Exploring the Therapeutic Relationship When Planning to Implement Patient Decision Aids Throughout the Implantable Cardioverter-Defibrillator Trajectory

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Preface: Contributions to this Thesis

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Approvals

The University of Ottawa research ethics board approved the study proposal (H-11-22-8655). According to the Ottawa Health Sciences Network – Research Ethics Board, the REB for studies conducted at the UOHI, an ethics application is only required from the University of Ottawa REB given the data was already collected and resides at the University of Ottawa (CC Keri Cullen, personal communication, September 26, 2022) (Appendix A).

Abstract

Encounters in which shared decision-making occur relies on patients and healthcare professionals establishing a partnership. Yet, little is known about the therapeutic relationship (TR) specifically for the implementation and use of patient decision aids (PDA) to facilitate shared decision-making. The aim of this thesis was to explore how the TR is considered when planning PDA implementation for patients eligible for or with an implantable cardioverter-defibrillator (ICD). Using Thorne's interpretive description approach, I conducted a secondary thematic analysis using transcripts with 17 healthcare professionals, ten patients and three family members. Findings were mapped to the TR elements. I identified three themes. First, *Pieces of the puzzle: Elements of the TR* revealed that while respect and therapeutic communication were identified as important for PDA implementation, other TR were either referred to implicitly or not at all. Second, *Good intentions and challenges of establishing a TR* revealed that healthcare professionals wanted to engage in TR but lacked time and felt discomfort navigating ICD decisions. Finally, in *PDA as support for the TR,* participants considered PDAs as being able to facilitate TR elements such as communication and respect, enhancing the consultation. In conclusion, there is a role for TR elements when planning PDA implementation. Further research is needed to explore the other therapeutic relationship elements of genuineness, manifesting a presence, active listening, and reciprocity.

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Chapter 1

Introduction

Research Problem

Implantable Cardioverter Defibrillators (ICDs) are battery-powered surgically implanted devices programmed to detect and correct life-threatening ventricular arrhythmias with anti-tachycardic pacing. The ICD's main benefit of preventing death from ventricular tachycardia and ventricular fibrillation is a compelling aspect for most patients at risk of sustained ventricular arrhythmias (Lewis, al., 2018b). However, several risks must be considered when deciding about whether to proceed with getting an ICD. These include procedural risks (Fudim et al., 2020; Kraun et al., 2014; Nery et al., 2010; Poole et al., 2010), inappropriate shocks (Daubert et al., 2008; Peterson et al., 2017), psychological risks (Kapa et al., 2010), and potential for harm and suffering at end-of-life (Goldstein et al., 2004; Stromberg et al., 2014). Furthermore, the anti-tachycardic pacing can be uncomfortable and the shock described by some as "a kick in the chest" (Bardy et al., 2005; Moss et al., 2002)

In fact, patients eligible for and with ICDs are faced with a trajectory of preference-sensitive decisions (Lewis et al., 2014a). First, they must decide whether to initiate the therapy. Five to eight years later, the battery depletes, which must be surgically replaced to ensure ongoing function. Patients are then faced with a second decision about whether to replace the battery. Finally, nearing the end of their life, some patients may be faced with the decision to deactivate the tachytherapies. Each of these decisions needs careful consideration to ensure that patients understand their treatment options given their clinical situation, the risks and benefits of each option and their possible outcomes, and that their preferences are elicited and considered (Lewis et al., 2018b). Also, health care professionals should ensure that patients are involved in decision-making at their preferred level of involvement, which can fall along a continuum from the patient

driven decision-making to the physician driven decision-making with various levels of involvement in between (Kon, 2010).

These considerations align with shared decision-making (SDM), a patient-centered approach to decision-making which has been endorsed in clinical practice guidelines for ICD therapy (Al-Khatib et al., 2018; Philippon et al., 2017). Yet, it remains that many patients eligible for or with ICD therapy are uninformed about their options and are not offered the opportunity to share their values and preferences (Lewis et al., 2014a; Lewis et al., 2018b; Mooney et al., 2019; Standing et al., 2016). Some patients experience regret after making the decision to receive an ICD. Reasons include lack of information received from healthcare professionals and experiencing complications associated with the device (Green et al., 2016; Pourshams et al., 2022; Varghese et al., 2020). Hence, in this context, patients require more support in their decision-making process to make quality decisions (Pourshams et al., 2022).

Nurses are well-positioned to support patients with decision-making (Registered Nurses Association of Ontario, 2006; Lewis et al., 2014b; Olling et al., 2021; Truglio-Londrigan & Slyer, 2018). Nurses are important members of the interprofessional team responsible for ensuring that patients are making quality decisions that are informed and based on their preferences and values (Lewis et al., 2016). Informing patients that choices exist is essential and an important part of the nursing role (Lewis et al., 2014b). This is a perspective shared by patients (Joseph-Williams, Elwyn, et al., 2014). As decisions about treatment are made, nurses often advocate and/or translate the patient's perspective to other team members convey the team's perspective back to the patient, thus bridging the personal and clinical viewpoints (Joseph-Williams, Elwyn, et al., 2014; Olling et al., 2021). To support patient involvement in SDM, nurses can rely on effective decision support interventions such as decision coaching and patient decision aids (PDAs) (Lewis et al., 2016). To

reap their full benefit, it is posited that use of these interventions in practice requires a relational process between the patient and the healthcare professional(s) involved in the circle of care (Hoefel et al., 2020; Lewis et al., 2016). This process is akin to the therapeutic relationship that is grounded in an interpersonal process to promote awareness of the decision that is being faced, through comfort, support and provision of care (College Nurses Ontario, 2006; RNAO, 2006).

Yet, the therapeutic relationship between patients, nurses and other interprofessional team members has been poorly investigated as a strategy to promote PDA implementation (Yu et al., 2019). This is surprising as encounters, in which SDM occurs and the process that PDAs intend to facilitate, rely on healthcare professionals and patients establishing a partnership (Makoul & Clayman, 2006). Understanding if, when and how patients and healthcare professionals consider the therapeutic relationship during the decision-making process may help increase the uptake of PDAs in clinical practice.

Implantable Cardioverter-Defibrillators

In Canada each year, there are approximately 7,000 ICDs implanted (Kelly et al., 2021). ICDs are lifesaving devices that decrease the risk of sudden cardiac death from ventricular dysrhythmias (Bardy et al., 2005; Moss et al., 2002). Patients with myocardial infarction and reduced left ventricular function are at risk of developing fatal ventricular arrhythmias (Moss et al., 2002). As a result of the ischemia from the myocardial infarction, these patients can present with a scarred myocardium putting them at high risk for sudden cardiac death. The implantation of an ICD improves survival in these patients, including others with non-ischemic causes of reduced ventricular function and arrhythmias such as dilated cardiomyopathy, sustained tachycardia and inducible ventricular tachycardia (Moss et al., 2002). Once the ICD is implanted just below the clavicle, it monitors the heart rhythm. If a ventricular arrythmia occurs (ventricular

tachycardia or ventricular fibrillation), the device recognizes it and delivers therapy in the form of anti-tachycardic pacing or a shock to restore sinus rhythm (Simpson, 2007).

Patients at risk of sudden cardiac death and identified as potential candidates for ICD therapy are faced with several preference-sensitive decisions along the tenure of their ICD. They must make a decision to initially implant the device, replace the pulse generator, and, some consider deactivation when nearing end-of-life (Lewis et al., 2014a). The decisions related to ICD therapy can be difficult for patients given the lifesaving nature of the device (Lewis et al., 2014a). Clinical practice guidelines recommend a SDM approach along the ICD trajectory to ensure that patients are aware of their options, are informed about the risks and benefits of the therapy and make decisions aligned with their values and preferences (Al-Khatib et al., 2018; Philippon et al., 2017). This approach is gaining traction. In the United States (US), the Centres for Medicaid and Medicare have mandated the use of a PDA, an intervention to facilitate a SDM process, for patients referred for ICD implantation as a condition for reimbursement (Merchant et al., 2018).

Shared Decision-Making: Defined

Shared decision-making is a shared process, whereby the healthcare professional provides their clinical expertise on the condition, the options, and the risks and benefits of the options, and the patient shares their expertise on their personal situation, and their values and preferences for the options (Makoul & Clayman, 2006). Together, they discuss the options and reach consensus on the best course of action as equal partners (Kon, 2010). The goal of the approach is to make quality decisions, defined as decisions that are based on the best available evidence and the patient's values and preferences for features and outcomes of options (Makoul & Clayman, 2006). A SDM process to engage patients in decision-making can be facilitated by various interventions, such as patient decision aids and decision coaching.

Patient Decision Aids. A PDA is an evidence-based complex intervention intended to help support people in making health decisions (Stacey & al., 2023). At a minimum, PDAs must make the health decision explicit, describe the health condition, present the different treatment options with the risks and benefits associated with each in a balanced manner, and help patients clarify their personal preferences and values for or against the options (Joseph-Williams et al., 2014b; Stacey et al., 2017). They can take various formats, whether in print, web-based, audio or video.

The International Patient Decision Aids Standards exist to ensure the quality of PDAs and to ensure that they minimize biased decision-making (Elwyn et al., 2006; Joseph-Williams, al., 2014b). PDAs can be used before, during or after a consultation with the healthcare professional to encourage discussion (Hoefel et al., 2020a). When patients were sent an invitation to review and engage with the PDA before their consultation, patients were more likely to use the PDA (Joseph-Williams et al., 2021). A study of brief PDAs called Option Grids, for use in the consultation showed they were used in different ways, but some key steps were: 1) the healthcare professional describes the goal of the Option grid (i.e. initiate a conversation about options); 2) the healthcare professional verifies with the patient if they wish to read it themselves or together, and encourage questions and a discussion; and 3) the patient takes the option grid home to deliberate his/her/their options (Elwyn et al., 2013). These steps reflect Makoul and Clayman's (2006) essential SDM behaviours.

Effectiveness of PDAs. PDAs have been linked to several positive outcomes. A Cochrane systematic review of 209 trials aiming to assess the effects of patient decision aids in adults considering treatment or screening decisions reported high certainty of evidence that people exposed to PDAs had better knowledge (n=107 trials) and accuracy of risk perceptions (n=25 trials), compared to those exposed to usual care (Stacey et al., 2023). There is moderate certainty

of evidence that people exposed to PDAs have better agreement between informed values & choice than those not exposed (n=21 trials). Regarding attributes related to the decision-making process and compared to usual care, PDAs decreased decisional conflict related to feeling uninformed (n=58 trials) and unclear personal values (n=55 trials), and reduced clinician-controlled decision-making (n=21 trials) (Stacey et al., 2023). In addition, it was found that PDAs reduced the proportion of undecided participants and appeared to have a positive effect on patient-healthcare professional communication. Moreover, those exposed to a PDA were either equally or more satisfied with the decision-making process compared to usual care (Stacey et al., 2017; Stacey et al., 2023). There were no harms related to emotional distress or decisional regret. Despite this quality evidence, PDA implementation has been challenging in Canada, a missed opportunity to facilitate SDM with patients eligible for or with an ICD (Légaré et al., 2022; Lewis et al., 2018b).

Decision Coaching. Decision coaching is another intervention to support patient involvement in SDM. It is non-directive guidance provided by a trained healthcare professional, or guided by a protocol, to develop patients' skills in decision-making including deliberation of options and exploration of values and preferences (Jull et al., 2021; Rahn et al., 2021). The role of decision coaching involves identifying patients requiring help with decision-making, guiding them through the decision-making process and using evidence-based information resources, such as PDAs (Stacey et al., 2012). A Cochrane systematic review of 28 trials revealed that decision coaching may improve participants' knowledge when used with evidence-based information (Jull et al., 2021). Although this review did not establish strong conclusions for other outcomes there were no harms reported. Decision coaching appears to provide an additional contribution to decision-making as the social, relational process that supports patients in clarifying and discussing

values, verifying understanding and facilitating the SDM process (Rahn et al., 2021; Stacey et al., 2012; Zhao et al., 2022).

Partnerships and PDA use to facilitate SDM. Factors influencing the use of SDM in various contexts have been widely explored (Alsulamy et al., 2020; Covvey et al., 2019; Légaré et al., 2008; Pel-Littel et al., 2021; Waddell et al., 2021). Many of these studies support PDAs as a facilitator to SDM when used in clinical practice (Alsulamy et al., 2020; Covvey et al., 2019). Yet, strategies to implement PDAs in clinical practice need to be explored further. Partnerships between the healthcare professional and patient, are one example – defined as a relationship promoting patient empowerment to achieve common health goals– which promotes participation in decision-making (Henderson, 2003; Loiselle et al., 2021; Stacey et al., 2020). Partnerships remain poorly described in SDM literature and listing partnerships alone may not be enough to truly support patients in their decision-making trajectory. Communication and trust, key elements of therapeutic relationships, have been reported as facilitators to SDM (Covvey et al., 2019; Waddell et al., 2021), highlighting the need and relevance to explore the role and importance of therapeutic relationships within a SDM approach. The therapeutic relationship has been explored and defined in nursing and psychology and offers an opportunity to further define the patient-healthcare professional partnership in the context of SDM (Mirhaghi et al., 2017; Sylvestre et al., 2020). The therapeutic relationship has not been formally investigated as a factor influencing PDA implementation in clinical practice (Joseph-Williams et al., 2021; Yu et al., 2019).

Therapeutic Relationship: Defined

The therapeutic relationship is a purposeful, goal-directed interaction between a healthcare professional and a patient concerned with the patient's best interest (Chalifour, 1999; Phaneuf, 2011). The relationship goes beyond a regular conversation to attain an fulsome understanding of

how the patient is living and feeling their health condition and associated healthcare experiences (Doherty & Thompson, 2014; Phaneuf, 2011; Sylvestre et al., 2020). It involves the feelings and attitudes that the patient and healthcare professionals have towards one another and a partnership of equals, thereby, limiting power imbalances (Mirhaghi et al., 2017; Sylvestre et al., 2020). A therapeutic relationship is intended to be caring, supportive, non-judgmental and displaying warmth, friendliness, genuine interest, and empathy (Kornhaber et al., 2016). Such a relationship also facilitates communication (Kornhaber et al., 2016). Doherty and Thompson (2014) defined it in the context of nursing practice as "one in which the patient feels comfortable being open and honest with the nurse and is linked to the development of a productive relationship and positive patient outcomes." (p.502). These relationships are associated with improvement in patient satisfaction, adherence to treatment, quality of life and decreased health care costs (Kornhaber et al., 2016; Sylvestre et al., 2020). The quality of this relationship creates a climate in which the patient feels confident in their health trajectory (Kornhaber et al., 2016; Phaneuf, 2011). A therapeutic relationship offers opportunity for the patient to understand their present situation, to accept it and to make decisions about treatments and health (Phaneuf, 2011).

Healthcare professionals can foster therapeutic relationships by employing listening and questioning techniques, providing information, giving support, and ensuring care is patient-oriented, as opposed to task oriented (Doherty & Thompson, 2014). It begins with the first interaction, and can last a brief moment or an extended period over many encounters (Chalifour, 1999; Kornhaber et al., 2016; Sylvestre et al., 2020). The therapeutic relationship is composed of various elements, including attitudes and actions held by healthcare professionals that are essential to creating this bond. These elements are empathy, trust, respect, genuineness, manifesting a presence, therapeutic communication, active listening, and reciprocity (Chalifour, 1999;

Kornhaber et al., 2016; Sylvestre et al., 2020) (see Table 1). Understanding how patients, caregivers and healthcare professionals consider the therapeutic relationship may provide some insights into how PDAs can be used to support SDM in clinical practice.

Table 1: Defined Elements of the Therapeutic Relationship

Therapeutic Relationship Element	**Definition**[1]
Empathy	A sentiment of profound comprehension from the HCP towards the patient.
Trust	A justified expectation that one can depend on another person's promise, commitment, or responsibility
Respect	Acknowledging the value of patients and accepting their individuality as well as their unique needs and rights
Genuineness	Ability to be open and honest with the patient.
Manifesting a presence	Being physically and psychologically present with the patient during encounters.
Therapeutic communication	Interpersonal exchange, using verbal and non-verbal messages, that expresses support, provides information and feedback, corrects distortions, and provides hope.
Active listening	Listening to hear and to understand the patient.
Reciprocity	Refers to the balance of giving and receiving in a relationship with the goal of creating a healthy and mutual beneficial partnership.

[1]*Browne (1993), Chalifour (1999), Geller (2020), Horner (2020), Phaneuf (2011), Servellen (2009), and Yu et al. (2019)*

Aim and Research Questions

The overarching aim of this research is to explore how the therapeutic relationship is considered when planning the implementation of PDA's in patients eligible for or with an ICD. Research questions include:

1. Is the therapeutic relationship and/or its elements referred when planning implementation of PDAs?

2. Is the implementation of PDAs perceived as requiring or contributing to the therapeutic relationship?

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Chapter 2

Literature Review

Literature Review

To gain a deeper understanding of what is known about the intersection between the therapeutic relationship, shared decision-making (SDM), and interventions to facilitate SDM, I conducted a literature review. Specifically, I sought to find if and how the therapeutic relationship is integrated in our understanding and execution of SDM, and whether it is considered a strategy to enhance PDA implementation in clinical practice. I explored the literature seeking the patient, family and healthcare professionals' perspectives, considered organizational influences generally, and as permitted, specifically in the context of the decision-making trajectory.

I begin this chapter by describing the search strategy and the inclusion and exclusion criteria. Then, I synthesized what is known about the context of SDM in arrythmia care and management, specifically throughout the ICD decision-making trajectory, including existing interventions to facilitate it. Finally, I explored the known barriers and facilitators of SDM and PDA implementation at three different levels (the patient, the healthcare professionals, and the organization) in relation to the therapeutic relationship.

Search Strategy

With the guidance of an academic librarian, I conducted a literature search in two electronic databases Medline and CINAHL. I searched the following keywords: *implantable cardioverter defibrillator*, *shared decision-making*, *patient decision aids*, and *therapeutic relationship*. They were used separately and together in different combinations (See Appendix B). Articles were included if they discussed decision support interventions such as PDA and SDM in arrhythmia care, ideally for ICD therapy or if they explored the role of the therapeutic relationship during a SDM approach in any health context, from any perspective (patients, family members, healthcare professionals, organizations/health systems). There were no limits on study designs; quantitative,

qualitative, mixed method, and knowledge syntheses studies were eligible. I included articles published from 1990 onwards as implantable cardioverter-defibrillators with key upgrades, still part of modern day devices, were introduced in the early 1990s, and the concept of SDM was steadily gaining momentum since its introduction in the 1980s (Bardy et al., 1992; Brody, 1980; Charles et al., 1999).

Search findings

Of 481 studies screened, 48 were included. There were 21 about ICDs, 26 about SDM, 17 about PDAs, and 11 about the therapeutic relationship. Most studies were published between 2016-2022 from different countries such as the United States, Canada, Australia, Netherlands, New Zealand, United Kingdom, England, Germany and Norway. Further details about the included studies can be found in Appendix C.

SDM in Arrhythmia Care and Management. A state of the science paper on SDM in electrophysiology and cardiac arrhythmia care was published in 2021 (Chung et al., 2021). The authors reviewed the evidence on the effects of interventions to facilitate SDM for arrhythmic conditions on SDM outcomes. Authors identified four trials of decision support interventions for anticoagulation for atrial fibrillation and two trials of decision support interventions for ICD therapy (Fraenkel et al., 2012; Kunneman et al., 2020; Man-Son-Hing et al., 1999; Thomson et al., 2007). For example, a randomized controlled trial conducted in the United Stated recruited 922 patients with atrial fibrillation and 151 healthcare professionals. They randomized patients to a PDA about options for anticoagulant therapy and reported several improvements in markers of SDM quality as well as improved patient involvement and healthcare professional satisfaction (Kunneman et al., 2020). Participants in both arms reported benefits in communication quality (Kunneman et al., 2020). Song et al. (2022) found similar results in SDM markers. They discussed

that training healthcare professionals in SDM knowledge and skills would be beneficial for PDA delivery and that implementing an interprofessional model would optimize care (Fraenkel et al., 2012; Song et al., 2022). They reported that the PDA was successful in promoting communication between patients and healthcare professionals (Fraenkel et al., 2012).

Current guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death recommend a SDM approach (Al-Khatib et al., 2018; Philippon et al., 2017) for all decisions as patient preferences for various treatments and their acceptance of their illness may evolve (Chung et al., 2021). Chung et al. (2021) noted that SDM may be particularly relevant in patients at high risk for device implants or procedures, or for treatment options in arrhythmic conditions with incomplete evidence (permanent pacing, cardiac resynchronization therapy, ablation, genetic testing, and sports participation) (Chung et al., 2021).

SDM and ICD Therapy. The preference sensitive nature of ICD therapy is well established, with SDM proposed as a desirable approach for patients facing its associated decisions. Joyce et al. (2013) introduced three central components of effective SDM tailored for ICD therapy, which reflect the essential elements of SDM discussed by other authors (also reviewed in Chapter 1) (Backman et al., 2020; Légaré et al., 2007; Makoul & Clayman, 2006). First, informing patients about the risks, benefits and consequences of an ICD which are known to be important to quality decision-making, including the downstream decisions such as battery replacement and possibility of deactivation (Joyce et al., 2013). Second, individualizing the risks and benefits of the ICD to the patient's characteristics, and eliciting individual values and preferences. Third, engaging patients including their family/significant other to their desired degree in decision-making about ICD implantation. These principles are to be extended to the

trajectory of preference-sensitive decisions from initial implantation of the device to replacement of the pulse generator, and the deactivation at end-of-life.

An integrative review of 25 articles by Lewis et al. (2014a) explored 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 healthcare professional enhance the care they provide to this population. This review revealed a significant degree of misunderstanding and inaccurate recall of information regarding ICD function at all decision points (Lewis et al., 2014a). Patients' perceptions and misunderstandings of the functionality of their ICDs impeded ICD management particularly in discussions about decisions (Lewis et al., 2014a). More recently, Mooney et al. (2019) investigated patients' knowledge and opinions about their ICD during life, illness and at the time of death and the factors that influence them. Results from this survey study showed that only 59% of patients (n=30) had sufficient knowledge about their device and that patients required more support from healthcare professionals and more opportunities for timely discussions about ICD therapy (Mooney et al., 2019). Standing et al. (2016) shared similar results from interviews with patients' and healthcare professionals' exploring their views during implantation and deactivation. The authors reported that patients in this qualitative study had variable knowledge about their conditions and the clinical rationale for ICD implantation which sometimes resulted in confusion about the potential benefits as it can only prevent arrhythmic death (Standing et al., 2016). Most recently, Barisone et al. (2022) synthesized patient's experiences with their ICD in a systematic review and meta-synthesis of 24 qualitative research articles. The authors revealed fear and insecurity among the participants about the impact of the ICD on their life, receiving shocks and a slow adaptation process (Barisone et al., 2022). Patients requested more information and support from healthcare professionals while showing gratitude for

the help they received and trust in their medical teams (Barisone et al., 2022). The involvement of family was also found to be essential for the decision-making process and eventual acceptance of the ICD (Barisone et al., 2022). Authors discussed that communication is essential for patients with ICDs to enhance decision-making and management (Mooney et al., 2019; Standing et al., 2016). Patients revealed a lack of information to support their decision-making (Barisone et al., 2022). Next, I will review the literature by specific ICD decision.

ICD Implantation. Despite previous reports of suboptimal patient involvement in ICD decision-making, Ali-Ahmed et al. (2019) found that most physicians report using a SDM approach when counseling patients about ICD implantation. In this United States-based survey study, 91% of physicians (n=102) self-reported adopting a SDM approach during general consent, taking patients' preferences and health goals into account (Ali-Ahmed et al., 2019). Only 43% of physicians reported using an existing PDA (Ali-Ahmed et al., 2019). The small sample size of this study may not be representative of the majority of attending physicians who counsel patients about ICDs and/or who implant them. Further, as this was a self-reported study, there is no way to verify whether SDM conversations were indeed taking place or what participants believe constituted a SDM process (Ali-Ahmed et al., 2019). In a qualitative study, Carroll et al. (2011) explored patients' experience during consent for ICD implant. They revealed that although some patients prefer to adopt an active decision-making approach, many rely on physicians' recommendations, their expertise, and the trust that patients place in them. Many patients prefer that physicians make the final treatment choice (Carroll et al., 2011; Lewis et al., 2014a). This may be explained by limited efforts to engage patients in the decision-making process, and patients' lack of knowledge or understanding of the stakes in this decision.

ICD Replacement. Only one study investigated the decision-making process specifically at the time of ICD pulse generator replacement (Lewis et al., 2014b). In a cross-sectional survey study, 14.2 % (n=106) of patients would have opted not to replace their ICD generator had they been aware of the option. This lack of knowledge extended to the risks and benefits of ICD therapy. Patients overestimated the survival benefit of the ICD and underestimated the risks, particularly of infection (Lewis et al.,2014b). This research team conducted subsequent work and revealed that ICD replacement is largely an automatic process with healthcare professionals' implicitly persuading patients to proceed with the replacement procedure by unequivocally stating that a potential saved life is the best outcome for all (Lewis et al., 2018a). Patients and relatives facing ICD decisions want to be offered choice, want balanced information about the risks and benefits of the available options, in particular the potential impact on psychological well-being and quality of life in the short and long term (Lewis et al., 2014b; Lewis et al., 2018b; Standing et al., 2016).

ICD Deactivation. Authors of three studies indicated that an important proportion of patients near end-of-life may no longer want the lifesaving shock therapy from their ICD (Choi et al., 2019; Maclver et al., 2016; Raphael et al., 2011). In a qualitative study of 54 patients, Raphael et al. (2011) explored the degree to which patients want to discuss device deactivation in a qualitative study. They found that 38% (n=54) of patients knew the device could be deactivated and that 84% of patients wanted to be involved in deactivation decisions (Raphael et al., 2011). In another study, most patients (n=17, 68%) said they would consider deactivation (Maclver et al., 2016). As a result of their findings, these Canadian authors recommended discussing ICD deactivation at three distinct stages: 1) prior to implantation; 2) with any deterioration but where patient is capable to engage and communicate their preferences and; 3) at end-of-life, when patients want a review of their preferences and wishes (Maclver et al., 2016). Using this process

may reduce the number of patients experiencing distressing shocks at end-of-life (Maclver et al., 2016). The patients' understanding of the device and the physician's willingness to approach the subject were identified as facilitators to end-of-life discussions when faced with ICD deactivation (Lewis et al., 2014a; Raphael et al., 2011). Choi et al. (2019) aimed to increase discussions regarding ICD deactivation with standardised education for healthcare professionals and decision support tools integrated into electronic medical records. They found that discussions regarding deactivation improved from 50% to 93% in comfort care patients and from 32% to 70% in DNR patients (Choi et al., 2019).

Interventions to Facilitate SDM for ICD Therapy Decision-Making. Current clinical practice guidelines for patients with ventricular arrythmias or at increased risk of sudden cardiac death recommend that healthcare professionals adopt a SDM approach at all decision points (ICD implantation, replacement, and deactivation) (Al-Khatib et al., 2018). Hence, interventions to facilitate SDM have been developed and evaluated to support the specific and nuanced decisions that fall along the ICD trajectory. To implement these guidelines, the centres for Medicaid and Medicare in the United States mandate the use of a PDA prior to primary prevention ICD implantation. The policy states that a formal SDM encounter must occur between the patient and a physician or qualified non-physician practitioner using an evidence-based decision tool prior to initial ICD implantation for eligible patients (Centers for Medicare and Medicaid Services, 2022). Rao et al. (2022) evaluated the impact of this government mandate on core SDM measures. Patients who underwent implantation of a primary prevention ICD between 2017 and 2019 (pre and post mandate) were surveyed on knowledge about the ICD, decisional conflict, values-choice concordance, and engagement in decision-making. Patients who had received their ICD after the mandate were also asked about PDA use. Of the 101 patients who completed the survey, 45

received their ICD before the mandate and 56 received their ICD after. There was no statistically significant difference in patients' knowledge about ICDs, decision conflict, values-choice concordance, or engagement in decision-making but patients felt more informed and appreciated the PDA (Rao et al., 2022). It found that SDM is appropriate for this population, but a mandate focused only on PDA use is insufficient to impact the SDM process (Rao et al., 2022). Another study in Canada evaluated the effectiveness of a PDA for new ICD candidates in a feasibility randomized trial. Compared to controls, patients exposed to the PDA (n=41 of 82) had improved knowledge and lower decisional conflict scores compared to usual care (Carroll et al., 2017). The PDA presented to ICD candidates in the intervention group was an 11-page interactive booklet that presented evidence-based information and probabilities about benefits and risks using lay terminology. Patients randomized to usual care did not receive any additional information and were provided with general educational materials delivered after consultation once the decision to accept the ICD was established.

The preliminary effectiveness of a PDA at battery replacement was also investigated. First, Lewis et al. (2018a) developed a PDA for patients facing ICD replacement in the Canadian context, while simultaneously exploring how to best implement it in clinical practice. Participants agreed that a need for individualization, through discussion of personal and clinical circumstances, was necessary as the PDA could not stand alone. Preliminary evaluation was conducted in a feasibility trial, where the PDA was delivered by a nurse decision coach (Lewis et al., 2021). It found that nurse-led decision coaching was helpful to identify what patients needed to know with PDA use and 71.4% of patients agreed it helped them feel good about their decision. Compared to controls, patients exposed to the PDA supported by nurse-led coaching had significantly better knowledge,

had a better understanding of the factors involved in the replacement procedure of their ICD, and were more involved in the decision-making process (Lewis et al., 2021).

CorHealth Ontario (2017) an organization formed by the merger of the Cardiac Care Network of Ontario and the Ontario Stroke Network, developed a decision guide to support patients and healthcare professionals in addressing deactivating ICD therapy (which was later endorsed by the Heart & Stroke Foundation of Canada). They developed to develop provincial recommendations to promote patient-centred care for people with ICDs engaging in goals-of-care discussions. These recommendations were based on review of clinical practice guidelines and relevant standards and policies from the College of Physicians and Surgeons of Ontario (CPSO), Registered Nurses Association of Ontario (RNAO) and College of Nurses of Ontario (CNO). No research measured decisional outcomes for this decision guide currently although the parent study included it as a decision aid for patients considering ICD deactivation (CorHealth, 2017).

Barriers and Facilitators of SDM related to the Therapeutic Relationship. To further understand the therapeutic relationship in context SDM, four systematic reviews on the facilitators and barriers to SDM implementation were examined (Alsulamy et al., 2020; Covvey et al., 2019; Pel-Littel et al., 2021; Waddell et al., 2021). One knowledge synthesis (Keij et al., 2023) and individual studies (Beyene et al., 2018; Ehrlich & Dannapfel, 2016; Reed & Jaxson, 2019; Yu et al., 2019) have focused specifically on SDM and the therapeutic relationship. With awareness of known facilitators and barriers to SDM, our research team can use these findings to further identify and understand the factors influencing the therapeutic relationship and PDA implementation. Given that the overarching aim of this study is to explore the role of the therapeutic relationship in enhancing PDA implementation, it was decided to focus on the facilitators and barriers as they specifically relate to the therapeutic relationship. Hence, it is beyond the scope of this literature

review to list all barriers and facilitators to SDM, but rather focus on the ones relevant to the therapeutic relationship at the level of the patient, the healthcare professionals, and the organization (Joseph-Williams et al., 2021).

Patient-Level. Keij et al. (2023) conducted a scoping review of qualitative literature that found important relationship-related characteristics considered to affect patient involvement in SDM. They found that an effective patient-clinician relationship had mutual trust that could facilitate SDM (Alsulamy et al., 2020; Keij et al., 2023). Patients tend to be more involved if they trust and respect their clinician, if they feel that their opinions and concerns are heard, and if they feel supported and encouraged to participate in decision-making (Keij et al., 2023; Younas et al., 2016). Involvement is also improved when patients are able to ask questions, are transparent and honest and speak about their symptoms, thoughts, feelings and preferences (Keij et al., 2023). Patient involvement can be hindered when patients feel disrespected and unheard (Ehrlich & Dannapfel, 2016; Keij et al., 2023; Larsson et al., 2011).

Yu et al. (2019) explored the link between the therapeutic relationship and SDM experiences via interviews with healthcare professionals (n=10) and patients with diabetes (n= 7). Patients emphasized the central role of their relationship with the healthcare professional, expressing not only the need for accessibility, comfort, and familiarity but the critical importance of trust, listening and dialog (Ehrlich & Dannapfel, 2016; Yu et al., 2019). Alsulamy et al. (2020) shared that the quality of the healthcare professional-patient relationship was clearly identified as a key enabler to SDM. The importance of a relational process with SDM has been explored in mental health care settings where a therapeutic relationship is considered to be essential (Beyene et al., 2018; Ehrlich & Dannapfel, 2016; Reed & Jaxson, 2019). No articles discussing the role of

the therapeutic relationship and SDM in a cardiovascular context have been located, yet a few findings can be drawn from PDA-specific studies.

The explicit invitation to engage with a PDA before a decision-making consultation with the physician acts as a prompt for the patient to engage (Joseph-Williams et al., 2021). A subsequent invitation from the healthcare professional to engage in further discussion helps the patient feel included and encourages them to share their preferences and values (Joseph-Williams et al., 2021). Conversely, if an explicit invitation to engage with a PDA or participate in the consult is not extended, then it may be less evident to patients that they are permitted to express their preferences (Joseph-Williams et al., 2021). This was also reported by Lewis et al. (2018a) when investigating the implementation of a PDA for ICD battery changes.

Healthcare professional-Level. While some healthcare professionals may agree with involving patients in health decisions, they do not always have the knowledge or skills to successfully do so (O'Donnell et al., 2006). For others, negative attitudes toward SDM, and their belief that patients do not want decisional responsibility can also hinder efforts to engage patients in decision-making (such as PDA use) (Joseph-Williams et al., 2021). Bunn et al. (1998) had previously reported that effective communication skills are essential to provide quality decision support and are central to any helping relationship yet these are lacking for many healthcare professionals. Authors go on further to suggest that having adequate communication skills is a prerequisite to being able to relate to patients (Bunn et al., 1998). Other healthcare professionals reported poor communication techniques, poor language choice and a lack of empathy as barriers to SDM (Covvey et al., 2019; Pel-I et al., 2021).

Facilitators to SDM included healthcare professionals' consideration of patient preferences and positive actions/behaviors (caring, trusting, relationship building, and strong communication)

(Covvey et al., 2019). A systematic review of 14 studies by Waddell et al. (2021) found that increasing conversations and giving patients time to engage in conversation with support of the interprofessional team greatly improves SDM. In addition, Henderson (2003) showed that nurses who openly share information, spend time with patients while talking about their needs, and actively listen made patients more comfortable and more inclined to participate in decisions about their care (Fisher et al., 2017; Henderson, 2003; Reed & Jaxson, 2019). Kalocsai et al. (2018) referred to this as building a therapeutic alliance with family members (n=19) of critically ill patient. In their qualitative study, they reinforced that an interprofessional effort and communication can come a long way in building a positive relationship (Kalocsai et al., 2018).

Specifically regarding the PDA, barriers included healthcare professional's unawareness of the existence of PDAs for a particular health decision (O'Donnell et al., 2006; Stacey et al., 2019). Others have reported a lack of trust in PDA content, lack of clarity about their purpose, and are concerned that they could increase consultation time and overall workload (O'Donnell et al., 2006).

Organization-Level. At this level, key facilitators include a system-level approach, SDM and PDA training, skill development and having dedicated clinical leadership to assist and support implementation and clinical use (Daniela et al., 2021; Joseph-Williams et al., 2021; Stacey et al., 2019). It was found that the organizational culture and teamwork efforts influence SDM implementation (Scholl et al., 2018). This includes staff autonomy to engage in SDM, shared views and goals about the process as well as communication skills and coordination of care (Scholl et al., 2018). It was suggested that leadership decision-making and organizational priorities (ex: patient centered care) could also influence SDM implementation positively or negatively depending on the degree to which SDM is encouraged (Scholl et al., 2018). Other organizational

barriers include a lack of sustainable funding to update the PDAs, a lack of funding to disseminate and implement the PDAs and a lack of research funding to evaluate implementation of PDA use in clinical practice (Stacey et al., 2019).

Gaps in our Understanding

In summary, this literature review revealed that SDM is particularly relevant for ICD therapy as patients face numerous preference-sensitive decisions throughout their trajectory of care. Yet, the role of the therapeutic relationship in achieving these shared decisions has not been explored in this specific context. The therapeutic relationship has been explored in relation to SDM, primarily in mental health settings where the therapeutic relationship is valued and is associated positively with SDM. Many key elements to a therapeutic relationship (effective communication, trust, empathy, active listening) were noted by patients and healthcare professionals as important factors for SDM in tertiary care settings. However these elements, and the therapeutic relationship as a whole, were less investigated in the context of arrythmia care (Alsulamy et al., 2020; Covvey et al., 2019; Kalocsai et al., 2018; Keij et al., 2023; Kingston et al., 2020; Pel-Littel et al., 2021; Waddell et al., 2021). It prompts the necessity for this study to investigate the role of the therapeutic relationship for PDA implementation to facilitate SDM in clinical practice.

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Chapter 3

Positionality and Theoretical Underpinnings

Positionality

As a registered nurse with four years of experience in post operative care for cardiac surgery and most recently in the intensive coronary care unit, I have cared for patients that are considering, have recently received, or have had an ICD for many years. As a registered nurse currently working at the University of Ottawa Heart Institute (UOHI), I provide support and teaching before and after ICD implantations and replacements, as well as navigate discussions about ICD deactivation. My interest for this project was initially prompted by numerous observations that many patients receiving or considering ICD therapy did not fully understand its implications and therefore were not making informed choices. Further, I have always valued the relational aspect of healthcare and sincerely believe that healthcare professionals who take the time to build a therapeutic relationship with their patients are better equipped to support and meet their needs. This prompted my interest to further explore the relationship between healthcare professionals and patients when important decisions such as receiving ICD therapy need to be made.

Pragmatic Paradigm

Pragmatism is the philosophical stance in which I find myself as a researcher. Pragmatism is defined as an approach that focuses on addressing problems or situations in a practical way (Scheffler, 1974). It rests on the notions that our ability to think about so-called external things, and steadily improve our understanding of them, rests upon our experience. Hence, within this paradigm, researchers value the lived experience of individuals, and aim to use these perspectives to propose changes in practice (Press, 2006; Scheffler, 1974; Thayer & Rosenthal, 2020). This philosophical stance aligns with my personal belief that fostering a therapeutic relationship with a patient facilitates a better understanding of their experience and contributes positively to their experience. The therapeutic relationship then creates opportunities to truly understand and meet

patients' needs. In addition, I believe that by finding solutions to existing clinical research problems informed by patients' or healthcare professionals' experiences, patient outcomes can improve.

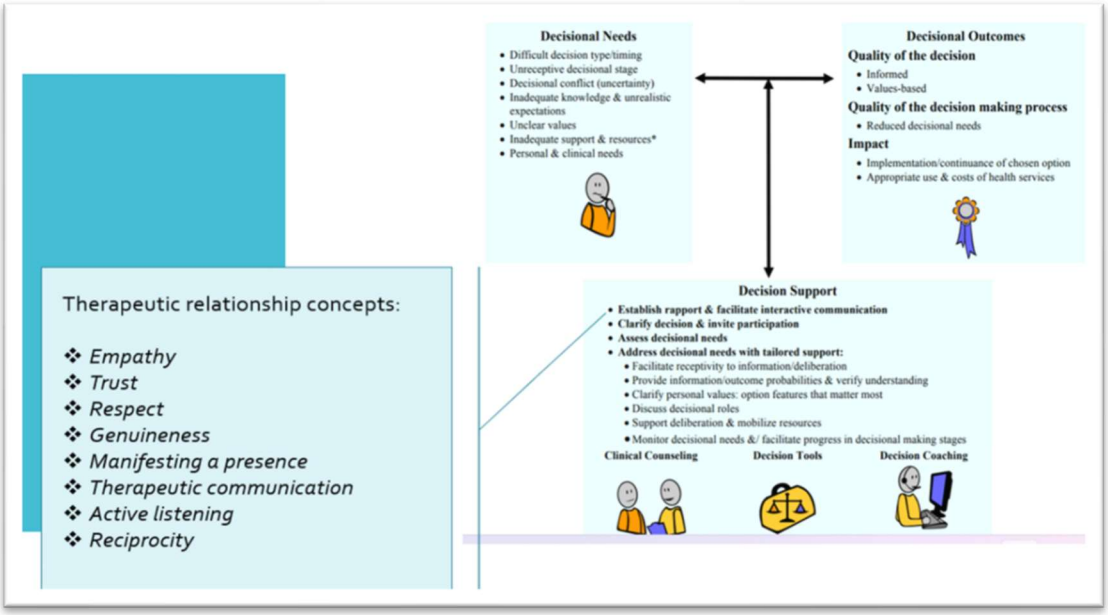
Theoretical Underpinnings

In the following section, I will describe the theoretical underpinnings that guided my thesis research. First, the Ottawa Decision Support Framework (ODSF) (O'Connor et al., 1998; Stacey et al., 2020) provided a lens through which to situate the PDAs to be implemented and to consider the additional decision support elements specifically related to establishing rapport and facilitating interactive communication to implement them. These two key elements to a therapeutic relationship are emphasized in the 2020 ODSF (Stacey et al., 2020), yet remain poorly described in the ODSF coding manual. This is an important gap in the framework in order to fully appreciate the importance of the therapeutic relationship and its elements to the provision of decision support and its impact on decisional outcomes (Hoefel et al., 2020). To achieve this, I concurrently considered all the essential elements of the therapeutic relationship as identified by Chalifour, 1999; Geller, 2020; Horner, 2020; Phaneuf, 2011; Servellen, 2009; Yu et al., 2019. Together with the ODSF, these formed my theoretical scaffolding approach, which is described as the background knowledge, disciplinary orientation, inclusive of the assumptions, values, and beliefs associated with them that a researcher brings into a study (Thorne, 2016).

Together, the ODSF and the essential elements of the therapeutic relationship offered a framework to: 1) explore the role of the therapeutic relationship and/or its elements when planning the use of PDAs to facilitate SDM with patients facing decisions about ICD therapy; and 2) determine if the use of PDAs require or contribute to elements of the therapeutic relationship to support SDM for patients eligible for or with an ICD. A visual depiction of this conceptual model

is included in Figure 1. In the following section, I describe the ODSF and therapeutic relationship and its elements.

Figure 1: Ottawa Decision Support Framework with Therapeutic Relationship Elements



(Adapted with permission from Ottawa Hospital Research Institute, 2023)

Ottawa Decision Support Framework (ODSF). The ODSF is a middle range theory that was first developed in 1998 based on theories and constructs of prospect theory, decision analysis, reasoned action, decisional conflict, social support, and self-efficacy (O'Connor et al., 1998). It was then updated in 2020 based on systematic reviews (Stacey et al., 2020). Its main goal is for patients to make decisions that are informed and based on what is most important to them (Hoefel et al., 2020a; Stacey et al., 2020). It recognizes that when patients are faced with a difficult decision, they may have unresolved decisional needs that can be addressed with decision support interventions (e.g., patient decision aids, decision coaching, and counselling). Improved decision quality may favorably affect patient's actions (e.g., reduce decision delay, continuance of chosen option) leading to positive downstream impacts (e.g., values-based health outcomes and

appropriate use/costs of health services) (Hoefel et al., 2020b). The three main pillars of the framework are decisional needs, decision support interventions and decisional outcomes, which are defined next.

Decisional needs. The first element in the ODSF is patients' decisional needs. Unresolved decisional needs can affect the quality of a decision. Patients can experience many types of decisional needs during the decision-making process (Stacey et al., 2020). *Decisional conflict*, a main decisional need that can arise at any time during the decision-making process, is defined as a state of personal uncertainty about which course of action to take when choosing amongst options that involve risk, loss, regret, or that challenge one's personal values (Stacey et al., 2020).

Lack of knowledge and *unrealistic expectations* regarding the health problem/condition/situation, or the available options and their relevant features (benefits, harms/risks, other outcomes/features; scientifically uncertain outcomes) are other common decisional needs that can complicate the decision-making process (Stacey et al., 2020). This has been reported in the context of ICDs. For instance, Matlock et al. (2011) demonstrated that patients who had declined an ICD were concerned that the device was unnecessary or believed that the risk of sudden cardiac death did not apply to them. In addition, patients described not learning many of the risks until after the device was implanted (Matlock et al., 2011).

Patients can have *unclear values* making it difficult for patients to express or clarify their personal desirability regarding the available options (Stacey et al., 2020). Depending on the patients' experience of their illness, their values and preferences can change over time, requiring timely and deliberate discussions by healthcare professionals. This is particularly pertinent in the context of ICDs with distinct and nuanced decisions interspersed throughout the treatment trajectory.

Inadequate access to timely support and quality resources could also affect the decision-making process (Stacey et al., 2020).

There are two types of unmodifiable decisional needs: complex decision characteristics and personal and clinical needs. *Complex decision characteristics* consist of 3 categories : 1) a difficult decision type (features of a decision that makes decision-making more difficult such as having multiple options or unknown outcomes); 2) a difficult decision timing (the time frame for deliberation such as urgency for instance); and 3) an unreceptive decisional stage (referring to the current phase of decision-making such as a lack of openness to receive information or being unable to deliberate) (Stacey et al., 2020). The patient could also be faced with *personal and clinical needs* that directly affect them during their decision-making process (Stacey et al., 2020). Examples of these personal needs include age, gender, marital status, ethnicity, occupation among others (Stacey et al., 2020). Clinical needs include diagnosis, health status, duration of condition (acute or chronic) or the patients cognitive and social functioning (Stacey et al., 2020).

In summary, the modifiable decisional needs can be addressed by decision support interventions and the non-modifiable decisional needs must be considered during the decision-making process. Interestingly, the ODSF does not refer to any decisional needs that directly relate to the elements of the therapeutic relationship.

Decision Support Interventions. To address these various modifiable decisional needs, the ODSF posits that decision support interventions can aid in resolving them. Decision support interventions are used to assist patients who are deliberating about their decision, which include PDAs and decision coaching (which were described in previous chapters) (Stacey et al., 2020). Decision support interventions are intended to be tailored to patients' decisional needs and aim to achieve decisions that are informed and based on patients' values (Stacey et al., 2020). The use of

decision support interventions involves establishing a rapport with the patient, inviting participation, and clarifying the decision that needs to be made (Stacey et al., 2020). In the most recent update of the ODSF, the steps of establishing rapport and facilitating interactive communication were added (Stacey et al., 2020). These changes align with elements of the therapeutic relationship such as active listening, therapeutic communication and reciprocity which will be described further.

Decisional Outcomes. The third pillar of the ODSF consists of evaluating outcomes related to the quality of the decision (Was it informed? Was it value based?) and the decision-making process (was there a reduction in decisional needs, reduction in perceptions of feeling uninformed and unsupported?) (Stacey et al., 2020). Other outcomes include evaluation of implementation or continuance of the chosen option by the patient while clinically appropriate and an appropriate use/costs of health services (an alignment of use with informed preferences and an alignment of costs with changes in over-use and under-use of services). Secondary outcomes can evaluate the potential for implementation and continuance of chosen options (Stacey et al., 2020). As previously stated reducing decisional conflict may favorably affect patient's actions (e.g., reduce decision delay, continuance of chosen option) leading to positive downstream impacts (e.g., values-based health outcomes, less regret, less blame on others for bad outcomes, and appropriate use/costs of health services) (Hoefel et al., 2020b).

The Therapeutic Relationship and its Elements. The therapeutic relationship is a purposeful, goal-directed interaction between a healthcare professional and a patient concerned with the patient's best interest (Chalifour, 1999; Phaneuf, 2011). A therapeutic relationship is intended to help the patient feel comfortable, supported and understood and it is linked to positive patient outcomes such as improvement in patient satisfaction, adherence to treatment, quality of

life and decreased health care costs (Chalifour, 1999; Doherty & Thompson, 2014; Kornhaber et al., 2016; Phaneuf, 2011). This relationship goes above regular conversations to attain an understanding of how the patient is experiencing their health-related concern (Doherty & Thompson, 2014; Phaneuf, 2011; Sylvestre et al., 2020). It involves the feelings and attitudes that the patient and healthcare professionals have towards one another and a partnership of equals limiting power imbalances (Mirhaghi et al., 2017; Sylvestre et al., 2020). Some consider this relationship as an intervention to help patients progress in their personal objectives and goals (Egan, 2005; Registered Nurses Association of Ontario, 2006). Nursing theorists have developed a variety of conceptualizations of the therapeutic relationships between clients and nurses mostly used by mental health nurses but can be applicable to most interpersonal relationships in all contexts (Chalifour, 1999; Hagerty & Samuels, 2018; O'Brien, 2001; Peplau, 1991). Many terms have been used to describe the therapeutic relationships: helping relationships, purposeful relationships, nurse-client relationships, and therapeutic alliances (Kornhaber et al., 2016; Mirhaghi et al., 2017; Sylvestre et al., 2020). In the context of this study, the therapeutic relationship is considered as a purposeful, goal-directed interaction between a healthcare professional and a patient concerned with the patient's best interest (Chalifour, 1999; Phaneuf, 2011).

I considered various theories about the therapeutic relationship, but none fit the needs of this project. For example, I looked at the Theory of Therapy and Personality Change by Carl Rogers (1959) which explores the required conditions for a therapeutic relationship to occur and its process. I did not select this theory as it focused on the therapeutic relationship as a process that encourages change in the patient and did not explain the important elements necessary to form the therapeutic relationship. I also explored the therapeutic relationship in the field of psychotherapy,

but none of the authors explained the concepts thoroughly (Bordin, 1979; Egan, 2005; Sylvestre et al., 2020). For example, no authors defined therapeutic communication, active listening and empathy which are important components of the therapeutic relationship. Therefore, I have decided to build a theoretical scaffold, as proposed by Thorne (2016), with the main concepts affiliated with the therapeutic relationship. These elements are empathy, trust, respect, genuineness, manifesting a presence, therapeutic communication, active listening, and reciprocity, which will all be defined next (Browne, 1993; Chalifour, 1999; Geller, 2020; Horner, 2020; Phaneuf, 2011; Servellen, 2009; Yu et al., 2019).

Empathy is a sentiment of profound comprehension expressed or felt by the healthcare professional towards the patient (Chalifour, 1999; Phaneuf, 2011). To exemplify this, the healthcare professional must have the ability to put themselves in the patient's situation to understand their feelings without actively feeling these emotions themselves to provide the comfort required (Phaneuf, 2011). Empathy is difficult to measure (Servellen, 2009). An empathetic response is facilitated by active listening, called empathetic listening. *Empathetic listening* involves an active process where the healthcare professional perceives the patient situation intentionally as the patient sees it themselves. This requires that the professional takes time and energy to listen and learn about the experience of the patient, which is said to promote understanding (Servellen, 2009).

Trust is a reasonable expectation that one can depend on another person's promise, commitment, or responsibility (Horner, 2020). The patient and healthcare professional must have a trusting relationship to engage in partnership and SDM (Horner, 2020). For trust to occur, two conditions must be met (Servellen, 2009): 1) The patient must perceive that the healthcare professional has their best interest in mind; and 2) the patient must perceive that this/these same

healthcare professionals are capable and competent to help them. Behaviours that evoke trust include, in no order: honesty, consistency, respect, caring, openness, genuineness, reliability, and congruence between verbal and non-verbal communication (Servellen, 2009).

Respect means acknowledging the value of patients and accepting their individuality as well as their unique needs and rights (Browne, 1993; Servellen, 2009). Respect builds feelings of trust, safety, and wellbeing. Examples of actions that are indicative of respect include: 1) non-verbal messages conveyed to a patient using eye contact, facial expression, posture, a position relative to the patient, and a sensitive use of touch; 2) verbal messages directed to a patient by adjusting tone of voice, use of a patient's real name, expressions of honesty and acceptance, and conveyance of a genuine interest in the patient as a person; 3) actions aimed at protecting a patient's privacy and sense of modesty, allowing a patient to make choices concerning his or her care, and explaining procedures fully before carrying them out (Browne, 1993).

Genuineness refers to a healthcare professional's ability to be open and honest with the patient (Servellen, 2009). The healthcare professional must show congruence between their verbal and non-verbal communication to demonstrate that they are genuine. It is often achieved by self-disclosures which leads to greater closeness with patients. For instance, within the limits of professional boundaries, the healthcare professional can share personal information about themselves or about past experiences in relation with the patient's situation. This ability helps the healthcare professional to develop a trusting, empathetic and respectful relationship with their patient.

Manifesting a presence means being physically and psychologically present with the patient during encounters (Phaneuf, 2011). It is a way of being fully present in the moment with a patient and seen as a developing factor of the therapeutic alliance and strengthening the working

relationship (Geller, 2020). It provides an invitation for patients to feel understood, inviting a sense of safety and optimal engagement (Geller, 2020). The healthcare professional should be physically close and emotionally calm which promotes a sentiment of trust in the patient (Phaneuf, 2011).

Therapeutic communication is an interpersonal exchange, using verbal and non-verbal communication that expresses support, provides information and feedback, corrects distortions, and provides hope (Servellen, 2009). Certain techniques can be used such as using silence, offering acceptance, as well as acknowledging and giving recognition (Servellen, 2009). The healthcare professional can share observations, summarize, and reflect on their own perception of the patients' thoughts, feelings, and reactions (Servellen, 2009). Focusing on the patient, prompting exploration of their experience, translating thoughts into feelings and feelings into thought can also be used (Servellen, 2009). In addition, it is important for the healthcare professional to validate the patient's perceptions and beliefs by asking questions and listening to what the patient's are sharing during interactions (Servellen, 2009). Non-verbal communication includes touch, invitations to continue speaking, encouraging looks and positions, and active listening (Chalifour, 1999; Servellen, 2009).

Active listening means going beyond simply hearing the words and aiming, through various techniques, to understand the patient as a whole (Phaneuf, 2011). This includes the use of silence when appropriate, paying attention and being open-minded towards the patient and their difficulties (Chalifour, 1999; Phaneuf, 2011). It also refers to the awareness of the patient's emotions and listening to what these emotions mean to the patient (Phaneuf, 2011). To encourage active listening, the healthcare professional should favor a quiet and private environment to hear what the patient is saying (Chalifour, 1999). The healthcare professional can pay attention to the patient's displayed non-verbal messages during verbal communication and they should be alert

and ready to really listen to what the patient is saying (Chalifour, 1999). They should listen to the entire information given by the patient and not just hone in on what is most interesting to them, or relevant from their perspective (Chalifour, 1999). The healthcare professional should also take the time to listen before intervening or responding.

Reciprocity is the practice of exchanging for mutual benefit. It refers to the balance of giving and receiving in a relationship with the goal of creating a healthy and mutual beneficial partnership (Yu et al., 2019). Themes of mutual understanding, connectedness, exchange, and complementarity should emerge.

Summary

While the ODSF emphasizes the importance of establishing rapport and communication, it alone does not exhaustively include the elements necessary to fully appreciate the role and importance of the therapeutic relationship as a necessity when providing decision support. Combining the ODSF with the therapeutic relationship's elements helped to fully consider the therapeutic relationship within the context of implementing decision support.

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Chapter 4

Is the Therapeutic Relationship Considered When Planning Patient Decision Aids Implementation Throughout the Implantable Cardioverter-Defibrillator Trajectory? A Qualitative Investigation

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What's New?

- Certain elements of the therapeutic relationship, in particular therapeutic communication, respect, empathy and trust, are important for PDA implementation.
- Healthcare professionals have good intentions for establishing therapeutic relationships but are faced with challenges.
- PDAs can help foster elements of the therapeutic relationship.

Keywords: Implantable Cardioverter Defibrillator, Decision Support, Therapeutic Relationship

Abstract

Background: Patient decision aids are decision support interventions that require a partnership to facilitate shared decision-making. Therapeutic relationships are a form of partnership established to gain an understanding of the patients' experiences of their health condition to best meet their needs and goals. Yet, the role of therapeutic relationships in PDA implementation has not been investigated.

Objective: To explore how the therapeutic relationship is considered when planning PDA implementation for patients eligible for or with an ICD.

Methods: Secondary qualitative analysis using Thorne's interpretive description approach. Analysis of individual interviews' and focus groups' transcripts of patients with ICDs (n= 10), their family members (n= 3), nurses (n=6) and physicians (n= 11) from one academic hospital in Ontario, Canada. We used thematic analysis.

Results: We revealed three themes. In theme 1, *Pieces of the relational puzzle: Elements of the therapeutic relationship,* participants identified communication, respect, empathy, and trust as important to PDA implementation. In Theme 2, *Good intentions, and challenges for building a therapeutic relationship,* healthcare professionals spoke of their good intentions for establishing relationships characterized by therapeutic relationship elements, (i.e., communication, respect, and active listening). Yet, challenges such as time and discomfort with these discussions made it difficult. In Theme 3, *PDAs help foster the therapeutic relationship,* participants viewed the PDA as a means to support therapeutic communication and respect, and identified a necessity for a relationship.

Conclusions: Our findings provided insight on the relevance of some, not all, elements of the therapeutic relationship when planning for PDA implementation.

Introduction

Implantable cardioverter-defibrillators (ICD) are surgically implanted devices that detect and treat ventricular arrhythmias. In appropriately selected patients, they decrease the risk of sudden cardiac death (SCD). [1,2] Despite its potential life-saving capacity, ICD therapy presents risks including procedural risks, [3–6] inappropriate shocks,[7,8] psychological harms,[9] and potential suffering at end-of-life from repeated shocks.[10,11] As such, patients identified as candidates for an ICD or those with an ICD need to weigh these risks and potential life-saving benefit when faced with the preference-sensitive decisions of whether to implant the device, replace the pulse generator, or deactivate the tachytherapies when nearing end-of-life[12]. Clinical practice guidelines recommend eliciting and integrating patients' informed values and preferences when considering these decisions. [13,14] This approach is referred to as shared decision-making (SDM).

Shared decision-making requires that patients and healthcare professionals collaborate to make decisions. Healthcare professionals provide their expertise on the health condition, the available treatment options, and the risks and benefits of these options; whereas patients share their expertise on their personal situation, and what matters most to them. [15] Interventions to facilitate this process include patient decision aids (PDA). [16–18]

PDAs are evidence-based interventions that explicitly states the health decision, describes the health condition, presents the options with the risks and benefits, and helps patients clarify their values for features of treatment options. [19,20] A systematic review of 209 trials has demonstrated high certainty of evidence that in comparison to usual care, PDAs improve patients' knowledge, accuracy of risk perceptions, decrease decisional conflict related to feeling uninformed and unclear personal values, and result in people being more active in decision-making. [18] PDAs also increase patients' satisfaction with the decision-making process. [18]

The Centres for Medicaid and Medicare in the United States have mandated the use of a PDA for patients referred for ICD implantation as a condition for reimbursement. [21–24] Mandated or not, there are challenges with their implementation. [25,26] Several SDM models discuss the importance of building a partnership between the healthcare professional and patient, defined as a collaborative relationship focused on a shared goal. [15,27,28] Studies have shown that partnerships between healthcare professionals and patients result in better communication and participation in decision-making. [29,30] When these partnerships are established to gain an understanding of the patients' experiences of their health condition and involves feelings and attitudes to best meet their needs and goals, this is referred to as a *therapeutic relationship*. [31–35] Therapeutic relationships are multi-dimensional and are composed of several elements: empathy, trust, respect, genuineness, manifesting a presence, therapeutic communication, active listening, and reciprocity (Table 1). [32,34,36] Although trust and communication have been reported as facilitators to SDM, [37,38] SDM models have yet to break down these partnerships into these key elements and consider their role in the delivery of decision support interventions such as PDAs. Specifically, little is know about how the elements of the therapeutic relationship – and the therapeutic relationship as a whole – influence PDA implementation. [26,39]

The overarching aim of this research is to explore how the therapeutic relationship is considered when planning PDA implementation for patients eligible for or with an ICD. Research questions include:

1. Is the therapeutic relationship and/or its elements referred to?

2. Is the implementation of PDAs perceived as requiring or contributing to the therapeutic relationship?

Methods

Study Design

We conducted a secondary qualitative analysis using Thorne's (2018)[40] interpretive description approach. We analyzed transcripts of individual interviews and focus groups from a multisite qualitative study that aimed to investigate effective approaches for the implementation of PDAs. Transcripts were re-analyzed to specifically explore the therapeutic relationship during the PDA implementation planning process. A secondary analysis is justified as the focus on the therapeutic relationship and its elements is closely aligned with the parent study's objective to investigate the implementation of PDA use to facilitate SDM for ICD-related decisions. In addition, our research questions are consistent with the evidence that patients benefit from individualized decision support offered by healthcare professionals to be engaged in decisions throughout the ICD trajectory.[41] We report the study using the Standards for Reporting Qualitative Research (SRQR) guidelines.[42] The University of Ottawa research ethics board approved this secondary analysis (H-11-22-8655).

Theoretical Underpinnings

Theoretical underpinnings included the Ottawa Decision Support Framework [29] and the therapeutic relationship elements (Table 1).[31,32,39,43–45] The ODSF's main goal is for patients to make decisions that are informed and based on what is most important to them – the ultimate goal of the PDAs that we intended to implement. [29,46] The ODSF was used in the parent study to situate the patient decisions aids and desired outcomes and supports the establishment of a rapport or relationship between healthcare professionals and patients. However, this has been poorly described in the framework, as such we integrated theoretical writings on elements of the therapeutic relationship, forming a theoretical scaffolding as proposed by Thorne. [31,32,39,40,43–45]

Table 2: Therapeutic Relationship Elements and their Definitions[1]

Therapeutic Relationship Element	Definition
Empathy	A sentiment of profound comprehension from the HCP towards the patient.
Trust	A justified expectation that one can depend on another person's promise, commitment, or responsibility
Respect	Acknowledging the value of patients and accepting their individuality as well as their unique needs and rights
Genuineness	Ability to be open and honest with the patient.
Manifesting a presence	Being physically and psychologically present with the patient during encounters.
Therapeutic communication	Interpersonal exchange, using verbal and non-verbal messages, that expresses support, provides information and feedback, corrects distortions, and provides hope.
Active listening	Listening to hear and to understand the patient.
Reciprocity	Refers to the balance of giving and receiving in a relationship with the goal of creating a healthy and mutual beneficial partnership.

1 Browne (1993), Chalifour (1999), Geller (2020), Horner (2020), Phaneuf (2011), Servellen (2009), and Yu et al. (2019)

Positionality

The research team was comprised of a graduate student and practicing cardiovascular nurse (AV) who values and prioritizes the relational aspect of healthcare, faculty advisors (DS, JC, HS, and KBL) all of whom are registered nurses and university faculty members, and a practicing advanced practice nurse in cardiac supportive and palliative care (FK). Team members believe that building relationships with patients, therapeutic or otherwise, better position healthcare professionals to support their patients and their decision-making needs. Team member expertise included decision support and knowledge translations to patients (DS, KBL), arrythmia care (KBL, FK), therapeutic relationship (JC, HS), and supportive and palliative care for patients with cardiac conditions (FK). The parent study was led by the supervising author (KBL) with participation from co-author (DS). We acknowledge our team is not exhaustive and does not represent the view of all those involved in the care of patients making decisions about ICDs.

Setting and Participants

Participants were recruited from one specialized arrhythmia site in Ontario, Canada serving about 1.3 million patients and implants on average 280 new implants and 170 replacements yearly (Electrophysiology Triage Coordinator, Personal Communication, May 2023). A shared care model is used meaning that patients may be seen by different healthcare professionals.

We re-analyzed the transcripts of five individual interviews and four focus groups of 1) 10 Patients and 3 family members who had an ICD or a non-replaced/deactivated ICD within the last year, and 2) 17 healthcare professionals with more than 1 year experience working with and making ICD related decisions with patients and families.

Data Collection

Participants provided written informed consent as part of the parent study. Some interviews/focus groups were conducted in person and others via video call due to data collection taking place pre and post COVID hospital lockdowns (February 2020 to September 2021). Individual interviews and focus groups were audio-recorded, transcribed and deidentified. All participants were sent the suite of PDAs (for initial ICD implantation, pulse generator replacement, and deactivation) in both paper and electronic format ahead of their scheduled interview.

Data Analysis

We re-analyzed de-identified transcripts in two groups: patients and family members, then healthcare professionals, guided by Braun and Clarke's thematic analysis framework. [47,48] Using an inductive stepwise yet iterative method based on our research questions, team members (AV, FK) independently read and re-read the transcripts to become familiar with the data; organized data systematically with open coding; and as relevant, mapped preliminary codes onto the therapeutic relationship elements. Both explicit and implicit mention of the therapeutic relationship and its elements were captured. We inferred implicit mention by referring to the element's definition and discussing whether the data represented it. Transcripts were re-examined for similarities and differences, and to ensure that newer codes were reflected in initially analyzed transcripts. AV, FK, and KBL reviewed, discussed, and modified the preliminary codes and grouped them into themes, ensuring that they were supported by the data, coherent, and distinct. All team members reached consensus about the themes through discussion.

Results

We included ten patients, three family members and seventeen health care professionals (Table 2). Patients and family members varied in age with nearly half (n=6; 46.2%) falling in the 50-59 years bracket and most self-identified as men (n=9;69.2%). More than half (n=7, 53.8%) reported a preference for sharing decisions with their healthcare professional while five participants (38.5%) preferred to make the decision on their own. Healthcare professionals were all under age 60 and most self-identified as men (n=10; 58.8%), with some having worked with patients with ICDs for less than 5 years (n=6; 35%) and others more than 16 years (n=3; 17.6%). The sample included people who identified as Caucasian, Black North American, East Indian, Latin American, West Indian, Asian and West Asian.

Table 3*:* Participant Characteristics

	Patients (n=10)	**Family members (n=3)**	**Healthcare professionals (n=17)**
Age (years)			
18-49	1 (10%)		11 (64.7%)
50-59	5 (50%)	1 (33.3%)	6 (35.3%)
60-69	1 (10%)	1 (33.3%)	
70-79	3 (30%)	1 (33.3%)	
Gender			
Male	8 (80%)	1 (33.3%)	10 (58.8%)
Female	2 (20%	2 (66.7%)	7 (41.2%)
Education level			
1. **Some high school/Elementary school**			
2. **High school graduate**	1 (10%)		
3. **Some college or University**	4 (40%)	1 (33.3%)	
4. **University degree**	3 (30%)		

5. **Post graduate University degree**	2 (20%)	2 (66.7%)	
Profession			
Cardiologist			1 (5.9%)
Electrophysiologist			6 (35.3%)
Electrophysiologist fellow			4 (23.5%)
Registered nurse			6 (35.3%)
Experience with ICD (yrs)			
Less or equal to 5	5 (50%)		6 (35.3%)
6-10	4 (40%)		3 (17.6%)
11-15			2 (11.8%)
More than 16	1 (10%)		3 (17.6%)

Is the therapeutic relationship and/or its elements referred to when planning PDA implementation?

Two of our three themes answer our first research question. Each theme is discussed, along with subthemes. Additional quotations by theme and sub-themes are included in Supplemental Table 1. A visual illustration of the results are found in Figure 1.

Pieces of the Puzzle: Some Elements of the Therapeutic Relationship. Participants did not mention the therapeutic relationship by name. Two of its elements, respect and therapeutic communication, were frequently identified as important for PDA use in the context of ICD decision-making. Participants also referred to empathy and trust but more so implicitly. Other elements of a therapeutic relationship such as genuineness, active listening, manifesting a presence and reciprocity were not mentioned.

Therapeutic communication. Therapeutic communication was similarly understood by both participant groups as the sharing of helpful information to make informed and values-based decisions. In many instances, therapeutic communication fell short. Shortcomings were primarily related either to information not being shared, or from misunderstandings. Patients and family members reported inadequate knowledge about the ICD and potential future related decisions. A family member, whose spouse was eligible for an initial ICD, reported*:*

> *There's a lot of information that I still feel I'm lacking. I know that at one point I might have to make some tough decisions but also the more information I have the better I will be equipped and the more I can gently approach the subject with him to also find what his wishes are*.

As a result, some patients and family members took it upon themselves to locate their own information. A patient reported*:*

> *I honestly did not think I'd be able to find the answers to all my questions or get them and I was basically writing them down to ask the doctor and I ended up finding most of the answers to my questions in literature before I even met with the doctor or had a chance to ask them to the doctors*.

These accounts highlight that patients and family members want and need to be informed to participate in decision-making.

Healthcare professionals shared different perspectives. Some reported having conversations with patients and their intentions of sharing knowledge related to future decisions. An electrophysiologist explained their usual script when meeting patients about initial ICD implantation*:*

When we first meet patients and discuss the implantation of an ICD, we talk to them and explain that it fits them for their current circumstance, but those circumstances do change and setting the scene early on means that we build upon that later and particularly when you have the more difficult discussion about deactivation of the device.

A registered nurse reported that patients do not always understand the purpose of their ICD and its implications:

A lot of the times people are being implanted in a position where they're not necessarily aware of the decision that's being made. Like if they come in with an MI (myocardial infarction) and they end up with an ICD, then it's like, "Well you know, what do you mean I have this?"

Respect. Participants from both groups identified *respect* as important for PDA implementation. Participants understood it as respecting the patient's role and voice in the decision-making process. A patient described learning about the right to choose ICD deactivation: *"They told me about that, that I could choose to have it turned off if at any point I no longer want to use it. That it can be done*." A registered nurse shared an encounter during which she acknowledged the importance of eliciting a patient's personal values and preferences and allowing choice:

One of [physician's name]'s cases, Lyme Disease. Now he doesn't need it [ICD]. Do you remove it[ICD]? Right? More than likely his choice is going to be to keep it. ... I'd be like get it out, but so you don't know where people's minds are at.

Participants also shared experiences of not being presented with options. A patient shared his experience facing ICD implantation:

We weren't asked very much. It wasn't like, you know, do you want one, yes or no. It was more like 'you need one. Here it is,' kind of thing.

When an ICD battery is automatically replaced prompted by battery depletion, respect for the patient's voice and wishes is overlooked. A registered nurse offers an example:

> *They don't really think there's a decision there, it's just work. Physicians are… were coming in and just saying, "There we go and …" So there's almost like not an open decision… I mean in certain situations where you think oh is this really something and then it gets discussed. But generally, with a lot of people it's just, oh the battery's low.*

*Empathy***.** Both participant groups raised the importance of *empathy* yet described it differently. Patients and family members described themselves as receiving empathy; the feeling of being reassured that the healthcare professional elicited and acknowledged their personal perspectives and preferences. Healthcare professionals described themselves as givers of empathy; they put themselves into the patient's situation and provide supportive measures. Patients and family members shared mixed experiences with empathy. A patient described a time they felt reassured when their healthcare professional acknowledged and addressed their concern about replacing the ICD. The patient recounted:

> *I asked him, because I was concerned, … And the surgeon said to me, he said, "No, don't worry about it, I will put that probe in before you know, I disconnect it..." Anyway, I was reassured everything was okay*.

Another patient described empathy as a personal, intrinsic characteristic that is displayed in various degrees from one healthcare professional to another: "*I mean don't get me wrong. Doctors are trained but they're not necessarily skilled in that field. They don't all have the same amount of empathy*."

Trust. Patients and family members talked about trust as having confidence in the healthcare professional, being comfortable with them and able to speak when desired. Healthcare professionals described trust as being open and honest with patients and having their patients' best interest at the forefront of their decisions. Patients and family members had mixed experiences with trust while healthcare professionals referred to themselves as being trustworthy.

A patient reported feeling confident in their healthcare professional when deciding about which type of ICD (Subcutaneous ICD versus traditional ICD) to get at initial implantation: "*I was super-impressed with that because I've dealt with a lot of doctors where the bias is the only thing that's influencing your decision. So, yeah, I had a lot of confidence in my medical team because of that*." Another patient shared a different perspective. When they had questions regarding their ICD, they were instructed to contact their healthcare professional with any questions or concerns yet doubted their commitment. The patient shared:

> *They always open the door and say you can talk with your doctor. So confusion. I'm going to send a lot of email to my doctor to ask him about if I can use my massage, my mobile massage machine. I'm not sure, he has a lot of things to do, right? He has a lot of patients. I'm not sure that he will have time to respond to m*e.

Discrepancies between messages and action hindered trust between this patient and their healthcare professional. An electrophysiologist acknowledged the individuality of patients and the importance of their personal beliefs, supports, and context and how these should be viewed alongside the research evidence as an indicator of trust:

It's such a mixture, isn't it, of someone's understanding, their beliefs, their family, those sorts of situations and I think the tools help us to see one thing from an information, from a research perspective maybe, what's the true risk for the patient

Good Intentions and Challenges of Establishing a Therapeutic Relationship.

Building a Relationship. For patients, building therapeutic relationships was about achieving connection and comfort level with certain healthcare professionals. A patient explained: "*I've reached out to (name1) because I feel more comfortable speaking with her one-on-one rather than taking (name2)'s time*" (Patient, Focus Group), a relationship which turned out to be very helpful for them for many years.

Good Intentions. Healthcare professionals described their good intentions of establishing and engaging in relationships with their patients. Specifically, they spoke of their intentions to ensure therapeutic communication and respect. A registered nurse shared her positive intentions about information sharing and respecting the patient's voice when considering ICD replacement:

I think that it's part of the informed consent. If you're going to go on having a replacement, the patient should have all the information possible for making that decision whether they want it replaced or not.

Challenges. A frequent challenge raised by healthcare professionals was that of insufficient time. An electrophysiologist suggested a way to overcome this:

I think that a proactive approach might be the way to mitigate the issue of the time crunch and supply that information there or if we have some kind of like a follow-up conversation that someone calls them, whether it's, you know, one of the nurses or one of the physicians or a

combination or whatever. To outside of the hectic time crunch that device clinic is, initiate that conversation so that it's separate, and you don't have the same pressure.

Other healthcare professionals discussed their discomfort navigating ICD decision-making encounters. For example, a registered nurse shared:

> *I feel like I wouldn't know what to say because we're so not used to talking about it, that like I would need some practice maybe to introduce the subject or because they'll have questions, like "What do you mean? I can have… there's an option that I can have it, like just leave it there?" So I would probably have to be more knowledgeable myself first.*

Although healthcare professionals want to engage with their patients, discomfort rooted in limited knowledge and skills on how to navigate ICD decision-making discussions made it difficult to do so.

Is the implementation of PDAs perceived as requiring or contributing to the therapeutic relationship?

The third and final theme is in direct relevance to our second research question. Additional quotations are included in Table 3.

PDAs can Help Foster Elements of the Therapeutic Relationship. All participants spoke about ways in which the PDAs could encourage therapeutic communication and respect.

Therapeutic Communication. The PDA was valued by both groups for its ability to raise awareness of future potential decisions. A registered nurse agreed: "*It'll give information for the patients to go home and think about and read with their family. So they'll be more informed*." The healthcare professionals considered the PDA as a useful tool to initiate conversations about issues

that they may otherwise find difficult to introduce. A registered nurse shared her perspective about using the PDA about deactivation:

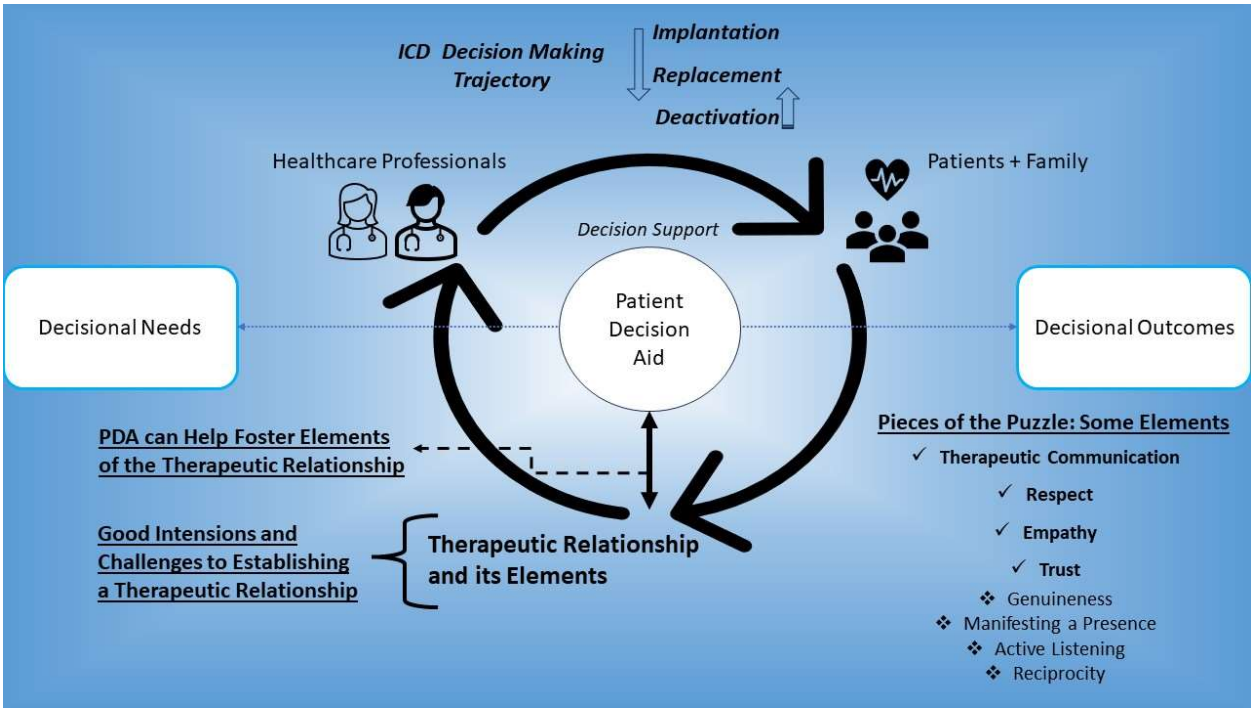
> *Even if they've seen it almost at implant and then [deactivation] is easier to bring up depending on the person, their cognition, it's not like you're just sort of at the last-minute saying, "So what are you still doing with that?*

Respect. With its explicit offering of choice amongst treatment options, the PDA fulfills the element of respect. A patient stated: *"I think that probably the single most important precursor of any of these documents is like, your doctor may be telling you that you need this but you need to decide what's right for you.*" Healthcare professionals agreed, further adding that the PDA can enhance patient knowledge about the options available. A registered nurse shared her perspective about the PDA for battery replacement: "*And to realize, that you've got an option, it's not just like, we're okay we're coming back to replace, it's like you feel like you've got some options here*."

Does Not Stand Alone. Many patients and family members mentioned that the tool should not stand alone and should be used in collaboration with the healthcare professional giving opportunity to foster therapeutic relationships. This belief was grounded in a patient's previous experience with a PDA:

> *I guess that's one thing I worry about with decision guides too, is that the only time I've ever been given one was in a hospital where doctors did not talk to patients. So I do kind of worry about them being used as a replacement for doctors actually being available to answer questions*.

Figure 2: Illustration of Results



Discussion

We explored how the therapeutic relationship and/or its elements are considered when planning the implementation of PDAs for patients facing decisions about ICD therapy. Not one participant mentioned the therapeutic relationship by name, yet many explicitly and implicitly raised elements of the therapeutic relationship. Our findings also suggest that PDAs can encourage therapeutic relationship elements within an encounter. Our observations lead us to three main points of discussion.

The therapeutic relationship and its elements are important to patients' health experiences, yet many of the elements are overlooked in the context of decision support. Although the therapeutic relationship was not explicitly named by participants, participants did refer to the importance of PDAs being used within an encounter with a healthcare professional. A systematic

review of 40 SDM models, frameworks, and theories identified fostering a partnership as an element important to both patients and healthcare professionals. [27] An integrative review of 52 articles revealed relationship building as the first step to SDM in a nursing SDM model. [49] The Ottawa Decision Support Framework also notes establishing a rapport[29]. Yet, these steps within existing SDM models, frameworks, and theories have yet to be dissected in terms of key elements as done with the therapeutic relationship. By doing so, we may enhance our understanding about how a therapeutic relationship can be operationalized to support the implementation of decision support interventions such as PDAs. In our study, only two of the eight therapeutic relationship elements were explicitly identified (i.e., therapeutic communication and respect) and two others implicitly identified (i.e., trust and empathy) which is in keeping with previous studies that have raised the importance of these same elements for SDM. [16,37–39,50,51] Humanistic communication has recently been raised as important to SDM encounters and aligns with some of the therapeutic relationship elements such as therapeutic communication and respect.[52,53] It originates from a commitment to the dignity of each person while actively listening, respecting the patient, acting with compassion, integrity, and empathy in both the manner and the content of interactions.[52] Kunnerman et al.'s[52] systematic review emphasized that warmth, interest, and empathy have been neglected in SDM research. Their findings indicated that studies that evaluate SDM tend to focus primarily on technique such as providing information rather than the quality of the interaction.[52] They reported that trust, clear communication, active listening and empathy contribute to the quality decision-making processes and better patient-healthcare professional relationships.[54,55] A recent qualitative study with Black American patients reported that humanistic communication during SDM is preferred.[53] In this study, healthcare professionals felt the PDA changed the way they approached the encounter which is similar to our findings that the PDA can help foster

elements of the therapeutic relationships.[56] Hence, PDAs may offer an opportunity to promote the development and growth of therapeutic relationships.

In the context of ICDs, a potentially life-saving intervention, PDAs are to be used within an encounter. If used alone, the PDA content may be insufficient to support the decisional needs of patients with ICDs, and may not reach their potential.[18] And our findings align with Rao et al[22] who concluded that a mandate focused on PDA use alone was insufficient to improve patient decision-making and decision quality outcomes. They found no major differences on measures of knowledge, decisional conflict, value choice concordance or patient engagement in patients' who had received their ICD before the mandate and after.[22] This was also suggested by Lewis et al[41,57] who recognized the need for healthcare professionals to tailor a decision support intervention (PDA and decision coaching) based on patients' decisional and healthcare needs. Navigating conversations about life or death cannot be reduced to a tool alone. To tailor decision support to patients' decisional needs about a life-saving therapy and navigate such sensitive discussions, a therapeutic relationship – or at minimum, one characterized by its elements – is desirable.

Given the importance and relevance of therapeutic relationships in SDM, particularly in the context of decisions about life-saving treatments, knowledge and skill-building for establishing them should be integrated into interprofessional team training for PDA implementation use in the clinical setting. For instance, the Ottawa Patient Decision Aids Group includes a communication skill tool based on the Ottawa Decision Support Framework to assist in the provision of decision support that supports therapeutic communication.[58] This tool explains key communication techniques such as listening skills, questioning skills and sending messages, whether providing information or feedback.[58] A recent pilot study, adapted and evaluated a SDM training module for allied health and social care professions which was initially designed for mental healthcare

professionals with the goal of expanding its use to other contexts.[59] This training discussed the components of collaborative relationships as well as the contributions of PDAs to the SDM process using a range of interactive methods (e.g., slide presentations, group exercises and discussions).[59] This mixed-method study explored the views of the participants on the training process with questionnaires and discussions throughout the modules.[59] Participants reported difficulty with introducing the principles of SDM into their relationship with patients and faced challenges such as time as reported in our findings.[59] Cultural and organizational contexts were also reported as influencing their relationships with patients and challenged implementation of their training into practice.[59,60] Although, they agreed that defining the quality of relationships at different levels could improve implementation.[59] Establishing therapeutic relationships or partnerships has not been well included in all healthcare professional training including for SDM, and our findings suggest that it would be pertinent especially when planning to implement PDAs.

Strengths and Limitations

According to Lincoln and Guba's[61] criteria to enhance the trustworthiness and credibility, we triangulated findings between patients/family and healthcare professionals, and triangulated data between team members conducting the analysis. We used data collected from one site, and those with an indication for ICD only without cardiac resynchronization. Perhaps patients, family members, and healthcare professionals from other sites and with other types of cardiac devices have had different experiences and expectations. Although many ethnicities/races were represented in our sample, further cross-cultural research is indicated to explore the transferability to other clinical and cultural contexts. Given the secondary use of data, interview questions did not explicitly pertain to the therapeutic relationship. Hence, the lack of mention of the elements of genuineness, active listening, manifesting a presence and reciprocity does not mean they are not

important. Primary studies are required to investigate this directly. Finally, while findings from a secondary analysis may not be considered formally transferable, it can further our understanding of the role of the therapeutic relationship when planning PDA implementation.

Conclusion

Our findings suggest that certain elements of the therapeutic relationship, in particular therapeutic communication, respect, empathy and trust, are important for PDA implementation. The therapeutic relationship and its elements should be considered when developing implementation strategies as PDA and when measuring their use. Further research is needed to explore the role and importance of the other therapeutic relationship elements of genuineness, manifesting a presence, active listening, and reciprocity.

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Supplemental Table 1: Additional Quotations

Sub-themes	**Quotes**
Theme 1: Pieces of the Puzzle: Some Elements of the Therapeutic Relationship	
Therapeutic Communication	Example of therapeutic communication: *''when we first meet patients and discuss the implantation of an ICD, we talk to them and explain that it fits them for their current circumstance, but those circumstances do change and setting the scene early on means that we build upon that later and particularly when you have the more difficult discussion about deactivation of the device''* (Electrophysiologist, Focus Group)
	Example of poor therapeutic communication: *"I don't think it was ever told to me when it was installed that, you know, to look 50 years ahead that when, you know, how do you turn it off or when do you get rid of it, and we never really talked about that because my understanding was it's a permanent thing to have, right"* (Patient, Focus Group) "W*e had somebody on the wing, they're like, "What? You've changed my what?" And so they don't know what's actually being implanted a lot of the time. Right?''* (Registered Nurse, Focus Group)
	Consequences of poor therapeutic communication:

	"But he said probably what's going to happen is you're going to leave here with an ICD. So, basically that was my cue to start doing my research. [Laughs] And yeah, I mean, I basically knew that I had to make a decision fast because if I wanted to avail myself of the options that [city]had you know, it's not like I could just… I had the liberty of you know, well I'm going to go home for a few weeks and think about it, it's like you know, I have to learn everything I can and then decide what I want.'' (Patient, Interview)
Respect (for patient role and voice in the decision-making process)	Example of respect for patient's voice in decision-making: *"It was like here, you know, basically our involvement (physician) in your decision-making stops where the science stops. And to me, that's like a perfect doctor/patient relationship. It's like you tell, you get me, you know you tell me what the science is but I'll [0:29:56, inaudible/audio cuts out] my lifestyle will be impacted and whether you know, what's, you know, whether the benefits outweigh the harms or whatever, right."* (Patient, Interview)
	Example of limited respect for patient's voice in decision-making: *"I mean at replacement as I understand it, they basically said well it's time for a new one and I said yes and I guess it was never really raised that I don't need it anymore"* (Patient, Focus Group)
	Theme 2: Good Intentions and Challenges of Establishing a Therapeutic Relationship.
Building a Relationship	Establishing a relationship:

	"I really enjoy the people that you have to educate us about the procedure, the medication and what to expect, how it all works. It's been a lifeline for me." (Family Member, Focus Group)
Good Intentions	Positive intention toward therapeutic communication: *"To better inform the patient. Like I don't think any of us wouldn't want to do that, because we're sending them out there and okay, here's your decision and having seen some pretty nasty infections in people that may not'' ''that may have decided not to if they knew the risks and such. I think we're all for giving them as much information as we can possibly provide them."* (Registered Nurse, Focus Group)
Challenges	Time as a challenge to decision-making discussions: *"Like I don't like having these discussions in the device clinic, I find it takes too much time and, you know, I can show them all the tools and they could have read all of them but, you know, if I'm sitting there for half an hour it's kind of... I'm not sure how good of a job I would do, you know, no matter what training you give me at that time."* (Electrophysiologist, Focus Group)
	Discomfort navigating decision-making discussions :

	"Patients may have questions that I don't really know how to answer necessarily." (Registered Nurse, Focus Group).
Theme 3: PDAs can Help Foster Elements of the Therapeutic Relationship	
Therapeutic Communication	PDA as an informative tool: *"To better inform the patient. Like I don't think any of us wouldn't want to do that, because we're sending them out there and okay, here's your decision and having seen some pretty nasty infections in people that may have decided not to if they knew the risks and such. I think we're all for giving them as much information as we can possibly provide them."* (Registered Nurse, Focus Group) "*I think that's it's a part of the informed consent. If you're going to go on having a replacement, the patient should have all the information possible for making that decision whether they want it replaced or not."* (Registered nurse, Focus Group)
Respect (raising options)	PDA seen as a means for raising choice: *"If there's something I like about it (PDA), I mean there was at least one that spelled that out a little bit and said, you know, you get to choose. I mean it clearly, like you know, you get to choose if this is right for you or not. And I think maybe that's like a really important thing to have like at the very beginning of these. Like no*

	matter what your doctor says, this is your choice. Because I think a lot of patients don't feel that way, like they feel like if their doctor says it, then that's what happens." (Patient, Interview).
Does Not Stand Alone	Needs to be used with an encounter: "*I think it's not a pamphlet you just want to throw at somebody without the doctor first talking to them''* (Patient, Focus Group) "*have even a nurse talk them through the pamphlet might be useful as well"* (Patient, Focus Group).

Chapter 5

Integrated Discussion

The aims of this final chapter were three-fold. First, I summarized the findings of the thesis, including the literature review, theoretical underpinnings, and the qualitative investigation. Second, I discussed the findings within existing empirical and theoretical literature. Third, I offered implications for nursing practice, education, and research.

Summary of the Thesis

The purpose of this thesis was to determine how the therapeutic relationship is considered when planning PDA implementation for patients eligible for or with an implantable cardioverter-defibrillator (ICD). In the literature review (Chapter 2), it reveals that SDM is particularly relevant for ICD therapy, as indicated by the development and evaluation of decision support interventions (e.g., patient decision aids, decision coaching) for the decision to initially implant the device and replace the pulse generator. However, the role of the therapeutic relationship had not been explored in this context. It has, however been explored in the mental health and tertiary settings where the therapeutic relationship elements of trust and communication were described as important facilitators of SDM. Then, I conducted a secondary analysis of transcripts of interviews and focus groups with healthcare professionals, family members and patients from one Canadian tertiary care site eligible or receiving ICD therapy using Thorne's (2016) interpretive descriptive approach (Chapter 3). To ground my study, I used a theoretical scaffolding approach as proposed by Thorne (2016). I used the Ottawa Decision Support Framework (ODSF) and the therapeutic relationship elements (Chapter 3). Specifically, I referred to the elements of empathy, trust, respect, genuineness, manifesting a presence, therapeutic communication, active listening, and reciprocity, as described by Chalifour (1999),Geller (2020), Horner (2020), Phaneuf (2011), Servellen (2009) and Yu et al. (2019). This theoretical scaffolding permitted exploration of the therapeutic

relationship elements during decision support; a unique union of concepts that has not yet been described.

In the secondary analysis, my qualitative inquiry revealed three themes (Chapter 4). The first theme *Pieces of the Puzzle: Some Elements of the Therapeutic Relationship* demonstrated that respect and therapeutic communication were explicitly expressed as important for PDA use. Participants also referred to empathy and trust, although implicitly. The other therapeutic relationship elements (i.e., genuineness, manifesting a presence, active listening, and reciprocity) were not mentioned. The second theme *Good Intentions and Challenges of Establishing a Therapeutic Relationship* revealed that healthcare professionals have good intentions towards establishing therapeutic relationships with patients, in particular using therapeutic communication and respect. However, they reported challenges such as inadequate time and being ill-equipped and uncomfortable navigating ICD decision-making discussions, limiting their ability to establish therapeutic relationships. The third theme *PDAs can Help Foster Elements of the Therapeutic Relationship* discussed ways in which the PDAs could specifically encourage therapeutic communication and respect, while the other elements were not noted. It also reaffirmed that PDAs are not intended to be used as stand-alone tools and should be used to enhance consultation with a healthcare professional.

Integrated Discussion

The overarching findings of this thesis lead me to three main points of discussion. First, I discussed the role of the therapeutic relationship as contributing to informed and value-based decision making. Second, I discussed the need to revisit consent throughout the ICD process. Third, I discussed the relevance of integrating and expanding on the therapeutic relationship and its elements in the Ottawa Decision Support Framework.

Therapeutic Relationship Elements Contributing to Informed and Value-Based Decision Making. The therapeutic relationship offers opportunity to improve and contribute to informed and value-based decision making. As revealed in the literature review (Chapter 2), patients eligible for or who have an ICD, experience a significant degree of misunderstanding and inaccurate recall of information regarding the function of their ICD (Lewis et al., 2014a). Some patients experience decision regret as a result; not fully understanding the implications of the treatment at the time of consent (Barisone et al., 2022; Mooney et al., 2019; Standing et al., 2016). The results of the qualitative investigation suggest that elements of the therapeutic relationship can offer opportunity to support and improve decision support encounters between patients and healthcare professionals (Chapter 4). In this study, I revealed that therapeutic communication and respect were important during the ICD decision-making trajectory and for PDA implementation in this context (Chapter 4). When therapeutic communication is suboptimal between patients and healthcare professionals, patients may not receive the necessary information to fully understand the potential consequences of the implantation or replacement procedures. This results in inadequate knowledge, and ultimately impacts the degree to which the consent process is truly informed.

Informed consent is defined as an interaction between patients and healthcare professionals that leads to full knowledge and understanding of risks and benefits and available options before acceptance of care, treatment, or services (The Consent Act, 1996; Spatz et al., 2016). For refusal of treatment, patients tend not to sign consent. Although, healthcare professionals would document refusal of treatment in the patient chart. Patients and healthcare professionals shared experiences of suboptimal therapeutic communication which affected patient and family members' understanding of the risks of the procedure to receive the device, and the implications of living

with it. This was noted in patients considering initial implantation, and those at the point of replacement, demonstrating that many are living with a device that they do not fully comprehend. Numerous authors have reported inadequate knowledge in patients considering or with an ICD (Lewis et al., 2014c; Lewis et al., 2014a; Mooney et al., 2019; Standing et al., 2016). It is then understandable that some patients may be opting for procedures that they would otherwise not agree to, leading to costly, unwanted and unnecessary procedures (Moulton et al., 2013). In fact, Lewis et al. (2014c) had found that 14.2% (n=106) of patients would have opted not to replace their ICD generator had they been aware of the option of non-replacement (Chapter 2). In a later study, it was reported that ICD replacement is largely an automatic process where healthcare professionals proceed with the pulse generator replacement without thoroughly discussing available options with patients (Lewis et al., 2018). Further, Varghese et al. (2020) found that 10% (n=434) of ICD recipients regretted their decision after implant and reported a lack of preoperative information as a predictor of regret. Other predictors included educational levels, ICD complications and experiencing anxiety and depression in relation with therapy. Similarly, Green et al. (2016) found that 19% (n=295) of patients reported not wanting their ICD at the time of implant. The findings from these studies are like those revealed in my study, where many patients revealed they were not presented with the options (Chapter 4).

Therapeutic communication could be utilized to decrease decision regret, improve patient involvement in decision-making and increase information exchange between the healthcare professional and patient. In the context of SDM, conceptualizing respect as offering choices amongst treatment options, explaining procedures before carrying them out, and allowing all patients the same access to resources and knowledge about their ICD regardless of their sociodemographic characteristics, health history, and personal and social identities could result in

higher quality decisions. In summary, the quality of patients' and family members' decisions throughout ICD trajectory risks being suboptimal unless they fully understand all related implications, options, and possible complications. The establishment of a therapeutic relationship may help avoid this.

Revising Consent Throughout ICD Therapy. There are specific implications for informed consent in the context of ICD therapy. Some patients may live many years – some decades – with an ICD. Given this lengthy tenure, there is potential for altered goals of care and treatment preferences as time goes on due to lived experiences with the device. This includes the influence of lived experiences on anxiety, depression, and post-traumatic stress from the internal shocks, or improvement or deterioration of the health condition which could impact their motivation for having the device or not (Eiser et al., 2018; Lewis et al., 2014). Hence, healthcare professionals should assure ongoing consent throughout the ICD trajectory (Lewis et al., 2014). These patients are followed in the cardiac device clinic every six months, hence there are frequent touch points to remind patients of this and to assess their lived experience with the device. The therapeutic relationship is a means to attain an understanding of the patients' experience within their health condition and the treatments they receive (Chapter 3) (Chalifour, 1999; Doherty & Thompson, 2014; Phaneuf, 2011; Sylvestre et al., 2020). The therapeutic relationship and its elements can facilitate exploration of the patient's understanding, preferences, and goals by encouraging the sharing of helpful information (therapeutic communication), offering options, and respecting the patient's voice in the decision (respect) and establishing comfort and commitment (trust) by the healthcare professional throughout the ICD trajectory. Such an approach assures that ongoing consent is achievable (Chapter 4). At present, the initial ICD implantation consent process tends to focus on periprocedural risks during the implantation procedure and recovery

(Eiser et al., 2018). Future decisions such as battery replacement and the possibility of deactivation should be discussed in the initial consent discussions and throughout the trajectory (Eiser et al., 2018; Joyce et al., 2013; Maclver et al., 2016). In addition, there are persistent quality of life considerations such as possible driving restrictions, potential impact on psychological well-being, impact on sexual activity and inaccurate shocks among others that need to be addressed (Eiser et al., 2018). These lifestyle considerations are included in the PDAs and can facilitate the ongoing consent process by assuring that patients are knowledgeable and understand the implications of their chosen option.

Beyond this, my findings suggest that PDAs can help foster therapeutic relationship elements, in particular therapeutic communication and respect. This is particularly helpful for the context in which the study was conducted, given the device clinic's shared care model. Meaning that patients may be seen by different healthcare professionals for different visits. It was also recently reported that patients who received a PDA were more likely to report complete trust in their healthcare professional (Brodney et al., 2022). This comparative survey study (n=700) found that the PDA effect on trust can be attributed to the increase in SDM Process Score, indicating that patients had greater involvement in decision-making (Brodney et al., 2022). The authors concluded that providing patients with a PDA will improve trust which may improve communication between healthcare professionals and patients helping them make better health decisions (Brodney et al., 2022). It was established that an effective patient-healthcare professional relationship is a facilitator to SDM and that patients tend to be more involved in decision-making if trust and respect are present (Alsulamy et al., 2020; Keij et al., 2023; Younas et al., 2016). Fostering the therapeutic relationship and its elements within decision support interventions seems to be complimentary and facilitates proper informed consent and value-based decision making.

Integration of the Therapeutic Relationship in the ODSF. At present, there is limited consideration of the therapeutic relationship and its elements in shared decision-making models, including the Ottawa Decision Support Framework (ODSF). The ODSF is one of the most used frameworks for PDA development. I initially aimed to solely use the ODSF to guide this study as it guided the parent study and it provided patients with a decision support intervention to improve their health outcomes. Although, despite the 2020 revised ODSF listing "establishing rapport and communication", it does not go into great depth describing what is required to successfully achieve these steps, nor does it expand on its role and importance in the provision of decision support.

In 1998, Bunn and colleagues reported that effective communication skills are essential to providing quality decision support and are central to any helping relationship. Furthermore, they developed a resource for considering the influence of communication on decision support. The ODSF includes a *communication skill tool to assist in providing decision support* which was adapted by Bunn et al.'s (1998) work. This resource briefly describes key communication techniques such as listening skills, questioning skills and sending messages (providing feedback and providing information) that are arguably still relevant in our current times, yet it remains that it is over 25 years old and warrants revision (Bunn et al., 1998). "Establishing a rapport and communication" was added to the ODSF as a result of Loiselle et al. (2021)'s research. Loiselle et al. (2021) reported that a trusting relationship enabled patients to participate in decision-making. However, this study did not define the meaning of *rapport* any further.

Rapport is commonly referred to as fundamental to clinical relationships. In a scoping review of 34 studies, English et al. (2021) revealed that "rapport" is generally a vague term with multiple definitions and conceptualizations as reported by various authors/sources. It appears that rapport and relationship are used interchangeably in literature, given distinct similarities. Both

rapport and relationships are focused on 1) building a connection with patients based on respect, empathy, harmony and commitment (Epstein & Street, 2007; Insua-Summerhays et al., 2018); and 2) the use of verbal and non-verbal communication to achieve that connection. Given the therapeutic relationship has a much more established definition from frequently cited sources, the term may be more commonly used.

Our findings confirmed the importance of establishing rapport in the ODSF. It may be reasonable to consider integrating elements of the therapeutic relationship within the ODSF's pillar of decision support interventions, in particular expanding on building rapport and communication. In addition, modifications could be considered to ODSF based tools such as the coding manual and the communication skill tool. I acknowledge that more research is needed in this space, given my findings are a result of a secondary analysis. These reflections can be used to consider the value-add of the therapeutic relationship to enhance the relational requirement of decision support and to demonstrate that PDAs are not intended to be used as stand-alone tools (Stacey et al., 2023; Stacey et al., 2017). At a minimum, greater attention to the therapeutic relationship is warranted in SDM, as its goal of patient engagement in health decisions aligns with those of SDM and patient-centred care (Alsulamy et al., 2020; Covvey et al., 2019; Huang et al., 2022; Kalocsai et al., 2018; Kunneman et al., 2020; Waddell et al., 2021).

Nursing Implications

Implications for Practice

The findings of this project raise implications for clinical practice for nurses and members of the interprofessional team. First, they suggest that attention is warranted to the establishment of a therapeutic relationship, and at a minimum some of its elements, when using PDAs with patients

eligible for or with an ICD. Nurses are key members of interprofessional teams. It is within their scope of practice to engage patients in decision-making with decision support interventions (PDAs and decision coaching) (Lewis et al., 2016). The therapeutic relationship is also central to nursing practice (Lewis et al., 2014; Olling et al., 2021; Registered Nurses Association of Ontario [RNAO], 2006; Truglio-Londrigan & Slyer, 2018). Nurses and other interprofessional team members wanting to engage in effective therapeutic relationships must acquire different forms of knowledge, as suggested by the RNAO (2006). These include: 1) the healthcare professional's background knowledge (e.g., education, personal life, and professional work experience); 2) theoretical knowledge of interpersonal and developmental theories to gain an understanding of the development of the sense of self and how it influences our way of being with others (Erikson, 1963; Freud, 1912; Orlando, 1961; Peplau, 1952); 3) knowledge of the patient including their values, preferences, and life circumstances; 4) knowledge of the patient's health condition including symptoms, actual and potential interventions, medications and best practices as well as other possible healthcare influences (accessibility, resources) that could affect the patient is useful; and 5) knowledge of the healthcare system itself and how it operates to help guide the patient to navigate it with assistance.

This knowledge base supports healthcare professionals to ensure that therapeutic relationships are effective when treating patients in the device clinic and/or in virtual care. The nurses and other health professionals will ideally feel more prepared to navigate the interaction and explore the patient's needs. The PDA has been found to foster elements of the therapeutic relationship (therapeutic communication and respect) which could be beneficial when attempting to engage in SDM with this population (Chapter 4). Using the PDA before and during consultation with patients considering or receiving ICD therapy should improve communication and respect.

Self-reflection is highly recommended when engaging in therapeutic relationships. As nurses or healthcare professionals get to know themselves, self-reflection allows for them to act purposefully rather than automatically, thus creating genuine relationships (RNAO, 2006). The ability to self-reflect on our personal practice, thoughts, feelings, needs, fears, strengths and weaknesses, and understanding how these might affect nursing practice and healthcare professional-patient relationships, is referred to as reflective practice (RNAO, 2006). Healthcare professionals should have capacities of self-awareness, self-knowledge, empathy and awareness of boundaries and limits of the professional role as part of their reflective practice (RNAO, 2006). One can engage in reflective practice individually and/or under clinical supervision where exploration of the healthcare professionals' role in the therapeutic relationship can be addressed. It is an opportunity for personal and professional growth without penalties or judgment to promote quality in practice (RNAO, 2006).

Implications for Education

To acquire the forms of knowledge to establish effective therapeutic relationships outlined above, nurses and members of the interprofessional team involved in the management of patients eligible for or that have and ICD, require more support. Training targeting working professionals could be provided by cardiac devices clinics in the form of modules explaining collaborative relationships in SDM. A SDM training module was recently adapted and evaluated in a pilot study (Gutman et al., 2021). The training addressed SDM as well as PDAs with a focus on collaborative relationships using a range of interactive methods (eg., slide presentations). Findings suggest that defining relationships could improve SDM implementation. A similar training could be given to interprofessional teams across cardiac devices clinics. Given therapeutic relationships are not limited to this clinical setting, this training can begin in all entry-level nursing programs and

undergraduate studies for all healthcare professionals (RNAO, 2006). It can be integrated using various pedagogical approaches. For example, lectures can address theoretical content about the therapeutic relationship elements and associated theories which would increase knowledge among healthcare professionals. Simulation laboratories could focus on communication skills, offering a safe space to practice these skills and increase familiarity, comfort and confidence prior to entering a real clinical setting. Clinical placements and practicums could encourage the observation of clinicians working with patients, seeking the therapeutic relationship in action (RNAO, 2006). Post-clinical conferences could facilitate student group discussions on the topic and identify areas for growth. For nurses and healthcare professionals in practice, a reflective practice approach is encouraged to improve therapeutic relationships (College of Nurses of Ontario, 2006; RNAO, 2006). Team debriefing after incidents and promoting positive interprofessional relations will help staff feel supported and promote a learning environment. Engaging in true therapeutic relationships requires time which is a finite resource in healthcare amidst clinical demands. As much as possible, organizations should be mindful of this and assure adequate time to ensure healthcare professionals' wellbeing as vital to the development of therapeutic relationships, and ultimately the patients' healthcare experiences and satisfaction, including the healthcare professionals' experience (RNAO, 2006).

Implications for Research

It remains that this thesis was a secondary analysis of a study that did not include the therapeutic relationship as its main focus. Primary research is required to explore the relevance of the therapeutic relationship as a whole and its other elements not mentioned in this study including genuineness, manifesting a presence and reciprocity. This will further knowledge about their relevance and how they might be used to enhance SDM and decision support intervention

implementation and use in clinical practice. Observing interactions between patients and healthcare professionals during decision support may be useful to gain a more accurate understanding of the degree and depth of therapeutic relationships during SDM encounters. Further qualitative research is warranted to explore the perspectives of patients, family members, nurses and other healthcare professionals of therapeutic relationship interactions, and to further understand the link between therapeutic relationship elements and decision support.

In addition, feelings and emotions between the patient and healthcare professionals also play an important role in therapeutic relationships (Chalifour, 1999; Mirhaghi et al., 2017; Phaneuf, 2011; Sylvestre et al., 2020). However, these were not explored in our study. Further research is required to explore the role and presence of feelings and emotions during interactions that incorporate decision support interventions such as PDAs.

Strengths and Limitations

This thesis is novel in that it explored the role of the therapeutic relationship, a particular and specific type of partnership focused on patients' goal in the setting of decision support intervention implementation. I was unable to identify the existence of a model/theory/framework and analysis tool to understand the connection between the therapeutic relationship and decision support, hence, I created my own analysis tool and theoretical scaffolding (Thorne, 2016). Both were revised with input from the research team. The theoretical scaffold highlighted that certain therapeutic relationship elements are important, and more research is required to fully understand this. In conducting this thesis, I was supported by a team of experts with various perspectives on SDM, PDA implementation and the therapeutic relationship as well as experience in research, clinical practice, and undergraduate nursing education. Data analysis was triangulated to increase

rigor as the analysis was conducted by various team members with different roles and perspectives. Data was triangulated between patients/families and healthcare professionals. Trustworthiness and credibility were also enhanced with an audit trail.

This thesis is not without limitations. Many writings on the therapeutic relationship exist and even though a theoretical scaffolding approach was used, it is likely that not all important concepts/elements were addressed. However, my theoretical scaffolding clearly defined the elements that were explored based on literature. Even though the analysis tool was revised by team members, we note that it is not a formally validated tool. As this is a secondary analysis, it was impossible to control the collected data and its quality (Fortin & Gagnon, 2016). We could not integrate any theoretical perspective about the therapeutic relationship to the interview guide limiting exploration of the concept.

Conclusion

The therapeutic relationship is an important component of nursing care for patients in any setting, including for those eligible for and with ICDs. In this thesis, I explored how the therapeutic relationship is taken into account when considering implementation of PDAs in patients eligible for or with an ICD. According to the interviews and focus groups with patients, family members, and healthcare professionals from one Canadian site, we found that the therapeutic relationship elements of therapeutic communication and respect were frequently identified as important for PDA implementation. The elements of empathy and trust were identified more so implicitly and that the other elements (genuineness, manifesting a presence, active listening, and reciprocity) were not mentioned. Healthcare professionals described their good intentions towards ensuring therapeutic communication and respect. Challenges to engaging in therapeutic relationships

included a lack of time and discomfort navigating decision-making encounters. Our findings confirmed "establishing rapport" in ODSF. Lastly, we found that the PDA can help foster the elements of therapeutic communication and respect and PDAs should be used in collaboration with a healthcare professional. In the future, the therapeutic relationship and its elements should be considered when implementing decision support interventions.

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Appendix A: Personal Communication

RE: Ethics application for secondary analysis

Keri Cullen <kecullen@ohri.ca>

Mon 9/26/2022 10:11 AM

[redacted]

Attention : courriel externe | external email

Hi Krystina,

No need to forward the Protocol. If this is a uOttawa nursing student project that will take place at uOttawa and your role is supervision, OHSN-REB review/approval is not required – the study would need to go through uOttawa REB.

Thank you for checking – let me know if you have any other questions.

Keri Cullen (she/her | elle)
Research Ethics Coordinator | Coordonnatrice en éthique de la recherche
Ottawa Health Science Network Research Ethics Board (OHSN-REB) | Conseil d'éthique de la recherche du réseau de science de la santé d'Ottawa
Ottawa Hospital Research Institute | Institute de recherche de l'Hôpital d'Ottawa

The Ottawa Hospital Research Institute | L'Hôpital d'Ottawa Institut de recherche

Inspired by research. Driven by compassion.
Inspiré par recherche. Guidé par la compassion.

725 Parkdale Avenue, Ottawa, ON, K1Y 4E9

[redacted]

Appendix B: Search History

Medline- Ovid

▼ Search History (23) View Sa

	# ▲	Searches	Results	Type	Actions	Annotations
☐	1	Decision Support Techniques/	22277	Advanced	Display Results More	
☐	2	Decision support tools.mp.	1749	Advanced	Display Results More	
☐	3	PDAS.mp.	1145	Advanced	Display Results More	
☐	4	patient decision aid*s.ti,ab,kf.	578	Advanced	Display Results More	
☐	5	1 or 2 or 3 or 4	24992	Advanced	Display Results More	
☐	6	shared decison making.ti,ab,kf.	2	Advanced	Display Results More	
☐	7	Decision Making, Shared/ or Decision Making/ or shared decision making*.mp. or Patient Participation/	133248	Advanced	Display Results More	
☐	8	6 or 7	133248	Advanced	Display Results More	
☐	9	Defibrillators, Implantable/	18711	Advanced	Display Results More	
☐	10	(implantable cardioverter defibrillator*s or Internal cardioverter-defibrillator*).ti,ab,kf.	4617	Advanced	Display Results More	
☐	11	9 or 10	19768	Advanced	Display Results More	
☐	12	Nurse-Patient Relations/	35980	Advanced	Display Results More	
☐	13	nurse-patient relationship*.ti,ab,kf.	1127	Advanced	Display Results More	
☐	14	therapeutic relationship*.ti,ab,kf.	3770	Advanced	Display Results More	
☐	15	nurse-patient partnership*.ti,ab,kf.	15	Advanced	Display Results More	
☐	16	therapeutic alliance*.ti,ab,kf.	3219	Advanced	Display Results More	
☐	17	Patient Participation/ or Nurse-Patient Relations/ or Nurse's Role/	100131	Advanced	Display Results More	
☐	18	12 or 13 or 14 or 15 or 16 or 17	106567	Advanced	Display Results More	
☐	19	5 and 8 and 11 and 18	5	Advanced	Display Results More	
☐	20	5 and 8 and 11	14	Advanced	Display Results More	
☐	21	5 and 8 and 18	1241	Advanced	Display Results More	
☐	22	8 and 11 and 18	43	Advanced	Display Results More	
☐	23	8 and 18	30418	Advanced	Display Results More	

CIHNAL

	Search ID#	Search Terms	Search Options	Actions
☐	S10	S2 AND S3 AND S4	**Expanders** - Apply related words; Apply equivalent subjects **Search modes** - Boolean/Phrase	View Results (0) | View Details | Edit
☐	S9	S1 AND S2	**Expanders** - Apply related words; Apply equivalent subjects **Search modes** - Boolean/Phrase	View Results (1,092) | View Details | Edit
☐	S8	S2 AND S4	**Expanders** - Apply related words; Apply equivalent subjects **Search modes** - Boolean/Phrase	View Results (214) | View Details | Edit
☐	S7	S2 AND S3	**Expanders** - Apply related words; Apply equivalent subjects **Search modes** - Boolean/Phrase	View Results (196) | View Details | Edit
☐	S6	S1 AND S2 AND S3	**Expanders** - Apply related words; Apply equivalent subjects **Search modes** - Boolean/Phrase	View Results (6) | View Details | Edit
☐	S5	S1 AND S2 AND S3 AND S4	**Expanders** - Apply related words; Apply equivalent subjects **Search modes** - Boolean/Phrase	View Results (0) | View Details | Edit
☐	S4	TI (therapeutic relationship or therapeutic alliance or nurse-patient partnership) OR AB (therapeutic relationship or therapeutic alliance or nurse-patient partnership)	**Expanders** - Apply related words; Apply equivalent subjects **Search modes** - Boolean/Phrase	View Results (5,750) | View Details | Edit
☐	S3	TI (implantable cardioverter defibrillator OR internal cardioverter defibrillator OR ICD) OR AB (implantable cardioverter defibrillator OR internal cardioverter defibrillator OR ICD)	**Expanders** - Apply related words; Apply equivalent subjects **Search modes** - Boolean/Phrase	View Results (11,107) | View Details | Edit
☐	S2	TI (Shared decision making OR decision making OR Shared decision-making) OR AB (Shared decision making OR decision making OR Shared decision-making)	**Expanders** - Apply related words; Apply equivalent subjects **Search modes** - Boolean/Phrase	View Results (81,515) | View Details | Edit
☐	S1	TI (Decision support tools OR PDAS OR Patient decision aids) OR AB (Decision support tools OR PDAS OR Patient decision aids)	**Expanders** - Apply related words; Apply equivalent subjects **Search modes** - Boolean/Phrase	View Results (5,135) | View Details | Edit

Appendix C: Included Articles

Authors, Year, Country	Aim	Methodology	Study Design	Data source	Participants	Results
Ali-Ahmed et al. (2019). US	Determine if and how physicians are incorporating SDM in counselling patients about ICD and if they are aware of sex and race-based differences in patients' perceptions of ICDs.	Quantitative	Cross-sectional study	Survey	Physicians (n=124)	Most physicians (88%) stated they engaged in SDM during the general consent process. Sixty-three (62%) physicians discuss end of life issues while obtaining general consent. Forty-four (43%) physicians said they use an existing SDM tool with the Colorado SDM tool being the most common (39, 89%).
Alsulamy et al. (2020) Various (UK, USA, CAN..)	Provide a summation of evidence base of key barriers and facilitators to implementing SDM.	Mixed-method	Umbrella review	Systematic reviews (n=5) and scoping reviews (n=2)	Peer Reviewed Literature	Five themes identified were: patient factors, professional factors, environmental factors, relationship factors, and factors related to information provision.
Barisone et al. (2022) Various.	Explore and synthesize the results of qualitative studies addressing the experiences of patients with an ICD.	Qualitative	Systematic review and meta-synthesis	24 studies	Peer Reviewed Literature	Six themes emerged: fear and insecurity, the need for information, new impacts on life, living with ICD shocks, gender differences, and the role of the family.
Beyene et al. (2018) Norway	Explore how mental healthcare professionals describe SDM in a therapeutic milieu.	Qualitative	Explorative and Descriptive	Focus group	Mental healthcare professionals: nurses (n=7), social educators (n=1)	The theme, practicing SDM when balancing between power and responsibility to form safe care, was based on three categories: internalizing the mental health-care professionals' attributes, facilitating patient participation, and creating a culture of trust.

Authors, Year, Country	Aim	Methodology	Study Design	Data source	Participants	Results
Bunn et al. (1998)	Examine the role of communication in the practitioner-client interview; Outline a structure for providing tailored decision support through the interview process based on the ODSF.	Qualitative	Discussion paper with Case Study	N/A.	Peer Reviewed Literature	The Practitioner's Decision Support Analysis tool is used to evaluate the process of decision support and related communication.
Carroll et al. (2011) Canada	Explore the decision-making process for patients who accept or decline an ICD for primary prevention of SCD	Qualitative	Grounded theory	Interviews	Patients considering ICD implantation (n=44)	Patients decision-making approaches fell along a continuum, from active and engaged to passive and indifferent. Patients' approaches were influenced most by the following: (i) trust; (ii) social influences and (iii) health state.
Carroll et al. (2011) Canada	Test the feasibility and evaluate the preliminary effects of the ICD-specific PDA. Determine if differences in preliminary effects (decision quality) are present post-ICD implantation.	Quantitative	Randomized control trial	Questionnaire, Decisional conflict scale	Patients referred for a primary prevention ICD	ICD candidates who received the PDA intervention experienced less decisional conflict.
Choi et al. (2019)	Increase the percentage of discussions regarding ICD deactivation in both the comfort care and DNR cohorts.	Quantitative	Comparative study	Survey and Chart Reviews	HCP and patients on medicine and cardiology services made DNR/comfort care.	The rates of discussions regarding deactivation of ICDs improved from 50% to 93% in comfort care patients and from 32% to 70% in DNR patients. The rates of deactivated ICDs improved from 45% to 73% in comfort care patients and from 29% to 40% in DNR patients.

Authors, Year, Country	Aim	Methodology	Study Design	Data source	Participants	Results
Chung et al. (2021) Various	Examine and assess SDM methodology, tools, and available evidence on outcomes in patients with heart rhythm disorders to help determine the value of SDM.	Mixed method	Review	N/A	Peer Reviewed Literature	SDM may be particularly relevant in patients at high risk for device implants or procedures, or in areas of incomplete evidence, as in some decisions on pacing, CRT, ablation, genetic testing, and sports participation.
Covvey et al. (2019) US	Examine the patient-related barriers and facilitators to SDM in oncology care.	Qualitative synthesis	Systematic review	Systematic review (n=35)	Peer reviewed literature	Themes for facilitators for SDM included physician consideration of patient preferences, positive physician actions and behaviors, and use or encouragement of support systems.
Daniela et al. (2021) Netherlands	Explore patient, clinician, and organizational success factors for implementing a PDA in oncology care.	Quantitative	Pre and post implementation trial	Data tracking and questionnaires	Patient with Breast Cancer	If the report of the multidisciplinary team stated that radiation treatment "had to be discussed with the patient", patients were more likely to use the PDA.
Ehrlich & Dannapfel (2017) Australia	Investigate the current experience of people with severe mental illness regarding their physical health.	Qualitative	Explorative	Semi-structured Interviews	Patients (n=32) with mental illness	All participants stated that their relationship with their GP was important. Qualities such as being respectful, understanding, supportive and making participants feel comfortable by taking their issues seriously were valued highly
Fisher et al. (2018) Australia	Explore clinicians' views and experiences of Bipolar II disorder treatment decision-making.	Qualitative	Explorative	Semi-structured interviews	Clinicians (n=20)	Half of the clinicians, irrespective of patient involvement preferences, reported that a strong, collaborative therapeutic relationship founded on mutual trust was imperative to good treatment decision-making

Authors, Year, Country	Aim	Methodology	Study Design	Data source	Participants	Results
Green et al. (2016) US	Explore patients' perceptions of their decision-making experiences related to ICDs.	Quantitative	Cross-sectional study.	Survey	Patients who received an ICD (n=295)	79% reported that they were as involved in the decision as they wanted. However, 28% reported that they were not told of the option of not getting an ICD and 37% did not remember being asked if they wanted an ICD.
Henderson et al. (2003) Australia	Explore and describe nurses' and patients' views about partnership in care in hospital.	Qualitative	Grounded theory	Interviews	Nurses (n=33) and patients (n=32)	If nurses and patients are to work as partners, it is important that nurses make every effort to equalize the power imbalance. One way to do this is for nurses to share and give information to patients readily and to be open in their communication with them.
Hess et al. (2020) Various.	Summarize patient and providers attitudes towards device placement, device efficacy and effectiveness, periprocedural complications, long-term events such as shocks and generator replacement, and quality of life and costs.	Mixed method	Literature Review	Meta-analysis, systematics reviews, and others.	Peer Reviewed literature	Advanced age has been shown to be an independent risk factor associated with complications at the time of ICD implantation.
Joseph-Williams et al. (2021) Various (US, Can, UK, Australia, Chili….)	Develop context-specific program theories that explain why and how PDA are successfully implemented	Mixed method	Rapid Realist Review (N=29)	N=29 including 23 unique studies.	Peer Reviewed literature	Developed 8 refined theories to describe the mechanisms by which PDAs become successfully implemented into routine clinical settings.

Authors, Year, Country	Aim	Methodology	Study Design	Data source	Participants	Results
Joyce et al. (2013) Europe, North America, Australasia.	Determine how clinical practice guidelines incorporate the patient perspective into supporting decision-making about ICDs.	Mixed method	Review	Clinical practice guidelines (n=6)	Peer Reviewed Literature	The guidelines revealed three key aspects of SDM that were considered: (a) outcomes that are important to the patient, (b) guidance for clinicians on personalising risks and benefits and (c) patient involvement (and family/significant other if desired) in decision-making.
Kalocsai et al. (2018) Canada	Explore family members' perspectives on the enablers and challenges to establishing therapeutic alliance.	Qualitative Study	Explorative	Semi-structured interviews	Family members of ICU patients (n=19)	Family members identified informal interactions as missed opportunities for relationship-building. While informal interactions with nurses at the bedside facilitated therapeutic alliance, inconsistent interactions related to routine decision-making hindered family empowerment.
Keij et al. (2023) Europe and North America	Identify patient-related characteristics considered to affect patient involvement in SDM about treatment.	Qualitative	Scoping Review (N=70) (1994-2022)	70 qualitative studies.	Peer Reviewed literature	Identified many different patient-related characteristics, which we grouped into four categories related to: (1) the individual who is facing the decision, (2) the decision, (3) the relationship between the patient and the clinician and others involved in the decision, and (4) the healthcare context.
Kingston et al. (2020) New Zealand	Explore the lived experience of mental health nurses engaging in therapeutic relationships.	Qualitative Study	Interpretive phenomenology	Interviews	Mental Health nurses (n=8)	Themes: (1) Crisis, crisis, crisis; (2) scattered structures and redundant rules; (3) Making space to practice; (4) and joining the patient's world and exploring with.

Authors, Year, Country	Aim	Methodology	Study Design	Data source	Participants	Results
Kunneman et al. (2020) US	Assess the extent to which the use of an SDM tool affects the quality of SDM and anticoagulant treatment decisions in at-risk patients with atrial fibrillation.	Quantitative	Randomized trial,	Survey	Patients with nonvalvular AF (n=922) and clinicians (n=244)	The use of an SDM encounter tool improved several measures of SDM quality and clinician satisfaction, with no significant effect on treatment decisions or encounter duration.
Larsson et al. (2011)	Explore barriers for patient participation in nursing care with a special focus on adult patients with experience of inpatient physical care. care.	Qualitative	Explorative	6 Focus groups	Patients (n=21) from different contexts (Heart failure ward, neurological ward...)	The barriers for patient participation were identified as four categories: Facing own inability, meeting lack of empathy, meeting a paternalistic attitude and sensing structural barriers, and their 10 underlying subcategories.
Lewis, Birnie et al. (2018) Canada	Develop a PDA for patients facing ICD replacement.	Mixed method	Interpretive description	Questionnaires and semi-structures interviews	Patients + family (n=6) and clinicians (n=12)	The PDA was identified to support a shared decision-making (SDM) process, not to be used as a stand alone instrument. To shift current practices to an SDM process, participants identified that an invitation to discuss the option of ICD replacement is required whether initiated by the patient or the clinician
Lewis, Carroll et al. (2018) Canada	Review challenges awith ICD decision-making in adults; to discuss SDM as a solution; to summarize effective interventions to facilitate SDM.	Mixed method	Literature review	Not specified.	Peer Reviewed Literature	High-quality decisions depend on the careful communication and accurate 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.

Authors, Year, Country	Aim	Methodology	Study Design	Data source	Participants	Results
Lewis, Birnie et al. (2021) Canada	Evaluate the feasibility of a decision support intervention for patients faced with the decision to replace their ICD.	Quantitative	Pilot feasibility randomized control trial.	Outcome measurements by phone or email.	Patients (n=30) approaching ICD battery replacement	The decision support intervention has the potential to improve ICD replacement decision quality.
Lewis, Nery et al. (2014) Canada	Assess current decision-making practices at the time of ICD generator replacement from patients and health care professionals' perspectives.	Quantitative	Cross-sectional study	Survey	ICD patients who underwent ICD replacement	Most patients are unaware of the option of ICD pulse generator replacement. Patients want information about options prior to making an informed decision and health care professionals have acknowledged that changes are required.
Lewis, Stacey et al. (2017) Canada	Evaluate the PDAs acceptability and usability and elicit which features of the PDA and its use in the clinical workflow are perceived to facilitate implementation in practice with HCPs and patients.	Qualitative Study	Exploratory	Semi-Structured interviews	Patients, spouses, nurses, clinicians	Participants identified that the patient or clinician must provide an invitation to discuss the option of ICD replacement. All participants believed the PDA to be a valuable intervention that could help facilitate a standardized SDM process.
Lewis, Stacey et al. (2014) Various (US, CAN, UK..)	Explore patients' ICD decision-making experiences from the decision to implant to the consideration of deactivation at end of life.	Mixed method	Integrative Review (n=25)	Qualitative, mixed-method, quantitative	Peer Reviewed Literature	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.

Authors, Year, Country	Aim	Methodology	Study Design	Data source	Participants	Results
Lewis, Starzomski et al. (2014) Various (Europe, North America, Australia/New Zealand)	Use a relational lens to localize the role of the nurse in SDM and recommend ways in which nurses can be involved in SDM.	Mixed method	Integrative Review	17 articles included	Peer Reviewed Literature	Analysis revealed four themes that helped us articulate nurse involvement in SDM: knowledge as a basis for SDM, sharing power in the nurse-patient relationship, utilization of decisional support strategies, and communication.
Maclver et al. (2016) Canada	Determine patient awareness, preferences and timing of ICD deactivation discussions	Qualitative study	Grounded theory	Semi structured interviews	Patients (n=25)	Patients identified three stages where they felt implantable cardioverter-defibrillator deactivation should be discussed: (1) prior to implantation, (2) with any significant deterioration but while they were of sound mind to engage in and communicate their preferences and (3) at end of life.
Mooney et al. (2019) Ireland	Investigate patients' knowledge and opinions about their ICDs during life, illness and at the time of death and the factors that might influence these.	Quantitative	Cross-sectional, correlational, non-experimental study.	Questionnaire	Patients (n=30)	Patient education and communication are essential for patients with ICDs to enhance decision-making about ICD management at the end of life.
O'Donnell et al. (2006) Canada	Provide an overview of the barriers related to the uptake of PDAs within the process of care and the strategies, opportunities and research priorities to overcome them.	Mixed method	Review	N/A	Peer Reviewed Literature	The success in implementing PDAs into the process of care hinges on many factors including the attributes of the PDAs itself, the practitioners and patients who use them and the practice environment in which they are used.

Authors, Year, Country	Aim	Methodology	Study Design	Data source	Participants	Results
Pel-Little et al. (2021) Various (US, Canada, Sweden, Norway, Netherlands, Australia, Germany, UK)	Describe barriers and facilitators for SDM as experienced by older patients with multiple chronic conditions, informal caregivers and health professionals.	Mixed method	Systematic Review (n=28) (1980-2019)	Qualitative (n=19), quantitative (n=5), Mixed method (n=4)	Patients, caregivers and healthcare professionals	An explicit invitation to participate in SDM is important to older adults. Health professionals need a supporting organizational context and good communication skills to devise an individualized approach for patient care.
Rao et al. (2022) US.	Gain a deeper understanding of patients' ICD decision-making process beyond decision aid use.	Qualitative	Descriptive	interviews	Patients (n=20)	Understanding patients' ICD decision-making paths, especially in the context of encounters with primary cardiologists, can inform the implementation strategies of hared decision-making help to enhance its impact. Components of decision aids focusing on the experience of living with an ICD rather than probabilistic data may also be more impactful, although the nature of their impact will differ.
Rao et al. (2022) US	Observe impact of the Centers of Medicare and Medicaid mandate (physician must document and conduct a SDM interaction using PDA for individuals)	Quantitative	Pre and Post comparative study	Survey	Patients (n=369)	There were no major differences between knowledge, decisional conflict, values choice concordance, or patient engagement. Compared to patients with ICDs placed before the mandate, patients with ICDs after the mandate were more likely to subjectively feel more informed about the benefits of the procedure but were less likely to be able to correctly identify the frequency of complications.

Authors, Year, Country	Aim	Methodology	Study Design	Data source	Participants	Results
Raphael et al. (2011) England	Explore if and when the end of life and device deactivation should be discussed with patients and how much patients want to know prior to ICD implantation.	Qualitative	Explorative	Interviews	Patients (n=54)	Most patients were not aware that the ICD could be deactivated. The vast majority of patients (84%) wanted to be involved in the deactivation decision; 40% felt this discussion should be prior to ICD implantation but others felt the discussion should only occur if the patient was terminally ill (16%) or in the last few days of life (5%).
Reed & Jaxton (2019) New Zealand	Investigate the experiences of qualified mental health practitioners in using a SDM approach.	Qualitative	Descriptive	Semi-structured interviews	Healthcare Professionals (n=4)	Three themes uncovered during data analysis were; knowing the client; the awareness of the practitioner; and the therapeutic relationship.
Scholl et al. (2018) Various (US, UK, Australia..)	Compile a comprehensive overview of organizational- and system-level characteristics that are likely to influence the implementation of SDM, and to describe strategies to address those characteristics.	Mixed Method	Scoping review	48 studies	Peer Reviewed literature	Described system-level characteristics included policies, clinical guidelines, incentives, culture, education, and licensing. We identified potential strategies to influence the described characteristics, e.g., examples how to facilitate distribution of decision aids in a healthcare institution.

Authors, Year, Country	Aim	Methodology	Study Design	Data source	Participants	Results
Song et al. (2022) Various (Netherlands, Canada, US..)	Evaluate the effects of PDAs on atrial fibrillation patients' knowledge, decisional conflict, and on the incidence of stroke and bleeding; and(ii) explore characterizing factors associated with enhanced PDA effectiveness.	Quantitative	Meta-analysis and Systematic Review (n=10)	10 studies were compared	Patients with atrial fibrillation who received a PDA vs usual care.	PDAs are promising in promoting SDM and oral anticoagulant uptake in patients with AF. To facilitate the use of such effective tools in clinical practice, parallel efforts should be provided to training the healthcare professionals to obtain knowledge and skills of SDM. Interprofessional SDM model is encouraged, and nurses should play a more active role in SDM to better support patients with AF in making tough decisions.
Spencer-Bonilla et al. (2020) US	Explore factors that promote or hinder implementation of SDM tools; evaluate the effectiveness of a SDM conversation tool for patients with atrial fibrillation considering anticoagulation therapy.	Quantitative	Cross-Sectional Study	Survey	Clinicians (n=183)	Clinicians paid significant attention to making sense of the tool. Tool buy-in seemed to depend heavily on their ability to see the tool as accurate and "evidence-based" and their perceptions of having time in the consultation to use it.
Standing et al. (2016) UK	Explore views of decision-making about ICD and CRT-D implantation and deactivation, to identify facilitators and barriers and decision-support needs for SDM.	Qualitative	Explorative	Observation of clinical encounters, interviews and interactive group workshops	Patients, relatives (n=44) and clinicians (n=29)	Patients/relatives wanted more information about, and more involvement in, deactivation decisions, and expressed a preference that these decisions be addressed at the time of implantation.

Authors, Year, Country	Aim	Methodology	Study Design	Data source	Participants	Results
Stoevelaar et al. (2020) Netherlands	Gain insight in the experiences of patients with advance care planning conversations about ICD deactivation.	Qualitative study	Explorative	Focus groups	Patients (n=41)	Patients expressed a need for advance care planning conversations with a healthcare professional about deactivation, but few had had these. Some patients were hesitant to record their preferences about deactivation because they were unsure whether their current preferences would reflect future preferences.
Waddell et al. (2021) Various (US, CAN, Germany..)	Synthesise evidence on the barriers and facilitators to the implementation of SDM interventions in tertiary care.	Qualitative	Systematic Review	14 qualitative studies	Peer Reviewed Literature	Themes were Environmental Context and Resources, Social/Professional Role and Identity, Knowledge and Skills, and Beliefs about Capabilities. A wide range of barriers and facilitators across individual, organisational, and system levels were reported.
Wallace et al. (2021) US	Develop and pilot ICD decision aids for patients considering primary prevention ICDs.	Mixed method	Randomized pilot test	Interviews + survey	Patients (n=21)	Participants preferred the in-depth paper tool and video PDAs. Access to a nurse during the decision-making window encouraged questions and improved participant-perceived confidence.
Younas et al. (2016) UK	Explore the views and experiences mental health pharmacists regarding the use of SDM in antipsychotic prescribing in people diagnosed with serious mental health illnesses.	Qualitative	Explorative	Semi-structured Interviews	Mental health pharmacists (n=13)	SDM was perceived to be linked to positive clinical outcomes including adherence, service user satisfaction and improved therapeutic relations.

Authors, Year, Country	Aim	Methodology	Study Design	Data source	Participants	Results
Yu et al. (2019) Canada	Explore decision-making experiences of health professionals and patients with diabetes and co-morbidities, then develop an intervention employing user-centred design to facilitate Interprofessional-SDM and goal setting.	Qualitative	Explorative	Semi-structured interviews	Patients and clinicians (11 dyads)	A decision aid can provide information, facilitate clinician-patient dialog and strengthen the therapeutic relationship. Implementation of the decision aid can fit into a model of team care that respects and exemplifies professional identity and can facilitate intra-team communication.

Supplemental Table 2*:* Data Analysis Tool for Patients and Family Members

The goal of this analysis guide is to uncover and identify the therapeutic relationship elements embedded in the transcripts. It is based on literature by Browne (1993), Chalifour (1999), Geller (2020), Horner (2020), Phaneuf (2011), Servellen (2009), and Yu et al. (2019). Questions were formulated from statements describing the elements of the therapeutic relationship. These questions have not been used in previous studies.

Elements	**From the patient's or family members perspective**	**Supporting quotations**	**Notes/Reflections**
1. Empathy ***Definition:*** *a* sentiment of profound comprehension from the healthcare professional towards the patient.	Does the patient/family member refer to: a) feeling understood during or after their conversations with the healthcare professional (HCP)? b) feeling comforted after sharing their perspectives c) having the impression that the HCP acknowledged their perspectives d) that the HCP put themselves into their situation		

2. Trust ***Definition:*** a justified expectation that one can depend on another person's promise, commitment, or responsibility.	Does the patient/family member refer to: a) feeling like the HCP has their best interest in mind b) Identify that the HCP is capable and competent c) That the HCP is: I. Honest II. Consistent III. Respectful IV. Caring V. Open VI. Genuine VII. Reliable d) That the HCP's verbal and non-verbal communication are congruent		

3. Respect ***Definition:*** acknowledging the value of patients and accepting their individuality as well as their unique needs and rights.	Does the patient/family member reference: a) That the HCP uses: I. eye contact II. facial expression III. posture IV. a position relative to them V. a sensitive use of touch b) That the HCP is directing their verbal messages to them by: I. adjusting tone of voice II. using of the patient's real name c) That the HCP conveys a genuine interest in them as a person d) That the HCP allows them to make choices concerning their care		

	e) That the HCP explains procedures fully before carrying them out f) That the HCP would treat them the same no matter who they were		
4. Genuineness ***Definition:*** healthcare professional's ability to be open and honest with the patient.	Does the patient/family member reference: a) That the HCP is open and honest with them b) That the HCP's verbal and non-verbal communication is congruent c) That the HCP makes self-disclosures in an appropriate and relevant manner		
5. Manifesting a presence ***Definition:*** being physically and psychologically present with the patient during encounters.	Does the patient/family member reference: a) That the HCP is physically and psychologically present during encounters b) That the HCP is physically close during encounters		

	c) That the HCP is emotionally calm during encounter d) Feeling understood		
6. Therapeutic communication ***Definition:*** interpersonal exchange, using verbal and non-verbal messages, that expresses support, provides information and feedback, corrects distortions, and provides hope.	Does the patient/family member reference: a) That the HCP is: I. using silence II. offering acceptance III. acknowledging IV. giving recognition V. making and offering observations VI. summarizing VII. reflecting on their own perception of their thoughts, feelings, and reactions VIII. focusing on the patient IX. prompting exploration		

	X. translating their thoughts into feelings and feelings into thoughts XI. validating their perceptions and beliefs		
7. Active Listening ***Definition:*** listening to hear and to understand the patient.	Does the patient/family member reference: a) that a favorable environment was used for encounters b) That the HCP pays attention to their displayed non-verbal messages during encounters c) That the HCP really wanted to hear what they were saying d) That the HCP listened to the entire information given and not just what was interesting to them		

	e) That the HCP took the time to hear before intervening / responding		
8. Reciprocity ***Definition:*** refers to the balance of giving and receiving in a relationship with the goal of creating a healthy and mutual beneficial partnership.	Does the patient/family member refer to: a) feeling understood by the HCP b) understanding the HCP's point of view c) understanding what the HCP is saying d) feeling a connection with their HCP e) That the HCP exchanged dialog that was complementary to what they were saying		
Other questions not directly related to the above elements	1. Is there any reference to a relationship/rapport between the patient/family member and the HCP? 2. Did the patient/ family member attempt to engage the HCP in a relationship/rapport (therapeutic or otherwise)?		

	3. Is there any reference that the relationship supported decision-making? 4. Is there any reference that the relationship hindered decision-making?		

Supplemental Table 3: Data Analysis Tool for Healthcare Professionals

The goal of this analysis guide is to uncover and identify the therapeutic relationship elements embedded in the transcripts. It is based on literature by Browne (1993), Chalifour (1999), Geller (2020), Horner (2020), Phaneuf (2011), Servellen (2009), and Yu et al. (2019). Questions were formulated from statements describing the elements of the therapeutic relationship. These questions have not been used in previous studies.

Elements	**From the healthcare professionals' perspective**	**Supporting quotations**	**Notes/Reflections**
1. Empathy ***Definition:*** *a* sentiment of profound comprehension from the HCP towards the patient.	Does the HCP refer to: a) acknowledging the patient's feelings b) understanding the patient's feelings c) being comforting when the patient shares their perspectives d) putting themselves into the patients' situation		
2. Trust ***Definition:*** a justified expectation that one can depend on another person's promise,	Does the HCP refer to: a) having the patient's best interest in mind b) being honest c) being consistent		

commitment, or responsibility.	d) being respectful e) being caring f) being open g) being genuine h) being reliable i) being congruent with their verbal and non-verbal communication		
3. Respect ***Definition:*** acknowledging the value of patients and accepting their individuality as well as their unique needs and rights.	Does the HCP refer to: a) using eye contact b) using facial expressions c) using posture d) using a position relative to the patient e) using a sensitive use of touch f) directing their verbal messages to the patient by:		

	I. adjusting tone of voice II. use of the patient's real name g) having a genuine interest in the patient as a person h) protecting the patient's privacy and modesty i) allowing the patient to make choices concerning their care j) explaining procedures fully before carrying them out k) treating everyone the same no matter who they are		
4. Genuineness ***Definition:*** HCP's ability	Does the HCP refer to:		

to be open and honest with the patient.	a) Being open and honest with his patients b) Being congruent in his verbal and non-verbal communication c) Making self-disclosures in an appropriate and relevant manner		
5. Manifesting a presence ***Definition:*** being physically and psychologically present with the patient during encounters.	Does the HCP refer to: a) Being physically and psychologically present with the patient during encounters b) Being physically close during encounters c) Being emotionally calm during encounters		
6. Therapeutic communication	Does the HCP refer to:		

Definition: interpersonal exchange, using verbal and non-verbal messages, that expresses support, provides information and feedback, corrects distortions, and provides hope.	a) using silence b) offering acceptance c) acknowledging d) giving recognition e) making and offering observations f) summarizing g) reflecting on their own perception of the patient's thoughts, feelings, and reactions h) focusing on the patient i) prompting exploration j) translating the patients' thoughts into feelings and feelings into thoughts k) validating the patient's perceptions and beliefs		
7. Active listening	Does the HCP refer to:		

Definition: listening to hear and to understand the patient.	a) favoring an environment to hear what the patient is saying b) paying attention to the patient's displayed non-verbal messages during encounters c) really wanting to hear what the patient is saying d) listening to the entire information given by the patient and not only what is perceived to be relevant e) taking the time to hear before intervening / responding		
8. Reciprocity ***Definition:*** refers to the balance of giving and receiving in a relationship with the goal of	Does the HCP refer to: a) attempting to understand the patient b) understanding the patient's point of view		

creating a healthy and mutual beneficial partnership.	c) understanding what the patient is saying d) attempting to connect with the patient exchanging dialog that is complementary to the patient		
Other questions not directly related to the above elements	1. Is there any reference to a relationship/rapport between the patient/family member and the HCP? 2. Did the patient/ family member attempt to engage the HCP in a relationship/rapport (therapeutic or otherwise)? 3. Is there any reference that the relationship supported decision-making?		

	4. Is there any reference that the relationship hindered decision-making?		