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Optimizing Advance Care Planning in the Acute Cardiac Care Setting: A combined quality improvement and knowledge translation approach.

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Optimizing Advance Care Planning in the Acute Cardiac Care Setting: A combined quality improvement and knowledge translation approach.

by

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Abstract

Advance care planning (ACP) is a process by which patients are able to prepare for future in-the-moment medical decision making and share their values, wishes and preferences. ACP is important as patients are often not well informed about life sustaining treatments, they can endure more invasive care at end of life than they would want, and they spend more time in hospital than they prefer. Despite known benefits of ACP and recognition of its importance, its integration into regular clinical workflow remains limited.

We conducted three studies to examine and address the problem of integrating ACP process into clinical workflow. The first study utilized qualitative methods to characterize ACP process across clinical contexts. In the second study, we utilized an integrated knowledge translation approach to design and implement a multifaceted intervention to routinize ACP process in one hospital unit. We assessed outcomes using an interrupted time series design, and collected data for thirty-two weeks; before, during and after the intervention period. In our third study, we utilized multiple methods to conduct a process evaluation to better understand the effectiveness of our ACP intervention implementation procedure.

From our first study, we found that there was significant variability of ACP process both across and within clinical contexts. Segmented regression analysis from our ACP intervention, showed an increase in the proportion of patients to be discharged with a prepared green sleeve, containing their ACP documentation. No significant change was measured for the remaining process and outcome measures. The process evaluation indicated that limitations in the engagement of physicians may have constrained the impact of the intervention. Future opportunities have already begun to address implementation challenges of this work and are using tailored and targeted approaches to improve the reach of intervention components.

This program of study comprised of an effort to improve the integration of ACP process into clinical workflow using an iKT approach. Process evaluation helped to provide a deeper understanding of the implementation process. Future research can help to address implementation challenges of this study by focusing on tailored engagement of knowledge users and a strengthening of skill and team building.

Preface

The program of study developed for this thesis, contains the following manuscripts, all of which have been submitted or are ready to be submitted to peer-reviewed journals. For each manuscript, Marta Shaw led the manuscript writing, data analysis and interpretation. Study design was led by Marta for all chapters, except chapter two, which in virtue of describing an integrated knowledge translation project, necessitated a collaborative study design among team members. Each stage of development and writing was guided by her thesis committee (Drs. Jayna Holroyd-Leduc, Jessica Simon, Deborah White, Ward Flemons and Andrew Grant) and are co-authors. All authors contributed important intellectual content and provided critical review of the respective manuscripts.

Shaw M, Raffin S, Robertson L, Booker R, Holroyd-Leduc J, White D, Grant D, Simon J. (2019) *Context is everything: How clinical context influences interpretation and use of an advance care planning policy.*

Shaw M, Simon J, Sharma N, Kaba A, White D, Grant A, Fassbender K, Sharma N, Holroyd-Leduc J. (2019) *A method for combining integrated knowledge translation with quality improvement processes in the implementation of an advance care planning intervention.*

Shaw M, Holroyd-Leduc J, White D, Grant A, Simon J. (2019) *Assessing the impact of an advance care planning intervention on clinical team process measures and patient reported outcomes using interrupted time series design.*

Shaw M, Holroyd-Leduc J, Kaba A, White D, Grant A, Simon J. (2019) *Promoting in-hospital advance care planning process: A process evaluation of an implementation intervention in a cardiac setting*

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1 CHAPTER ONE: AN INTRODUCTION TO CLINICAL TEAM PROCESS FOR ADVANCE CARE PLANNING ENGAGEMENT IN HEALTHCARE SETTINGS

1.1 Overview

1.1.1 Overview and statement of the problem

With developing medical advancements, individuals are living longer with complex medical comorbidities. The increasing complexity of medical interventions versus quality of life trade-offs, put patients at risk of receiving care that does not align with their wishes (1), particularly when they are acutely ill and not able to communicate their preferences (2). Advance care planning (ACP) is a process that enables adults to develop and share their values, goals, and preferences regarding future medical care (1). Patients have widely been shown to be receptive to and have positive attitudes toward ACP (3).

Despite known benefits to ACP engagement, including decreased burden on families and increased concordance between patient wishes and the care received, engagement between patients and healthcare providers is low (4-9). Patient knowledge and understanding of their engagement in ACP is also inadequate. For example, when patients are engaged in ACP, they are often unaware of having participated in this process (10, 11). Only 30% of patients in Alberta who have a medical order (Goals of Care designation- GCD) directing their care are aware of it, despite a provincial policy expectation that patients be active in this type of decision-making (12). Patients also often rate the quality of ACP that they engage in with healthcare providers as poor, particularly in specialist settings, where it is crucial to address the burden and treatment of a specific disease (9, 13). Finally, documentation of ACP discussions between patients and healthcare providers is also suboptimal. The frequency of documentation is low, documentation is difficult for other healthcare providers to find in follow-up and details regarding conversations are inadequate (13).

1.1.2 Research objectives

1. To characterize ACP process across clinical contexts, including factors that influence initiation and timing of ACP between patients and healthcare providers (paper 2).
2. To describe a novel application of a combined integrated knowledge translation and quality improvement method to implement an ACP process intervention into clinical workflow (paper 3).
3. To analyze the impact of this ACP process intervention on process measures and patient reported outcomes using interrupted time series design (paper 4).
4. To evaluate and characterize the implementation process of this ACP intervention (paper 5).

1.2 Thesis Outline

The chapters in this manuscript-based thesis consist of four papers with specific research aims formatted for publication in a peer-reviewed journal. The chapters aim to inform the development, implementation and evaluation of process-based interventions for improving quality of ACP using knowledge translation and quality improvement methods.

Informing the background and rationale for our intervention is a study characterizing existing ACP processes within and between clinical contexts from the perspectives of healthcare providers (chapter 2). We sought to gain an understanding of ACP processes in various clinical settings and the factors that impact the initiation and timing of ACP.

We utilized this gained understanding to form the rationale for a process-based ACP intervention, the methodology of which we describe in chapter 3. This novel methodological design utilizes a knowledge translation approach and framework with local quality improvement processes to support the implementation of an ACP intervention on a cardiac in-hospital unit.

In chapter 4 we describe the findings from the implementation of the ACP process intervention. We utilized an interrupted time series analysis to examine the impact of the intervention on patient knowledge of their medical order, satisfaction with ACP on the unit, prepared patient green sleeves containing up to date ACP documentation and healthcare providers documentation of ACP discussions on the designated tracking record.

In chapter 5, we present a process evaluation examining key aspects of implementation of the ACP intervention. The purpose of this evaluation is to assess the degree to which the intervention was implemented as intended and what, if any, factors impacted implementation, in order to provide context for the findings presented in chapter 4 and be better able to improve this intervention in future iterations of implementation.

A summary of this this thesis is presented in chapter 6. We summarize the findings and relevance of this program of study, including its strengths and limitations. This includes a discussion of clinical and future research implications. This body of work can be used to inform the integrated knowledge translation programs, the development of process interventions to improve ACP in a hospital setting and to guide implementation strategies for complex clinical interventions in ACP.

1.3 Background

1.3.1 Advance Care Planning

Medical advancements are allowing people to live longer with chronic conditions. As a result, individuals can be faced with medically complicated circumstances near the end of life. At the same time, a gradual conceptual shift has been forming in medicine, in which the autonomy of patients is paramount and they are seen as active participants in their healthcare rather than passive recipients (14). Along with this, a shift toward patient-centered care has encouraged healthcare providers to focus on patients and families rather than disease (15). Patient centered care is that which is respectful to patient values and wishes, which in turn inform clinical decision. This shift in focus has had the effect of encouraging patient engagement in clinical decisions.

In much of medicine, this conceptual shift may not amount to significant consequence other than an emphasis on improving patient-physician communication. However, as patients age or are faced with life-limiting illness, active participation and an exertion of autonomy become much more important and relevant. Approximately half of older adults have to make decisions regarding their care at end of life (16).

Advance care planning (ACP) was coined in the early 1990's in order to protect individual self-determination and improve upon Advance Directives as tools for making healthcare related decisions (17). Advance care planning is a process by which patients are able to share their values, wishes and preferences for future medical care (1). ACP activities consist of the selection and preparation of a surrogate decision-maker, preparation for medical decision-making, documentation of wishes in an advance (or personal) directive, and participation in the completion of medical (GCD) orders and plans (Figure 1) (10). The development of ACP,

generally, and across Canada has been driven by the principle of autonomy and self-determination (14). The enactment of autonomy has happened through the conceptualization and application of practices regarding informed consent. This has varied across Canada, and as a result has had unique implications in different provinces, including Alberta. These implications involve the nature of the consenting process and the evolution of *advanced* decision-making towards decision preparation. Best practice, as indicated by the ACP/GCD provincial policy (www.conversationsmatter.com) advise that patients be asked about prior documents and conversations, have further conversations as needed with health care providers, that the physician determines a GCD for that admission "after discussion with the patient or alternate decision-maker, where possible, and the members of the patient's health care team" and the physician documents both the GCD and the conversation with the patient. The GCD should then travel with the patient in a "green sleeve" (standardized folder that crosses all health sectors), and the patient should know how their GCD documents are to be used. Commonly, specific health care providers initiate only select parts of the ACP discussion or documentation. For example, physicians are ultimately responsible for completing GCD documentation, but nursing staff might be involved in introducing the conversation or preparing the final set of documents to go home with patients. The ACP/GCD provincial policy and procedure is focused on the interaction between clinician and patient, rather than prescribing how this process should be implemented in a consistent or standardized fashion.

The conceptualization of ACP in the context of decision making has shifted over a number of years from advanced decision making to advanced preparation for in-the moment decision making (18). In the early developmental stages of ACP, it was thought that the goal of ACP should be to facilitate decision making regarding a time in the future when a patient was no

longer able to communicate. This would help to ensure that patient wishes were honored and respected even if they could not communicate these themselves. In fact, in many Canadian jurisdictions, formal ACP documentation still asks about or enables patients to make decisions about mechanical ventilation or CPR for the future (14). However, it has become clear that this not the ideal function of ACP. In-advance decisions do not reliably align with wishes at the time that the decision is to be instantiated (18) Patients change their mind. Part of the reason is that they tend to underestimate their adaptability (19). Values and appraisal of quality of life or the things that make life worth living shift as health deteriorates. Therefore, rather than eliciting decisions about interventions in advance, ACP is now conceived of as helping patients select an SDM and prepare for in-the-moment decision making (18). At minimum, ACP should involve patients communicating with families and working in collaboration with healthcare providers. ACP is pertinent to patients in most subspecialist care, as well as those under the care of general practitioners (20). Physicians directly caring for a patient may be best situated to understand their expected prognosis and options for care. ACP is meant to be an ongoing process, rather than a one-time occurrence, as patient preferences and values may change with changing circumstances (21). The quality of ACP has many metrics but the three most important are that care aligns with goals, assignment and documentation of a surrogate decision maker, and documentation of wishes and preferences (22).

When it comes time to make a decision, the types of decision-making that a patient can engage in fall along a spectrum. Paternalistic decision-making, in which a patient assumes a passive role, is one where physicians are seen as the expert and guardian of the patient's best interest (23). The informed decision-making model is on the other end of the spectrum and has the physician as a passive actor whose role is to provide information and instantiate patients'

decisions. Shared decision-making happens when the clinician provides the patient or SDM with treatment options, discusses the risks and benefits of each and allows the patient to express their preferences and values before negotiating a decision (15). This type of decision making is meant to protect patient autonomy and control while challenging physician authority (24). As such, it is meant to decrease the knowledge and power imbalance between patient and physician. For these reasons, shared decision-making aligns well with patient-centered care and is increasingly being promoted as preferred decision-making model in ACP (and for most healthcare decisions) (24).

1.3.2 ACP engagement as Shared Decision Making in Patient Centered Care

Patient centered medicine is an emerging model of medical care that is focused on improving care for the individual patient, while accommodating the increased role that patients have taken on in the healthcare system and in managing their health (25). Patient centered medicine is defined as the practice of medicine focused on improving outcomes of individual patients in clinical practice, while taking account of their preferences, objectives, and values. An important part of patient centered care is engaging patients as active participants in shared decision making (15).

ACP is patient centered care precisely because it is so individualized. In order to be done well, ACP will not be the same from patient to patient. Each patients' values, wishes and needs will be unique and quality ACP requires that healthcare providers focus on the uniqueness of each patient when engaging them. As such, patients should have an understanding of the decisions in which they are participating. Thus, in the case of ACP, if patients are not aware that they are participating in the process of ACP, that there are resulting medical orders that direct their care and that they are able to document or communicate their wishes as part of that process, then they cannot be said to have really participated in shared decision making. A study by

Heyland et al., that examined the correlation between values and treatment preferences highlighted the need for better quality discussions by showing that less than half of patients with a medical order knew of its existence and patients did not fully understand risks, benefits and alternatives of various treatments (11).

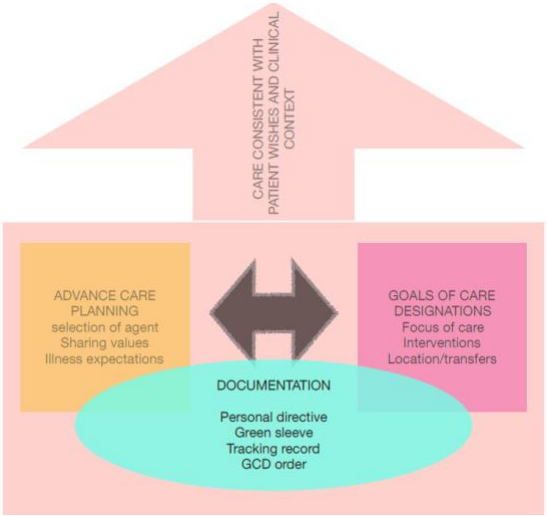
When considering how ACP integrates into the philosophy of patient-centered care, it is important to consider that not all patients wish to be active and engaged participants in decision-making. Some patients wish to abstain from decision-making entirely, while others wish to be involved but to a lesser degree. Despite this spectrum of preference around ACP involvement, patients consistently report wanting information regarding their prognosis, to know what they can expect, and to be given the opportunity to have their questions and concerns addressed (26). Thus, each patient should be asked about their particular preference regarding decision-making involvement and desire to know their prognosis and care plan.

1.3.3 Benefit of ACP engagement

ACP helps to promote patient centered care by ensuring patients have the opportunity to explore and express their concerns and wishes regarding disease, prognosis and treatment options. The healthcare system errs on the side of prolonging life and using “aggressive” or interventional treatments to achieve this thus, ACP engagement can enable patients to express wishes against such aggressive care (6). In fact, ACP has been shown to help align care with patient wishes and patients who participate in ACP are less likely to receive life-prolonging care (7). Moreover, ACP has been shown to decrease depression, anxiety, stress and family burden pertaining to decision-making (27). Family members report feeling more prepared to cope with the death of a loved one (28). Finally, with ACP, patients are more likely to be enrolled in hospice and are less likely to die in hospital (6).

Figure 1

Advance Care Planning and associated activities (adapted from ACP GCD team AHS, Calgary zone conceptual model)



1.3.4 Barriers to ACP and the Importance of Context

Reported barriers to ACP engagement result from clinician, patient (and family) and system factors. Common clinical barriers include competing demands at work as well as a lack of time to dedicate to ACP (29). Physicians also report inadequate training on how to engage patients in ACP (30-32). Although the vast majority of physicians report ACP conversations are important, only about a third report having received formal training in these discussions. This is a problem because physicians report feeling burdened by the emotional and interactional nature of ACP conversations (29). Clinicians further report not knowing the right time to initiate ACP discussions with patients and families (32).

System barriers are also commonly pertain to a lack of available resources (21). One example of this are the lack of easily accessible resources to share decisions and patient preferences across and within healthcare organizations (29).

The clinical context also influences interpretation and application of ACP. Different clinical contexts can uniquely influence the attitudes, approaches and processes of ACP (5, 10, 33, 34). These multiple clinician barriers make it challenging to integrate ACP into routine work flow (35).

1.3.5 Documentation of ACP discussions

Research has suggested that ACP documentation completed by healthcare providers should include detailed information, such as reasons and rationale for the ACP conversation and materials that were offered to the patient (i.e. literature, forms). Documentation should also include an overview of components of quality ACP such as current quality of life, hopes and fears for the future, and clarification of expectations and preferences (36). In traditional ACP research, a measure of quality ACP was simply the inclusion of any ACP documentation. However, this type of documentation does not reflect anything about the quality of ACP conversations that were had. Poor quality ACP documentation is a widespread issue (13, 36). Even when ACP documentation is present, it often lacks any accompanying explanation of discussions or context. Issues around documentation have also been reported from the perspective of physicians. Physicians often report facing a poor system for recording patient wishes and ACP discussions (37). Moreover, physicians report a lack of electronic system set up to transfer ACP discussion information between clinical settings (ex. from hospital to primary care) (10). Further, physicians report that ACP documentation is difficult to access and find (36).

1.3.6 Challenges to Implementation

Many attempts have been made to improve ACP engagement between patients and physicians by targeting patient knowledge and initiation. These include personalized and tailored websites, videos, stories, and personalized health messages (38-42). These interventions are

largely informed by theories of readiness for behavior change. Thus, they aim to increase patients' likelihood to engage by moving them through the four stages of readiness. Many of these interventions have not been successful (43). Part of the problem is that although patient interventions may increase the likelihood that patients complete an advance directive, patients are still waiting for ACP discussions to be initiated by a healthcare provider. Often, patients do not feel it is their role to initiate these conversations or they are unsure of the correct timing. Patients are more likely to initiate ACP if they have experienced the death of someone close to them (27). Thus, facilitating a process in which HCP readily initiate ACP with patients may be needed to increase rates of engagement.

Another set of interventions have targeted healthcare providers. In particular, these interventions tend to target healthcare provider communication skills, conversation starters and ACP training (44). However, a common problem with interventions that are not targeted at the system, is that while gains may be made during the intervention period, these are not sustained due to the extra time and resources required to maintain the intervention. Thus, it may be more effective to create context-specific and standardized process changes for ACP engagement, that are simply integrated into existing workflow, rather than utilizing external facilitators or extra resources that may be time-limited.

However, efforts to integrate ACP into clinical workflow have also been challenging. Systematic, team-based ACP process in the hospital setting is associated with concordance between treatment received and patient wishes (13). However, routine team processes around ACP are not the norm (paper 1). In fact, clinicians are often unaware of whether a local ACP policy or guideline exists (5, 10). For example, research has shown that in the heart failure context, process variability is the norm, with physicians rarely engaging in key aspects of ACP,

such as eliciting patient preferences, outlining prognosis, or explaining ACP documentation (33). Canadian clinicians have reported that work-flow is indeed a persistent problem for ACP and suggest addressing patient knowledge factors, team communication, interprofessional collaboration, education and access to resources to achieve change (21, 45). This suggests that routinizing ACP into regular workflow must be done with a focus on implementation, such that specific contextual barriers are identified and appropriately addressed in order to ensure relevance and thus, sustainability of any new process.

1.3.7 Knowledge Translation (KT)

Healthcare providers and researchers face a persistent and widespread challenge to successfully implement evidence into clinical practice. Although evidence guiding the improvement of patient care, clinical decision making, and medical interventions is constantly emerging, little of it is ever translated into practice (46-48). This is known as the knowledge-to-practice gap (49). Various reasons are behind the knowledge-to-practice gap, including the lack of time and skill healthcare providers have to keep up with, appraise and assimilate constantly emerging literature, a tendency to maintain the status quo, as well as organizational incapacity to adapt to emerging evidence (49). The knowledge-to-practice gap captures the challenge of ACP, where evidence for the benefit of ACP has been established but the translation of this evidence into regular practice has not yet been achieved.

Knowledge translation (KT) is the synthesis, dissemination, exchange and application of knowledge to improve health, health services and make the healthcare system more effective. The application of KT aims to move the spread of evidence beyond the typical diffusion of knowledge through peer-reviewed journals (50). Essentially, KT is both the creation of useable knowledge and the action taken to translate it to practice. KT is most appropriately applied to the

understanding and addressing of complex and clinically relevant health or health system issues that can require the engagement of multiple stakeholders in both the research and change processes (50). The specific goal of KT is often to change provider behavior. Consequently, interventions have to target this behavior change. To do this, KT science suggests: 1. Using theory to design behavior change interventions, 2. Assessing barriers to behavior change or determinants of behavior and 3. Using evidence-based behavior change strategies to target barriers. In the context of ACP, this suggests that interventions aimed at integrating ACP into regular workflow, must be sensitive and responsive to the particular clinical setting in which they are applied, in order to ensure that existing barriers are addressed, and process change is relevant and feasible.

In order to achieve this, KT relies on the use of theory in the design of behavior change interventions (51). Theory helps researchers develop a robust rationale for the selection of that particular intervention, strengthens reporting of the implemented process, helps in the development of a systematic way to evaluate interventions and facilitates easy replication (52, 53). While theory can help researchers develop a rationale for their intervention on the basis of the behavioral factors amenable to change and possible strategies for targeting these, evidence informs which strategies have been shown to be effective in facilitating change, while practical considerations aid researchers in determining the feasibility of proposed interventions in a particular setting (50). By asking ‘who needs to do what differently’, researchers can begin to examine current behaviors and compare these with target behaviors in deciding how to plan an intervention. Broadly, methods are based on planned action theories.

Specific theoretically informed strategies are used in the development of change interventions. Utilized in this program of study, the Theoretical Domains Framework (TDF) (54)

was systematically derived via an expert consensus process from 33 psychological theories of behavior change. The TDF identifies 14 domains to explain the determinants of behavior change. Each of these domains contains component constructs that help researchers identify with specificity existing barriers and facilitators to behavior change. The 14 domains are: knowledge, skills, social/professional role and identity, beliefs about capabilities, beliefs about consequences, motivation and goals, memory, attention and decision processes, environmental context and resources, social influences, emotion regulation, behavioral regulation and nature of the behavior (51). The TDF domains can be summarized by the COM-B model, which asserts that behavior change can be produced only when capability, opportunity and motivation are optimized (55). Thus, the combination of the TDF and COM-B allow researchers to examine the current determinants of behavior and identify which domains need to be addressed through an intervention in order to produce behavior change.

In order to effectively produce behavior change, identified barriers to change or determinants of behavior must be paired to appropriate change strategies. In fact, both theory and evidence show that different behavior change barriers are more or less responsive to change depending on the strategy employed to affect that barrier (51). Therefore, regardless of the KT framework chosen for the implementation of an intervention, it is important for researchers to ensure that they select appropriate change strategies to target the behavior changes they seek. One option, utilized in this program of study is to apply the Behavior Change Wheel (56). This theoretically derived and empirically validated model matches behavior change determinants, from the COM-B (and TDF) to behavior change strategies. These strategies can then inform the design of an intervention. The TDF and Behavior change Wheel provide researchers with testable frameworks for consideration when looking for guidance to design implementation

interventions seeking behavior change or looking for explanations for why implementation might be failing. In the context of ACP, these KT change strategies can help to identify specific team and HCP behaviors that can be targeted for change in order to improve ACP process, and provide theoretical and evidence-based choices for strategies that can be matched to identified behaviors in order to achieve change.

1.3.8 Integrated Knowledge Translation (iKT)

IKT is an approach to research in which researchers and practitioners/or policymakers collaborate to address a complex problem that is relevant to clinical practice and to create applicable knowledge (57, 58). iKT is based on the concept of participatory research through the promotion of collaboration in every step of the research process. It is sometimes referred to as collaborative research, action research, participatory research, coproduction of knowledge, and engaged scholarship. Knowledge users also help to define methods, interpret findings and disseminate research as appropriate. Knowledge users benefit from reflection on their own actions, increased knowledge and improved skills, improved ability to engage in research and the formation of new partnerships (59). The end product of this research process is highly likely to be applicable to clinical care and informed by evidence.

Action research has been found feasible for application to ACP (60) in the community palliative care setting in order to achieve sustainable increase in ACP documentation. Moreover, although research on ACP has involved input from healthcare providers on intervention components, this work has not explicitly integrated end users into the research team and these interventions have not been based in KT or QI principles (35).

1.3.9 Addressing process through Quality Improvement and KT

One approach to facilitating the translation of research into clinical practice is the systematic use of quality improvement (QI) processes. Quality improvement attempts to change clinician behavior, as well as support more consistent, appropriate, and efficient application of established clinical interventions, with the aim of improving care and patient outcomes (61). Quality improvement is an intrinsic part of good clinical practice and is designed to bring about immediate improvements in health care in local settings (62). Quality improvement assumes that quality and safety are characteristics of health care systems, and many QI activities involve groups of clinicians, managers, and staff cooperating to improve procedures and practices (63). At the center of QI is patient safety and improved patient outcomes

QI in healthcare has its foundations in industrial processes, such as Lean and Six Sigma. The goal of Lean techniques is to increase value through increased capacity (improving the service for the customer), usually in part by reducing waste and increasing efficiency (64, 65). Six Sigma QI strategies, designed originally by Motorola, is focused on an evaluation of quality, generation of measurable results, and establishing and achieving quality goals in a system. QI also employs PDSA (Plan-Do-Study-Act) to perform rapid cycles of improvement and assessment (66).

KT and QI methods and processes differ in many ways, but also overlap in others. As such, the two terms are sometimes used interchangeably in the literature (67). They both have the explicit goal of improving patient care by addressing clinical process and changing behavior. Most of the identifiable difference between them can be attributed to the independent development of each within a unique lens. KT science is a field of research that evolved in part out of planned action theories, while QI is practice-based change based in systems theory (61,

68). This difference is important in the change methods that each of these approaches has adopted. KT, based in planned action theories, rests epistemologically in theories of individual behavior and behavior change in order to impact implementation of evidence. QI, with a systems perspective, is more concerned with how to make changes in the system in order to produce behavior change. As a consequence of this difference, QI utilizes managed change as a key change approach, as this is how systems are impacted. In contrast, KT utilizes a variety of behavior change theories and strategies to influence change.

The impact of QI and KT (iKT in particular) on research in healthcare settings go beyond the potential to improve the relevance of a research question or the success of change implementation. Traditionally, research has been conceived as something that only researchers do and that fits strictly within the scope of academic expertise (69). QI and iKT can empower knowledge-users and decision-makers to participate and even lead knowledge production and transfer.

Utilization of combined QI and KT approaches to design and implement healthcare interventions, particularly in complex clinical settings, is beginning to be perceived of as an additive strength. KT and QI are different in their lens, framework and methods but there are many commonalities. Both KT and QI focus on improving outcomes by changing practice, attempt to understand complex contexts, evaluate clinical performance and implementation of change, and consider sustainability of change interventions (70).

2 CHAPTER TWO: CONTEXT IS EVERYTHING: HOW CLINICAL CONTEXT INFLUENCES INTERPRETATION AND USE OF AN ADVANCE CARE PLANNING POLICY

This manuscript will be submitted as: Shaw M, Raffin S, Robertson L, Booker R, Holroyd-leduc J, White D, Grant A, Simon J. (2019) *Context is everything: How clinical context influences interpretation and use of an advance care planning policy*

Abstract

BACKGROUND: Advance care planning (ACP) is a process through which individuals share their values, goals and preferences regarding future medical treatments with the purpose of aligning care received with patient wishes. Implementation of consistent and effective ACP remains challenging despite recognition of its importance. The objective of this study was to explore perspectives from patients and clinicians in four clinical settings to understand how context influences interpretation and application of advance care planning processes.

METHODS: This study utilized a qualitative interpretive descriptive design. Participants were thirty-two patients and thirty-three clinicians across four clinical settings (Cancer, Heart Failure, Renal and Supportive Living). Data were collected using recorded one-on-one semi-structured interviews.

RESULTS: Themes common to all four contexts were: i) lack of shared understanding between patients and clinicians and ii) a lack of consistent clinical process related to ACP. ACP understanding, and process varied significantly between contexts. This variation seemed to be driven by differences in i) perceptions around disease burden and ii) the nature of the physician-patient relationship.

DISCUSSION: Provision of a system-wide policy and procedural framework is not sufficient in and of itself to form a standardized approach to ACP, as significant variability exists in the meaning associated with ACP between clinical contexts. Quality improvement methods that consider local processes, gaps and barriers, can help in developing a consistent comprehensive process. To better align care with patient wishes and values, widespread adoption of programs to enhance communication through clinician education or ACP facilitators can be helpful.

2.1 Introduction

There is a growing demand for person-centered care that reflects the values and wishes of patients (71). All individuals with capacity can consent to or decline medical interventions; however, seriously ill people and those nearing death may no longer be capable of making or communicating their decisions (72). Advance care planning is a process that supports adults at any age or stage of health in sharing their values, goals, and preferences regarding future medical care (1). To improve concordance between patient wishes and provided care, health systems across Canada are engaged in efforts to increase frequency and quality of ACP. Starting in 2008, Alberta Health Services (AHS) began implementing and disseminating a policy and procedure for ACP and a framework for communicating health care decisions and medical orders called, "Goals of Care Designations". The policy provides broad guidelines and emphasizes early initiation of conversations, but it does not give concrete timelines for ACP activities (Table 1). Implementation of ACP was accompanied by the building of infrastructure (web site, patient resources, standardized forms for Goals of Care orders and an ACP GCD conversation tracking record) and education via a healthcare provider e-module and seminars.

Table 1

Alberta Health Services ACP Policy and Procedure (2014)

Advance Care Planning	*"All adults should be given the opportunity to participate in Advance Care Planning as a part of routine care, started early in a longitudinal relationship with a healthcare provider and revisited when the health or wishes of an adult changes" Page 1*
Goals of Care Designations	*"Goals of care conversations shall take place, where clinically indicated with the patient, as early as possible in a patient's course of care and/or treatment. These discussions explore the patient's wishes and goals for clinically indicated treatment framed within the therapeutic options that are appropriate for the patient's clinical condition" Page 1*

Rates of ACP engagement and concordance between patient wishes and care provided

remain low in Canada (11, 73, 74). Various patient and clinician factors impact the uptake of ACP (8). Different clinical contexts can also uniquely influence the attitudes, approaches and processes of ACP (75-77). These differences have not been examined within a single study in one health region that operates under the same system-wide policy and procedure. This is important because it is difficult to gain a robust understanding of the factors influencing ACP uptake among clinical contexts if these are compared across varying health regions, each with unique ACP policies and priorities. Further, ACP interventions that have been successful tend to target ACP processes (29). Thus, understanding the factors that might uniquely impact ACP processes across clinical contexts can help researchers and clinicians frame interventions to address these unique considerations. The objective of this study was to compare patient and clinician perceptions from four different clinical contexts: cancer, chronic disease (heart failure and renal failure) and seniors care (Supportive Living residents). We aimed to understand how clinical context may influence interpretation and uptake of existing ACP policy and procedure.

2.2 Methodology

Design

We applied a qualitative interpretive descriptive design in order to gain an understanding of what the ACP process is between and among these four contexts and how this process is shaped (78). Interpretive descriptive design (ID) is a non-categorical qualitative research methodology that aims to generate knowledge pertaining to a practice question of inquiry. It is well suited to the aim of this study as it promotes the creation of knowledge for the purpose of informed action.

Ethical approval was obtained from the Conjoint Health Research Ethics Board of the University of Calgary and the University of Alberta and included administrative approval from

the manager of each clinic. Written informed consent was obtained from each participant.

Participants

Patient inclusion criteria included aged 18 years or older, English speaking, and the presence of one or more of the following conditions: congestive heart failure, cancer, chronic renal failure, or residing in Supportive Living (79). Exclusion criteria included lack of capacity to consent. Health care providers (HCP) were eligible for participation if they were employed within one of the clinical contexts under study.

Setting

Participants were enrolled between April 2014 and June 2015 from four clinical settings in Calgary and Edmonton, Alberta: Renal Failure out-patient clinic, Blood and Marrow Transplant program out-patient clinic, supportive living residential facilities and Heart Function out-patient clinics. Patients were interviewed in the clinic or Supportive Living facility. Clinicians were interviewed in their location of choice.

Data Collection

We used semi-structured interviews with patients and clinicians. Interview guides (detailed elsewhere (34)) were structured to ask broad questions about ACP process, individual roles, barriers and facilitators. Patients were invited to participate by nurse managers in each context. Clinicians were recruited using snowball sampling (80). Four trained interviewers conducted all interviews, with a single interviewer assigned to each clinical setting. Interviews were audio recorded, transcribed verbatim and uploaded to the Health and Research Data Repository, a secure virtual research environment at the University of Alberta. Field notes captured additional observations. Interviews continued until data saturation of ACP perspectives was reached, as determined by regular meetings among the interviewers.

Analysis of Data

In accordance with the flexibility of ID, we performed a thematic analysis, via the following actions (81). First, we analyzed context specific data by: 1. Immersion in the data during data collection. Interviewers listened to each interview, read transcripts and made notes to gain a familiarity with overarching messages; 2. Coding by each interviewer with guidance and scrutiny from content and methodological experts on the team. Coded data were entered into the computer software NVIVO (QSR International, Doncaster Australia); and 3. Development of a sub-theme template by grouping codes and refine patterns through a constant comparative method. Emerging patterns between groupings were challenged, reviewed and revised (82).

The research team met over the course of four months to analyze data between clinical contexts by: 1. Familiarization with the data through the review of notes, codes (with associated quotes) and groupings; 2. Amalgamation of sub-theme templates through refinement via assessment of similarities/differences and patterns; and 3. Development of final themes (Figure 2) completed inductively from the analysis. The guiding goal was: 1. To describe ACP process among and between contexts and 2. To gain an understanding of the factors that influence that process. Through reflection, debate and comparison, sub-themes were used to develop a hierarchical system of overarching (i.e. conversation drivers) and more narrow themes (ie. Patient-clinician relationships). The researchers were focused on addressing the stated analytic goal, while also being receptive to any interview information that might alter or expand the purpose.

2.3 Results

Participants characteristics are summarized in Table 2. Two themes emerged common to all four contexts: i) lack of shared understanding between patients and clinicians; ii) a lack of

consistent clinical process related to ACP. ACP understanding, and process was varied between contexts, driven by disease burden and by the nature of the physician-patient relationship (Figure 1).

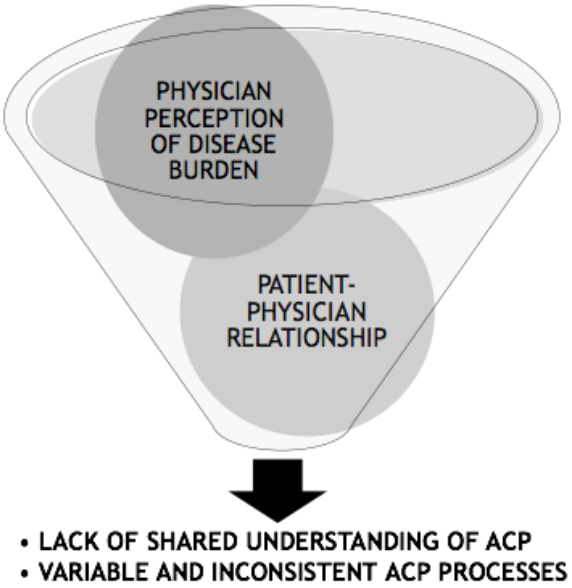
Table 2

Summary of participants by role

Participants					
	Patients	Nursing specialties	SW	Dietician	MD
Supportive Living	10	5	1	0	3
Heart Function out-patient Clinic	8	2	0	1	6
Renal out-patient Clinic	10	3	1	0	4
Cancer out-patient Clinic	6	3	1	0	4

Figure 2

Relationship among themes



Lack of shared understanding of ACP

Patients and clinicians expressed varying conceptualizations of ACP (Table 3). Advance care planning was often not a term familiar to patients, and many associated ACP exclusively

with the completion of related end-of-life activities, such as transitioning to non-independent living, planning one's funeral or completing a will. Sometimes, ACP was felt to be synonymous with planning the next medical intervention. When asked directly about specific activities, patients demonstrated a thoughtful approach to key ACP steps (thinking, discussing, documenting).

Table 3

Variable Understanding of ACP

PATIENTS	*"…I think it just means…where you go and what you do when you get to the point where you can't look after yourself.*" (SL)
	"*Oh yeah, my will's all done*" (HF)
	"*Yeah, we have done that…we have our funeral arrangements all made." (SL, Female)*
	"We've gone through the process of arranging our, what do they call it, the finances and I believe the health issues if we're unable to make decisions." (Renal)
	"Well...you could say that the...bone marrow transplant was care planning because the uh, Rituxan didn't work, so we're looking to plan for the next. Yeah, and then after that, we planned for the next event because we knew it's [lymphoma] gonna come back or we assumed it would come back, so we got into bendamustine." (Patient with lymphoma)
	"I guess first of all…you'd have to be afraid of dying in order to do a whole bunch of the advance planning. I'm not scared to die….you know…I don't wanna live in a bed or a wheelchair…so if that's called advance planning, then that's as far as I've ever gone because I just don't wanna be a burden to anybody else." (HF)
	"Oh, we spent a lot of time thinking about what we wanted. This isn't something you can just sign, you have to really think about it.", (SL)
CLINICIANS	*"…originally, I thought it was something that got you right to the resources, but now I understand it's a way of thinking, a way of managing, way of preparing family and the patient to think about what they want to do for the next stage of their life" (HF Dietician).*
	"…it's our obligation for us to keep people informed about what may happen to them in the future ..how they can participate and decide what happens to them" (HF physician).
	"often they would push the Goals of Care sheet across to the family and say now, "Do you want them left where they are right now, or should we put them at another level?" And like – you know, I - I'm not in charge of that whole process, but it's kind of like, "Let's just take a step back for a minute and let's talk about what changes maybe you've seen in the last year." (SL Nurse)
	"...the situation where I work, I think it's more, um, starting a conversation, um, about patients' wishes...both the patient and their family, um, with the ultimate goal at least to put something on paper ..." (BMT Physician)

In contrast to patients, clinicians expressed a complex understanding of ACP terminology and activities. A conceptual model of ACP as a process by which to elicit values and preferences for future healthcare, particularly in life threatening conditions and to communicate prognosis

was shared by clinicians across all contexts. Still, there was concern among clinicians that a greater emphasis was sometimes placed on completion of medical order forms (GCD) rather than other aspects of ACP, such as conversations and elucidation of values.

Lack of shared ACP process and uncertainty around roles

In the contexts where ACP was considered to be a multidisciplinary activity, role challenges were particularly apparent (Table 4). In the heart failure context, ACP is often nurse-led but communication between physicians and nurses is not standardized and physicians were sometimes unsure about how the process functioned. In supportive-living, non-physician clinicians were conflicted by the knowledge that they have a responsibility in the ACP process but uncertain about the extent of that responsibility. Often these clinicians were uncertain about what aspects of the ACP conversation they can initiate. In the renal context, ACP "tasks" were described to be inconsistently passed between clinical staff, physicians, a dedicated ACP nurse or palliative care consultants. One nursing staff member indicated that they alert the physician annually to ensure that GCD forms and discussions are up to date, while physicians stated they refer patients to the ACP nurse or used palliative care consultants for ACP conversations. These various approaches are not mutually exclusive but indicate a lack of consistency in the initialization of ACP. In the cancer setting, ACP appeared to be primarily, if not exclusively the responsibility of physicians, which some embrace while others express unease.

Table 4

Inconsistent process and role uncertainty

HEART FUNCTION	*"I know that…the heart failure clinics are very structured. So, nursing, I'm certain…approaches patients about that early on in their interactions with them…whether that happens on the first encounter, we're not sure'. (Physician)*
	Usually it's the nurse who brings it up. Sometimes it's the physician. It depends on the situation but it's definitely not a conversation that we do on a regular basis. (Physician)
BMT	*"It's just like anything else. Uh, do you have an allergy? Are you on any medications? What are your goals...what do you want us to achieve here?" (Physician)*

	"as the physician, it's my responsibility. I hate it - I absolutely hate it, especially if I don't know the person" (Physician)
SUPPORTIVE LIVING	"*They [nurses] don't know whether - how far they should go, what they should do." (Nurse)*
	"*…I really think that the multi-disciplinary team don't know… there's this huge role." (Nurse)*
RENAL	*"we make sure that once a year like when they come in, the patient comes in to see their nephrologist that the goals of care are up to date and if they're not just letting the nephrologist know, so then that nephrologist can have that conversation with the patient." (Nurse)*
	'we have an advanced care planning nurse so we kind of let her do her thing," (Physician)

Conversation drivers

The nature and timing of ACP conversations appeared to be driven by two related considerations that varied between contexts and clinician role (Table 5). These were: 1) clinicians' perception of disease burden and 2) the relationship between clinicians and patients.

Table 5

Perceptions on Disease Burden

	The challenge with chronic conditions, especially in cardiac, is the trajectory of their illness is unknown and it's up and down and up and down, so there may…be points where they're feeling…'these are my wishes'…and then the course of their illness changes so their idea of what they want to continue on with changes…but that's where it becomes REALLY important…that you're having those conversations on more than one occasion" (HF Physician)
	"Oh fine. Yeah, I don't mind talking about it. I know I'm going to die. Sooner or late". (HF Patient)
	…we have to talk to people about their prognosis…in part because we can modify it by giving them drug therapies or device therapies…and some of those therapies, also have a benefit in terms of how people feel, and some of them don't. So, it automatically generates a discussion about whether that's a value to them." (HF Physician)
	'I guess I want to be in control of my life…and if I have to rely on somebody else to feed me and dress me and take me to the toilet, I don't want that. I refuse…that's quality of life" (HF Patient)
	"Unfortunately, we get asked when we're in the midst of being acutely ill. And therefore, you're not equipped to come up with those answers as easily as you would've if you were feeling well" (female HSCT patient
	"My own view is that there's a certain threshold that you cross, and once you cross that threshold, that's when these conversations happen more easily, right?" (HSCT recipient)
	"My practice is mostly lymphoma so there might be patients who I meet the first time in the um, consultation...I'd say, 'Ok, look, you have a very aggressive lymphoma. I'm not sure this [transplant] is going to work. We're going to try this going in but at some point, if things aren't working, we're going to have a different discussion'...So for some patients it's really obvious I can do that and then others, it's a pretty straightforward thing...'No, no, we're still heading into cure' and I don't have to talk about the negatives" (Physician, BMT)
	"Um...probably if, the doctor, um, brought it up as something that, um, that I need to look into. Like, having the doctor's - a doctor's encouragement would make it...would make the process easier." (Patient, BMT)

	"*The medical community does note when patients are declining, and I have been asking other roles to consult changing the goals of care when patients are declining."* (Renal Nurse)
	, "If I feel like patient I don't see very good prognosis… that death is to happen in a very near future…then I absolutely need to bring up earlier." (Renal Physician)
	"[ACP is] something that was never really thought about… I'm still pretty much on the healthy side. Although I have kidney failure and I have to take the dialysis." (Renal Patient)
	"*I mean the bigger philosophical question is whether or not…the life is worth living at that point and that, that becomes very hard especially with dementia.*" (SL Clinician)
	"*…I tend to be less fatalistic…with some families who are saying C1 [level of care]…has got dementia, not the man he used to be, wouldn't want to live like this, we promised he wouldn't go to nursing home and, and I look at him and I say well he's attending programming, and he's eating full meals, and he still recognizes his family". (SL physician)*
	SL patient: "*… When you get into 90 and you're not, you don't have the best of health and- and I wouldn't put my family through that. You know, so we did talk about it and they all agreed at the end.*
	I think once your starting to see more frailty, and more contact with the system, I think probably then is the time, you know if it's been awkward up 'till this point, I think for sure here going to hospital, you know if you're over 75 and you've been in the hospital twice in the last year, I mean if you haven't had the conversation, you probably should.(SL Physician)

Disease Burden: Physician perceptions of disease burden emerged as a major driving force in ACP conversations, including the subjective assessment of the impact of disease on the patient's function, quality of life, expected degree of benefit from treatments and expected trajectory of illness. Beliefs regarding when a disease has become "burdensome" appear to determine when conversations are initiated, which in-turn establishes the purpose of ACP conversations.

Illness complexity and fluctuation factor into the ACP approach for heart failure, renal and cancer contexts. However, the ways in which these drive ACP are unique to each context. In heart failure, ongoing and practically focused ACP is pursued in anticipation of the fluctuation embedded in disease decline. ACP conversations determine treatments and interventions currently and throughout the course of illness or health decline to optimize patients' quality of life as related to physical functioning. In the cancer setting, the possibility of cure appeared to hinder physicians from engaging in ACP, which was thus reserved for a change in patient health status, usually associated with treatment failure. ACP conversations were used to determine end-of-life care after curative interventions were proven ineffective. Similarly, in the renal setting,

ACP is triggered by substantial or acute health decline, and therefore, focused on planning for end-of-life. In the supportive living context, initiation of ACP conversations was driven by clinicians' perception of patients physical functioning and frailty, where the purpose of ACP was to develop treatment plans based on patients' current state. Determinations of quality of life were expressed as difficult by physicians due to the high prevalence of dementia.

Early and ongoing ACP was reflected in heart failure patients' acceptance and comfort in having these conversations. Cancer patients felt deteriorating health status lent itself well to initiation of ACP, although some highlighted the problematic nature of initiating conversations during an acute medical event. They were receptive to ACP at any time if initiated by physicians. Uniquely, in the renal setting, there was a striking agreement between patients and clinicians, opting to leave ACP discussions until a time when patients are acutely ill and in substantial health decline. When SL patients were asked, their considerations for medical intervention were prioritized based upon prospects for physical independence, quality of life and family considerations, rather than specifically the physical functioning that drove healthcare providers to initiate ACP.

Patient-clinician relationships: The relationship between patient and clinician was a second important conversation driver (Table 6). Clinicians value building rapport before engaging in ACP discussions, but professional role influences the content of conversations. Allied healthcare professionals tend to emphasize the importance of providing support and understanding a patients' values. Conversely, many physicians described taking a directive role in the relationship, focusing on the specifics of illness and treatment options or availability.

Table 6

Relationships as conversation drivers

HF	*"Well, I don't offer them a carte blanche here. Usually, I tell them about the disease…different ways of dying…and..options…but I wouldn't discuss transplant in someone who's 80 years old and has renal failure…so I don't offer options that are not really available for that patient". (Physician)*
	"I would say..do you know about this program, and it could maybe ease your family and yourself…reduce the stressors…if you can plan ahead as to how you would want things done". (nurse)
SL	"*You have to draw people out through your relationship and understand their values." (SW)*
	"*I don't do it on the first 'Hello, how are you? I like to develop rapport with patients before introducing the topic."* (Physician)
	think it can be a little, I think with the goals of care can, there's a problem with, although it always intended to be this is the patients wish, this needs to be respected throughout the sector, I think sometimes it's not necessarily the patients wish but there's a bullishness to how it's, this is you know there's like a…what become dogmatic, this is an M1, or this is a C1 (Nurse)
Renal	*"I'm gonna continue to bring it up at every single meeting until we get this document because this is just really important for us to know." (Physician)*
BMT	*"I don't really give them a choice. I just tell them, 'Ok, this is what's happening. I think if something drastic happens to you – like if you have a cardiac arrest or something serious happens, because of your disease and how terminal it is, my recommendation is that we don't do resuscitation." (BMT Physician)*
	"My approach is often to suggest to patients what they would…what they should want in this situation." (BMT Physician)

Our findings show that there are few instances where clinicians and patients are congruent in their understanding and conceptualization of ACP. ACP process is inconsistent within and between settings, compounded by some providers' uncertainty about their role in the process. ACP conversations are driven by professionals' perceptions around progression of disease and the relationship between providers and patients. Role challenges and uncertain ACP process was common among settings, while perceptions around disease burden appeared to be setting-specific. These perceptions in turn, determined the timing and content of ACP conversations.

2.4 Discussion

The findings from this study provide in-depth understanding of why ACP processes vary across and within different clinical contexts within a single health system. The provision of a system-wide policy and procedural framework does not appear sufficient in and of itself to form

a standardized approach to ACP, as significant variability exists in specific clinical considerations that impact and determine ACP. Our study adds to the literature by identifying disease burden perception as a key determinant of the timing and content of ACP. In some contexts, disease burden considerations do in fact delay ACP, while in others, they enable it to begin early.

ACP process has not been widely studied and has not been previously compared across clinical contexts. Most studies focus on barriers to ACP engagement, rather than the engagement process and its influences, although inter-professional and system factors have been identified as potential facilitators (29). As was found in this study, patients, particularly as they age, are willing to engage in ACP (34). At the same time, patient knowledge of ACP has been shown to be limited (83). Uncertainty regarding illness course and clinician beliefs around appropriate treatments play a key role in the evaluation of disease burden and the subsequent timing of ACP conversations. These findings are consistent with those showing that physician uncertainty related to illness trajectory, prognosis and roles are barriers to implementation efforts aimed at increasing ACP (29, 37). These factors can prevent appropriate timing of ACP (29). In fact, ACP has been shown to be delayed until the very end of life for both cancer and hemodialysis patients (84). This is especially problematic as patients might receive limited benefit from care services, such as hospice care.

This study was limited to English speakers and therefore may not represent diverse populations. Additionally, findings from our sample of patients and clinicians from a hematological malignancy context may not be representative of perspectives of those with solid tumors with a different disease trajectory. Patient participants were identified by nurse managers, and therefore may not be representative of patients in each clinical context.

This study's finding that ACP is driven by healthcare provider perceptions of disease burden suggests that in making this determination, patient input is not necessarily sought. A practice shift is needed to prioritize the voice of the patient, irrespective of context because patient wishes are not reliably predicted by healthcare providers (73). Engaging the patient in sharing the decision-making process regarding interventions and care can help to reduce unnecessary over and underuse of medical care and lead to better patient outcomes (85).

Further, there is a tension between the desire to reduce practice variance and to support contextual adaptation for any policy implementation within healthcare systems (86). Reducing variation in contextual processes cannot be done through written procedure alone. Quality improvement methods applied at both the micro- and macro-system level, that consider local processes, gaps and barriers, can help in developing a consistent comprehensive process (87). Some specific practice recommendations based upon the findings of this study are: 1) To engage clinical teams in simple quality improvement exercises in order to establish current ACP practice, ideal practice and determine changes and role clarifications necessary to fill the gaps between the two and 2) Adopt use of simple conversation guides and tools to help clinicians expand the focus of ACP conversations to better encompass patient values and quality of life considerations (88). The Serious Illness Conversation Program is one example that can assist clinicians in framing discussions to elicit patient values (89) as training physicians in communication around ACP has been shown to improve ACP engagement. Respecting Choices (C-TAC Innovations, LaCrosse, Wisconsin USA) Training Manual is an example of facilitator-led process (90). Such programs can be adapted to disease context, while also providing quality communication.

3 CHAPTER THREE: A METHOD FOR COMBINING INTEGRATED KNOWLEDGE TRANSLATION WITH QUALITY IMPROVEMENT PROCESSES IN THE IMPLEMENTATION OF AN ADVANCE CARE PLANNING INTERVENTION

In this chapter, we build upon the knowledge developed in the qualitative study exploring ACP process across clinical contexts. This manuscript describes the novel methodology we used to design and implement a multi-faceted intervention aimed at improving ACP process on a cardiac hospital ward. This study utilized an integrated knowledge translation approach and our method was guided by the knowledge-to-action framework. The implementation phase was supported by QI process. The findings from this study are reported in Chapter 3 of this thesis.

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Abstract

BACKGROUND: Advance care planning (ACP) is a process that helps adults understand and share their values, goals, and preferences regarding future medical care, with the purpose of ensuring that people receive care that is consistent with their wishes. However, making ACP a routine part of patient care is an ongoing challenge. Addressing clinical processes through the combination of integrated knowledge translation (iKT) and quality improvement (QI) methodologies can help to routinize ACP processes in a relevant, feasible and sustainable manner. The purpose of this paper is to present a novel method for developing and evaluating an implementation intervention that combines iKT theories and strategies with a QI implementation plan to achieve ACP process change on an acute cardiac unit.

METHOD: This combined iKT/QI project was guided by the knowledge-to-action cycle, a local QI process, simulation-based learning and behavior change theories in the design, implementation and sustainability plan of a complex ACP process change intervention. An interrupted time series study design was utilized, and both process and outcome data were examined.

DISCUSSION: Key strengths of this project was the utilization of both iKT and QI methods and tools in the implementation of ACP practices. This methodological approach made implementation feasible and focused on addressing a clinically relevant problem. Challenges included timeline constraints and difficulty achieving full project ownership among all team members.

3.1 Background

Advance care planning (ACP) is a process that helps adults understand and share their values, goals, and preferences regarding future medical care, with the purpose of ensuring that people receive care that is consistent with their wishes (1). ACP is an important aspect of quality patient-centered care because it enables clinicians and caregivers to resolve questions regarding what patients may or may not want. It also helps to generate plans for medical action that reflect patient wishes (8). Without ACP, patients can receive care incongruent with their wishes and worse quality of life (7, 91).

Efforts aimed at increasing the frequency of operationalization of ACP in hospital settings have had limited success to date (8). A primary barrier to ACP uptake appears to be related to implementation (29). Recent qualitative work has shown that ACP processes are inconsistent both within and between clinical contexts, despite a recognition of the importance of ACP among clinicians (10, 34, 77). Furthermore, the main healthcare provider barriers to ACP are process and behavior related, including competing priorities, insecurity around communication and the inconsistency around timing of ACP delivery (29). Even when interventions target communication factors, there continue to be problems around integrating regular ACP into existing workflow, suggesting that practice variation continues to be a problem (29). A further issue in ACP uptake has been one of sustainability. Successful ACP interventions often involve the integration of an ACP facilitator, which is a resource usually only made available during the research processes (92). This level of support is no longer available once the research team leaves, which makes the intervention unsustainable. Despite evidence to support the benefits of ACP, there are ongoing struggles to increase the frequency and quality of interactions between patients and healthcare providers. The challenges of implementing a

sustainable ACP process that is responsive to clinical context remains. Addressing team process must take into account known barriers to ACP, including skills, communication and clinician time constraints. Hence, the design of a complex intervention must be responsive to existing contextual realities and priorities that are setting-specific.

Knowledge Translation (KT) describes a set research approaches and methods derived from planned action theories, to close the knowledge-to-action gap by promoting research use in clinical settings with the goal of improving health service delivery (60). Originally conceived of as a problem of knowledge-transfer, the knowledge-to-action gap, is now better understood as being also driven by a problem of knowledge production (58). Integrated knowledge translation (iKT) is a research approach particularly well suited to addressing knowledge production and transfer in complex healthcare settings by engaging knowledge users and decision makers as co-investigators in the research (49). Practically, KT necessitates change in behavior and decision-making as the end product of knowledge production and transfer. iKT facilitates this type of complex change by engaging individuals with varied expertise and perspectives in an iterative process and allows for communal assessment of change mechanisms and goals (57). Thus, iKT can be effective in the implementation of behavior change strategies that address an existing evidence-based problem, are highly relevant to the clinical setting, feasible for implementation and help knowledge users and decision makers take on active roles in the research process (93-95). The success of iKT as a broad research approach in healthcare is dependent on a nuanced understanding of how iKT is interpreted in a complex environment and how end-users, decision-makers and researchers' roles are defined and incentivized within this context (96). For example, it has been found that when iKT is formally incentivized through national funding in health service delivery programs, the number of 'iKT projects' increased but the actual research process

was investigator-driven and impact on service delivery and outcomes was small (97). Thus, it was imperative that the collaboration between various team members was based upon a shared belief in the value of the project goal.

Similar to KT, quality improvement (QI) is an important part of clinical practice designed to generate immediate improvements in local settings (65). QI in healthcare seeks to generate more consistent, appropriate, and efficient processes using a systems lens for continuous improvement (67). The application of KT with QI can be complementary as they both have the same goal of improving care for patients, while approaching this goal from different lenses and utilizing different methods to achieve this same goal (67). Health regions and organizations are increasingly making QI teams available for clinical research, process improvement and change management efforts (98). However, a key feature of the success of continuous quality improvement in clinical settings has been identified as the embedding of implementation science experts (99). This, along with the increasing application of iKT is important for empowering knowledge users to be active participants and leaders in knowledge production and transfer (69).

Addressing process factors in an effort to increase and optimize ACP is a type of complex quality intervention that requires an iKT approach in order to maximize clinical engagement, feasibility, applicability and sustainability of change. QI process can specifically aid in the routinization of clinical team processes with the goal of improving quality and efficiency. There are limited published examples of the explicit integration of iKT science with QI methods and the integration of these two approaches are not well described (67, 100, 101). The specific purpose of our study was to utilize a combined iKT and QI approach to enhance care through improvement of ACP processes in an acute care cardiac unit.

In this paper, we present a novel method for developing and evaluating a clinical intervention that combines KT methods with a QI process improvement methodology to achieve ACP process change. We describe the steps at which knowledge-users and decision makers were engaged, our method of engagement, process for reaching consensus and making decisions as a team, implementing simulation-based learning for team building and generating a sustainability plan. The presented method constitutes a necessary methodological contribution to the literature that is currently lacking in the application of iKT studies (93). This work can advance knowledge and strategies for the application of iKT.

3.2 Method

This study utilized an iKT approach, guided by the knowledge-to-action (KTA) cycle as our main framework (Figure 3). The KTA cycle integrates knowledge creation and action/implementation, while adopting a systems perspective, emphasizing social interaction and local culture(68). This overarching theoretical framework provides a practical and evidence-informed stepwise knowledge generation and implementation process. The KTA cycle utilizes knowledge beyond research knowledge, such as contextual and experiential knowledge, which is key in a research setting in which the knowledge-users bring their own experience and expertise to the co-creation of interventions (102). We used a locally developed QI process, Alberta Health Services Improvement Way (AIW), in the intervention implementation and sustainability phases of the KTA cycle (103). We also used simulation-based learning (AHS eSIM Provincial Simulation program) to facilitate applied learning and team skill building during the implementation phase.

Quality Improvement - Alberta Health Service Improvement Way (AIW) Model

Alberta Health Services Improvement Way (AIW) is a locally developed quality improvement process that is based in the process improvement methodology of LEAN and Six Sigma principles applied to healthcare (104). AIW has four interrelated steps for process improvement. The first is Defining the Opportunity. In this step, the need for change is expressed, general goals are outlined, and champions and thought leaders are identified and engaged. In the second step, Build Understanding, current processes are mapped, and Root Cause Analysis completed to understand the mechanism associated with the change opportunity. From this, existing behaviors are identified, ideal processes are designed, possible interventions are brainstormed and categorized, and an evaluation plan developed. During the Act to Improve phase (step three), the selected interventions are implemented, measured, reviewed and refined using the PDSA-cycle (plan, do, study, act). QI uses short PDSA (plan-do-study-act) iterative cycles to rapidly test change strategies (105). In the final step, the Sustain Results phase, a sustainability plan is developed, enacted and monitored. This AIW process was integrated into the KTA cycle to guide the steps of barrier assessment, intervention development and implementation, as well as to monitor and sustain our ACP implementation intervention. AIW process improvement was an important facilitation of actual change element implementation due to their structured process for practically based implementation that readily takes into account clinical realities.

Simulation based Learning

The local simulation team, Alberta Health Services provincial simulation program (eSIM), was engaged to facilitate experiential learning for each team member, as part of the intervention step of the KTA cycle. Simulation is an evidence-based practice that involves learners participating in a simulated scenario, followed by a facilitated, structured debrief (106).

Participation in simulation is designed to strengthen learning through skill development and reflection. Simulation was done with front-line clinicians to build motivation regarding having ACP discussions, develop ACP communication skills with patients and families and solidify interprofessional team process in each clinical setting.

Knowledge Translation - Behavior Change

The selection and verification of behavior change intervention components was guided by the Theoretical Domains Framework (TDF), the COM-B, and the behavior change wheel. These models are used to identify barriers and target behavior change strategies. The TDF contains 14 domains to identify the determinants of behavior change for implementation interventions (107). When assessing barriers and opportunities for behavior change, each of the 14 domains can be examined to determine targets for change. The targeted behavioral domains can then be matched to change strategies using the Behavior Change Wheel (108). The TDF domains are: i) knowledge, ii) skills, iii) social/professional role and identity, iv) beliefs about capabilities, v) optimism, vi) beliefs about consequences, vii) goals, viii) memory, attention and decision processes, ix) environmental context and resources, x) social influences, xi) emotion, xii) reinforcement, xiii) intentions, and xiv) behavioral regulation. We utilized the TDF to guide the identification of behavior change determinants when assessing existing barriers to ACP engagement.

The 14 TDF behavior change determinants can be summarized into the COM-B model (Capability, Opportunity and Motivation), which represents the three elements necessary to achieve behavior change (56). The COM-B model is then mapped onto the behavior change wheel, which matches change strategies to behavior change determinants (9 intervention functions and 7 policy categories). The change strategies comprise validated intervention

strategies that are most likely to successfully change a target behavior (54). We used the COM-B and behavior change wheel, in combination with the TDF, to ensure that our developed change strategies were appropriately targeted to the identified barriers to ACP implementation.

Applying the Models

Each step of the KTA cycle was comprised of a set of activities, informed by specific theoretical constructs and models (Figure 3).

Figure 3

Summary of Models, Timeline and Activities

ACTION CYCLE STEPS	Identify knowledge to action gap	Adapt knowledge to local context	Assess barriers to knowledge use	Select, tailor and implement interventions	Monitor knowledge use	Evaluate outcomes	Sustain knowledge use
	Sept 2015-March 2016	April-June 2016	August – October 2016	October-December 2016	August 2016 - April 2017		May 2017 +
ACTIVITIES	Review of literature Completion of exploratory research Developing local problem statement	Formation of clinical, research and implementation teams Role clarification Development of study goals	Process mapping Assessment of healthcare provider barriers Baseline process/outcome data collection	Enactment of implementation plan using 1. Root cause Analysis, 2. Priority matrix, 3. Actions tracking list	Process/outcome data collection using interrupted time series Clinic-specific: 1. Monitoring strategies, 2. Education strategies Tabletop exercise	Process/outcome data collection Using interrupted time series	Sustainability of intervention Data analysis End of grant KT: Project website development
DATA COLLECTION			Pre-Healthcare provider survey Chart audit Patient Survey	Chart audit Patient Survey			Post-intervention interviews Post-Healthcare provider survey
FRAMEWORKS/MODEL	AIW- Define opportunity	TDF AIW- Define opportunity	TDF AIW- Build understanding	COM-B + Behavior Change Wheel AIW- Act to improve Simulation Learning	AIW- Act to improve	AIW- Act to improve	AIW- Sustain results NHS sustainability model

STEP 1: Identifying knowledge to practice gap.

Our project research team consisted of an ACP researcher and palliative care physician and a doctoral student in health services research. Additional research team members helped facilitate step one and two of this project. This team included a knowledge translation expert, nephrologist with ACP research expertise, a health economist and a statistician. This larger research team examined existing population-level research and systematic reviews to identify broad gaps in the application of ACP. Next, available national, provincial and regional data from audits and surveys were used to quantify the knowledge to practice gap locally. Finally, this information was synthesized to define the specifics of the existing knowledge to practice gap and outline broad targets for closing said gap.

STEP 2: Adapting knowledge to local context

The research team then defined the key quality care features that must be addressed to optimize ACP process and outcomes for patients, within the existing local ACP policy and considering available evidence. Provincial policy best practices served as a guide: the Alberta ACP/GCD provincial policy and procedure (www.conversationsmatter.com), advises that i) patients be asked about prior documents and conversations, ii) have further ACP conversations as needed with health care providers early in the course of illness, iii) when clinically appropriate the physician determines a GCD (goals of care designation) and iv) the physician documents both the GCD and the conversation with the patient leading to its determination on the "ACP tracking record" document. These documents should then travel with the patient in a "green sleeve" (standardized folder that crosses all health sectors), and the patient should know how their GCD documents are to be used. Using this framework and the compiled research, the

following indicators were identified as critical for successful implementation of ACP in the local context: i) increase in quality and frequency of ACP conversations between healthcare providers and patients; ii) consistent and appropriate documentation of ACP conversations and goals of care discussions in the designated ACP tracking record; iii) ensuring that patients are provided with a Green Sleeve containing their ACP documentation and instructed regarding how to best use it.

Researchers engaged with other key stakeholders, forming the iKT project team. The local health region (Alberta Health Services) has prioritized addressing ACP in the cardiac setting, so the project had administrative leadership and QI (AIW and eSIM) consultancy support. The researchers used data synthesized to date to engage clinical leadership and gain their support for the project. Finally, front-line clinicians, clinical educators and managers were invited to participate in the co-creation of the implementation project. Each team's role and participation in the project was clearly defined. Through multiple early phase meetings between team members, members were able to facilitate early ownership of the project, more clearly specify the knowledge-to-practice gap identified by the researchers, appraise the developed quality care ACP indicators and translate them into more specific project goals. This resulted in the development of a project charter document (Appendix 1). Over the course of four months, the entire iKT team met to facilitate the initial planning of the implementation project. This included development of the project framework, goals and targets, discussion of current processes and potential barriers to achieving targets, determination of roles and timelines, and development of an action plan.

STEP 3: Assessing barriers to knowledge use

Assessment of barriers was completed through four processes and synthesized in the AIW 'build understanding' phase. First, potential barriers to ACP were brainstormed by front line clinicians, clinician managers and educators at iKT team meetings, informed by their experience and clinical expertise. Next, known ACP clinician barriers were anonymously assessed through an electronic survey, used previously to assess provincial clinician barriers, of frontline clinicians (109). Third, researchers collected baseline process and outcome data for 6 weeks using a chart audit and patient ACP engagement survey. Baseline data were shared with the full iKT team during scheduled meetings. Lastly, QI (AIW) consultants facilitated a process mapping and root cause analysis exercise. The clinical team members were able to prioritize the process that they thought was most pertinent to map, based on their experience, expertise and the feedback they had already received. The intake/discharge process was selected for mapping by the iKT team. Process mapping elicited the current ACP process, ideal ACP process, gaps between the two, and root cause analysis. Root cause analysis determined three key areas for intervention: 1. Process triggers and prompts, 2. Forms/IT and 3. Role clarity/knowledge/skills.

Data on ACP barriers and process from meeting notes, survey and audit data as well as process maps were compiled to help the iKT decide which barriers and behaviors to target for change (in step 4). This was aided by exploring elements of the COM-B/TDF models in relation to the desired ACP behaviors and by contribution from content expertise of team members in simulation and process change (Table 7). This step was completed by the AIW, research team and clinical educators.

Table 7

Behavioral barriers and the corresponding TDF behavior change determinant for in-patient unit

TDF Behavior change determinant	**ACP Barrier**

Knowledge	Lack of knowledge regarding use of ACP tracking record, use of GCDs in hospital
	Lack of knowledge around importance of patients' use of green sleeves
Skills	Some uncertainty about how/when/who should initiate ACP conversations
	Uncertainty about who/how to use the ACP tracking record
Memory, attention and decision processes	Physicians' uncertainty about time to have ACP and to document in tracking record
	Not sure they will remember to use the ACP tracking record
Beliefs about consequences	Physicians not sure about utility of ACP tracking record
Social influences	Currently low use of ACP tracking record and sending patients home with the green sleeve among all members of all clinical teams

STEP 4: Selecting, tailoring and implementing the intervention

During the 'Act to Improve' stage of the AIW process, the iKT team participated in a brainstorming session to select intervention strategies and develop these for the local context. The teams engaged in root cause analysis with the developed process maps in order to identify potential causes for gaps and inefficiencies in the ACP process on the unit (110). Some of these gaps were identified to be targets for healthcare provider behavior (Table 8).

Table 8

Sample target behaviors identified in root cause analysis of process mapping exercise

Team Communication/role clarity
SKILLS: ACP conversation skill development
KNOWLEDGE: Knowledge of ACP components
SKILLS: Experience with use of ACP resources (ex. Green sleeve, Advance Directives)
BELIEFS ABOUT CONSEQUENCES: Communication across clinical contexts (i.e. tracking record)
MEMORY/ATTENTION: Documentation of ACP conversations

Potential strategies for behavior change aimed at these targets were brainstormed and validated against recommendations from the behavior change wheel in order to ensure that developed

strategies were appropriate for targeting necessary behaviors (54). Through this brainstorming exercise, dozens of possible change strategies and interventions were suggested and recorded (Table 9). To aid with narrowing down the list, decisions were made by the clinical team (with guidance from the remaining iKT team) using priority matrices (Figure 4). Low effort, high impact strategies were implemented, while low effort, high effort and low impact strategies were not (Figure 4). Strategies that were found to be in either of the other two categories were then selected or rejected based upon feasibility. Decisions about how to implement selected strategies were made using the development of gantt charts. These spreadsheets were monitored at weekly meetings and track details regarding the implementation goal, identify the responsible clinical lead for facilitating that goal, set time-lines for implementation, track progress and record reach and scope of implementation. Once a schedule for implementation was finalized, actions tracking lists were used to track implementation and adjust strategies as needed during weekly meetings among iKT team members. These strategies were implemented using a single PDSA cycle. It was possible to utilize a second PDSA cycle after the intervention period of this study, in order to better implement simulation learning but the clinical team elected not to begin a second cycle.

Figure 4 Example of priority matrix and implementation selection

Description of implementation goal	Impact score (1-10)	Effort score (1-10)	Change strategy
Formal review of Green Sleeve and SCM info by MD and RN at admission for old or conflicting information.	9.5	3.5	1. Formal education 2. Monitoring
Use simple terms and language that patients and family can understand	10	5	1. Rehearsal 2. Modeling

Table 9

Summary of behavior determinants, matched change strategies and actions taken for acute in-patient unit

TDF Domain	COM-B	Recommended Strategies	Action taken for implementation
Knowledge	Capability-psychological	Information regarding behavior/outcome	Formal education sessions led by ACP/GCD educators Facilitated debriefing sessions following the eSIM clinical scenarios to help simulate key process improvements in having conversations and use of ACP and GCD documentation.
Skill	Capability-psychological	Specify goal/target Monitoring/self-monitoring Incentives Graded tasks Modeling Homework Perform behavior in different settings Rehearsal	Goals and targets set by clinical team Modeling done champion physicians, nurse educators Simulation of initiating ACP conversations through targeted scenarios, developed by clinical team and facilitated by eSIM trained facilitators
Memory, attention, decision processes	Capability-psychological	Monitoring Planning/implementation Prompts/triggers cues	Monitoring ACP tracking record use through development and use of dashboards ACP tracking record prompts installed on unit computers
Beliefs about consequences	Motivation-reflective	Monitoring Persuasive communication Information regarding behavior/outcome Feedback	Monitoring ACP tracking record use through development and use of dashboards Formal education sessions led by ACP/GCD educators. Debriefing sessions led by trained eSIM facilitators focused a) initiation of ACP Process, b) having the Conversation (content, length), c) ACP/GCD Education and d) Teamwork and Role Clarity.

Social Influences	Opportunity-social	Modeling Social support, pressure, encouragement	Nursing management implemented a requirement that all patients have green sleeve included as part of their discharge package, ACP conversations be documented on the ACP tracking record and newly admitted patients are provided with an introduction to ACP and accompanying pamphlet

STEP 5: Monitoring knowledge use

Monitoring knowledge use and evaluating outcomes (detailed in the next section) were activities derived from the study design and research questions that informed this project. In KT research, both outcomes and knowledge use must be measured in order to assess the degree to which the implemented intervention was successful in changing outcomes (patient, clinician or system) but also the degree to which knowledge use has spread among the target population. This can be achieved by measuring level of knowledge, understanding or attitude (known as *conceptual* monitoring) or by measuring change in behavior or practice (known as *instrumental* monitoring). During the AIW 'Act to Improve' phase of this study, the focus was on instrumental monitoring, while knowledge and understanding were assessed by clinical managers, but not formally measured.

The clinical team members selected, and in some cases developed, their own tools for monitoring knowledge use. Instrumental monitoring included the creation of a dashboard to monitor clinician ACP tracking record use and whether patients had a prepared green sleeve in their discharge package. Conceptual monitoring included monthly staff meetings to discuss individual progress with implementation goals and address any emerging barriers, as well as tracking clinicians attending ACP education sessions.

STEP 6: Evaluating Outcomes

Research Question and Design

An interrupted time series (ITS) design was selected to evaluate the outcomes of this study. The researchers sought to answer three questions that were derived in STEP 1 by the research team and informed by factors necessary for quality ACP. Data were collected to answer these questions, but the data collection tools were reviewed with the clinical team, who were able to select additional data points of interest that were analyzed and presented back to them throughout the study period. The research questions to assess quality and frequency of ACP: 1) Are patients aware of having a Goals of Care Designation order?; 2) Do patients indicate having been engaged in ACP by their healthcare provider?; 3) Are patients satisfied with the ACP they have engaged in during this hospitalization?

Additional process data collected sought to answer: Are ACP conversations that documented in the ACP tracking record?; Are patients provided with a green sleeve containing their ACP documentation? And what is the concordance between recorded GCD and patient preferences?

Participants

Participants were patients on one cardiac in-patient unit at the Foothills Medical Centre. Exclusion criteria were cognitive impairment, lack of English language and acute illness.

Tools

Patient data were collected using a chart audit and a condensed version of the nationally used ACCEPT survey (73). This survey is an accepted and validated tool for measuring ACP-related factors and has been used nationally since 2010. The tool has been implemented in the hospital setting, with elderly patients, as well as in primary care. The condensed ACCEPT tool

consists of 11 items and 6 demographic questions. The survey items ask patients about their knowledge of ACP, their knowledge of their own involvement with the process, their satisfaction with the process, current wishes for treatment, and any decisional conflict. Clinician barriers to ACP were also measured using a survey administered before and after the implementation period.

Data Collection

Data were collected by MS bi-weekly for 6 weeks before implementation, 16 weeks during implementation, and 10 weeks post-implementation, for a total of 32 data collection points. Data were collected using a paper ACP survey administered to patients by MS and a chart audit completed using both the electronic medical record and patient chart. Eligible patients were approached by the bed-side nurse for participation. In total, 171 patients participated in this study.

Data Analysis

Data was analyzed using ITS analysis, consisting of segmented regression analysis, calculating a change in slope and trend for each time period (pre-intervention, intervention and post-intervention) in order to estimate any change in outcome variables over time. Clinician survey data was analyzed using chi-square analysis.

STEP 7: Sustaining Knowledge Use

Sustaining change was comprised of AIW processes and guided by the NHS Sustainability Model (111). Sustainability was discussed and addressed throughout the study process (Table 10). Organizational factors were considered even before the initiation of the project, with the realization that unless a receptive organizational culture exists, sustainability is

unlikely. Members of the iKT team then met every three months post-implementation for a total of 12 months, in order to review sustainability efforts and to facilitate implementation changes based upon sustainability progress. Some elements that were incorporated into the project, with the aim of increasing sustainability such as the notion that use of the ACP Tracking Record would decrease work burden on physicians (in addition to improving patient care and communication), were not consistently perceived to reduce work burden by clinicians. As a result, through ongoing sustainability efforts, changes are being made to infrastructure and the electronic health record system in order to better address clinician needs.

Table 10

Project sustainability elements

NHS Sustainability Factors	**Successful**	**Work-in progress**	**Actions**
Process	Credible evidence Adaptable Progress monitoring in place	Benefit beyond simply helping patients	Intervention emerged from known practice gap and intervention elements are based in theory Intervention elements were selected by clinicians Ongoing unit monitoring using dashboard and chart audits Effort to improve functionality of ACP tracking record
Staff	Training provided Staff involved in training development		Ongoing formal and information training available
Organization	Intervention elements fit with goals and culture of organization	Infrastructure (IT)	ACP optimization is a stated health region goal Effort to adapt electronic patient record system to more

			effectively be utilized for ACP and GCD documentation

3.3 Discussion

The goal of increasing ACP quality and uptake between patients and healthcare providers is challenging, despite known patient benefits (7, 8, 29). This iKT project linked theoretical KT strategies with a practical QI approach in the design and implementation of an intervention aimed at optimizing ACP process. The iKT team included researchers, local QI consultants, front-line clinicians, decision-makers and simulation-based learning content experts, enabling the development of research questions that were contextually relevant, implementation strategies and targets that were feasible, and project ownership by key stakeholders.

Benefits and challenges to models used

There are limited published examples of the integration of KT with QI, making this project methodologically unique but presenting challenges for evaluating it against existing literature (112). Potential benefits in combining KT science with QI methods in a context-dependent practice like ACP can be anticipated. The goals of KT and QI overlap, including the endeavor to implement evidence-based practices targeted at improving clinical care. Many hospitals and health regions utilize local QI teams to guide clinical staff and decision makers in implementing practice improvement initiatives (113). However, there is little evidence for the uptake effectiveness of QI projects in clinical settings as these can be informal, and lack appropriate rigor and attention to implementation (113). Partnering KT science and QI methodology can help ensure that the utilization of varied types of knowledge (scientific, theoretical, experiential) are combined in a formal implementation framework, a predictor of implementation success, is pursued from the beginning of a change initiative (49).

However, challenges to using iKT exist. First, unsuccessful iKT projects may actually discourage knowledge-users and decision makers from future engagement in research endeavors, particularly if they feel that the significant time and effort commitment was not worthwhile (58). Second, due to a relative paucity of iKT studies, it is difficult to evaluate collaborative strategies and approaches that work, as well as determining the barriers and facilitators to effective iKT. A recent small scoping review has attempted to address these issues and has identified barriers as: differing needs and priorities among team members, lack of skill and understanding of iKT, and attitudes about research. Enablers include an emphasis on opportunities for interaction and strong leadership commitment (57). This review was limited to iKT involving only decision-makers as collaborators, thus more description and evaluation of studies such as this are needed to gain a full understanding of how to best execute iKT research projects using diverse collaborative team members.

Strengths and Limitations

A major strength of this study is its novelty in utilization of combined iKT and QI methods to address the knowledge-practice gap in ACP engagement. Consequently, this study demonstrates the development and implementation of a theory informed framework to address existing process and team challenges to quality ACP. The integration of QI process with KT science and the ongoing collaboration with end-users, provides a step-wise method for identifying and addressing uniquely contextual issues pertaining to local ACP processes.

Two main limitations emerged from the utilization of this iKT approach. The first was that the timeline for gathering baseline data for evaluation purposes. One of the challenges of bringing together various stakeholders into an iKT team is that each member has timeline and workload considerations that need to be accommodated. Thus, baseline data collection was only

six weeks duration to accommodate the scheduling of the process mapping. It is important to prevent undue research burden on any one partner. Therefore, it was also important to use evaluation data sources that were readily available.

The second limitation of our iKT approach was that, although we made a concerted effort to facilitate project ownership among all team members in an effort to support sustainability, the KT literature does not yet propose best practices to achieve this. As a result, ownership was not consistent among all team members (114). In order to facilitate ownership, high level sponsors signed the project charter, and we engaged team members early and regularly throughout. Specific strategies for ownership development can be borrowed from action research, which is distinct from but related to iKT. These should focus on an analysis of participant dynamics, motivation of participants, facilitation and empowerment.

3.4 Conclusion

This iKT study utilized a novel approach to combine KT frameworks and strategies with QI process, while engaging end-users as research collaborators to address ACP process. Our approach enabled the facilitation of practical, contextually relevant implementation of strategies aimed at improving and standardizing ACP process, that were also evidence-based and theoretically informed in their selection and application. This manuscript details our theoretical project framework and implementation process. The results from the study evaluation will be used to determine whether this combined iKT and QI intervention was able to meet the study goals.

4 CHAPTER FOUR: RESULTS OF AN INTERRUPTED TIME SERIES STUDY

This paper depicts the results of an implementation intervention described in Chapter 2, utilizing an interrupted time series design. The analysis examines both process and outcome measures pertinent to ACP process. In particular, we examined patient knowledge of components of ACP discussions, satisfaction with ACP during hospitalization as well as healthcare provider documentation of ACP discussions on the designation electronic tracking record and preparation of green sleeves (containing patient ACP documentation) to be given to patients on discharge. The nature of the implementation process is further analyzed in Chapter 4, with the goal of understanding the results from this paper in the context of factors related to implementation.

This manuscript will be submitted as: **Shaw M**., Holroyd-Leduc, J. Simon, J. (2018) *Assessing the impact of an advance care planning intervention on clinical team process measures and patient reported outcomes using interrupted time series design.*

Abstract

BACKGROUND: Medical advancements mean that patients are living longer with chronic and acute conditions but also having to make increasingly complex decisions about their preferences for care. Discordance between patient wishes and care received is an ongoing problem. Advance care planning (ACP) is a method for preparing patients for decision making and enabling them to share wishes and preferences for care. ACP has been shown to help align preferences with medical care and to reduce healthcare cost. International guidelines and local policy recommend engaging patients in the ACP process early in disease trajectory, however observational and qualitative studies suggest that care is not concordant with policy guidelines, especially in the hospital setting. We utilized integrated knowledge translation and quality improvement methods to design, implement and evaluate a multi-pronged intervention to facilitate ACP engagement in hospitalized patients on a cardiac medical unit.

METHOD: This quasi experimental study utilized an interrupted time series analytic design with 172 adult patients, with a stay of over 48 hours, admitted to one cardiac in-patient unit between August 15, 2016 and April 4, 2017. The integrated KT team, consisting of front line staff, managers, educators, the research team, simulation learning team and quality improvement process team developed and implemented a multi-pronged ACP intervention consisting of process mapping, root cause analysis, education, electronic prompts and feedback. The 16-week intervention was designed using the knowledge-to-action cycle. We measured temporal changes in patient knowledge of their engagement in ACP and satisfaction, as well as process measures on documentation of ACP on the unit.

RESULTS: Immediately after the start of the intervention implementation period, there was a significant increase in the absolute proportion of patients receiving green sleeves (containing their ACP documentation) as part of their discharge package (+90%, z= 7.6, p<0.01, 95% -1.02- -0.76). No significant changes between the start of the intervention and end of the intervention were observed for knowledge of GCD (+8%, z= 0.66, p=0.50, 95% -0.30- 0.15) and patient satisfaction (+.53, t=2.23, p=0.032, 95% CI -0.10—0.05). There were no significant pre-post differences observed for concordance between patient wishes and documented medical orders (-7%, 95% CI -0.19-.33, z=0.53, p=0.6) and use of the ACP tracking record (+3.2%, z=0.48, p=0.63, 95% CI -0.15-0.09).

CONCLUSION: Our integrated KT intervention was associated with mixed change in patient reported outcomes and clinical process. Significant and sustained change was observed for use of the green sleeves to provide patients with their ACP documentation, but no significant change was observed for the remaining measures. A significant challenge in this study was the short pre-intervention data collection period (6 weeks), which made it difficult to establish baseline trends for the outcomes of interest.

4.1 Introduction

Advance Care Planning enables adults to communicate and document their values and preferences for health care (1). This process can involve assignment of a surrogate decision maker, and completion of a personal directive as well as medical orders. Most patients have to make decisions regarding medical interventions near end of life but are commonly unable to communicate these at that time. Advance care planning has been shown to benefit patients and family members by increasing the likelihood that patient wishes will be followed when they are not able to communicate. ACP helps to ensure that end of life wishes are known and decreases the emotional burden on families (7, 18). However, the problem of ACP quality engagement persists. Patients are often not engaged in ACP and when they are, their awareness of this participation is low (11). Efforts to improve ACP in clinical settings are limited in their success, often due to persistent practice variability and barriers to implementing ACP into regular workflow. We combined knowledge translation (KT) methods with quality improvement (QI) strategies in the implementation of a team-based intervention to routinize ACP process and decrease practice variability. This paper presents the findings of a multi-component intervention improve ACP team process.

Research Questions

In an effort to improve ACP quality and process, the research team determined key indicators of ideal ACP, using an expert consensus process. Since the ultimate goal of ACP, that patients receive care concordant with their wishes, was not a feasible measurement in the scope of this study, surrogate indicators were identified (22). Patient knowledge of the medical order (GCD) directing their care is an important marker of their awareness and participation in the ACP process with a healthcare provider in a hospital setting. Based upon provincial policy and

best practices, every patient should have an assigned GCD, that was arrived at through consultation with the patient (115). Furthermore, although a GCD is based upon or derived from patient values, these are not always readily known to patients and thus, a process of formulation of values, particular, to trade-offs around health and medical care is required to achieve quality ACP. Patient knowledge of this process is an important marker of that quality engagement. Patient satisfaction with their engagement in the current ACP process is another important indicator of the subjective quality of ACP from the patient perspective. Routinizing process is marked by healthcare providers documenting ACP conversations in a designated ACP tracking record and ensuring that patients are sent home with a green sleeve containing their ACP documentation so that this documentation can then be shared with family, GP, and stored appropriately in case of emergency. Thus, this study sought to answer the following research questions: Does the implementation of an integrated knowledge translation intervention aimed at routinizing and improving ACP increase the: *1. Proportion of patients who know that they have a medical order (GCD) (as well as the proportion of patients who can correctly identify their GCD)?* and *2. Reported patient satisfaction with the ACP conversations they have had during the current hospitalization?*

We further aimed to assess the following process measures in order determine the success of implementation:

1. Concordance between patients' stated ACP GCD and the documented ACP GCD

2. Proportion of patient charts with a Green Sleeve (containing ACP documentation).

3. Proportion of patients with documented ACP/GCD conversations in the clinical ACP Tracking Record.

We anticipated a significant increase in the absolute proportion (pre and post) of the outcomes/measures of interest and an ITS analysis that supports these findings, showing an increase that is associated with the intervention and is sustained.

The Intervention

Integrated knowledge translation (iKT) is a method for translating evidence to practice while engaging end-users as collaborators throughout the research process. This study's iKT team consisted of the study researchers, front line clinical staff (nursing, physicians, unit clerks, social work), nursing managers, clinical educators, a local QI team, ACP educators and a simulation learning team. The development of a multi-faceted intervention aimed at improving ACP process on one cardiac unit (detailed elsewhere) was done through ongoing collaboration between iKT team members. Implementation consisted of a pre-intervention baseline data collection period, an intervention period during which behavior change strategies were implemented, and a post-intervention data collection period. Using baseline data and QI processes (derived from Six-Sigma and Lean principles (67)), the iKT team derived an ideal ACP process on which to base the intervention development:

1. Provide patients with ACP information upon admission to unit
2. Engage all patients in ACP discussions, even if simply to affirm those patients who are and will be R level designation
3. Document in ACP tracking record
4. Provide patients with completed ACP documentation to take home on discharge

The intervention consisted of behavior change strategies that were informed by a local

Using the knowledge-to-action framework as a guide, the iKT team identified local barriers to behavior change through process mapping and root cause analysis, intervention strategies to achieve ideal process, monitored implemented interventions, collected outcome data and implemented strategies for sustainability. The intervention involved the following change strategies:

1. Process mapping/root cause analysis
2. Simulation learning to enhance ACP communication and influence change of ACP team process.
3. Prompts/electronic reminders to encourage documentation of ACP/GCD discussions.
4. ACP education sessions to highlight role clarity, characteristics of quality ACP and importance of appropriate documentation of ACP/GCD discussions.
5. Feedback of baseline outcome/process data and monthly rates of ACP/GCD documentation on tracking record.

4.2 Method

This quasi-experimental study design utilized a single-group interrupted time series (ITS) evaluation methodology (116). ITS is utilized to analyze a unit of observation (in this case, one hospital unit); where the dependent variable is a serially ordered time series and observations are collected at multiple points, in regular intervals both before and after an intervention. ITS has been shown to have good internal and external validity, the latter, being stronger when results are generalizable (117). It has further been demonstrated to be more flexible and easier to use than randomized control trial (118). The key strength of this methodology is the ability to apply it in real life settings.

Location

This study took place on a single in-patient cardiac unit at the Foothills Medical Centre in Calgary, Alberta. Although mainly a cardiac unit, with both pre-surgical and other cardiac patients, this unit also contains internal medicine and hospitalist patients. This unit represents the complexity of large hospital units, with a multitude of specialists, allied health staff and changing patient population. This unit has 38 beds, which were filled for the duration of the study period. Attending physicians changed weekly, residents and fellows changed monthly, and allied health staff work in teams according to a shift schedule.

Population

Study participants were all patients on the unit who had been admitted a minimum of 48 hours prior. This was chosen to ensure that any acute illness was likely managed by the time they were asked to participate. Exclusion criteria were a lack of English language, serious cognitive impairment, current severe illness, or patients in the process of being discharged, as determined by the bed-side nurse from their subjective assessment of the patient.

Data collection

Two audit and survey dates per week were selected prior to the start of the intervention for data collection. These days rotated to ensure that each day of the 5-day week was represented equally. On the selected days, MS received a list of current patients. Those who had been on the unit for a minimum of 48 hours were identified. MS approached each bed-side nurse on the unit with the identified patients and inquired about recruiting them. Bed-side nurses excluded patients who were too ill, cognitively compromised, actively dying, not able to speak English or in the process of being discharged. The remaining patients were approached by their bed-side nurse with a short description of the study and asked if MS could discuss potential study participation with them. Patients who agreed were introduced to the study and consent was obtained from those willing to participate. The survey was completed at the bed-side with MS. This took approximately 10-minutes. After completion of the study, a chart audit was completed using both the paper and electronic patient charts. Completed anonymous paper surveys and chart audits were entered into the ReDCap software system at University of Calgary. This secure system stores study data and enables extraction for analysis. At the end of the study period, the data was extracted into STATA software for analysis. Data was collected for 6 weeks before the intervention period, 16 weeks during the intervention period and 10 weeks after the intervention period. Generally, eight weeks of data collection per time period are recommended to maximize

reliability of data trends. However, due to the complexity of time constraints in the unit and with the clinical iKT team, it was not possible to collect data for a full 8 weeks before the start of the intervention period (119).

Tools

A condensed version of the patient ACCEPT questionnaire was used to collect patient reported information regarding their current and past experiences with ACP, treatment preferences and decisional conflict (73, 74). The ACCEPT questionnaire has been shown to have good validity, clarity and low psychological burden. It has been utilized in Canada for the study of ACP since 2012. The survey is focused on asking patients about the essential components of ACP including: values/wishes for care at end of life, communication about prognosis, discussion with family and healthcare providers, deciding on future care, and documentation of wishes that is accessible to healthcare providers (73). We selected the elements of the survey that were pertinent to the outcomes of interest for our study.

A chart audit was used to collect basic demographic data about patients and information regarding the specialty of their treating physician, their assigned GCD, use of the ACP tracking record, whether the patient was involved in the ACP conversation, whether any additional ACP documents were requested or included in the patient chart.

Data analysis

Descriptive statistics were calculated for survey and audit items, including means, frequencies and proportions. ITS analysis was completed using segmented regression analysis. Analysis was performed using the *ITSA* function in STATA (V15.0). Segmented regression analysis estimates the value of the slope of the outcome variable across time using a linear regression for each intervention period (pre-intervention, intervention, post-intervention). The

values estimating statistical significance given in the output represent a comparison of the slope to that of the slope in the prior time period. This allows the researcher to estimate whether the slope has changed compared to the previous period. Segmented regression analysis also estimates the change in level at the start of the intervention and at the end of the intervention (and start of the post-intervention period). A predicted regression line was fitted to each time period. ITS assumes that the relationship between time and the outcome of interest is linear. The general linear regression model is:

$$Y_t = b_0 + b_1 * \text{time}_t + b_2 * (\text{intervention})_t + b_3 * (\text{time start intervention})_t + b_4 * (\text{after intervention})_t + b_5 * (\text{time after intervention})_t + e_t$$

Yt is the proportion of patients or charts with the outcome in week t
Time is the time in weeks at time t from the start of the observation period. This ranges from 1-32 weeks.
Intervention is an indicator for time t occurring before the intervention (intervention=0) and after the intervention (intervention=1), which was implemented in week 7.
Time start intervention is the number of weeks after the start of the intervention at time t, coded *0* before the start of the intervention and (*time-7*) after the start of the intervention
After intervention is an indicator for time t occurring before the end of the intervention (after intervention=0) and after the end of the intervention (after intervention =1), which was after week 22 in the time series
Time after intervention is the number of months after the intervention at time t, coded 0 before the end of the intervention period and (time-22) after the end of the intervention period.
$\boldsymbol{e_t}$ is the error term at time t that represents the unexplained random variation in the model

The regression coefficients are defined as:

$b0$, proportion of patients/charts with the outcome at baseline
$b1$, trend prior to the intervention (baseline trend)
$b2$, change in level immediately after the introduction of the intervention
$b3$, change in trend during the intervention period
$b4$, change in level immediately after the end of the intervention period
$b5$, change in trend in the post-intervention period

For each ITS analysis, to test for autocorrelation, an OLS model was fitted with a lag of 0 and then autocorrelation was tested in the error distribution. Thirty-one lags (weeks) were tested for auto-correlation using the Cumby-Huizinga test for auto-correlation. The Durbin-Watson statistic was also performed to check for auto-correlation. D can range between 0 and 4. D=2 under the null hypothesis. Less than 2 indicates positive autocorrelation, while a value greater than 2 suggests negative correlation. The Durbin-Watson statistic generated d=2.48, suggesting no serial correlation. If serial correlation (autocorrelation) had been found, the data would have been fitted to a prais model (OLS for serially correlated data). However, because no autocorrelation was found, a newey model was fitted.

Any study questions where it was not appropriate to utilize ITS analysis due to extremely small number of responses, a pre-post analysis was completed using a two-sample z-test to examine whether any change could be observed in the periods before and after the intervention.

4.3 Results

Descriptive Statistics

In total, 451 participants were identified as meeting criteria for participation (Table 11). Bed-side nurses further excluded 208 patients and 72 decline to participate. Patients were excluded due to acute illness, imminent discharge, language or speaking difficulty, severe cognitive impairment or off-unit appointments. Thus, 171 participants took part in the study. According to intervention period, 22 participants were recruited in the pre-intervention period, 101 in the intervention period and 54 in the post-intervention period. The average age of participants was 68.6 years (*SD* 14.3). More males (67.3%) participated than females (32.7%) and this trend was consistent in each time period. Participant age varied between time periods, with an older cohort of patients participating in each time period. The majority (70.1%) of

patients in this study were admitted under the cardiology service and an even larger percentage (79.5%) had a primary cardiac diagnosis. Some of these patients were treated by a hospitalist.

Table 11

Descriptive Statistics

		Total (n=171)	**Pre-intervention (N=20)**	**Intervention (N=102)**	**post-intervention (N=49)**
Age		**68.6 (SD 14.3), (R 20-99)**	**61.9 (3.94)**	**67.7 (1.4)**	**73.4 (1.68)**
Sex	Male Female	**67.3% (115)** **32.7% (56)**	**65%** **35%**	**70.6%** **29.4%**	**61.2%** **38.8%**
Marital status	Married Widowed Never married Divorced/Separated	**(98)** **(46)** **(10)** **(23)**			
Place of residence	Home Other (LTC, with family, Assisted living, Lodge, etc.)	**90%** **10%**			
Education	No high-school High-school diploma Post-secondary	**(10)** **(40)** **(119)**			
Has heard of ACP	Yes	**23.7% (40)**	**5.56%**	**28.43%**	**20.41%**
Considered treatments in case of severe illness or hospitalization	Yes No	**63.9% (108)** **36.1% (61)**	**72.2%**	**60.78%**	**67.35%**
Discussed treatment preferences in case of severe illness or hospitalization	Yes No	**61.5%** **38.5%**	**75%** **25%**	**54%** **45%**	**69.4%** **30.61%**
	With Family GP MD during this hospitalization	**74.0%** **23.1%** **60.0%**	**85.7%** **28.3%** **40.0%**	**75.0%** **26.8%** **58.93%**	**67.6%** **14.7%** **70.0%**
Has a healthcare provider discussed the following with you:	Asked you what was important to you as you consider health care decisions at this stage of your life (i.e. values, spiritual beliefs, other practices)	**10.7%** **48.5%**	**10.0%** **45.0%**	**8.82%** **49.02%**	**14.29%** **46.94%**

	Talked to you about a prognosis (life expectancy or predicted course of illness)	**42.6%**	**25.0%**	**44.12%**	**44.9%**
	Given you the opportunity to express your fears or discuss what concerns you	**26.0%**	**25.0%**	**29.41%**	**18.37%**
	Asked you what treatments you prefer to have or not have if you were to develop a life-threatening illness	**11.8%**	**5.0%**	**14.71%**	**8.16%**
	Asked you if you had prior discussions or written documents about ACP	**42.0%**	**40.0%**	**43.14%**	**38.78%**
	None of the above				
How important are ACP discussions (for those how have not had one) (N=70)	Very important Important Somewhat Not very Not at all	**5.7%** **34.3%** **30.0%** **27.1%** **2.9%**	**0** **37.5%** **25%** **37.5%**	**4.65%** **30.23%** **27.91%** **32.56%** **4.65%**	**10.5%** **42.1%** **36.8%** **10.5%** **0**
Satisfaction with current acp discussions (if had) (N=90)	Very Satisfied Satisfied Somewhat Not very Not at all	**43.3%** **43.3%** **11.1%** **2.2%** **0%**	**0%** **(N=7)** **71.43%** **28.57%** **0**	**55.56%** **29.63%** **11.1%** **3.7%** **0**	**31.0%** **(N=29)** **62.1%** **6.9%** **0** **0**
Written acp wishes	Yes No	**30.2%** **69.8%**	**50.0%**	**29.41%**	**24.49%**
Patient has green sleeve (from survey)	Yes No Unsure	**6.5%** **79.2%** **14.3%**	**11.11** **66.67** **22.2**	**4.0%** **83.17%** **12.9%**	**10.2%** **75.5%** **14.3%**
Patient knowledge of GCD presence	Yes	**30.9%**	**27.9%%**	**30.39%**	**34.6%**
GCD Match (knowledge) (N=53)	Yes	**37.74**	**40.0%** **(N=5)**	**48.39%** **(N=31)**	**17.65%** **(N=17)**
GCD match with preference (N=161)	Yes	**57.8%**	**54.54%**	**63.64%**	**47.62%**
Decisional conflict/support (YES)	Do you feel sure about the best choice for you?	**83.9%**	**83.3%**	**84.31%**	**81.63%**
	Do you know the benefits and risks of each option?	**61.9%**	**55.56%**	**60.78%**	**65.31%**
	Are you clear about which benefits and risks matter to you most?	**75.7%**	**66.67%**	**75.49%**	**79.59%**
	Do you have enough support/advice to make a choice?	**89.3%**	**83.33%**	**89.22%**	**91.84%**
Admitted under	Cardiology Medicine	**70.1% (120)** **5.3% (9)**			

	Hospitalist	**24.6% (42)**			
Primary diagnosis	Cardiac Other (Cancer, internal medicine, etc.)	**79.5% (136)** **20.5% (35)**			
Greensleeve in patient chart (from audit)	Yes	**83.6%**	**5%**	**92.16%**	**97.96%**
Assigned gcd	Yes No	**99.4%** **0.6%**			
Proportion of GCD designation	R M C	**77.65%** **20.0%** **2.35%**	**85%** **10%** **5%**	**80.39%** **18.63%** **1%**	**68.73%** **27.08%** **4.17%**
Use of the ACP tracking record	Yes	**6%**	**5%**	**5%**	**8%**

Pre-post and Segmented regression analysis

Figure 5 shows the three time series graphs. Details of the analyses are summarized below. ITS analysis and pre-post t-tests depict varied results across the outcomes of interest. This suggests that some outcomes of interest were more amenable to change than others, given the implemented intervention.

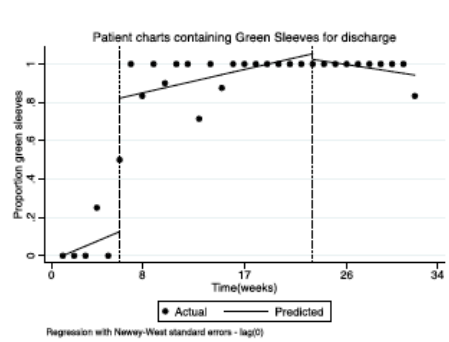
Reported GCD Presence : Overall awareness of GCD was measured at 30.9%. A comparison of the time period before the introduction of the intervention and after the intervention period demonstrates no significant changes in the proportion of patients reporting they have a GCD (Table 1) (+8%, z= 0.66, p=0.50, 95% -0.30- 0.15). There were no significant changes in trend in the weekly proportion of patients reporting having a GCD in the pre-intervention period, intervention and post-intervention periods (relative to the preceding period) (Table 2). There were also no significant changes in level of the weekly proportion of patients reporting the presence of their GCD at the start of the intervention period or at the start of the post-intervention period. Looking at the post-trend estimates (Table 3), there was no significant change in proportion of patients reporting a GCD throughout the intervention or post-

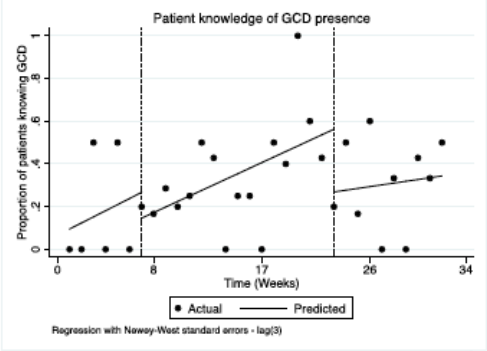
intervention periods. Our intention in this analysis was to also evaluate patients' identification of their recorded GCD. However, due to the fact that there were few patients who believed they knew their GCD (N=53), with only 5 in the pre-intervention period and 17 in the post intervention period, it would have been difficult to establish a baseline and post-intervention trend for an ITS analysis. Examining the proportions in each time period, there is a significant decrease in concordance between patients' stated GCD and their documented GCD (48.39% to 17.65%, z=2.10, p=0.04). It is not possible to determine whether this change represents a true difference, as it was not possible to reliably establish a baseline trend.

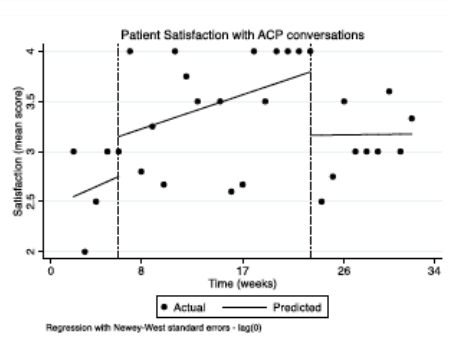
Use of the ACP tracking record: Overall use of the ACP tracking record was 6%. It was not possible to analyze ACP tracking record data using ITS as intended due to the very low use of the tracking record (N=10) over the course of the study (Table 12). Still, a small non-significant increase in tracking record use was observed (+3.2%, z=0.48, p=0.63, 95%CI -0.15-0.09). Graphical representation of the data (proportion of tracking record use per week) (Figure 5) suggest that certain healthcare providers were early adopters of this system and use was high when they were working.

Figure 5

Interrupted time series analysis for weekly proportion of charts containing green sleeves and patient knowledge of GCD presence, concordance between patient GCD preference and recorded GCD and mean patient satisfaction scores of ACP discussions during current hospitalization.







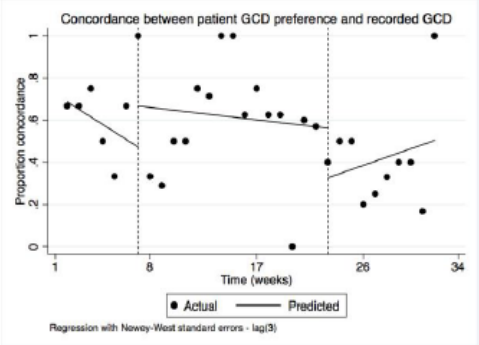


Table 12

Summary of Interrupted Time Series Analysis for main outcomes

	Coefficient estimate	95 % CI	t-statistic	p-value
Presence of GCD				
b_0	0.095	-0.088-0.28	1.07	0.295
b_1	0.028	-0.04, 0.096	0.87	0.392
b_2	-0.12	-0.44, 0.201	-0.77	0.448
b_3	-0.003	-0.07, 0.67	-0.08	0.94
b_4	-0.3	-0.60, 0.02	-1.94	0.06
b_5	-0.02	-0.05, 0.02	-1.10	0.28
Green Sleeve				
b_0	-0.033	-0.055, 0.055	0.0	1.00
b_1	0.025	-0.036, 0.086	0.84	0.41
b_2	0.70	0.37, 1.02	4.33	<0.01
b_3	-0.01	-0.07, 0.05	-0.37	0.71
b_4	-0.03	-0.14, 0.08	-0.54	0.60
b_5	-0.02	-0.05, 0.0003	-2.09	0.05
Patient satisfaction				
b_0	2.55	1.6, 3.47	0.0	0.0
b_1	0.05	-0.35, 0.45	0.26	0.80
b_2	0.40	-0.63, 1.40	0.80	0.43
b_3	-0.01	-0.42, 0.39	-0.06	0.95
b_4	-0.63	-1.6, 0.35	-1.33	0.20
b_5	-0.03	-0.17, 0.10	-0.53	0.60

Concordance between patient GCD preference and GCD recorded in patient chart				
b_0	0.687	.60, .76	17.37	0.000
b_1	-0.036	-.07, .004	-1.83	0.078
b_2	0.194	-.186, .575	1.05	0.305
b_3	0.029	-.018, .077	1.25	0.224
b_4	-0.236	-.608, .136	-1.30	0.204
b_5	0.026	-.032, .084	0.92	0.367

Table 13

Post-trend estimates

	Intervention	Post-intervention
Patient knowledge of GCD Presence	b 0.026, p=0.013 (95% CI: 0.0061-0.046)	b 0.0083 p=0.54 (95% CI: -0.0198-0.0364)
Presence of green sleeve	b 0.014 p=0.10 (95% CI: -0.0029-0.0302)	b -0.0091 p=0.23 (95% CI: -0.02-0.006)
Patient satisfaction	b 0.0379 p=0.13 (95% CI: -0.0114-0.0873)	b 0.0013 p=0.98 (95% CI: -0.13-0.14)
Concordance between patient GCD preference and GCD recorded in patient chart	b -0.0065 p=0.67 (95%CI -0.04-0.02)	b 0.019 p=0.43 (95%CI -0.0311-0.705)

Green sleeve to be discharged with patients: Comparison of the proportion of green sleeves (containing ACP documentation) in patient charts in the period before and after the intervention, shows there was a significant increase (Table 12) (+90%, z= 7.6, p<0.01, 95% -1.02- -0.76). From the ITS analysis (Figure 5), following a non-significant positive trend in the proportion of weekly green sleeve use, a significant change in level is observed immediately after the start of the intervention period (b2). There is no significant change in the weekly trend of green sleeve use during the intervention period and no change in level at the start of the post-intervention period. This is likely due to the fact that green sleeve use was incorporated into regular workflow by nursing and clerk staff immediately at the start of the intervention, reaching a maximum use

quickly and plateauing. A decreasing trend in the weekly proportion of green sleeve use, approaching significant (b5) is noted in the post-intervention period, compared with the intervention period. Looking at the post-trend estimates (Table 13), there was a significant change (p=0.013) in proportion of patient charts containing a prepared green sleeve throughout the intervention.

Patient Satisfaction with current ACP: Comparison of average patient reported satisfaction scores from before and after the intervention period show a significant increase in score (+.53, t=2.23, p=0.032, 95% CI -0.10—0.05). However, it must be noted that only 7 participants gave a satisfaction score in the pre-intervention period as this was the number of patients indicating having had an ACP discussion during this hospitalization. Patient satisfaction did not significantly increase in level or trend during the pre-intervention, intervention and post-intervention periods (compared to the preceding periods) (Table 12). A non-significant positive trend was observed during the pre-intervention and intervention periods, that did not continue in the post-intervention period. Looking at the post-trend estimates (Table 13), there was no significant change in mean satisfaction score throughout the intervention or post-intervention periods.

Concordance between recorded GCD and patient preferences: Overall concordance between patients stated preferred GCD and GCD documented in their medical record was 57.8%. A comparison of the time period before the introduction of the intervention and after the intervention period demonstrates no significant changes in the concordance (Table 11) (-7%, 95%CI -0.19-.33, t=0.53, p=0.6). There were no significant changes in trend in the weekly

proportion of concordance in the pre-intervention period, intervention and post-intervention periods (relative to the preceding period) (Table 12). There were also no significant changes in level of the weekly proportion of concordance. Looking at the post-trend estimates (Table 13), there was no significant change in proportion of concordance throughout the intervention or post-intervention periods.

4.4 Discussion

This ITS study evaluating changes in patient reported ACP outcomes and clinical process measures with a multifaceted intervention found only a significant and sustained change for the preparation and inclusion of green sleeves in patient admission and discharge packages. For patient reported GCD knowledge, a significant intervention effect was not observed. Patient satisfaction did increase based upon a pre-post analysis but closer inspection using ITS demonstrates that neither trend nor level changes were significant in any time period compared to the prior period, suggesting no intervention effect. Similarly, no significant increase in tracking record use was observed. Concordance between patients' stated GCD and that documented in the patient chart was not assessed using ITS due to low patient numbers. Although, concordance decreased significantly between the intervention and post intervention period, when patients' current preferences for care were compared with recorded GCD in the charts, there was no significant change across the three time periods.

With a notable increase in the number of green sleeves prepared for patients, it appears that the intervention was successful in altering the work-flow of nursing staff and unit clerks to encompass the preparation and dissemination of green sleeves, containing ACP documentation for most patients. In contrast use of the tracking record to document goals of care conversations

required changes on the part of physicians who, by local policy, are primarily responsible for these conversations, although nurses and other clinicians can also conduct and document the conversations they have as part of the broader ACP process. A key challenge of KT is achieving behavior change in clinicians (120). There are limitations in current research on how to best facilitate behavior change in clinicians (51). Although useful, practical and theoretically based strategies for change exist in both the KT and QI literature, it is difficult to find guidance specifically on implementation (51). In this study, limited reach to physicians during implementation may have prevented the intervention from impacting physicians' behavior in documenting ACP conversations in the designated tracking record. Only two physicians attended education sessions (compared to all unit nursing and unit clerk staff) and only four physicians attended simulation learning sessions (compared with 12 allied health professionals). Moreover, changing team process requires a focus on team cognition (121). This means that in order for change to occur, the team must collectively change their approach to the work-flow process. This cognitive shift is heavily influenced by social factors among team members, as both KT and QI research has shown (122). Change occurs when opinion or thought leaders within a clinical field are engaged and able to influence team members (122). Only a single physician was engaged in this study as a change facilitator and this was likely insufficient. In the nursing team, clinical managers as well as nursing educators, nursing staff and unit clerks were engaged in intervention development and implementation. Additionally, due to the integrated nature of the nursing team, educators and nursing managers were easily able to facilitate and monitor adoption of change strategies for green sleeve use (and other unit selected process measures, such as providing patients with informational pamphlets on ACP, which were outside of the scope of the researchers' evaluation). Due to both the low number of physicians engaged in the intervention,

and the distributed nature of physician teams, the engagement approach utilized in this intervention was not sufficient to affect team cognition and produce change in ACP documentation. This is particularly true because previous studies aimed at increasing documentation have not been successful in making change (123, 124). Changing habits related to documentation are particularly difficult to overcome, partly because there is a lack of motivation when it comes to documenting (36). These difficulties illustrate the challenges faced in implementation of evidence-based interventions when multidisciplinary teams are the target of the intervention. There cannot be an assumption that different types of clinicians can be engaged using the same methods. For example, in expanding this work to other units at our hospital, we have adopted the strategy of engaging nursing staff as a team but engaging each unit physician *individually* to recruit them to either participate as collaborators or to prime them for the project and impending change goals.

We did not see an intervention effect for either patient reported GCD knowledge or patient satisfaction with ACP discussions. Patient knowledge of GCD in this study (~30%) was consistent with prior research in this area (125) These domains are reflective of the quality of ACP (and GCD) discussions between patients and clinicians and a recent study has reported success in making significant change in these patient reported outcomes (13). Change was achieved by priming physicians for GCD communication in order to address known communication barriers (8, 13). Our study similarly attempted to address these barriers through both passive and simulated learning, in order to teach clinicians, the principles of ideal ACP communication and give them the opportunity to practice these skills and debrief in order to solidify this knowledge. Most unit nurses received an information session on ACP communication and a simulation learning session was held, which was attended by four

physicians (out of 46 who work on the unit) and nine nursing staff (out of 55 who work on the unit). It has been established that passive learning is a less effective change strategy than simulation and modeling (126). Thus, it may simply be the case that an insufficient number of staff were given the opportunity to engage in simulation learning to produce widespread change in improving the quality of conversations such that these are then reflected in patient reported knowledge.

Limitations

The most significant limitation of this study was the short pre-intervention period that we had for accumulating a baseline trend. Power calculations for ITS are complex and highly variable depending on number of measurements and subjects at each measurement time point, which cannot always be predicted before the start of an intervention. Generally, eight pre and eight post intervention points are recommended for robust power (119). Due to the dynamic and complex nature of iKT, we were only able to accommodate six weeks of data collection prior to the start of the intervention. This problem can be overcome if data is generated from an already existing or available database. Our study required the bedside nurse of each patient to allow the researcher to approach the patient. As a result, nurses could determine which patients they were willing to allow to be approached. Consequently, far fewer patients were interviewed than were patients on the unit on any given week. Due to the small number of participants at each measurement point, it can be difficult to establish a baseline trend with confidence. For example, a significant difference was observed before and after the intervention in mean satisfaction scores, however, the pre-intervention period contains only seven patients, making it difficult to know whether the observed trend is reflective of the true baseline and therefore, unlikely that the observed difference reflects an intervention effect, particularly when examined in combination

with the non-significant ITS findings. In contrast, due to the comprehensive nature of the study and in-depth interaction between knowledge users and researchers, we knew from clinical staff that prior to the start of the study, green sleeves were very rarely prepared for patients and given on discharge. Therefore, we can be confident that the observed change during the intervention reflects change in ACP process.

A second limitation was the fact that participants were older in each time period compared to the prior period. The change in age was likely due to the fact that bedside nurses became more familiar with the project and with the research assistant and thus allowed her to see older and more frail patients as time passed. The researchers chose not to disclose information (beyond what was necessary to facilitate recruitment) to bedside nurses about the project during the pre-intervention period as to not influence their behavior prior to the start of the intervention. This is the reality of working within a clinical setting that is constrained by various complex contextual factors. Using a control group may have helped address this potential problem as it is a likely factor in any type of research design where research assistants are asking to speak with elderly sick patients (117).

A third limitation was that we used single-group ITSA. This type of design is inferior to controlled studies and it can be challenging to attribute cause and effect to an intervention. Therefore, it should be considered preliminary (117). For the purposes of this study, this was nevertheless an acceptable and only feasible option. The main reason for this was that the contextual complexity of the intervention unit (i.e. multiple types of patients and multiple specialties of physician) was unique and it was challenging to identify a comparable unit that could serve as a control. Nevertheless, comparing baseline and demographic data from this study to prior other provincial ACP work that has utilized an expanded version of the patient survey

and a chart audit, we can identify similar rates of patient knowledge of their GCD (<30%) and use of the tracking record (<10%), indicating that baseline findings are representative of a typical hospital unit.

4.5 Conclusion

This combined iKT QI project involved the implementation of a multi-component intervention that was associated with mixed results in improving patient reported outcomes and process measures pertaining to ACP processes on a cardiac in-patient unit. More effective analysis of this type of intervention can occur with a longer pre-intervention data collection period and possibly the use of a control group. Future implementation work should focus on prioritization of a lengthy data collection period, recognizing the complexity of establishing strict timelines within the context of iKT research.

5 CHAPTER FIVE: PROMOTING IN-HOSPITAL ADVANCE CARE PLANNING PROCESS: A PROCESS EVALUATION OF AN IMPLEMENTATION INTERVENTION IN A CARDIAC SETTING

This chapter describes a process evaluation study that was done to better understand the mixed results described in Chapter 3, especially when considering various aspects of implementation. We assessed implementation by examining the context in which the intervention was implemented, the causal assumptions of the intervention, fidelity, dose and reach of the intervention as well as participants' responsiveness and mechanisms of impact. Both qualitative and quantitative methods were used to address different aspects of these implementation components.

This manuscript will be submitted as: Shaw M., Holroyd-Leduc J., Kaba A., White D., Simon J. (2018) *Promoting in-hospital advance care planning process: A process evaluation of an implementation intervention in the cardiac context*

Abstract

BACKGROUND Advance care planning (ACP) is an important part of patient-centered care. Challenges with implementing ACP into clinical work flow on hospital units remains despite health policies advising on ACP engagement. A multi-faceted integrated knowledge translation intervention was implemented to improve ACP process on a cardiac hospital unit with the goal of improving patient knowledge of ACP engagement, satisfaction with discussions and healthcare provider documentation practices. This study describes a process evaluation to evaluate the implementation of a multi-faceted ACP intervention, guided by the Medical Research Council (MRC) framework.

METHOD This multi-method process evaluation utilized both qualitative and quantitative data to describe and analyze context, assumed mechanisms of impact and implementation characteristics of the ACP intervention. Qualitative data were collected from both one-on-one interviews and non-participant observation. Quantitative data were collected through a healthcare provider survey to assess known barriers to quality ACP. Qualitative data from interviews and documents were analyzed using content analysis. Survey data were analyzed using descriptive statistics.

RESULTS Findings from this evaluation suggest that while planned intervention components were mostly delivered, variability in the dose and reach of intervention components between nursing and physician teams may have limited intended impact of the intervention. Implementation was perceived to be successful in aspects of collaboration between teams and establishing admission and discharge ACP process. However, it was likely limited by a perceived lack of sufficient education and skills training.

CONCLUSION The complexity of engaging patients in ACP and incorporating the process into regular practitioner workflow requires attention to ongoing communication skills and ACP and process development for healthcare providers. In addition, although collaboration in implementation with front-line staff can be impactful in facilitating provider behavior and process change, researchers must account for the unique context of each clinical team and tailor recruitment and reach efforts accordingly.

5.1 Introduction

The process of Advance care planning (ACP) allows patients and healthcare providers (HCP) to partner in order to elicit and document patient values, wishes and preferences for medical care, with the goal of increasing patient (and family) preparedness for in-the-moment decision making (1). Advance care planning is meant to be an ongoing, long-term process, as circumstances and patient's wishes may change over time. ACP has been shown effective in reducing unwanted medical interventions and helping patients stay out of the ICU at end of life (16, 74).

ACP engagement between patients and HCP is suboptimal in terms of frequency, quality of discussions and documentation (37, 75, 127, 128). ACP discussions are complicated, time consuming and difficult to initiate (29, 109). Documentation of these discussion is often not done and even when completed, lacks appropriate level of detail (36, 123, 124). For example, use of the designated ACP electronic tracking record to document ACP discussions is less than 10% (129). The problem of integrating ACP into regular clinical work-flow in the hospital setting is ongoing (8, 13). Prior research in the field of ACP has shown that ACP process in clinical teams is variable and lacks consistency in implementation, despite the fact that HCP believe ACP is an important aspect of patient care (32). Facilitating HCP behaviour change and better implementation of ACP process into clinical teams' work is needed.

To address the problem of routinizing ACP process into clinical workflow, we designed, implemented and evaluated a collaborative, multi-faceted intervention that aimed to improve ACP process on one hospital unit (see CHAPTER 3: *A method for combining integrated knowledge translation with quality improvement processes in the implementation of an advance care planning intervention*). To best facilitate HCP behavior change, we collaborated with HCP

through an integrated knowledge translation (iKT) approach with the purpose of maximizing the relevance and feasibility of an ACP process change intervention that could be scaled across our health region. iKT promotes design and implementation of interventions through a collaborative effort between researchers and knowledge-users (49).

Complex interventions, such as this, are difficult to implement as intended in virtue of the challenge in facilitating and accommodating the many pieces of and influences on the intervention (100). Systematic reviews have shown complex interventions to be more effective than simple interventions but it is not yet clear why exactly this is, what precisely makes a good complex intervention or how to best implement it (130). Thus, a narrow focus on the analysis of specified outcomes is usually not sufficient to give a full understanding of the impact and potential of an intervention. Rather, gaining an understanding of implementation can help to put results from the intervention study into context, identify limitation of the implementation plan and areas for improvement in future implementation (131). Results from the intervention evaluation may be due to the intervention itself but they may instead be better explained by implementation factors. Process evaluation involves assessing whether implementation was delivered as planned, what was delivered and what were the perceptions of those exposed to the intervention (98, 132-134). A good process evaluation determines the conditions under which an intervention is effective, for whom it is effective and how it can be optimized (135).

In this paper, we describe a process evaluation of our complex ACP process intervention in an acute cardiac hospital unit. A process evaluation for an ACP process intervention has not been previously done, to the best of our knowledge. This evaluation can be used by researchers and clinicians alike to guide and facilitate adaptation to this intervention in order to better routinize ACP. We utilized a multiple methods design, guided by the elements of the MRC

framework in order to ensure we addressed salient features of process evaluation. Our specific study objectives were: 1. To understand participant responsiveness to implementation of the ACP process intervention and 2. To identify factors that may have impeded or facilitated the intended mechanisms of impact of the intervention.

5.2 Method

Study Design

This process evaluation utilized multiple methods to gain an in-depth understanding of the implementation of an iKT ACP process intervention on one cardiac in-patient unit. In particular, we wanted to understand participant responsiveness to the implementation process and to identify factors that may have influenced our intended mechanisms of change. Qualitative and quantitative data contributed separately to address different aspects of the study goals. Qualitative data were the main source for this process evaluation because data from both participant interviews and non-participant observation documents facilitate a rich description and depth that cannot be captured through quantitative methods (136). We were interested in fully capturing the evolving process of implementation and any associated responses or perspectives from those were involved in designing and implementing the intended intervention and those who experienced it clinically (131). Participants' perspectives were supplemented with summarized attendance and participation records to complete an overview of fidelity and dose of implementation (131). Quantitative pre-post HCP survey was used to explore association between implementation and known barriers to ACP. The elements of the process evaluation were guided by the Medical Research Council (MRC) framework (131).

Ethics for this process evaluation was obtained from the Conjoined Ethics board at the University of Calgary.

Participants

Participants who took part in one-on-one interviews for this process evaluation were required to have been involved in some aspect of the design of the intervention or experienced the intervention or were involved in implementation of intervention components (or any combination of these). Survey participants were simply required to be employed on the unit. Participants included unit clerks, bed-side nurses, nursing managers, nursing educators and unit physicians.

Data Collection

Non-Participant Observation: Structured meeting notes were taken at every meeting between iKT team members from January 2016 to June 2017. In the initial design phase, from January 2016 to August 2016, monthly meetings were held, with the expanded iKT team to develop a project charter which outlined the team member roles and broad protocol for the ACP intervention. From August 2016 to June 2017, weekly meetings were held between all iKT team members to update on the implementation progress for the intervention. Planning of implementation activities and monitoring of implementation were also recorded using structured non-participant observation notes. These structured meeting notes were taken by MS and consisted of the following information: 1. Purpose of meeting, 2. Invitees and attendees, 3. What was discussed, 4. Speaker characteristics (i.e. was there someone who spoke most or dominated discussion, was there someone who did not speak, etc.). Note taking was recorded on paper. Attendance notes were also kept for education sessions.

Healthcare provider survey: Healthcare providers working on the intervention unit were emailed a link to an anonymous survey prior to the start of the intervention (October 2016) and four

months following the end of the intervention period (June 2017). This 6-item survey was condensed from a 14-item survey developed locally based upon the fourteen domains of the theoretical domains framework, examining barriers and facilitators to ACP engagement. Top barriers identified in prior use of this survey were: competing tasks (54%), patient preparedness (52%) and role confusion (43%) (109).

Participant interviews: Qualitative data were collected using semi-structured one-on-one interviews with a sample of 15 participating HCP. Perspectives from a broad range of members of the multidisciplinary team and those who held a variety of roles in the intervention process were combined to gain an understanding of the processes in the intervention and to increase credibility of the findings. Interviews were conducted with consenting participants once post-intervention data had been collected. Semi structured interviews were broadly designed to inquire about participants' perceptions of ACP process, intervention design, implementation processes as well as perceived outcomes in order to fully address the goals of the process evaluation.

Data Analysis

Interview data: Interview data were analyzed using qualitative content analysis (137). Content analysis is a systematic and objective way of describing phenomena. The aim of content analysis is to achieve a condensed and broad description of the phenomenon of interest, with an output of concepts or categories (138). Our analysis process consisted of reading and re-reading the interviews to gain an understanding of their message as a whole. Next, MS coded each interview while separating codes into three content areas: 1) Pre-intervention processes, 2) Intervention

and 3) Post-Intervention. Codes represent one abstracted meaning unit. Codes were grouped into categories using the constant comparative method by which codes were compared for similarities and differences. Creating categories is a key aspect of content analysis and this process mainly deals with an expression of manifest content. Categories have to be exhaustive and mutually exclusive (138). This process was reviewed with the project PI and all codes and categories were questioned and verified. Finally, the categories were linked together by a theme that underlies the meanings or message across all categories.

Healthcare Provider Survey: Survey data were analyzed using descriptive statistics, including percentages as well as inferential two-way test of proportion using z-scores to assess change in the percentage of physicians perceiving a particular barrier before and after implementation of the intervention.

Non-Participant Observation: Content analysis was used to guide interpretation of observation data. Observation data were recorded and summarized according for meetings and implementation activities. Objective notes (i.e. identified planned activities, completion of planned activities and attendance at activities) were simply summarized. Qualitative meeting notes were read, and pertinent information flagged. In particular, notes were categorized according to pre, intervention and post-intervention groupings. These categories were compared and contrasted with interview data categories, looking for similarities and differences. Via this process, observation categories were integrated into interview data categories according to categories in pre, intervention and post intervention periods. The note-taker, MS, took a passive role in the design and implementation process. MS was responsible for collecting all process,

outcome and process evaluation data. One potential challenge with note-taking is that it may change participant behavior if participants know they are being watched (131). However, due to the fact that notes were not taken during activities for which outcome data were collected, and the fact that note taking took place regularly over a long period of time, allowing for participants to adjust, it is unlikely that this caused any behavior modification in participants.

Table 14

Data sources for MRC components

COMPONENT		**OTHER**	**ONE-ON-ONE HCP INTERVIEWS**	**NON-PARTICIPANT OBSERVATION**	**HCP SURVEY**
INTERVENTION AND ASSUMPTIONS		Review of implementation literature	X	Meeting Notes: 1. QI Processes, 2. Simulation learning	X
IMPLEMENTATION	**Fidelity**		X	Meeting notes on 1. planned/implemented activities, 2. Minutes from meetings	X
	Dose		X	Meeting notes on attendance (from invitees) at 1. Education sessions, 2. Simulation, 3. Table-top exercise, 4. Process mapping	X
	Responsiveness		Perspectives on implemented components/how they were implemented	X	X
MECHANISMS OF IMPACT			Perspectives on salient/common mechanisms of impact	X	Assessment of known barriers to quality ACP
CONTEXT		1. Provincial ACP/GCD Policy, 2. Descriptive data on unit composition	Perspectives on ACP processes and contextual factors impacting engagement prior to intervention implementation	X	X

The Medical Research Council (MRC) Framework

The content of this process evaluation was guided by elements of the Medical Research Council (MRC) framework (131). This framework suggests that a complete process evaluation will seek to describe:

1. *Context*. Context refers to social and physical aspects of the environment. More specifically, it is the physical, organizational, institutional, and legislative structures that enable and constrain, and resource and realize, people and procedures.
2. *Assumptions about how implementation will affect change*. Describing these assumptions clearly elucidates expectations around how the intervention was anticipated to facilitate desired change. A good intervention will be informed by a wide breadth of change assumptions, including on system and individual levels.
3. *Implementation and responsiveness*. Implementation refers to both the quality (fidelity) and quantity (dose) of what was delivered as part of the intervention. More specifically, implementation requires a description of what was delivered and how this was done (Table 14). Participant responsiveness is an important component of the MRC when considering implementation factors. Responsiveness can refer to either those receiving the intervention or those implementing it. Responsiveness can help to elucidate whether the delivery process was appropriate for achieving the intended goal or whether the facilitation strategies were effective.
4. *Mechanisms of impact*. According to the MRC guidance, participants are not passive recipients of an intervention but rather interact with interventions. Thus, we need to gain an understanding of the intermediate mechanisms through which intervention activities produced intended or unintended effects.

Context

According to the MRC, the description of the context should consider cultural and organizational factors that can impact the translation of evidence. In the present context, there is a provincial policy and procedure in place emphasizing and guiding the participation of HCP in ACP and GCD completion, including engaging patients in discussions and using the ACP Tracking record to record any discussions (129). Moreover, patients are meant to be provided with a plastic 'Green Sleeve' (also known as a Health Passport), which contains their up-to-date ACP documentation (i.e. copies of advance directive, GCD, ACP tracking record). The green sleeve should accompany patients on medical visits as the source of truth for current ACP decisions and be kept on the refrigerator in case of an emergency. Prior to the start of the intervention, the cardiac department head acknowledged that ACP was a priority for their department and provided support for this project, the staff time needed and the various implementation components. We were able to recruit a physician champion for the project, who did not have an official leadership role in the department but rather an interest in ACP. Moreover, a medical resident champion was also recruited to the team. Nursing champions included the two nursing managers for the unit and the two lead nursing educators for the cardiac units. The participating cardiac ward has a particularly complex clinical make-up. In addition to multi-professional clinical teams working on the ward, the physicians working on the unit are not all cardiologists. Although a cardiac ward, this unit contains many hospitalist patients with their corresponding physicians and some internal medicine patients with their corresponding physicians. There are forty-six cardiologists who regularly rotate through this unit and fifty-five nursing staff who work in shifts. This means that in seeking to implement an intervention, physician providers are not a uniform and easily accessible group. This unit has 38 beds, which were occupied for the duration of the study period. This unit is mainly a short-term stay unit and

admits patients with a variety of cardiac conditions, those waiting for cardiac surgery, hospitalist patients (usually with an underlying cardiac condition) and some internal medicine patients. To gain an understanding of cultural factors that influence context, perceptions regarding ACP process on the unit, prior to the start of the intervention were explored using one-on-one interviews (Table 14). These are reported in the next section of this paper.

Intervention and assumptions about causes of change

Details of the ACP cardiac unit process change intervention have already been described (see paper 2) however for the purpose of this paper key aspects are summarized here.

The intervention consisted of 4 parts: 1) Formal ACP education facilitating consensus on project statement and goals, timelines and details of intervention period, 2) Process mapping and root cause analysis; 3) Simulation learning and 4) PDSA cycles testing behavior change strategies, with weekly feedback and monitoring (Figure 6). The intervention process was guided by the Knowledge-To-Action cycle and the implementation phase was supported by a local quality improvement (QI) process team (139). The iKT team, who designed and implemented the intervention consisted of front line staff, nursing managers, nursing educators, the researchers, local QI team, simulation learning team and ACP educators. This group was representative of the key knowledge users on the study unit. A knowledge user is defined as an individual who is likely to be able to use research results to make informed decisions about health policies, programs and/or practices. A knowledge user can be, but is not limited to, a practitioner, a policy maker, an educator, a decision maker, a health care administrator, a community leader or an individual in a health charity, patient group, private sector organization or media outlet (140).

Outcome and process measures data collected via a patient reported survey and chart audit were: patient knowledge of their GCD medical order, satisfaction with ACP discussions, HCP use of the tracking record and HCP preparation of green sleeves to be given to patients on discharge (Table 15). The outcome evaluation of the implemented intervention showed significant increase in the preparation of green sleeves to be given to patients on discharge containing their up-to-date ACP documentation. There was no significant change in any outcome measures (patient knowledge of their GCD order and patients' satisfaction with ACP discussions) or the documentation of ACP discussions in a designated electronic tracking record.

Figure 6

Knowledge-to-action cycle and corresponding intervention components

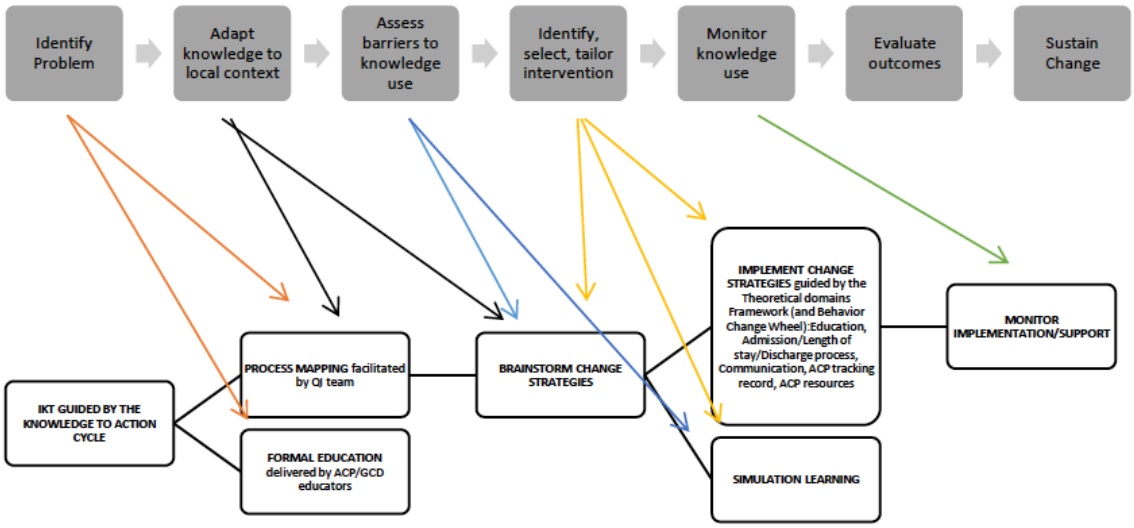


Table 15

Logic Model for ACP process intervention

Logic model for an ACP/GCD process change intervention

PROBLEM	EVIDENCE	RESOURCES	ACTIVITIES	SHORT TERM OUTCOMES	MEDIUM TERM OUTCOMES	LONG TERM OUTCOMES
Lack of routinized ACP team process on clinical teams is a barrier to engaging hospitalized patients in quality ACP, which helps to align their wishes with the care that they receive.	ACP allows patients to form and express wishes for care and it prepares them (and their families) for in the moment decision making.	Departmental support	IKT development of intervention goals, purpose, timeline and team members	Established ACP process for admission, stay and discharge	Increase in patients who are aware that they have a GCD that is meant to represent the type of care they wish to receive if they can not communicate	Improved concordance between patient wishes and care received
	ACP reduces burden on families and increases concordance between wishes and care received (as well as medical orders directing care)	Quality Improvement (process improvement) support team to facilitate design and implementation of intervention	Process mapping, root cause analysis, brainstorming and selection of change strategies for iKT team	Patients are engaged in ACP/ GCD conversations during their hospital admission by HCP	Improved patient satisfaction with ACP during hospital admission	
	Patients rarely know that they have been engaged in ACP	Simulation learning support team to support development around ACP team and communication skills	Tabletop exercise for nursing and physician staff to review new process and identify further improvements	ACP/GCD conversations are recorded in the electronic ACP tracking record by HCP		
	Implementing ACP process into regular work flow continues to be a challenge	ACP/GCD educators to support formal education on ACP process and components	Two simulation learning cases to develop ACP skills and team process for nursing, physician and allied health staff	Patients are discharged with green sleeve (health passport) containing their up to date ACP documentation		
			Formal ACP education sessions for nursing, physician staff and iKT team members			

Interventions often reflect many causal assumptions from a variety of sources including theory, experience and common sense (98). In order to maximize the potential impact of this ACP change project, causal and theoretical assumptions on individual, team and systems levels guided implementation. The overarching causal assumption was that iKT research, in virtue of engaging knowledge-users as collaborators throughout the research process would increase the efficacy of an intervention by being more relevant, feasible and applicable to the local context compared with an intervention designed exclusively by a research team (58).

Additionally, a quality improvement (QI) process improvement lens guided the actual implementation of the multi-faceted intervention. QI serves to increase efficiency in process, using exercises like process mapping, root cause analysis, ongoing monitoring and support as well as a tabletop exercise to enable a verbal summary of the new process with specific focus on further improvements. These activities were expected to affect change by facilitating collective understanding of current processes followed by the design of more effective and efficient process (110). This process was paired to individual-level KT behavior change strategies requiring identification of 'who needs to do what differently and with whom', thus specifying a target behavior, for barriers and facilitators can be identified and addressed (49).

Specific strategies for facilitating behavior change, including simulation learning also contributed assumptions about how change could be caused. Simulation learning and debriefing, based on active learning theories, consists of simulated real-life scenarios that require team-based skill application, followed by a team debrief. Through this process, simulation builds teams and helps to identify team roles and develop skills (126).

Participant responsiveness and Implementation

Measurements of implementation, including fidelity (the extent to which the intended intervention components were in fact delivered) and dose (who received the intervention components) were summarized using non-participant observation notes and attendance from activity logs from meetings and intervention sessions (Table 15) (131). A master list of planned activities was kept by the QI process improvement team. Each activity was marked when it was initiated. Dose was calculated as a percentage based upon the intendent recipients of the intervention (i.e. invitees) and participants who actually attended.

Participant responsiveness was assessed in two additional ways in order to gain a fulsome understanding of how participants responded to the implementation process. Responsiveness was measured objectively using a HCP survey to assess participant perceptions of known barriers to ACP both pre and post the intervention. Participant responsiveness was also explored through one-on-one interviews (Table 15) to gain an in-depth understanding of participant perceptions of the implementation process.

Mechanism of impact

Perceptions around mechanisms of impact were explored through one-on-one interviews. Participants were asked about their perceptions of the effectiveness of the intervention as well as factors that both potentially impeded and facilitated the developed project goals.

5.3 Results

Findings from this process evaluation reflect the study goals as described below. Description of MRC components including context, intervention components and assumptions regarding contributors to change were provided in the methods section. In this section, analysis from participant interviews, documents and a HCP survey on ACP barriers address the two stated goals of this study: responsiveness to the implementation process and perspectives on mechanisms of impact that inhibited and facilitated intended change.

Participant responsiveness to implementation process

Characterizing implementation: For most planned aspects of this intervention, fidelity was achieved as the intervention component was implemented as intended in the planning stage (Table 16). Low fidelity was noted for electronic reminders that were planned to be sent to physicians weekly to remind them to use the electronic tracking record for documenting ACP

discussions. Low fidelity was also noted for planned system-based changes for the electronic medical record. These were not completed due to lag time required for actualizing system-wide change. The intended changes will be implemented with the next update of the local electronic medical record system. Examination of dose suggested that nursing team members were much more likely to participate in intervention components compared with physician staff. For example, Table 16 shows that other than the actual implementation of the simulation learning exercise, physicians were less likely than nursing and other staff to participate education sessions, the table top exercise, process mapping or engage in ongoing monitoring/weekly support sessions.

Table 16

Details of implementation

Activity	**Time**	**Duration**	**Fidelity**	**Dose**	**Notes**
SIMULATION LEARNING EXERCISE	Once	4 Hours (+ 2 hours to design scenarios)	√	100% (4 physicians, 2 unit clerks, 1 nurse practitioner, 8 nursing staff)	For simulation design, the 4 invited physicians did not participate
EDUCATION	Multiple sessions	1 hour each	√	50% physician (2/4) 100% unit nursing staff (44/44)	sessions were mandated by nursing managers
TABLE TOP EXERCISE	Once	Half day	√	0% physician (0/2) Representation from other key groups: Nursing managers, nursing educators, front line nursing staff and unit clerks	
PROCESS MAPPING EXERCISE	Once	2 Hours+ preparation with some team members	√	50% physician (1/2) 100% allied health professional (9/9) (Nurse practitioner, nursing managers, nursing educators, unit clerks, social work, bedside nursing)	
MONITORING/SUPPORT	1 hour	Weekly (August 2016-April 2017)	75% of the time	Each session was attended by nursing managers and 10% of sessions were attended by physician	

ELECTRONIC REMINDERS FOR TRACKING RECORD USE	N/A	Weekly (November 2016-February 2017)	12.5% of the time (2/16 weeks)	All physicians	
INFORMATION PAMPHLETS IN PATIENT/FAMILY ROOMS	N/A	N/A	√	N/A	
COMPUTER BASED INSTRUCTION FOR USE OF TRACKING RECORD	N/A	N/A	√	N/A	
AUDIT OF GREEN SLEEVESIN PATIENT CHARTS	N/A	Weekly	√	N/A	
MAKING CHANGES TO EMR TO MAKE TRANSFER EASIER BETWEEN CLINICAL SETTINGS	Once	N/A	0%	N/A	

Responsiveness to known ACP barriers: In total, 39 healthcare providers completed the electronic survey measuring barriers to effective and quality ACP engagement. Twenty-six completed before the intervention and thirteen after the intervention. Due to the fact that the survey was anonymous, it is not known whether the any of the post-intervention participants were the same as the pre-intervention participants. Twenty-one females and eighteen males participated. On average, healthcare providers were employed for 3.92 years in their current role (range from 1-6 years). Fifteen self-identified as physicians, twenty-three identified as nursing staff and one was an allied health professional. Participant responses are summarized in Figure 7. The 7-point Likert scale (7= always, 1=never) responses for the 6-item survey were converted to binary responses, where a score of 5-7 were scored as a ‘yes’ and 1-4 were scored as ‘no’. We wanted to compare pre and post scores and this approach was best to capture barriers given the small number of respondents in the post-intervention period. We used a z-score two-way test of proportions to assess whether the proportion of respondents indicating a barrier was significantly different pre and post intervention. No statistically significant differences were found. Although

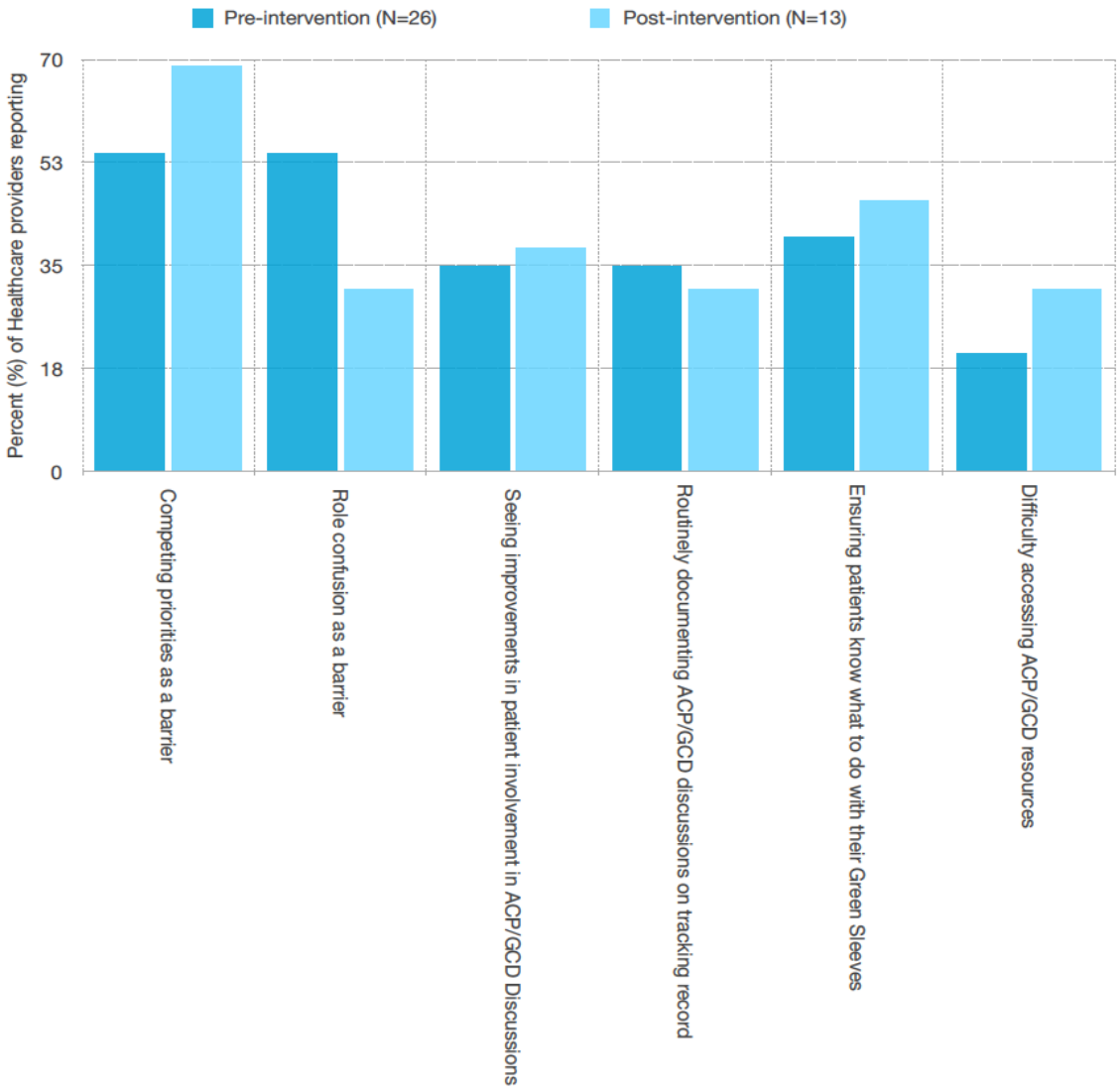
statistical significance was not detected, the data show that while some positive and expected changes were observed, including a decrease in perceived role confusion, other items that may have been expected to improve with the intervention did not (ex. Seeing improvement in patient involvement or documenting on the tracking record). Only a slight increase in ensuring patients know what to do with their green sleeves was measured even though presumably, green sleeves are being regularly given to patients, according to our outcomes evaluation (paper 3). This may be explained by the fact that providing green sleeves at discharge is the responsibility of a small number of staff, however this was not further examined in the HCP survey. HCP reported a small increase in difficulty accessing resources and seeing competing priorities as a barrier. A trend in decreasing role confusion was also noted. Thus, overall, there was no meaningful change in highly rated HCP barriers to ACP, despite the implementation of a process intervention designed in collaboration with clinicians and other knowledge-users.

Figure 7

Summary of findings from pre-post intervention HCP survey

Healthcare Providers perspectives on known barriers to ACP (%)

DESCRIPTION	COMPETING PRIORITIES AS A BARRIER	ROLE CONFUSION AS A BARRIER	SEEING IMPROVEMENTS IN PATIENT INVOLVEMENT IN ACP/GCD DISCUSSIONS	ROUTINELY DOCUMENTING ACP/GCD DISCUSSIONS ON TRACKING RECORD	ENSURING PATIENTS KNOW WHAT TO DO WITH THEIR GREEN SLEEVES	DIFFICULTY ACCESSING ACP/GCD RESOURCES
Pre-intervention (N=26)	54	54	35	35	40	20
Post-intervention (N=13)	69	31	38	31	46	31



Qualitative perspectives on responsiveness

To explore quality of implementation, it was first necessary to report on patients' perceptions of the initial need for an intervention (Appendix 3). One on one interviews provided insight into participant perspectives on the pre-intervention processes and the state of ACP on their unit. Participants unilaterally highlighted the need for the ACP process intervention by elucidating gaps in existing ACP process that they had noticed (Appendix 4). Participants

highlighted the lack of an established ACP process prior to the intervention: '*There was nothing structured specifically on how to do ACP conversations for any individuals, for any levels that even you're a nurse or a physician or part of the multidisciplinary team, it was completely missing' (physician)*. They also shared that they had little prior knowledge ACP resources, including what the green sleeve (health passport) was intended for or whom it was to be given to. Participants also felt that the pre-intervention documentation of a GCD was not sufficient to fully reflect patient wishes on its' own, highlighting the need for both more in-depth conversations and good documentation of those conversations. Furthermore, participants indicated a lack of clarity around roles and responsibilities for various aspects of ACP (Appendix 4). Thus, despite an established ACP policy and verbal prioritization of ACP as an important aspect of patient care in the department, this complex unit lacked an established ACP process, role clarity for many HCP and uncertainty about function of key elements of ACP, including the green sleeve and tracking record.

Implementation of the intervention was associated with participants feeling that they had gained an understanding of key aspects of ACP: '*If you ask me how my perception on the goals of care has changed, the aha moment for me is that each goals of care designation should actually be arranged on the same level rather than R1 being on the top, you know, and see all those things…So the patients get the exact same level of care, the exact same quality of care, but the bundle of care that comes along with that is designation differs'(nurse)*. They felt they had gained familiarity with the complexity of engaging in it *'It was interesting to learn how many people were not comfortable having the conversations' (physician)*. Participants also indicated that the intervention had helped to establish a process (particularly for admission and discharge): '*We know that we've been giving the green sleeves at the time of admission, 100% of the time, we*

know that goals of cares are being updated during their inpatient hospital stay, and we know that we're doing very well in updating the green sleeves and we know that at discharge, we're also giving the green sleeves to our patient before they leave' (nurse educator) and provided role clarity *'It made me reconsider who should be having these conversations- that it needs to be a team process'(nurse).*

Despite perceived utility of implementation, challenges with the dose and limited reach to physicians were evident. Part of the problem seemed to come from resistance to further implementation from some physicians. When plans were made to provide weekly electronic reminders (via the physician champion), to all incoming physicians, negative feedback prevented this from becoming a regular activity, *'I got pushback right away from some physicians, saying 'stop messaging me about this' (physician).* This type of resistance resulted in more limited formal engagement with the physician team. Instead of weekly reminders, they received a description of the tracking record and its' location during a monthly staff meeting, while nursing staff on the unit received formal education on ACP and bi-weekly feedback on process change from their management.

Consequently, some participants felt that expectations regarding engagement with the intervention were unequal among clinical professions. There appeared to be a discrepancy in how standard setting was achieved between the teams from nursing staff: *'For me, my nurses do not have buy-in on this. If I set an expectation, you better do it. That's a standard I will say. That's not, your preference so you have to buy-in…it's the standard of care that we're providing. I just think that there is a lack of leadership with physicians' (nurse manager).* This also created some disillusionment regarding the potential of ACP process to become fully integrated into workflow: '*So at the end of the day, we create a process of printing the tracking record form of*

the goals of care designation and then we put it on the green sleeve. How useful is that when the physicians' conversations are all on MPR [physician-only electronic medical charting]?' (nurse educator).

Thus, while fidelity of implementation was largely achieved, and participants felt they had gained understanding of key ACP concepts and processes as well as having established some ACP processes, the dose and reach of the intervention were limited and this was reflected in participants' perspectives on challenges with physician engagement.

Characterizing potential factors influencing implementation and impact

Participant interview data highlighted additional important mechanisms of change associated with implementation with regard to the functioning of the iKT team.

Collaborative partnerships: Participants felt the iKT team functioned as a collaboration between various participants: '*I found this project a partnership between the multidisciplinary teams'(unit clerk)* Working as a team may have also have helped to create a culture of seeking improvements that may not have existed prior to the project*: 'I don't know what the appetite for change would have been before and I think if you look at overall from an outcome of the project…it's super successful because it has built a culture of people wanting to explore this more' (nurse educator).* The ongoing supports provided through the QI (AIW) team helped to facilitate implementation '*I am very, very thankful that there is that main project coordinator, that was [name if coordinator], because without him I don't think we can keep the momentum going. He keeps us on track, he writes note, he looks at action items, delegate them appropriately, he looks for follow-up so that's great' (nurse manager)*. Thus, various elements of coming together as an iKT team were perceived to be important in facilitating implementation.

Need for further education and skill building: On the other hand, issues of insufficient training, education and organization were thought to have limited the impact of implementation. Participants expressed a desire for more skills-oriented education to help prepare clinicians to better deal with complex and uncomfortable ACP discussions, and consequently make them more comfortable initiating conversations: *'How do they apply that knowledge into practice, because it's really uncomfortable talking about that conversations for people that have never really realized that this is part of their practice, so it should be part of their practice. So that's what I want to see is, you know, or I wish from the get-go, the educational team' (nurse educator).* In particular, participants expressed a desire for more simulation learning scenarios: *'I think that we need more eSIM. I think we need more educational piece and I think that's what's missing' (nurse).* Although a desire for more simulation learning was common among participants, some felt that scenarios needed to be more complex and realistic to be of benefit for healthcare providers.

Inadequate organization of educational elements was described as a limitation of the potential gains. There seemed to be unmet expectations around whose role it was to set up education sessions (as needed) and to determine the content of education sessions: '*I mean they could also argue…ask us what you guys need and my counter argument on that is, well, I think we really need to start from ground up, and I don't know what I don't know and you guys, you know, should provide that for us.' (nurse manager).*

Key stakeholders: Finally, the notion that implementation would have been improved by engaging a greater breadth of knowledge-users was common, with participants suggesting

involving physician leadership, training residents, and engaging a greater number of hospitalists in future efforts. Residents were repeatedly noted as being an important target group for ACP process as they are often the first to engage in ACP. Thus, they are often having and documenting ACP conversations: '*Residents do a lot of this work. They have a lot of these discussions and do the documentation' (physician).* Hospitalists were also identified as a group that could have been better engaged. Although the project had a hospitalist physician champion, reach to physicians as a group was generally low and participants felt that more active engagement from hospitalists was needed.

Thus, exploration of elements impacting mechanisms of change suggests that the iKT team worked as intended in terms of promoting a collaborative environment, supporting healthcare providers in meeting their implementation needs and helping to create a culture of seeking out improvements. On the other hand, a few key elements may have impeded intended mechanisms of change. Insufficient quantity, complexity and organization of skills and team training may have impeded intended gain from education so that HCP could meaningfully improve ACP engagement. Finally, targeting of relevant stakeholders and opinion leaders appears to have been inadequate.

5.4 Discussion

The findings from this process evaluation provide a basis for contextualizing and understanding the process of implementation from the ACP process intervention study. Exploration of participant responsiveness to implementation shows that participants experienced a change in perspective, knowledge and understanding of ACP, roles and scope. They gained an appreciation for the complexity of engaging patients in ACP and the discomfort that can

accompany it. However, limitations in fidelity and scope and dose for the physician group were observed. Intervention changes were achieved through collaborative design and implementation and facilitated by supports from the QI team. Although participants expressed that regular feedback was helpful, as was team-based skill building, they nevertheless highlighted a need for further and better organized training. This finding is consistent with the literature on complex interventions, which indicates that a vital predictor of success is tailored, and highly integrated facilitation of intervention components that is responsive to the local context (141). The benefit of making specialized efforts to adequately expose all potential knowledge users to the intervention has also been reported (30).

The evaluation showed that for most planned aspects of the intervention, including process mapping, selection of change strategies, implementation of education sessions and weekly monitoring fidelity was achieved. This is likely due to the fact that the intervention was not strictly pre-planned but rather was designed and implemented with collaboration from clinical team members, meaning that they are likely to plan to implements intervention components that they think are feasible and appropriate for implementation (142).

In-depth exploration of responsiveness further revealed the possible emergence of unintended consequences associated with the intervention. Although findings were not statistically significant, trends were noted for increasing perceptions of competing priorities and greater difficulty accessing ACP resources. It is possible that these findings were directly the result of increased awareness of components of quality ACP, which made providers realize that they were expected to do more than they had been doing thus far. This may further relate to perceptions regarding an ongoing need for greater skills training. Once HCP were educated on

the components of ACP, they may have become more aware of their own discomfort engaging in these components and this may have increased their sense of burden for engaging in ACP.

Participants expressed an appreciation of education and simulation learning but felt that they needed more targeted simulation learning scenarios and skill building support. It can be assumed that since ACP is an expected part of clinical practice, staff understand how to engage patients (143). Rather, although participants knew the importance of ACP, they felt this project helped them to begin to develop the skills to do it. Although reach to physicians was limited, reach to nursing staff was not and through the course of this project, they were expected to use the tracking record. However, if education and skills building was not sufficient, then they still may not have felt comfortable enough to have ACP conversations and to subsequently document these. Change literature shows that the most important factors for change are effective team communication, leadership and workload (144). The intent of simulation learning was to build on these factors, however, only a single session was held.

Most importantly, this process evaluation highlights the important contextual differences between clinical teams, which may not have been adequately addressed in the implementation of the intervention. The make-up of a clinical team (e.g. nurses or physicians), determines how that team is best engaged in implementation. Assuming that clinical or thought champions can be engaged the same way for any team, may be incorrect. Ultimately, how well a team is engaged will impact the dose delivered of the intervention components, the reach of that intervention and participant responsiveness. For example, in nursing, managers are important in facilitating practice change (141). However, for physicians, establishing physician champions, conducting physician outreach and tailored education have all been established as necessary for successful implementation (145, 146). Feedback has been identified as important in influencing behavior

change for all HCP (141). There is also a discrepancy in resources allocated to clinical teams for educational and participatory activities. Nursing team members were reimbursed for the time they committed to participate in the various design and education sessions associated with this intervention. Physicians, as independent consultants are not. A limitation of iKT research is an underlying assumption that financial resources exist to support clinical teams (147). In order to address this problem in future iterations of this intervention approach, we are now facilitating one-on-one engagement with physicians prior to implementation, providing educational credits for attending training sessions, using an influential MD champion and providing monthly team-based feedback to the physician group.

Limitations

One limitation of this process evaluation is that participants were only interviewed after the intervention period was complete. Consequently, their perspectives were influenced by the fact that they had already experienced the intervention. Seeking to establish context, in particular, might have been better achieved if participants had also been interviewed prior to the start of the intervention in order to gain an understanding of their current perspectives.

A second possible limitation may have been that only participants who had taken part in intervention design or had a greater involvement in implementation were interviewed. It might have been informative if some who had not been exposed to this process were interviewed to get a better sense of the reach of the intervention.

One of the limitations of using simulation-based learning in this project was lack of staff engagement and exposure to simulation-based education prior to the intervention. Evidence in literature for behavioral change using simulation-based education is limited for teams who have limited exposure to simulation-based learning. Ideally for sustainability, we should have

considered building a train the trainer with nurse educators/manager on the unit for ongoing coaching to develop monthly/quarterly interprofessional simulations scenarios and debriefing sessions that would be inclusive of nursing, allied health and physicians staff.

A final limitation was that we intended to implement changes to the electronic medical system in order to make it easier for physicians to use the ACP tracking record to transfer data on ACP conversations to patients' specialist out-patient and family physicians. Unfortunately, it was not possible to make this complex system change in the duration of the intervention period. This change may have increased the use of the tracking record, because physicians might have found its utility to be more apparent. Influencing change in electronic system use is very challenging in the clinical setting (36, 124). We could have discussed needed changes with representative HCP prior to the start of even the pre-intervention period, knowing that any planned system change would be time consuming and must be initiated early in order to be completed within the window of time that is needed.

5.5 Conclusion

This process evaluation of a quasi-experimental iKT intervention to improve ACP process on one hospital ward has been used to examine factors related to implementation that may help to explain the mixed results of the outcomes evaluation. The process evaluation suggests that the intervention was effective in increasing HCP awareness and understanding of ACP as well as initiating process change in some domains. Implementation however was impeded by limited reach to physician teams on the ward.

6 CHAPTER SIX: SUMMARY OF FINDINGS

6.1 Summary of key findings

Rates of ACP discussions between older adults and HCP are low. Even when these conversations are had, the quality of ACP is often suboptimal (36, 123, 124). The implementation of ACP discussions into clinical work flow is an ongoing challenge. Our research program was intended to guide the implementation of an intervention aimed at routinizing ACP process into regular workflow. The ultimate goal for this work was to create an effective and sustainable implementation intervention for improving the ACP process across clinical units, which can be scaled and spread across other contexts.

6.1.1 Characterizing ACP process

In order to gain an understanding of the ACP process across clinical settings, which considers the different local contexts, we conducted a study using qualitative methods within cardiac, renal, supportive living and cancer contexts. We discovered ACP processes varied both within and between contexts, despite the existence of a provincial policy and procedure guiding ACP engagement. Furthermore, we found that although patients had engaged in various ACP activities, their awareness of having engaged in ACP was low.

6.1.2 Combining KT and QI methods for implementation

Having gained an understanding of the variability in ACP processes within and across clinical settings, we developed an implementation intervention to improve and routinize ACP. We implemented and evaluated this intervention on one hospital ward, using an interrupted time series study. The intervention included application of strategies known to help achieve process change, such as engaging clinician end-users as collaborators throughout the research process, applying KT change strategies, and utilizing locally available QI and educational supports.

Process change was achieved in nursing protocols for admission and discharge preparation of ACP (green sleeve) packages. However, significant change was not measured for processes changes that are largely physician dependent e.g. healthcare provider use of the designated ACP tracking record to document ACP discussions. Similarly, significant change was not observed with the outcome measures of patient knowledge regarding having a medical order directing their care, or in satisfaction with ACP engagement during hospitalization.

6.1.3 Evaluating implementation process

Due to the complexity of ACP engagement and the multi-faceted implementation intervention, a process evaluation study was used to gain an understanding of implementation and the associated mechanisms of influence. This multi-methods study highlighted both the successes and limitations of implementation and how these may have contributed to the mixed results of the evaluation study. Although fidelity was largely achieved, dose and reach were both limited, in particular with the physician group. Furthermore, healthcare providers expressed a greater need for education and skills training for more effective implementation.

6.2 Clinical Implications

There are two main clinical implications of this work. The first is that we implemented and evaluated an ACP process intervention on in inpatient ward that can be useful for patient healthcare between clinical contexts. With an up-to-date ACP document (or green sleeve), patients will have all necessary resources to transfer ACP information between hospital to community care. This means that all healthcare providers would be informed of the status of any ACP that has been done to date, enabling them to continue the conversation as appropriate. Having a starting point might make it easier for physicians to have ACP conversations, knowing

that the patient has some familiarity with the topic and will likely be receptive to ongoing discussions.

The second clinical implication of this program of study is that, through use of the KTA framework and the subsequent process evaluation study, the existing barriers to implementing an optimal ACP process and strategies to address these barriers were discovered. Furthermore, important partnerships developed between clinical providers and managers with local QI and simulation learning experts, enabling ongoing process improvement and skill building beyond the official end of the project.

6.3 Strengths and Limitations

6.3.1 Strengths

This program of study exemplified a number of important clinically and research relevant strengths. The first is that we were able to design and implement a change intervention utilizing evidence, as well as locally developed QI resources relevant for process improvement.

Second, although results from the outcomes evaluation were mixed, the process evaluation study enabled us to learn how to improve this type of intervention in the future. Technical challenges are those that concern a specific problem, and for which a solution can be generated and implemented through identifiable knowledge or skills needed (148). Technical problems require a logical sequence of thought. Adaptive challenges go beyond what is required to solve technical challenges and are not easily addressed through expertise or implementation of a standard process. Rather, they require ongoing experimentation, discovery and adjustment in order to help change understanding, beliefs and habits. This is one of the strengths of this study. We embarked on a process of experimentation, discovery and adjustment to address an adaptive challenge, realizing some gains in knowledge implementation and practice change. We gained a

better understanding of barriers to change, pertaining to implementation engagement strategies and study design planning that can inform future process adjustments related to ACP implementation.

6.3.2 Limitations

This program of study had both design and logistical limitations that are important considerations for implementation work in clinical settings. The first key limitation was that our intervention study design did not include a control group. This is a common problem in implementation research as it is difficult to find a comparable group to use as a control and an experimental design is not feasible (149). We considered using a sister unit, as this was the most comparable unit available but since the nursing staff and physicians worked across both units contamination would have been inevitable. It was not possible to find a comparable unit at another hospital and lack of resources was a barrier to pursuing this option further. Instead, we utilized audit data from 3 cycles of a national (with a local arm) ACCEPT study, which utilizes the same patient survey as we did to confirm that no meaningful change in quality of ACP is occurring across other contexts outside of our intervention (ACCEPT), However, an interrupted time series is still recognized as an appropriately rigorous study design for our context. Limited rigor in study design is an existing limitation of any QI and iKT studies, hindering the advancement of the research field of iKT (93).

A second limitation resulted from the researchers' limited ability to design the study timelines. Bringing together research, clinical, QI and educational teams was very complex. As a result of the limited capacity of each team to incorporate intervention activities into their clinical day, scheduling had to accommodate these limitations. Consequently, the start of the intervention period, marked by the scheduled process mapping session, gave less time for

baseline outcomes and process data collection than the research team had planned. Ideally, a ten-week data collection period would have been preferred to establish a reliable baseline trend (150). Unfortunately, only 6 weeks of baseline data collection were possible. During analysis, this made it challenging to establish a pre-intervention slope for the interrupted time series.

A final limitation in this program of study pertains to challenges in dose and reach of the intervention, as indicated by the process evaluation. We made an incorrect assumption that the same implementation strategies could be utilized with nurses and physicians. Both frontline nursing staff and managers were team members, involved in the design and implementation of the intervention. This enabled the nursing managers to set a new ACP process expectation for the unit nurses as a whole, regarding ACP. Conversely, due to the fact that physicians work as independent consultants, engaging a small number of them in the iKT project was not sufficient to ensure the intervention spread to all involved physicians.

6.4 Future Directions

6.4.1 Improving implementation

Learnings from this project have led us to incorporate changes based upon our process and outcomes evaluation, which will allow for tailored implementation of ACP process on other units and within other clinical setting. For example, a similar process change intervention being implemented by our team on an internal medicine ward involves one-on-one meetings with each staff physician prior to the implementation starting in an effort to explore their readiness for participation, provide a compelling rationale for the need to improve, providing monthly group-based feedback and offering maintenance of certification credits as an enticement to participate in education sessions. Moreover, a champion MD is now setting expectations for implementation with staff physicians,

including by having one conversation per physician per week regarding adoption progress. This type of personal contact with researchers has been identified by knowledge-users as a key factor influencing their use of evidence in practice (151). Similarly, learnings from this project regarding implementation are being applied to an ACP process change program of study on a surgical ward at another hospital in the province.

6.4.2 End-of-grant knowledge translation

The methodology and findings from this project have been presented (verbally and in writing) to clinical and organizational decision-makers throughout our health region and beyond. As a result, this project has been set as an implementation priority by the Quality Council of the Foothills Medical Centre, with the goal of implementing ACP skills training, ACP tracking record documentation process and green sleeve discharge across the hospital. We have also created a web-based QI package that includes templates for our tools and an in-depth description of our protocols for use on other units by implementation teams. Storing all materials in one easy to use location can enable other units to swiftly initiate projects with less effort in selecting metrics. Over time, as teams gain expertise on how to implement change interventions, they may have less use for facilitation by QI process teams, as we did in our intervention.

6.5 Conclusions

This program of study was the first attempt to address the problem of integrating ACP process into clinical workflow using an iKT approach combined with QI methodology. We characterized the variability of ACP process within clinical contexts in a region with an existing

provincial policy. We partnered with front line staff, physicians, clinical managers and educators as well as ACP educators, simulation learning experts and QI process experts to design and implement a multi-faceted intervention to improve ACP for hospitalized patients. We utilized knowledge translation strategies including education, skill development, monitoring and prompting with the goal of improving the frequency, quality and documentation of ACP conversations between patients and healthcare providers. We aimed to impact patient knowledge of the content of their ACP conversations and their satisfaction with these conversations. Improvement was measured in the proportion of patients with a prepared green sleeve, containing their ACP documentation, provided to them on hospital discharge. Although no significant change was measured for the remaining process and outcome measures, a process evaluation study indicated that limitations in the reach and dose of implementation may have limited the impact of the intervention. Future opportunities have already begun to address implementation challenges of this study and we are using tailored and targeted approaches to improve the reach of the intervention components.

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APPENDIX 1

ACP PROJECT CHARTER

ACP and GCD Team Process Improvement

A. Define Opportunity

Alberta Health Services has a Provincial Level One Advance Care Planning (ACP) and Goals of Care Designation (GCD) policy that was implemented across all Health Sectors in Alberta in 2014. This policy provides the direction for having conversations with patients regarding their values and wishes for health care and determining associated goals of care according to their health circumstances. Patient and health care provider (HCP) resources have been developed to inform conversations and practices. These conversations can then in turn be documented and inform the GCD order that is intended to inform all health care determinations across health sectors. The policy, and associated infrastructure, has been well established and provides the opportunity to now assess and measure compliance with clinical and business processes. There are known, measurable patient quality and safety outcomes of ACP and GCD policy and procedure, these include:

1. Patients should be informed about their GCD order and understand how this aligns with their values, wishes and health circumstances.
2. Patients should have a green sleeve that travels with them across health sectors and contains their GCD order, Tracking Record with documented HCP conversations and a copy of their Personal Directive (if they have one).
3. All patient-HCP ACP and GCD conversations should be documented in the Tracking Record.

To date however, only 30% of patients with a GCD know that they have a GCD,[1] concordance between patients' preferences and GCD order is low (approximately 30%)[2] and the tracking record that would enhance communication of patient values across sectors is not being used (<10% in acute care).[3] A survey of over 500 Alberta healthcare providers[4] (HCP) found that four out of the five most frequently perceived barriers for engaging in ACP GCD activities are in team process domains:

1. Competing priorities and time constraints
2. Role confusion as to which HCP is responsible for different aspects of the process
3. Feeling unsupported by managers and leaders to engage in ACP GCD activities
4. Feeling that the people they work with are not routinely incorporating ACP GCD into their practice.

Current poor application of the AHS Advance Care Planning (ACP)[1] and Goals of Care Designation (GCD)[2] policy and procedure is impacting patient safety and quality of care.

[1] ACP is a process of communicating wishes and values for health care, choosing an alternate decision maker and documentation for use on the loss of capacity for medical decision-making. Engagement in ACP prepares for "in-the-moment decision-making", can bring peace of mind, improved quality of care before death, better outcomes in bereavement, increased concordance between personal preferences and healthcare received and efficient use of health service resources.

[2] GCDs provide a framework for the efficient communication on the general intent of a person's care (resuscitative, medical or comfort care) and provide direction on specific interventions and locations of care

2

As a result, patients are at risk of receiving care that they do not value, particularly when critically unwell and lacking capacity to communicate their wishes. HCP can suffer moral distress when a patient's goals are uncertain. There are also resulting health economic consequences: it has been reported that when goals-of-care-type medical orders match patient preferences it may yield as much as $94022 in mean cost savings per patient in the terminal hospitalization.[5]

To address these issues AHS Calgary Zone ACP GCD team are proposing a demonstration team process improvement project in partnership with clinical teams in four healthcare sectors that care for patients with heart failure, AHS Improvement Way (AIW) and the Provincial Simulation Program (E-Sim). Additional partnership with researchers from the AIHS funded, "ACP CRIO" research program will allow collection of data on key outcome measures before and after the process improvement intervention.

Together we will seek to understand and enhance the processes that create high quality ACP GCD conversations and documentation among interdisciplinary team members and patients.

B. Goal Statement

By the end of 12 weeks of process improvement projects in the four heart failure care sectors, and compared to baseline measures, there will be:

- 30% of patient charts will have a conversation documented on the ACP tracking record (if baseline measures are >30%, then a 10% absolute increase will be achieved).
- 10% absolute change of patients' knowledge of having a GCD.
- 10% reduction in the number of HCP perceiving that competing priorities/time and role confusion are barriers in engaging in ACP and GCD activities.
- Demonstrate a statistically significant improvement in team effectiveness behaviors (MHPTS) when compared to prospectively collected baseline measures during Simulation.
    - A.) Pre-Post self-assessment of HCPs team effectiveness behaviors using the MHPTS
    - B.) Pre-Post observational data collected from facilitator's assessment of team effectiveness behaviors using the MHPTS.
- Demonstrate a statistically significant improvement in team behavior attitudes (T-TAQ) compared to prospectively collected baseline measures.

C. Project Outline

The framework of the project is the AIW process:

Build Understanding
Identify and understand team and process-based barriers to effective ACP and GCD determination as well as opportunities for quality and efficiency improvement. Clinical teams from each heart failure sector will engage in:

3

- Process mapping, with multidisciplinary input from each sectors on ACP GCD process, as well as roles within and across sectors. This will also understanding of how ACP GCD activities fit in existing team processes such a CoACT and HF pathways.
- Baseline data collected through patient survey, clinician survey and chart audit for 8 weeks prior to initiation of project.

Act to Improve
Elements to improve will be determined by each sector (e.g. Closing gaps in existing processes such as completing tracking record for each patient or patients leaving the sector with their green sleeves). The interventions to achieve these improvements will include:
- eSIM scenarios designed to address team effectiveness behaviors within the ACP process. All scenarios with be followed by Interprofessional debriefings.
- Inter-disciplinary education provided by CZ ACP GCD educators tailored to identified needs e.g. ACP process best practices or conversation training on how to elicit patient's own goals for living and how to relate these to GCD.
-

Sustain Results
Learning will be shared within and across the healthcare sectors through the process maps, value stream maps and standard operating procedures produced along with knowledge products such as the esim scenarios. We will produce an "A3" report with recommendations for improved uptake in ACP and GCD activities. Ten weeks of post project data collection provided by the ACP CRIO research team will help to sustain changes in each sector and in addition ACP CRIO will report on health resource utilization data used in the subsequent 12 months by patients in the pre and post project data collection. This will be used to estimate the cost-recovery amount for the project.

A key to success of this initiative is that we are using collaboration between existing AHS teams and resources in the co-creation and implementation of the project. This will enable AHS to spread ACP GCD process improvement across the HF context and into other clinical areas provincially. Colleagues in Edmonton Zone are already planning the same ACP GCD team process improvement project in the Cross Cancer Institute.

D. Project Scope

To conduct the project with four health care sectors that care for patients with heart failure (In-patient cardiac unit, Out-patient heart function clinic, Primary Care clinic and Heart failure home care service).

E. Out of Scope Activities

Changes to exisiting AHS policy or procedure for ACP and GCD.
Changes to electronic health record processes (netcare, SCM)

F. Project Constraints

Use of existing ACP GCD, AIW, eSIM and clinical unit resources only.

G. Assumptions

During this project the provincial policy and process on ACP GCD will remain largely unchanged. The ACP GCD, AIW, eSim teams will all be operating over timeframe of the project.

H. Project Risks

Risk	Probability	Mitigation strategy
Pre data collection delayed	Medium	Project start date flexible
Clinical teams only able to participate at different times of the year	Medium	Teams can go through AIW in series or parallel, shared learning can happen iteratively. Start date flexible.
Change in project members	Medium	Allows project to demonstrate process improvement is not person dependent
Project scope creep	Low	Adequate project planning with stakeholders and clear project charter.
Project deliverable does not meet stakeholders needs	Low	Regular contact and review of work with project stakeholders and sponsors
Inadequate time to complete project	Medium	Project scope defined with recognition of time constraint.

I. Project Team and Sponsors

Appendix 1

J. Review and Reporting Frequency and Special Authority Limits

Requirements	Audience	Frequency
Define Opportunity Review (update Charter)	Sponsors	One-time only
Charter sign off	Sponsors	One-time only
Build Understanding review (sign off)	Sponsors	One-time only
Act to improve review (sign off)	Sponsors	One-time only
Sustain Results Review (close out document)	Sponsors	One-time only
Report	Clinical teams	1-2 times
Report	Stakeholders	1-2 times
One year health resource utilization outcome report	Stakeholders and Sponsors	One-tie only about 18 months post project completion.

APPENDIX 2

Figure 8. Distribution of age by time period

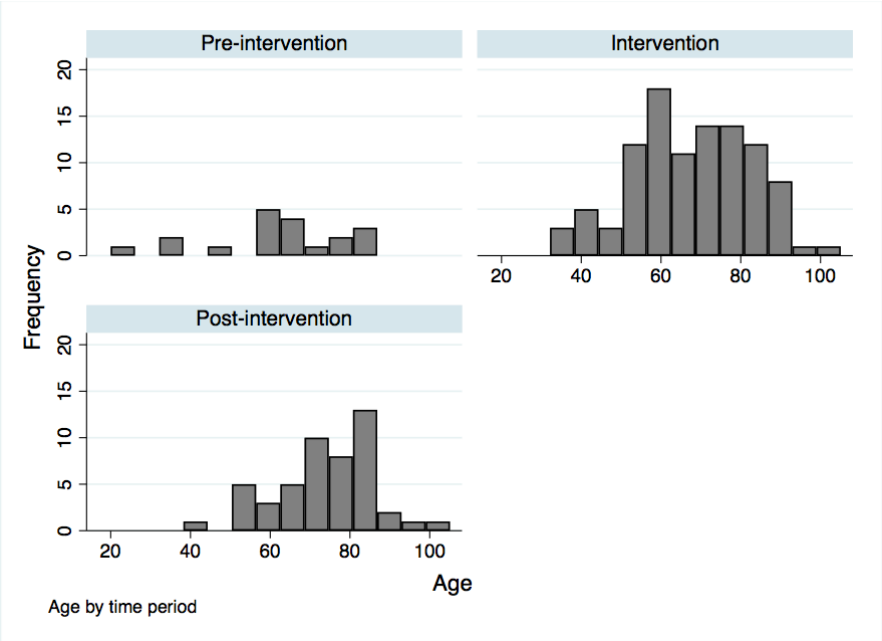
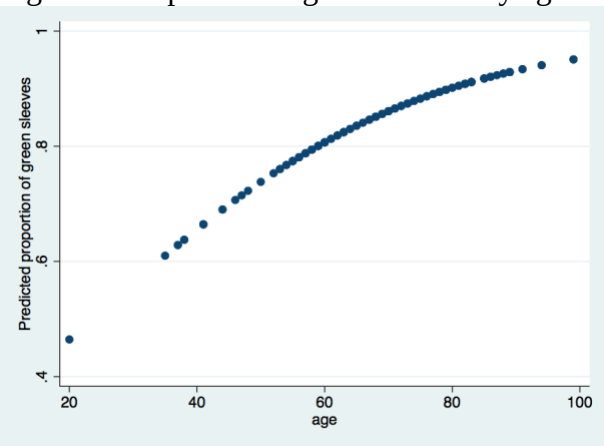


Figure 9. Proportion of green sleeves by age



Recommendations regarding the prioritization of ACP have suggested that older, more critically ill patients should be identified first for ACP discussions. It is therefore, in keeping with this recommendation that older patients were more likely to have a prepared discharge package containing a green sleeve and ACP documentation

APPENDIX 3

Qualitative Process Evaluation Questions- Unit 81

1. Thinking back before the project started, what did you think about the ACP and GCD process in your clinical area?
   a. Did you have concerns then about how conversations were had or documented? Please describe.

2. What changed, if anything, for you in your perception of ACP and GCD over the course of the project?
   a. What changed within your clinical team in terms of how conversations were had or documented over the course of the project?

3. What were the main areas for improvement in terms of structures (e.g. physical space, equipment, and human resources) and/or process issues (e.g. the delivery of care and patient education) identified during the 'build understanding' phase of this project?
   a. Were there other issues that you think are important that should have been identified?

4. Which stakeholders, in terms of individuals or groups, should have been engaged in the planning and implementation processes?
   b. Were there potentially more effective ways to engage with these stakeholders?

5. What was your experience with the 'build understanding' phase in terms of current processes and identified areas for improvement?
   a. What did you find useful in this phase?
   b. What would you have done differently?

6. What has been your experience of the change (or implementation) phase?
   a. What have you found useful within this phase?
   b. What was your experience of participating in the e-sim activities?
   c. What would you have done differently?

7. What are important indications or measures of change that you have observed as a result of this process?
   b. What do you think should be done next to create further change?

8. What do you think should be done to sustain any positive changes that have been made?

9. Overall, what is your impression of this project?
   ` a. What do you think worked well?
   b. What would you suggest be done differently next time?

Have you seen goal statements/achievements?

- What do you think these results tell us?
- Half of the goals were achieved. Why do you think this/that changed?
- Would it have been informative to ask a question around current skill level both before and after study?

Appendix 4

Sample Qualitative Analysis: Process evaluation

	Theme	Category	Code	Condensation	Quote
BEFORE IMPLEMENTATION	Developing understanding and implementation of ACP process has increased awareness of key issues and initiated behavior change but continued efforts need to address more complex ACP process elements	Lack of process and clarity around ACP	Conversation gap	Identifiable gap in having conversations	We did struggle with the conversations happening...there was a real identifiable gap there before the project started
			GCD insufficient	GCD does not sufficiently represent patient wishes	You feel like you're not sure that you know what the expectation was for that patient by the goal of care
			Unclear green sleeve purpose	Lack of understanding of green sleeve purpose	It's all of us...we never really understood what that green sleeve is there for
			Lack role clarity	Know ACP is important but no role clarification as to who should be doing it...	We know that it is something important but there is no role clarification as to who should be doing it...
			Lack multidisciplinary structure	Lack of structure for multidisciplinary team members on ACP conversations	There was nothing structured specifically on how to do ACP conversations for any individuals, for any levels that even you're a nurse or a physician or part of the multidisciplinary team. It was completely missing
DURING IMPLEMENTATION		Understanding of ACP elements developed	Responsibility of all HCP	Ownership for conversations falls on all of us	Conversations really occur at all levels and the ownership falls on all of us to really identify those cues from our patients and to open up the conversations
			Uncovering discomfort	HCP not comfortable with conversations	Discomfort has been uncovered now and it's a hard place to jump off from but I think it's been uncovered because we dove into so many logistical pieces
			Same quality, different bundle	Goals of care are same quality of care but a different bundle	The aha moment for me is...so the patient gets the exact same level of care, the exact same quality of care but the bundle of care that comes with that designation differs
		Admission/discharge process built	Built process around green sleeve	Green sleeve was not being used to capacity and we built a process	There's no specific equipment needed for this process but there's this already available tool, the green sleeve, that is not truly understood and not being used ultimately to its full capacity, so we built a process around it
			Increased role clarity	Biggest change was role clarity	So what changed? Role clarity is a big thing for me. I think the biggest piece of it is the perception of who should really be a part of these conversations
		Team collaboration and support impact implementation	Team work a success	Bringing teams together worked well	Bringing the teams together worked really well to develop the project
			Coordinator keeps track	Great to have coordinator keep team on track	I am very thankful that there was that main coordinator because without him I don't think we can keep the momentum going. He keeps us on track, he writes notes, he looks at action items, delegates them appropriately and looks for follow-up so it's great
			Increased change exploration	People want to explore change more	I don't know what the appetite for change would have been before and I think if you look, overall from an outcome of the project, it may not look that successful but it's super successful because it has built a culture of people wanting to explore this more
			Multidisciplinary partnership	Project a multidisciplinary partnership	I find this project a partnership between the multidisciplinary teams
AFTER IMPLEMENTATION		Continued challenges with optimizing team process and skill building	Teach tracking record use	Need to teach tracking record use	We need to teach people about using the tracking record
			Conversation Education needed	Not confident with amount of targeted education done to support staff in conversations	I'm not confident at this point...if we've done enough targeted education to support our staff and improve their ability to converse with our patients
		Expanding reach of implementation	Training medical residents	ACP training for medical residents	How to involve and train medical residents. The issue is they do a lot of this work. They have a lot of these discussions.
			Involve more MD types	Should have involved more types of MDs	I recognize we had a sample of everyone and I think that was right but it would have been nice to have a few more people from these groups. Like more hospitalized and more cardiologists
			More leadership to solidify expectations	Leadership needed to solidify expectations on tracking record use	We need more leadership and understanding and solidify that expectation that [conversations] really must be on the tracking record, or else what are we doing here?
		Lack of consistency across clinicians and teams on process goals	Inconsistent expectations	Inconsistency between expectations on nurses and physicians on tracking record	So our expectation of our nurses is to always document on the tracking form when it comes to goals of care or any issue. But our physicians are not doing that. It's inconsistent because physicians always have an excuse not to do it
			Tracking record use difficult goal to unite on	Difficult to unite HCP behind tracking record goal	Certainly this project made me realize how difficult it is to get everyone on board with that [tracking record] goal