectiveness," the majority of the included studies did not fit with this quality appraisal checklist. Hence we used the Critical Appraisal Skills Program (CASP) criteria for cohort, case-control, or observational studies.¹³ Studies were rated as high quality ($\geq 80\%$ of criteria met), moderate (60-79% of criteria met), or weak ($< 60\%$ of criteria met).

3.2.4 Outcomes

Outcomes considered were major and minor complications related to the ICD replacement procedure post replacement, ICD therapies, and costs. Definitions for major and minor complications were taken directly from two large multicenter studies, the REPLACE registry⁵ and the Ontario ICD Database.⁶ Major complications were defined as death, and any complication that placed the patient at significant risk necessitating hospitalization, or surgical intervention (e.g., infection requiring explant).^{5,6} Minor complications were any other complication associated with significant symptoms or a decline in status, not requiring surgical intervention (e.g., pocket hematoma, incisional infection).^{5,6} Appropriate ICD therapy included anti-tachycardia pacing (ATP) and shocks for ventricular tachycardia or ventricular fibrillation. If ICD therapy was received for any other reason, the therapy was classified as inappropriate. Economic outcomes including cost-effectiveness analyses, cost-utility analyses, and cost-benefit analyses were sought.¹²

3.2.5 Data Synthesis

Findings were synthesized using descriptive statistics. Meta-analysis could not be conducted due to heterogeneity in study designs, lack of formal control groups, and outcomes measured. Since data were not normally distributed and enrollment in included studies varied significantly, measures of central tendency were reported as medians and measures of spread as ranges.

3.3 Results

Of 1,483 citations screened not including hand searching, 17 English peer-reviewed studies met our inclusion criteria (Figure 3.1). Sixteen studies were observational studies without a control group, and one was a case-control study.¹⁴ Nine studies had more than 500 patients, six had between 100-500 patients, and two had less than 100 patients, totalling a sample of over 100,000 patients. Duration of follow-up ranged from 1 month to over 4 years. Characteristics of included studies and quality ratings are listed in Table 3.3.

3.3.1 Risks of ICD Replacement

3.3.1.1 Major complications

The median rate of major complications was 4.05% (range 0.55%-7.37%) (Table 3.4). Frequently reported major complications included infection requiring antibiotic therapy and/or extraction (median 1.70%, range 0.0%-5.23%, 9 studies), hematoma requiring evacuation (0.57%, range 0.0%-1.55, 8 studies), reoperation for any other reason such as lead damage, repositioning of the device due to intolerable pain, and pocket erosion (1.56%, range 0.07%-3.24%, 10 studies), and stroke (0.45%, range 0.01%-0.82%, 5 studies) (Table 3.4). Five studies reported no procedure-related deaths, while two studies reported rates of 0.10%¹⁵ and 0.44%.¹⁴ A sub-analysis of the six high quality studies revealed a higher median rate of complications of 5.18% (2.16%-7.37%, 6 studies). Higher rates were also revealed for infection (2.22%, range 0.8%-5.23%, 5 studies), hematoma requiring evacuation (0.75%, range 0.0%-1.55%, 5 studies), and reoperation for other reasons (1.99%, 1.21%-3.24%, 6 studies).^{5, 6, 14, 16-18} A forest plot with point estimates sized according to cohort sizes can be seen in Figure 3.2 which displays the

likely dominance of the studies using National Cardiovascular Data Registry (NCDR) data in comparison to the other studies.

Some research has suggested that procedural time, operator training and volume, and defibrillation threshold testing (DFT) can have important effects on complication rates. None of the studies included in this review reported procedural time. Operator training and volume was considered by three studies. One study found no significant difference between surgeons and nonsurgeons.⁶ By contrast, Prutkin et al.¹⁹ reported an association between infection and operators with nonelectrophysiology training and lower implant volume. And, Gould et al.¹⁴ reported a significant increase in complications with single operators - in particular consultants alone - as compared to consultant and fellow together. As for DFT testing, three studies reported that it was conducted as part of their replacement procedure, yet none identified it as a predictor of complications.^{5, 20, 21}

3.3.1.2 Minor complications

The median rate of minor complications was 3.50% (range 0.36%-7.37%). Frequently reported minor complications included incisional infection (median 0.90%, range 0.01%-1.77%, 5 studies), pocket hematoma (0.93%, range 0.35%-3.49%, 5 studies), and discomfort or pain at site (0.44%, range 0.39%-0.45%, 3 studies). Sub-analysis of highest quality studies did not show a difference in the findings.

3.3.2 Benefit of ICD Replacement

There were no randomized controlled trials (RCTs); hence no reports of the true risk reduction provided by the ICD following replacement. A single cohort study reported the all-cause mortality risk of 111,826 patients at 1, 3, and 5 years post replacement, which were 9.8%, 27.0%, and 41.2%, respectively.²² The distribution of arrhythmic versus non-arrhythmic death was not reported.

3.3.2.1 Appropriate ICD therapies

In all cohorts, 4.1% to 45.0% (in 42 ± 24 months) patients received appropriate ICD therapies at a median annualized appropriate shock rate of 10.52% (range 2.42% to 75.00%, 7

studies) (Table 3.5). To consider the risk of ICD therapy in certain groups, we stratified patients into two subgroups.

3.3.2.2 Patients no longer meeting primary prevention criteria

Two studies evaluated the rate of appropriate therapies in patients no longer meeting primary prevention indication at time of replacement. Kini et al. defined this patient subset as those with improved ejection fraction to $\geq 40\%$ and who had not received any appropriate therapies in their first generator life.²³ Whereas Naksuk et al. defined this patient subset as those with an ejection fraction $> 35\%$ and a $\geq 10\%$ improvement in ejection fraction since original implant, irrespective of shock burden.²⁴ Following ICD replacement, these patients received appropriate therapy at an annualized rate of 2.42% ²³ and 12.72% ²⁴, respectively.

3.3.2.3 Patients without prior ICD therapy at time of replacement

Four studies reported the rate of appropriate therapies in patients with primary or secondary prevention ICD without prior appropriate therapy at time of replacement.^{17, 18, 21, 25} These patients received appropriate therapy following generator change at a median annualized rate of 6.70% (range 4.36% - 10.52% , 4 studies).

3.3.2.4 Inappropriate ICD Therapies

Two studies measured the incidence of inappropriate ICD therapies after device replacement: 4.69% (in 26.4 ± 18 months)²⁰ and 8.27% (in 30 ± 24 months).¹⁸ No study reported the distribution of inappropriate ATP versus shocks.

3.3.3 Cost Outcomes

One study compared three cost models for the routine replacement of primary prevention ICDs: 1) replacement of all ICD generators; 2) non-replacement of ICD generators in patients for whom ICDs were no longer indicated; and, 3) echocardiograms for patients with unclear ICD indications (assuming that the percentage of patients for whom ICD therapy was not indicated would be the same as in the second model and not replacing generators in patients with left ventricular ejection fraction $\geq 40\%$).²³ In their cohort of 231 patients, the estimated cost savings of foregoing the ICD replacement procedure (\$22,891) in 58 patients no longer meeting criteria was $> \$1.5$ million US dollars. The model considered the cost of explants (\$1,907.55) and

echocardiograms (\$580).²³ The downstream costs of follow-up and potential complications associated with ICD replacement were not included.

3.4 Discussion

We systematically reviewed the risks, potential benefits, and costs associated with ICD pulse generator replacement in 17 studies including over 100,000 patients. Our review revealed substantial median rates of major and minor complications associated with ICD pulse generator replacement of 4.05% (range 0.55%-7.37%) and 3.50% (range 0.36%-7.37%), respectively. There were no studies that included a non-replacement group, hence the true risk reduction provided by the ICD following replacement is unknown. Our analysis did not identify a subgroup of patients with low risk of therapies following generator replacement. Specifically, patients with no therapies in their first generator life and patients no longer meeting ICD criteria at replacement were found to experience appropriate therapies at non-trivial rates following generator change. Finally, one study suggested substantial cost-savings with a more deliberate approach to generator replacement.

3.4.1 Association Between ICD Replacement and Complications

We found substantial rates of major and minor complications associated with ICD replacement. Despite low median rates of 0.0% for death and 0.45% for stroke, it is important to note that the risk for such major complications exists. Reasons for reoperation, including infection, hematoma, and device malfunction issues, were often interrelated. Importantly, infection risk increased with each repeat procedure, whether for hematomas, reoperation because of a painful pocket, or subsequent generator replacements.^{6, 7, 14, 16, 19, 26} While not explored in the setting of this review, but also meaningful, are complications associated with lead damage, dislodgments, and additions. Reintervention for these reasons, including system upgrades, can raise the risk of complications such as infection, and should be discussed in the overall assessment of risk.²⁶ Further insights into these associations may be obtained from DECODE, a prospective multi-center registry currently in progress.²⁷ This registry is recording 1 and 5 year complication rates, predictors of complications, and costs associated with 800 patients having ICD replacement with and without a planned transvenous lead addition.

The consequences associated with any of these procedural complications can result in morbidity for patients, and a burden at the systems level. In particular, the consequences of infection are serious given the potential for life-threatening complications, the requirement for full system extraction, prolonged hospitalization, and intravenous antibiotics. Other complications may not be directly life-threatening; however, in patients who are frail, extra days in hospital treating these complications can contribute to their decline.²⁸

3.4.2 Potential Benefits of ICD Replacement

ICD benefit post replacement is not well understood for two main reasons.^{1, 2, 29} First and most obviously, there are no studies with a non-ICD control group. Without this, the true risk reduction of ICD therapy cannot be determined. It is not appropriate to directly extrapolate survival benefit from primary prevention ICD trials, which specifically excluded patients aged greater than 80 years and patients with significant comorbidity. The propensity for selection bias and inclusion of the “well” elderly in these trials further support this stance. The same is true of secondary prevention trials.³⁰ Few studies have considered the effectiveness of the ICD in the frail elderly. The studies that have shown that as age increases, the benefit attenuates due to competing morbidity risks, competing causes of death, and limited sample sizes of older patients.^{31, 32} Perhaps the best data that emphasize these issues is a recent study of 34 octogenarians receiving elective ICD generator replacement. The study found that 50% died within 1 year. In all patients, no true episodes of ventricular fibrillation was detected after replacement.³³ Second, using the incidence of appropriate ICD therapy as a surrogate for life-saving therapy is problematic. While ICD therapies for ventricular arrhythmias may be appropriate, the therapy may be unnecessary; thereby resulting in an exaggerated mortality benefit.³⁴

It has been suggested that specific sub-groups of patients may be at lower risk for sustained ventricular arrhythmias; namely those with an event-free first generator life, or those no longer meeting primary prevention criteria.²³ Comparison of these subgroups with their comparator groups revealed that while these subgroups are at lower risk for sustained ventricular arrhythmia, they remain vulnerable for ventricular arrhythmias. For example, our findings show that patients with prior ICD therapies received appropriate therapies at an annualized rate of

49.43% (2 studies) post replacement whereas those without prior therapy received them at an annualized rate of 6.70% (4 studies). Those who continued to meet primary prevention criteria received appropriate therapies at an annualized rate of 11.49% whereas those who did not received them at an annualized rate of 7.57%. It is important to note that these rates are higher than the annualized ICD therapy rates reported in the large primary prevention RCTs (e.g., PREPARE and SCD-HeFT of 5.4% and 5.1% respectively).^{2, 35} Hence these subgroups should not be considered low risk when facing ICD replacement.

A multicenter RCT evaluating ICD replacement versus a non-replacement strategy for frail and/or elderly patients presenting at ICD elective replacement could be conducted to determine the benefit of ICD replacement in this population. Using prognostic survival scores (e.g. Charlson score^{36, 37} or REPLACE DARE score³⁸) and screening for treatment preferences of personal inclination towards replacement or refusal of generator replacement, eligible patients could be identified and randomized to ICD replacement or non-replacement. Some skeptics may highlight insurmountable barriers of such a trial. First, selecting and justifying inclusion and exclusion criteria may be challenging because at this time, no one factor in isolation – or factors combined – have been identified to justify unequivocal non-replacement. Second, the emphasis on ICD implantation and re-implantation as a Class I recommendation in clinical practice guidelines may impact clinician buy-in, and thus limit recruitment. Third, securing funding would be very difficult due to a fourth critical reason, the ethical concern of withdrawing a potentially life-saving therapy from a previously consenting individual.

Despite these obstacles, equipoise justifies the need for such a trial due to lack of high quality data supporting the use of ICDs for the frail and elderly population. Underpinning this limited body of evidence may be a greater ethical concern: a lack of clarity about whether automatic generator replacement is of true benefit to all individuals. The current approach may be inflicting more harm than good on the health and quality of life of individuals, and hence, a greater disservice towards our patients, and towards the health-economics and sustainability of our healthcare system.

3.4.3 Shared Decision-Making at ICD Replacement

Given the current state of the evidence, no one factor in isolation can justify unequivocal non-replacement. Hence decisions about ICD replacement should consider a thoughtful combination of the best available evidence, the patient's clinical status, and their informed preferences. Prior to consenting to treatment, patients should be informed of the highest quality and most current evidence related to the benefits and risks of each feasible option.³⁹ Mortality risk prediction tools after cardiac device replacement, such as the REPLACE DARE score, have been developed to quantify the survival benefit of individuals faced with replacement.³⁸ Further, comprehension of this information should be confirmed as patients often overestimate treatment benefits and underestimate harms.^{10, 40} Others have reported only truly understanding the risks and effects of ICD therapy after having personally lived with one.⁴¹ Such misunderstandings are prevalent in healthcare, and extend far beyond ICDs and cardiovascular treatments.⁴⁰

Yet, it continues to be standard practice in many centres to routinely replace ICD generators when batteries are depleted with minimal discussion.^{9, 10} In these instances, the generic risks of complications are often communicated to satisfy requirements for informed consent. SDM principles should guide this discussion to achieve a high quality decision based on current scientific evidence and a patient's informed values and preferences.⁴² A patient's value for their ICD can decrease as their health and contextual circumstances change.^{43, 44} Ethical considerations regarding ICD replacement include providing patients and their families relevant and meaningful evidence-based information regarding the risks and benefits of continuation and discontinuation of ICD therapy, aligning this information to their preferences and values, and offering patients the opportunity to exercise their right to discontinue ICD therapy if they so choose. Shared decision-making can be facilitated in clinical practice by implementing patient-mediated interventions such as patient decision aids and decision coaching in the process of care.⁴⁵ Patient decision aids are evidence-based tools that make explicit the decision to be made, provide information on options, benefits, and harms, and help patients clarify their values in association with the options.⁴⁶ Evidence from 115 RCTs show they improve patients' knowledge, expectations of outcomes, participation in decision-making, and improve values-choice concordance.⁴⁶ Decision coaching is provided by a trained professional who is non-directive and provides support in preparation for the consultation with the physician.⁴⁷ The

findings derived from this systematic review are being used to populate the risks and benefits of ICD generator replacement within a patient decision aid. We are currently in the process of validating and testing this patient decision aid for acceptability and usability. Furthermore, developers of ICD clinical practice guidelines should consider integrating principles of shared decision-making in recommendations.^{48, 49}

3.5 Limitations and Strengths

Several limitations should be considered when interpreting the results of this review. At the review level, no RCT was identified and almost all studies were observational without control groups. Included studies lacked homogeneity in the reporting and measurement of outcomes, and only seven studies identified and adjusted for a non-exhaustive and variable list of confounders.^{4, 6, 14, 15, 17, 18, 22} For these reasons, results could not be pooled. Four studies included a minority of patients who underwent lead addition or replacement. Every effort was made to extract these cases from our results, but we cannot state with absolute certainty that complications reported in these trials were not a result of lead involvement. We would have liked to report the occurrence of ICD therapy by indication for implantation; however, we were unable to due to the lack of sub-analyses provided by the original articles for the replacement population. As per our *a priori* design, we intended to categorize complications as short versus long-term, yet the heterogeneity in reported follow-up periods rendered this impossible. As for strengths, our *a priori* protocol was registered in PROSPERO, a comprehensive literature search was conducted, and screening, extraction and quality appraisals were conducted by two independent reviewers.

3.6 Conclusions

The competing risks and the uncertainty obscuring the life-saving benefit of ICD replacement should be disclosed to patients to ensure that an informed high quality decision based on personal preferences can be made. Shared discussions should occur with patients about the best available evidence, their healthcare goals, risk tolerances, and feelings about life and death trade-offs to enable high quality decisions about ICD replacement. Future studies examining ICD replacement should use rigorous prospective designs, stratify ICD replacement

recipients into subgroups to assess risk of future therapies, include patients who choose not to get their ICD replaced, and examine its impact on cost utilization.

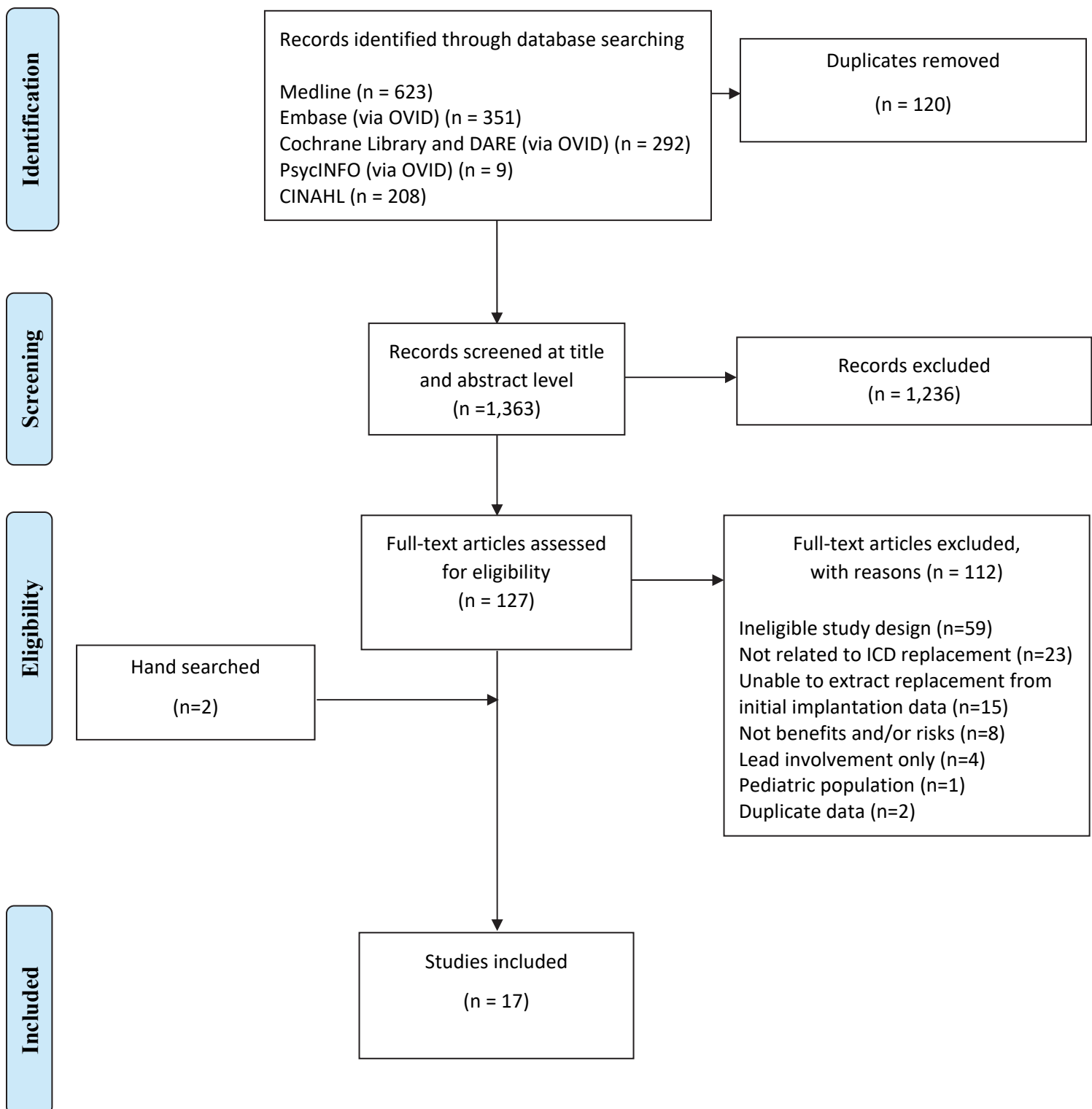
Figure 3.1 Literature Flow Diagram

Table 3.1 Eligibility Criteria

Criteria	Included	Excluded
Participants	Adults ≥ 18 years and older with primary or secondary prevention ICD who have undergone ICD pulse generator replacement.	Children younger than 18 years of age
Intervention	ICD pulse generator replacement	PPM or CRT replacement or upgrade only ICD pulse generator change with lead replacement only Abdominal ICD implant
Comparator	No ICD pulse generator replacement (if applicable)	Not applicable
Outcomes	Major complications Minor complications Appropriate ICD therapy Inappropriate ICD therapy Economic outcomes	Not applicable
Study Design	Randomized controlled trial Non-randomized controlled trial Interrupted time series Controlled before and after Cohort study Observational	Qualitative studies Case reports Literature reviews Opinion/Editorials/Commentary
Languages	All languages	No restrictions
Publication Status	Published Peer reviewed	Unpublished Non-peer reviewed

CRT: cardiac resynchronization therapy; ICD: implantable cardioverter-defibrillator; PPM: permanent pacemaker.

Table 3.2 Medline Search Strategy

1. Defibrillators, Implantable/
2. (icd adj1 pulse adj1 generator*).tw.
3. (implantable adj2 cardioverter-defibrillator*).tw.
4. defibrillat*.tw.
5. (implantable adj2 cardiac adj2 defibrillator*).tw.
6. or/1-5
7. Device Removal/
8. (device* adj2 removal*).tw.
9. (device* adj3 withdraw*).tw.
10. (generator adj2 replacement*).tw.
11. (generator adj2 change*).tw.
12. (batter* adj2 replacement*).tw.
13. (batter* adj2 change*).tw.
14. (ICD adj1 replacement*).tw.
15. reoperation*.tw.
16. or/7-15
17. 6 and 16
18. limit 17 to yr="2000 -Current"

Table 3.3 Characteristics of Included Studies

Author	Year	Study Design	N*	Single or Multicentre	Mean follow-up (months)	ICD indication n(%)	Outcomes reported	Study Quality using CASP
Borleffs et al.	2010	Retrospective Registry	746	Single	38	Primary and secondary [‡]	Major complications	High
Costea et al.	2008	Prospective Observational	222	Single	3	Primary and secondary [‡]	Major complications Minor complications	Weak
Erkapic et al.	2013	Prospective Observational	510	29 centres	22	Primary 64 (12.5%) Secondary 446 (87.5%)	Major complications Appropriate therapies	High
Gould et al.	2008	Nested case-control	451	12 centres	12	Primary 115 (30.6%) Secondary 261 (69.4%) [§]	Major complications Minor complications	High
Kapa et al.	2007	Retrospective Chart review	732	Single	2	Primary and secondary [‡]	Major complications	Weak
Kawata et al.	2010	Retrospective Chart review	115	Single	26	Primary 38 (28%) Secondary 90 (72%)	Appropriate therapies	Weak

						Inappropriate therapies		
Kini et al.	2014	Retrospective Chart review	231	2 centres	42	Primary 231 (100%) Secondary 0 (0%)	Appropriate therapies Cost analysis	High
Koa-Wing et al.	2007	Retrospective Chart review	33	Single	49	Primary and secondary [‡]	Appropriate therapies	Moderate
Krahn et al.	2011	Prospective Registry data	1,081 [†]	18 centres	12.5	Primary and secondary [‡]	Major complications Minor complications	High
Kramer et al.	2013	Prospective Registry data	103,984 [†]	1,489 centres	24.5	Primary 67,655 (65.1%) Secondary 36,330 (34.9%)	Major complications Minor complications	Moderate
Kramer et al.	2014	Prospective Registry data	111,826 [†]	Multicenter (nr)	24	Primary 73,394 (65.6%) Secondary 38,432 (34.4%)	Major complications, specifically mortality	Moderate
Naksuk et al.	2013	Retrospective Chart review	91	Single	26	Primary 91 (100%) Secondary 0 (0%)	Appropriate therapies	Moderate
Poole et al.	2010	Prospective Registry data	1,031	72 centres	6	Primary and secondary [‡]	Major complications Minor complications	High

Prutkin et al.	2014	Prospective Registry data	44,403	1,348 centres	6	Primary and secondary [‡]	Major complications	Moderate
Steckman et al.	2014	Retrospective Registry data	50,691	Multicenter (nr)	14	Primary 36,124 (71.3%) Secondary 14,567 (28.7%)	Major complications	Moderate
Van Welsenens et al.	2011	Retrospective Registry	114	Single	25	Primary 114 (100%) Secondary 0 (0%)	Appropriate therapies	Moderate
Yap et al.	2014	Prospective Registry	266	2 centres	1	Primary 266 (100%) Secondary 0 (0%)	Major complications Minor complications Appropriate therapies Inappropriate therapies	High

ICD: implantable cardioverter-defibrillator; nr: not reported.

*ICD pulse generator replacement without lead involvement only, unless otherwise specified.

[†] Includes some with lead involvement

[‡] Numbers not reported for ICD replacement cohort

[§] Data missing

Table 3.4 Total and Frequently Reported Major Complications

Study	N° major events, n(%)	Procedure related death, n(%)	Stroke, n(%)	Infection* n(%)	Hematoma requiring evacuation, n(%)	Reoperation for other reasons†, n(%)
Borleffs 2010	55 (7.37%)	nr	nr	39 (5.23%)	7 (0.94%)	9 (1.21%)
Costea 2008	9 (4.05%)	0 (0.0%)	1(0.45%)	0 (0.0%)	1 (0.45%)	7 (3.15%)
Erkapic 2013	11 (2.16%)	nr	2(0.82%)	nr	nr	9 (1.76%)
Gould 2008	29 (6.43%)	2 (0.44%)	nr	10 (2.22%)	7 (1.55%)	10 (2.22%)
Kapa 2007	9 (1.23%)	0 (0.0%)	nr	5 (0.68%)	3 (0.41%)	1 (0.14%)
Krahn 2011‡	47 (4.34%)	0 (0.0%)	6 (0.56%)	23 (2.13%)	0 (0.0%)	35 (3.24%)
Kramer 2013‡	567 (0.55%)	nr	25(0.02%)	nr	nr	197(0.19%)
Poole 2010	41 (4.0%)	0 (0.0%)	nr	8 (0.78%)	7 (0.68%)	14 (1.36%)
Prutkin 2014	752 (1.7%)	nr	nr	752 (1.70%)	nr	nr
Steckman 2014	302 (0.60%)	52 (0.10%)	7(0.01%)	16 (0.03%)	86 (0.17%)	34 (0.07%)
Yap 2014	16 (6.01%)	0 (0.0%)	nr	6 (2.26%)	2 (0.75%)	6 (2.26%)
Summary (median,range)	4.05% (0.55%-7.37%)	0.0% (0.0%-0.44%)	0.45% (0.01%-0.82%)	1.70% (0.0%-5.23%)	0.57% (0.0%-1.55%)	1.56% (0.07%-3.24%)

ICD: implantable cardioverter-defibrillator; nr: not reported.

* Infection including the use of antibiotic therapy with or without device extraction.

† Reoperation for other reasons include device migration, discomfort requiring relocation, lead damage, lead dislodgement, system protrusion, pocket erosion, system malfunction, incisional dehiscence.

‡ Studies include some lead replacements/upgrades.

Figure 3.2 Sensitivity Analysis for Total Major Complications

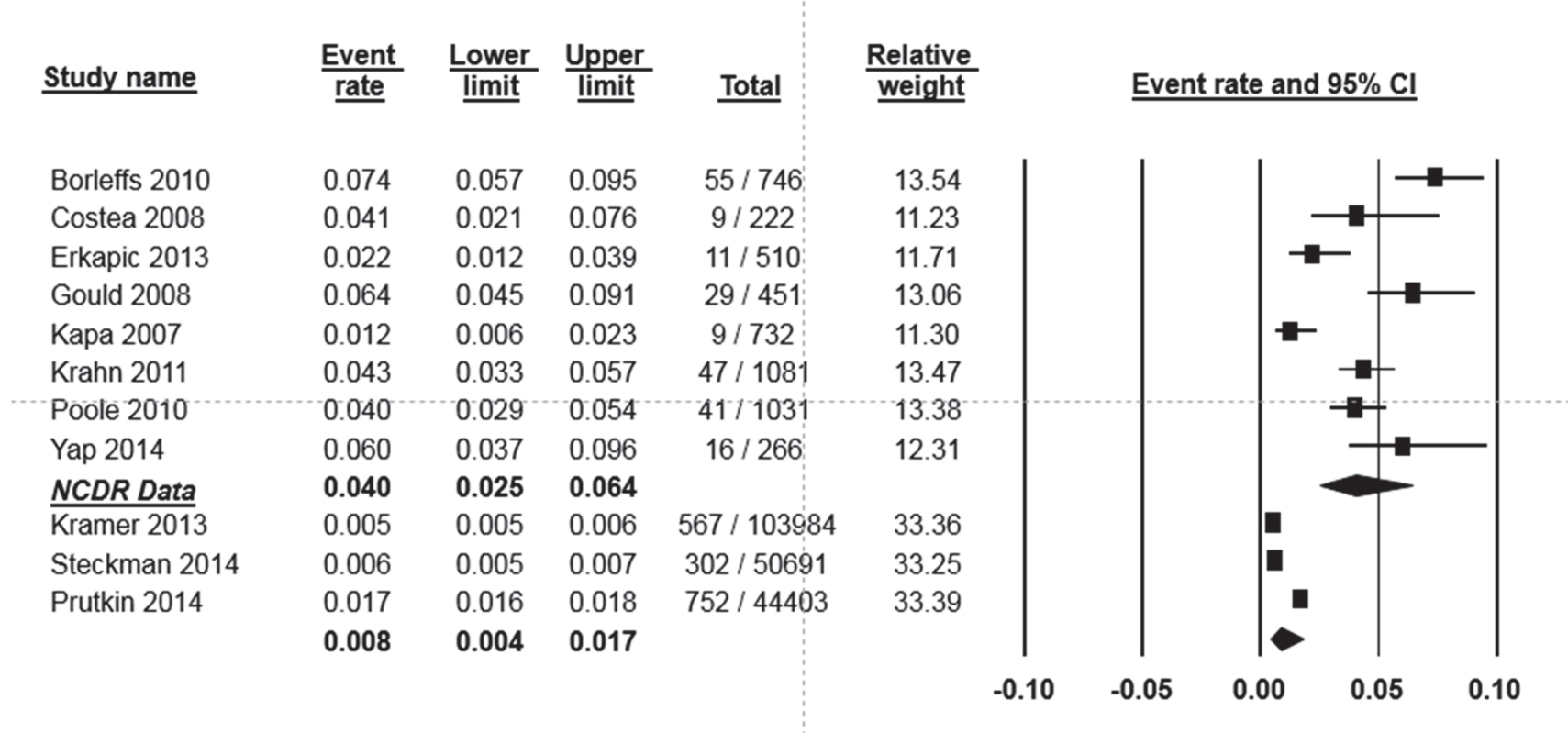


Table 3.5 Incidence of Appropriate ICD therapies from Replacement Date in Defined Subgroups

Study	ICD Indication	Mean follow-up (months +/- SD)	Number of Subjects, (n)	Number of events, n(%)	Annualized event rate
No prior ICD therapy					
Erkapic 2013	Primary and Secondary	22 ± 16	265	51 (19.25%)	10.52%
Koa Wing 2007	Primary and Secondary	49.2 ± 19.9*	13	4 (30.77%)	7.50%
Van Welsenes 2011	Primary	25 ± 15	114	14 (12.28%)	5.90%
Yap 2014	Primary	30 ± 24	266	29 (10.90%)	4.36%
Prior ICD therapy					
Erkapic 2013	Primary and Secondary	22 ± 16	245	107 (43.67%)	23.86%
Koa Wing 2007	Primary and Secondary	7.2 ± 5.6	20	9 (45.00%)	75.00%
Meets 1° prevention ICD criteria					
Kini 2014	Primary	42 ± 24	93	nr	10.70%
Naksuk 2013	Primary	25.2 ± 18	66	17 (25.76%)	12.27%
No longer meets 1° prevention ICD criteria					
Kini 2014	Primary	42 ± 24	59	5 (8.47%)	2.42%
Naksuk 2013	Primary	26.4 ± 19.2	25	7 (28.00%)	12.72%
All patients					
Kawata 2010	Primary and Secondary	26.4 ± 18	128	20 (15.63%)	7.10%

SD: standard deviation; ICD: implantable cardioverter defibrillator; nr: not reported

* Time to first appropriate therapy from initial implantation date.

3.7 References

1. Moss AJ, Zareba W, Hall WJ, Klein H, Wilber DJ, Cannom DS, Daubert JP et al. for the Multicenter Automatic Defibrillator Implantation Trial III. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med*. 2002;346:877-83.
2. Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R, Domanski M et al. for the Sudden Cardiac Death in Heart Failure Trial I. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med*. 2005;352:225-37.
3. Connolly SJ, Hallstrom AP, Cappato R, Schron EB, Kuck KH, Zipes DP, Greene HL et al. Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials. AVID, CASH and CIDS studies. Antiarrhythmics vs Implantable Defibrillator study. Cardiac Arrest Study Hamburg. Canadian Implantable Defibrillator Study. *Eur Heart J*. 2000;21:2071-8.
4. Kramer DB, Kennedy KF, Noseworthy PA, Buxton AE, Josephson ME, Normand SL, Spertus JA et al. Characteristics and outcomes of patients receiving new and replacement implantable cardioverter-defibrillators: results from the NCDR. *Circ Cardiovasc Qual Outcomes*. 2013;6:488-97.
5. Poole JE, Gleva MJ, Mela T, Chung MK, Uslan DZ, Borge R, Gottipaty V et al. for the REPLACE Registry. Complication rates associated with pacemaker or implantable cardioverter-defibrillator generator replacements and upgrade procedures: results from the REPLACE registry. *Circulation*. 2010;122:1553-61.
6. Krahn AD, Lee DS, Birnie D, Healey JS, Crystal E, Dorian P, Simpson CS et al. Predictors of short-term complications after implantable cardioverter-defibrillator replacement: results from the Ontario ICD Database. *Circ Arrhythm Electrophysiol*. 2011;4:136-42.
7. Nery PB, Fernandes R, Nair GM, Sumner GL, Ribas CS, Menon SM, Wang X et al. Device-related infection among patients with pacemakers and implantable defibrillators: incidence, risk factors, and consequences. *J Cardiovasc Electrophysiol*. 2010;21:786-90.
8. Magyar-Russell G, Thombs BD, Cai JX, Baveja T, Kuhl EA, Singh PP, Montenegro Braga Barroso M, et al. The prevalence of anxiety and depression in adults with implantable cardioverter defibrillators: a systematic review. *J Psychosom Res*. 2011;71:223-31.
9. Kramer DB, Buxton AE and Zimetbaum PJ. Time for a change--a new approach to ICD replacement. *N Engl J Med*. 2012;366:291-3.
10. Lewis KB, Nery PB and Birnie DH. Decision making at the time of ICD generator change: patients' perspectives. *JAMA Intern Med*. 2014;174:1508-11.

11. Owens DK, Qaseem A, Chou R, Shekelle P et al. High-value, cost-conscious health care: concepts for clinicians to evaluate the benefits, harms, and costs of medical interventions. *Ann Intern Med.* 2011;154:174-80.
12. Higgins JPT and Green S. *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0. 2011.
13. Critical Appraisal Skills Programme. *CASP Checklists.* 2014.
14. Gould PA, Gula LJ, Champagne J, Healey JS, Cameron D, Simpson C, Thibault B et al. Outcome of advisory implantable cardioverter-defibrillator replacement: one-year follow-up. *Heart Rhythm.* 2008;5:1675-81.
15. Steckman DA, Varosy PD, Parzynski CS, Masoudi FA, Curtis JP, Sauer WH and Nguyen DT. In-hospital complications associated with reoperations of implantable cardioverter defibrillators. *Am J Cardiol.* 2014;114:419-26.
16. Borleffs CJ, Thijssen J, de Bie MK, van Rees JB, van Welsenes GH, van Erven L, Bax JJ et al. Recurrent implantable cardioverter-defibrillator replacement is associated with an increasing risk of pocket-related complications. *Pacing Clin Electrophysiol.* 2010;33:1013-9.
17. Erkapic D, Sperzel J, Stiller S, Meltendorf U, Mermi J, Wegscheider K, Hugl B et al. Long-term benefit of implantable cardioverter/defibrillator therapy after elective device replacement: results of the INcidence free SURvival after ICD REplacement (INSURE) trial--a prospective multicentre study. *Eur Heart J.* 2013;34:130-7.
18. Yap SC, Schaer BA, Bhagwandien RE, Kuhne M, Dabiri Abkenari L, Osswald S, Szili-Torok T et al. Evaluation of the need of elective implantable cardioverter-defibrillator generator replacement in primary prevention patients without prior appropriate ICD therapy. *Heart.* 2014;100:1188-92.
19. Prutkin JM, Reynolds MR, Bao H, Curtis JP, Al-Khatib SM, Aggarwal S and Uslan DZ. Rates of and factors associated with infection in 200 909 Medicare implantable cardioverter-defibrillator implants: results from the National Cardiovascular Data Registry. *Circulation.* 2014;130:1037-43.
20. Kawata H, Noda T, Kurita T, Yamagata K, Yamada Y, Okamura H, Satomi K et al. Clinical effect of implantable cardioverter defibrillator replacements: when should you resume driving after an implantable cardioverter defibrillator replacement? *Circ J.* 2010;74:2301-7.
21. Van Welsenes GH, Van Rees JB, Thijssen J, Trines SA, Van Erven L, Schalij MJ and Borleffs CJ. Primary prevention implantable cardioverter defibrillator recipients: the need for defibrillator back-up after an event-free first battery service-life. *J Cardiovasc Electrophysiol.* 2011;22:1346-50.

22. Kramer DB, Kennedy KF, Spertus JA, Normand SL, Noseworthy PA, Buxton AE, Josephson ME et al. Mortality risk following replacement implantable cardioverter-defibrillator implantation at end of battery life: results from the NCDR. *Heart Rhythm*. 2014;11:216-21.
23. Kini V, Soufi MK, Deo R, Epstein AE, Bala R, Riley M, Groeneveld PW et al. Appropriateness of primary prevention implantable cardioverter-defibrillators at the time of generator replacement: are indications still met? *J Am Coll Cardiol*. 2014;63:2388-94.
24. Naksuk N, Saab A, Li JM, Florea V, Akkaya M, Anand IS, Benditt DG et al. Incidence of appropriate shock in implantable cardioverter-defibrillator patients with improved ejection fraction. *J Card Fail*. 2013;19:426-30.
25. Koa-Wing M, Wright I, Peters NS, Davies DW, Francis DP and Kanagaratnam P. Experience of ICD management at a UK center: cardiovascularly stable VT presentation predicts higher risk for appropriate ICD therapy. *Pacing Clin Electrophysiol*. 2007;30:1369-75.
26. Polyzos KA, Konstantelias AA and Falagas ME. Risk factors for cardiac implantable electronic device infection: a systematic review and meta-analysis. *Europace*. 2015;17:767-77.
27. Diemberger I, Parisi Q, De Filippo P, Narducci ML, Zanon F, Potenza DR, Ciaramitaro G et al. Detect Long-term Complications After ICD Replacement (DECODE): Rationale and Study Design of a Multicenter Italian Registry. *Clin Cardiol*. 2015;38:577-84.
28. Krumholz HM. Post-hospital syndrome-an acquired, transient condition of generalized risk. *N Engl J Med*. 2013;368:100-2.
29. Klein HU and Reek S. The MUSTT study: evaluating testing and treatment. *J Interv Card Electrophysiol*. 2000;4 Suppl 1:45-50.
30. Healey JS, Hallstrom AP, Kuck KH, Nair G, Schron EP, Roberts RS, Morillo CA et al. Role of the implantable defibrillator among elderly patients with a history of life-threatening ventricular arrhythmias. *Eur Heart J*. 2007;28:1746-9.
31. Hess PL, Al-Khatib SM, Han JY, Edwards R, Bardy GH, Bigger JT, Buxton A et al. Survival benefit of the primary prevention implantable cardioverter-defibrillator among older patients: does age matter? An analysis of pooled data from 5 clinical trials. *Circ Cardiovasc Qual Outcomes*. 2015;8:179-86.
32. Yung D, Birnie D, Dorian P, Healey JS, Simpson CS, Crystal E, Krahn AD et al. Survival after implantable cardioverter-defibrillator implantation in the elderly. *Circulation*. 2013;127:2383-92.
33. Goonewardene M, Barra S, Heck P, Begley D, Fynn S, Virdee M, Grace A et al. Cardioverter-defibrillator implantation and generator replacement in the octogenarian. *Europace*. 2015;17:409-16.

34. Ellenbogen KA, Levine JH, Berger RD, Daubert JP, Winters SL, Greenstein E, Shalaby A et al. Are implantable cardioverter defibrillator shocks a surrogate for sudden cardiac death in patients with nonischemic cardiomyopathy? *Circulation*. 2006;113:776-82.
35. Wilkoff BL, Williamson BD, Stern RS, Moore SL, Lu F, Lee SW, Birgersdotter-Green UM et al. Strategic programming of detection and therapy parameters in implantable cardioverter-defibrillators reduces shocks in primary prevention patients: results from the PREPARE (Primary Prevention Parameters Evaluation) study. *J Am Coll Cardiol*. 2008;52:541-50.
36. Charlson ME, Pompei P, Ales KL and MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis*. 1987;40:373-83.
37. D'Hoore W, Bouckaert A and Tilquin C. Practical considerations on the use of the Charlson comorbidity index with administrative data bases. *J Clin Epidemiol*. 1996;49:1429-33.
38. Chung MK, Holcomb RG, Mittal S, Steinberg JS, Gleva MJ, Mela T, Uslan DZ et al. REPLACE DARE (Death After Replacement Evaluation) score: determinants of all-cause mortality after implantable device replacement or upgrade from the REPLACE registry. *Circ Arrhythm Electrophysiol*. 2014;7:1048-56.
39. Sokol DK. Update on the UK law on consent. *BMJ*. 2015;350:h1481.
40. Hoffmann TC and Del Mar C. Patients' expectations of the benefits and harms of treatments, screening, and tests: a systematic review. *JAMA Intern Med*. 2015;175:274-86.
41. Matlock DD, Nowels CT, Masoudi FA, Sauer WH, Bekelman DB, Main DS and Kutner JS. Patient and cardiologist perceptions on decision making for implantable cardioverter-defibrillators: a qualitative study. *Pacing Clin Electrophysiol*. 2011;34:1634-44.
42. Wennberg JE. Unwarranted variations in healthcare delivery: implications for academic medical centres. *BMJ*. 2002;325:961-4.
43. Lampert R, Hayes DL, Annas GJ, Farley MA, Goldstein NE, Hamilton RM, Kay GN et al. HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy. *Heart Rhythm*. 2010;7:1008-26.
44. Lewis KB, Stacey D and Matlock DD. Making decisions about implantable cardioverter-defibrillators from implantation to end of life: an integrative review of patients' perspectives. *Patient*. 2014;7:243-60.

45. Légaré F, Stacey D, Turcotte S, Cossi MJ, Kryworuchko J, Graham ID, Lyddiatt A et al. Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database Syst Rev*. 2014;9:CD006732.
46. Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, Holmes-Rovner M et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2014;1:CD001431.
47. O'Connor AM, Stacey D and Légaré F. Coaching to support patients in making decisions. *BMJ*. 2008;336:228-9.
48. Allen LA, Stevenson LW, Grady KL, Goldstein NE, Matlock DD, Arnold RM, Cook NR et al. Decision making in advanced heart failure: a scientific statement from the American Heart Association. *Circulation*. 2012;125:1928-52.
49. Joyce KE, Lord S, Matlock DD, McComb JM and Thomson R. Incorporating the patient perspective: a critical review of clinical practice guidelines for implantable cardioverter defibrillator therapy. *J Interv Card Electrophysiol*. 2013;36:185-97.

Chapter 4: User-Centered Development of a Decision Aid for Patients Facing Implantable Cardioverter-Defibrillator Replacement: A Mixed-Methods Study

Published: Lewis, K.B., Birnie, D., Carroll, S.L., Clark, L., Kelly, F., Gibson, P., Rockburn, L., Stacey, D. User-centered development of a decision aid for patients facing implantable cardioverter-defibrillator replacement: A mixed-methods study. (2018). *Journal of Cardiovascular Nursing*. Mar 29, 2018. doi: 10.1097/JCN.0000000000000477. [Epub ahead of print]

Abstract

Background: Due to battery depletion, an implantable cardioverter-defibrillator (ICD) generator requires surgical replacement every 5 to 7 years. Routine replacement is the norm without discussion with patients about whether or not to proceed.

Objective: To develop a patient decision aid for patients facing ICD replacement and plan for its implementation.

Methods: An embedded mixed methods study was conducted using questionnaires and semi-structured interviews focused on current ICD replacement practices, PDA acceptability, usability and content, and PDA implementation. Transcripts were analyzed using constant comparative analysis.

Results: Eighteen PDA end-users in 16 interviews characterized the current ICD replacement approach as automatic without consideration for patient preferences. The PDA was positively received and the content iteratively revised four times during the interviews. Changes were related to missing and excess information, language and wording. The PDA was identified as a means to support a shared decision-making (SDM) process, not to be used as a standalone tool. To shift current practices to a SDM process, participants identified that an invitation to discuss the option of ICD replacement is required – whether initiated by the patient or the clinician.

Conclusion: Currently, the option of ICD replacement is rarely offered and patient preferences are seldom elicited. Participants believed the PDA to be a useful intervention that could help facilitate a SDM process for patients facing ICD replacement. Preparing for implementation

during the development phase will allow us to strategize effectively to overcome perceived barriers and capitalize on perceived facilitators during actual implementation.

What is New?

- Currently, ICD replacement is automatic without risk re-stratification based on clinical characteristics or patients' preferences for continued therapy.
- An evidence-based patient decision aid can support a shared decision-making process by offering a formalized opportunity for clarifying patients' evolving preferences for continued ICD therapy and revising the benefits and risks of ICD therapy according to the patient's clinical risk profile.
- An integrated knowledge translation approach was valuable to develop a patient decision aid created by and for patients and the interprofessional/interdisciplinary team and plan for its implementation. This approach increased confidence in PDA content and willingness to integrate it into existing workflows.

4.1 Introduction

Implantable cardioverter-defibrillators (ICD) are life-saving in appropriately selected patients at high risk of sudden cardiac death from ventricular arrhythmias. Routine replacement of the ICD generator is the norm without a discussion about whether or not a patient should proceed.^{1, 2} Over 50% who had previously undergone replacement did not know it was optional.² In the context of older age or serious illness, 5-14% of patients would not replace the ICD, and 16% were undecided.^{2, 3} For a more patient-centered approach, each patient should be re-stratified according to risks and survival benefit in the context of advancing age, worsening (or improving) heart function, and/or non-cardiac comorbidities.⁴ This should be paired with the patient's informed preferences and values for ICD therapy.⁵ Most patients want to be offered choice, want information about the risks and benefits of each option, and want to be asked about their preferences.^{6, 7} This is known as shared decision-making (SDM) and can be facilitated by a patient decision aid (PDA); an evidence-based intervention that makes explicit the decision, the options, the chances of risks and benefits occurring, and the clarification of personal preferences and values.⁸ PDAs improve knowledge, realistic expectations, and result in values-choice agreement. Despite their established effectiveness in research, the uptake of PDAs in routine clinical practice has been slow.^{9, 10}

The overall aim of this study was to develop a PDA for patients facing ICD replacement and plan for its implementation by involving the interprofessional team, patients and family in the development process. Specific aims included: 1) to understand the current approach towards ICD replacement; 2) to seek feedback on PDA content, acceptability and usability; and 3) to elicit feedback on how best to implement it in clinical practice.

4.2 Methods

4.2.1 Study Design

An embedded mixed methods study was conducted using acceptability and usability questionnaires and semi-structured interviews. An interpretive description design guided the qualitative methods to generate clinically-relevant knowledge and hence inform clinically-relevant solutions.¹¹ The Normalization Process Theory (NPT), a middle-range theory of implementation, guided implementation planning.¹² Ethical approval was received from the

Ottawa Health Science Network Research Ethics Board (20150308-01H) and the University of Ottawa Research Ethics Board (A09-15-05). All participants provided written consent.

4.2.2 Setting and participants

This study was conducted in an ambulatory cardiac device clinic in a Canadian tertiary care hospital. In this hospital, 180 ICDs were replaced by cardiac electrophysiologists between April 1st 2016 and March 31st 2017 (Cardiac Care Network, Wait Times Information System). Patients and their ICDs are assessed semi-annually in this device clinic by one of five nurses and one of eight rotating cardiac electrophysiologists.

Purposeful sampling was used to recruit members of the interprofessional team with one or more years of clinical experience with ICDs, and patients and family members who have previously accepted or declined ICD replacement. Interdisciplinary members external to the device clinic but involved in the care these patients were also invited. Patients with pacemaker dependency or cardiac resynchronization therapy were excluded.

4.2.3 Systematic Patient Decision Aid Intervention Development

PDA content and development was guided by the International Patient Decision Aids Standards systematic process^{13, 14} (Figure 4.1). First, formal and informal needs assessments were conducted with patients and clinicians.² Second, we conducted a systematic review to synthesize the risks and benefits of ICD replacement.¹⁵ The risks derived from this review were included in the PDA (Table 4.1). Given the paucity of survival benefit data post ICD replacement, pooled data from five randomized controlled trials, meta-analysis and a registry were used to communicate the survival benefit by age and ICD indication.¹⁶⁻¹⁹ The probabilities were peer reviewed by expert cardiac electrophysiologists external to our institution.

Third, using an integrated knowledge translation approach, a steering committee composed of two cardiac nurses, a cardiac electrophysiologist, nurse administrator, expert researchers in PDA development, two patients with an ICD and a family member was established. Committee members contributed to the initial development and iterative revisions of the paper-based PDA prototype, and the interpretation and approval of study results. Prototype design was based on the Ottawa Decision Support Framework.²⁰ Once the initial prototype was

developed by the steering committee, broad feedback was sought from anticipated end-users external from the steering committee via semi-structured interviews.

4.2.4 Data Collection

4.2.4.1 Semi structured interviews

Two semi-structured interview guides – one tailored for patients and families, the other for clinicians - were developed by the researchers and pilot tested prior to study commencement with individuals representative of our target sample but otherwise not involved in the study. The guides were focused on current ICD replacement practices, PDA acceptability, usability and content, and PDA implementability into the clinical workflow, asking participants to reflect on their past experiences with ICD replacement and drawing on their knowledge of current clinic workflows. Demographics were collected. According to the NPT, understanding the current approach is crucial prior to exploring how a novel complex intervention can be adopted in practice. Participants were asked to review the PDA prior to the interview for feedback and rating its acceptability, usability and implementability.

4.2.4.2 Acceptability and usability

Selected questions have been extensively used for PDA acceptability²¹ and usability evaluations.^{22, 23} Quantitative data on the comprehensibility of PDA components, length, amount of information, and overall balance of the PDA's presentation of treatment options were collected.²³

4.2.5 Data Analysis

Taped interviews were transcribed verbatim. Inductive analytical methods with constant comparative methods were used.²⁴ The qualitative analysis process occurred in six phases: 1) Broad open coding; data describing the current ICD replacement approach was analyzed separately from data describing PDA implementation; 2) Codebook development; initial categories arose from the data but were framed around study aims; 3) Interpretation of initial

categories to generate overarching and sub-themes; 4) Coding conducted by a second independent reviewer; 5) Codebook refinement based on discussion between reviewers and consensus; and 6) Independent coding repeated by reviewers using the refined codebook. NVivo 11 software (QSR International, London, UK) was used for data management and analysis. Demographic, PDA acceptability and usability data were analyzed descriptively.

4.3 Results

4.3.1 Participant Characteristics

There were 18 end-users in 16 interviews, including 12 clinicians (nurses, cardiac electrophysiologists, palliative care specialist, psychologist), four patients, and two spouses (Table 4.2). All patients had accepted ICD replacement at least once.

4.3.2 Current approach: Automatic implantable cardioverter-defibrillator replacement

The current ICD replacement approach was viewed by participants as automatic. Once battery depletion was detected on ICD interrogation, patients were informed it was time for a device replacement with the procedure performed within weeks. Three subthemes were identified (Table 4.3).

4.3.2.1 Implicit persuasion

This theme refers to a clinician's manner of implicitly steering patients towards a particular choice because that is what *they* perceive to be the best for patients.²⁵ Guided by strong clinical trial evidence, clinicians believed that the mortality benefit of ICDs outweighed potential burdens. This was evidenced in the way ICD therapy was presented to patients: as a lifelong treatment where ICD replacement is a necessary course of action. Consequentially, patients unequivocally anticipated replacement once their next battery ran low, some erroneously believing it was the only choice. The omission of the option of ICD non-replacement was not considered inappropriate, but rather justified by the perception of acting in the best interest of the patient.

4.3.2.2 Influence of previous encounters

This theme referred to how the earliest consultations and conversations about ICD therapy shaped patients' understanding about how the ICD functions and how the therapy is understood. Relying heavily on the information received (or not received) upon initial ICD implant, participants reported mixed messaging, inaccuracies and omitted information. At the time of replacement, clinicians reported not raising the option to decline ICD replacement in fear of surprising or upsetting patients. Mixed messaging was attributed in part to the device clinic's shared care model, where patients may be seen by any one of the rotating nurses or cardiac electrophysiologists on any given visit. Device clinic staff suggested that the source of patients' misunderstandings about how the ICD functions, overestimation of benefits, and underestimation of risk stemmed from inaccurate information obtained from non-cardiovascular clinicians within their circle of care and/or other sources of information such as family, friends or the internet.

4.3.2.3 Not knowing the patient

Not knowing the patient was frequently cited as a barrier to initiating discussions about ICD replacement. Clinicians expressed wanting to know more about the patient's overall clinical status, personal circumstances, and preferences and values related to the ICD to best prepare for the sensitive nuances inherent to ICD replacement discussions. Building meaningful rapport was considered difficult due to environmental barriers of time pressures, the shared care model, and the inability to obtain documentation from external (non-cardiac) encounters. This was particularly true for patients followed by clinicians in independent practice, patients living far away, or for those with unscheduled admissions to community hospitals, as frequently, documentation related to these encounters are not available on our institution's documentation system and hence not available to the device clinic staff unless brought by the patients themselves. This impacted clinicians' ability to be informed of recent changes to a patient's non-cardiac clinical status, and whether advanced care planning discussions occurred with others.

4.3.3 PDA content, acceptability and usability

The PDA was positively received and iteratively revised four times over the course of the interviews. All participants were willing to use the PDA or recommend its use. Acceptability and

usability results are in Table 4.4. PDA content was revised based on missing information (e.g. how the ICD affects the way a person passes away; influence of co-morbidities), excess information (e.g., presentation of probabilities tailored to patient's risk profile), and wording. Following revisions, the PDA's readability level was Flesh-Kincaid level 7.1. Revision details are available in Table 4.5.

4.3.4 Patient decision aid implementation to support a shared decision-making process

All participants agreed that the PDA is valuable for use in clinical practice, but not to be used as a standalone tool. Participants believe that the PDA needs to be integrated within a standardized and evidence-based SDM process where information about ICD replacement is provided over time, and is consistent for all patients but tailored to the individual. This, to minimize variations in care from one patient to the other. Four subthemes were identified (Table 3).

4.3.4.1 Need for individualization

This was a theme described as requiring a discussion of survival benefits tailored to individuals based on their age, clinical status, comorbidities, and ICD indication. Also, patient reported outcomes such as quality of life, and their values and preferences for continued ICD therapy were recognized as contextual with the potential to change over time; hence, necessary to review throughout the ICD pathway. Cognitive function, health literacy and preference for role in decision-making (active versus passive) were also noted.

4.3.4.2 Timing – Describing the options then later discussing the options.

Presenting the option of ICD replacement needed to occur at two distinct time points. First, described prior to the initial implant or at the first device clinic appointment post insertion. Second, discussed upon intensified follow-up usually 6 months to 1 year prior to battery depletion; a discussion supported by the PDA. Participants favoured this two-step approach for two reasons. First, the presentation of options would be expected. Second, would allow for unhurried deliberation with family members and other members of the patient's healthcare team.

A palliative care physician noted the value of the PDA for informing about advanced care planning. Raising awareness about ICD concepts and trade-offs at the time of replacement can be useful for the future. It is a way of adjusting the way in which ICD therapy is framed: not as an irrevocable treatment but one of appropriate use based on a patient's health status and their evolving values and preferences for it.

4.3.4.3 Team approach including patient and family

A team approach was described as essential to PDA implementation with the commitment, collaboration and communication between all those involved in the care of ICD patients. Since battery depletion is detected and monitored in the device clinic, most agreed that device clinic staff should initiate, control, and lead this process. Device clinic nurses and physicians agreed with shared responsibility in describing and discussing ICD replacement options. General practitioners, heart function specialists, palliative care specialists were also considered to have roles in supporting PDA use and related discussions. One participant suggested that a palliative cardiovascular service should be established to support these conversations. However, prior to pursuing any decision, the most responsible physician – often from the device clinic - needed to be assured from their conversation that the patient was making an informed decision.

4.3.4.4 Education about ICDs and SDM

Education was suggested as a proposed solution to best prepare all team members to meaningfully participate in this decision. Education was considered the remedy for patients' misunderstanding of ICD function, benefit, and potential burdens. And, most importantly, necessary for patients to understand the sudden vs prolonged trade-offs of ICD therapy. It was hypothesized that clinicians external to the device clinic may be fueling patient misunderstandings given their lower levels of device-related knowledge. While device clinic staff are experts in cardiac devices, they admitted to not being skillfully prepared to engage patients in discussions about ICD replacement citing that doing so was difficult and uncomfortable. Education about ICDs and SDM was proposed as the solution for all those involved.

4.3.5 Shifting from an automated approach to a shared decision-making process

To shift the current automated approach to a SDM process, an invitation to discuss ICD replacement is required. Clinicians, particularly nurses, referred to the need for a “hint” from their patients to ensure that raising the option of ICD replacement would be well received. The hint could be in the form of a declaration of a recent diagnosis, of worsening prognosis, or of not coping well with the ICD, for example. Conversely, other participants believed that the invitation should be provided by the clinician - considered the gatekeeper of the information - as some patients may otherwise be unaware or unsure of whether the topic can or should be discussed.

4.4 Discussion

Our study was designed to engage end-users in the development process for a new PDA for ICD replacement to ensure that it is implementable in existing workflows. Overall, the PDA for ICD replacement was considered a useful tool to guide eventual end-users through this increasingly common, yet complex decision.

There was unanimous agreement amongst participants that a SDM process is needed for patients approaching ICD replacement. The PDA – if paired with a discussion with an interprofessional team member - was considered “the invitation” that could facilitate SDM by offering an opportunity for revising ICD function, risks and benefits, and clarifying patients’ evolving preferences for ICD therapy, which are often overlooked.²⁶ It was also considered useful to minimize variations in information provision, a current consequence of the setting’s shared care model, and to inform patients of the option of ICD deactivation when nearing end-of-life. Nurses are well suited for decision support delivery because supporting patients in decision-making deliberation fits within the discipline’s scope of practice, requires evidence-based information to communicate the details of each option, and requires a relational process to build partnerships with patients.²⁷ Our intervention may be a potential answer to the field’s call for better tools and strategies to help clinicians integrate SDM throughout the ICD pathway.^{4, 28}

By collaborating with PDA end-users on our steering committee and by listening to participants in the interviews, we developed an intervention ready for implementation in clinical practice. The participatory nature of this study allowed us to adapt the intervention to the local context, and generate buy-in. As well, we were able to uncover the priorities and needs of

clinicians, patients, and administrators for ICD replacement decision-making; which is necessary for proposed best practices in user-centered design of PDAs.²⁹ The engagement of patient and family members in this process has been proposed as one pathway to greater success of SDM implementation.³⁰ Finally, our experiences of involving patients and family members on the steering committee are consistent with other studies indicating that it is feasible, helpful, and ensured true rather than tokenistic engagement.³¹

Planning for PDA implementation during the development phase will allow for preparation to address and overcome features anticipated to facilitate or hinder its uptake in clinical practice. Reasons for limited uptake in the traditional PDA ‘referral model’ include lack of confidence in PDA content, fears of disruption in established workflows and indifference amongst clinicians.¹⁰ We attempted to mitigate these attitudinal barriers by seeking feedback from clinical leaders, front-line device clinic staff, and patients with ICD replacement experience. The involvement of an administrator on our steering committee attempted to obtain support at the organizational level. Involvement of hospital administrators throughout the research process may help in addressing barriers, creating policies and practices, allocating resources, and establishing a process to monitor and assess SDM and PDA use.³²

4.5 Strengths and Limitations

To enhance the credibility of our results, we sought the perspective of multiple members of the interprofessional and interdisciplinary teams, including patients and family. Only four patients were interviewed and we were unable to recruit a patient who had declined ICD replacement. However, two patient representatives contributed through their role on the steering committee, and additional acceptability/usability data will be collected from patients facing ICD replacement in the field-testing phase. Data analysis was conducted by two team members independently. Although our findings may be limited to the local context in which the study was conducted – or other centres with similar device clinic structures and/or workflows, we enhanced transferability by providing a detailed description of the setting.

4.6 Conclusions and Future Directions

Currently, the option of ICD replacement is rarely offered and patient preferences for continued ICD therapy are seldom elicited. The PDA was considered a useful intervention that

could support a SDM process at this decision point within the ICD pathway. Engaging patients and the interprofessional team in the PDA development process may have increased confidence in its content and willingness to integrate it into existing workflows. Preliminary effectiveness data for this PDA is currently being collected in a feasibility trial (ClinicalTrials.gov # NCT02668900). Only when implemented will we be able to determine whether our integrated knowledge translation approach was effective in overcoming barriers to PDA implementation.

Figure Legend

Figure 4.1 Flow chart of PDA development and testing process based on International Patient Decision Aids Standards' Model Development Process¹³. The box (— — — —) delineates the study processes described in this manuscript.

Abbreviations:

CRT: Cardiac resynchronization therapy

ICD: Implantable cardioverter-defibrillator

RCT: Randomized Controlled Trial

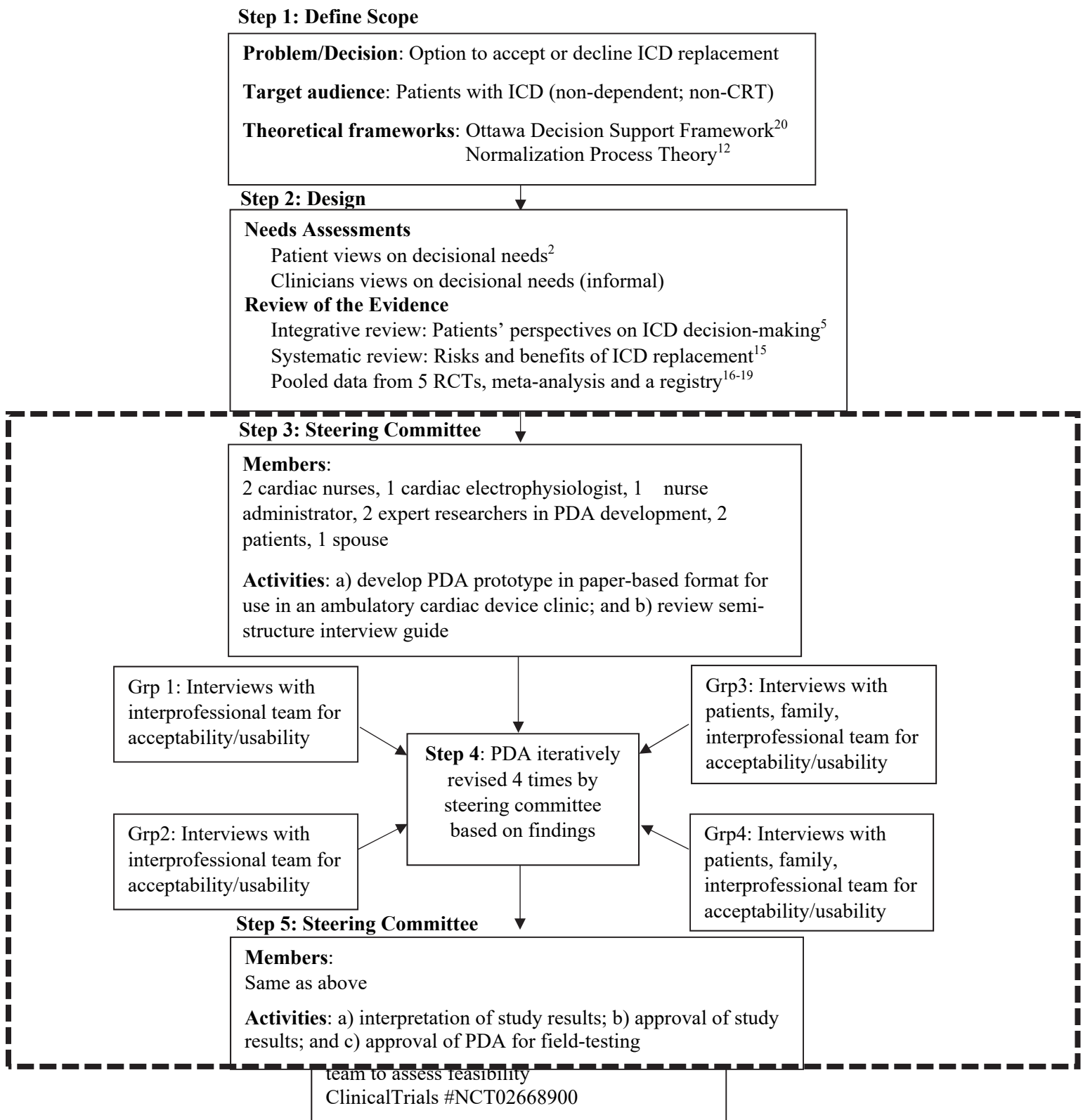
Figure 4.1 Flow Chart of PDA Development and Field-Testing Process

Table 4.1 Patient Decision Aid Content

Introduction	Introduce the decision Verify patient eligibility Review of ICD function Self-reflection on ICD experience to date
Step 1. Know your options	Why choose to replace your ICD? Why choose not to replace your ICD? How the ICD affects the way a person passes away
Step 2. Weigh the risks and benefits of each option	Risks of ICD replacement (major and minor) Benefit of ICD replacement by age and ICD indication Checklist of non-cardiac comorbidities
Step 3. Consider your preferred option	Explicit value clarification exercise. [Likert rating scale with option to include personal reasons for either option].
Step 4. Check your knowledge about the options	Six questions about ICD replacement
Step 5. What else do you need to make a choice?	SURE test ³³ Which option do you prefer? What role do you prefer to take when making health decisions? Free space to list questions for clinician
Frequently asked questions	For example: How long is the recovery after surgery? If I choose not to replace my ICD, is it taken out? If I choose not to replace my ICD, do I still need to come in for regular visits to the device clinic?
Selected references	Patient online resources Citations of sources used for risks and benefits

Table 4.2 Demographic Characteristics of Participants

Characteristics	Clinicians (n=12)	Patients and Family (n=6) ^A	Total (n=18)
Age (in years):			
30-39	1	0	1
40-49	7	0	7
50-59	3	1	4
60-69	1	1	2
≥70	0	4	4
Sex:			
Male	5	3	8
Female	7	3	10
Highest level of education:			
High School	0	2	2
College degree	1	2	3
Undergraduate degree	4	2	6
Graduate degree	7	0	7
Role:			
Employed			
Physician	4	0	4
Registered Nurse	7	0	7
Allied Health	1	0	1
Other	0	2	2
Retired	0	4	4
Experience with ICD:			
Less than 5 years	1	0	1
More than 5 years	11	6	17

^A 2 interviews were conducted with patient-spouse dyad

Table 4.3 Themes – From Current ICD Replacement Approach to PDA Implementation

Subthemes	Example of quotations
Current approach: Automatic ICD replacement	<i>“I don’t look forward to having it done again when the batteries run low but you know we’ll wait for the experts here to tell me it’s got to be done.” Patient</i> <i>“When the battery was replaced it as like oh you need the battery replaced we’re scheduling you” Patient</i> <i>“Right now, we’re not giving them the option” RN</i> <i>“I don’t think [patients’] personal goals are really acknowledged or discussed. They just, you know, take the path of least resistance.” Cardiac electrophysiologist</i> <i>“The patient is informed that their battery is coming down and that they will need to have it replaced. The question is rarely asked in my opinion, as to whether they want to have it replaced. We’re not doing our job. We’re recommending replacement of a device just because it’s at ERI [elective replacement indicator] which might not be the right thing for the patient - that’s not medicine” Cardiac electrophysiologist</i>
1. Implicit persuasion	<i>“They’re [physicians] just like absolutely get a replacement. It’s the purpose factor, right. In medicine they want to lower all of your odds all the time and that’s good but that’s if you want them to do it. That’s what doctors fight against, right, so to them any time death wins, they lose” Patient</i> <i>“Overall, I think the patients are just are more or less told they needed a defibrillator that this is the best solution for them and therefore they get a defibrillator.” RN</i> <i>“...encouraging an ICD, but in some ways I think that’s actually the appropriate thing.” Palliative care specialist</i> <i>“As a clinician you have to believe that these devices are really important, right, that they are going to save lives and we’re very focused on that one aspect.” Psychologist</i>
2. Influence of previous encounters	Interviewer: <i>Would it have come as a surprise if they would have offered you to not replace it?</i> Patient: <i>Probably it would have come as a surprise because that’s never been discussed.</i> <i>“That’s why it’s the initial conversation and how that is broached is so important because it’s very easy to lead a patient to make their mind up.” RN</i> <i>“It’s tough because you’re up against often either ill-informed patients, ill-informed relatives, ill-informed physicians usually outside the clinic.” RN</i> <i>“It’s a little fuzzy to us what gets said...Because [patients] bring different answers from people depending on how the information is presented.” RN</i>

	<i>"Patients may have received different messages because of the shared care model"</i> Cardiac electrophysiologist <i>"Patients sometimes talk about inconsistencies so they may have talked to more than one of the clinicians in the clinic."</i> Psychologist
3. Not knowing the patient	<i>"I don't think I've ever seen the same doctor twice in the clinic. So for them to come in and do this it's kind of like hit and miss"</i> Patient <i>"I think we tend to see patients in this particular clinic as a device. We want to know everything about you but I'm only looking after your device today. ..not everybody can build a rapport in 5 minutes."</i> RN <i>"I totally get that it's difficult if you've never seen the patient before especially if it's never ever been discussed before. I mean the other thing is I haven't really had an opportunity to get to know these people."</i> Cardiac electrophysiologist <i>"We don't necessarily know what discussions have occurred outside of [the device] clinic"</i> Cardiac electrophysiologist <i>"It's the patients who are in other parts of the hospital; when no one actually realizes they have an ICD that this becomes a real issue."</i> Palliative care specialist
Shifting from an automated approach to a SDM process	
1. Patient-driven	<i>"I checked with my cardiologist I happened to have an appointment with him and asked him. He said 'no go ahead with [ICD replacement]', but I did have that sort of a doubt bit of a concern at that point"</i> Patient <i>"I'm not going to hit them with it [the option of not replacing the ICD] if they don't have some kind of condition where this may need to be discussed."</i> RN Interviewer: <i>How do you see this decision aid being used in the process of care in our clinic?</i> RN: <i>I think for sure with anybody that expresses a wish or desire to have it replaced or not replaced</i>
2. Clinician-driven	<i>"I didn't want to say anything but I did have a concern"</i> Patient <i>"We should be asking the question and a discussion needs to occur with the doctor. I think we can all hand out this PDA and say you know this is a thoughtful document that we've prepared and, you know. if you would like to read through it and see if it would be helpful we'd be happy to discuss it with you either now or later probably later and we can set aside time for those patients."</i> RN <i>"He [the patient] was so relieved when I actually broached the subject and I don't think he was sure whether or not it was an option. He was relieved when he found out it was an option and it was almost like you know I could feel he would make this decision and he felt afraid confronting medicine you know"</i>

	<i>and people in the white coat and so he was almost relieved he was being given that choice.” RN</i> <i>“It is a values-based decision and the values are more than just alive and dead most people get that but they need an invitation to talk about it. We need to give them the invitation and we don’t.” Cardiac electrophysiologist</i>
PDA implementation to support a SDM process <i>“I don’t think you can just send this [PDA] to somebody and have them make a decision from that. In the end it has to be a one-on-one situation” Patient and spouse</i> <i>“We have to have procedures and protocols in place and they need to be fairly direct and distinct.” RN</i> <i>“If we have a fairly standard way of discussing this and you know that you’re discussing it with everyone.” Cardiac electrophysiologist</i> <i>“I think there has to be a very systematic approach for every single patient obviously and there has to be an algorithm where you have at you know the 6-month point you know this is we’re approaching this time.” Psychologist</i>	
1. Need for individualization	<i>“No two people perceive these things in the same manner ... sometimes people later in life for whatever reason, just decide they’ve had enough.” Patient</i> <i>“You have to have a client/patient who is willing to want to hear that. It depends on the individual patients because they may not want to go there from the word go. Like it’s like deciding to make it’s like sorting out your will it’s not everybody’s ready for that.” RN</i> <i>“I do think this is much more philosophical than numbers. So the decision aid should not be strictly based on mortality, they need to be based on philosophy and life” Cardiac electrophysiologist</i> <i>“A lot of social cultural background life matters. Your religious beliefs matters. Your general attitude to life matters as to how you approach this problem.” Cardiac electrophysiologist</i>
2. Timing: Describing the options then later discussing the options	<i>“I think the whole idea of being able to not replace it or discontinue needs to be brought up before the defibrillators are implanted.” Patient</i> <i>“When we start seeing patients every 3 months because they’re getting nearer replacement time, or medically, we see something that we capture information that you know what they’ve got chemo they’ve got radiation...It’s all timing and it’s all appropriate and I think that you don’t have to wait for the alarm to ring to start having that conversation.” RN</i> <i>“I think it should be started very early if not at the time they get their initial implant. They’ll skim over it like the rest of us and but it will plant the seed...When the first ERI [elective replacement] approaches ... have that talk” Cardiac electrophysiologist</i>

	<i>"...it begins earlier the process that eventually I'm going to have to be dealing with in the deactivation at the end of life. So even if they choose to replace their battery what I find this decision aid to be most helpful for is it already introduces concepts that would be very, very helpful later on."</i> Palliative care specialist
3.3 Team approach including the patient and family	<i>"You should really be doing it with your partner or your—somebody that's significant to you because this is where you really start to have those sort of hard conversations, right."</i> Patient <i>"I'd say probably review the PDA with the nurse first. The nurse would scan the document to see if there were any anomalies or things that would put up a red flag and then bring in the physician thereafter. So it would be a 2-step process."</i> Patient <i>"Family is a big huge piece of the puzzle. They are very important in making the decision."</i> RN <i>"I think it would need to be a team approach and consistency so that no one feels threatened by it—patient or staff."</i> RN <i>"The nurse can do all: they answer all the questions, explain it all, and do all the emotional support required to help the patient get to a decision. But I think when the physician comes in they have to have some way of ensuring that they are confident this patient is making the best decision."</i> Cardiac electrophysiologist <i>"Anything that moves people gently and is actually bought into it by their tool as a cardiology group it will have a huge impact beyond the actual group of patients who will actually use it. Because the clinicians are being educated through the tool as much as the patients are being helped, I would say."</i> Palliative care specialist
3.4 Education about ICDs and SDM	ICD Education: <i>"I think that there needs to be more information for patients when the ICD is put in about things like being able to turn it off."</i> Patient <i>"Well it's always helpful to get as much information as is available then that way you can, you do have that always have that choice but I think if you're well informed then you'd make the right decision"</i> Patient <i>"If we educated [general] cardiologists and family doctors to be more knowledgeable about the devices maybe it wouldn't be as foreign a concept to the patient."</i> RN <i>"The commonest misconception is that this somehow will prevent further heart attacks, prevent further heart damage, improve quality of life all of which are not true. The second thing is that it will prevent arrhythmias. The third one is</i>

	<i>that it will always protect them no matter what. They [patients] are not aware.” Cardiac electrophysiologist</i> <i>“It may prevent your death but it’s not keeping you alive. There’s a difference and that difference isn’t well understood.” Cardiac electrophysiologist</i> SDM Education: <i>“I think it is difficult. I think we could probably benefit from some sort of teaching on how to present this.” RN</i> <i>“In my experience it was just a lack of awareness and fear you know it takes a bit of courage to so you know and you know fear and ignorance are usually behind most behaviors and you know the antidote to that is education.” RN</i> <i>“I think the person would need very good training on their communication skills and their sensitivity to this...So I think there would be an element of training around the person that’s doing this” RN</i>
--	--

Table 4.4 Patient Decision Aid Acceptability and Usability per Iteration

Items	V1 (n=4)	V2 (n=6)	V3 (n=3)	V4 (n=3)	Total (n=16)
Amount of information					
Much less than I wanted	0	0	0	0	0
A little less than I wanted	1	0	0	0	1
About right	3	4	3	3	13
A little more than I wanted	0	2	0	0	2
Much more than I wanted	0	0	0	0	0
Balanced presentation of options					
Clearly slanted towards replacing the ICD	0	0	0	0	0
Slightly slanted towards replacing the ICD	1	1	0	1	3
Completely balanced	2	2	3	2	9
Slightly slanted towards not replacing the ICD	1	3	0	0	4
Clearly slanted towards not replacing the ICD	0	0	0	0	0
Font size and readable					
Yes	2	6	3	3	14
No	2	0	0	0	2
Enough space to write in the PDA					
Yes	3	5	3	3	14
No	1	1	0	0	2
Language in the PDA makes sense					
Yes	3	4	3	3	13
No	1	2	0	0	3
Information Missing					
No	2	4	3	3	12
Yes	2	2	0	0	4
Important tool to have in practice? <i>mean</i> (1=not at all important / 5=extremely important)	4.0	4.6	5.0	5.0	4.6
Important topic to discuss with patients? <i>mean</i> (1=not at all important / 5=extremely important)	5.0	5.0	5.0	5.0	5.0
Clarity of the information by section	Poor	Fair	Good	Very Good	
Introduction	0	1	5	10	
Step 1. Be clear about the options	0	2	4	10	
Step 2. Weigh the options	0	4	3	9	
Step 3. Consider your preferred options	0	0	4	12	
Step 4. Check your knowledge about the options	0	1	4	11	
Step 5. What else do you need to make a choice	0	0	6	10	
Frequently asked questions	0	0	7	9	
References	0	0	4	12	

Table 4.5 Revisions to Patient Decision Aid Content

Participant Comment	Supporting quotations	Revision
Category: Missing information		
Insufficient information about how the ICD affects the way a person passes away	<i>“DA needs to be based on philosophy and life – not just numbers about mortality”</i> Cardiac electrophysiologist <i>“it’s so important to discuss how the ICD can affect the way you pass away”</i> RN	Added section: “It is important to discuss how the ICD can affect the way you pass away.”
Insufficient information about co-morbidities which may affect long-term mortality.	<i>“It’s not all about the heart. Other diseases need to be considered.”</i> RN	Added checkboxes for common comorbidities which can be used to individualize the discussion, and phrase “estimates of survival vary based on your overall health status including...”
Include definition of primary prevention vs. secondary prevention	<i>“secondary prevention, primary prevention, it would be helpful to have the distinction in an information box”</i> Patient	Revised. Difference between primary and secondary prevention highlighted as part of an information box prior to presenting the benefits.
Revise the way in which an infection is described. In its current form it does not adequately describe the seriousness of it.	<i>“if you want to highlight infection as a problem I don’t think this is doing it”</i> Cardiac electrophysiologist	Reworded to: “An infected ICD site is serious. It often requires surgery to remove the whole ICD and the wires, and 6 weeks of antibiotics in hospital”
In the introduction, add a bullet that the ICD will not stop the progression of the patient’s heart disease.	<i>“actually say it will not stop the progression of your heart disease”</i> Palliative care specialist	Revised. Bullet point added.

Consider adding personal stories	<i>"I think certainly testimonials would be helpful because that looks you know you see it through somebody's eyes who has experienced it."</i> Patient	There is insufficient evidence that adding personal stories increases a PDA's effectiveness to support people's informed decision making. It is also challenging to include personal stories and maintain balance across the options.
Category: Excess information		
Presentation of risks and benefits could be more concise.	<i>"ICD benefit section is too long and overwhelming."</i> RN	Benefit presented according to the individual patient based on age and ICD indication (using a sticker).
Remove knowledge test	<i>"checking knowledge again it tends to as in most knowledge quizzes may emphasize the kind of nitty little details as opposed to the broad issues"</i> Palliative care specialist <i>"Check your knowledge about the options I think that's very well done. It just brings it all back and you're testing yourself at the same time you're answering. Do I really know this and then you can just go back in the document and check it so it's very well done."</i> Patient	No change. Verifying actual knowledge is important.
Remove references	<i>"references...I marked down here more than what I wanted"</i> Patient	No change. Required as per IPDAS criteria.
Category: Language		

Simply “arrhythmic death” and “non-arrhythmic death”	<i>“rephrase arrhythmic and non-arrhythmic”</i> RN	Reworded to “passing away from a fast dangerous heart rhythm (e.g., ventricular tachycardia; ventricular fibrillation), and all other ways, not related to a fast dangerous heart rhythm”
Replace the word “alarm” as not all devices have alarms – some vibrate.	<i>“Not all devices alarm, not all devices do it for 30 seconds and some it’s not an audible alarm it’s a vibration.”</i> RN	Revised. “You may hear or feel an alert from your ICD (e.g., audible alarm or sensed vibration)” where appropriate.
Should be made clearer that it is the tachytherapies that are turned off, not the entire ICD.	<i>“to have the ICD turned off I think is a misnomer it’s to have the tachytherapies of the ICD turned off”</i> RN	Reworded to “you may request to have the tachytherapies (e.g. anti-tachycardic pacing and shocking function) of the ICD turned off”
Remove <i>morally</i> from: “It is not morally or legally wrong to stop any medical treatment if it no longer serves your or your loved one’s purposes”	<i>“They might be offended if you tell them what’s morally wrong or not morally wrong.”</i> RN	Reworded “It is not wrong to stop any medical treatment if it no longer serves your or your loved one’s purposes”
Not all patients describe shocks as painful. As such, description of shocks should be revised.	<i>“the shock was not painful, it was surprising”</i> Patient	Revised. “Painful” removed.
Change the word “protecting” from dangerous heart rhythms with more neutral language as using this term may be making the ICD more appealing.	<i>“by saying ‘to continue to be protected from’ we may be leading the patients towards replacement – who wouldn’t want protection?”</i> Cardiac electrophysiologist	Reworded to “respond” where applicable.
Value statement: “I prefer to die naturally and/or suddenly without life	<i>“we’re lumping together both naturally and/or suddenly...we’re almost saying that’s the same thing but the patient</i>	Reworded to “How important is it for you to allow a natural death without life saving

prolonging therapy like an ICD” is tough and may be too difficult to answer	<i>probably won't see it that way.” Palliative care specialist</i>	measures to restart your heart if you go into sudden cardiac arrest?”
The patient can insist to have the generator removed if they opt for non-replacement. Therefore, do not present as an absolute.	<i>“even though most people would probably say we strongly recommend that you leave it in I think it shouldn't be as clear-cut as no it stays in.” RN</i>	Revised to “Usually, the ICD is left in place. We strongly suggest that you leave it in place”

ICD: Implantable cardioverter-defibrillator; IPDAS: International Patient Decision Aids Standards; PDA: Patient Decision Aid; RN: Registered Nurse

4.7 References

1. Kramer DB, Buxton AE, Zimetbaum PJ. Time for a change--a new approach to ICD replacement. *N Engl J Med*. 2012;366:291-3.
2. Lewis KB, Nery PB, Birnie DH. Decision making at the time of ICD generator change: patients' perspectives. *JAMA Intern Med*. 2014;174:1508-11.
3. Thylén I, Moser DK, Chung ML et al. Are ICD recipients able to foresee if they want to withdraw therapy or deactivate defibrillator shocks? *IJC Heart & Vessels*. 2013;1:22-31.
4. Merchant FM, Quest T, Leon AR et al. Implantable Cardioverter-Defibrillators at End of Battery Life: Opportunities for Risk (Re)-Stratification in ICD Recipients. *J Am Coll Cardiol*. 2016;67:435-44.
5. Lewis KB, Stacey D, Matlock DD. Making decisions about implantable cardioverter-defibrillators from implantation to end of life: an integrative review of patients' perspectives. *Patient*. 2014;7:243-60.
6. Levinson W, Kao A, Kuby A et al. Not all patients want to participate in decision making. A national study of public preferences. *J Gen Intern Med*. 2005;20:531-5.
7. Mazur DJ, Hickam DH. Patients' preferences for risk disclosure and role in decision making for invasive medical procedures. *J Gen Intern Med*. 1997;12:114-7.
8. Légaré F, Stacey D, Turcotte S et al. Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database Syst Rev*. 2014;9:CD006732.
9. Elwyn G, Légaré F, van der Weijden T et al. Arduous implementation: does the Normalisation Process Model explain why it's so difficult to embed decision support technologies for patients in routine clinical practice. *Implement Sci*. 2008;3:57.
10. Elwyn G, Scholl I, Tietbohl C et al. "Many miles to go ...": a systematic review of the implementation of patient decision support interventions into routine clinical practice. *BMC Med Inform Decis Mak*. 2013;13 Suppl 2:S14.
11. Thorne S. *Interpretive description: qualitative research for applied practice*. Routledge; 2016.
12. May CR, Mair F, Finch T et al. Development of a theory of implementation and integration: Normalization Process Theory. *Implement Sci*. 2009;4:29.
13. Coulter A, Stilwell D, Kryworuchko J et al. A systematic development process for patient decision aids. *BMC Med Inform Decis Mak*. 2013;13 Suppl 2:S2.

14. Elwyn G, O'Connor A, Stacey D et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*. 2006;333:417.
15. Lewis KB, Stacey D, Carroll SL et al. Estimating the Risks and Benefits of Implantable Cardioverter Defibrillator Generator Replacement: A Systematic Review. *Pacing Clin Electrophysiol*. 2016;39:709-22.
16. Connolly SJ, Hallstrom AP, Cappato R et al. Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials. AVID, CASH and CIDS studies. Antiarrhythmics vs Implantable Defibrillator study. Cardiac Arrest Study Hamburg . Canadian Implantable Defibrillator Study. *Eur Heart J*. 2000;21:2071-8.
17. Healey JS, Hallstrom AP, Kuck KH et al. Role of the implantable defibrillator among elderly patients with a history of life-threatening ventricular arrhythmias. *Eur Heart J*. 2007;28:1746-9.
18. Hess PL, Al-Khatib SM, Han JY et al. Survival benefit of the primary prevention implantable cardioverter-defibrillator among older patients: does age matter? An analysis of pooled data from 5 clinical trials. *Circ Cardiovasc Qual Outcomes*. 2015;8:179-86.
19. Yung D, Birnie D, Dorian P et al. Survival after implantable cardioverter-defibrillator implantation in the elderly. *Circulation*. 2013;127:2383-92.
20. O'Connor AM, Tugwell P, Wells GA et al. A decision aid for women considering hormone therapy after menopause: decision support framework and evaluation. *Patient Educ Couns*. 1998;33:267-79.
21. Barry MJ, Cherkin DC, Chang Y et al. A randomized trial of a multi-media shared decision-making program for men facing a treatment decision for benign prostatic hyperplasia. *Disease Management and Clinical Outcomes*. 1997;1:5-14.
22. Kushniruk AW, Patel VL. Cognitive and usability engineering methods for the evaluation of clinical information systems. *J Biomed Inform*. 2004;37:56-76.
23. O'Connor AM. User Manual – Acceptability. 2002. Available from: https://decisionaid.ohri.ca/docs/develop/user_manuals/UM_acceptability.pdf. Accessed August 24, 2017.
24. Thorne S, Riemer Kirkham S, O'Flynn-Magee K. The analytic challenge in interpretive description. *International Journal of Qualitative Methods*. 2004;3:1-21.
25. Engelhardt EG, Pieterse AH, van der Hout A et al. Use of implicit persuasion in decision making about adjuvant cancer treatment: A potential barrier to shared decision making. *European Journal of Cancer*. 2016;66:55-66.

26. Mulley A, Trimble C, Elwyn G. Stop the silent misdiagnosis: Patients preferences matter. *BMJ* 2012; 345:e6572.
27. Lewis KB, Starzomski R, Young L. A Relational Approach to Implantable Cardioverter-Defibrillator Generator Replacement: An Integrative Review of the Role of Nursing in Shared Decision-Making. *Can J Cardiovasc Nurs*. 2014;24:6-14.
28. Lampert R, Hayes DL, Annas GJ et al. HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy. *Heart Rhythm*. 2010;7:1008-26.
29. Witteman HO, Dansokho SC, Colquhoun H et al. User-centered design and the development of patient decision aids: protocol for a systematic review. *Syst Rev*. 2015;4:11.
30. Frosch DL, Carman KL. Embracing patient and family engagement to advance shared decision making. In: Elwyn G, Edwards A, Thompson R, eds. *Shared Decision Making in Health Care*. 3rd ed. New York: Oxford University Press; 2016.
31. Domecq JP, Prutsky G, Elraiyah T et al. Patient engagement in research: a systematic review. *BMC Health Serv Res*. 2014;14:89.
32. Nelson WA, Donnellan JJ, Elwyn G. Implementing shared decision making: An organizational imperative. In: Elwyn G, Edwards A, Thompson R, eds. *Shared Decision Making in Health Care*. 3rd ed. New York: Oxford University Press; 2016.
33. Légaré F, Kearing S, Clay K et al. Are you SURE?: Assessing patient decisional conflict with a 4-item screening test. *Can Fam Physician*. 2010;56:e308-14.

Chapter 5 : A Feasibility Randomized Trial of a Decision Support Intervention for Patients Facing Implantable Cardioverter-Defibrillator Replacement

Authors: Lewis, K.B., Stacey, D., Carroll, S. L., Brousseau-Whaley, C., Clark, L., Birnie, D.

Manuscript formatted for submission.

Abstract

Background: Proceeding with an implantable cardioverter defibrillator (ICD) replacement because of battery depletion requires trade-offs of benefit and harms. Decision support can prepare patients to reach an informed decision that is reflective of their preferences. We aimed to evaluate the feasibility of conducting a definitive trial to evaluate a decision support intervention for adult patients facing ICD replacement and to obtain preliminary effectiveness on decision quality and decision-making process.

Methods: We conducted a feasibility randomised controlled trial with 1:1 allocation to two study arms: decision support intervention (PDA booklet + nurse-led decision coaching) versus usual care. Patients with an ICD approaching battery depletion were eligible. Main feasibility outcomes were recruitment rates, intervention use, and completeness of questionnaire data. Secondary outcomes were knowledge, values-choice concordance, decisional conflict, choice, and perception of involvement in decision-making.

Results: Of 48 eligible patients, 30 (62.5%) were randomized to the decision support intervention (n=15) or usual care (n=15). The intervention was used as intended, with less than 2% missing questionnaire data. All patients rated the PDA as acceptable. Acceptability of decision coaching was variable. Patients exposed to the intervention had better knowledge on a questionnaire of risks and benefits of ICD therapy (77.4% versus 51.1%). At 6 months, 7 out of 12 in the intervention group and 9 out of 14 in the usual care group accepted ICD replacement. One patient in the usual care group declined. There was no difference in decisional conflict, and perception of involvement in decision-making between groups.

Conclusion: It was feasible to recruit patients, administer the decision support intervention, and collect outcome measures. Patients exposed to the intervention had better knowledge scores. The results from this feasibility trial will inform modifications to the intervention, and the design and sample size of a larger definitive trial.

Trial registration: ClinicalTrials.gov Identifier: NCT02668900

Keywords: implantable cardioverter-defibrillator, generator replacement, patient decision aid, shared decision-making

5.1 Introduction

Much can change over the course of an implantable cardioverter defibrillator (ICD) generator life. A patient's ejection fraction can improve, heart failure can progress, non-cardiovascular comorbidities can arise, and accrued life experience with an ICD. Clinically, such changes may result in the ICD's attenuated benefit based on increasing age and competing comorbidities, or ineligibility based on initial implantation guideline recommendations, as in the case of improved ejection fraction or limited life expectancy less than 1 year.¹ From a patient's preference perspective, such changes may result in altered goals of care.² Despite these considerations, risk re-stratification and elicitation of patients' evolving preferences do not routinely occur when an ICD battery approaches depletion.^{3, 4} Hence, patients and family members are often not aware that they have the option to accept or decline ICD pulse generator replacement.⁴⁻⁶

ICD battery depletion offers an opportunity to review if the factors that prevailed at the time of initial implantation are still present, whether the patient's overall condition has changed, and whether additional treatment options are available.⁷ It is also a time to re-evaluate patient preferences for the attributes of the options available to them.

Shared decision-making (SDM), a process by which patients and clinicians make healthcare decisions jointly based on current evidence and the patient's personal preferences, has recently been endorsed by clinical practice guidelines at the time of ICD replacement.^{8, 9} SDM can be facilitated by decision support such as patient decision aids (PDAs) and decision coaching which are known to increase patients' level of satisfaction with care decisions by better meeting information needs and incorporating values into health care decisions.^{10, 11} A shortage of these interventions exists for this decision. To fill this gap, our group systematically developed a PDA based on international patient decision aid standards (IPDAS) for patients approaching and/or facing the decision to accept or decline ICD replacement.^{12, 13}

Following the development of a novel complex intervention, preliminary evaluation via feasibility and pilot studies to estimate the parameters for a definitive trial is recommended by the Medical Research Council framework.¹⁴ The main objective of this study was to assess the feasibility of conducting a randomized controlled trial of a decision support intervention (PDA

booklet + nurse-led decision coaching) compared to usual care in terms of ease of recruitment, intervention use, and completeness of data collection. We also aimed to obtain acceptability and usability ratings of the decision support intervention, and preliminary effectiveness data on attributes of decision quality (e.g. knowledge, values-choice concordance) and decision-making process (e.g. decisional conflict, choice, and perception of involvement in decision-making).

5.2 Methods

5.2.1 Study Design

We conducted a single-center, two-arm, parallel-group feasibility randomised controlled trial with 1:1 allocation. It is reported using the CONSORT extension for pilot and feasibility studies¹⁵ and the SUNDAE reporting guidelines for evaluation studies of PDAs.¹⁶ Ethical approval was received from the Ottawa Health Science Network Research Ethics Board (20160037-01H). The trial was registered on ClinicalTrials.gov Identifier: NCT02668900.

5.2.2 Setting

This study was conducted in an ambulatory cardiac device clinic in a Canadian tertiary care centre. Patients routinely have their ICDs assessed every 6 months by one of eight nurses and one of eight rotating cardiovascular electrophysiologists. At every encounter, the ICD's battery voltage is noted, among other device and lead parameters. When an ICD battery approaches depletion as indicated by a pre-specified voltage, the frequency of visits increases to every 3 months for closer monitoring.¹⁷

5.2.3 Eligibility criteria

Eligible patients included adults aged 18 years and older with an ICD approaching or reaching the indicator for elective replacement. Patients needed to be able to speak and read English to use the PDA. Patients were ineligible if they required the pacemaker function of their ICD, or met criteria for an upgrade to cardiac resynchronization therapy. Informed written consent was obtained from patients, and if unable to due to cognitive problems, consent was obtained from their substitute decision-maker.

5.2.4 Decision Support Intervention

The decision support intervention was a paper-based PDA and 1:1 nurse-led coaching, developed based on the Ottawa Decision Support Framework.¹⁸ The details of our PDA development process are published elsewhere.³ Briefly, our PDA booklet provides information on accepting or declining ICD replacement. The content was supported by an integrative review of patients' preferences on ICD decision-making,¹⁹ and the probabilities of risks and benefits informed by a systematic review,²⁰ pooled data from five randomized controlled trials,²¹ meta-analysis,²² and ICD registry.²³ The uncertainty of the evidence related to the survival benefit of ICD replacement is described.

Decision coaching was conducted by a nurse research assistant (RA) trained in decision coaching. Following a pre-specified script, the decision coach's role was to make explicit the decision and describe the options, clarify values for benefits and harms of the options, identify the patient's preferred treatment option, assess pressure from others, assess for decisional conflict and screen for remaining decisional needs (e.g. knowledge, values clarity, and support). The aim of the decision support intervention was to raise patient awareness of the options, improve their knowledge of the benefit and harms, and facilitate the elicitation of patients' health goals, values for the outcomes of the options and preference. All patients receiving the decision support intervention were followed in the cardiovascular device clinic and received usual care.

5.2.5 Usual Care

Usual care included in-clinic or remote ICD follow-ups, or a combination of the two. The amount of detail provided about ICD generator replacement was at the discretion of the clinicians involved in that patient's care or based on patients' own inquiries. Patients received usual information, a 1-page educational document describing the logistics of the ICD replacement procedure.

5.2.6 Procedures

Screening for patients occurred in the cardiac device clinic. Eligible patients were approached by the RA to introduce the study and obtain consent. Data were collected at three time points during the study: baseline, 2-4 weeks, and 6 months. At baseline, sociodemographic

information, data on ICD experience to date (e.g. years implanted, therapy delivered (shocks), previous ICD replacements), the Short Form (SF)-36v2 measuring a patient's generic quality of life on two dimensions namely physical and mental^{24, 25}, the Florida Patient Acceptance Survey measuring the degree to which a patient has accepted their ICD²⁶, and their preferred option (replace ICD, do not replace ICD, or unsure), further quantified using the 15-point Choice Predisposition Scale demonstrating the degree of inclination toward their preferred option (1=do not replace and 15=replace)²⁷ were collected.

Eligible patients were randomly assigned 1:1 to the decision support intervention or usual care by the RA. A clinician researcher not otherwise involved in the trial prepared a randomization schedule using <http://www.randomization.com/>. The sequence was generated using a permuted block design with randomly varying blocks of 4 to 8. Allocation was concealed using sequentially numbered, opaque, sealed envelopes. In an attempt to blind patients to group allocation, they were only told that the study was comparing "*a new approach to support patients who are facing ICD battery replacement with the current way we do it.*" The RA and clinicians in the clinic could not be blinded due to the nature of the intervention.

Once randomized, the RA provided patients with either the PDA booklet (intervention group) or the 1-page educational document (usual care group). Two to four weeks later, the RA telephoned patients. Patients assigned to the intervention arm received decision coaching following a script to follow the PDA. Patients allocated to the usual care arm were also telephoned and had the opportunity to ask questions. Following the call, patients in both groups completed follow-up questions by telephone or email collecting measures of preferred choice (e.g. accept or decline ICD replacement or unsure), knowledge, values for the possible outcomes, and decisional conflict. Those randomized to the intervention were asked to rate it on measure of acceptability and usability. If the patient preferred to respond by telephone, another team member (KL) completed this in an attempt to avoid performance bias given the RA had delivered the intervention. At 6 months, patients were contacted to measure decisional conflict scores, and if relevant, their actual choice (e.g. accept or decline ICD replacement) and perception of involvement in decision-making. Dates to confirm the replacement procedure were obtained from the electronic medical record.

5.2.7 Outcomes

The main feasibility outcomes were rates of recruitment based on our eligibility criteria, intervention use and completeness of data collection.²⁸ Acceptability and usability measures of the intervention were collected after exposure (intervention group only). Preliminary effectiveness outcomes collected at 2 to 4 weeks and 6 months included knowledge, decisional conflict, preferred versus actual choice, and perception of involvement in decision-making.

5.2.8 Outcome measurement instruments and/or questionnaires

5.2.8.1 Acceptability and usability of the intervention (after exposure; intervention group only)

The PDA was rated using validated questions that have been extensively used for PDA acceptability²⁹ and usability evaluations.^{30, 31} Decision coaching acceptability was measured using the Genetic Counseling Satisfaction Scale and perceptions of decision coach neutrality.^{32 33} This scale has face validity and a reliability coefficient of alpha 0.80 to 0.90 in a genetic counselling contexts with adults.

5.2.8.2 Knowledge (2-4 weeks; both groups)

Patients' knowledge was assessed using six true or false questions (i.e., ICD function, risks of replacement surgery, battery depletion alerts, options for deactivation of tachytherapies) developed by the PDA development team. The percentage of correct answers was calculated to give the overall knowledge score.

5.2.8.3 Values (2-4 weeks; both groups)

Four value items associated with the possible outcomes of the options were developed by the PDA development team, some of which had been previously utilized in a PDA for the initial implantation of a prophylactic ICD.³⁴ Value items were: 1) How important it is for you to lower your chances of a sudden cardiac arrest?; 2) How important is it for you to avoid the risks from the ICD replacement surgery?; 3) How important is it for you to have peace of mind that a fast dangerous heart rhythm could be corrected?; and 4) How important is it for you to allow a natural death without life saving measures to restart your heart if you go into sudden cardiac arrest? Value items were rated from 1=not important to 5=very important.

5.2.8.4 Decisional conflict scale (DCS) (2-4 weeks, 6 months; both groups)

The DCS was used to measure personal perceptions of feeling certain, informed, clear about what mattered most, supported, and effective decision-making. The DCS has an alpha coefficient of >0.78 and good predictive validity. Total scores can range from 0 to 100 where scores < 25 are associated with implementing the decisions and scores > 37.5 are associated with decision delay and feeling unsure about implementation.³⁵

5.2.8.5 Preferred option (2-4 weeks; both groups)

Preferred option was measured by asking patients whether they preferred to replace or not replace their ICD. This outcome was further quantified using the 15-point Choice Predisposition Scale demonstrating a patient's inclination toward a given option (1=do not replace and 15=replace) with the centre of the scale indicating no preference or uncertainty. This scale has a test-retest coefficient >0.90 .²⁷

5.2.8.6 Actual choice (6 months; both groups)

Actual choice was determined based on patients' final decision: accept or decline ICD replacement. ICD replacement dates were confirmed using the electronic medical record.

5.2.8.7 Perception of involvement in decision-making (6 months; both groups)

Only when the actual choice had been made, the Control Preference Scale was used to assess the degree of control patients' perceived they held in making the final decision.^{36, 37} This scale has been tested in a variety of populations and is proven to be a clinically relevant, valid and reliable instrument.³⁸

5.2.9 Statistical Analyses

As this was a feasibility study, a formal sample size calculation was not required but we estimated the number of participants required based on the rate of ICD generator replacements conducted annually in our centre (180 ICDs were replaced by cardiac electrophysiologists

between April 1st 2016 and March 31st 2017). Feasibility outcomes were summarized using descriptive statistics. Categorical outcomes were expressed as frequencies and proportions. Continuous outcomes were expressed as means and standard deviations. Estimates of difference in outcomes between groups are presented using 95% confidence intervals, which will be useful to inform the sample size of a definitive trial. Inferential comparisons between groups were not performed as the study was not powered for this analysis.

Values-choice concordance was analyzed descriptively due to small sample size and insufficient outcome variability in actual/preferred choice at 6 months to permit logistic regression. Patients rated the four value items from 1=not important to 5=very important. All value items were re-scored to a binary format such that a value item was deemed important if it was scored a 4 or 5, and not important if scored 1, 2 or 3. Two items (2 and 4) required reverse scoring so that all high scores (4-5) were compatible with valuing the ICD, and all low scores (1-3) were compatible with not valuing the ICD. A values concordant choice occurred when the item was rated as important and the patient subsequently accepted ICD replacement at 6 months, or if an item was rated as not important and the patient subsequently declined ICD replacement. All analyses were conducted using IBM SPSS Statistics for Windows, Version 24.0 (IBM Corp., Armonk, NY).

5.3 Results

5.3.1 Characteristics of the sample

Patient demographics indicated that the average participant was 63 years old, male, Caucasian, and lived with someone (Table 5.1). Nearly half of patients had previously been shocked (48.3%), while fewer have had their ICD replaced (27.4%). Mean mental and physical dimensions of quality of life scores were within normal range in both groups, and mean device acceptance scores (FPAS) out of 100 were moderate across groups, intervention group 83.3 standard deviation (SD) 20.1 and usual care group 78.4 SD 12.1. There was no statistically significant difference between the groups on any baseline characteristics.

5.3.2 Feasibility

Between May 2016 and October 2017, 129 patients were screened for eligibility of whom 81 were not eligible (Figure 5.1). Of 48 eligible patients, 30 patients (uptake of 62.5%) were randomized to the intervention group (n=15) and usual care (n=15). All patients consented for themselves. One participant randomized to the intervention withdrew consent citing personal reasons prior to baseline data collection and receipt of the intervention. The remaining 14 completed the intervention as intended. Of 29 patients, there were 2% missing questionnaire responses due to one participant lost to follow-up at 6 months. Missing data could be obtained on actual choice from the hospital health information system.

5.3.3 Acceptability and usability of the decision support intervention

Of the 14 patients who received the intervention, 13 rated the PDA as having the right amount of information, the right length, and completely balanced across both options (Table 5.2). For ratings on acceptability of the decision coaching, 8 patients agreed strongly that the nurse coach helped them identify what they needed to know, 8 agreed it helped them determine a preferred option, and 10 agreed it helped them feel better about their decision (Table 5.3). Overall, 10 patients believed the coaching session helped them prepare for their next in-clinic follow-up.

5.3.4 Preliminary evaluation of the decision support intervention

5.3.4.1 Knowledge

Mean knowledge scores for patients exposed to the intervention were 77.4% compared to 51.1% in the usual care group. There was a 26.3-point difference (95% CI, 10.4, 42.1) in knowledge scores between intervention and usual care group. (Table 5.4).

5.3.4.2 Values-choice concordance

As only one patient declined ICD replacement, this outcome was evaluated within the entire study cohort. Almost all patients scored value item 1 “Lower your chances of sudden

cardiac arrest” (28/29, 96.6%), and value item 3 “Peace of mind” (26/29, 90.0%) as important which demonstrated their value to avoid sudden cardiac death, and hence replace their ICD. Ratings of importance were variable across items 2 “Avoid risks” and 4 “Allow a natural death,” with 15/29 (52%) patients rating them as important. For those who preferred or chose to replace their ICD at 6 months, the concordance between patients’ values and their choice was 96% on value item 1, 44% on value item 2, 88% on value item 3, and 44% on value item 4.

5.3.4.3 Decisional conflict

Total decisional conflict scores were low in both groups at both time points. At 2 to 4 weeks, patients exposed to the intervention had a mean (SD) score of 8.0 ± 13.8 compared to 14.3 ± 18.4 in the usual care group, with a -6.2-point difference (95% CI, -18.7, 6.2) between groups. At 6 months, patients exposed to the intervention had a mean (SD) score of 16.2 ± 13.5 and patients exposed to usual care scored 14.6 ± 16.14 , with a 1.6-point difference (95% CI, -10, 13.3) between groups. There was no meaningful difference between groups on any of the decisional conflict subscales.

5.3.4.4 Preferred choice

At baseline, 13 out of 14 patients in the intervention group and 13 out of 15 patients from the usual care group stated their preference to replace their ICD. At 2 to 4 weeks after exposure to the intervention, 13 out of 14 patients in the intervention group preferred to replace their ICD, as compared to 14 out of 15 patients in the usual care group. Choice Predisposition Scale mean (SD) scores were 14.0 ± 1.8 for the intervention group and 13.1 ± 3.3 for the usual care group, with a 0.9-point difference (95% CI -1.2, 2.9) between groups. At 6 months, 5 out of 13 patients in the intervention group and 4 out of 15 patients in the usual care group’s battery had not yet depleted to the point of requiring a replacement. All but one patient in the usual care group preferred to replace their ICD.

5.3.4.5 Actual choice

At 6 months, 7 out of 13 patients in the intervention group and 9 out of 15 patients in the usual care group accepted ICD replacement. One patient in each group declined ICD replacement.

5.3.4.6 Perception of involvement in decision-making

For the patients who had made their actual choice (intervention group=8; usual care group=10), we assessed the degree of control they perceived they held in making this final decision. More patients in the usual care group believed the physician made the final decision (3/10, 30.0%) as compared to those in the intervention group (0/8, 0.0%). Four patients (50.0%) in the intervention group and three patients (30.0%) in usual care group perceived they had made the decision alone.

5.4 Discussion

This study assessed the feasibility of conducting a definitive trial to deliver a decision support intervention to patients facing the decision to accept or decline ICD replacement. Adhering to IPDAS' systematic process of PDA development, we field-tested a novel PDA with decision coaching in a feasibility trial with 30 ICD patients.¹³

5.4.1 Feasibility of a Definitive Trial

Our study found that it was feasible to administer the decision support intervention, collect outcome measures, and recruit patients. However, the proportion (48/129) of eligible patients was low, resulting in slow recruitment. New inclusion/exclusion criteria will be developed for a future trial. In addition, one third of eligible patients declined to consent to the study. The main reasons included general disinterest and a lack of time. One patient misinterpreted the goal of the study and feared their participation could result in not getting their ICD replaced. Clarity of the decision support aims are essential for a future study.

Overall, the ratings demonstrated that patients are open and willing to discuss options related to ICD therapy. Acceptability ratings for the PDA were unanimously favorable. Acceptability ratings for nurse-led decision coaching were variable highlighting that the coaching intervention may not have been needed by all patients. Decision coaching has been shown to increase knowledge¹¹, result in greater patient participation³⁹, and positive psychological outcomes.⁴⁰ Yet, little is known about when, at what “dose,” and for whom decision coaching is needed or desired when paired with PDAs.⁴¹ For example, in a trial where patients were given the option of decision coaching, few accepted.⁴²

5.4.2 Preliminary Effectiveness of Decision Support Intervention

Our preliminary effectiveness data is consistent with the Cochrane review of PDAs which shows better knowledge for patients exposed to a PDA.⁴³ For values-choice concordance, small sample size and insufficient outcome variability resulted in unstable modelling precluding logistic regression analysis. However, a descriptive analysis suggested that two value items (1 and 3) were most important in determining values-choice concordance for patients who accepted ICD replacement. Strong values-choice concordance for the value item “How important is it to you to lower your chances of a sudden cardiac death?” was also found in a PDA trial for patients considering ICD for primary prevention.³⁴ A future study could consider using this one statement exclusively to assess patients’ values for the potential benefit of ICD therapy.

We provide two explanations for low decisional conflict scores. First, that ICD replacement is a decision in which the majority of patients are certain about their choice. Our results are consistent with scale norms which state that scores lower than 25 are associated with decision implementation.³⁵ Second, due to the nature of the decision support intervention and the trial being conducted in one ambulatory care clinic in one centre, clinic staff was informed of the study’s purpose, familiar with the intervention, and could not be blinded to patient group assignment. Hence, a Hawthorne effect may be responsible for an improvement in usual care practices towards the discussion of options with patients approaching ICD replacement. This could also explain why only a small minority were unsure or preferred not to replace their ICD at baseline, and only one patient declined ICD replacement despite previous studies revealing that a

significant minority (5 to 14%) would choose not to replace their ICD on future subsequent replacements, or were undecided (16%).^{4, 44}

Previous literature has revealed that PDAs can potentially impact rates of elective surgeries, particularly when base rates are high.⁴³ For most patients, the ICD is highly valued when implanted and continues to be as long as the patient prefers to do everything possible to prolong life. This aligns with Prospect Theory, which states that when people are faced with potential loss, they tend to seek more risk.⁴⁵ In the context of ICD therapy, the human desire for self-preservation prevails: The majority of patients are willing to accept the potential burdens of ICD therapy in spite of the uncertainty of benefit and attenuation of benefit in select subgroups for a chance at survival.^{2, 5, 19} However, it is known that some informed patients choose to live at risk by declining or deactivating their ICD for various reasons.⁴⁶⁻⁴⁹ It is for these reasons that decision support at the time of replacement is needed.

5.5 Strengths and Limitations

One trained nurse who did not work in the device clinic consistently delivered the decision coaching intervention. This helped reduce contamination between groups and ensured fidelity of intervention delivery but did limit the amount of information gathered about its use within the clinical workflow. Second, the study was conducted in one Canadian centre which may influence the generalizability of the results. Three, we did not collect information from the subsequent consultations with device clinic nurses and electrophysiologists following study exposure. Hence, the influence of these consultations on the final choice is unknown, but most outcomes were collected prior to these encounters.

5.6 Future Implications

Informed by the findings of this feasibility study, the required sample size for a proposed definitive multicentre trial using knowledge and decisional conflict as primary outcomes is 136 patients per group. This is required to detect a clinically significant difference of 10% in knowledge and an effect size of 0.4 in decisional conflict³⁵ between groups using a two-sided t-

test at 5% level of significance with 80% power. To account for 10% loss of follow-up, 151 patients per group will be needed.

A more inclusive PDA containing the nuances of cardiac device replacement across device types (e.g. pacemaker, cardiac resynchronization therapy), lead involvement (e.g. revision, replacement) is being developed. This will allow much broader inclusion of trial patients and also meet the decision making needs of a wider proportion of patients. An electronic version of this PDA is currently in development to offer web-based access. Our PDA development process with assessment for implementation revealed high automatic re-implantation of ICDs without shared decision-making with patients.³ Future research should evaluate SDM within these encounters.

5.7 Conclusions

This trial demonstrated that it was feasible to deliver the intervention, collect data, but had slower than expected patient recruitment rates. Patients rated the PDA as highly acceptable, but there was greater variability across acceptability ratings for decision coaching. This decision support intervention has the potential to inform patients about this decision and support clinicians when eliciting patients' values and preferences to prepare patients for SDM with the device clinic interprofessional team.

Table 5.1 Baseline Patient Demographics

	Intervention (n=14)	Usual Care (n=15)
Age (years), mean (SD)	63.8 (10.4)	63.4 (16.2)
Male, n(%)	13 (92.9)	13 (86.7)
Caucasian, n(%)	13 (92.9)	15 (100)
Education Level, n(%)		
Secondary school	6 (42.9)	8 (53.3)
College/Undergraduate degree	5 (35.7)	3 (20.0)
Graduate/Professional degree	3 (21.4)	4 (26.7)
Retired, n(%)	6 (42.9)	7 (46.7)
Lives Alone, n(%)	4 (28.6)	2 (13.3)
Initial ICD implant (years), mean (SD)	9.4 (2.7)	11.1 (4.0)
Shocked, yes, n(%)	7 (50.0)	7 (46.7)
Appropriate shocks, mean (SD)	2.7 (2.9)	4.3 (5.2)
Inappropriate shocks, mean (SD)	51 (68.6)	5 (0)
ICD previously replaced, n(%)	3 (21.4)	5 (33.3)
Quality of Life – SF-36v2 ^a , mean(SD)		
Physical (PCS)	44.5 (13.9)	47.8 (11.7)
Mental (MCS)	53.6 (9.7)	49.4 (10.9)
Overall Device Acceptance ^b , mean (SD)	83.3 (20.1)	78.4 (12.1)
Return to Life	78.6 (25.0)	67.1 (21.5)
Device-Related Distress	86.2 (24.7)	78.7 (19.3)
Positive Appraisal	79.9 (23.2)	83.8 (11.0)
Body Image Concerns	92.9 (15.3)	90.0 (15.8)
Preferred option, n(%)		
Replace ICD	13 (92.9)	13 (86.7)
Not replace ICD	0 (0.0)	1 (6.7)
Unsure	1 (6.1)	1 (6.7)
Choice predisposition scale ^c , mean (SD)	12.9 (3.5)	12.6 (3.8)

ICD: implantable cardioverter-defibrillator; MCS: Mental Component Summary; PCS: Physical Component Summary; SD: standard deviation.

^a Generic health related quality of life measured using the SF-36v2, wherein raw scale values (0-100) are converted into a mean score of 50 (SD 10). Normal score falls between 45-55.^{24, 25}

^b Device acceptance measured using the Florida Patient Acceptance Survey (FPAS), by which a lower score means lesser device acceptance (scale, 0-100).²⁶

^c Choice predisposition measures a person's leaning towards an option, where 0=Do not replace the ICD and 15=Replace the ICD.²⁷

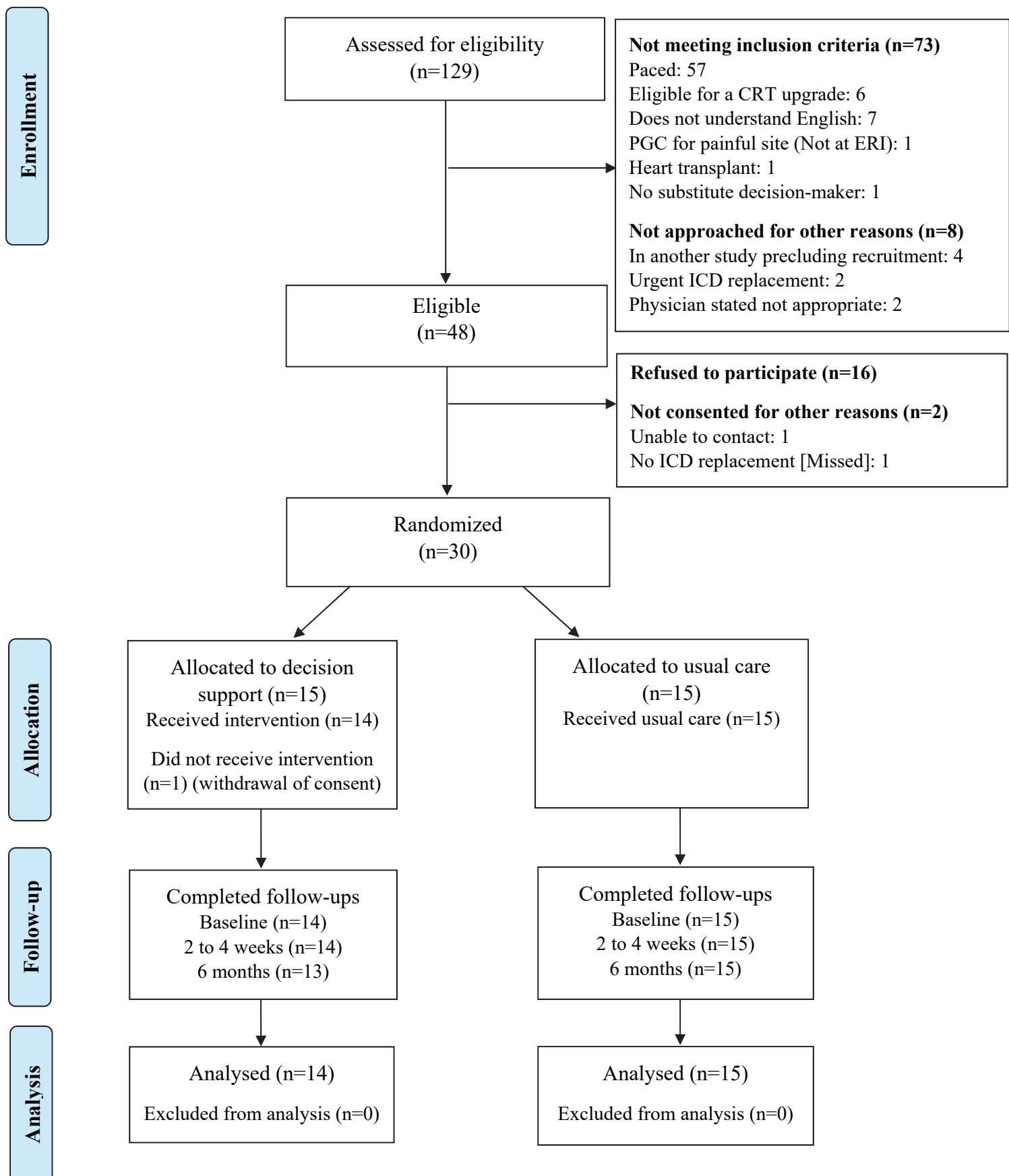
Figure 5.1 CONSORT Flowchart

Table 5.2 Acceptability of the Patient Decision Aid

Patient Decision Aid Acceptability	Intervention (n=14)
Amount of information	
Much less than I wanted	0
A little less than I wanted	0
About right	13
A little more than I wanted	1
Much more than I wanted	0
Length of the PDA	
Much too long	0
A little too long	1
About right	13
Should have been a little longer	0
Should have been much longer	0
Balanced presentation of options	
Clearly slanted towards replacing the ICD	0
Slightly slanted towards replacing the ICD	1
Completely balanced	13
Slightly slanted towards not replacing the ICD	0
Clearly slanted towards not replacing the ICD	0
Font size and readable	
Yes	13
No	1
Enough space to write notes	
Yes	13
No	1
Language in the PDA makes sense	
Yes	14
No	0
PDA fits into discussion with clinician	
Yes, as it is	10
Yes, but with some alterations	1
No	3

Table 5.3 Acceptability of the Decision Coaching

Decision Coaching Acceptability	Assigned to intervention (n=14)
1. The decision coach seemed to understand the stresses I was facing	
Agree strongly	11
Agree somewhat	1
Neutral	2
Disagree somewhat	0
Disagree strongly	0
2. The decision coach helped me to identify what we needed to know to make decisions about what would happen to me	
Agree strongly	9
Agree somewhat	2
Neutral	3
Disagree somewhat	0
Disagree strongly	0
3. I felt better about my decision after meeting with the decision coach	
Agree strongly	7
Agree somewhat	3
Neutral	2
Disagree somewhat	2
Disagree strongly	0
4. The decision coach was concerned with my well-being	
Agree strongly	11
Agree somewhat	0
Neutral	3
Disagree somewhat	0
Disagree strongly	0
5. The decision coaching session was valuable to me	
Agree strongly	8
Agree somewhat	4
Neutral	0
Disagree somewhat	2
Disagree strongly	0
6. How helpful was the decision coaching in helping you come to a preferred option?	
Very helpful	7
Somewhat helpful	1
A little helpful	3

Not helpful	3
7. Would you recommend decision coaching to others facing the same decision?	
I would definitely recommend it	11
I would probably recommend it	1
I would probably not recommend it	2
I would definitely not recommend it	0
8. The decision coaching session was about the right length of time	
Agree strongly	9
Agree somewhat	3
Neutral	2
Disagree somewhat	0
Disagree strongly	0
9. Did the coaching session prepare you for a follow-up with the nurse or physician in the device clinic?	
Yes	11
Unsure	1
No	2

Table 5.4 Preliminary Effectiveness Outcomes

	2-4 weeks			6 months		
	Intervention (n=14)	Usual Care (n=15)	Difference between groups Mean[95% CI]	Intervention (n=13) ^a	Usual Care (n=15)	Difference between groups Mean[95% CI]
Knowledge, mean % (SD)	77.4%(16.8)	51.1%(24.0)	26.3 [10.4, 42.1]	-	-	-
Decisional Conflict, Total score (mean, SD) ^b	8.0 (13.8)	14.3 (18.4)	-6.2 [-18.7, 6.2]	16.2 (13.5)	14.6 (16.1)	1.6 [-10.0, 13.3]
Subscales:						
Uninformed	6.5 (12.7)	14.4 (13.9)	-7.9 [-18.1, 2.3]	19.9 (21.7)	14.4 (20.5)	5.4 [-11.0, 21.8]
Unclear values	7.7 (12.0)	15.6 (18.3)	-7.8 [-19.7, 4.1]	21.8 (16.9)	16.1 (19.3)	5.7 [-8.5, 19.9]
Unsupported	7.1 (12.6)	13.9 (20.1)	-6.7 [-19.6, 6.1]	16.0 (13.8)	15.6 (16.9)	0.5 [-11.7, 12.6]
Uncertainty	10.1 (17.4)	14.4 (22.6)	-4.3 [-19.8, 11.1]	14.7 (14.9)	17.8 (22.0)	-3.0 [-17.9, 11.8]
Ineffective decision	8.5 (15.0)	13.3 (20.7)	-4.9 [-18.7, 9.0]	10.6 (12.3)	10.4 (12.0)	0.2 [-9.3, 9.6]
Choice Predisposition Scale, mean (SD) ^c	14.0 (1.8)	13.1 (3.3)	0.9 [-1.2, 2.9]	14.0 (2.2)	13.0 (2.4)	1.0 [-2.7, 4.7]
Choice, n(%)						
Preferred choice - Intention to replace the ICD	13 (92.9%)	14 (93.3%)		5 (38.5%)	4 (26.7%)	
Preferred choice - Do not replace the ICD/Unsure	1 (7.1%)	1 (6.7%)	-	0 (0.0%)	1 (6.7%)	-
Actual choice - Replaced the ICD	0 (0.0%)	0 (0.0%)		7 (53.8%)	9 (60.0%)	
Actual choice – Did not replace the ICD	0 (0.0%)	0 (0.0%)		1 (7.7%)	1 (6.7%)	
Perception of involvement in decision-making, n(%) ^d						
Physician decided				0 (0.0%)	3 (30.0%)	
Physician decided with patient's opinion				2 (25.0%)	1 (10.0%)	
Physician and patient decided together	-	-	-	0 (0.0%)	2 (20.0%)	-
Patient decided with physician's opinion				2 (25.0%)	1 (10.0%)	
Patient decided				4 (50.0%)	3 (30.0%)	

CI: confidence interval; ICD: implantable cardioverter-defibrillator; SD: standard deviation

^a n=1 lost to follow-up^b According to scale norms, scores < 25 are associated with decision implementation and scores >37.5 are associated with delayed decisions^c At 6 months, intervention group n=5 and usual care group n=4 (only patients reporting a preferred choice)^d At 6 months, intervention group n=8 (1 lost to follow-up) and usual care group n=10 (only patients reporting an actual choice)

5.8 References

1. Bennett M, Parkash R, Nery P, Senechal M, Mondesert B, Birnie D, Sterns LD, Rinne C, Exner D, Philippon F, Campbell D, Cox J, Dorian P, Essebag V, Krahm A, Manlucu J, Molin F, Slawnych M and Talajic M. Canadian Cardiovascular Society/Canadian Heart Rhythm Society 2016 Implantable Cardioverter-Defibrillator Guidelines. *The Canadian journal of cardiology*. 2017;33:174-188.
2. Merchant FM, Quest T, Leon AR and El-Chami MF. Implantable Cardioverter-Defibrillators at End of Battery Life: Opportunities for Risk (Re)-Stratification in ICD Recipients. *J Am Coll Cardiol*. 2016;67:435-44.
3. Lewis KB, Birnie D, Carroll SL, Clark L, Kelly F, Gibson P, Rockburn L, Rockburn L and Stacey D. User-centered development of a decision aid for patients facing implantable cardioverter-defibrillator replacement: A mixed-methods study. *Journal of Cardiovascular Nursing*. Accepted for publication.
4. Lewis KB, Nery PB and Birnie DH. Decision making at the time of ICD generator change: patients' perspectives. *JAMA Intern Med*. 2014;174:1508-11.
5. Svanholm JR, Nielsen JC, Mortensen P, Christensen CF and Birkelund R. Refusing Implantable Cardioverter Defibrillator (ICD) Replacement in Elderly Persons-The Same as Giving Up Life: A Qualitative Study. *Pacing Clin Electrophysiol*. 2015;38:1275-86.
6. Standing H, Exley C, Flynn D, Hughes J, Joyce K, Lobban T, Lord S, Matlock D, McComb JM, Paes P and Thomson RG. *A qualitative study of decision-making about the implantation of cardioverter defibrillators and deactivation during end-of-life care* Southampton (UK); 2016.
7. Philippon F, Sterns LD, Nery PB, Parkash R, Birnie D, Rinne C, Mondesert B, Exner D and Bennett M. Management of Implantable Cardioverter Defibrillator Recipients: Care Beyond Guidelines. *Can J Cardiol*. 2017;33:977-990.
8. Makoul G and Clayman ML. An integrative model of shared decision making in medical encounters. *Patient Educ Couns*. 2006;60:301-12.
9. Al-Khatib SM, Stevenson WG, Ackerman MJ, Bryant WJ, Callans DJ, Curtis AB, Deal BJ, Dickfeld T, Field ME, Fonarow GC, Gillis AM, Hlatky MA, Granger CB, Hammill SC, Joglar JA, Kay GN, Matlock DD, Myerburg RJ and Page RL. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Circulation*. 2017.
10. Légaré F, Stacey D, Turcotte S, Cossi MJ, Kryworuchko J, Graham ID, Lyddiatt A, Politi MC, Thomson R, Elwyn G and Donner-Banzhoff N. Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database Syst Rev*. 2014;9:CD006732.
11. Stacey D, Kryworuchko J, Bennett C, Murray MA, Mullan S and Légaré F. Decision coaching to prepare patients for making health decisions: a systematic review of decision coaching in trials of patient decision AIDS. *Med Decis Making*. 2012;32:E22-33.

12. Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, Thomson R, Barratt A, Barry M, Bernstein S, Butow P, Clarke A, Entwistle V, Feldman-Stewart D, Holmes-Rovner M, Llewellyn-Thomas H, Moumjid N, Mulley A, Ruland C, Sepucha K, Sykes A, Whelan T and International Patient Decision Aids Standards C. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*. 2006;333:417.
13. Coulter A, Stilwell D, Kryworuchko J, Mullen PD, Ng CJ and van der Weijden T. A systematic development process for patient decision aids. *BMC Med Inform Decis Mak*. 2013;13 Suppl 2:S2.
14. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M and Medical Research Council G. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008;337:a1655.
15. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, Lancaster GA and group Pc. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355:i5239.
16. Sepucha K, Abhyankar P, Hoffman A, Bekker HL, LeBlanc A, Levin C, Ropka M, Shaffer VA, Sheridan SL, Stacey D, Stalmeier P, Vo H, Willis C and Thomson R. Standards for UNiversal reporting of patient Decision Aid Evaluation studies: the development of SUNDAE Checklist. *BMJ Qual Saf*. Published Online First: 21 December 2017. doi: 10.1136/bmjqs-2017-006986
17. Slotwiner D, Varma N, Akar JG, Annas G, Beardsall M, Fogel RI, Galizio NO, Glotzer TV, Leahy RA, Love CJ, McLean RC, Mittal S, Morichelli L, Patton KK, Raitt MH, Ricci RP, Rickard J, Schoenfeld MH, Serwer GA, Shea J, Varosy P, Verma A and Yu CM. HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. *Heart Rhythm*. 2015;12:e69-100.
18. O'Connor AM, Tugwell P, Wells GA, Elmslie T, Jolly E, Hollingworth G, McPherson R, Bunn H, Graham I and Drake E. A decision aid for women considering hormone therapy after menopause: decision support framework and evaluation. *Patient Educ Couns*. 1998;33:267-79.
19. Lewis KB, Stacey D and Matlock DD. Making decisions about implantable cardioverter-defibrillators from implantation to end of life: an integrative review of patients' perspectives. *Patient*. 2014;7:243-60.
20. Lewis KB, Stacey D, Carroll SL, Boland L, Sikora L and Birnie D. Estimating the Risks and Benefits of Implantable Cardioverter Defibrillator Generator Replacement: A Systematic Review. *Pacing Clin Electrophysiol*. 2016;39:709-22.
21. Hess PL, Al-Khatib SM, Han JY, Edwards R, Bardy GH, Bigger JT, Buxton A, Cappato R, Dorian P, Hallstrom A, Kadish AH, Kudenchuk PJ, Lee KL, Mark DB, Moss AJ, Steinman R, Inoue LY and Sanders G. Survival benefit of the primary prevention implantable cardioverter-defibrillator among older patients: does age matter? An analysis of pooled data from 5 clinical trials. *Circ Cardiovasc Qual Outcomes*. 2015;8:179-86.
22. Healey JS, Hallstrom AP, Kuck KH, Nair G, Schron EP, Roberts RS, Morillo CA and Connolly SJ. Role of the implantable defibrillator among elderly patients with a history of life-threatening ventricular arrhythmias. *Eur Heart J*. 2007;28:1746-9.

23. Yung D, Birnie D, Dorian P, Healey JS, Simpson CS, Crystal E, Krahn AD, Khaykin Y, Cameron D, Chen Z and Lee DS. Survival after implantable cardioverter-defibrillator implantation in the elderly. *Circulation*. 2013;127:2383-92.
24. McHorney CA, Ware JE, Jr., Lu JF and Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. *Med Care*. 1994;32:40-66.
25. McHorney CA, Ware JE, Jr. and Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Med Care*. 1993;31:247-63.
26. Burns JL, Serber ER, Keim S and Sears SF. Measuring patient acceptance of implantable cardiac device therapy: initial psychometric investigation of the Florida Patient Acceptance Survey. *J Cardiovasc Electrophysiol*. 2005;16:384-90.
27. O'Connor AM, Tugwell P, Wells GA, Elmslie T, Jolly E, Hollingworth G, McPherson R, Drake E, Hopman W and Mackenzie T. Randomized trial of a portable, self-administered decision aid for postmenopausal women considering long-term preventive hormone therapy. *Med Decis Making*. 1998;18:295-303.
28. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, Robson R, Thabane M, Giangregorio L and Goldsmith CH. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol*. 2010;10:1.
29. Barry MJ, Cherkin DC, Chang Y, Fowler F and Skates S. A randomized trial of a multi-media shared decision-making program for men facing a treatment decision for benign prostatic hyperplasia. *Disease Management and Clinical Outcomes*. 1997;1:5-14.
30. Kushniruk AW and Patel VL. Cognitive and usability engineering methods for the evaluation of clinical information systems. *J Biomed Inform*. 2004;37:56-76.
31. O'Connor AM and A C. User Manual – Acceptability. 2002.
32. Schwalm JD, Stacey D, Pericak D and Natarajan MK. Radial artery versus femoral artery access options in coronary angiogram procedures: randomized controlled trial of a patient-decision aid. *Circ Cardiovasc Qual Outcomes*. 2012;5:260-6.
33. Tercyak KP, Johnson SB, Roberts SF and Cruz AC. Psychological response to prenatal genetic counseling and amniocentesis. *Patient Educ Couns*. 2001;43:73-84.
34. Carroll SL, Stacey D, McGillion M, Healey JS, Foster G, Hutchings S, Arthur HM, Browne G and Thabane L. Evaluating the effects of a patient decision aid in ICD candidates: A randomized controlled feasibility trial. *Pilot and Feasibility Studies*. 2017;3:49. doi: 10.1186/s40814-017-0189-9.
35. O'Connor A. User Manual - Decisional Conflict Scale. 2010.
36. Strull WM, Lo B and Charles G. Do patients want to participate in medical decision making? *JAMA*. 1984;252:2990-4.
37. Légaré F, Labrecque M, Cauchon M, Castel J, Turcotte S and Grimshaw J. Training family physicians in shared decision-making to reduce the overuse of antibiotics in acute respiratory infections: a cluster randomized trial. *CMAJ*. 2012;184:E726-34.

38. Degner LF, Sloan JA and Venkatesh P. The Control Preferences Scale. *Can J Nurs Res*. 1997;29:21-43.
39. Harrington J, Noble LM and Newman SP. Improving patients' communication with doctors: a systematic review of intervention studies. *Patient Educ Couns*. 2004;52:7-16.
40. Griffin SJ, Kinmonth AL, Veltman MW, Gillard S, Grant J and Stewart M. Effect on health-related outcomes of interventions to alter the interaction between patients and practitioners: a systematic review of trials. *Ann Fam Med*. 2004;2:595-608.
41. Stacey D, Kryworuchko J, Belkora J, Davison BJ, Durand MA, Eden KB, Hoffman AS, Koerner M, Légaré F, Loiselle MC and Street RL, Jr. Coaching and guidance with patient decision aids: A review of theoretical and empirical evidence. *BMC Med Inform Decis Mak*. 2013;13 Suppl 2:S11.
42. Solberg LI, Asche SE, Sepucha K, Thygeson NM, Madden JE, Morrissey L, Kraemer KK and Anderson LH. Informed choice assistance for women making uterine fibroid treatment decisions: a practical clinical trial. *Med Decis Making*. 2010;30:444-52.
43. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Thomson R and Trevena L. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2017;4:CD001431.
44. Thylén I, Moser DK, Chung ML, Miller J, Fluor C and Stromberg A. Are ICD recipients able to foresee if they want to withdraw therapy or deactivate defibrillator shocks? . *IJC Heart & Vessels*. 2013;1:22-31.
45. Tversky A and Kahneman D. The framing of decisions and the psychology of choice. *Science*. 1981;211:453-8.
46. Carroll SL, Strachan PH, de Laat S, Schwartz L and Arthur HM. Patients' decision making to accept or decline an implantable cardioverter defibrillator for primary prevention of sudden cardiac death. *Health Expect*. 2013;16:69-79.
47. Matlock DD, Jones J, Nowels CT, Jenkins A, Allen LA and Kutner JS. Evidence of Cognitive Bias in Decision Making Around Implantable-Cardioverter Defibrillators: A Qualitative Framework Analysis. *Journal of cardiac failure*. 2017.
48. Hill L, McIlpatrick S, Taylor BJ, Dixon L, Cole BR, Moser DK and Fitzsimons D. Implantable cardioverter defibrillator (ICD) deactivation discussions: Reality versus recommendations. *European journal of cardiovascular nursing : journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology*. 2016;15:20-9.
49. Ottenberg AL, Mueller PS, Topazian RJ, Kaufman S and Swetz KM. "It's not broke, so let's not try to fix it": why patients decline a cardiovascular implantable electronic device. *Pacing Clin Electrophysiol*. 2014;37:1306-14.

Chapter 6 : Incorporating Patients' Preference Diagnosis in Implantable Cardioverter-Defibrillator Decision-Making: A Review of Recent Literature

Citation: Lewis, K.B., Carroll, S.L., Birnie, D., Stacey, D., Matlock, D.D. (2018). Incorporating Patients' Preference Diagnosis in Implantable Cardioverter-Defibrillator Decision-Making: A Review of Recent Literature. *Current Opinion in Cardiology*. 33(1):42-49. doi: 10.1097/HCO.0000000000000464

Abstract

Purpose of review: Strong recommendations exist for implantable cardioverter-defibrillators (ICD) in appropriately selected patients. Yet, patient preferences are not often incorporated when decisions about ICD therapy are made. Literature published since 2016 was reviewed aiming to discuss current advances and ongoing challenges with ICD decision-making in adults, discuss shared decision-making (SDM) as a strategy to incorporate preference diagnoses, summarize current evidence on effective interventions to facilitate SDM, and identify opportunities for research and practice.

Recent findings: Advances in risk stratification can identify patients who will most and least likely benefit from the ICD. Interventions to support SDM are emerging. These interventions present options, the risks and the benefits of each option, and elicit patients' values and preferences regarding possible outcomes.

Summary: Appropriate patient selection for initial or continued ICD therapy is multi-factorial. It requires accurate clinical diagnosis using careful risk stratification and accurate preference diagnosis based upon the patient's personal life circumstances. SDM aims to unite the variables that constitute these two equally important diagnoses. High quality decision-making will be difficult to achieve if patients lack or misunderstand information, and if evolving patient preferences are not incorporated when making decisions.

3-5 keywords: implantable cardioverter-defibrillator, shared decision-making, patient preferences

Key points

- Diagnosis of patient preferences for the potential outcomes of ICD therapy are not often elicited when making decisions throughout the ICD pathway.
- High quality decisions depend on the accurate communication and understanding of the options, risks and benefits around ICD therapy and its role in sudden cardiac death prevention, linked to the patients' preferences for the potential outcomes of the options.
- High quality decisions can be achieved using a shared decision-making process.
- Interventions to support shared decision-making throughout the ICD pathway are emerging.

6.1 Introduction

Implantable cardioverter defibrillators (ICD) reduce mortality from ventricular arrhythmias in appropriately selected patients. It is a treatment decision that can impact a patient for years, offering hope for improved survival when threatened by the risk of ventricular arrhythmias. The potential mortality benefit is compelling, but research has shown it is not the only consideration for all patients [1]. A number of preference-sensitive outcomes accompany ICD therapy and may lead some patients to decline implantation or eventually request its withdrawal [2]. As such, it is not sufficient to confirm initial and ongoing ICD eligibility based on clinical presentation alone. An accurate preference diagnosis is equally as important [3]. Clinical practice guidelines provide recommendations for clinicians in the selection and management of patients at risk for sudden cardiac death [4, 5]. However, within these, there is limited information on how to elicit, diagnose, and incorporate patient preferences in these decisions and little regard for outcomes other than survival [6].

The aims of this paper are: 1) to review recent challenges and advances with ICD decision-making in adults; 2) to discuss shared decision-making (SDM) as a solution to mitigate these challenges; 3) to summarize the evidence on effective interventions to facilitate SDM; and 4) to identify opportunities for practice and research. Sources of evidence used to inform this review are listed in Table 6.1.

6.2 Recent Challenges and Advances with ICD Decision Making

Appropriate patient selection for ICD implantation is challenging. Strong recommendations exist for primary prevention in patients with ischemic and non-ischemic cardiomyopathy with left ventricular ejection fraction (LVEF) $\leq 30\%$, and for secondary prevention in those with cardiac arrest and sustained ventricular tachycardia in the presence of structural heart disease. Yet emerging data is contradicting older data; recently, the DANISH trial results found no benefit from ICD use in patients with heart failure from non-ischemic causes [7]. Subsequent pooled analyses supported continued ICD use in this patient population [8-10]; however, specific observations derived from the DANISH trial - for example the ICD's effectiveness in the elderly population with non-ischemic cardiomyopathy - have re-ignited debate [11].

A significant proportion of individuals evaluated for ICD implantation or replacement are not well represented in major ICD trials. Clinicians are faced with a difficult task when they evaluate patients with advancing age, chronic comorbid conditions, frailty, cognitive dysfunction, and specific cardiac diseases for ICD therapy. Registry-based studies have demonstrated “real-world” ICD use. When the burden of comorbidity is high, mortality and hospitalization rates worsen [12]. According to National Cardiovascular Data Registry ICD Registry data (n=83 792), approximately 1 in 10 patients receiving an ICD for primary prevention was considered frail (10%) and/or had dementia (1%) prior to implantation [13]. One-year mortality rates for these patients was 22% and 27%, respectively. Several comorbid combinations were associated with higher 1-year mortality rates including frailty with chronic obstructive pulmonary disease (25%), frailty with diabetes mellitus (23%), and frailty with dementia (29%).

The Canadian Cardiovascular Society ICD Guidelines recommend screening for frailty and assessing the burden of comorbidities. These co-morbidities should be weighed against the factors increasing the patient’s risk of sudden cardiac death [4]. Multiple sources agree that chronological age alone should not be a decisive factor as both young and old experience similar rates of appropriate ICD therapies and survival benefit from the ICD, despite higher all-cause mortality in older age groups due to non-arrhythmic causes [14-16]. In recognition of this changing patient landscape, risk stratification scores have been developed to aid in the identification of patients who are most (or least) likely to benefit from the ICD.

6.2.1 Risk stratification scores

Risk stratification scores are based on a composite of clinically relevant predictors of mortality. Seven risk scores exist, with moderate predictive abilities in forecasting mortality risk in patients receiving ICDs for primary prevention [17-21], hypertrophic cardiomyopathy [22], and elective generator replacement [23]. Barra et al. validated six scores for patients facing elective ICD replacement [24]. Bilchik et al.’s score outperformed all others [AUC 0.813±0.038, p<0.001], which included parameters of age ≥75 years, NYHA Class III, CKD, atrial fibrillation, LVEF ≤20%, chronic obstructive pulmonary disease, and diabetes mellitus [17]. Recently, a novel targeted approach using cardiac imaging and computational modelling was proposed, which assesses the interplay between abnormal myocardial structure and electrical instability that predisposes a post-infarcted heart to ventricular arrhythmia [25]. In a proof-of-concept study

including 41 patients, this non-invasive approach outperformed existing metrics such as LVEF and electrophysiology testing to predict future arrhythmic events.

These risk estimates can help individualize discussions about the potential benefits and risks of ICD therapy, helping those with greater risk reductions quantify their potential benefits, and helping those with the least, quantify the burden of risk for potentially little to no benefit. But when used in isolation, risk scores do not assure patient understanding of the potential life versus death trade-off, do not highlight the potential for important morbidity and unavoidable harms such as clinically futile shocks at end-of-life, and do not incorporate the preference-sensitive nuances of ICD therapy. These elements are essential in achieving quality patient-clinician communication [3].

6.2.2 Inadequate patient-clinician communication

Patients depend on their clinician as their primary source for ICD-specific information [26, 27]. Prior studies report that clinicians omit, minimize, or even deny quality of life issues, potential burdens, and deactivation discussions related to ICD therapy in fear of reducing hope and causing distress [28-30]. Many clinicians feel challenged when asked to consider patient preferences. As a result, clinicians tend to rely on mortality-informed practice guideline recommendations [31] and avoid ones that recommend preference-sensitive discussions such as ICD deactivation [30, 32]. Inadequate clinician communication has significant impact on patients; patients are susceptible to cognitive biases and their recollection of benefits and harms of the ICD is heavily influenced by the way the information is presented [32]. In a qualitative study of 48 patients, framing, default and halo effects around both the clinician and ICD technology itself were prevalent in favour of the ICD [1].

Many studies suggest that at ICD implantation, replacement and nearing end-of-life, patients were not offered choice, were uninformed about their options, and did not have the opportunity to share their values and preferences for potential outcomes – despite expressing a wish to be involved [33-36]. In a survey study, 19% of ICD recipients (50/263) did not want their ICD at the time of implantation [33]. These patients reported less participation in decision-making, were younger (<65 years old; 74% vs 43%, $P < 0.001$) and reported higher decision regret (31/100 vs 11/100, $P < 0.001$). When facing ICD replacement, decision-making was influenced by past experiences with ICD implantation surgeries, and present day social and

financial considerations. The time leading up to ICD replacement was useful for deliberation and logistical planning [37].

Patients want to be offered choice and they want accurate and balanced information about the available options and outcomes other than mortality including potential impact on psychological well-being and quality of life [24, 38, 39]. High quality decisions depend on an accurate understanding of the ICD in sudden cardiac death prevention, and linking patients' priorities for the potential outcomes of options. In summary, risk stratification scores exist to better identify the likelihood of benefits and harms associated with ICD use in adults. However, interventions are required to better prepare clinicians to diagnose and discuss patient preferences.

6.3 Shared Decision-Making

A component of patient-centered care, SDM is the process of engaging patients in decisions about their health. Makoul and Clayman (2006) identified nine essential elements that comprise SDM [40] (Table 6.2). In SDM, patients and clinicians exchange information and deliberate together to achieve the best possible outcomes for the patient. Clinicians are accountable for providing and explaining treatment options (including doing nothing) based on the best available evidence including the risks and benefits of each option, and verifying patients' understanding. Patients are responsible for sharing their preferences and values for the outcomes of each option. Jointly, the clinician(s) and patient and/or family members deliberate to reach agreement. Clinicians can help patients clarify their values by helping them consider their preferences for key characteristics, and outcomes of the benefits and risks of the decisions they face. This aims to achieve values-choice concordance, where a decision matches what is most desirable to the patient and what option is actually selected; a measure of decision quality [41]. As a patient's clinical presentation changes over time, so might their values and preferences towards ICD therapy.

6.3.1 Discussing trade-offs throughout the ICD pathway

Patients with ICDs identified three distinct moments when the sudden versus prolonged death trade-offs should be shared: 1) prior to initial implantation; 2) with significant deterioration; and 3) when nearing end-of-life [36]. ICD replacement has also been identified as an opportune moment for risk re-stratification and a well-informed discussion revising the risks, potential benefits, and evolving goals of care [42, 43]. MacIver et al[36] named these phases

“Describe-Discuss-Decide” which delineates a process of gradual intensification towards the difficult decisions individuals with ICDs may need to consider. How the information is presented between the stages is outlined in Table 6.3.

Most clinicians agree with SDM, and many believe they already involve patients in this process. Yet, research suggests that few clinicians involve patients in decision-making, and even fewer adjust recommendations to patient preferences [44]. The following section summarizes the evidence on interventions that can facilitate SDM.

6.3.2 Interventions to Facilitate Patient Involvement in SDM

Without formalized opportunities for patient engagement, SDM is less likely to occur [45]. In a review of barriers and facilitators to patient involvement in SDM, building individual capacity to participate in SDM requires knowledge and power [46]. Patients obtain knowledge by way of information about the options explained in a simple manner, and with support to identify their personal preferences and goals for the options. Power is more difficult to attain, but depends on the patient’s confidence in their knowledge and skills to participate in the consultation, and whether they perceive to have permission to participate. Decision support tools such as patient decision aids (PDAs), decision coaching, and question prompts can facilitate this by helping patients prepare for the consultation.

PDAs are written or video-based tools that help patients become involved in decision-making. In a Cochrane review of PDAs, 105 studies involving 31,043 participants showed that individuals exposed to PDAs are more knowledgeable, better informed, and clearer about their values [47]. They are also more active in decision-making and have greater accurate risk perceptions, without any adverse effects on health outcomes or participant satisfaction. They are also associated with a reduction in elective surgical rates, particularly if base rates are high. Some PDA trials incorporated decision coaching, defined as non-directive support aimed at building deliberation and decision implementation skills [48]. Registered nurses and social workers are well suited for decision coaching as they often have in-depth conversations with patients and can offer important insights in identifying preferences [49-51].

PDAs for ICD decision-making have been developed and field-tested [52, 53]. Preliminary evaluation of a PDA for primary prevention ICD showed that individuals exposed to a PDA were more knowledgeable, had lower decisional conflict, and better values-choice

concordance than those exposed to a usual care arm[54]. A PDA for ICD replacement was developed using a user-centred design. A trial is currently underway (ClinicalTrials.gov # NCT02668900).

Additionally, the “Ask 3 questions” campaign (Table 6.4) and question prompts can strengthen patient-clinician communication by improving the quality of the information provided by clinicians and facilitating patient interaction and involvement [55, 56]. Importantly, when considering any intervention for SDM, those that target both patients and healthcare professionals are more effective than those that target only one or the other [57].

6.4 Implications for Future Research and Practice

Prior to initial implantation, patients should have a clear overview of the ICD pathway to help them understand the subsequent decisions points such as ICD replacement and possibilities for deactivation [29]. An emphasis on ICD therapy as a trajectory of dynamic decisions that are subject to review may help patients, families, and clinicians adjust their expectations of ICD therapy, not as an irrevocable treatment but one of appropriate use based on the clinical situation and aligned with the patient’s evolving preferences and health goals. To help guide conversations with patients and families, preference-sensitive attributes for the potential outcomes of ICD therapy are listed in Table 6.5.

Future clinical practice guideline updates could recommend the use of PDAs to facilitate SDM at these decision points. The same evidence used to update future guidelines can be used to develop accompanying PDAs or scripts for decision coaches. Within them, outcomes known to be important to patients could be used to elicit patients’ preferences by having them rate their importance [6, 58] and risk stratification scores could ensure that the information is tailored to the patient’s clinical risk profile.

Further research is necessary to understand factors interfering with the integration of patient preferences in ICD decision-making. These insights could help inform skill-building interventions such as simulations and role play to improve the communication of the options, risks and benefits, values and preferences and linking these to ICD-related outcomes [30, 59]. Evidence-based strategies to support SDM along the ICD pathway could be implemented in parallel. Educational opportunities should not be limited to clinicians specialized in arrhythmia. All professions and disciplines involved in the care of patients with ICDs should be targeted.

This includes clinicians in primary care and particularly those involved nearing the end-of-life such as critical care, hospice, or long-term care.

Finally, to improve accountability and provide quantitative measure of value-based care, the development of quality indicators such as the documentation of patient preferences along the ICD pathway - particularly when approaching end-of-life - should be considered by health care funders and professional bodies [60, 61].

6.5 Conclusions

Appropriate patient selection for initial or continued ICD therapy is multi-factorial. It requires careful risk stratification based the patient's clinical presentation. It also requires an accurate preference diagnosis based upon the patient's reality. SDM aims to unite essential elements that constitute these two equally important diagnoses. However, SDM will be difficult to achieve if patients have inadequate knowledge about the options and are not asked about their preferences, and if clinicians are unable or unwilling to diagnose and incorporate patient preferences when making decisions. The right choice is dependent on the accurate communication and understanding of the options tailored to the patient's individual risk/benefit profile and the patient's informed preferences.

Table 6.1 Sources of Evidence

MEDLINE and CINAHL searches January 2016-June 2017. Key words: Defibrillators, Implantable; Decision Making; Decision Support Techniques; Consumer Participation; Informed Consent; Professional-Patient Relations

Primary and secondary sources on patient-clinician decision-making as related to ICD implantation, generator replacement and deactivation

Reference lists of retrieved literature

Clinical Practice Guidelines on Implantable Cardioverter Defibrillators:

Canadian Cardiovascular Society/Canadian Heart Rhythm Society 2016 Implantable Cardioverter Defibrillator Guidelines [4]

2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society [5]

Heart Rhythm Society 2010 Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices in patients nearing end of life or requesting withdrawal of therapy [2]

.

Table 6.2 Nine Essential Elements to Shared Decision-Making

Define and explain the problem

Present the options

Discuss the pros/cons, benefits/risks

Elicit values and preferences for possible outcomes

Discuss patient's ability to follow agreed upon plan

Healthcare professional to offer recommendations, informed by preference diagnosis

Check and clarify understanding

Make or explicitly defer decision

Arrange follow-up

*Based on Makoul & Clayman (2006) [40]

Table 6.3 Format for ICD Replacement and Deactivation Discussions

	Describe	Discuss	Decide
When	Pre-implantation	- 6-12 months prior to estimated battery depletion - With any change in health status: - Transition to end-stage heart failure - New non-cardiac diagnosis - Increasing frailty - Improvement in cardiac function - Whenever patient desires	- Prior to battery depletion - Nearing or at end-of-life
Purpose	Inform about the options at all decision points	- Re-evaluate benefit/risk ratio - Reflect on lived experience to date - Elicit patient preferences and values - Incorporate preference diagnosis in decision-making	- Preferences from last review are used to inform discussion - Make or explicitly defer decision
Format	- Pre-implant discussions with interprofessional team - Patient education materials - Patient decision aids	- Formal meeting with interprofessional team, patient and family - Patient education materials - Patient decision aids	- Formal or informal meeting with patient and family - Communication with other healthcare professionals involved in their care
Outcome	Raise awareness and verify understanding that: - ICD therapy can be reconsidered nearing battery depletion - ICD can be deactivated - Values and personal preferences for ICD therapy can change over time - management of ICD may be included in advance directives	- Remind patient of options - Document patient preferences for possible outcomes in clinical record - Record how preferences have changed over time - Arrange follow-up	- Decision regarding ICD replacement and/or deactivation - Arrange follow-up, if needed

*Adapted from MacIver et al. (2016) [36]

Table 6.4 “Ask-3 Questions” to Facilitate Patient Involvement

1. What are my options?
2. What are the possible benefits and risks of those options?
3. How likely are the possible benefits and risks of each option to occur?

From Shepherd et al. (2011) [55]

Table 6.5 Preference-sensitive Attributes of ICD Therapy

Attributes	Potential benefits and harms of attributes	Example questions to elicit patient preferences <i>“How important is it for you to...”</i>
Nature of the procedure	Risks associated with the surgery Battery powered, requires surgical replacement every 5-7 years	- Avoid any surgery? - Avoid complications from surgery? - Avoid repeat surgeries?
Mode of delivery	Shocks; appropriate and inappropriate therapy Advisories and/or malfunction	- Live as long as possible? - Avoid appropriate shocks? - Avoid inappropriate shocks? - Avoid the consequences of a device advisory/malfunction (e.g. intensify follow-up; repeat surgery?) - Avoid the consequences of a lead problem?
Duration of the therapy	No predetermined endpoint; can be lifelong Ongoing follow-ups required	- Be able to deactivate the shocking function?
Mode of death	Life-saving potential with shock and/or ATP Potential for shock(s) at end-of-life	- Avoid SCD indefinitely? - Desire to die quickly – that is, in one’s sleep? - Die naturally without life prolonging procedures? - Avoid the risk clinically futile shocks at the end-of-life? - Avoid the risk of prolonged and progressive heart failure?
Physical effects	Scar and/or prominence of device generator Impact on body image	- Minimize impact on perceived body image?

	Impact on intimacy/sex	
Emotional effects	Risk of psychological problems Effect on body image Mode of death	- <i>Avoid the risk of psychological problems (considering prior history)?</i>
Social effects	Driving restrictions Limitations to physical activity Avoiding EMI Shock avoidance behaviours	- <i>Avoid driving restrictions?</i> - <i>Limit physical activity? (e.g. type, intensity)</i> - <i>Be able/be unable to avoid EMI?</i>

* Original Table.

ATP: Anti-tachycardic pacing; EMI: Electromagnetic interference; SCD: Sudden cardiac death

6.6 References

- [1] Lewis KB, Stacey D, Matlock DD. Making decisions about implantable cardioverter-defibrillators from implantation to end of life: an integrative review of patients' perspectives. *Patient* 2014; 7:243-260.
- [2] Lampert R, Hayes DL, Annas GJ, *et al.* HRS Expert Consensus Statement on the management of cardiovascular implantable electronic devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy. *Heart Rhythm* 2010; 7:1008-1026.
- [3] Mulley A, Trimble C, Elwyn G. Stop the silent misdiagnosis: Patients preferences matter. *BMJ* 2012; 345:e6572.
- [4] Bennett M, Parkash R, Nery P, *et al.* Canadian Cardiovascular Society/Canadian Heart Rhythm Society 2016 implantable cardioverter-defibrillator guidelines. *Can J Cardiol* 2017; 33:174-188.
- ** Recent update of Canadian ICD guidelines include recommendations on when it is reasonable to withhold the ICD on the basis of comorbidities. The guidelines recommend reaching a decision that is consistent with the patient's values and preferences, particularly in the setting of frailty.**
- [5] Epstein AE, DiMarco JP, Ellenbogen KA, *et al.* 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Circulation* 2013; 127:e283-352.
- [6] Joyce KE, Lord S, Matlock DD, *et al.* Incorporating the patient perspective: a critical review of clinical practice guidelines for implantable cardioverter defibrillator therapy. *J Interv Card Electrophysiol* 2013; 36:185-197.
- [7] Kober L, Thune JJ, Nielsen JC, *et al.* Defibrillator implantation in patients with nonischemic systolic heart failure. *N Engl J Med* 2016; 375:1221-1230.
- [8] Golwala H, Singh Bajaj N, Arora G, *et al.* Implantable cardioverter-defibrillator for nonischemic cardiomyopathy: an updated meta-analysis. *Circulation* 2017; 135: 201-203.
- [9] Romero J, Chaudhary R, Garg J, *et al.* Role of implantable cardioverter defibrillator in non-ischemic cardiomyopathy: a systematic review and meta-analysis of prospective randomized clinical trials. *J Interv Card Electrophysiol* 2017, 49:263-270.
- [10] Barakat AF, Saad M, Elgendy AY, *et al.* Primary prevention implantable cardioverter defibrillator in patients with non-ischaemic cardiomyopathy: a meta-analysis of randomised controlled trials. *BMJ Open* 2017; 7:e016352.

[11] Nery PB, Lewis KB, Birnie DH. Letter by Nery et al Regarding Article, "Implantable Cardioverter-Defibrillator for Nonischemic Cardiomyopathy: An Updated Meta-Analysis". *Circulation* 2017; 135:e1198-e1199.

[12] Boriani G, Berti E, Belotti LMB, *et al.* Cardiac device therapy in patients with left ventricular dysfunction and heart failure: 'real-world' data on long-term outcomes (mortality, hospitalizations, days alive and out of hospital). *European journal of heart failure* 2016; 18:693-702.

[13] Green AR, Leff B, Wang Y, *et al.* Geriatric conditions in patients undergoing defibrillator implantation for prevention of sudden cardiac death: prevalence and impact on mortality. *Circ Cardiovasc Qual* 2016; 9:23-30.

**** Cohort study determined the prevalence of frailty and dementia among patients ≥ 65 years receiving a new primary prevention ICD. These patients had a higher 1-year mortality rate than patients with other chronic conditions. Some chronic comorbid combinations were also associated with higher 1-year mortality rates. This is an important study highlighting the need to carefully consider geriatric conditions and contextual circumstances in older patients eligible for an ICD.**

[14] Hess PL, Al-Khatib SM, Han JY, *et al.* Survival benefit of the primary prevention implantable cardioverter-defibrillator among older patients: does age matter? An analysis of pooled data from 5 clinical trials. *Circ Cardiovasc Qual* 2015; 8:179-186.

[15] Yung D, Birnie D, Dorian P, *et al.* Survival after implantable cardioverter-defibrillator implantation in the elderly. *Circulation* 2013; 127:2383-2392.

[16] Fauchier L, Alonso C, Anselme F, *et al.* Position paper for management of elderly patients with pacemakers and implantable cardiac defibrillators: Groupe de rythmologie et stimulation cardiaque de la Societe francaise de cardiologie et Societe francaise de geriatric et gerontologie. *Arch Cardiovasc Dis* 2016; 109:563-585.

***Comprehensive review of cardiac implantable electronic devices use in the elderly based on clinical factors only. Overall, states that ICD decision-making should not be based on chronological age alone, but must be inclusive of factors such as physiological age, general health status, and comorbidities.**

[17] Bilchick KC, Stukenborg GJ, Kamath S, Cheng A. Prediction of mortality in clinical practice for medicare patients undergoing defibrillator implantation for primary prevention of sudden cardiac death. *J Am Coll Cardiol* 2012; 60:1647-1655.

[18] Parkash R, Stevenson WG, Epstein LM, Maisel WH. Predicting early mortality after implantable defibrillator implantation: a clinical risk score for optimal patient selection. *Am Heart J* 2006; 151:397-403.

[19] Kraaier K, Scholten MF, Tijssen JG, *et al.* Early mortality in prophylactic implantable cardioverter-defibrillator recipients: development and validation of a clinical risk score. *Europace* 2014; 16:40-46.

- [20] Goldenberg I, Vyas AK, Hall WJ, *et al.* Risk stratification for primary implantation of a cardioverter-defibrillator in patients with ischemic left ventricular dysfunction. *J Am Coll Cardiol* 2008; 51:288-296.
- [21] Providencia R, Boveda S, Lambiase P, *et al.* Prediction of nonarrhythmic mortality in primary prevention implantable cardioverter-defibrillator patients with ischemic and nonischemic cardiomyopathy. *JACCEP* 2015; 1:29-37.
- [22] O'Mahony C, Jichi F, Pavlou M, *et al.* A novel clinical risk prediction model for sudden cardiac death in hypertrophic cardiomyopathy (HCM risk-SCD). *Eur Heart J* 2014; 35:2010-2020.
- [23] Chung MK, Holcomb RG, Mittal S, *et al.* REPLACE DARE (Death After Replacement Evaluation) score: determinants of all-cause mortality after implantable device replacement or upgrade from the REPLACE registry. *Circ Arrhythm Electrophysiol* 2014; 7:1048-1056.
- [24] Barra S, Goonewardene M, Heck P, *et al.* Implantable cardioverter-defibrillator elective generator replacement: a procedure for all? *J Interv Card Electrophysiol* 2016; 45:209-218.
** Validation study of six risk stratification scores for patients undergoing elective ICD replacement.
- [25] Arevalo HJ, Vadakkumpadan F, Guallar E, *et al.* Arrhythmia risk stratification of patients after myocardial infarction using personalized heart models. *Nat Commun* 2016; 7:11437.
* A proof-of-concept study which describes a novel non-invasive personalized approach using clinical magnetic resonance imaging data to predict future arrhythmic risk.
- [26] Chan LL, Lim CP, Aung ST, *et al.* Patient barriers to implantable cardioverter defibrillator implantation for the primary prevention of sudden cardiac death in patients with heart failure and reduced ejection fraction. *Singapore Med J* 2016; 57:182-187.
* Largest study assessing the demographic and social factors of 240 patients who declined ICD implantation. The strongest predictor for reconsideration of the ICD was an accurate understanding of the role of ICDs in preventing sudden cardiac death, suggesting that the careful presentation of ICD purpose and confirming patient understanding is important.
- [27] Knoepke CE, Matlock DD. Preliminary Development of an Informational Media Use Measure for Patients with Implanted Defibrillators: Toward a Model of Social-Ecological Assessment of Patient Education and Support. *Health Soc Work* 2017. [epub ahead of print]
* Development of a preliminary measure of health information acquisition activities reported by patients with ICDs. Knowing how patients obtain information about ICDs can assist with the development and distribution methods of educational and supportive interventions.
- [28] Hauptman PJ, Chibnall JT, Guild C, Armbrecht ES. Patient perceptions, physician communication, and the implantable cardioverter-defibrillator. *JAMA Intern Med* 2013; 173:571-577.

[29] Standing H, Exley C, Flynn D, *et al.* A qualitative study of decision-making about the implantation of cardioverter defibrillators and deactivation during end-of-life care. *Health Serv Deliv Res* 2016; 4:32.

** Qualitative study using observations of clinical encounters, interviews and workshops with clinicians and patients/relatives exploring experiences of decision-making practices about cardiac device implantation and deactivation to determine information and decision support needs for shared decision-making. Identifies need for multifaceted SDM interventions targeting clinicians and patients.

[30] Hill L, McIlfatrick S, Taylor BJ, *et al.* Implantable cardioverter defibrillator (ICD) deactivation discussions: Reality versus recommendations. *Eur J Cardiovasc Nurs* 2016; 15:20-29.

*Chart review aimed to determine the frequency of deactivation discussions prior to implantation and throughout the ICD trajectory. Highlights that shared decision-making about ICD therapy is difficult to achieve when patients lack information.

[31] Caverly TJ, Al-Khatib SM, Kutner JS, *et al.* Patient preference in the decision to place implantable cardioverter-defibrillators. *Arch Intern Med* 2012; 172:1104-1105.

[32] Matlock DD, Jones J, Nowels CT, *et al.* Evidence of cognitive bias in decision making around implantable-cardioverter defibrillators: a qualitative framework analysis. *J Card Fail* 2017. [epub ahead of print]

* First study showing evidence of cognitive bias in decision-making favoring ICD implantation.

[33] Green AR, Jenkins A, Masoudi FA, *et al.* Decision-making experiences of patients with implantable cardioverter defibrillators. *Pacing Clin Electrophysiol* 2016; 39:1061-1069.

* Survey study reveals that a considerable number of patients who underwent ICD implantation did not want it. Suggests areas for improvement to assist patients making decisions regarding ICD implantation.

[34] Carroll SL, Strachan PH, de Laat S, *et al.* Patients' decision making to accept or decline an implantable cardioverter defibrillator for primary prevention of sudden cardiac death. *Health Expect* 2013; 16:69-79.

[35] Lewis KB, Nery PB, Birnie DH. Decision making at the time of ICD generator change: patients' perspectives. *JAMA Intern Med* 2014; 174:1508-1511.

[36] MacIver J, Tibbles A, Billia F, Ross H. Patient perceptions of implantable cardioverter-defibrillator deactivation discussions: A qualitative study. *SAGE Open Med* 2016; 4:1-8.

** Grounded theory qualitative study that revealed patients want to know about the option of ICD deactivation. Authors offer an information sharing process about ICD deactivation throughout the ICD pathway.

[37] Jakub KE, Sandelowski M. Reimplantation surgery in patients with implantable cardioverter defibrillators: A qualitative study. *Heart Lung* 2016; 45:48-55.

* A qualitative study of patient experiences with recurrent ICD replacement surgeries highlighted areas for improvement: 1) communicating the potential somatic outcomes, and

logistical and social details of the procedure; and 2) incorporating the patient's previous experience with cardiac device surgeries when making the decision.

[38] Levinson W, Kao A, Kuby A, Thisted RA. Not all patients want to participate in decision making. A national study of public preferences. *J Gen Intern Med* 2005; 20:531-535.

[39] Mazur DJ, Hickam DH. Patients' preferences for risk disclosure and role in decision making for invasive medical procedures. *J Gen Intern Med* 1997; 12:114-117.

[40] Makoul G, Clayman ML. An integrative model of shared decision making in medical encounters. *Patient Educ Couns* 2006; 60:301-312.

[41] Sepucha KR, Fowler FJ, Jr., Mulley AG, Jr. Policy support for patient-centered care: the need for measurable improvements in decision quality. *Health Aff (Millwood)* 2004; Suppl Variation:VAR54-62.

[42] Kramer DB, Buxton AE, Zimetbaum PJ. Time for a change--a new approach to ICD replacement. *N Engl J Med* 2012; 366:291-293.

[43] Merchant FM, Quest T, Leon AR, El-Chami MF. Implantable cardioverter-defibrillators at end of battery life: opportunities for risk (re)-stratification in ICD recipients. *J Am Coll Cardiol* 2016; 67:435-444.

** Comprehensive review on opportunities for risk stratification prior to implantable cardioverter defibrillator replacement. Discusses how decision-making approaches prior to replacement may impact end-of-life experiences for patients with ICDs.

[44] Couet N, Desroches S, Robitaille H, *et al.* Assessments of the extent to which health-care providers involve patients in decision making: a systematic review of studies using the OPTION instrument. *Health Expect* 2015; 18:542-561.

[45] Stevenson FA, Cox K, Britten N, Dundar Y. A systematic review of the research on communication between patients and health care professionals about medicines: the consequences for concordance. *Health Expect* 2004; 7:235-245.

[46] Joseph-Williams N, Elwyn G, Edwards A. Knowledge is not power for patients: a systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient Educ Couns* 2014; 94:291-309.

[47] Stacey D, Légaré F, Lewis K, *et al.* Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2017; 4:CD001431.

[48] O'Connor AM, Stacey D, Légaré F. Coaching to support patients in making decisions. *BMJ* 2008; 336:228-229.

[49] Pasalic D, Buchhalter LC, Gazelka HM, *et al.* Palliative care consultation and associated end-of-life care after pacemaker or implantable cardioverter-defibrillator deactivation. *Am J Hosp Palliat Care* 2016; 33:966-971.

* Chart review of patients who underwent ICD deactivation. Suggests that palliative care consultations may help patients with ICDs manage their symptoms and clarify goals of care when nearing end-of-life.

[50] Knoepke CE, Johnson-Koenke R. Shockingly uninvolved: potential for social work practice and leadership in implanted defibrillator care. *Health Soc Work* 2016; 41:e38-e43.

* Development of a trajectory model for the role of social workers in the care of patients with implantable cardioverter-defibrillators.

[51] Lewis KB, Starzomski R, Young L. A Relational approach to implantable cardioverter-defibrillator generator replacement: an integrative review of the role of nursing in shared decision-making. *Can J Cardiovasc Nurs* 2014; 24:6-14.

[52] Carroll SL, McGillion M, Stacey D, *et al.* Development and feasibility testing of decision support for patients who are candidates for a prophylactic implantable defibrillator: a study protocol for a pilot randomized controlled trial. *Trials* 2013; 14:346.

[53] Jenkins A, Jones J, Mellis BK, *et al.* Development and pilot of four decision aids for implantable cardioverter-defibrillators in different media formats. Presented at the Annual Meeting of the Society for Medical Decision Making. St Louis, Missouri: 2015.

[54] Carroll SL, McGillion M, Stacey D, *et al.* Patient decision aids in new implantable cardioverter defibrillator candidates: Feasibility of conducting a randomized controlled trial. *Eur J Cardiovasc Nurs* 2016, 15(S1), P229. Presented at the European Cardiovascular Congress. Rome, Italy.

[55] Shepherd HL, Barratt A, Trevena LJ, *et al.* Three questions that patients can ask to improve the quality of information physicians give about treatment options: a cross-over trial. *Patient Educ Couns* 2011; 84:379-385.

[56] Sansoni J, Grootemaat P, Duncan C, *et al.* Systematic literature review on question prompt lists in health care (Final Report). Centre for Health Service Development; University of Wollongong 2014.

[57] Légaré F, Stacey D, Turcotte S, *et al.* Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database Syst Rev* 2014; 9:CD006732.

[58] Allen LA, Stevenson LW, Grady KL, *et al.* Decision making in advanced heart failure: a scientific statement from the American Heart Association. *Circulation* 2012; 125:1928-1952.

[59] Berkhof M, van Rijssen HJ, Schellart AJ, *et al.* Effective training strategies for teaching communication skills to physicians: an overview of systematic reviews. *Patient Educ Couns* 2011; 84:152-162.

[60] Friedman DJ, Al-Khatib SM. Measuring quality in electrophysiology. *J Interv Card Electrophysiol* 2016; 47:5-10.

[61] Canadian Cardiovascular Society. Quality Project. Available from <http://ccs.ca/en/health-policy/programs-and-initiatives/quality-project>. Accessed July 20, 2017.

Chapter 7 : Integrated Discussion

My dissertation was focused on the development and preliminary evaluation of a decision support intervention for adults faced with implantable cardioverter-defibrillator (ICD) replacement. In this chapter, I summarize the findings of my five studies, reflect and discuss how they contribute to the broader literature, and propose future directions.

7.1 Summary of Dissertation Findings

7.1.1 Objective 1: Integrative Review

An integrative review of patients' perspectives and responses to ICD decision-making at implantation, generator replacement, and deactivation was conducted using Whittemore and Knafl's (2005) approach (Chapter 2). Databases were searched from 2000 to 2013. Three common themes were revealed from 25 included articles: the influence of the patient-practitioner consultation on knowledge uptake, patients' decision-making preference, and patients' desire to live. Patients often misunderstood ICD function, or overestimated its benefit. The life and death trade-off amidst potential risks made ICD decision-making difficult for some patients. From this review, I concluded that a paucity of information regarding decision-making processes at ICD generator replacement exists, and that clinicians involved in the care of this patient population could provide better information and support. Since interventions to facilitate a shared decision-making (SDM) process are increasingly recommended to address such preference-based decisions, I begun the systematic PDA development process for this patient population.

7.1.2 Objective 2: Systematic Review

A systematic review was conducted to quantify the risks, benefits, and costs of ICD pulse generator replacement in adults to populate the probabilities on outcomes of options in the PDA (Chapter 3). In the review, 17 studies were identified that reported outcomes on the procedural risks, survival benefit and/or costs related to ICD generator replacement. Our results revealed that complication rates are higher at replacement as compared to initial implant, and the mortality benefit post ICD replacement is not well understood. As well, a patient's risk profile can change from initial implant, affecting the ICD's effectiveness in the same patient over time.

The findings from this study were used to inform the probabilities for the risks and benefits of ICD replacement included in the systematically developed PDA.

7.1.3 Objective 3: Embedded Mixed Methods

Using IPDAS' systematic development process and an integrated knowledge translation (iKT) approach, a paper-based PDA prototype was iteratively developed (Chapter 4). The iKT approach involved establishing a team of health care professionals, an administrator, researchers and patients with family. The systematic development process involved (a) forming an advisory committee; (b) drafting a PDA based on international standards and current evidence; (c) obtaining feedback from potential end-users on the PDA draft on content, acceptability and usability and its use within current workflows; and (d) iteratively revising the PDA draft based on end-user feedback. Eighteen end-users in 16 interviews agreed that the current ICD replacement process is automated, and needs to shift towards a SDM process that elicits patient's preferences. The PDA was considered the invitation required to initiate this explicit offering of options, but was not to be used as a standalone tool. Participants provided thoughtful suggestions to inform revisions to PDA content, and to recommend ways in which it could be implemented into clinical practice. As part of the IPDAS systematic process, the next phase was to obtain feedback from users during the decision-making process.

7.1.4 Objective 4: Feasibility pilot randomized controlled trial

Patients approaching ICD replacement were randomized to PDA with nurse decision coaching or usual care (Chapter 5). Thirty patients were randomized. The main conclusions were that it was feasible to recruit patients, deliver the intervention and collect data, but with a slower than expected rate of patient recruitment. Acceptability and usability for the PDA was unanimous. Acceptability for decision coaching was variable. Preliminary effectiveness data on decision quality and decision-making process revealed improved knowledge for the intervention group and low decisional conflict in both groups. The PDA was rated as acceptable and usable by all users randomized to the intervention arm. Greater variations in the ratings of the decision coaching were noted, suggesting that some participants may prefer a lower amount of decision support than others.

7.1.5 Objective 5: Narrative Review

Since launching this research three and a half years ago, advancements in the state of the evidence on ICD decision-making have been noted. Hence, I discussed this three-year evolution based on 16 newly published articles to better inform how this dissertation fits within the current literature and what implications for future clinical practice and research must be considered.

7.2 Dissertation Findings in the Context of Evolving Literature

I conducted this series of five complementary studies with teams of clinicians, patients and families, administrators, and researchers. In this section, I will discuss how these findings contribute to the broader literature. First, findings from these five studies indicated that decision support for patients facing ICD replacement needs to be tailored to patients' characteristics and tailored according to the amount of decision support required for the individual patient. Second, in order to truly involve patients in this discussion, a reframing of ICD therapy culture as a pathway approach from implantation to the consideration of non-replacement and/or deactivation should be considered. I examine how this dissertation contributed to theory with respect to the complementary use of the Ottawa Decision Support Framework (ODSF) and the Normalization Process Theory (NPT) to guide PDA development while concurrently planning for implementation. Finally, implications for nursing practice, education, leadership, and research are explored.

7.2.1 Decision Support at ICD Replacement Needs to be Tailored

The decision support intervention developed and tested as part of this dissertation demonstrated positive impact on patients as indicated by favorable acceptability and usability data, and better knowledge scores (Chapter 4 and 5). For those randomized to the intervention, the results suggest that some patients may prefer a lower "dose" of decision support than others (Chapter 5). To my knowledge, no primary study has considered how best to tailor the dose of decision support. Kaltoft, Nielsen, Salkeld, and Dowie (2016) argued that a person him/herself should have the opportunity to opt-in to the amount and type of information they wish to obtain prior to making a healthcare decision. Whilst knowledge of information is only one criterion that constitutes a quality decision, this argument could also be extended to the dose of decision support a patient receives.

During the PDA development process, some clinicians expressed concern about patients' potential unfavorable response to being presented with the option of ICD non-replacement (Chapter 4). Yet, patients' favorable acceptability and usability ratings for the PDA – coupled with no expressions of concern – suggested that these patients, who are years into a chronic cardiovascular diagnosis and have personal experience living with the ICD, are able and willing to discuss these options. These findings align with previous literature which stated that patients prefer to engage in SDM once the acute stages of a disease have passed (Clark et al., 2009). The amount of time leading up to ICD replacement is a further advantage for logistical planning and non-pressured deliberation prior to making a decision (Jakub et al., 2016).

Based on my findings, the intervention needs to be tailored at two levels. First, at the level of the patient's characteristics, cardiovascular and non-cardiovascular health status (Chapter 4) and at level of the intervention whereby patients can receive the “dose” of decision support needed to meet and resolve individual decisional needs (Chapter 5). We attempted to achieve this tailoring at the patient level by the inclusion of probabilities of ICD survival benefit by age and by ICD indication. In response to Chapter 4's findings, the addition of a decision coaching script for clinicians' use with the PDA to satisfy the *need for individualization* and the assessment and resolution of individual decisional needs. The computation of the survival benefit probabilities was challenging due to the fact that the patient population facing ICD replacement is markedly heterogeneous. First, available statistics on ICD benefit are derived primarily from initial implantation clinical trials conducted in the early 2000s which may not wholly represent the patients undergoing replacement today. For example, current day ICD recipients and those undergoing ICD replacement are older than ICD trial participants (Cutro, Rich, & Hauptman, 2012). Also, there is now substantially greater use of beta blockers, angiotension-converting-enzyme inhibitor or angiotensin receptor blockers, and mineralocorticoid-receptor, all of which are known to reduce the incidence of sudden death (Al-Gobari, El Khatib, Pillon, & Gueyffier, 2013; Bapojé et al., 2013; Domanski et al., 1999; Solomon et al., 2004). In a recent pooled analysis of >40,000 patients enrolled in ICD trials from 1995-2014, Shen and colleagues (2017) concluded that

The decreased risk of sudden death in contemporary trials involving patients with a high use of guideline-recommended therapies, coupled with data from previous trials and

registries on the likely benefits and complications of ICDs, suggests that it may be difficult to show a significant benefit of ICD implantation for primary prevention in most patients with heart failure with reduced ejection fraction in the current era (p. 47).

Predicting sudden death is complex. Current ongoing studies are aiming to provide clarity on this elusive task (e.g. REFINE-ICD [NCT00673842], BEYOND-EF). Second, limited evidence exists for non-target groups such as the frail elderly, those with multiple comorbidities, and those with improved heart function who have never experienced an appropriate shock. The systematic review (Chapter 3) found emerging evidence that the incidence of future appropriate therapies in select patient groups is less certain - yet still present. Hence, it remains unclear if ICDs are still clinically indicated in these subgroups. What *is* clear is that the benefit of the ICD attenuates with advancing age and increasing comorbidities (Bennett et al., 2017; Hess et al., 2015; Merchant, Quest, Leon, & El-Chami, 2016; Yung et al., 2013). For this reason, I believed it was important to communicate this attenuation to patients. A key step in our PDA development was obtaining external peer review from experts in the field of cardiac electrophysiology on the inclusion of these probabilities (Chapter 4). This provided the endorsement needed on the probabilities used, and opportunities for evaluation beyond this single site.

Moving forward, it will be important to build upon and refine this decision support intervention to ensure that the PDA is inclusive, effective, and reflective of the current state of the evidence for all patients with cardiac devices approaching battery depletion. A more inclusive PDA containing all the nuances of cardiac device replacement across device types (e.g. pacemaker, cardiac resynchronization therapy with and without defibrillation) and lead involvement (e.g. revision, replacement), for example, may be the answer to increase the intervention's generalizability and applicability to a wider proportion of patients. An electronic modular PDA would be most useful for numerous reasons. First, it would allow for the integration of a risk stratification score for ICD replacement to tailor survival benefit probabilities to the individual patient (Barra et al., 2016). Second, the decisional attributes most important to each patient could be selected and highlighted for greater in-depth discussion as required. Third, the amount of information could be tailored according to individual patient needs by building a platform displaying information using a layered approach, whereby more detailed information is provided should the user want it. Lastly, updates of the literature may be

more easily streamlined, and as such, revisions to the PDA could be made in a timely manner (Hoffman et al., 2013).

7.2.2 Reframing ICD therapy “culture”: A pathway approach

Findings generated from this dissertation calls for a re-framing of ICD therapy from an permanent implantable cardiac device requiring repeated replacement procedures until the end-of-life, to an elective, appropriately used treatment deliberately *chosen* based on periodical revisions of a patient’s clinical situation and the elicitation of evolving preferences. Patients have expressed desire to know their options prior to the initial implantation of their ICD, when approaching battery replacement, and with any significant decline in their health (Lewis, Nery, & Birnie, 2014; MacIver, Tibbles, Billia, & Ross, 2016; Standing et al., 2016). Being informed can result in an improved sense of control for patients, as they are equipped to initiate discussion about ICD non-replacement and/or deactivation when they are ready (Chapter 4). In previous studies, patients considered their end-of-life solely as an opportunity to *review* previously established preferences and decisions about ICD deactivation – not a time to shape them (MacIver et al., 2016). To avoid this, the shaping of personal preferences and values for ICD therapy could occur iteratively and longitudinally over the course of ICD tenure within the context of existing therapeutic relationship(s). This was supported by the palliative care physician in the PDA development study, who stated

...it begins earlier the process that eventually I’m going to have to be dealing with in the deactivation at the end of life. So even if they choose to replace their battery what I find this decision aid to be most helpful for is it already introduces concepts that would be very, very helpful later on. (Chapter 4)

Essential to this “reframing of ICD therapy,” is the acknowledgement that a patient’s preference for or against treatment can shift from the initial implantation to battery replacement(s). This shift can occur due to considerations that were non-existent upon initial implantation. Yet, the qualitative interviews revealed that current ICD replacement practices remains largely automatic due to clinicians’ implicit persuasion in favor of continued ICD therapy, clinicians not knowing enough about the patient, and the influence of previous encounters (Chapter 4). Indeed, the way in which the ICD is presented prior to implantation can result in cognitive bias in favor of the ICD, and hence shape patients’ understanding of ICD

therapy throughout its tenure (Matlock et al., 2017), with many patients remaining unaware of their options when faced with replacement (Lewis et al., 2014). Furthermore, clinicians felt deterred to initiate a conversation about the option of replacement as they feared this “new” information would surprise, unsettle, or upset patients (Chapter 4). This is a valid concern as some patients decline decisional responsibility for these reasons (Elwyn et al., 2012).

Unfavorably, however, a lack of awareness of ICD therapy options has been associated with decisional regret (Green et al., 2016; Standing et al., 2016). By raising awareness of the options earlier in the trajectory, patients are granted a degree of control to established advanced directives and re-initiate the discussion when they are prepared to do so. For many patients with an ICD, this control is preferred (Thylén et al., 2013). Regardless of whether a patient chooses to replace their ICD or not, exposure to these concepts is beneficial for future device replacements or upon consideration of deactivation when facing the end-of-life (Chapter 4).

It was revealed that the optimization of the implementation of the decision support intervention in clinical practice would require an interprofessional and interdisciplinary team approach, including clinicians external to the device clinic engaged in therapeutic relationships with these patients (e.g. heart failure nurses, general practitioners) (Chapter 4). These external members are often centralised points of contact outside of device clinic appointments. Pursuing this collaborative route, evidence-base strategies for interprofessional learning and collaboration should be fostered between other members of the circle of care and the device clinic team including heart function specialists and heart function nurses, cardiologists, family physicians, and palliative care, as required. Within these strategies, the role of the external clinicians in the initiation and support of ICD replacement and deactivation discussions should be further explored.

A clinical pathway of the ICD trajectory could ensure the individualization of patients’ clinical and decision-making needs, the involvement of appropriate clinicians, guided by evidence and clinical practice guidelines. Clinical pathways are defined as evidence-based multidisciplinary plans of care that provide standardised steps in a course of treatment or care, time-frames, and communicative cues to engage patients, families and clinicians in decisions about their care (Kinsman, Rotter, James, Snow, & Willis, 2010). They are known to reduce unnecessary variations in care, outline a common “game plan”, improve documentation, and

improve patient satisfaction by involving patients and their families throughout the care pathway (Gurzick & Kesten, 2010; Pearson 1995; Rotter et al., 2010). Communicative cues could provide reminders for clinicians to describe ICD therapy options to their patients and families upon implantation, revise ICD function, risk and benefits, impact on quality of life, and the valid options of non-replacement and deactivation. Potential trigger points for non-replacement and/or deactivation discussions could also be embedded within this formalised protocol for appropriate and timely discussions about the option of no active ICD therapy (Standing et al., 2016). Hence, a clinical pathway could help address barriers identified in Chapter 4, namely the *Influence of previous encounters* by standardizing the information provided to patients embarking on the ICD trajectory, and *Not knowing the patient* by providing an designated area for the documentation of evolving patient preferences throughout the ICD trajectory accessible by all interprofessional team members at any time in the electronic medical record (Chapter 4).

7.2.3 Contributions to theory validation using complementary frameworks

Two complementary theoretical frameworks, the ODSF and NPT, were used to provide a link between intervention development and implementation planning.

The ODSF was used to inform the content and development of the PDA, ensure that elements needed to achieve quality decision aid based on the International Patient Decision Aid Standards were included in the PDA, and inform the choice of preliminary effectiveness measures (O'Connor et al., 1998). The ODSF provided a useful structure at the level of the intervention, to assist with the design and content of the PDA, the decision coaching script, and its delivery to patients facing ICD replacement. The study findings validated these assumptions as evidenced by preliminary effectiveness findings of improved knowledge after exposure to the PDA compared to usual care (Chapter 5). As expected, the sample size was not adequate to determine a difference in total decisional conflict score or any of its subscales (Chapter 5).

The NPT was used prospectively to ensure the clinical practice needs were considered to support the eventual goal of intervention implementation into practice (May & Finch, 2009). It was used to supplement where the ODSF was deficient by acknowledging the involvement of all interprofessional team members – including patients and families, considering where and how the intervention fit within the clinical context, and guiding plans for implementation as part of routine clinical practice (May & Finch, 2009).

To further understand the inherent issues underlying implementation difficulties of decision support interventions in clinical practice, Elwyn et al. (2013) called for attention beyond the widely used “barriers and facilitators” approach. As such, the NPT was selected as the framework to think through issues of implementation in terms of the social and collective processes needed to embed complex interventions into the clinical workflow. In the mixed methods study, the NPT was used to help shape the research questions, to determine the steering committee and study participant eligibility criteria, to structure the interview guide, to compose the interview questions, and to guide the interpretation of the findings (Chapter 4). It also ensured that the decision support intervention’s potential for implementation was maximized throughout the initial prototype design phase. In the feasibility trial, the NPT helped ensure the applicability of the trial procedures to match that of the established clinical workflow (Chapter 5). Table 7.1 provides a summary of the findings as interpreted through the four NPT constructs. When viewed through the NPT constructs, the decision support intervention appeared to have a good fit with the clinical workflow in which it was studied. However, it is clear that its mere availability was deemed insufficient for change as evidenced by participants’ expressed need for skill-building and education, policy and procedures to better support patient engagement in decision making, and the establishment of a collaborative approach with interprofessional/interdisciplinary team members internal and external to the device clinic. These identified needs will help inform future research in this area.

Table 7.1 Use of NPT in Decision Support Development and Preliminary Evaluation

NPT Component	Application to PDA Development and Evaluation
Coherence (i.e. meaning and sense-making) <i>What is the work?</i>	- It was understood that the “work” is the use of decision support for patients facing ICD replacement - Use of decision support was differentiated from current norms - The aim of decision support, shared by all potential end-users, was understood to facilitate awareness of a decision to be made, options, awareness of risks and benefits, patient and family involvement, and to improve patient-clinician communication - Decision support was perceived to be beneficial for patients, families, and clinicians by all participants
Cognitive Participation	- PDA use was considered from interprofessional and interdisciplinary perspectives - Device clinic staff were engaged and motivated

(i.e. commitment and engagement) <i>Who does the work?</i>	- Device clinic staff recognized that patients need to be better supported in this decision - There was lack of agreement on who, external to the device clinic, should be involved in this process and to what degree. - The majority of potential end-users agreed that the PDA is a facilitator of a SDM process – not to be used as a standalone tool - Device clinic staff did consider these processes as research (i.e., recruiting patients to a study), rather than part of clinical care. Hence, decision support delivery currently peripheral to their main task of delivering patient care
Collective Action (i.e. work required) <i>How does the work get done?</i>	- For staff internal to the device clinic: Training and skills building required in SDM - For staff external to the device clinic: Education needed about ICD therapy, including the communication of risk and the communication about options - For patients and families: Education needed about ICD function, risks and benefits of each option - Development of policies and procedures to ensure consistency - Identification of prespecified time points to describe, discuss and decide about the options - Team approach– invitation to discuss the option of ICD replacement can be initiated from clinicians and/or patients - More investigative work required to address concerns about potential increased time burden.
Reflexive Monitoring (i.e. reflection and appraisal of the intervention) <i>How is the work understood?</i>	- Since this dissertation was focused on implementation <i>planning</i>, this component could not be assessed.

Despite a lack of best methods to achieve patient engagement in research (Domecq et al., 2014), our iKT approach was feasible and successful as evidenced by participation at in-person meetings, responses to emails, phone calls, membership retention throughout the project, and all team members named on conference proceedings and publications. Previous knowledge translation research showed that engaging patients in the research process may result in a product that is more readable and understandable by other patients (Nilsen, Myrhaug, Johansen, Olive, & Oxman, 2006). Similarly, this dissertation findings resulted in a PDA that was rated acceptable and usable by all stakeholders involved in the mixed methods study (Chapter 4), and by all patients facing the decision in the feasibility trial (Chapter 5).

In this dissertation, both patients and healthcare professionals were targeted and involved throughout the development, implementation planning, and feasibility testing of the intervention which has been shown to improve uptake of SDM (Légaré et al., 2014). In the context of this study, including potential end-users in devising the implementation process increased confidence in the content, and buy-in in the process. Interprofessional team members interviewed as part of our implementation planning study unanimously agreed that patient involvement via decision support for ICD decision-making is needed (Chapter 4). Their involvement is essential to this work as they are perceived to hold decisional power by patients (Joseph-Williams, Elwyn, & Edwards, 2014). It is not until this intervention is actually implemented into the established workflow that we will be able to determine whether this approach was successful. Nevertheless, current potential end-users attitudes towards this initiative are promising prior to executing the work of implementation.

7.3 Implications for Nursing

The findings from these studies have implications for nursing practice, education, leadership, policy, and research.

7.3.1 Nursing Practice.

The healthcare professionals and patients interviewed in the mixed methods study agreed that nurses were well positioned to support patients considering their options related to ICD therapy and/or those experiencing decisional conflict about which option to choose (Chapter 4). In the feasibility trial, the PDA and decision coaching were successfully delivered by one trained registered nurse (Chapter 5). This decision coach role is within the nursing scope of practice and aligns with professional values (Stacey et al., 2012). Through the cultivation of a trusting and mutual partnership with patients, nurses can elicit personal and social contexts, personal values, and goals of care that can be used to inform their choice. This could be particularly helpful for patients who need assistance to develop confidence and skills to participate in decision-making. For patients incapable of providing informed consent (e.g cognitive barriers) nurses can promote their participation to the extent possible, together with their substitute decision-maker (Canadian Nurses Protective Society, 2009). These listed responsibilities encompass a primary value

underpinning ethical nursing practice, namely, the promotion and respect of informed decision-making (Canadian Nurses Association, 2017).

At the core of ICD replacement decision-making is the nurses' responsibility to recognize a competent patient's right to request the withdrawal of potential life-saving therapy based on informed preferences and values. Such a request *may* be easier to accept if a patient no longer meets ICD eligibility criteria or is approaching their end-of-life. A greater challenge presents if a patient remains a candidate for ICD therapy and continues to be at high risk for potentially lethal ventricular arrhythmia. Clinical practice guidelines state that it is both ethically and legally acceptable to deactivate an ICD or chose to not replace a battery when it is consistent with patient goals (Lampert et al., 2012). This is similar to it being acceptable to refuse ICD therapy prior to its initial implant (Lampert et al., 2012; Wright, Klein, & Gula, 2012).

The Registered Nurses Association of Ontario (RNAO) (2009) offers practical recommendations on how nurses can support patients in decision-making in their clinical practice guideline entitled "*Decision Support for Adults Living with Chronic Kidney Disease.*" This guideline, which is relevant beyond chronic kidney disease, recommends that nurses identify the key decision(s) that patients face at particular points in time, screen for decisional conflict, and if present, identify the source(s) of the uncertainty. These recommendations can be achieved using PDAs and/or decision coaching (Légaré et al., 2014). For decision coaching, nurses are supportive but non-directive. This neutrality permits nurses to be "mediators" of information, listeners of patients' preferences, and messengers of expressed preferences to the physicians ultimately responsible for implementing the decision (Joseph-Williams et al., 2014). Hence, nurses are well-positioned and capable of independently initiating patient engagement in ICD decision-making by informing patients that they have options and, at a minimum, by informing patients they can ask their physician about their options. Nurses should be able to do so independent of physicians' orders or expectations, and by doing so, would be contributing to interprofessional SDM efforts where the physician and other key players are equally as committed to its attainment (Stacey, Légaré, & Brière, 2016). In the following section, I discuss ways in which nurses can acquire the necessary skills to foster patient engagement.

7.3.2 Nursing Education.

The nurses involved in this study were willing to engage in SDM but expressed that they lacked the knowledge and skills to do so (Chapter 4). To achieve this, nurses proposed training for themselves to raise awareness, knowledge and skills in SDM (Chapter 4). Participants also proposed training for the entire interprofessional team to alleviate the limitations associated with the device clinic's shared care model which would equip all team members with the same decision support strategies and communication cues to ensure consistent messaging regardless of whom the patient sees on subsequent visits (Chapter 4). In the feasibility trial, the nurse delivering the decision coaching intervention was trained in SDM via an online module and a graduate-level decision-making course (Chapter 5). The nurse was also given a decision coaching script to enhance transparency of the role and ensure consistency across patients.

This reported need for education is consistent with systematic reviews on PDAs and decision coaching (Stacey et al., 2017; Stacey et al., 2012). Engagement in SDM education is a predictor of SDM in clinical practice (Légaré et al., 2014), and as such, nurses need to have the skills in SDM to engage in SDM. SDM education can be offered at various levels of nursing: pre-licensure, workplace orientation, and continuing professional development for employed and experienced nurses (RNAO, 2009). Since the principles of decision support are the same across clinical decisions, then it is possible that training may not be required as long as the nurse has previously acquired the skills.

For nurses in training, exposure to principles of decision support as a threaded theme throughout undergraduate nursing education has been proposed to increase students' awareness of patients' decision making needs, resources to support patients, and develop decision support competencies to inform future practice (Stacey et al., 2009). Inclusion of SDM should be considered in Entry to Practice Competency documents for registered nurses and nurse practitioners (College of Nurses of Ontario, 2014; 2018). As SDM expands to incorporate an interprofessional perspective, the integration of relational and risk communication competencies - ideally alongside interprofessional colleagues-in-training - would provide formalized opportunities for nurses at the pre-licensure level to learn and reflect upon their roles and responsibilities towards patient and family engagement in health care decisions (Diouf, Menear, Robitaille, Painchaud Guérard, & Légaré, 2016; Légaré et al., 2013).

For nurses who are orientating to a new clinical environment, employed and/or experienced, building competence in decision support can be achieved in various ways. First, theory-based educational interventions exist to build SDM capacity by introducing nurses to the fundamental concepts, roles and key resources related to decision support. Many of these training materials are available free of charge from the Patient Decision Aids Group from the Ottawa Hospital Research Institute and Laval University's Inventory of Shared Decision-Making programs for Health Professionals. For example, a self-paced online tutorial such as the Ottawa Decision Support Tutorial aims to improve health professionals understanding of decision support by (a) describing concepts of decision support, (b) identifying decisions requiring decision support, (c) explaining how to assess decisional needs, (d) tailoring decision support to patient's needs, and (e) explaining how to use and evaluate decision support interventions (O'Connor, Stacey & Boland, 2015). Second, interactive interprofessional activities can provide opportunities to practice with simulated patients and foster communication skills required to engage in SDM (RNAO, 2009). Such activities can include skill-building in the documentation of patients' preferences and proper follow-up in accordance to patients' expressed preferences. This could ensure that professional standards related to documentation are met (College of Nurses of Ontario, Professional Standards, 2002). Third, a device clinic staff nurse with demonstrated interest in decision support can be formally recognized as a clinical champion by his/her peers: a designated expert with a knowledge-based beyond their peers who can serve as a supportive voice for innovation, provide real-time feedback to reinforce decision support education and skill-building, build momentum on accrued progress, and be used as an ally in research efforts to implement decision support into the established workflow (Coulter, 2012). Four, when new nurses are orientating to the device clinic, an emphasis on principles of decision support throughout the ICD pathway may be considered.

Support for and mobilization of these pedagogical decision support education programs for staff nurses often lies in the hands of nursing leadership. Hence, a high degree of nursing management support is integral to decision support implementation in an organization (Creehan, 2015).

7.3.3 Nursing Leadership and Policy

The participation of the Director of the Arrhythmia Service and the device clinic Nurse Manager as members of the research team helped to obtain organizational level support (Chapter 4 and 5). Previous iKT research has shown that the involvement of administrators throughout the research process may help address barriers, create policies and procedures, allocate resources, and establish a process to monitor and assess intervention use (Joseph-Williams et al., 2017; Nelson, Donnellan, & Elwyn, 2016). Beyond mere involvement in isolated projects, it is the “visionary leadership” of nursing administrators towards the common goal of patient and family centered care that is imperative to transformational and sustainable change (Coulter, 2012). The nursing culture of an organization as promoted and fostered at the upper echelons of an institution has important bearing on the development of decision support skills for its employees, and the implementation of PDAs and the decision coaching role in practice (Belkora, Loth, Volz, & Rugo, 2009; Stacey, Graham, O’Connor, & Pomey, 2005; Woolf et al., 2005).

At a policy level, the Government of Ontario’s Seniors Strategy states that older individuals have the right to know what their options are to make informed decisions, even if they opt to live at risk (Government of Ontario, 2012). I argue that all individuals have the right to know their options and make informed decisions based on their personal preferences and values. Recently published American Heart Association/American College of Cardiology/Heart Rhythm Society guidelines for the management of patients with ventricular arrhythmias recognized ICD replacement as an important time to consider all patients’ values and preferences in association with their health care goals (Al-Khatib et al., 2017). Further, the development of clinical practice guidelines specifically for ICD generator replacement for patients with primary prevention ICDs was recently proposed (Dixit & Kini, 2017). Should this initiative be launched, it may be a prime opportunity to develop concomitant patient decision support tools informed by the same evidence (van der Weijden et al., 2012).

There is broad consensus within the health policy landscape that SDM represents the best practice model for medical decisions. In a National Academy of Medicine report on PDAs, Alston and colleagues (2014) encouraged the widespread adoption of PDAs as they “*trigger the robust communication that is necessary for shared decision making to occur.*” Recent research in this area has identified that SDM can be facilitated by: (a) training and engaging

interprofessional clinical teams, (b) making available high quality decision support tools, and (c) having a robust plan to implement these tools, all of which are dependent on support from executive leadership and senior organizational leaders (Joseph-Williams et al., 2017; Nelson et al., 2016; Stacey, Légaré, & Brière, 2016).

7.3.4 Nursing Research

In preparation for the definitive effectiveness trial, key barriers identified during our feasibility trial will need to be addressed (Chapter 5): (a) the ineligibility of many patients due to our selected exclusion criteria, particularly those who are pacemaker dependent and those with cardiac resynchronization therapy or eligible for upgrade to cardiac resynchronization therapy; (b) the PDA's absence of a validated risk stratification score to tailor the ICD survival benefit for each patient on multiple variables; (c) the need to modify the PDA format to an electronic modular platform; and (d) the need for members of the interprofessional team to build skills in SDM and risk communication. These findings will be used to modify the intervention and design a randomized controlled trial.

Ultimately, a cluster randomized controlled trial at the level of institutional device clinics with two study arms (decision support intervention (PDA + nurse decision coaching) tailored to patient needs *versus* individually navigated PDA) would be most ideal for the following reasons. First, the seventh update of a Cochrane systematic review of 105 PDA evaluation trials showed that PDAs improve decision quality and decision-making processes without harm (Stacey et al., 2017); hence another PDA trial conducted within a controlled clinical research environment would contribute minimally to the current state of the PDA literature. Second, as I aim towards implementation, a focus on PDAs embedded as part of the established clinical workflow would ensure particular attention to the pragmatics of intervention delivery, which could inform future scaling up and sustainability. Third, clustering randomization at the institution level will control for contamination bias, as it is not feasible to train some members of the interprofessional team from the same device clinic in SDM skills and decision coaching while others not. Similarly, it would not be feasible to assign randomized patients to specific nurses and physicians. Finally, from a feasibility perspective, there are over 15 specialized institutions in Canada that implant and replace ICDs, some of which have already expressed interest in pursuing this work in their centre.

Considering additional outcomes for this future trial, a dyadic approach to measuring the effects of decision support would be a useful, inclusive, and novel method to assess the views and interactions between patients and clinicians involved in ICD replacement consultations (Kenny et al., 2010; Légaré et al., 2012). Instruments with satisfactory psychometrics properties that provide dyadic subjective measures of the decision-making process at both the individual and dyad levels include the values clarification and uncertainty subscales of the Decisional Conflict Scale (O'Connor, 1995), the information verifying subscale of the Medical Communication Competence Scale (Cegala, Coleman, & Turner, 1998) and the perception of control subscale from the Theory of Planned Behaviour (Ajzen, 1988; Légaré et al., 2009). Ideally, a future trial would also include objective measures of patient and family member involvement in the decision-making process during consultations with clinicians. To facilitate this, consultations could be video or audio recorded and analyzed using validated instruments with good interrater reliability such as MAPPIN'SDM (Kasper, Hoffmann, Heesen, Kopke, & Geiger, 2012) and the Observing Patient Involvement in Decision-Making (OPTION) instrument (Elwyn et al., 2003; Elwyn et al., 2005). This approach could also provide information on fidelity of intervention delivery. Finally, to maximize the relevance and applicability of this research to all individuals with ICDs, a more thorough assessment of sex and gender differences is warranted.

Finally, it is unknown whether initial patient perspectives about ICD therapy, their disease trajectory, and/or personal experiences with the ICD influence future decision-making at ICD replacement or when approaching end-of-life. A longitudinal study could explore the downstream effects of decision support throughout the ICD pathway beginning prior to implantation on the advent and execution of advance care plans and advanced directives. A primary goal of this line of inquiry would be to find sustainable ways to ensure that patients' views on ICD deactivation are known and documented prior to approaching end-of-life to avoid undesired consequences in a patient's last days and hours.

7.4 Conclusions

Between 2014 and 2018, a series of studies resulted in a novel decision support intervention to prepare patients with ICDs and their families for SDM about whether to replace their ICD. The PDA was developed using an iKT approach and informed with evidence from the

integrative review (Chapter 2) and the systematic review of estimated risks and benefits of ICD replacement (Chapter 3). The embedded mixed methods study confirmed that automatic referral for ICD replacement was the norm, but found enthusiastic acceptance for a shift towards PDA implementation to facilitate a SDM process (Chapter 4). The feasibility trial demonstrated that the decision support intervention was used as intended and the PDA acceptable to users, with minimal missing data, but low patient eligibility and consequently, low recruitment rates (Chapter 5). Some adaptations to the intervention and intervention delivery will be required prior to conducting a future definitive study. Finally, to conclude this series of studies, an update of the literature revealed that risk stratification scores have been recently validated for ICD replacement aiming to identify patients who will most and least likely benefit from the ICD. In the future, the integration of these risk scores into PDAs to support SDM could be considered.

As the number of ICD replacements increases as a result of expanding indications and patients living longer, it is imperative that health professionals embrace strategies to ensure the appropriate use of ICDs based on a thorough assessment of a patient's clinical situation and their personal preferences and values. The decision support intervention resulting from this dissertation has the potential to facilitate the elicitation of patients' values for ICD therapy to empower them to choose the option that will allow them to live out the life they have left, as they choose to live it.

7.5 References

- Ajzen, I. (1988). *Attitudes, personality and behavior*. Keynes M, editor: Open University Press.
- Al-Gobari, M., El Khatib, C., Pillon, F., & Gueyffier, F. (2013). β -Blockers for the prevention of sudden cardiac death in heart failure patients: a meta-analysis of randomized controlled trials. *BMC Cardiovascular Disorders*, 13, 52. doi: 10.1186/1471-2261-13-52.
- Al-Khatib, S. M., Stevenson, W. G., Ackerman, M. J., Bryant, W. J., Callans, D. J., Curtis, A. B., ...Page, R. L. (2017). AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: Executive summary: A report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines and the Heart Rhythm Society. *Journal of the American College of Cardiology*, pii: S0735-1097(17)41305-2. doi: 10.1016/j.jacc.2017.10.053
- Alston, C., Berger, Z., Brownlee, S., Elwyn, G., Fowler, F. J., Hall, L. K.,...Henderson, D. (2014). Shared decision-making strategies for best care: patient decision aids. National Academy of Medicine. Retrieved from <http://nam.edu/perspectives-2014-shared-decision-making-strategies-for-best-care-patient-decision-aids> [Accessed November 20, 2017].
- Bapojé, S. R., Bahia, A., Hokanson, J. E., Peterson, P. N., Heidenreich, P. A., Lindenfeld, J.,...Masoudi, F. A.(2013). Effects of mineralocorticoid receptor antagonists on the risk of sudden cardiac death in patients with left ventricular systolic dysfunction: a meta-analysis of randomized controlled trials. *Circulation: Heart Failure*, 6(2), 166-173. doi: 10.1161/CIRCHEARTFAILURE.112.000003
- Barra, S., Goonewardene, M., Heck, P., Begley, D., Virdee, M., Fynn, S.,...Agarwal, S. (2016). Implantable cardioverter-defibrillator elective generator replacement: a procedure for all? *Journal of Interventional Cardiac Electrophysiology*, 45, 209-218. doi:10.1007/s10840-015-0087-0
- Belkora, J., Loth, M. K., Volz, S., & Rugo, H. S. (2009). Implementing decision and communication aids to facilitate patient-centred care in breast cancer: A case study. *Patient Education and Counseling*, 77(3), 360-368. doi: 10.1016/j.pec.2009.09.012
- Bennett, M., Parkash, R., Nery, P., Sénéchal, M., Mondesert, B., Birnie, D.,...Philippon, F. (2017). Canadian Cardiovascular Society/Canadian Heart Rhythm Society 2016 implantable cardioverter-defibrillator guidelines. *Canadian Journal of Cardiology* 33, 174-188. doi: 10.1016/j.cjca.2016.09.009
- Canadian Nurses Association. (2017). Code of ethics. Ottawa, Canada: Author
- Canadian Nurses Protective Society. (2009). Consent for the incapable adult. Info LAW Bulletin. Ottawa, Canada: Author. Retrieved from <http://www.cnps.ca/index.php?page=102> [Retrieved November 20, 2017].
- Cegala, D. J., Coleman, M. T., & Turner, J. W. (1998). The development and partial assessment of the medical communication competence scale. *Health Communication*, 10; 261e88.
- Clark, N. M., Nelson, B.W., Valerio, M.A., Gong, Z.M., Taylor-Fishwick, J.C., & Fletcher, M., (2009). Consideration of shared decision making in nursing: a review of clinicians'

- perceptions and interventions. *Open Nursing*, 3, 65–75. doi: 10.2174/1874434600903010065.
- College of Nurses of Ontario (2002). Professional Standards – Revised 2015. Toronto, Canada: Author. Retrieved from www.cno.org/globalassets/docs/prac/41006_profstds.pdf. [Retrieved November 20, 2017].
- College of Nurses of Ontario (2014). Competencies for entry-level Registered Nurse Practice. Toronto, Canada: Author. Retrieved from <http://www.cno.org/en/news/2014/january-2014/rn-competencies-document-revised/> [Retrieved June 8, 2018].
- College of Nurses of Ontario (2018). Entry-level competencies for Nurse Practitioners. Toronto, Canada: Author. Retrieved from <http://www.cno.org/en/learn-about-standards-guidelines/magazines-newsletters/the-standard/december-2017/np-competencies/> [Retrieved June 8, 2018].
- Coulter, A. (2012). Leadership for patient engagement. London: The King's Fund
- Creehan, S. (2015). Building Nursing Unit Staff Champion Programs to Improve Clinical Outcomes, *Nurse Leader*, 13(4), 31-35.
- Cutro, R., Rich, M. W., Hauptman, P. J. (201). Device therapy in patients with heart failure and advanced age: too much too late? *International Journal of Cardiology*, 155, 52-55. doi: 10.1016/j.ijcard.2011.01.078
- Diouf, N. T., Menear, M., Robitaille, H., Painchaud Guérard, G. & Légaré, F. (2016). Training health professionals in shared decision making: Update of an international environmental scan. *Patient Education and Counseling*, 99(11), 1753-1758. doi:10.1016/j.pec.2016.06.008.
- Dixit, S. & Kini, V. (2017). Generator replacement in primary prevention ICD patients: Is it time to develop guideline recommendations? doi: 10.1016/j.jacep.2017.04.018 [Epub ahead of print]
- Domanski, M. J., Exner, D. V., Borkowf, C. B., Geller, N. L., Rosenberg, Y., & Pfeffer, M. A. (1999). Effect of angiotensin converting enzyme inhibition on sudden cardiac death in patients following acute myocardial infarction: a meta-analysis of randomized clinical trials. *Journal of the American College of Cardiology*, 33(3), 598-604.
- Domecq, J. P., Prutsky, G., Elraiyah, T., Wang, Z., Nabhan, M., Shippee, N.,... Murad, M. H. (2014). Patient engagement in research: a systematic review. *BMC Health Services Research*, 14, 89. doi: 10.1186/1472-6963-14-89.
- Elwyn, G., Edwards, A., Wensing, M., Hood, K., Atwell, C., & Grol, R. (2003) Shared decision making: developing the OPTION scale for measuring patient involvement. *Quality & Safety in Health Care*, 12, 93–99.
- Elwyn, G., Frosch, D., Thomson, R., Joseph-Williams, N., Lloyd, A., Kinnersley, P.,... Barry, M. (2012). Shared decision making: a model for clinical practice. *Journal of General Internal Medicine*, 27(10), 1361–1367.

- Elwyn, G., Hutchings, H., Edwards, A., Rapport, F., Wensing, M., Cheung, W. Y., & Grol, R. (2005). The OPTION scale: measuring the extent that clinicians involve patients in decision-making tasks. *Health Expectations*, 8, 34–42.
- Elwyn, G., Scholl, I., Tietbohl, C., Mann, M., Edwards, A., Clay, K.,... Frosch, D. (2013a). "Many miles to go...": A systematic review of the implementation of patient decision support interventions into routine clinical practice. *BMC Medical Informatics and Decision Making*, 13(Suppl 2), S14. doi: 10.1186/1472-6947-13-S2-S14
- Government of Ontario. Ministry of Health and Long-Term Care. Living Longer, Living Well. 2012. Toronto, Ontario.
- Green, A. R., Jenkins, A., Masoudi, F. A., Magid, D. J., Kutner, J. S., Leff, B., & Matlock, D. D. (2016). Decision-making experiences of patients with implantable cardioverter defibrillators. *Pacing and Clinical Electrophysiology*, 39, 1061-1069. doi: 10.1111/pace.12943
- Gurzick, M. & Kesten, K. S. (2010). The impact of clinical nurse specialists on clinical pathways in the application of evidence-based practice. *Journal of Professional Nursing*, 26(1), 42-48. doi: 10.1016/j.profnurs.2009.04.003
- Hess, P. L., Al-Khatib, S. M., Han, J. Y., Edwards, R., Bardy, G. H., Bigger, J. T.,...Saunders, G. (2015). Survival benefit of the primary prevention implantable cardioverter-defibrillator among older patients does age matter? An analysis of pooled data from 5 clinical trials. *Circulation and Cardiovascular Quality and Outcomes*, 8, 179-186. doi: 10.1161/CIRCOUTCOMES.114.001306.
- Hoffman, A. S., Volk, R. J., Saarimaki, A., Stirling, C., Li, L. C., Härter, M., Kamath, G. R., & Llewellyn-Thomas, H. (2013). Delivering patient decision aids on the internet: definitions, theories, current evidence, and emerging research areas. *BMC Medical Informatics and Decision Making*, 13(Suppl 2), S13. doi: 10.1186/1472-6947-13-S2-S13
- Jakub, K. E. & Sandelowski, M. (2016). Reimplantation surgery in patients with implantable cardioverter defibrillators: a qualitative study. *Heart Lung*, 45, 48–55. doi: 10.1016/j.hrtlng.2015.09.007
- Joseph-Williams, N., Elwyn, G. & Edwards, A. (2014). Knowledge is not power for patients: A systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient Education and Counseling*, 94, 291-309. doi: 10.1016/j.pec.2013.10.031
- Joseph-Williams, N., Lloyd, A., Edwards, A., Stobbart, L., Tomson, D., Macphail, S.,... Thomson, R. (2017). Implementing shared decision making in the NHS: lessons from the MAGIC programme. *BMJ*, 357, j1744. doi: 10.1136/bmj.j1744.
- Kahneman, D. & Tversky, A. (1979). Prospect theory: an analysis of decision under risk. *Econometrica*, 47, 263–291.

- Kaltoft, M. K., Nielsen, J. B., Salkeld, G., & Dowie, J. (2016). Who should decide how much and what information is important in person-centred health care? *Journal of Health Services Research & Policy*, 20(3), 192–195. doi: 10.1177/1355819614567911
- Kapa, S., Rotondi-Trevisan, D., Mariano, Z., Aves, T., Irvine, J., Dorian, P., & Hayes, D. L. (2010). Psychopathology in patients with ICDs over time: results of a prospective study. *Pacing and Clinical Electrophysiology*, 33(2), 198–208. doi: 10.1111/j.1540-8159.2009.02599.x
- Kasper, J., Hoffmann, F., Heesen, C., Köpke, S., & Geiger, F. (2012). MAPPIN' SDM – The multifocal approach to sharing in shared decision making. *PLoS ONE*, 7(4), e34849. doi: 10.1371/journal.pone.0034849
- Kenny, D. A., Veldhuijzen, W., van Weijden, T., Leblanc, A., Lockyer, J., Légaré, F., & Campbell, C. (2010). Interpersonal perception in the context of doctor-patient relationships: a dyadic analysis of doctor-patient communication. *Social Science and Medicine*, 70(5), 763–8. doi: 10.1016/j.socscimed.2009.10.065
- Kinsman, L., Rotter, E., James, T., Snow, P., & Willis, J. (2010). What is a clinical pathway? Development of a definition to inform the debate. *BMC Medicine*, 8, 31. doi: 10.1186/1741-7015-8-31
- Lampert, R., Hayes, D. L., Annas, G. J., Farley, M. A., Goldstein, N. E., Hamilton, R. M., ... Zellner, R. (2010). HRS Expert Consensus Statement on the management of cardiovascular implantable electronic devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy. *Heart Rhythm*, 7, 1008–26. doi: 10.1016/j.hrthm.2010.04.033
- Légaré, F., Moumjid-Ferdjaoui, N., Drolet, R., Stacey, D., Härter, M., Bastian, H., ... Thomson, R. (2013). Core competencies for shared decision making training programs: Insights from an international, interdisciplinary working group. *Journal of Continuing Education in the Health Professions*, 33(4), 267–273. doi: 10.1002/chp.21197
- Légaré, F., Stacey, D., & Brière, N. (2016). Engaging clinical teams in an interprofessional approach to shared decision-making (Chapter 11). In G. Elwyn, A. Edwards & R. Thompson (Eds.), *Shared decision making in health care: Achieving evidence-based patient choice* (pp. 64–69). Oxford: Oxford University Press.
- Légaré, F., Stacey, D., Turcotte, S., Cossi, M. J., Kryworuchko, J., Graham, I. D., ... Donner-Banzhoff, N. (2014). Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database of Systematic Reviews*, 9, CD006732. doi: 10.1002/14651858.CD006732.pub3.
- Légaré, F., Stewart, M., Frosch, D., Grimshaw, J., Labrecque, M., Magnan, M., ... Elwyn, G. (2009). EXACKTE(2): exploiting the clinical consultation as a knowledge transfer and exchange environment: a study protocol. *Implementation Science*, 4, 14. doi: 10.1186/1748-5908-4-14.
- Légaré, F., Turcotte, S., Robitaille, H., Stewart, M., Frosch, D., Grimshaw, J., ... Elwyn, G. (2012). Some but not all dyadic measures in shared decision making research have

- satisfactory psychometric properties. *Journal of Clinical Epidemiology*, 65, 1310-1230. doi: 10.1016/j.jclinepi.2012.06.019
- Lewis, K. B., Nery, P. B., & Birnie, D. H. (2014). Decision-making at the time of ICD generator change: patients' perspectives. *JAMA Internal Medicine*, 174(9), 1508-1511. doi:10.1001/jamainternmed.2014.3435
- MacIver, J., Tibbles, A., Billia, F., & Ross, H. (2016). Patient perceptions of implantable cardioverter-defibrillator deactivation discussions: A qualitative study. *SAGE Open Medicine*, 4, 1-8. doi: 10.1177/2050312116642693
- Magyar-Russell, G., Thombs, B. D., Cai, J. X., Baveja, T., Kuhl, E. A., Singh, P. P.,... Ziegelstein, R. C. (2011). The prevalence of anxiety and depression in adults with implantable cardioverter defibrillators: a systematic review. *Journal of Psychosomatic Research*, 71(4), 223-231. doi: 10.1016/j.jpsychores.2011.02.014
- Matlock, D. D., Jones, J., Nowels, C. T., Jenkins, A., Allen, L. A., & Kutner, J. S. (2017). Evidence of cognitive bias in decision making around implantable-cardioverter defibrillators: a qualitative framework analysis. *Journal of Cardiac Failure*. doi: 10.1016/j.cardfail.2017.03.008 [Epub ahead of print]
- Merchant, F. M., Quest, T., Leon, A. R., & El-Chami, M. F. (2016). Implantable cardioverter-defibrillators at end of battery life: Opportunities for risk (re)-stratification in ICD recipients. *Journal of the American College of Cardiology*, 67(4), 435-444. doi: 10.1016/j.jacc.2015.11.033.
- Nelson, W. A., Donnellan, J. J., & Elwyn, G. (2016). Implementing shared decision making: An organizational imperative (Chapter 5). In G. Elwyn, A. Edwards & R. Thompson (Eds.), *Shared decision making in health care: Achieving evidence-based patient choice* (pp. 24-29). Oxford: Oxford University Press.
- Nilsen, E. S., Myrhaug, H. T., Johansen, M., Oliver, S., & Oxman, A. D. (2006). Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. *Cochrane Database of Systematic Reviews*, 3, CD004563.
- O'Connor, A. M. (1995). Validation of a decisional conflict scale. *Medical Decision Making*, 15, 25e30.
- O'Connor, A., Stacey, D., & Boland, L. (2015). Ottawa Decision Support Tutorial: Improving Practitioners' Decision Support Skills. Ottawa Hospital Research Institute: Patient Decision Aids. Retrieved from <https://decisionaid.ohri.ca/ODST/index.php> [Accessed November 20, 2017].
- Pearson, S. G. F. (1995). Critical pathways as a strategy for improving care: Problems and potential. *Annals of Internal Medicine*, 123, 941-94.
- Registered Nurses Association of Ontario (2009). Decision support for adults living with chronic kidney disease. Toronto, Canada: Registered Nurses Association of Ontario.

- Rotter, T., Kinsman, L., James, E., Machotta, A., Gothe, H., Willis, J.,...Kugler, J. (2010). Clinical pathways: effects on professional practice, patient outcomes, length of stay and hospital costs. *Cochrane Database of Systematic Reviews*, 17(3), CD006632. doi: 10.1002/14651858.CD006632.pub2.
- Shen, L., Jhund, P. S., Petrie, M. C., Claggett, B. L., Barlera, S., Cleland, J. G. F.,...McMurray, J. J. V. (2017). Declining Risk of Sudden Death in Heart Failure. *New England Journal of Medicine*, 377(1), 41-51. doi:10.1056/NEJMoa1609758
- Solomon, S. D., Wang, D., Finn, P., Skali, H., Zornoff, L., McMurray, J. J.,...Pfeffer, M. A. (2004). Effect of candesartan on cause-specific mortality in heart failure patients: the Candesartan in Heart failure Assessment of Reduction in Mortality and morbidity (CHARM) program. *Circulation*, 110(15), 2180-2183.
- Stacey, D., Graham, I. D., O'Connor, A. M., & Pomey, M. P. (2005). Barriers and facilitators influencing call centre nurses' decision support for callers facing values sensitive decisions: A mixed methods study. *Worldviews on Evidence Based Nursing*, 202, 184-195.
- Stacey, D., Higuchi, K. A., Menard, P., Davies, B., Graham, I. D., O'Connor, A. M. (2009). Integrating patient decision support in an undergraduate nursing curriculum: An implementation project. *International Journal of Nursing Education and Scholarship*, 6(1), 10. doi: 10.2202/1548-923X.1741
- Stacey, D., Kryworuchko, J., Bennett, C., Murray, M. A., Mullan, S., & Légaré, F. (2012). Decision coaching to prepare patients for making health decisions: a systematic review of decision coaching in trials of patient decision aids. *Medical Decision Making*, 32, E22-E33. doi: 10.1177/0272989X12443311
- Stacey, S., Légaré, F., & Brière, N. (2016). Engaging clinical teams in an interprofessional approach to shared decision making (Chapter 11). In G. Elwyn, A. Edwards & R. Thompson (Eds.), *Shared decision making in health care: Achieving evidence-based patient choice* (pp. 64-69). Oxford: Oxford University Press.
- Standing, H., Exley, C., Flynn, D., Hughes, J., Joyce, K., Lobban, T., ...Thomson, R. G. (2016). A qualitative study of decision-making about the implantation of cardioverter defibrillators and deactivation during end-of-life care. *Health Services and Delivery Research*, 4, 32.
- Thylén, I., Moser, D. K., Chung, M. L., Miller, J., Fluor, C., & Stromberg, A. (2013). Are ICD recipients able to foresee if they want to withdraw therapy or deactivate defibrillator shocks? *IJC Heart & Vessels*, 1, 22-31.
- van der Weijden, T., Boivin, A., Burgers, J., Schunemann, H. J., Elwyn, G. (2012). Clinical practice guidelines and patient decision aids. An inevitable relationship. *Journal of Clinical Epidemiology*, 65(6), 584-589. doi: 10.1016/j.jclinepi.2011.10.007
- Whittemore, R. & Knafl, K. (2005). The integrative review: updated methodology. *Journal of Advanced Nursing*, 52(5), 546-53.

- Woolf, S. H., Chan, E. C. Y., Harris, R., Sheridan, S. L., Braddock, C. H., Kaplan, R. M., ...Tunis, S. (2005). Promoting informed choice: Transforming health care to dispense knowledge for decision making. *Annals of Internal Medicine*, 143(4), 293-300.
- Wright, G., Klein, G., & Gula, L. (2012) Ethical and legal perspective of implantable cardioverter defibrillator deactivation or of implantable cardioverter defibrillator generator replacement in the elderly. *Current Opinion in Cardiology*, 28(1), 43-49.
- Yung, D., Birnie, D., Dorian, P., Healey, J. S., Simpson, C. S., Crystal, E.,...Lee, D. S. (2013). Survival after implantable cardioverter-defibrillator implantation in the elderly. *Circulation*, 127, 2383-2392. doi: 10.1161/CIRCULATIONAHA.113.001442.

Chapter 8: Contribution of Collaborators

This chapter specifies each collaborator's distinct contribution to the published papers and/or manuscripts included in this doctoral dissertation. Decisions around authorship were made in accordance with the International Committee of Medical Journal Editors (2017) and the Faculty of Graduate and Postdoctoral Studies at the University of Ottawa (2012).

8.1 Primary Researcher and Thesis Committee

This multi-methods doctoral dissertation was conceived in collaboration with my supervisor and committee members. The primary researcher, Krystina B. Lewis, was responsible for conducting all research activities, and as such, accepts full responsibility for each manuscript and the dissertation as a whole. Main collaborators included KL's primary supervisor, Dr. Dawn Stacey RN, PhD, CON(C) and two committee members Dr. David Birnie MD and Sandra Carroll RN, PhD. All three main collaborators participated in the design of the research, development of the research proposal, and approved the research plan. All members provided methodological and content expertise during study execution, participated in the analysis, and contributed important intellectual content prior to approving the final version of each manuscript for publication.

8.1.1 Primary Researcher

I am a registered nurse with a Bachelor in Nursing Science (Queen's University), Masters of Nursing (University of Victoria), and specialty in cardiovascular care nursing (Canada). I worked on an inpatient cardiology unit from 2007 to 2012 at the University of Ottawa Heart Institute. In 2012, I transferred to its ambulatory care clinic for patients with cardiac implanted electronic devices, including implantable cardioverter-defibrillators. My doctoral studies were financially supported by a Canadian Institutes for Health Research doctoral fellowship (2016-2018), Ontario Graduate Scholarships (2014-2016), and Excellence Scholarships from the University of Ottawa (2013-2018). Study specific funding was awarded by the Hebert and Corinne Zagerman Nursing Research Scholarship Award from the Ottawa Hospital (2014-2015), and the Canadian Council of Cardiovascular Nurses (2015-2016); none of which had a role in

study design, data collection and analysis, publication decisions, or preparation of the manuscripts or dissertation.

8.1.2 Members of the Thesis Committee

Dr. D. Stacey is a registered nurse and Professor in the School of Nursing at the University of Ottawa and Senior Scientist at the Ottawa Hospital Research Institute. She holds the University Chair in Knowledge Translation to patients and is Director of the Patient Decision Aids research group at the Ottawa Hospital Research Institute. DS is the lead author on the Cochrane review of patient decision aids, and co-lead on the Cochrane review for interventions to facilitate shared decision-making. Dr. D. Birnie is Staff Cardiac Electrophysiologist and Director of the Arrhythmia Service at the University of Ottawa Heart Institute. He is a Professor in the Division of Cardiology, Department of Medicine, at the University of Ottawa. Dr. S. L. Carroll is a registered nurse, Associate Professor and Interim Dean in the School of Nursing at McMaster University, and Director of the Clinical Health Professional Research at the Hamilton Health Sciences.

8.2 Other Collaborators and Acknowledgements

Although not part of the thesis committee, other members of the research team made important contributions (Table 8.1). A detailed account of member contributions are listed.

8.2.1 Integrative Review (Chapter 2)

Dr. Daniel D. Matlock MD, MPH, an attending physician and Associate Professor at the University of Colorado in Denver with expertise in ICD decision-making, participated in the screening, data abstraction and quality appraisal of included studies. He provided helpful direction in the early phases of data analysis, and contributed important intellectual content during manuscript revisions and approved the final version.

I also acknowledge the contributions of Agnieszka Szczotka, reference librarian at the University of Ottawa Heart Institute, for her assistance with the literature search.

8.2.2 Systematic Review (Chapter 3)

Laura Boland, doctoral candidate in Population Health at the University of Ottawa, participated in the screening, data abstraction, and quality appraisal of included studies. Lindsay Sikora, a health science research liaison librarian at the University of Ottawa helped develop the search strategy and adapted it to several databases. Both contributed important intellectual content during manuscript revisions and approved the final version.

I also acknowledge the contributions of Anton Saarimaki, computer systems analyst at the Ottawa Hospital Research Institute, who organized the web-based title and abstract screening application, Brian Hutton, Scientist in the Clinical Epidemiology Program at the Ottawa Hospital Research Institute, who provided statistical assistance, and Intissar Souli, research assistant and PhD candidate in the School of Nursing, who independently extracted the data from studies included in the systematic review.

8.2.3 Embedded Mixed Methods for PDA Development (Chapter 4)

Freya Kelly, a Masters student in the School of Nursing at the University of Ottawa at the time of data analysis, participated in the coding and verification of coding of the interviews. Patient and family stakeholders, Lloyd and Louise Rockburn and Paul Gibson were patient representatives on the PDA development advisory committee, and as such, involved in every step of the research process. Lorraine Clark, nursing manager of the ambulatory cardiac device clinic at the Heart Institute, was also a member of the advisory committee. She helped facilitate potential end-user recruitment. All of these individuals contributed important intellectual content during manuscript revisions and approved the final version.

I also acknowledge the contributions of Elaine Parker who transcribed the interviews.

8.2.4 Feasibility Pilot Randomized Controlled Trial (Chapter 5)

Carolynne Brousseau-Whaley, a Masters prepared registered nurse at the University of Ottawa Heart Institute, assisted with recruitment, data collection, and provided the decision coaching intervention. Her contribution to the success of the research is gratefully acknowledged. Lorraine Clark helped facilitate recruitment and enabled access to necessary facilities and resources.

I acknowledge the contributions of Monica Taljaard PhD, Senior Scientist in the Clinical Epidemiology Program at the Ottawa Hospital Research Institute and Ranjeeta Mallick PhD, Senior Statistician at the Ottawa Methods Centre of the Ottawa Hospital Research Institute for their guidance in the statistical analysis. Also, I acknowledge the assistance of Drs. Green, Redpath, Nair, Nery, Sadek, and Davis, electrophysiologists at the University of Ottawa Heart Institute, who were involved in the management of patients recruited in the study.

8.2.5 Narrative Review (Chapter 6)

Dr. Daniel D. Matlock MD, MPH provided valuable direction for the overarching structure of the manuscript following an initial draft, contributed important intellectual content during manuscript revisions, and approved the final version. I thank Sarah Visintini, BA, MLIS, a health sciences research librarian, who assisted with the development of the search strategy and adapted it to two databases.

8.3 References

Faculty of Graduate and Postdoctoral Studies at the University of Ottawa (2012). *Preparing a thesis or a research paper at the University of Ottawa*. Retrieved from <http://www.grad.uottawa.ca/default.aspx?tabid=1373>

International Committee of Medical Journal Editors (2017). *Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals*. Retrieved from <http://www.icmje.org/recommendations/>

Table 8.1 Contribution of Collaborators For Published Articles and Prepared Manuscripts

Element	Chapter 2 (Published)	Chapter 3 (Published)	Chapter 4 (Accepted for publication)	Chapter 5 (Manuscript)	Chapter 6 (Published)
Title	Making Decisions About Implantable Cardioverter-Defibrillators from Implantation to End of Life: An Integrative Review of Patients' Perspectives	Estimating the Risks and Benefits of Implantable Cardioverter Defibrillator Generator Replacement: A Systematic Review	User-centered development of a patient decision aid for implantable cardioverter-defibrillator replacement: A mixed-methods study	A Feasibility Randomized Trial of a Decision Support Intervention for Patients Facing Implantable Cardioverter-Defibrillator Replacement	Incorporating Patients' Preference Diagnosis in Implantable Cardioverter-Defibrillator Decision-Making: A Review of Recent Literature
Conceptualization and design	KBL DS DDM	KBL DS SLC DB	KBL DS SLC DB	KBL DS SLC DB	KBL SLC DS DDM
Data collection	KBL DDM	KBL DS LB LS	KBL	KBL CBW	KBL
Data analysis and interpretation	KBL DS DDM	KBL DS DB	KBL DS FK SLC	KBL DS DB SLC	KBL SLC DS DDM
Draft manuscript	KBL	KBL	KBL	KBL	KBL
Manuscript revisions for important intellectual content	KBL DS DDM	KBL DS SLC LB LS DB	KBL DB SLC LC FK LR PG DS	KBL DS SLC CBW LC DB	KBL SLC DB DS DDM
Approval of final version for publication	KBL DS DDM	KBL DS SLC	KBL DB SLC	KBL DS SLC	KBL SLC DB

		LB LS DB	LC FK LR PG DS	CBW LC DB	DS DDM
Responsible for overall content	KBL	KBL	KBL	KBL	KBL

Appendices

Appendix A - Additional Search Strategies for Systematic Review

Embase Search Strategy

1. implantable cardioverter defibrillator/
2. (icd adj1 pulse adj1 generator*).tw.
3. (implantable adj2 cardioverter-defibrillator*).tw.
4. defibrillat*.tw.
5. (implantable adj2 cardiac adj2 defibrillator*).tw.
6. aicd.tw.
7. or/1-6
8. device removal/
9. (device* adj2 removal*).tw.
10. (device* adj3 withdraw*).tw.
11. (generator adj2 replacement*).tw.
12. (generator adj2 change*).tw.
13. (batter* adj2 replacement*).tw.
14. (batter* adj2 change*).tw.
15. (ICD adj1 replacement*).tw.
16. reoperation*.tw.
17. or/11-16
18. 7 and 17
19. limit 18 to yr="2000 -Current"

PsycINFO search strategy

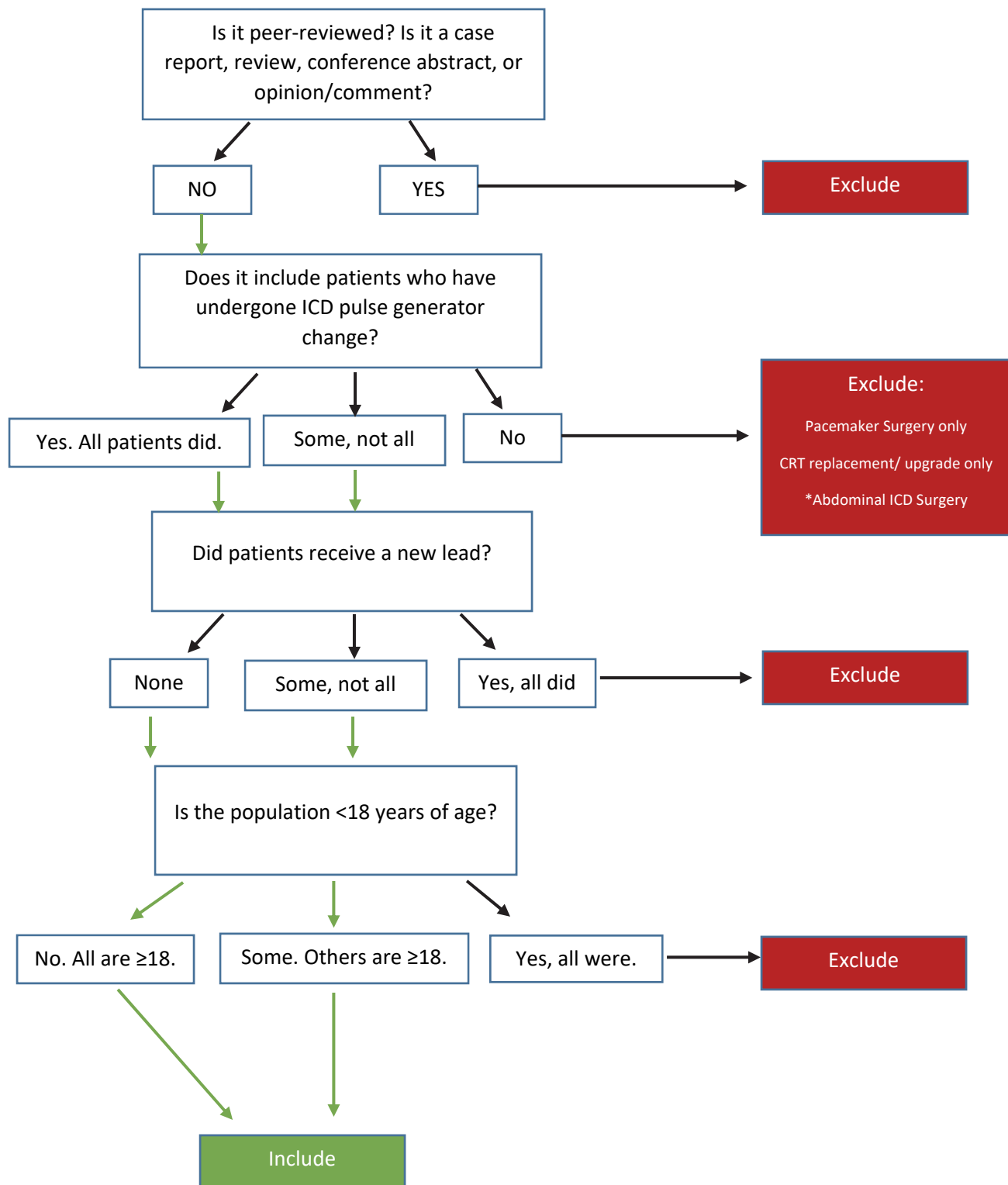
1. medical therapeutic devices/
2. (implantable adj2 cardioverter-defibrillator*).tw.
3. defibrillat*.tw.
4. (implantable adj2 cardiac adj2 defibrillator*).tw.
5. 1 or 2 or 3 or 4
6. reoperation*.tw.
7. (device* adj2 removal*).tw.
8. (device* adj3 withdraw*).tw.
9. (generator adj2 change*).tw.
10. (generator adj2 replacement*).tw.
11. (batter* adj2 change*).tw.
12. (batter* adj2 replacement*).tw.
13. (ICD adj1 replacement*).tw.
14. 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15. 5 and 14
16. limit 15 to yr="2000-Current"

CINAHL search strategy

1. (MH "Defibrillators, Implantable")
2. icd pulse generator*
3. implantable cardioverter-defibrillator*
4. implantable defibrillator*
5. implantable cardiac defibrillator*
6. defibrillator*
7. S1 OR S2 OR S3 OR S4 OR S5 OR S6
8. (MH "Device Removal")
9. device removal
10. device withdraw*
11. generator replacement*
12. generator change*
13. batter* replacement*
14. batter* change*
15. ICD replacement*
16. (MH "Reoperation")
17. S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16
18. S7 AND S17

Cochrane and DARE (via OVID)

1. (device* adj2 removal*).tw.
2. (device* adj3 withdraw*).tw.
3. (generator adj2 change*).tw.
4. (generator adj2 replacement*).tw.
5. (batter* adj2 change*).tw.
6. (batter* adj2 replacement*).tw.
7. (ICD adj1 replacement*).tw.
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. (icd adj1 pulse adj1 generator*).tw.
10. (implantable adj2 cardiac adj2 defibrillator*).tw.
11. (implantable adj2 cardioverter-defibrillator*).tw.
12. defibrillat*.tw.
13. 9 or 10 or 11 or 12
14. 8 and 13
15. limit 14 to yr="2000 -Current

Appendix B - Title and Abstract Screening Criteria

Appendix C - Full Text Screening Criteria

Criteria		Yes	No
1. Population	Adults ≥18 years with primary or secondary prevention ICD who have undergone ICD pulse generator replacement	☐	☐
2. Intervention	a. Conventional ICD pulse generator replacement	☐	☐
	b. pacemaker surgery <u>only</u>		
	c. cardiac resynchronization therapy replacement or upgrade <u>only</u>	☐	☐
	d. abdominal or subcutaneous ICD surgery	☐	☐
	e. ICD extraction (without replacement)	☐	☐
	f. asking patients about hypothetical pulse generator change	☐	☐
	g. did <u>all</u> patient receive a new lead?	☐	☐
3. Comparator	ICD non-replacement or none	☐	☐
4. Outcomes	Include at least one of the following:		
	a. risks/complications of ICD replacement		
	b. benefits of ICD replacement	☐	☐
	c. costs of ICD replacement	☐	☐
5. Study design	a. original study investigation in peer reviewed journal	☐	☐
	b. case report	☐	☐
	c. review	☐	☐
	d. opinion/editorial/commentary	☐	☐
	e. conference abstract	☐	☐

Instructions:

1. Population: If yes, include and move to criteria 2. If no, exclude.

2. Intervention:

- If a, yes, include and move to b. If no, exclude.
- If b, no, include and move to c. If yes, exclude.
- If c, no, include and move to d. If yes, exclude.
- If d, no, include and move to e. If yes, exclude.
- If e, no, include and move to f. If yes, exclude.

- If f, no, include and move to g. If yes, exclude.
 - If g, no, include and move to criteria 3. If no, exclude.
3. Comparator: If yes, include and move to criteria 4. If no, exclude.
4. Outcomes: If yes (for at least one outcome listed), include and move to criteria 5. If no, exclude.
5. Study design:
- If a, yes, include and move to b. If no, exclude.
 - If b, no, include and move to c.
 - If c, no, include and move to d.
 - If d, no include and move to e

Appendix D - Ottawa Health Science Network Research Ethics Board Initial Approval for Mixed Methods Study



**Ottawa Health Science Network Research Ethics Board/ Conseil d'éthique de la recherche du
Réseau de science de la santé d'Ottawa**

Civic Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-798-5555 ext 14902 Fax : 613-761-4311
<http://www.ohsn.ca/ohsn-reb>

September 16, 2015

Dr. David Birnie
Division of Cardiology, Room H123
University of Ottawa Heart Institute
40 Ruskin Street
Ottawa, ON K1Y 4W7

Dear Dr. Birnie:

**Re: Protocol # 20150308-01H Development of Decision Support for Adults Faced With
Implantable Cardioverter-Defibrillator Replacement:
A Qualitative Study**

The OHSn-REB acknowledges receipt of the letter from Krystina Lew dated September 2, 2015, for the above-listed study. The interview guide, version dated September 2, 2015 and Decision aid version dated September 2, 2015 were reviewed, changes were reviewed and are acceptable. A translation exemption has been granted until the decision aid is finalized.

OHSN-REB complies with the membership requirements and operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization - Good Clinical Practice: Consolidated Guideline; the provisions of the Personal Health Information Protection Act 2004

Sincerely,

A handwritten signature in black ink, appearing to be "M. ...", written over the word "Sincerely,".

Appendix E - Participant Informed Consent Form for Mixed Methods Study



Ottawa Hospital
Research Institute
Institut de recherche
de l'Hôpital d'Ottawa

PARTICIPANT INFORMED CONSENT FORM

Title of Study:

Development of Decision Support for Adults Faced With Implantable Cardioverter-Defibrillator (ICD) Battery Replacement: A Qualitative Study

Principal Investigator (PI):

Dr. David Birnie MD

Phone: 1-613-798-5555 ext. 14705

Sponsor (or Funding Agency): Hebert and Corinne Zagerman Nursing Research Award

Participation in this study is voluntary. Please read this Participant Informed Consent Form carefully before you decide if you would like to participate. Ask the study team as many questions as you like. We encourage you to discuss your options with family, friends, and your health care team.

Why am I being given this form?

You are being asked to participate in this research study because you have faced the decision to replace or not replace your implantable cardioverter-defibrillator (ICD) battery. You may be a patient who has faced this decision, a family member of someone who has faced the decision, or you may be a health care professional involved in the care of patients who have faced ICD battery replacement.

Why is this study being done?

The ICD is a small medical device that can detect unsafe heart rhythms and deliver a shock to stop them. ICDs require a battery to function. The battery needs to be replaced using surgery every four to seven years to maintain normal function. At present, ICDs are automatically changed. Patients are not offered the option of not replacing it. The aim of this study is to get your feedback on a decision aid that has been created to help patients who are faced with the decision to replace their ICD. With your feedback, we hope to make this decision aid useful for patients who will face this decision in the future.

We plan to enroll 15 people in this study from the Heart Institute. We are asking patients with ICDs and family members to participate. We are also asking doctors and nurses who are involved in the care of patients with ICDs to participate.

How is the study designed?

A decision aid for the decision to replace or not replace an ICD was created by a team of researchers and clinicians. In this study, we will interview people who have faced this decision in the past, and others who have helped people face this decision (family members, doctors, nurses). The information collected during these interviews will help us make changes to the decision aid to make it as useful as possible for future people facing this decision.

What is expected of me?

You will be asked to participate in an interview. It will last about 45 to 60 minutes. This in-person interview will be scheduled at a time that is convenient for you. With your consent, the interview will be audio recorded. During the interview, we will:

1. Ask you questions about your experiences with the ICD change decision making process.
2. Walk you through the decision aid and give you time to review the decision aid on your own.
3. Ask you questions about the format and content of the decision aid.
4. Ask you questions about how this decision aid could be used in practice.
5. Ask you some questions about yourself (e.g. age, education, etc.)

You may skip any questions that make you uncomfortable or that you do not wish to answer. Information collected will be used to make changes to the decision aid so it can best help patients, family members, and the health care team involved in this decision. Once all interviews are done, we will share our results with you and give you the chance to comment on them.

Will my research data be used in future research?

The information collected from these interviews will be used to make changes to the decision aid. The revised decision aid will be used in a future study to evaluate it with patients who are actually facing the decision in real time.

How long will I be involved in the study?

Study participation will be a one-time interview lasting about 45-60 minutes. The entire study will last about 6 months. Once all interviews are done, we will share our results with you and give you the chance to comment on them.

What are the potential risks I may experience?

You may find the interview distressing, tiring, or lengthy. You might not like the content of the decision aid. You might not like all of the questions that you are asked. You do not have to answer any questions that make you uncomfortable.

Can I expect to benefit from participating in this research study?

You may not receive any direct benefit from your participation in this study. Your participation may allow the researchers to improve the patient decision aids being developed. This may benefit future patients.

Do I have to participate? What options do I have?

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later without affecting the medical care, education, or other services to which you are entitled or are presently receiving at this institution. If applicable, your decision will not affect your current or future employment at the University of Ottawa Heart Institute.

If I agree now, can I change my mind and withdraw later?

You may withdraw from the study at any time. You are under no obligation to participate or to answer any questions. If you choose not to participate, your decision will not affect your care. If you choose to withdraw, all data gathered until the time of withdrawal will be used for the study unless you do not approve, in which case it will be destroyed.

Will I be paid for my participation or will there be any additional costs to me?

You will not be paid for your participation in the study.

How is my personal information being protected?

We will take all reasonable steps to keep your research information confidential.

- All personal health information (PHI) and your personal identifying information (PII), such as your name, date of birth, etc. will be kept confidential.
- Release of your PHI/PII information will only be allowed if it is legally required.
- The data collected as audio recordings of interviews, transcripts and notes will be kept in a secure locked office. The study staff will have access to the study findings.
- As a participant, you will be assigned a coded study number that will be used throughout the study on all your study records.
- A Master List provides the link between your identifying information and the coded study number. This list will only be available to Dr. David Birnie, the Principal Investigator, and Co-Investigators, Dr. Dawn Stacey and Krystina Lewis, and will not leave this site.
- The Master List and coded study records will be stored securely. Electronic records will be stored on the Institutional secure server, not on a computer's C drive. Files will be password protected. No portable devices may contain PII.
- For audit purposes only, your original medical records may be reviewed under the supervision of Dr. David Birnie, Dr. Dawn Stacey, or Krystina Lewis by representatives from:
 - the Ottawa Health Science Network Research Ethics Board (OHSN-REB), and the University of Ottawa Heart Institute
- You will not be identified in any publications or presentations resulting from this study.

- Research records will be kept for 10 years, as required by the OHSN-REB.
- At the end of the storage time, all paper records will be shredded and all electronic records will be securely deleted.

Do the investigators have any conflicts of interest?

There are no conflicts of interest to declare related to this study.

What are my responsibilities as a study participant?

It is important to ask Dr. David Birnie, Dr. Dawn Stacey, or Krystina Lewis if you have any questions or concerns.

Will I be informed about any new information that might affect my decision to continue participating?

You will be told in a timely fashion of any new findings during the study that could affect your willingness to continue in the study. You may be asked to sign a new consent form.

Who do I contact if I have any further questions?

If you have any questions about this study, or if you feel that you have experienced a study-related injury or illness, please contact Dr. David Birnie at xxx-xxx-xxxx ext. xxxxx, Dr. Dawn Stacey at xxx-xxx-xxxx ext. xxxxx, or Krystina Lewis at xxx-xxx-xxxx.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed this protocol. The Board considers the ethical aspects of all research studies involving human participants at the University of Ottawa Heart Institute. If you have any questions about your rights as a study participant, you may contact the Chairperson at xxx-xxx-xxxx, extension xxxx.



Consent to Participate in Research

- I understand that I am being asked to participate in a research study about providing feedback on a decision aid for adults faced with the decision to replace or not replace their ICD.
- This study was explained to me by _____.
- I have read, or have had it read to me, each page of this Participant Informed Consent Form.
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this study.
- I will be given a copy of this signed Participant Informed Consent Form.
- I agree to my interview being audio recorded (please check one) YES ☐ NO ☐

Participant's Printed Name

Participant's Signature

Date

Investigator or Delegate Statement

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

Investigator/Delegate's Printed Name

Investigator/Delegate's Signature

Date

Appendix F - Semi-Structured Interview Guide for Patients, Families and Clinicians

Date: _____

Participant Code: _____

Interviewer:

Hello. My name is Krystina. I am a nurse at the Heart Institute and a student at the University of Ottawa. Recently, our team has been looking at the way we approach the time when a person's ICD battery is running low. Our team is working on a project to develop a tool, a patient decision aid, for people facing the decision to replace their ICD. The purpose of this interview is to help us understand how to best support the involvement of patients in decisions regarding ICD replacement, and also discuss the usefulness of a decision aid in helping people make this decision. There are no right or wrong answers; we would just like your feedback on this decision aid and your opinion on how it could be used in practice.

SECTION 1: INTRODUCTION and CURRENT PROCESS OF ICD REPLACEMENT

To begin, I'd like to ask a few questions to get to know you a bit better.

For patients	For members of the healthcare team
1. How long have you had your ICD?	1. What is your role at the Heart Institute?
2. How would you describe your time with your ICD?	2. In which area do you spend most of your time?
3. How many times have you faced ICD replacement?	3. How long have you been practising in this capacity?
4. The last time you were faced with a battery that was running out, did you decide to replace or not replace your battery?	4. How often are you involved in the care of patients facing ICD replacement (% , # of times per week, etc)?
5a. <u>If accepted replacement</u> : Tell me how the decision was made to replace your ICD? b. <u>If declined replacement</u> : Tell me how the decision was made not to replace your ICD. Prompts: <i>[How is the decision made?]</i> <i>[Who is involved?]</i> <i>[What kind of information is provided?]</i> <i>[Where/when?]</i> <i>[Facilitators]</i> <i>[Barriers]</i> <i>[Overcoming barriers]</i>	5. Tell me the current process used for deciding about battery replacement when a patient's ICD battery is low in voltage and approaching the need to replace it? Prompts: <i>[What do you do?]</i> <i>[What do others do?]</i> <i>[Barriers and facilitators?]</i>
6. From your perspective, can this be a difficult decision for patients?	6. From your perspective, can this be a difficult decision for patients?

7. What would you consider benefits of getting it replaced?	7. What would you consider the benefits of ICD replacement?
8. Can you think of reasons why some people might choose not to replace it?	8. Can you think of reasons why some people might choose not to replace it?
9. What did you think when you first heard about this idea of offering patients the option of replacing their ICD?	9. What did you think when you first heard about this idea of offering patients the option of replacing their ICD?

SECTION 2: THE DECISION AID

For patients and members of the healthcare team:

Now, I would like to hear your thoughts on the patient decision aid that we developed for patients facing the decision to replace their ICD battery. This decision aid intended to be used in preparation for discussing this decision with the doctor in the clinic and/or any other healthcare provider involved in your care. Have you had a chance to review it?

10. What was your overall impression of the decision aid?

Lets go through section by section, as I would like to know what you think of each individual part.

11. Let's start with the **title page**. Does it make it clear as to what the decision aid is about?

Prompts: *[Font, Font size, Picture]*

Rating: poor fair good excellent

12. Next is the **Table of Contents**. Do you have any comments about it?

Rating: poor fair good excellent

13. What do you think about the **Introduction**? Is the decision clear? Are the options clear?

Prompts: *[decision clear?, options clear?, review of how ICD functions]*

Rating: poor fair good excellent

14. Moving on to **Step 1: Be clear about the options.**

Prompts: *[sufficient information about each option?]*

[is it clear why someone would choose either option?]

Rating: poor fair good excellent

15. How about **Step 2: Weigh the options?**

Prompts: *[Are the benefits clear?, Are the risks clear?, Is the way in which the information is presented clear?, Evidence]*

Rating: poor fair good excellent

16. **Step 3: Consider Your Preferred Option.** Does it make sense as to why these 4 questions are listed here? Would you be able to answer them?

Rating: poor fair good excellent

17. **Step 4: Check your knowledge about the options.** Would you have been able to answer these questions?

Prompts: *[Did you try the quiz?, Check answers with answer key?]*

Rating: poor fair good excellent

18. What do you think of **Step 5: What else do you need to make a choice?**

Rating: poor fair good excellent

19. As for the **Frequently Asked Questions** section. Did you find the questions helpful? Are there any other questions you would like to see in this section?

Rating: poor fair good excellent

20. And finally, the **References.**

Rating: poor fair good excellent

21. Did you find that the amount of information included in the PtDA was:

- ☐ Less than I wanted
- ☐ About right
- ☐ More than I wanted

22. Did you find that the length of the patient decision aid was:

- ☐ Too long
- ☐ About right
- ☐ Too short

23. Are the font and icons (check boxes etc.) readable (i.e. font type and size)?

☐ Yes ☐ No

24. Is there enough space to write in the decision aid?

☐ Yes ☐ No

25. There are a lot of words used in the decision aid. Did all the words make sense to you?

☐ Yes ☐ No – If no, which words did not make sense? _____

26. Did you find that the balance of the patient decision aid was:

- ☐ Clearly slanted to replacing the ICD
- ☐ Slightly slanted to replacing the ICD
- ☐ Completely balanced
- ☐ Slightly slanted to not replacing the ICD
- ☐ Clearly slanted to not replacing the ICD

27. Is there information missing that you would like to see added?

- ☐ Yes ☐ No – If yes, please describe

For patients	For members of the healthcare team
28. The next time your battery is running low, would you find this type of resource helpful? ☐ Yes, as it is ☐ Yes, but with some alterations ☐ No	28. Would you find this type of resource helpful for patients presenting with depleting ICD batteries? ☐ Yes, as it is ☐ Yes, but with some alterations ☐ No
29. Would you tell someone about the decision aid? ☐ Yes ☐ No	29. Would you give your patients this decision aid? ☐ Yes ☐ No
30. Do you have any further comments on the decision aid?	30. Do you have any further comments on the decision aid?

SECTION 3. USING THE DECISION AID IN PRACTICE

Next, I will ask you questions about what you think would be the best way to give this decision aid to patients.

For patients	For members of the healthcare team
31. How do you see this decision aid being used in the process of care at the Heart Institute? <i>Prompts: [Distribution]</i> <i>[The way the nurses and physicians give them to patients]</i>	31. How do you see this decision aid being used in the process of care at the Heart Institute? <i>Prompts: [Distribution]</i> <i>[The way the nurses and physicians give them to patients]</i>

32. What do you think would be the easiest way to give this patients so that they would use it?	32a. As a physician/nurse, what do you believe would be your role and responsibilities in using this DA with patients? 32b. What would be the roles and responsibilities of others? <i>[Nurses, Physicians, Management, Administrative staff]</i>
33. At what point do you think it would be the right time to receive this decision aid?	33a. When do you think would be the right time to distribute this decision aid to patients? 33b. If patients review the decision aid before the consultation, what would you want or need so you can understand what is important to the patient?
34. Do you foresee any challenges to distributing them to patients?	34a. How do you think it relates to current work practices at the Heart Institute? 34b. What changes would need to be made in practice to use this decision aid?
35. Do you think this decision aid is a worthwhile tool to use in practice?	35. How do you think it should be documented that the decision aid has been given to a patient?
36. On a scale from 1 (not at all important) to 5 (extremely important), how important is it to have something like this to use in practice? 1 2 3 4 5	36. Other than the device clinic, could you see this being used elsewhere in the Heart Institute? <i>[other settings, time, contexts]</i>
	37a. From your perspective, what is the aim of using this decision aid with patients? 37b. What is the expected outcome of using this decision aid?
	38. Do you think this decision aid is a worthwhile tool to use in practice?
	39. On a scale from 1 (not at all important) to 5 (extremely important), how important is it to have something like this to use in practice? 1 2 3 4 5

SECTION 4. DEMOGRAPHICS

We are almost finished. To wrap up, I would like to ask you a few questions about yourself.

For patients
1. What year were you born?
2a. What do you do for work?
2b. If no longer working, what type of work did you do?
3. What is the highest level of education you have completed?

Is there anything else you would like to share with me regarding the decision aid or this interview process? Thank you for taking the time to go through this interview with me. Your feedback will be used to make revisions to this patient decision aid.

Appendix G - Ottawa Health Science Network Research Ethics Board Initial Approval, Amendment Approval, and Annual Renewal for Feasibility Trial



Ottawa Health Science Network Research Ethics Board/ Conseil d'éthique de la recherche du Réseau de science de la santé d'Ottawa

Civic Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-798-5555 ext. 14002 Fax : 613-761-4311
<http://www.ohri.ca/ohsn-reb>

February 5, 2016

Dr. David Birnie
 Division of Cardiology, Room H123
 University of Ottawa Heart Institute
 40 Ruskin Street
 Ottawa, ON K1Y 4W7

Dear Dr. Birnie:

Re: Protocol # 20160037-01H Evaluation of Decision Support for Adults Considering Implantable Cardioverter-Defibrillator Pulse Generator Replacement: A Pilot Randomized Controlled Study

Protocol approval valid until - February 4, 2017

I am pleased to inform you that this protocol underwent expedited review by the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and is approved. No changes, amendments or addenda may be made to the protocol or the consent form without the OHSN-REB's review and approval.

The following are approved:

- Protocol, Version 2, dated January 25, 2016
- English Telephone Script, Version 1, dated January 25, 2016
- English Participant Informed Consent Form, version date January 18, 2016
- Decision Coaching protocol, version dated January 18, 2016
- English Baseline Questionnaire version date January 25, 2016
- English Follow-up Supplemental Questionnaire version date January 25, 2016
- English 6 month Follow-up Questionnaire, version dated January 25, 2016
- English Primary Prevention ICD Decision Aid tool
- English Making a Decision to Replace or Not Replace your Implantable Cardioverter-Defibrillator (ICD) dated September 2015

The REB acknowledges case report forms version dated January 25, 2016.

The request for French translation is granted at this time. It is incumbent upon investigator to insure that any French speaking patients recruited are sufficiently fluent in English. If a larger study is contemplated in the future French translation of documents will be required.

....2

The REB no longer requires a 'valid until' date at the bottom of all approved informed consent forms. The consent forms currently approved for use by the REB are listed above.

If the study is to continue beyond the expiry date noted above, a Renewal Form should be submitted to the REB approximately six weeks prior to the current expiry date. If the study has been completed by this date, a Termination Report should be submitted.

OHSN-REB complies with the membership requirements and operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization - Good Clinical Practice: Consolidated Guideline; the provisions of the Personal Health Information Protection Act 2004.

 Yours sincerely,



Ottawa Health Science Network Research Ethics Board/ Conseil d'éthique de la recherche du Réseau de science de la santé d'Ottawa

Civic Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-708-5555 ext. 14902 Fax : 613-761-4311
<http://www.dhn.ca/ohsn-reb>

April 25, 2016

Dr. David Birnie
 Division of Cardiology, Room H123
 University of Ottawa Heart Institute
 40 Ruskin Street
 Ottawa, ON K1Y 4W7

Dear Dr. Birnie:

Re: Protocol # 20160037-01H Evaluation of Decision Support for Adults Considering Implantable Cardioverter-Defibrillator Pulse Generator Replacement: A Pilot Randomized Controlled Study

The OHSN-REB acknowledges receipt of the correspondence from Ms. Krystina Lewis dated March 24, 2016 to March 29, 2016 for the above-listed study.

Approval is for the following:

- Protocol amendment report dated March 24, 2016
- Revised Baseline Questionnaire, version date March 24, 2016
- Revised 2-4 weeks, Follow-up questionnaire, version date March 24, 2016
- Revised 2-4 week Supplemental Questionnaire, Intervention Group only, version date March 24, 2016
- Revised 6 month Follow-up Questionnaire, version March 24, 2016
- Revised 12 month Follow-up Questionnaire, version date March 24, 2016
- Revised Case Report Form, Baseline version 5, dated March 25, 2016
- Revised 2-4 week Follow-Up Case Report Form, version March 24, 2016
- Revised 2-4 week supplemental, Intervention Group Only, Case Report Form, version March 24, 2016
- Revised 6 month Follow-up Case Report Form, version date March 24, 2016
- English Telephone Recruitment Script, version date March 24, 2016
- Revised English Participant Informed Consent Form, version date March 24, 2016
- Revised Decision Making tool Making a Decision to Replace or Not Replace Your Implantable Cardioverter-Defibrillator Battery dated March 2016
- Revised Individualized ICD Benefits Sticker, dated March 24, 2016
- Revised Protocol Version 2 dated March 24, 2016
- ICD replacement Study Feasibility of Contact and Measures, version March 24, 2016

...2

OHSN-REB complies with the membership requirements and operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization - Good Clinical Practice: Consolidated Guideline; the provisions of the Personal Health Information Protection Act 2004.

Sincerely, 



**Ottawa Health Science Network Research Ethics Board/ Conseil d'éthique de la recherche du
Réseau de science de la santé d'Ottawa**

Chric Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-708-5555 ext. 14002 Fax : 613-761-4311
<http://www.ohri.ca/ohsn-reb>

January 11, 2017

Dr. David Birnie
 Division of Cardiology, Room H123
 University of Ottawa Heart Institute
 40 Ruskin Street
 Ottawa, ON K1Y 4W7

Dear Dr. Birnie:

**RE: Protocol# - 20160037-01H Evaluation of Decision Support for Adults Considering Implantable
Cardioverter-Defibrillator Pulse Generator Replacement: A Pilot
Randomized Controlled Study**

Renewal Expiry Date - February 4, 2018

I am pleased to inform you that your Annual Renewal Request was reviewed by the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and is approved. No changes, amendments or addenda may be made in the protocol or the consent form without the OHSN-REB's review and approval.

Renewal is valid for a period of one year. Approximately one month prior to that time, a single renewal form should be sent to the REB office.

The English Participant Informed Consent Form, version date March 24, 2016 is currently approved.

The Tri-Council Policy Statement requires a greater involvement of the OHSN-REB in studies over the course of their execution. As well, you must inform the Board of adverse events encountered during the study, here or elsewhere, or of significant new information which becomes available after the Board review, either of which may impinge on the ethics of continuing the study. The OHSN-REB will review the new information to determine if the protocol should be modified, discontinued, or should continue as originally approved.

[Handwritten signature]

Appendix H - Participant Informed Consent Form for Feasibility Trial



PARTICIPANT INFORMED CONSENT FORM

Title of Study:

Evaluation of Decision Support for Adults Considering Implantable Cardioverter-Defibrillator (ICD) Pulse Generator Replacement: A Pilot Randomized Controlled Trial

Principal Investigator (PI):

Dr. David Birnie MD

xxx-xxx-xxxx ext. xxxxx

Sponsor (or Funding Agency): Canadian Council of Cardiovascular Nurses

Participation in this study is voluntary. Please read this Participant Informed Consent Form carefully before you decide if you would like to participate. Ask the study team as many questions as you like. We encourage you to discuss your options with family, friends, and your health care team.

Why am I being given this form?

You or your family member is being asked to participate in this research study because the battery in your ICD is depleting.

Why is this study being done?

The ICD is a small medical device that can detect unsafe heart rhythms. If detected, the ICD can deliver a shock to stop them. ICDs need a battery to function. It needs to be replaced by surgery every 5 to 7 years to maintain normal function. The aim of this study is to see how best we can support patients faced with the decision to replace their ICD. We plan to enroll 80 people in this study from the Heart Institute. We are asking patients with ICDs that are nearing the time when they would need to replace their ICD to participate.

How is the study designed?

This study compares a new approach to support patients who are facing ICD battery replacement with the current way we do it. We refer to the new strategy as *intervention*. We

refer to the current way as *usual care*. Whether you get the intervention or usual care is decided at random. This means that you are put into a group by chance – like a flip of a coin.

What is expected of me?

There will be a total of four visits over the course of 12 months.

1. At the **first visit** you will meet a member of the study team. They will find out if you can be in this study. If you can and you agree to participate, you will be assigned at random to one of two groups. Whether you are assigned to *usual care* or *intervention*, you will talk about ICD replacement with a study nurse and receive information about it. You will be asked questions about yourself, your ICD, your quality of life, and your preference towards replacing your ICD battery after your clinic visit.

2. The **second visit** will be 2-4 weeks later. This can either be done in-person or over the phone. It will last 30 to 60 minutes. At this visit we will answer any questions you may have about ICD replacement, and ask you questions about your preference towards replacing your ICD battery, your thoughts on how easy or difficult it is to make the decision, your knowledge about your ICD and the ICD replacement surgery, and what risks and benefits of ICD replacement are most important to you. You may skip any questions that make you uncomfortable or that you do not wish to answer.

3. The **third and fourth visits** will occur 6 and 12 months later. Each will last about 15-30 minutes. These can either be done in-person, or over the phone. At this visit we will ask you questions about whether you chose to replace or not replace your ICD, your thoughts on how easy or difficult it was to make the decision, how involved you felt in making the decision, and your quality of life.

Table 1. Boxes marked with an X show what questions will be asked at each visit.

Survey (number of items per survey)	Visit 1	Visit 2 (2-4 weeks)	Visit 3 and 4 (6 and 12 months)
Demographics (6)	X	-	-
ICD Acceptance (15)	X	-	-
Quality of Life (36)	X	-	X
Acceptability and Usability of New Approach (<i>Intervention group only</i>) (21)	-	X	-
Knowledge (6)	-	X	-
Your values about ICD replacement (4)	-	X	-
Decisional Comfort (16)	-	X	X

Preferred Choice (1)	X	X	X
Your involvement in the decision (1)	-	-	X
Actual Choice (1)	-	-	X

Will my research data be used in future research?

The data collected from this study will be used to inform whether we should conduct a larger trial with patients who are faced with the decision to replace their ICD.

How long will I be involved in the study?

The entire study will last approximately 1-2 years. Your participation in the study will last about 6 months. Over this time, we will make contact with you at least 3 times. Follow-up visits can be arranged in person, over the phone, or by mail.

What are the potential risks I may experience?

Decision support strategies like the ones we are evaluating in this study do not pose direct risks. You may find the questions distressing, tiring, or lengthy. Or, you might not like the content of it. You do not have to answer any questions that make you uncomfortable.

Can I expect to benefit from participating in this research study?

You may not receive any direct benefit from your participation in this study. Your participation may allow the study team to improve the decision support strategy being developed. This may benefit future patients.

Do I have to participate? What alternatives do I have?

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later without affecting the medical care, education, or other services to which you are entitled or are presently receiving at this institution. If you choose not to participate, usual care and a discussion with your health care team about your options are available. Your study doctor can discuss these options with you.

If I agree now, can I change my mind and withdraw later?

You may withdraw from the study at any time. You are under no obligation to participate or to answer any questions. If you choose not to participate, your choice will not affect your care. If you choose to withdraw, all data gathered until the time of withdrawal will be for the study unless you do not approve, in which case it will be destroyed.

Will I be paid for my participation or will there be any additional costs to me?

You will not be paid for your participation in the study. There will be no additional costs.

How is my personal information being protected?

We will take all reasonable steps to keep your research information confidential.

- All personal health information (PHI) and your personal identifying information (PII), such as your name, date of birth, medical history related to your ICD, etc. will be kept confidential.
- Release of your PHI/PII information will only be allowed if it is legally required.
- The data collected as surveys and study notes will be kept in a secure locked office. The study staff will have access to the data.
- As a participant, you will be assigned a coded study number that will be used throughout the study on all your study records.
- A Master List provides the link between your personal information and the coded study number. This list will only be available to the Principal Investigator, Dr. David Birnie, Co-Investigators, Dr. Dawn Stacey and Krystina Lewis MN, RN, and research assistant Carolynne Brousseau RN. The list will not leave this site.
- The Master List and coded study records will be stored securely. Electronic records will be stored on the Institutional secure server, not on a computer's C drive. Files will be password protected. No portable devices will contain PII.
- For audit purposes only, your original medical records may be reviewed under the supervision of Dr. Dawn Stacey, or Dr. David Birnie by representatives from:
 - the Ottawa Health Science Network Research Ethics Board (OHSN-REB), and the University of Ottawa Heart Institute
- You will not be identified in any publications or presentations resulting from this study.
- Research records will be kept for 10 years, as required by the OHSN-REB.
- At the end of the storage time, all paper records will be shredded and all electronic records will be securely deleted.

Do the investigators have any conflicts of interest?

There are no conflicts of interest to declare related to this study.

What are my responsibilities as a study participant?

It is important to ask Dr. David Birnie, Dr. Dawn Stacey, or any other research team member if you have any questions or concerns.

Will I be informed about any new information that might affect my decision to continue participating?

You will be told in a timely fashion of any new findings during the study that could affect your willingness to continue in the study. You may be asked to sign a new consent form.

Who do I contact if I have any further questions?

If you have any questions about this study, or if you feel that you have experienced a study-related injury or illness, please contact Dr. David Birnie at xxx-xxx-xxxx ext. xxxxx, or Dr. Dawn Stacey at xxx-xxx-xxxx ext. xxxxx. The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed this protocol. The Board considers the ethical aspects of all research studies involving human participants at the University of Ottawa Heart Institute. If you have

any questions about your rights as a study participant, you may contact the Chairperson at xxx-xxx-xxxx, ext. xxxxx.



Consent to Participate in Research

- I understand that I or my family member is being asked to participate in a research study about the impact of a decision support strategy for adults faced with the decision to replace or not replace their ICD.
- This study was explained to me by _____.
- I have read, or have had it read to me, each page of this Participant Informed Consent Form.
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this study.
- I will be given a copy of this signed Participant Informed Consent Form.

Participant's Printed Name

Participant's Signature

Date

Investigator or Delegate Statement

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

Investigator/Delegate's Printed Name

Investigator/Delegate's Signature

Date

Assistance Declaration

Was the participant assisted during the consent process? ☐ Yes ☐ No

☐ The consent form was read to the participant/substitute decision-maker, and the person signing below attests that the study was accurately explained to, and apparently understood by, and consent was freely given by the participant/substitute decision-maker.

☐ The person signing below acted as a translator for the participant/substitute decision-maker during the consent process. He/she attests that they have accurately translated the information for the participant/substitute decision-maker, and believe that the participant/substitute decision-maker has understood the information translated.

Name of Person Assisting (Print)

Signature

Date

Appendix I - Patient Decision Aid As Used in the Feasibility Trial

Making a Decision to Replace or Not Replace Your Implantable Cardioverter-Defibrillator (ICD) Battery

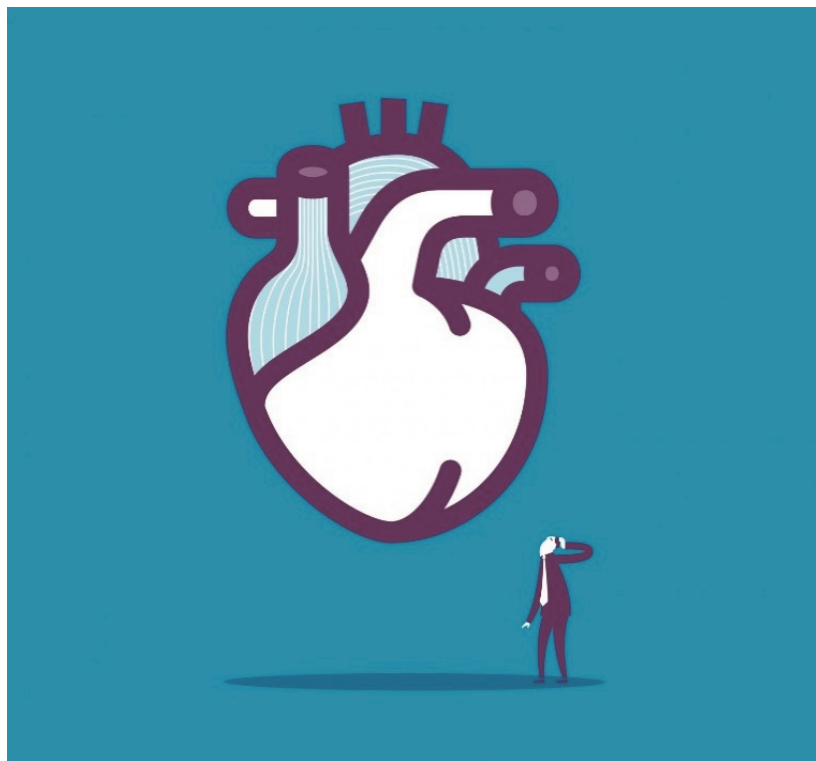


Table of Contents

Introduction	3
Step 1 – Know Your Options.....	4
Step 2 – Weigh the Risks and Benefits of Each Option	6
What are the risks of ICD battery replacement?	6
What is the benefit of ICD battery replacement?	7
Step 3 – Consider Your Preferred Option	8
Step 4 – Check Your Knowledge About the Options.....	9
Step 5 – What Else Do You Need to Make a Choice?	10
Frequently Asked Questions	11
Selected References	12

* The information provided in this decision aid is designed to help you make a decision with your health care provider(s). It is not meant to replace the advice from your health care provider(s).

Introduction

You have been given this decision aid because your ICD (implantable cardioverter defibrillator) battery is nearing the time for replacement. You have the option to replace your ICD battery or not replace it. This decision aid will help you prepare to talk about this with your doctor or nurse.

How does the ICD work?

This decision aid is for you if:

- ✓ You have an ICD
- ✓ Your ICD battery is nearing the time for replacement
- ✓ You are NOT dependent on the pacemaker part of your ICD
- ✓ You do NOT have a cardiac resynchronization therapy defibrillator (CRT-D)

The ICD keeps track of your heart rate and rhythm. It is meant to treat sudden cardiac arrest in people who are at risk of fast dangerous heart rhythms (e.g., ventricular tachycardia, ventricular fibrillation). ICDs monitor the heart rhythm, detect a dangerous fast rhythm, and deliver an electrical shock to restore a normal heart rhythm. Those who have had a shock describe it as receiving a “kick in the chest.”

Some facts about what your ICD will not do:

- ✓ Your ICD does not relieve symptoms like shortness of breath, fatigue, or chest pain.
- ✓ Your ICD will not prevent dangerous heart rhythms from starting.
- ✓ Your ICD will not treat irregular heart rhythms such as atrial fibrillation.
- ✓ Your ICD will not stop the progression of your heart disease.
- ✓ Your ICD does not prevent all causes of death. It can only save your life from a fast dangerous heart rhythm. Even with an ICD, you may die from another heart related or non-heart related cause.

Self reflection. What has it been like to live with your ICD (e.g., how has it affected your physical status, your emotions, and/or your social life)?

STEP 1: Know Your Options

The decision to have your ICD battery replaced is not a simple one. The answer depends on what is right for you, and whether the ICD still meets your needs. The doctors and nurses want to help you make the best decision for you. Feel free to ask them any questions you might have.

Did you know?

About 3 months before the battery is fully worn out, you may hear or feel an alert from your ICD (e.g., alarm or vibration). In these last 3 months, the ICD will still function if it detects a fast dangerous heart rhythm. If you hear or feel the alert, call the clinic at 613-761-4142.

OPTION A: To replace your ICD battery

Why choose to replace your ICD battery? Some people replace their ICD battery as they want it to continue to respond to fast dangerous heart rhythms.

The ICD battery is changed using minor surgery. An incision is made to open the skin where your ICD is located. The current ICD unit is removed and a new ICD unit is inserted in the same place. You are awake during the surgery. The doctor will inject freezing into the area and will give you medicine to relax you. The surgery lasts about 45 minutes. After surgery, you must stay in hospital for 2 to 4 hours so that you can be monitored by a team of nurses and doctors. You return home on the same day. You are seen in the device clinic about 4 weeks later.

In the future, there may come a time when you wish to have your ICD therapies turned off. This does not require surgery and can be done in the device clinic.

OPTION B: To not replace your ICD battery

Why choose not to replace your ICD? Some people do not replace their ICD battery because their health has changed (e.g., a worsened heart condition, other serious health issues, or terminal illness); they no longer want to have ICD shocks; they worry too much about the ICD; they are in the last stage of life; or for other personal reasons. In the last weeks, days, or hours of life, 1 in 5 people with ICDs have shocks that are surprising and/or painful. These cause concern for the patient, and their family and friends that the person with the ICD is not comfortable. This is why some people choose to no longer have active ICD therapies (e.g. anti-tachycardic pacing and shocks).

When a person chooses not to replace the ICD battery, it is usually left in place. When the ICD battery is fully worn out, there will be no alert. This would NOT cause death; but it would no longer respond to fast dangerous heart rhythms. If you choose not to have your ICD battery replaced, it can function until the battery is fully worn out. Or, you may request to have the ICD therapies turned off. This can be done in the device clinic.

It is important to discuss how the ICD can affect the way you pass away.

There are a number of ways in which a person can pass away.

Here, we divide them in 2 main ways:

1. A fast dangerous heart rhythm (e.g., ventricular tachycardia; ventricular fibrillation)
2. All other ways, not related to a fast dangerous heart rhythm

Passing away from a fast dangerous heart rhythm is also known as sudden cardiac death. People often refer to this as “dying in your sleep.” Many people believe this is a peaceful way to die. When people get older and sicker, many prefer this type of death. Having an ICD will prevent this.

With an ICD:



Without an ICD:



Source: Matlock, D; University of Colorado Anschutz Medical Campus; 2014

The second way includes all others ways not related to fast dangerous heart rhythms. This includes conditions such as lung failure, heart failure, kidney failure, stroke and cancer. These conditions can be progressive and usually cause a slower death. Often, they are preceded by being in hospital, sometimes in the intensive care unit, on a ventilator or with dialysis. As people get older, deaths not related to fast dangerous heart rhythms become much more common. Having an ICD will not prevent this type of death and may lead to getting shocks from your ICD. It is for this reason that some people choose to no longer have an ICD.

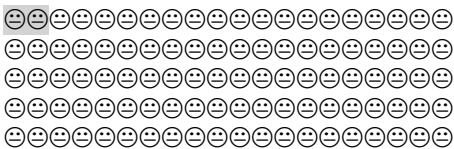
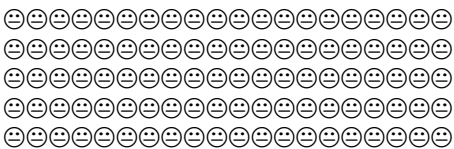
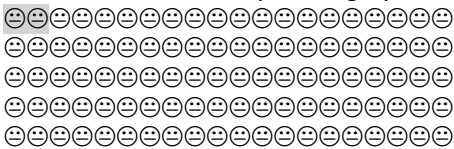
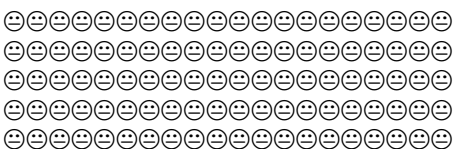
You should know: It is not wrong to stop any medical treatment if it no longer serves one's health care goals.

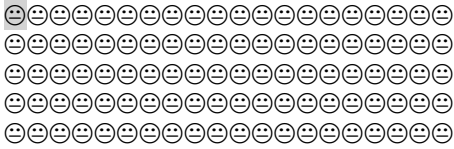
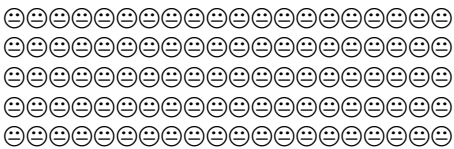
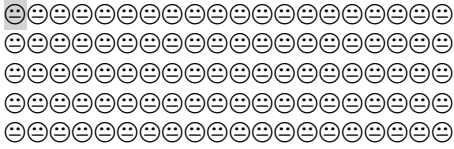
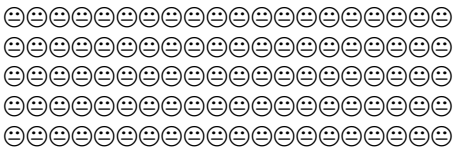
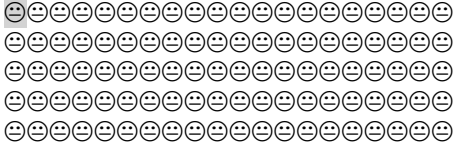
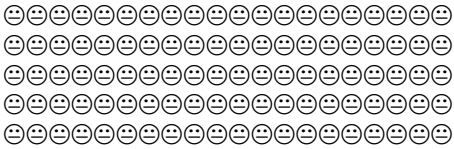
STEP 2: Weigh the Risks and Benefits of Each Option



What are the risks of replacing your ICD battery? These 100 faces (☺)

show a best estimate of what happens to 100 people. The shaded faces show the number of people affected. These estimates of risk may increase if you are older, have other health issues, if you take certain medicines, or if you have had your ICD replaced before. There is no way of knowing what will happen to you.

RISKS – Major complications	Replacing ICD	Not replacing ICD
Infected ICD site within 12 months after the ICD is replaced. An infected ICD site is serious. It often requires surgery with a laser to remove the ICD unit and the wires, and up to 6 weeks of antibiotics in hospital. 1 out of 100 people with an infection will die.*	2 have an infection 98 have no infection 	0 has an infection 
Repeat surgery within 12 months after the ICD is replaced due to a problem such as bleeding, problem with the wires, or pain.*	2 need repeat surgery 98 do not need repeat surgery 	0 needs repeat surgery 

RISKS – Minor complications	Replacing ICD	Not replacing ICD
Infection of the incision within 12 months of the ICD being replaced that does not require surgery.*	1 has an incisional infection 99 do not need repeat surgery 	0 has an incisional infection 
Persistent pain and/or discomfort of the incision within 12 months of the ICD being replaced that does not require surgery.*	1 has a pain/discomfort 99 do not need repeat surgery 	0 has pain/discomfort 
Large bruise at the incision which may cause discomfort, pain, and/or discoloration within 12 months of the ICD being replaced.*	1 has a large bruise 99 do not have a large bruise 	0 has a large bruise 

* These estimates are based on the current research; they could change if a new study is done.

What is the benefit of replacing your ICD battery?

To best calculate the life-saving benefit of the ICD for you, it is helpful to know:

Your age _____ years

Reason for which you have an ICD ☐ Primary prevention ☐ Secondary prevention

Whether you have had shock(s) for fast dangerous heart rhythms: ☐ Yes ☐ No

What is the difference between a primary prevention and secondary prevention ICD?

If you have not had a fast dangerous heart rhythm, but your heart condition or family history makes you at risk for them, you have an ICD for **primary prevention**.

If you have had a fast dangerous heart rhythm such as ventricular tachycardia or ventricular fibrillation, you have an ICD for **secondary prevention**.

These 100 faces (☺) show a best estimate of what happens to 100 people with and without an ICD. There is no way of knowing what will happen to you. These estimates of survival vary based on age, the reason for which you have an ICD, and your overall health status. The potential life-saving benefit of the ICD for you over the next 5 years is:

Please apply ICD benefit sticker according to patient's **age** and **ICD indication**

Also, estimates of survival vary based on your overall health status including your heart condition, other health issues (e.g., kidney disease, lung disease, stroke, and diabetes), and whether you have had shocks for fast dangerous heart rhythms. Speak to your doctor about how these may affect the benefit of the ICD for you.

I have the following health conditions (check ☒ all boxes that are relevant to you):

☐ Kidney Disease

☐ Lung Disease

☐ Diabetes

☐ Prior stroke

☐ Congestive Heart Failure

☐ Dementia

☐ Cancer

☐ Other(s): _____

STEP 3: Consider Your Preferred Option

This step will help you consider the risks and the benefits of replacing or not replacing your ICD battery that matter most to you. There are no right or wrong answers.

How important is it for you to lower your chances of a sudden cardiac arrest?

Not important Very important

| | | | |

1 2 3 4 5

How important is it for you to avoid the risks from the ICD replacement surgery?

Not important Very important

| | | | |

1 2 3 4 5

How important is it for you to have peace of mind that a fast dangerous heart rhythm could be corrected?

Not important Very important

| | | | |

1 2 3 4 5

How important is it for you to allow a natural death without life saving measures to restart your heart if you go into sudden cardiac arrest?

Not important Very important

| | | | |

1 2 3 4 5

List any OTHER reasons you may choose to replace or not replace your ICD battery:

Not important Very important

| | | | |

1 2 3 4 5

Not important Very important

| | | | |

1 2 3 4 5

STEP 4: Check Your Knowledge About the Options

Check your knowledge about ICD therapy and ICD replacement by answering the following 5 questions. Check ☒ only one per question.

1. The ICD prevents all causes of death.

- ☐ True
- ☐ False
- ☐ I am unsure

2. With every ICD replacement surgery, the risk of complications increase.

- ☐ True
- ☐ False
- ☐ I am unsure

3. Two people out of 100 who have the ICD replaced will have an infection needing a second surgery to remove the ICD and up to 6 weeks of antibiotics in hospital.

- ☐ True
- ☐ False
- ☐ I am unsure

4. I will hear or sense an alert from my ICD (e.g. alarm or vibration) when the battery is fully worn out.

- ☐ True
- ☐ False
- ☐ I am unsure

5. The survival benefit of an ICD varies based on age, the reason for which you have an ICD, your heart condition, other health problems such as kidney disease, lung disease, prior stroke, and diabetes, and whether you have had shocks for dangerous heart rhythms.

- ☐ True
- ☐ False
- ☐ I am unsure

6. If I have my ICD replaced, I can choose to ask my doctor to turn off/deactivate the ICD therapies at a later time.

- ☐ True
- ☐ False
- ☐ I am unsure

STEP 5: What Else Do You Need to Make a Choice?

Do you know the benefits and risks of each option? ☐ Yes ☐ No

Are you clear about which benefits and risks matter most to you? ☐ Yes ☐ No

Do you have enough support from others to make a choice? ☐ Yes ☐ No

Are you choosing without pressure from others? ☐ Yes ☐ No

Do you feel sure about the best choice for you? ☐ Yes ☐ No

Adapted from The SURE Test ©2008 O'Connor & Légaré

Is there anything else making your decision difficult?

Which option do you prefer? Check ☒ one.

- ☐ I want to replace my ICD battery
- ☐ I do not want to replace my ICD battery
- ☐ I am not sure

What role do you prefer to take when making your health care choices? Check ☒ one.

- ☐ I prefer to choose on my own after hearing the views of others.
- ☐ I prefer to share this choice with _____.
- ☐ I prefer that someone else choose for me.

List any questions or concerns you want to talk about with your health care provider(s).

The information is not meant to replace the advice of your health care provider(s). We urge you to share your answers with your health care provider(s), and family and friends. This will help them understand how you think about the options.

Frequently Asked Questions



How long would I have to wait for replacement surgery?

The wait time to have an ICD replaced is about 3 to 6 weeks.

How long is the recovery after surgery?

For 7 days after surgery, we ask you to leave the incision dry (do not get the incision wet), and avoid lifting any object greater than 10 pounds.

Can I drive after the surgery?

On the day of surgery, you need a ride home. If you were able to legally drive before having your ICD replaced, you may drive after.

If I choose not to replace my ICD battery, is the ICD taken out?

Usually, the ICD is left in place. Removing the ICD requires surgery. Any surgery places you at increased risk of problems such as infection or bruising. We strongly suggest that you leave it in place.

If I choose not to replace my ICD battery, do I still need to come in for regular visits to the device clinic?

No, there is no need to come to the device clinic for regular visits. But, if you wish to have the ICD therapies (e.g. anti-tachycardic pacing and shocks) or alerts turned off before the battery is fully worn out, you need to come to clinic. At any time, if you have any questions or concerns, the staff in the device clinic can answer them by phone (613-761-4142).

Is it possible to reverse my decision regarding replacement or turning off/deactivating my ICD?

Yes, you may change your mind at any time. If you change your mind, please contact either the device clinic nurse or your doctor. If the battery has depleted and you want to have it replaced, you will need surgery.

Selected References

For more information, please refer to these online documents:

American Heart Association: Implantable Cardioverter-Defibrillator (ICD). 2014.

Available from: http://www.heart.org/HEARTORG/Conditions/Arrhythmia/PreventionTreatmentofArrhythmia/Implantable-Cardioverter-Defibrillator-ICD_UCM_448478_Article.jsp

Snipes G, Rosman J, Sears S: End-of-life and Heart Rhythm Devices. Heart Rhythm Society 2014.

Our statistics about the risks and benefits of replacing and not replacing the ICD were informed by:

Connolly SJ, Hallstrom AP, Cappato R, Schron EB, Kuck KH, Zipes DP, Greene HL, et al. Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials. AVID, CASH and CIDS studies. *Eur Heart J* 2000;21:2071-2078.

Healey JS, Hallstrom AP, Kuck KH, Nair G, Schron EP, Roberts RS, Morillo CA, et al. Role of the implantable defibrillator among elderly patients with a history of life-threatening ventricular arrhythmias. *Eur Heart J* 2007;28:1746-1749.

Hess PL, Al-Khatib SM, Han JY, Edwards R, Bardy GH, Bigger JT, Buxton A, et al. Survival benefit of the primary prevention implantable cardioverter-defibrillator among older patients: does age matter? An analysis of pooled data from 5 clinical trials. *Circ Cardiovasc Qual Outcomes* 2015;8:179-186

Lampert R, Hayes DL, Annas GJ, Farley MA, Goldstein NE, Hamilton RM, Kay GN, Kramer DB, Mueller PS, Padeletti L *et al*: HRS expert consensus statement on the management of cardiovascular implantable electronic devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy. *Heart Rhythm* 2010, 7(7):1008-1026.

Statistics Canada. Deaths 2009. Catalogue no. 84F0211X. Available from <http://www.statcan.gc.ca/pub/84f0211x/84f0211x2009000-eng.pdf> [Accessed September 2, 2015]

Yung D, Birnie D, Dorian P, Healey JS, Simpson CS, Crystal E, Krahn AD, et al. Survival after implantable cardioverter-defibrillator implantation in the elderly. *Circulation*. 2013;127:2383-2392.

* * *

Note 1. This patient decision aid was developed by a team of researchers and clinicians with expertise in shared decision-making and implantable cardioverter-defibrillators, and individuals with an ICD and their family members.

Note 2. None of the authors stand to gain or lose from the choices patients make. For more information, please contact K. Lewis directly at kblewis@ottawaheart.ca

Version date : March 2016

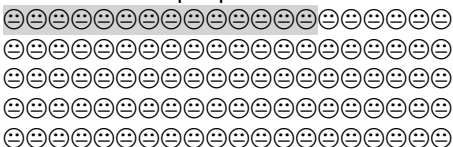
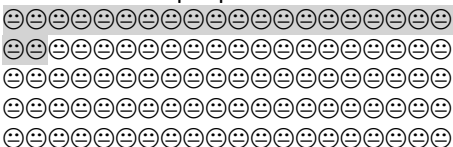
Next update due: March 2018

Appendix J - ICD Survival Benefit Probabilities “Sticker” by Age and ICD Indication

Select the appropriate table for each individual patient and place the sticker in the designated area on p.7 of the patient decision aid.

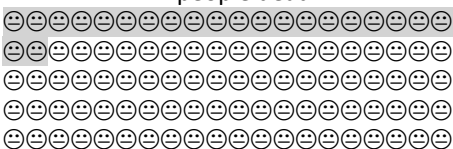
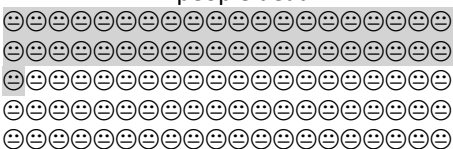
If you have a PRIMARY PREVENTION ICD and

...you are less than 55 years

Potential life-saving benefit of a Primary Prevention ICD	With an ICD	Without an ICD
Within 5 years*:  Number of people who die  Number of people who live	86 people alive 14 people dead 	78 people alive 22 people dead 

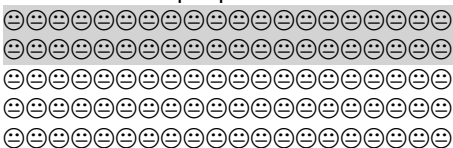
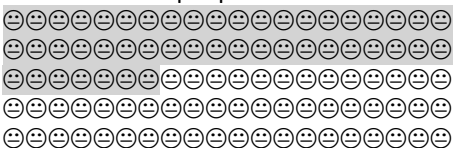
* These estimates are based on the current research; they could change if a new study is done.

...you are between 55-64 years

Potential life-saving benefit of a Primary Prevention ICD	With an ICD	Without an ICD
Within 5 years*:  Number of people who die  Number of people who live	78 people alive 22 people dead 	59 people alive 41 people dead 

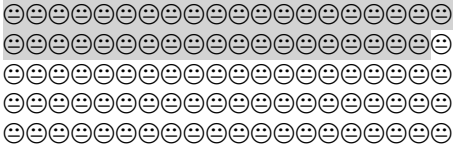
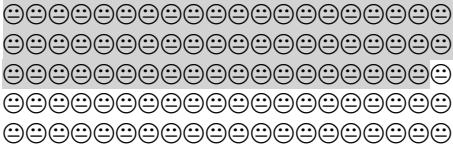
* These estimates are based on the current research; they could change if a new study is done.

...you are between 65-74 years

Potential life-saving benefit of a Primary Prevention ICD	With an ICD	Without an ICD
Within 5 years*:  Number of people who die  Number of people who live	60 people alive 40 people dead 	53 people alive 47 people dead 

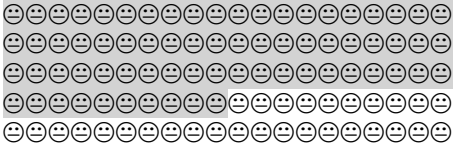
* These estimates are based on the current research; they could change if a new study is done.

...you are between **75-79** years

Potential life-saving benefit of a Primary Prevention ICD	With an ICD	Without an ICD
Within 5 years*: ☹ Number of people who die 😊 Number of people who live	61 people alive 39 people dead 	41 people alive 59 people dead 

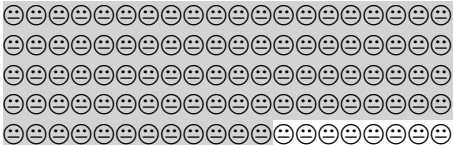
* These estimates are based on the current research; they could change if a new study is done.

...you are between **80-84** years

Potential life-saving benefit of a Primary Prevention ICD	With an ICD	Without an ICD
Within 5 years*: ☹ Number of people who die 😊 Number of people who live	Little evidence exist for people 80-84 years with a primary prevention ICD. We do not know if there is a difference in survival in people of this age with an ICD and those without an ICD.	30 people alive 70 people dead 

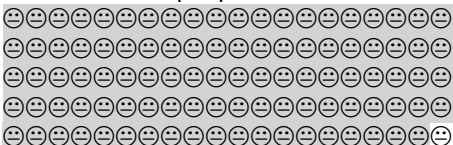
* These estimates are based on the current research; they could change if a new study is done.

...you are between **85-89** years

Potential life-saving benefit of a Primary Prevention ICD	With an ICD	Without an ICD
Within 5 years*: ☹ Number of people who die 😊 Number of people who live	Little evidence exist for people 85-89 years with a primary prevention ICD. We do not know if there is a difference in survival in people of this age with an ICD and those without an ICD.	8 people alive 92 people dead 

* These estimates are based on the current research; they could change if a new study is done.

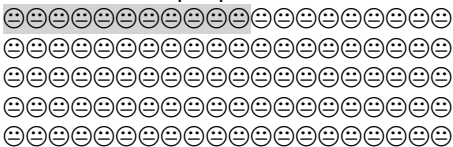
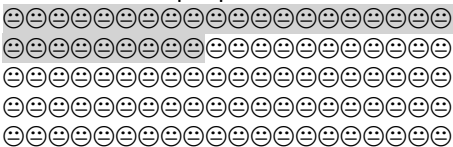
...you are over **90** years

Potential life-saving benefit of a Primary Prevention ICD	With an ICD	Without an ICD
Within 5 years*: ☹ Number of people who die 😊 Number of people who live	Little evidence exist for people over 90 years with a primary prevention ICD. We do not know if there is a difference in survival in people of this age with an ICD and those without an ICD.	1 person alive 99 people dead 

* These estimates are based on the current research; they could change if a new study is done.

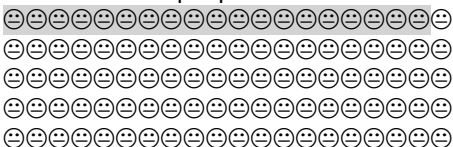
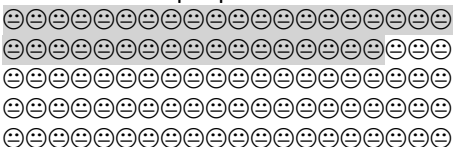
If you have a SECONDARY PREVENTION ICD and

...you are less than 50 years

Potential life-saving benefit of a Secondary Prevention ICD	With an ICD	Without an ICD
Within 5 years*:  Number of people who die  Number of people who live	89 people alive 11 people dead 	71 people alive 29 people dead 

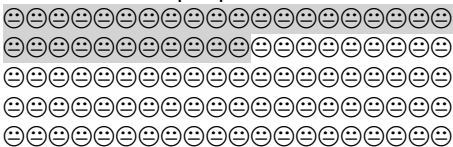
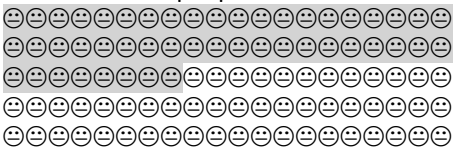
* These estimates are based on the current research; they could change if a new study is done.

...you are between 50-59 years

Potential life-saving benefit of a Secondary Prevention ICD	With an ICD	Without an ICD
Within 5 years*:  Number of people who die  Number of people who live	81 people alive 19 people dead 	63 people alive 37 people dead 

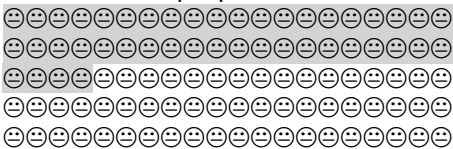
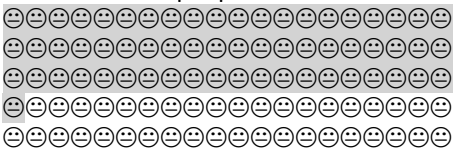
* These estimates are based on the current research; they could change if a new study is done.

...you are between 60-69 years

Potential life-saving benefit of a Secondary Prevention ICD	With an ICD	Without an ICD
Within 5 years*:  Number of people who die  Number of people who live	69 people alive 31 people dead 	52 people alive 48 people dead 

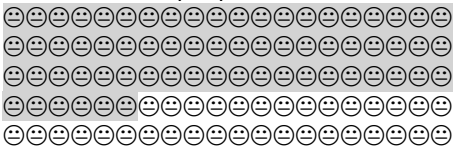
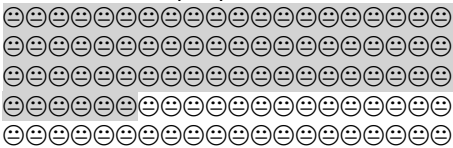
* These estimates are based on the current research; they could change if a new study is done.

...you are between **70-74** years

Potential life-saving benefit of a Secondary Prevention ICD	With an ICD	Without an ICD
Within 5 years*:  Number of people who die  Number of people who live	57 people alive 44 people dead 	39 people alive 61 people dead 

* These estimates are based on the current research; they could change if a new study is done.

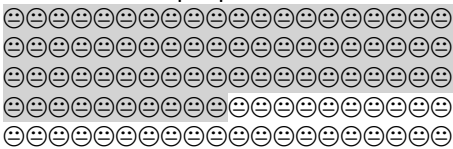
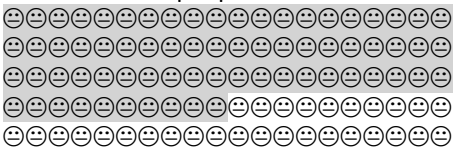
...you are between **75-79** years

Potential life-saving benefit of a Secondary Prevention ICD	With an ICD	Without an ICD
Within 5 years*:  Number of people who die  Number of people who live	34 people alive 66 people dead 	34 people alive 66 people dead 

Please note. The evidence that exists for people 75-79 years with an ICD for secondary prevention suggests that there is no difference in survival with an ICD or without an ICD.

* These estimates are based on the current research; they could change if a new study is done.

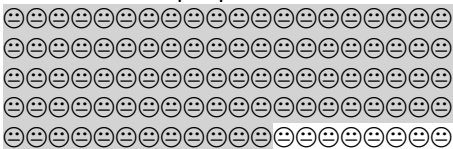
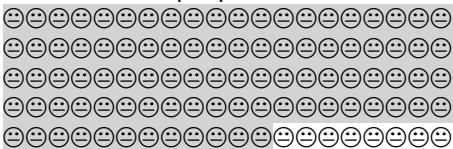
...you are between **80-84** years

Potential life-saving benefit of a Secondary Prevention ICD	With an ICD	Without an ICD
Within 5 years*:  Number of people who die  Number of people who live	30 people alive 70 people dead 	30 people alive 70 people dead 

Please note. The evidence that exists for people 80-84 years with an ICD for secondary prevention suggests that there is no difference in survival with an ICD or without an ICD

* These estimates are based on the current research; they could change if a new study is done.

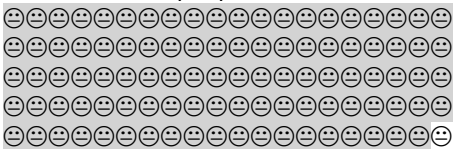
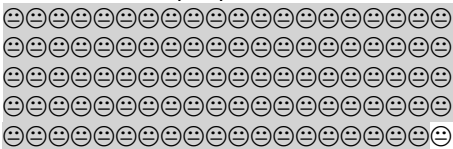
...you are between **85-89** years

Potential life-saving benefit of a Secondary Prevention ICD	With an ICD	Without an ICD
Within 5 years*:  Number of people who die  Number of people who live	8 people alive 92 people dead 	8 people alive 92 people dead 

Please note. The evidence that exists for people 85-89 years with an ICD for secondary prevention suggests that there is no difference in survival with an ICD or without an ICD

* These estimates are based on the current research; they could change if a new study is done.

...you are over **90** years

Potential life-saving benefit of a Secondary Prevention ICD	With an ICD	Without an ICD
Within 5 years*:  Number of people who die  Number of people who live	1 person alive 99 people dead 	1 person alive 99 people dead 

Please note. The evidence that exists for people over 90 years with an ICD for secondary prevention suggests that there is no difference in survival with an ICD or without an ICD

* These estimates are based on the current research; they could change if a new study is done.

Appendix K - 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 <i>Prompts:</i> 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? <i>[If yes, encourage them to write them down in Step 5 of PDA].</i> 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

Appendix L - Baseline Questionnaire – Feasibility Trial**Part 1. Getting to know you**

1. What is your month and year of birth?

Year ____ Month ____

2. Are you:

☐ Male

☐ Female

3. What best describes your ethnicity?

☐ Aboriginal (e.g. First Nations, Inuit, Métis)

☐ African American

☐ Asian

☐ Caucasian

☐ Latin American/Hispanic

☐ South Asian

☐ Other: _____

4. What is the highest education level you have achieved?

☐ Elementary school

☐ High school

☐ College diploma

☐ Undergraduate university degree

☐ Graduate/Professional degree

5. What is your employment status?

☐ Working full time

☐ Working part time

☐ Disability

☐ Retired

6. Do you live alone?

☐ Yes

☐ No

When thinking about ICD replacement **TODAY**, which option do you prefer?

- Think about your decision. On a scale from 1-15 (1 = not at all wanting to replace the ICD battery and 15= absolutely wanting to replace the battery) where do you stand right now? Please circle the number that best corresponds to your current state of mind.



	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Thinking about the ICD makes me depressed.					
When I think of my ICD, I avoid doing things I enjoy.					
I avoid my usual activities because I feel disfigured by my ICD.					
It is hard for me to function without thinking about my ICD					

My ICD is my best treatment option.					
I am confident about my ability to return to work if I want to					
I am safer from harm because of my ICD					
The positive benefits of this ICD outweigh the negatives					
I would receive this ICD again					
I am careful when hugging or kissing my loved ones					
I have returned to a full life					
I feel that others see me as disfigured by my ICD					
I feel less attractive because of my ICD					
I am not able to do things for my family the way I used to					
I am concerned about resuming my daily physical activities					

Part 4: Quality of Life

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

SF-36v2® Health Survey © 1991, 2002 QualityMetric Incorporated and Medical Outcomes Trust. All rights reserved.

SF-36® is a registered trademark of Medical Outcomes Trust.

(SF-36v2® Health Survey Standard, Canada (English))

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. <u>Vigorous activities</u> , such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b. <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☒ 2	☐ 3
c. Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d. Climbing <u>several</u> flights of stairs	☒ 1	☐ 2	☐ 3
e. Climbing <u>one</u> flight of stairs	☐ 1	☐ 2	☐ 3
f. Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g. Walking <u>more than a kilometre</u>	☐ 1	☐ 2	☐ 3
h. Walking <u>several hundred metres</u>	☐ 1	☐ 2	☐ 3
i. Walking <u>one hundred metres</u>	☐ 1	☐ 2	☐ 3
j. Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☒ 3	☐ 4	☐ 5
b. <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☒ 4	☐ 5
c. Were limited in the <u>kind</u> of work or other activities	☐ 1	☒ 2	☐ 3	☐ 4	☐ 5
d. Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)	☒ 1	☒ 2	☐ 3	☐ 4	☐ 5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life?	☐ 1	☐ 2	☐ 3	☒ 4	☐ 5
b. Have you been very nervous?	☐ 1	☐ 2	☐ 3	☒ 4	☐ 5
c. Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☒ 2	☒ 3	☐ 4	☐ 5
d. Have you felt calm and peaceful?	☒ 1	☒ 2	☐ 3	☐ 4	☐ 5
e. Did you have a lot of energy?	☒ 1	☐ 2	☐ 3	☐ 4	☐ 5
f. Have you felt downhearted and depressed?	☐ 1	☒ 2	☐ 3	☐ 4	☐ 5
g. Did you feel worn out?	☒ 1	☐ 2	☐ 3	☐ 4	☐ 5
h. Have you been happy?	☒ 1	☐ 2	☐ 3	☐ 4	☐ 5
i. Did you feel tired?	☒ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true ▼	Mostly true ▼	Don't know ▼	Mostly false ▼	Definitely false ▼
a. I seem to get sick a little easier than other people.....	☐ 1	☐ 2	☐ 3	☒ 4	☐ 5
b. I am as healthy as anybody I know.....	☐ 1	☐ 2	☒ 3	☒ 4	☐ 5
c. I expect my health to get worse.....	☐ 1	☐ 2	☐ 3	☒ 4	☐ 5
d. My health is excellent.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

Part 1: What is Your Preferred Option TODAY?

☐ Replace my ICD.

☐ Not replace my ICD.

☐ I am unsure. There are still some thing I would like to discuss with the health care team and my family.

The following questions look at how certain you are about your decision. Please rate the extent to which you agree or disagree with each of the following statements. Check the box ☒ with the best response for you.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
I know which options are available to me					
I know the benefits of each option					
I know the risks and side effects of each option					
I am clear about which benefits matter most to me					

I am clear about which risks and side effects matter most to me					
I am clear about which is more important to me (the benefits or the risks and side effects)					
I have enough support from others to make a choice					
I am choosing without pressure from others					
I have enough advice to make a choice					
I am clear about the best choice for me					
I feel sure about what to choose					
This decision is easy for me to make					
I feel I have made an informed choice					
My decision shows what is important to me					
I expect to stick with my decision					
I am satisfied with my decision					

Part 3: Knowledge of ICD and ICD Replacement

What do you know about key facts about your ICD and the ICD replacement? Check ☒ the best answer.

1. The ICD prevents all causes of death.

- ☐ True
☐ False
☐ I am unsure

2. With every ICD replacement surgery, the risk of complications increase.

- ☐ True
☐ False
☐ I am unsure

3. Two people out of 100 who have the ICD replaced will have an infection needing a second surgery to remove the ICD and up to 6 weeks of antibiotics in hospital.

- ☐ True
☐ False
☐ I am unsure

4. I will hear or sense an alert from my ICD (e.g. alarm or vibration) when the battery is fully worn out.

- ☐ True
☐ False
☐ I am unsure

5. The survival benefit of an ICD varies based on age, the reason for which you have an ICD, your heart condition, other health problems such as kidney disease, lung disease, prior stroke, and diabetes, and whether you have had shocks for dangerous heart rhythms.

- ☐ True
☐ False
☐ I am unsure

6. If I have my ICD replaced, I can choose to ask my doctor to turn off/deactivate ICD therapy at a later time.

- ☐ True
☐ False
☐ I am unsure

Part 4: What is most important to you?

	Not important		Not sure		Very important
	(1)	(2)	(3)	(4)	(5)
How important is it for you to lower your chances of a sudden cardiac arrest?					
How important is it for you to avoid the risks from the ICD replacement surgery?					
How important is it for you to have peace of mind that a fast dangerous heart rhythm could be corrected?					
How important is it for you to allow a natural death without life saving measures to restart your heart if you go into sudden cardiac arrest?					

Appendix N - 2-4 Week Questionnaire – Supplemental for Intervention Group Only**Part 1: Acceptability and Usability of the Patient Decision Aid**

The next questions are seeking your thoughts on the patient decision aid that you received 2-4 weeks ago. Check one ☒ per question.

1. Did you find that the amount of information included in the PtDA was:

- ☐ Much less than I wanted
- ☐ Little less than I wanted
- ☐ About right
- ☐ Little more than I wanted
- ☐ Much more than I wanted

2. Did you find that the length of the patient decision aid was:

- ☐ Much too long
- ☐ Little too long
- ☐ About right
- ☐ Should have been a little longer
- ☐ Should have been much longer

3. Are the font and icons (check boxes etc.) readable (i.e. font type and size)?

- ☐ Yes ☐ No

4. Is there enough space to make notes in it?

- ☐ Yes ☐ No

5. Do the words/language in the patient decision aid make sense?

- ☐ Yes ☐ No

6. What you think about the clarity of the information presented in each section (circle the best answer):

Introduction	poor	fair	good	excellent
Know Your Options	poor	fair	good	excellent
Weigh the Benefits and Risks of Each Option	poor	fair	good	excellent
Consider Your Preferred Option	poor	fair	good	excellent
Check Your Knowledge About the Options	poor	fair	good	excellent
What Else Do You Need to Make a Choice?	poor	fair	good	excellent
Frequently Asked Questions	poor	fair	good	excellent
References	poor	fair	good	excellent

7. Did you find that the balance of the patient decision aid was:

- ☐ Clearly slanted to replacing the battery
- ☐ Slightly slanted to replacing the battery
- ☐ Completely balanced
- ☐ Slightly slanted to not replacing the battery
- ☐ Clearly slanted to not replacing the battery

8. Is there information missing that you would like to see added or removed?

- ☐ Yes – Please describe _____
- ☐ No

9. Do you see this patient decision aid fitting into the discussion with your clinicians (e.g. physician, nurse, pharmacist, etc.)?

- ☐ Yes, as it is
- ☐ Yes, but with some alterations
- ☐ No

10. Would you use it and/or tell someone about the decision aid?

- ☐ Yes
- ☐ No

11. What do you like or not like about the decision aid?

12. Do you have any further comments on the patient decision aid?

Part 2: Acceptability and Usability of the Decision Coaching

The next questions are seeking your thoughts on the decision coaching that you received today.

Check one ☒ per question.

1. The decision coach seemed to understand the stresses I was facing

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neutral
- ☐ Disagree somewhat
- ☐ Disagree strongly

2. The decision coach helped me to identify what we needed to know to make decisions about what would happen to me

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neutral
- ☐ Disagree somewhat
- ☐ Disagree strongly

3. I felt better about my decision after meeting with the decision coach.

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neutral

☐ Disagree somewhat

☐ Disagree strongly

4. The decision coach was truly concerned with my well-being.

☐ Agree strongly

☐ Agree somewhat

☐ Neutral

☐ Disagree somewhat

☐ Disagree strongly

5. The decision coaching session was valuable to me.

☐ Agree strongly

☐ Agree somewhat

☐ Neutral

☐ Disagree somewhat

☐ Disagree strongly

6. How helpful was the decision coaching in helping you come to a preferred option?

☐ Very helpful

☐ Somewhat helpful

☐ A little helpful

☐ Not helpful

7. Would you recommend decision coaching to others facing the same decision?

☐ I would definitely recommend it

☐ I would probably recommend it

☐ I would probably not recommend it

☐ I would definitely not recommend it

8. The decision coaching session was about the right length of time.

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neutral
- ☐ Disagree somewhat
- ☐ Disagree strongly

9. Did this session prepare you for a follow up with your health care provider (e.g. physician, nurse in the device clinic)?

- ☐ Yes
- ☐ Unsure
- ☐ No

Part 1B. Actual Choice

i) Which option did you choose?

☐ I chose to replace my ICD.

What date was it replaced? ____ / ____ / ____ (DD/MM/YYYY)

☐ I chose not to replace my ICD.

☐ I chose to defer the ICD replacement

ii) How do you feel the decision about ICD battery replacement was made? Please check ☒ one.

☐

The physician made the decision

☐

The physician made the decision but strongly considered my opinion

☐

The physician and I made the decision together

☐

I made the decision but strongly considered the physician's opinion

☐

I made the decision

Part 2: Decisional Comfort

The following questions are looking at how certain you are about your decision. Please rate the extent to which you agree or disagree with each of the following statements. Check the box ☒ with the best response for you.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
I know which options are available to me					
I know the benefits of each option					
I know the risks and side effects of each option					
I am clear about which benefits matter most to me					
I am clear about which risks and side effects matter most to me					
I am clear about which is more important to me (the benefits or the risks and side effects)					
I have enough support from others to make a choice					
I am choosing without pressure from others					
I have enough advice to make a choice					
I am clear about the best choice for me					
I feel sure about what to choose					
This decision is easy for me to make					
I feel I have made an informed choice					
My decision shows what is important to me					
I expect to stick with my decision					
I am satisfied with my decision					