UNDERSTANDING THE MECHANISMS OF PROTOCOL IMPLEMENTATION FOR THE
EARLY RECOGNITION AND TREATMENT OF PROBABLE SEPSIS

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Abstract

The purpose of this research was to construct a program theory that identifies and describes the salient contexts and mechanisms that can lead to successful implementation of a sepsis screening intervention. Successful implementation of evidence-based clinical practice is governed by human and environmental factors that can differ between local settings (Sales, Smith, Curran, & Kochevar, 2006). Failed or partial implementation of clinical practices is common (Davies, Walker, & Grimshaw, 2010) impacting negatively on patient safety, patient outcomes, and systemic inefficiencies. A theory-based approach to implementation provides a structure that can allow local teams the ability to move away from ad hoc or intuitive planning (Eccles, Grimshaw, Walker, Johnston, & Pitts, 2002).

A customized Rapid Realist Review was used to identify the hypothetical implementation resources, context, and mechanisms that are salient in causing successful implementation of sepsis screening interventions. This process included a rapid review of the literature using a realist analytical lens and multi-phase refinement of the theoretical propositions with 15 physicians and nurses.

The final program theory included multiple outcomes that must be reached in order to achieve successful implementation. Successful implementation was defined as achieving fidelity and sustainability of the intervention. Salient implementation resources and context were identified that trigger three middle-range promoting mechanisms and two inhibiting mechanisms. Within each of these mechanisms there are multiple lower level mechanisms operating that are salient for all clinicians and professional sub-groups.

The final program theory hypothesized the salient features of a complex reality that can be applied or adapted for the implementation of a sepsis screening intervention in other local contexts or for the implementation of other similar small-scale interventions.

Acknowledgements

Dedication

This manuscript is dedicated to my wife, Doria, and my daughter, Hazel. Their love, support, and patience afforded me the opportunity to pursue developing my academic skills and enabled me to persevere to see it through to completion.

Table of Contents

List of Tables

List of Figures

List of Abbreviations

CA – Consolidated Account

CFIR – Consolidated Framework for Implementation Research

CM – Context-Mechanism

CMO – Context-Mechanism-Outcome

CO – Context-Outcome

EA – Explanatory Account

ED – Emergency Department

EGDT – Early Goal-Directed Therapy

C – Context

HSMR – Hospital Standardized Mortality Ratio

ICU – Intensive Care Unit

M – Mechanism

MO – Mechanism-Outcome

NPT – Normalization Process Theory

O – Outcome

PDSA – Plan-Do-Study-Act

qSOFA – Quick Sequential Organ Failure Assessment

R – Resources

RRR – Rapid Realist Review

Sepsis-3 – Third International Consensus on Sepsis

SHR – Saskatoon Health Region

SSC – Surviving Sepsis Campaign

SIRS – Systemic Inflammatory Response Syndrome

TDF – Theoretical Domains Framework

1.0 Introduction

1.1 Statement of the Problem

Implementation of evidence-based clinical practice in large healthcare organizations is often difficult, because success is governed by human and environmental factors that can differ between local settings (Sales et al., 2006). Failed or partial implementation of clinical practices is common impacting negatively on patient safety, patient outcomes, and systemic inefficiencies (Davies et al., 2010; Eccles & Grimshaw, 2004; Sales et al., 2006). The implementation of clinical practice changes and interventions at the local level (i.e. clinical area) is often done ad hoc or through intuitive planning despite the evidence that support better success using a theory-based approach (Eccles et al., 2002).

Theory allows for an understanding of the determining factors and the relationships between those factors that inform how to plan, execute, and sustain the implementation of clinical interventions. Choosing, adapting and applying the best theory from the multitude that exist to suit local needs requires experience and expertise that are often not present within local clinical teams or available for small-scale local implementations. Local needs often dictate that the implementation of a clinical intervention is done rapidly (Saul, Willis, Bitz, & Best, 2013), involve iterative evaluation (Taylor et al., 2014), and occurs in a dynamic environment (Damschroder et al., 2009). Such environments include fluctuating personnel, evolving evidence supporting practice, and responses to changing patient and family needs.

Continuous quality improvement is a common problem solving approach used in health care and involves implementation of change as a step in iterative Plan-Do-Study-Act (PDSA) cycles (Taylor et al., 2014). However, this approach often lacks incorporating knowledge about how and why implementation can be successful and instead treats implementation as a task in the problem-solving process rather than a complex process in and of itself. A theory of implementation is a hypothesis for how and why implementation occurs (Nilsen, 2015), and program theory is a type of theory that can explain how small-scale implementation occurs in local settings (Pawson, 2013).

Evidence-based clinical interventions designed for the early recognition and treatment of sepsis have been developed and implemented in a variety of settings. However, the ability to successfully implement these interventions has been mixed (Otero et al., 2006). Multiple

approaches to the screening, diagnosis, and treatment of sepsis have been explored (Focht, Jones, & Lowe, 2009; Turi & Ah, 2013; Westphal et al., 2011) but a practical understanding of how to successfully introduce these approaches in the clinical setting is not well understood. Implementation is often hampered by the multi-level system complexity that surrounds the different contexts in which implementation is to occur to achieve desired outcomes. The problem becomes that the consequence of failing to successfully implement clinical interventions, such as that for the early recognition and treatment of sepsis, directly affects patients and the health system (Al Khalaf et al., 2015; Gauer, 2013).

Thus, understanding the theoretical mechanisms that can lead to successful implementation of a sepsis protocol will help to inform successful implementation of this intervention in other similar settings and potentially other future similar interventions. Eliciting lessons from previous implementation experiences and applying it in new related work can lead to positive results on desired outcomes (Pawson & Tilley, 1997).

1.2 Research Question

The central question in this research is: *How, why, for whom, and in what circumstances does successful implementation of an intervention for the early recognition and treatment of probable sepsis occur in medical, surgical and emergency clinical areas?*

1.3 Purpose of the Study

The purpose of this research was to construct a program theory that identifies and describes the salient resources (R), contexts (C), and mechanisms (M) that lead to an outcome (O) of successful implementation of a sepsis screening intervention. The implementation of a sepsis screening tool at St. Paul's Hospital, Saskatoon, in 2015 combined with existing literature, provided a recent suitable case study to create a program theory. The objective was to construct a program theory that reflects the salient features of a complex reality that can be applied or adapted for the implementation of a sepsis screening intervention in other local contexts or for the implementation of other similar small-scale interventions.

A realist approach was used to develop a program theory that hypothesizes the successful implementation of a clinical intervention for the early recognition and treatment of probable sepsis. The first step was to generate a general program theory derived from the literature that

explained implementation from a variety of settings. The second step involved knowledge users to validate and refine the theoretical propositions within the program theory to reflect a reality based on their experience and expertise, thereby explaining how and why implementation is successful in their local context.

1.4 Theoretical and Analytical Perspective

A realist ontology and epistemology guided the development of an understanding of how implementation of a sepsis screening tool successfully can occur. This understanding will come from the articulation of the key mechanisms and associated contexts that occur when certain resources are used. In order to develop this understanding, a rapid realist review was used to analyze and integrate information from the literature and knowledge users who experienced the implementation of a sepsis screening tool. The rapid realist review was customized in order to address the nature of the research question and produce a program theory that would be sufficiently useable by knowledge users.

2.0 Background Literature

2.1 Sepsis

Sepsis is a common and deadly condition that occurs in all patient populations throughout a hospital (Tillmann & Wunsch, 2017). Elderly patients and children, those with suppressed immune systems, and those who have received surgery, are particularly at risk (Tillmann & Wunsch, 2017). Sepsis is a condition that can rapidly progress necessitating urgent attention for less severe cases and emergent intervention as severity increases. It is associated with a high rate of morbidity and mortality if not rapidly recognized and treated (Dellinger et al., 2013; Wang, Xiong, Schorr, & Dellinger, 2013; Yende et al., 2016). For the most severe cases, known as septic shock, mortality has been found to increase by a mean of 7.6% for every hour delay in treatment (Kumar et al., 2006). Diagnosing sepsis is complicated, as the hallmark criteria are a constellation of vital sign changes, risk factors, and the presence of an infection (Singer et al., 2016). Yet, the salient vital sign changes can also indicate other pathologies and all infections do not lead to sepsis. Thus, there is an ongoing debate about how to define, screen, and diagnose sepsis and subsequently, variation in clinical practice and an ongoing need to improve patient outcomes.

2.1.1 Sepsis characteristics. Between the late 1970s and early 2000s, the incidence of sepsis had been increasing globally (Martin, Mannino, Eaton, & Moss, 2003) and as a result, an international consensus committee was formed to address this called the Surviving Sepsis Campaign (SSC) (Dellinger et al., 2013). Revised in 2012, the SSC guidelines defined sepsis as a systemic inflammatory response to infection, categorized by severity as sepsis, severe sepsis, and septic shock (Dellinger et al., 2013). The characteristics in this definition include signs of a systemic inflammatory response syndrome (SIRS) (e.g. increased temperature, heart rate, respiratory rate and decreased level of consciousness) and a documented or probable source of infection. Severe sepsis was defined using the same sepsis criteria in addition to signs of hypoperfusion (e.g. decrease in blood pressure) reflective of a physiological state progressing to cellular dysfunction and organ damage. Septic shock involves the progression of persistent low blood pressure despite fluid resuscitation that requires advanced clinical interventions found in an intensive care setting, such as mechanical ventilation and inotropic medications (Kleinpell,

Aitken, & Schorr, 2013). More detail on sepsis pathophysiology can be found in Shankar-Hari and Singer (2018).

Since the 2012 SSC guidelines were published, there has been debate in the international community on how to define sepsis (Seymour et al., 2016; Singer et al., 2016). The main points of contention with the SSC definition are that the focus on inflammation is too great and that viewing sepsis as a syndrome, such that manifestations are categorized on a continuum of severity, is misleading (Singer et al., 2016). It has been argued that the current means of screening and diagnosing sepsis using the SIRS criteria results in the treatment of patients who are not septic and minimizes the importance of intervening early in the least severe cases. This was supported by the fact that deaths due to sepsis have remained high despite several iterations of SSC guidelines (Seymour et al., 2016; Singer et al., 2016). Singer et al. (2016) argued that because there have been advances in pathobiology, sepsis management, and epidemiology, the current physiological picture of sepsis differs from the SSC guidelines.

In 2016, the Third International Consensus on Sepsis (Sepsis-3) refined the definition of sepsis to be "...a life-threatening organ dysfunction caused by a dysregulated host response to infection" (Singer et al., 2016, p. 805). In this definition, the concept of sepsis as a continuum was discontinued, including the use of severe sepsis as a category. It was argued that dropping this category was necessary, because there cannot be a gold standard diagnostic test for syndromes. Sepsis cases were thus being under-identified and treated (Seymour et al., 2016). It was also suggested that, by dropping the severe sepsis label, clinicians would perceive greater urgency and respond sooner, because the severe sepsis label leads to delays in responding to sepsis until a patient is more acutely ill. Thus, more convincing that their condition was truly sepsis as opposed to another differential diagnosis. The new definition stressed organ dysfunction as the physiological indicator of sepsis characterized by an increased respiratory rate, altered mentation, and hypotension. In the 2016 revised SSC guidelines, severe sepsis was dropped but the use of SIRS for screening was maintained (Rhodes et al., 2017).

2.1.2 Epidemiology. Internationally sepsis kills more than 5 million people annually and costs over $24 billion in hospital costs per year in the United States (Tillmann & Wunsch, 2017). In-hospital mortality due to severe sepsis has been found to range from 25 to 30% and for septic shock upwards of 40 to 70% (Gauer, 2013). The one-year mortality rate for initial survivors of

severe sepsis is reported to be anywhere between 7 and 43% (Gauer, 2013). Sepsis contributes to a significantly lower quality of life for those that survive it, which includes an increased incidence of post-traumatic stress disorder, cognitive dysfunction, physical disability and persistent pulmonary dysfunction (Al Khalaf et al., 2015; Gauer, 2013; Heyland, Hopman, Coo, Tranmer, & McColl, 2000; Hofhuis et al., 2008; Yende et al., 2016). The seriousness of sepsis necessitates a high level of acute care, such as intensive-care unit (ICU) admissions, and is therefore, a significant financial burden on any health system (Dellinger et al., 2013). Patients with sepsis account for upwards of 15% of intensive care unit patients (Dombrovskiy, Martin, Sunderram, & Paz, 2007) and have been found to represent an annual economic burden of $17 billion in the United States (Martin et al., 2003).

At St. Paul's Hospital in Saskatoon, Canada, the 2014 Hospital Standardized Mortality Ratio (HSMR) for in-hospital sepsis deaths per 1000 discharges was 2.8, which represented an observed mortality rate greater than expected (CIHI, 2016a). The HSMR is a risk-adjusted rate of mortality identified from patients after admission, which is calculated by dividing the observed number of cases of death due to sepsis by the expected number multiplied by the Canadian average (CIHI, 2016b). Given that early identification and intervention of sepsis can significantly reduce deaths, the higher than expected mortality rate prompted the local health authority to focus on reducing sepsis deaths as part of a patient safety quality improvement strategy.

2.1.3 Screening and management. Initially published in 2001, and revised in 2004, 2012 and most recently in 2016, the SSC developed 93 clinical practice recommendations organized into bundles, that have guided the management of sepsis in different types of clinical areas (e.g. emergency departments and intensive care units) (Rhodes et al., 2017). These bundles include recommendations for screening, testing, monitoring, treatment and management. The evidence supporting these recommendations is varied including 32 statements that are based on strong evidence and 39 on weak evidence.

The purpose of screening is to recognize sepsis as early as possible and prompt timely intervention. In a survey of intensivists using vignettes to test individual clinical diagnosis of sepsis, it was found that the diagnosis was subjective and variable with an interrater agreement of only 0.29 using Fleiss' kappa (Rhee et al., 2016). Diagnostic variation for such a severe malady reinforces a need for standardized objective criteria and methods to identify and treat sepsis. The

SIRS criteria have been used for screening sepsis since the first published SSC guidelines. However, the individual vital sign parameters that make-up SIRS are not unique to sepsis; thus, sepsis is not a clear-cut diagnosis compared to other medical conditions of a similar magnitude such as heart attack and stroke. Abnormal vital signs within SIRS together with the overall clinical presentation might lead clinicians to consider other diagnoses, in addition to sepsis. It can occur that sepsis is not the primary consideration in a differential diagnosis until the patient becomes critically ill, at which point a patient can rapidly decline necessitating emergent intervention and care with less assured outcomes (Vanzant & Schmelzer, 2011).

Despite the attempt to standardize sepsis screening and treatment, often referred to as early goal-directed therapy (EGDT), there has been significant variation in the degree of success with screening interventions. Multiple individual studies have demonstrated the benefit of using SIRS-based EGDT to reduce the odds of sepsis related death and hospital length-of-stay (Armen et al., 2016; Castellanos-Ortega et al., 2010; Moore et al., 2009; Solh, Akinnusi, Alsawalha, & Pineda, 2008). A meta-analysis, published by Lu et al. (2016), indicated that EGDT for severe sepsis and septic shock reduced overall mortality. Similarly, a large international prevalence study on sepsis found that there was a 36 – 40% decrease in the odds of dying due to severe sepsis and septic shock in hospital when the SSC bundles were used (Rhodes et al., 2015).

However, there is evidence that standardized sepsis screening and treatment does not always result in improved outcomes. A living systematic review of EGDT for severe sepsis and septic shock concluded that there was no overall difference in mortality when comparing early-goal directed care and usual care, and that there was no correlation between sepsis severity and reduced mortality (Simpson, Gaines, Hussein, & Badgett, 2016). In a large randomized trial across 31 centres, an EGDT protocol for early septic shock was tested to determine generalizability of the approach from that of previous studies (The ProCESS Investigators, 2014). They looked at the effect on 60-day, 90-day and 1-year mortality and need for organ support and found no significant differences. Similarly, a trial conducted in 51 centers throughout Australia and New Zealand found that early-goal directed therapy based on the SSC guidelines did not result in any difference in survival time, in-hospital mortality, or hospital length of stay for patients with early septic shock (ARISE Investigators & ANZICS Clinical Trials Group, 2014).

Other studies have indicated that degree of compliance with EGDT is positively associated with the degree of improvement in patient outcomes. Shapiro et al. (2006) found that when EGDT was used, time sensitive interventions were completed in less time but that there was no overall improvement in patient outcomes due to the variation in compliance. Levy et al. (2015) found that as compliance with the use of the 2004 SSC guidelines increased, in-hospital mortality decreased where a 0.7% reduction in mortality was achieved for every 3-months of using the bundles. This equated to a 4% reduction in length of stay for every 10% increase in compliance. In a review of the implementation of EGDT for sepsis in the emergency department (ED), both system and individual level issues were found to influence the use of SSC based interventions including initial antibiotic administration within the first hour after identification, laboratory testing, and invasive monitoring (Turi & Ah, 2013). Inhibiting system level factors included staffing pressures, a lack of advanced education needed to make the more specialized SSC recommendations (i.e. invasive hemodynamic monitoring) operationalized, and weak evidence behind some of the specific interventions within the SSC guidelines. The factors that promoted use were thought to be staff education and collaboration amongst different clinical areas (e.g. ED and ICU). It is a logical conclusion that variation in adherence with EGDT determines to a great extent the overall effectiveness of sepsis interventions.

The variation in patient outcomes when using SSC based interventions prompted the proposal for a new screening intervention consistent with the 2016 Sepsis-3 definition called Quick Sequential Organ Failure Assessment (qSOFA) (Singer et al., 2016). It has been argued that SIRS criteria might just reflect an appropriate adaptive host response that does not necessarily always lead to organ dysfunction therefore it is insufficient for consistent diagnosing of sepsis (Singer et al., 2016). qSOFA was proposed as an easy to use bedside criteria to identify adults at risk of sepsis and includes three criteria: altered mentation using the Glasgow Coma Scale, hypotension with a blood pressure of 100 mm Hg or less, and a respiratory rate greater than 22 per minute (Singer et al., 2016). qSOFA was adapted from the more detailed Sequential Organ Failure Assessment (SOFA) used in critical care to assess the severity of organ dysfunction (Vincent et al., 1998).

Despite the idea that qSOFA might be an improved method of sepsis screening, a recent systematic review and meta-analysis comparing SIRS and qSOFA found that SIRS had a significantly better pooled sensitivity for predicting in-hospital, 28-day, and 30-day mortality in

adults with sepsis from ICU, ED and inpatient wards (Fernando et al., 2018). Unlike a diagnostic criterion that aims to have high specificity, a screening intervention aims to have high sensitivity. In this study, the pooled sensitivity from multiple clinical areas was found to be 88.1% for SIRS compared to 60.8% for qSOFA. When separating out clinical areas, qSOFA had a higher sensitivity (87.2%) in the ICU only. This suggests that qSOFA might be more appropriate as a screening intervention in the critical care setting where patients are more acutely ill and more likely to advance clinically to organ failure. The overall difference suggests that although there might be legitimate issues with SIRS criteria being an appropriate gold standard for diagnosing sepsis, as a screening criterion in non-ICU areas it appears to be the most appropriate option (Fernando et al., 2018).

Most cases of sepsis are identified in the ED; therefore, screening is especially important in that setting. In a prospective comparison study of multiple sepsis screening criteria, it was found that qSOFA failed to identify two thirds of the patients admitted to the ED with severe sepsis (Askim et al., 2017). As a risk stratification tool for predicting 7 and 30-day mortality it was found that qSOFA had a sensitivity of 0.32 which made it less effective than the others at screening for sepsis to achieve the goal of early intervention (Askim et al., 2017). This reinforces that at present, SIRS is the better criteria for sepsis screening outside of ICU.

The majority of the literature on the early recognition and treatment of sepsis is focused on the development, effectiveness and efficacy of specific interventions based on SSC recommendations such as early antibiotic and fluid administration and invasive hemodynamic monitoring (Focht et al., 2009; Gurnani et al., 2010; Westphal et al., 2011). In most of these studies there is only passing or speculative commentary on what factors led to successful or unsuccessful adoption and compliance.

Regardless of the specific screening method, early identification and treatment of suspected sepsis leads to a reduction in morbidity and mortality. For example, Whippy et al. (2011) found that as the rate of compliance with a system wide approach to sepsis EGDT increased, risk-adjusted mortality and hospital length of stay decreased. It is therefore surprising how common the underutilization of evidence-based EGDT for sepsis is (Gao, Melody, Daniels, Giles, & Fox, 2005; Huang, Clermont, Dremsizov, & Angus, 2007; McIntyre, Hebert, Fergusson, Cook, & Aziz, 2007; Mikkelsen et al., 2010; Nguyen et al., 2007; Sivayoham, 2007). For example, a prospective cohort study on the implementation of a collaborative protocol for

sepsis EGDT in the ED and medical ICU found that there was an improvement in meeting the timelines for the targeted interventions (e.g. time to antibiotic and fluid administration) when the protocol was applied but only 48% of eligible patients had the protocol completed for them. In this case, the authors concluded that compliance was suboptimal because there was a failure to create an organizational culture of a standardized approach to sepsis (Casserly et al., 2011).

Another example comes from Bond et al. (2013) who found significant variation in uptake of an electronic clinical practice guideline for standardized sepsis management by emergency physicians. This intervention included a form detailing qualifying criteria, an EGDT order set, EGDT outcome indicators, and teaching boxes on specific guidelines such as vasopressor use. Interestingly, it also included a capability at multiple points where physicians could override the practice guideline and order alternate treatments based on their clinical judgement. Presumably, this was developed to address differences in clinical decision making that could secondarily result in resistance due to standardization, but this was not explicitly stated.

The reasons for variation of adoption and compliance with methods to integrate EGDT are mostly speculative or suggestive at various levels of application. System level rationales for successful adoption and compliance have included the presence of quality improvement or process improvement systems (Casserly et al., 2011; Damiani et al., 2015; Ferrer et al., 2008; Shapiro et al., 2006) and an institutional execution strategy including leadership alignment, standardization of evidence-based practices across clinical areas, project management, collection and use of timely, and actionable data available to practitioners (Whippy et al., 2011). In a systematic review of studies evaluating the impact of performance improvement programs and compliance with SSC guidelines, Damiani et al. (2015) found a significant degree of inconsistency in approaches across 50 observational studies. The use of a performance improvement program was associated with increased compliance with the 6 and 24-hour 2004 SSC bundles (OR 4.12 and 2.57) and reduced mortality (OR 0.66). However, there was insufficient detail on why increased compliance was achieved for those studies that demonstrated an improvement.

In an example of an institutional execution strategy, the goal of the approach was to create uniform, reliable, sustainable performance improvements that are owned by teams at the front line (Whippy et al., 2011). This included pilot testing involving multidisciplinary teams, a

comprehensive quality improvement plan, and ongoing progress assessment. The quality improvement plan included a PDSA playbook, screening and support tools, multidisciplinary education, a replication plan for other areas, and ongoing leadership, clinical, and quality improvement support. In general, patient outcomes were reported as having been improved. However, there was variation in successful implementation and minimal explanation for the variation observed.

Rationales for successful adoption and compliance at the local level, such as a specific clinical area, are equally variable and vague. There have been many strategies associated with adoption and improvements in mortality and hospital length-of-stay due to sepsis including; a hospital wide code sepsis and rapid response team (Beardsley et al., 2016; Focht et al., 2009; Guirgis et al.), standardized order sets (Beardsley et al., 2016; Focht et al., 2009; Guirgis et al.; MacRedmond et al., 2010; Winterbottom, Seoane, Sundell, Niazi, & Nash, 2011), decision making algorithms (Focht et al., 2009; MacRedmond et al., 2010), protocols allowing non-physicians to intervene early (Beardsley et al., 2016), targeted education (Guirgis et al.; MacRedmond et al., 2010), and electronic health record trigger (Guirgis et al.). Although this might be a helpful list of resources to consider in developing a strategy to improve sepsis identification and treatment goals there is little explanation why these do or do not work. For example, Focht et al. (2009) credited the emphasis on training, consistency in applying the protocol, relatively few changes from current practice, and low additional direct expenditures as being factors that enable implementation. However, they stop short of explaining the causative relationship.

Understanding why a given strategy works is key to being able to adopt and replicate in another setting because many of these same strategies have resulted in a failure to achieve the desired patient outcomes. For example, in a study of a nurse-initiated emergency department sepsis protocol based on the SSC bundles, Bruce, Maiden, Fedullo, and Kim (2015) found that overall there was no change in in-hospital mortality. A collaborative protocol that included staff education, quality monitoring, feedback and subsequent improvements also did not result in a benefit for patients (Casserly et al., 2011). Since most of the studies include interventions based on SSC bundles, it is interesting to highlight that in an analysis of the effectiveness of care bundles used for multiple clinical conditions (not just sepsis) it was found that care bundles may

reduce the risk of negative outcomes versus usual care but the evidence supporting this is low quality (Lavallee, Gray, Dumville, Russell, & Cullum, 2017).

Understanding why an intervention does not work or failed to be implemented is as valuable as knowing why it works and how successful adoption can occur. Although reasons for failure are rarely stated some studies have suggested a few possible reasons. Bond et al. (2013) noted that a significant challenge to achieving the goal of protocolized care for sepsis is physician behaviour and mentioned that debate about the particulars of a protocol can be a limiting factor. Wang et al. (2013) noted that a barrier to early, urgent sepsis care is the feeling amongst clinicians that a standardized sepsis bundle was unnecessary.

2.1.4 Sepsis trigger tool. In 2015, the former Saskatoon Health Region[1] initiated a patient safety quality improvement strategy at St. Paul's Hospital, focused on reducing in-hospital deaths due to sepsis. An interdisciplinary team developed a screening and treatment protocol, referred to collectively as a 'trigger tool', to facilitate the early recognition of sepsis and to standardize the initial treatment of probable sepsis using a subset of recommendations from the 2012 SSC bundles (Dellinger et al., 2013). The goals were to build consistency in recognizing sepsis amongst nurses; minimize the time between recognition and initial response (i.e. antibiotic and intravenous fluid administration and blood tests); and support consistent communication between nurses and physicians. The group used a quality improvement approach (Langley et al., 2009) that included rapidly reviewing the evidence, deciding on an intervention, implementation, evaluation and improvement within a 3-month period. Implementation involved basic education to nursing staff (including the rationale for the trigger tool, review of sepsis, and how to use the tool), raising awareness about the need for the tool with physician groups, and engaging with nursing managers and clinical educators to promote uptake and collect basic data on compliance.

The trigger tool was divided into three sections based on severity from the 2012 SSC guidelines including sepsis, severe sepsis, and septic shock (Appendix A). The tool was intended for nurses to identify probable sepsis and severe sepsis by incorporating screening in their normal workflow including admission assessments, scheduled vital sign checks, and at any time

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[1] As of December 2017, all regional health authorities in Saskatchewan, including the Saskatoon Health Region, were amalgamated into the Saskatchewan Healthy Authority.

where more frequent measurement was indicated, such as a patient's change in clinical status. The first section of the tool included criteria to recognize sepsis using vital signs (temperature, heart rate, respiratory rate, blood pressure), level of consciousness, and secondary indicators (the presence of risk factors and suspected or confirmed infection in the case of severe sepsis). The trigger tool was designed as a medical directive. A medical directive is a means to prescribe "a protocol, procedure, treatment or intervention that may be performed for a range of Patients who meet certain conditions" (Saskatoon Health Region, 2016, p. 1). It allows for nurses to perform the prescribed actions outside of their usual scope of practice without a physician's signature. For sepsis and severe sepsis there are corresponding time sensitive actions prescribed for nursing staff to complete. For sepsis this includes ordering laboratory blood work. For severe sepsis this includes ordering laboratory blood work and administering intravenous fluid. A communication tool was added to the reverse side of the tool to prompt efficient and effective communication with physicians once the actions were completed because all patients positively screened for any level of sepsis would require ongoing physician care. The protocol was trialed on general medicine, mixed general surgery and medicine, thoracic-vascular surgery and emergency department nursing units at St. Paul's Hospital.

2.2 Implementation Science

The ability to successfully implement clinical interventions like a sepsis screening tool is not guaranteed and is dependent on multiple changing factors. Understanding how successful implementation can occur puts the nature of this research in the domain of implementation science. Eccles and Mittman (2006) define implementation science as "… the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care" (p.1). Implementation is defined as "…the means by which an intervention is assimilated into an organization." (Damschroder et al., 2009, p. 3). Implementation science is a wide reaching and complex area of study. The following is a focused summary of the major themes in implementation science and how they relate to the implementation of clinical interventions.

Rather than a singular activity, implementation involves multiple planned and purposeful activities, resources, or interventions to operationalize a plan for the introduction of a clinical

intervention over time. Implementation interventions are often distinct from, but can be informed by, the clinical intervention that is to be implemented. As a result, there can be a degree of ambiguity in the jargon of implementation when speaking about clinical interventions versus implementation interventions (Eldh et al., 2017). For the sake of clarity, a clinical intervention (e.g. sepsis screening tool) involves healthcare practitioners using it for a specific clinical practice to achieved a patient outcome(s) (Eldh et al., 2017), whereas an implementation intervention involves activities that focus on changing the behaviour of healthcare practitioners so that a clinical intervention is adopted (Eldh et al., 2017).

In general, there is a persistent gap in the integration of evidence into clinical practice despite a constant need in health care for the successful implementation of evidence-based clinical practices (Damschroder et al., 2009; T. Greenhalgh, Robert, MacFarlane, Bate, & Kyriakidou, 2004; Grimshaw et al., 2004; Grol & Grimshaw, 2003; Lavallee et al., 2017). There are a myriad of potential reasons why such a gap exists that are related to both the intervention and implementation of the intervention. Intervention characteristics that have been suggested to influence adoption include the type of health issue the intervention is designed for (e.g. lower uptake of interventions for chronic conditions), the quality of evidence supporting the intervention, degree of skepticism amongst healthcare practitioners about the established practice, and degree of complexity of a new intervention (Grol & Grimshaw, 2003). Even for interventions that appear simple, based on high quality evidence, and designed to address a clear clinical need, successful implementation is surprisingly varied (Cabana et al., 1999; Kalil & Sun, 2008; Michie et al., 2005). Therefore, an evidence-based clinical practice can only be effective if it is effectively implemented (Eldh et al., 2017), and effective implementation is a Pandora's box of complexity.

It has been suggested that the ongoing issue of partially or failed implementation of clinical interventions is related to a lack of an applied theoretical understanding of how successful implementation of evidence-based clinical practices occurs (Craig et al., 2008; Damschroder et al., 2009; Davidoff, Dixon-Woods, Leviton, & Michie, 2015; Davies et al., 2010; Eccles & Grimshaw, 2004; Eccles et al., 2002; Jones, Shapiro, & Roshon, 2007; Lavallee et al., 2017; Liang et al., 2017; May, 2013; Michie et al., 2005; Michie, Stralen, & West, 2011; Oxman, Thomson, Davis, & Haynes, 1995; Sales et al., 2006; Shojania & Grimshaw, 2004). The effect of variable implementation can be the failure to achieve intended health outcomes, leaving

patients at risk of potentially suboptimal care (Grimshaw et al., 2004). In a review of the literature, Grimshaw et al. (2004) noted that a significant number of studies on the effectiveness and efficacy of clinical guideline dissemination and implementation strategies, showed only minimal to moderate improvements in care; a median improvement of 6-14%. The prevailing argument is that the use of theory in clinical implementation enhances the effectiveness of clinical interventions by focusing on the essential processes that cause behaviour change and ensuring that essential implementation strategies are developed from the guiding theory (Eccles et al., 2002).

2.2.1 Implementation theory. Theory is defined as a systematic way of understanding events or behaviours by explaining how the concepts, definitions, and propositions of phenomena are related and hypothetically cause other events or behaviours (Tabak, 2012). Theory can be categorized based on inherent characteristics. A true theory is inherently abstract, broadly applicable, not content- or topic-specific, and composed of a connected set of analytical principles designed to structure observation, understanding, and explanation of phenomena (Nilsen, 2015). A framework, also applicable in guiding implementation, is a theoretical strategic action-planning model that provides a systematic way to develop, manage, and evaluate interventions (Nilsen, 2015). Frameworks encapsulate more specific and narrowly applicable details and are suited to guiding work as opposed to explaining causation. Frameworks are often inherently theoretical when they are based on one or more substantiated theories. Although they might not explain causation, the action-planning functions are rooted in theoretical hypotheses. Therefore, implementation theory, either in the form of substantiated theory or frameworks, can guide a hypothesis of how implementation actions change behaviours so that an intervention is adopted. They allow for the identification of constructs and propositions that create a structure and describe a function that can lead to the hypothesized or predicted desired outcomes, namely the healthcare professional's behaviour change by adopting a new clinical practice (Michie et al., 2005).

A change in behaviour occurs by embedding new ways of thinking through the dissemination of evidence and relating evidence to practice; enacting and organizing practice; and linking implementation design and actions with meaningful patient outcomes (Damschroder et al., 2009; May, 2013; Michie et al., 2011; Tabak, Khoong, Chambers, & Brownson, 2012).

Theory offers a means to articulate why this occurs but determining how to practically achieve these, especially in the domains of clinical practice, is not straightforward. In her 2018 book *How to implement evidence-based healthcare,* Trisha Greenhalgh stated that "…the mismatch between what researchers produce and what clinicians want and need can be almost comical" (p. 15). This statement summarizes her argument that research is often misaligned with clinical practice because evidence is not a simple set of facts that when implemented into clinical practice leads a successful change. Whereas research tends to focus on narrowly defined questions involving abstract, and often controlled variables, clinical practice relies on objective evidence combined with a clinician's contextual judgement, the consideration of the subjective experience of the patient being cared for, and the real limitations of cyclical resource allocation (T. Greenhalgh, 2018). Therefore, it is clinicians as adopters that determine the extent to which an evidence-based intervention is applicable for their clinical practice and whether or not a new practice is adapted and behaviour changed. The challenge is how to apply implementation theory involving different individuals or groups in different circumstances.

In a review of 235 guideline development and implementation studies, only 22.5% were determined to have used theories of behaviour change (Davies et al., 2010). Of those studies that used theory, 16.6% of studies used a single theory, 4.3% used only selected constructs, and there was often no clear rationale for theory use. In a subsequent scoping review, it was found that 47% of studies used theory in guideline implementation (Liang et al., 2017). While this indicates an apparent trend towards greater theory-guided implementation, the overall number is lower than would reasonably be assumed.

In health care, the basic pragmatic approach towards implementation prevails (Lavallee et al., 2017). The pragmatic approach often relies on information dissemination, passive education materials, short education in-services, and use of reminders that at times can be valuable, but do not guarantee implementation success (Grol & Grimshaw, 2003). This is because such activities tend to generalize across settings, which precludes any consideration of the influence on contextual factors in implementation effectiveness. Context includes practice environment, prevailing opinion of the clinical practice, the knowledge and attitudes of those involved, and the organizational culture (Grol & Grimshaw, 2003; Scott, Mannion, Marshall, & Davies, 2003). In the absence of a guiding theory, the pragmatic approach fails to reliably address the reasons why

clinicians will change their behaviour other than the assumption that they simply have a lack of knowledge and understanding.

Using theory for the implementation of clinical practices is confusing and challenging for a variety of reasons. Firstly, there are many, and often overlapping, theories that makes choosing one theory for application difficult (Damschroder et al., 2009; Michie et al., 2011; Nilsen, 2015). Tabak et al. (2012) identified 61 proposed and applied implementation related theories and frameworks in their review of models for dissemination and implementation research. In their scoping review of knowledge translation theories, models, and frameworks, Strifler et al. (2018) found that 159 theories and frameworks had been applied in implementation related research, with 87% having been used in five or fewer studies and 60% used only once. For those seeking to apply implementation theory, this degree of variation in the literature makes understanding how to go about selecting and applying a theory overwhelming.

Secondly, it has been suggested that the utilization of theory is challenging because it takes too long to meet the real-world changing needs in health care policy development and clinical quality improvement (Saul et al., 2013). Some of the reason for this are that those in health care responsible for implementation do not have the requisite knowledge and capability for theory utilization (Saul et al., 2013). This is because theory utilization is not inherent in most health care professional training and it is often not a focus in health care operations. Even for those who might be trying to understand the role of theory in successful implementation of a particular intervention, they encounter the underreporting in clinical implementation literature on how a theory informed the methods and processes employed when theory was used (Proctor, Powell, & McMillen, 2013).

Thirdly, the tendency to generalize implementation theory leads to an underappreciation of how highly influential contextual factors can be and how to account for those factors in a meaningful way when implementing (Grol & Grimshaw, 2003).

Several taxonomies have been developed to make selecting and using implementation theory less confusing and challenging. Tabak et al. (2012) proposed a way to categorize dissemination and implementation models in three ways to guide selection. The first category is construct flexibility. Theories and frameworks are grouped from those with loosely defined constructs that allow for flexible application, to narrowly defined, step-by-step processes and actions. The second category describes whether the theory or framework focuses more on

dissemination, implementation, or a mix of both strategies. The final category is the applicable socio-ecologic level at which the theory or framework operates including the system, community, organization, or individual level.

Alternatively, Nilsen (2015) also proposed a taxonomy of implementation theories and frameworks to facilitate selection and application using five categories including process models, evaluation frameworks, determinant frameworks, classic theories, and implementation theories; with the latter three being the most useful for understanding what influences implementation outcomes. A determinant framework specifies the individual and types of determinants that influence outcomes both in terms of barriers or enablers. Classic theories, similar to previously mentioned true theories, originate from fields external to implementation but can be applied to understand or explain phenomena affecting implementation. Implementation theories are those specifically developed for implementation either from original evidence or the adaptation of existing theories.

The following is a brief description of several of the many theories and frameworks used in implementation to highlight the breadth and diversity of what is available to guide the implementation of clinical practice changes.

2.2.1.1 Diffusion of Innovations. Diffusion of innovations is a theory developed to spread and sustain innovations in health care delivery (T. Greenhalgh et al., 2004). It was developed in response to the sparse evidence on implementation and recognition that the process of implementation is complex. The theory focuses on the factors related to system readiness in early implementation and the successful routinization of practices defined by the intervention being implemented. The major factors that inform readiness and routinization include: adaptable and flexible organizational structures and processes; commitment and advocacy for a targeted change from top management; the motivation, capacity and competence of practitioners, specifically clinicians in the context of clinical practices; the effectiveness of communication within organizations; the provision of accurate and timely feedback; and the ability and degree to which adaptation and reinvention of the practice occurs in the local context. Nilsen (2015) categorizes diffusion of innovations as a classic theory, and Tabak et al. (2012) categorized it as focused on dissemination only, with a high degree of construct flexibility, and applicable at the community, organization, and individual levels.

2.2.1.2. Normalization Process Theory. Normalization process theory (NPT) is used to describe, assess, and enhance implementation potential through 4 main constructs: coherence, cognitive participation, collective action, and reflexive monitoring (May, 2013; May & Finch, 2009). NPT has been used for developing, evaluating, and implementing a range of interventions (McEvoy et al., 2014) such as fracture prevention services (Drew et al., 2015) and family violence and screening (Hooker, Small, Humphreys, Hegarty, & Taft, 2015). The NPT also includes a validated measurement instrument (May et al., 2015). Nilsen (2015) categorizes NPT as an implementation theory, and Tabak et al. (2012) categorizes it as implementation, applicable at the system, community, organization, and individual levels, with a construct flexibility between theory that is broad and loosely defined, and one that is highly operational with step-by-step actions.

2.2.1.3 Consolidated Framework for Implementation Research. The Consolidated Framework for Implementation Research (CFIR) is a meta-theory on implementation effectiveness derived from a synthesis of 19 theories and frameworks (Damschroder et al., 2009). The CFIR complements process theories in guiding how implementation should be planned, organized, and scheduled, as well as impact theories that hypothesize how activities lead to change. It includes a typology to promote implementation theory development and verification about what works where and why across multiple contexts in five major domains. The first domain is the outer setting which includes things such as patient needs, external policies and incentives for implementation. The inner setting is another domain that involves factors such as the social structure of the organization. Another domain is the characteristics of the intervention, including the strength and quality of evidence informing the intervention and the complexity in using it. The fourth domain is the individuals involved in the implementation including details such as their knowledge, beliefs, and self-efficacy. The final domain is the planning, engaging, and executing within the implementation process. The CFIR has been used in a wide variety of settings and for multiple units of analysis (Kirk et al., 2016) such as identifying barriers and facilitators in implementing internet-based communication services in multiple settings (Varsi, Ekstedt, Gammon, & Ruland, 2015). Nilsen (2015) categorizes the CFIR as a determinant

framework and Tabak et al. (2012) categorize it as a framework used only for implementation, with narrowly defined constructs, applicable at the community and organization levels.

2.2.1.4 Theoretical Domains Framework. The Theoretical Domains Framework (TDF) is a synthesis of 33 theories of behaviour, developed to make psychological theory more accessible to those working in implementation (Michie, Atkins, & West, 2014; Steinmo, Fuller, Stone, & Michie, 2015). It is comprised of 14 theoretical determinants of behavior change on which interventions are designed to change practice and transfer knowledge, such as guiding quality improvement (Mosavianpour, Sarmast, Kissoon, & Collet, 2016) and targeting interventions (Debono et al., 2017). For example, Debono et al. (2017) used TDF to identify multiple barriers related to environmental context and resources, and social/professional role and identity. Environmental barriers include staff time pressures and available technology. Social/professional barriers included conflict between behaviours dependent on the system versus what was expected as a professional. Nilsen (2015) categorized the TDF as a determinant framework. However, it does not appear in the taxonomy by Tabak et al. (2012) as it post-dates its publication.

2.3 Quality Improvement Science

Clinical quality improvement is a common systematic approach to problem-solving in health care that often drives the implementation of practice changes (Worsley, Webb, & Vaux, 2016). The approach uses real-time data to design, test and implement small scale change that is evaluated and improved as part of a continuous iterative process, often referred to as PDSA cycles (Taylor et al., 2014). The benefit of this approach is that it allows for data driven decision making in highly dynamic settings that are not conducive to more in-depth, time consuming, and resource intensive methods consistent with typical research. Conceptually, this process has been described as experimental learning by testing changes over time that leads to improvement (Reed & Card, 2016). Evidence suggests that when used properly the quality improvement approach is effective in creating clinical practice change (Wells et al., 2018). However, similar to implementation science, there are significant issues with variation in compliance and with the reporting of methods and results that makes appraising the overall effectiveness of the approach difficult (Taylor et al., 2014; Wells et al., 2018). Fidelity, an often underreported outcome in

quality improvement studies, is a central outcome in understanding if the overall success or failure of a practice change is related to the effectiveness of the new practice or the adherence to it (Lavallee et al., 2017).

Davidoff et al. (2015) argue that the typical behaviour in applying quality improvement is to move straight to implementation of a solution without considering what the behaviour, social, and technical processes are that need to change, how to create that change, and how to measure it. Along with Wandersman, Alia, Cook, and Ramaswamy (2015), Davidoff et al. (2015) argue that more informed use of theory in quality improvement would both strengthen the approach and facilitate its effectiveness. Failing to do so would continue the inhibition of learning, or failure to study the problem, through change that is central to improvement (Davidoff et al., 2015). A theory of implementation that can tie into quality improvement offers the greatest potential gain for creating change in clinical practice.

2.4 Program Theory

A program theory blends the functional utility of both theories and frameworks into a useable tool applicable for clinical implementation (Funnell & Rogers, 2011). Funnell and Rogers (2011) suggest that a program theory has two essential components – a theory related to change and a theory related to action. Change theory explains how certain variables and processes create change for individuals or groups and can be derived from substantiated, research-based theory or an implicit understanding about how things work (Funnell & Rogers, 2011). Action theory explains how an intervention activates the salient variables and processes within a theory of change and is the characteristic of a program theory that can align with clinical quality improvement.

Another form of program theory is middle-range theory. Middle-range theory includes change and action constructs that are captured for practical application (Pawson, 2013). A middle-range theory is sufficiently abstract so as to capture the diversity of concepts that can inform an understanding of social phenomena, such as behaviour change, while at the same time including explanations that can aid in translating knowledge into action (Pawson, 2013). The ability to guide action that is based on an understanding of causation makes program theory highly relevant in the implementation of clinical practices. As described in the next chapter, the

realist approach to building program theory offers a way to develop a useable middle-range

program theory that can hypothesize how successful implementation can occur.

3.0 Theoretical Framework

3.1 Realism

Successful implementation requires an understanding of which activities lead to success, who is important to that success, why success is achieved and how the context surrounding implementation activities play a role. Realism offers a way to answer these questions by uncovering and linking causal factors that influence the implementation of a clinical intervention. In realist terminology, causal factors are referred to as mechanisms, and a mechanism is triggered by certain contextual circumstances that lead to either intended or unintended outcomes (Pawson & Tilley, 1997). Context, mechanism and outcome are the central constructs in realist theory. These are assembled as a context-mechanism-outcome (CMO) proposition, which is the expressed relationship between them and forms the backbone of a causal explanation of real-world phenomena. Realist epistemology is centered on what works for whom in what circumstances, how and why (Pawson, 2013), where the success of an intervention is dependent on the complex relationships of various factors inherent within different contexts. Applied to implementation, the targeted outcome (O) of successful implementation results from the activation or inhibition of causal mechanisms (M) by the surrounding context where implementation interventions operate (Pawson, 2013). The configuration of multiple CMO propositions becomes a middle-range program theory, which are the hypotheses for how successful implementation occurs (Pawson & Tilley, 1997). The following paragraphs will outline the epistemological principles underlying a realist program theory and the characteristics of, and relationships between, context, mechanisms and outcomes.

3.1.1 Complexity. The main assumption underlying a realist program theory is that an intervention is inherently complex and subjected to complex social systems when in use (Pawson, 2013). Intervention complexity arises from the interplay of seven dynamic inherent characteristics which include volition, rivalry, emergence, context, time, outcomes and implementation. Pawson (2013) suggests these characteristics be the starting point when seeking to understand the nature of an intervention.

Volition reflects the active nature of an intervention, involving actors (individuals or groups) applying their reasoning to make a sequence of choices to achieve the goals of the

intervention (Pawson, Greenhalgh, Gill, & Walshe, 2005). Rivalry involves the impact of the pre-existing policy environment on an actor's actions in using the intervention and how the delivery of the intervention will be modified (Pawson, 2013). Emergence involves the consequences of duplication and long-term adaptation to the intervention, and any social changes and unintended consequences that impact the effectiveness of the intervention (Pawson, 2013). This can include actor networking and the cross-pollination of ideas that lead to intervention refinement, reinvention and adaptation in local settings (Pawson et al., 2005). Additionally, emergence can involve changing the context surrounding the intervention over time, thereby changing the circumstance that made it function in the first place, which results is unintended outcomes (Pawson et al., 2005). Context, in brief, includes micro and macro level circumstances and conditions within which an intervention exits (Pawson, 2013; Pawson et al., 2005). Time can refer to many different characteristics that create a dynamic context such as the actors' previous experience with the delivery, success and failures of similar interventions, and the timing and sequencing of actions (J. Greenhalgh et al., 2014). Outcomes are also dynamic and can involve such things as any disagreement with the monitoring systems or different stakeholder interpretations of performance measures (Pawson, 2013). Finally, implementation involves the resources, actors and their responsibilities, and underlying theories of change that guide the introduction of an intervention (Pawson, 2013).

Implementation, as a characteristic of intervention complexity, suggests that it is not necessarily a distinct phenomenon. However, as a series of purposeful actions intended to introduce an intervention, it can be a process that can involves factors separate from the intervention operating within complex social systems. An intervention provides actors external conditions and resources that are purposively drawn on, such as knowledge, skills and tools. In the implementation process there are often additional resources introduced that are intended to aid in the introduction and uptake of the intervention, such as education, trial introductions, and implementation teams. Therefore, understanding implementation complexity contributes to a better understanding of how an intervention operates.

In addition to complexity introduced by an intervention and the process of implementation itself, social systems capture another aspect of complexity. Social systems involve multilayered dynamic social forces operating between actors and groups (Pawson & Tilley, 1997). In health care settings, actors can include clinicians (nurses, physicians,

pharmacists, etc.), support staff and administrators who can operate as collaborative or isolated groups at the unit, hospital or organizational levels. Realism maintains that social forces are real and not constructions of an actor's mind as is suggested in constructivist epistemology (Pawson & Tilley, 1997). In realism, the actor introduces social forces through their agency, which, in turn, governs their interactions, choices and actions in response to an intervention. It also involves the cumulative effect of relationships, and the relative influence between actors (Pawson et al., 2005). Thus, it is suggested that theories of change be incorporated to understand social complexity when examining how an intervention, or implementation of that intervention, causes outcomes (T. Greenhalgh, 2018; Pawson, 2013).

Pawson (2013) argues that the realist approach overcomes deficiencies that exist in other ways of understanding the complexity of interventions. He argues that the positivist approach attempts to bring complexity under experimental control, which is not reflective of reality. This is because experimental control only admits to limited demonstrations of complexity as opposed to inherent continuous complexity that arises when interventions are subject to the social reality within context. Systems thinking acknowledges continuous complexity but by manipulating observations of reality in activities such as modeling, but the ability to practically capture complexity for the purposes of policy implementation is lost. Pawson (2013) excludes critical realism as a suitable process for developing program theory, as it focuses on ideology as opposed to the analysis of social reality. Finally, the pragmatist perspective is also insufficient in capturing complexity for real life use because it lends itself to more partial explanations because of the emphasis on urgent and theory-less approaches. Given the limitations of these other approaches, the realist approach pioneered by Pawson and Tilley (1997) was chosen as the methodology to develop a hypothesis explaining successful implementation of a sepsis intervention in the form of a program theory that reflects the complexity of real life but is also practically relevant.

3.1.2 Context. Context is the set of circumstances and conditions surrounding an intervention (Pawson, 2013). It includes micro (individual and group) and macro (organization or societal) level factors that are connected to an intervention and triggers, or modifies, a mechanism (Jagosh et al., 2014). At the micro level, these factors can include the actors' characteristics and capacities, and the interrelationships between actors, that facilitate the

function of a specific intervention or program (Pawson & Tilley, 1997). At the macro level, contextual factors can include the local rules, customs and norms as well as the social, cultural and economic infrastructure surrounding an intervention (Pawson & Tilley, 1997). Examples of relevant context can include the history of the community in which the intervention is implemented, the nature of existing social networks, the built intervention infrastructure, and geographic location (Jagosh et al., 2014).

3.1.3 Mechanism. A mechanism is the generative force that leads to an intended or unintended outcome triggered by one or more contextual factor(s) (Jagosh et al., 2014; Pawson, 2013; Pawson & Tilley, 1997). A mechanism "describe[s] how the resources embedded in a program [intervention] influence the reasoning and ultimately the behavior of program subjects" (Pawson, 2013, p. 115). The resources or strategies within a program are linked to the causal mechanisms, but do not describe them (Jagosh et al., 2014). The causal mechanism is an actor's reasoning in response to a resource, their cognitive capacity, emotion and choice making. These responses amongst multiple actors inform the social patterns of behavior, both challenges and successes, that ultimately determine the nature of the program outcome (Jagosh et al., 2014; Pawson & Tilley, 1997). Reasoning is not a binary construct; it is not the case where it is either present or it is absent. Rather, reasoning exists along a continuum for both individual actors and within groups, and it is contextual factors that reveal the extent to which a mechanism is sufficiently salient to be a generative force. Identifying salient mechanisms for specific interventions advances a synthesis from describing what happened to why it happened, for whom, and under what circumstances (Jagosh et al., 2014).

Sonia Dalkin, Greenhalgh, Jones, Cunningham, and Lhussier (2015) proposed a modification to the original Pawson and Tilley (1997) definition of a mechanism in order to address the confusion surrounding the application of realist methods in practice. They argued that applying realist theory requires significant reflection and creativity in revealing social mechanisms which has led to inconsistent conceptualizations and applications of the term mechanisms. Therefore, Dalkin et al. (2015) proposed purposefully differentiating resources and reasoning, where a resource refers to the component of a mechanism introduced into a context, and reasoning is what is maintained as the hidden intrinsic quality of the actors reflected through thinking and choice making. By not distinguishing in some way resource from reasoning, it is

inevitable that knowledge users new to realism and interested in applying realist methods will gravitate towards interpreting mechanisms as tangible resources and processes. This is due to the prevalence of positivism that skews thinking towards causation, including the belief that causal factors are measurable variables. Thus, any focus on reasoning as a determinant mechanism is at risk of becoming under-emphasized and less clearly articulated. The result is a less robust and relevant program theory. Differentiating resources and reasoning following Dalkin et al. (2015) is an intriguing option for researchers and knowledge users new to realism in order to discover and conceptualize explanatory cognitive and emotional forces.

3.1.4 Outcome. The definition of an outcome is fairly open-ended, depending on the nature of the program theory. Outcomes can be intended or unintended, and proximal, intermediate, or final relative to the overall program theory (Jagosh et al., 2014). This means that outcomes are not always inherently known and are revealed through the realist process of inquiry. For example, in their program theory for the appraisal of doctors as part of a professional development program, Brennan et al. (2017) describe multiple intermediate outcomes, such as individual insight and behavior change, that occur in the process of achieving maintained or improved performance (final outcome). In this case, the final outcome was intended but the realist review revealed the unintended intermediate outcomes that appeared to be salient for achieving the intended outcome. Examples of outcomes in this research were acceptability and feasibility of the intervention, and fidelity and sustainability.

4.0 Analytical Framework

4.1 Realist Synthesis

A realist synthesis, also referred to as a realist review, is the process of appraising, synthesizing, and disseminating a hypothesized program theory (Pawson, 2002). Realist syntheses identify, track and evaluate program theories from groups of similar interventions using any relevant data to build on what has been found to be successful and effective (Pawson et al., 2005). The goal of a realist synthesis is to articulate a program theory that explains how social forces affect the thinking and actions of actors in contexts that can lead to the development of practical interventions (Pawson & Tilley, 1997).

A detailed guide on the methods for a realist synthesis does not exist however, there are publication standards that include the essential elements of a realist synthesis that offer some practical steps (Wong, Greenhalgh, Westhorp, Buckingham, & Pawson, 2013). Pawson et al. (2005) first described the method in broadly applicable terms as an introduction to a new form of knowledge synthesis, because of the limitations in traditional systematic reviews and meta-syntheses. They wanted to be able to ask why, how, and for whom does a program or intervention work, and traditional approaches are not designed to produce these answers. They outlined how a realist synthesis differs by seeking to collect data on a range of explanations about how an intervention was supposed to work, how it worked well or why things went wrong. This line of inquiry introduces both quantitative and qualitative data that can originate from peer or grey literature sources. Data are not limited to examples from interventions directly related to the one at the focus of the synthesis, because there is often scant theoretical data available in implementation and evaluation studies. Broadly applicable data allows for the ability to reveal any potentially explicit underlying theory on how an intervention is meant to work in a context. This increases the ability to compare and contrast potential causative explanations when details on these factors are scant. As well, it allows for the application of theory across disciplines. Hallmarks of the realist synthesis process include: ongoing dialogue with the actors who develop and deliver the interventions; purposive and iterative information searching; theory construction and theory testing; and appraisal of evidence using a realist quality lens (Pawson et al., 2005). However, the method originally described did not include any details on how to consistently

apply it and is therefore reliant on experts with a background in realism having a role in guiding the nuanced review process.

Recently published realist syntheses have reflected multiple interpretations, adaptations and modifications to the realist review process (J. Greenhalgh et al., 2014; Kastner et al., 2015; Rycroft-Malone et al., 2012). The realist synthesis publication standards include nineteen essential elements for a realist synthesis (Table 4.1) however, these standards are not a protocol-driven approach (Wong et al., 2013). The underlying logic of realism, where an understanding complexity reveals context-dependant causal mechanisms, does not lend itself to a predetermined and prescriptive approach (Jagosh et al., 2014). Rather, the approach allows for, and promotes, the ability to customize the steps depending on the purpose of the synthesis. This characteristic strengthens its applicability when considering the volume of evidence on a topic, the multiple types of evidence, the dearth of contextual details in the evidence and whether or not the evidence reflects an underlying theory (Jagosh et al., 2014). The challenge is that it is difficult to conduct without previous experience applying realism in research.

Table 4.1. Items to be included in the reporting of a realist syntheses as described by Wong et al. (2013).

Reporting section	Key components
Title	
Abstract	
Introduction	• Rationale for review • Objectives and focus of review
Methods	• Changes in the review process • Rationale for using realist synthesis • Scoping the literature • Searching process • Selection and appraisal of documents • Data extraction • Analysis and synthesis processes
Results	• Document the flow diagram • Document characteristics • Main findings
Discussion	• Summary of findings • Strengths, limitations and future research directions • Comparison with existing literature • Conclusion and recommendations • Funding

Pawson et al. (2005) originally suggested that identifying an underlying middle-range theory at the outset of a synthesis could be done to guide the data collection process because it can facilitate the conceptualization of complex outcomes by aiding a reviewers' reasoning and inference. If there are well described constructs related to the phenomenon at the focus of the synthesis, then these can be incorporated, or used as a comparator, throughout the process. If constructs are not well described or are unknown, then referring to broader substantive theories can serve this function. A substantive theory is one that exists in the literature on change and action and is related to the field that is the subject of the synthesis (T. Greenhalgh et al., 2017b). Existing substantive theories help to make sense of the pattern of findings revealed in a realist synthesis and provides structure to the program theory.

However, in many areas, such as clinical practice research, such theory is absent or unclear in the literature. Jagosh et al. (2014) suggested that an iterative selection process of

identifying potentially relevant literature through abstract screening, literature selection with full paper review and appraisal by pairing articles based on potential theoretical similarity would illuminate as much underlying middle-range theory as would be available. These researchers noted that within the appraisal process a realist approach invites a heterogeneity of evidence that lacks conceptual clarity and can be complex. To manage these characteristics, they suggested that reviewers should create an iteratively-designed selection tool, actively refine the conceptualization of the middle-range theory throughout the process, and appraise the evidence based on realist relevance and rigour. Evidence is relevant if it addresses the middle-range theory of interest (Pawson et al., 2005). Evidence is rigourous if a particular inference is drawn by the original researcher in such a way that is has sufficient weight to make a methodologically credible contribution to the test of a particular intervention theory (Pawson et al., 2005). Therefore, it is suggested that establishing relevance and rigour in the screening and appraisal process can be done if there is one instance in an article, regardless of section, where the original researchers describe or reflect on the process and impact of the intervention (Jagosh et al., 2014).

Jagosh et al. (2014) provided suggestions on how to capture unintended outcomes from the literature, how to go about configuring CMOs and including middle-range theory, and how to use middle-range theory to advance outcome conceptualization after the selection process. Unintended outcomes can be revealed by looking across different studies as opposed to within single studies, which is facilitated by the pairing or grouping of evidence. CMOs are extracted using passages of text directly from studies and assigning elements within the passage as C, M or O. Revealing mechanisms requires interpretation and abductive reasoning on the part of the reviewers and the iterative synthesis of CMOs. Abductive reasoning is the iterative process of developing ideas about causal factors linked to the evidence (Jagosh et al., 2014). It incorporates induction (theory building based on observations), deduction (testing observations based on theory), and retroduction (building on hunches and exploring what are beneath observations and their causes) (T. Greenhalgh et al., 2017a).

Jagosh et al. (2014) suggested that during the CMO configuration process reviewers identify any middle-range theory that appears and include it in the ongoing iterative synthesis in order to eventually provide structure to the overall CMO configuration that is in line with established theoretical knowledge. Theoretical structure comes from an overarching explanatory understanding that connects individual CMOs or groups of CMOs. However, if these structures

are too broad, narrow, or abstract they are not representative of a middle-range theory and do not support the explanation and connection of CMOs. The process of identifying and incorporating middle-range theory is challenged by the subjective understanding of what middle-range theory is and the absence of truly theory based causative explanations from the literature being synthesized.

In the absence of clearly outlined methods for realist synthesis, a protocol can still be assembled using the original outline by Pawson et al. (2005), incorporating the suggestions on how to customize by Jagosh et al. (2014), and the publication standards outlined by Wong et al. (2013). A realist synthesis is an in-depth and time consuming approach, which challenges its applicability for inexperienced knowledge users and their need for timely application when faced with time (i.e. continuous process improvement) and resource (i.e. lack of access to realist expertise) constraints (Saul et al., 2013).

4.2 Rapid Realist Review

There has been a move to develop more rapid evidence synthesis approaches in response to the increasing need of practitioners, policy makers, and administrators for timely and accessible evidence to support the knowledge to action process (Khangura, Konnyu, Cushman, Grimshaw, & Moher, 2012; Tricco et al., 2015). Most rapid review approaches involve the purposeful reduction of established larger scale reviews, such as the systematic review, and greater involvement of knowledge users who are not the researchers (Tricco et al., 2015). Knowledge user involvement creates the ability to modify the synthesis process so that the results are timely, purposeful, available, user-friendly and trustworthy (Khangura et al., 2012).

Saul et al. (2013) first proposed a modified realist synthesis called the rapid realist review (RRR) as a rapid approach to realist synthesis. A RRR is intended to preserve the core standards of a realist synthesis (Wong et al., 2013) but modifying the process so that it can be more useful for responding to time-sensitive and emerging issues. The shorter period to complete an RRR means that it is useful for phenomenon that have a narrow focus and relies on knowledge user input and guidance.

Knowledge users' individual and collective knowledge and experience informs the scope and purpose of the review and provides components of testable theory in the form of explicit C-M-O configurations throughout the process (Pawson & Tilley, 1997). This is built from the

assumption that knowledge users know the most about the interventions they are responsible for, the context within which an intervention functions, and are the agents through which any change would occur. The usability of results from an RRR is also determined by the knowledge user, thus their insights need to be embedded in the review process. This allows for the development of practical solutions to problems faced in care delivery; to enhance the conceptual understanding for refining ideas in strategic thinking; and can be a benefit in circumstances when there is a minimal evidence base and where policy makers initiating the review are in a position to influence change (Saul et al., 2013).

A RRR works backwards from the intended intervention outcome(s) to reveal families of interventions and the surrounding contextual factors which trigger key mechanisms (Saul et al., 2013). Saul et al. (2013) argued that the RRR makes the merging of theory with practice more pragmatic as the results tend to be responsive to local policy or program needs and are more utilization-focused. These characteristics make the RRR method attractive for understanding implementation success. A RRR program theory is therefore focused on contextually relevant interventions that lead to specific outcomes in a particular setting as opposed to an in-depth theory that is transferrable across different domains. Table 4.2 outlines the steps in conducting a rapid realist review.

Table 4.2. Steps in conducting a Rapid Realist Review as proposed by Saul et al. (2013).

RRR Steps	Details
1. Development of the project scope	Clarify area of interest with knowledge users
2. Development of specific research questions	Questions knowledge users are most interested in answering
3. Identification of how findings will be used	Expressed intent on how results will be purposefully utilized
4. Development of search terms	Collaborative identification of terms relevant to project scope, purpose and research question
5. Identification of articles and documents for inclusion	Begin with list from knowledge users; use search terms to iteratively generate list of documents
6. Quality review	Narrow search terms based on results that are most relevant to the review; poll knowledge users to identify key documents
7. Extraction of data using a template	Similar to full realist synthesis
8. Validation of findings	Review with content experts to validate and identify gaps
9. Synthesis of findings in a report	Report formatted to meet the needs of knowledge users
10. Dissemination of results	Work with knowledge users to produce recommendations for policy, further knowledge gathering, or program evaluation

In this project, the RRR approach was used to establish an explanatory middle-range theory of successful implementation. Given the relative novelty of this methodology, RRR approach was customized to address the methodological gaps identified from the small number of peer-reviewed RRR that have been published to date. At the outset of this research, three published peer-reviewed RRRs existed that demonstrated variability in conducting a RRR (Saul et al., 2013; Tsang, Blakerman, Hegarty, Humphreys, & Harvey, 2016; Willis et al., 2014).

In their initial description of the RRR approach, Saul et al. (2013) highlighted that policy makers are interested in how interventions affect outcomes and therefore are less inclined to know the details of contextual and mechanistic factors. Although it may be true that policy makers in some settings may think de-emphasize the need to understand the key constructs of context and mechanism, failing to focus on gaining such an understanding takes away from the explanatory power of why and how the intervention leads to outcomes. A review that does not emphasize giving knowledge users information on why an intervention works, runs the risk of

being less than fully realist with findings of questionable legitimacy. Although not explicitly stated, this suggests that de-emphasis of the more nuanced realist constructs might be due to knowledge users not thinking or speaking in realist terms. Therefore, there is a need to engage knowledge users in realist content so that they understand and can apply the understanding of how and why an intervention works without losing them in the jargon and potentially foreign conceptualization of a program theory.

Willis et al. (2014) described how to simplify RRR methods into five steps in their review of improving organizational capacity to address health literacy in public health. These steps included,

- Developing and refining a purpose statement and question
- Searching and retrieving information
- Appraising evidence
- Synthesizing information, and
- Interpreting information.

Their process involved a group of Public Health Agency of Canada representatives (i.e. knowledge users) and an expert panel with representatives from a variety of government and non-government agencies involved in health literacy. They categorized strategies that improve organizational capacity for delivery health literacy services into three domains; government action, organizational/practitioner action, and partnership action.

Two methodological gaps are apparent in this RRR. Firstly, many of the described potential mechanisms appear to lack the essential element of being reflective of individual or group reasoning as they describe more tangible phenomenon that are more indicative of an intervention, context, or outcome. For example, they outlined that creating space for broad involvement, maximizing contributions from across organizations as a potential mechanism for influencing organizational capacity. This might be a significant factor, but it might more appropriately describe context as it does not reflect any hidden individual or group level reasoning.

Secondly, there is an absence of any described substantive theory underpinning the groups of potential mechanisms. This is reflected in how they outlined groups of interventions operating within groups of contexts relating to groups of potential mechanisms. By grouping these concepts, there is a lack of structure such that an understanding of causation is not clear.

Although Saul et al. (2013) articulated that the RRR is more about identifying families of interventions than creating a comprehensive program theory, the fact that the realist intent is to provide an explanation of causality means that even for the RRR there is a need to relate the propositions in the program theory to some element of established theory of action and change.

In their RRR on understanding the implementation of interventions to improve the management of chronic kidney disease in primary care, the work by Tsang et al. (2016) revealed another modified approach. The researchers used Normalization Process Theory (NPT) as a substantive theory at the outset to structure their program theory for successful implementation. In comparison to Willis et al. (2014), this method presented a more clearly outlined program theory by rigidly applying a substantive theory at the outset to structure a program theory, which was not done in either of the other RRRs. They had a single context within which five groups of mechanisms operate. Four of these groups were aligned with the four constructs of the NPT and one group was unique. However, within each group they also described several mechanisms that were more indicative of interventions or context than true mechanisms. For example, the researchers identified mechanisms to prolong sustainability. They proposed that patient involvement and ancillary staff were these mechanisms, which are not hidden constructs reflecting reasoning.

Tsang et al. (2016) also did not involve knowledge users in their RRR. It is not entirely clear whether they accounted for that by considering themselves the knowledge users as they were clinician researchers, or whether it was left out of their process for a particular reason. Saul et al. (2013) proposed that the role of a knowledge user was to guide the RRR process. This posed an interesting question for the current study: could the clinician researcher perspective be considered as a knowledge user perspective? Similarly, could the clinician researcher perspective also involve the role of an expert? Saul et al. (2013) described the role of an expert as one with expertise in the research area of interest that can accelerate the identification of key references. In this research, there was overlap in the roles of researcher, knowledge user, and expert, which became a factor that played a partial role in the analysis and conclusions.

5.0 Methods

The following steps of the RRR are based on those proposed by Saul et al. (2013) and the refinements proposed by Willis et al. (2014). The researchers adapted the process at several steps, using methods from other studies, to improve rigour and relevance as well as address methodological gaps in the RRR previously noted. No predetermined substantive theory was applied but considerable attention was paid to ensuring consistency in identifying potential mechanisms and incorporating any salient substantive theory revealed in the process. This included applying the definition of a mechanism as proposed by Dalkin et al. (2015), given that, of the few published RRRs, most demonstrated an inconsistent explanation of mechanisms.

5.1. Steps 1 – 3: Developing and refining the purpose, research question and how findings will be used

The first step of a RRR is to define a narrow content area of interest, develop a project scope, research question, and outline how the results of the review will be used (Saul et al., 2013). In the current project, the lead researcher (JM) was an employee of the former Saskatoon Health Region (SHR) and a member of the sepsis quality group that implemented the sepsis screening trigger tool. Some of the knowledge users in this project were also members of the group. At the outset of the quality improvement project, the group identified a need to understand how to successfully implement the sepsis trigger tool. This identified need formed the basis for the current project and the research question. The program theory developed in this study will be used by the group and health region to inform future work on how to successfully implement evidence-based practices and protocols.

5.2 Steps 4 – 6: Development of search terms, identification of articles and quality review

These steps involve the identification of search terms likely to be relevant to the project scope, purpose and question, and the identification of key references for inclusion (Saul et al., 2013). Knowledge users and content experts assist in the development of search terms as well as identifying any specific salient grey and published references for review. The literature search in a RRR is not intended to reveal a comprehensive list of the literature on a topic, rather it is intended to reveal key references that inform the research question. Therefore, the literature

search is rapid, iterative and includes knowledge user contribution and pearling. This more focused approach allows for the rapid identification of key informative material, efficient validation of findings, and an opportunity to suggest and explore alternate interpretations of results. For the current project, the results of searches already conducted by the knowledge user group were used to identify best practice for sepsis screening as well as additional searches to capture evidence focused on the implementation of sepsis screening interventions.

The review process was conducted by two reviewers, a post-doctoral fellow with realist research experience, and the lead researcher. The reviewers applied a subjective interpretation of relevance and rigour to the content within the references. Individual screening was followed by a discussion between the reviewers to arrive at final agreement on references to be included. The knowledge user group provided the key references that informed their work developing the trigger tool.

5.3 Step 7: Data extraction and program theory synthesis

This step involves both reviewers iteratively extracting and grouping theoretical data relating to elements within the reference texts that reveal potential contextual factors and mechanisms (Saul et al., 2013; Willis et al., 2014). Saul et al. (2013) argued that policy makers are more interested in families of interventions that inform the link between context and mechanism, therefore this was considered in the initial synthesis process. The process used by Jackson and Kolla (2012) was followed because it is a clear method for data extraction and CMO construct identification. This involved working backwards from the pre-defined outcome of interest, in this case successful implementation, and iteratively identifying emerging patterns of construct dyads (CM, MO, CO) and triads (CMO) to reveal context and mechanism constructs. This approach is consistent with that of Tsang et al. (2016), who also worked backwards from the same pre-defined final outcome to reveal mechanisms and contexts.

Using the methods of Pearson et al. (2015), constructs were organized into explanatory accounts (EA) and then consolidated accounts (CA), which allowed for a timely process while preserving relevance and rigor. Pearson et al. (2015) describe EAs as the building blocks of broader program theory. They are statements that express ideas about how potential realist dyads can best be linked through abductive interpretation. Information found within the texts of the references was extracted and assembled into an EA if it suggested a possible contextual factor

and/or mechanism. These were recorded in the form of 'if' and 'then' statements. For example, an EA statement would read as 'if the implementation of a clinical pathway is specifically timed then there is less of a burden of excessive information' suggesting specific timing is the context linked to the mechanism of being burdened.

Once an initial list of EAs was completed from all of the references, each reviewer independently grouped EAs by themes. Then together, the reviewers synthesized all the EAs within each group into a single CA. A CA has the same form as an EA, but because it is a synthesis of multiple EAs, its meaning can be more precise and theoretically rich (i.e. it accounts for 'how' and 'why' where the first element leads the second) (Pearson et al., 2015). A predetermined substantive theory was not included in the methods given the plethora of possible implementation theories to consider. Instead the reviewers examined the theory revealed in the literature that reflected successful implementation for a similar type of intervention.

5.4 Step 8: Validation of findings

Once a draft program theory has been created, knowledge users with experience in the field are engaged in order to identify gaps that exist in the literature and validate the findings (Saul et al., 2013). Because this step is not consistently described in RRR literature, this study ensured rigour and relevance by conducting a two-phase validation process. Phase one involved engaging with the knowledge users from the sepsis quality improvement group and phase two involved engaging with clinician end-users not associated with the working group but who were expected to adopt and use the sepsis screening protocol. The need for step two became apparent during the synthesis in phase one, because the knowledge users found the program theory to be overly linear and potentially missing pertinent linkages that reflect real-life complexity. The researchers deemed this lack of complexity to limit the rigour of the program theory. Additionally, some of the original draft propositions and constructs were judged to be too abstract, artificial or illogical requiring further knowledge user input in order to maintain relevance.

Jackson and Kolla (2012) remind us that participants do not always explicitly identify direct connections between realist constructs when engaging in realist research. This is a reasonable conclusion considering most knowledge users, especially clinicians, are not familiar with realist terms or think in terms of 'unseen' mechanisms of how and

why something works. Therefore, attempting to identify gaps in a realist program theory using realist jargon has the potential to lose knowledge users in the validation process thereby affecting the rigour and relevance of the overall program theory. As researchers went through the validation phases, visual depictions of CMO propositions were used with simplified descriptions or statements articulating the key components of the proposition.

5.4.1 Phase 1. The first phase of validation involved four volunteers from the sepsis working group participating in a focus group. Sampling was by convenience and represented nursing and physician clinical perspectives (i.e. professional role and clinical area) as well as experience in developing and trialing the trigger tool. Recruitment was done by sending an invitation to all members of the working group with a copy of the consent agreement. Focus group methodology was chosen because the literature-based program theory was vague and disconnected. As well, the lead researcher wanted to gain as much knowledge user contribution as possible in a short time. A focus group is a method to gather complex data quickly that can be applied in describing a phenomenon as it relates to theory or identifying and theorizing a phenomenon (Richards & Morse, 2013, p. 51), therefore it fit the methodological intent of this phase.

The principles and process of conducting a realist interview, described by Manzano (2016), were used to structure the focus group. Manzano (2016) described a research design using realist interviews that occurs over three phases: theory gleaning, theory refinement and theory consolidation. Manzano noted that not all studies will include all phases depending on the scope and intent of the research or evaluation, but regardless of the phase the researcher keeps the theory as the common denominator with the aim to better understand the evolution of interviewer knowledge. Theory gleaning involves exploring how contextual circumstances impact behaviour by drawing the interviewee into exploring context and comparing anything theoretical versus what has been experienced. The focus group provided a useful way of having knowledge users explore contextual circumstance in relation to theoretical constructs from the literature by interacting and building on each other's ideas. To facilitate the discussion and maintain the theory as the focus, three resources were used: a series of semi-structured questions, graphical representations of the literature-based program theory propositions, and text descriptions of the same propositions (Appendix C).

The semi-structured questions were used to facilitate the focus group. These questions were adapted from a standardized set of realist evaluation interview questions (Westhorp & Manzano, 2017). The original series was designed for individual interviews as part of an evaluation therefore in order promote group discussion the original list was shortened and slightly reworded to be more reflective of a theory gleaning line of inquiry. The focus group discussion was audio recorded and transcribed by the lead researcher.

5.4.2 Phase 2. Following the incorporation of focus group data in the revised program theory, the results were reviewed with the lead researcher's graduate committee. It was decided that the results were insufficiently clear and therefore another level of data was collected for further refinement. Manzano (2016) described theory refinement as learning from key informants with knowledge about how a program is really operating, by using more specific questions to refine outcome patterns.

In this phase, sampling was done by convenience and snowball methods. Recruitment activities included emails to identified key contacts, posters displayed in clinical areas, and referral from participants. Participants were included if they were a nurse, medical resident, or physician that practiced in the clinical areas where the trigger tool was trialed. Participation involved individual audio recorded interviews with the lead researcher. Participants were given statements summarizing each revised proposition and graphical representations of the same (Appendix D). Each proposition was read out loud and the participant was asked to confirm, refute or refine it. Refinement involved the participant and interviewer discussing why a statement needed refinement, what was missing or needed to be added, and exploring ideas and concepts that were identified in a participant's answer that were not necessarily directly related to the statement. If a response required further inquiry, the participants were engaged to reveal rationales and meaning behind their ideas and impressions. The recordings were deidentified and transcribed by contractors through the University of Saskatchewan Social Sciences Research Laboratory. All transcripts were reviewed for typographical mistakes.

5.5 Step 9: Synthesizing information

The incorporation and synthesizing of data from phase one and two with the literature-based program theory was an iterative process. In order to derive the explanatory quality of a

CMO proposition, the analysis and synthesis involved applying different kinds of reasoning through a number of analytical techniques as part of the iterative refinement of the program theory (Pawson, 2006). As previously stated, this involves abductive reasoning, which is the iterative process of developing ideas about causal factors linked to evidence (Jagosh et al., 2014).

Techniques used in realist methods include constructing, testing, and refining propositions (Pawson, 2006, pp. 73-78). Reconciling involves identifying differences between contradictory findings and adjudicating on what is interpreted to be realistic. Reconciling was used in the synthesis of EAs because at the level of individual studies there was variation in results and conclusions that at times conflicted. Reconciling was achieved through discussion and consensus on the relative strength and logic of the theoretical constructs. Consolidating is used to build multifaceted explanations of success that reflect a degree of real-life complexity. Consolidation was used to build middle range constructs from similarly themed phenomenon identified in the CAs, focus group discussions, and interviews. Situating is done by examining different combinations of construct configurations. For example, situating was used to integrate substantive theory constructs with draft CMOs when the substantive theory was identified in the iterative synthesis. Although these techniques and the underlying reasoning are the main analytical methods in step 9 of the RRR, they are used throughout steps 7 and 8 as well.

Saul et al. (2013) indicated that the product of a RRR must be formatted to meet the needs of knowledge users. Therefore, the synthesis was aimed at maintaining only theoretical propositions that were clear, logical and parsimonious while retaining the essential realist constructs. To maintain a manageable scope with the primary focus on successful implementation there needed to be two assumptions applied to the program theory; that the evidence-based intervention had already been identified (e.g. SIRS based sepsis screening protocol) and that the intended actors in this program theory were the end-user clinicians.

5.6 Step 10: Dissemination and Knowledge Translation

Implementation science is a domain of research that is intended on translating knowledge into action (Eccles & Mittman, 2006). The process and outcomes of conducting this research align with multiple components of the knowledge to action cycle (Straus, Tetroe, & Graham, 2013). This includes knowledge synthesis in the knowledge creation phase, and problem identification and adapting knowledge to local context of the action cycle.

5.6.1 Integrated Knowledge Translation. The inclusion of knowledge users as informants in identifying the research question and co-creators in the teacher-learner cycle of the focus group and interviews fulfilled the goals of integrated knowledge translation. The teacher-learner cycle involves reciprocal teaching and learning by both the interviewer and interviewee throughout the interview process (Manzano, 2016). Manzano (2016) describes this as the interviewer teaching the interviewee about the program theory and then the interviewee teaching the interviewer about the components that are salient. The roles are not static as both parties iteratively teach and learn before a common understanding of the phenomenon is achieved. These goals include the research being solutions focused with results more likely to be used in decision making (Straus et al., 2013).

5.6.2 End of Grant Knowledge Translation. At the conclusion of this research the aim is to share the program theory with the participants and knowledge users from the Saskatchewan Health Authority and Saskatchewan Health Quality Council. This will include a summary of results in print explaining how successful implementation can occur along with recommendations for applying this knowledge. The results will also be submitted for peer reviewed publication and presented at a relevant conference.

5.7 Ethics

This project was approved for ethical exemption by the University of Saskatchewan Research Ethics Board (U of S BEH 17-381) on November 8, 2017 (Appendix B). There were no known or anticipated risks to participants and each participant from phase one and two signed a participant consent agreement prior to any data collection (Appendix B).

6.0 Results

Three revised versions of the program theory were drafted throughout the iterative analyses. The first draft was based on the key literature identified in the rapid search, a second version after phase one knowledge user refinement, and the final version after phase two refinement.

6.1 Steps 1 – 3: Developing and refining the purpose, research question and how findings will be used.

The Saskatoon Health Region (SHR) sepsis quality improvement knowledge user group was seeking to understand how to successfully implement their sepsis screening trigger tool so that it could be replicated beyond the trial units at St Paul's Hospital. This was an unanswered query which offered the opportunity to explore it formally through realist research. As a member of this group, the researcher examined a real-world clinical practice question through an academic, rather than just practical, lens and applied an alternative methodology to do so. The information derived from this RRR will be shared with the same knowledge user group, as well as the larger health care organization, to help inform how future implementation processes for acute care clinical interventions can be successful.

6.2 Steps 4 – 6: Development of search terms, identification of articles and quality review.

The literature used in this synthesis came from three different sources; an initial search of MEDLINE and EMBASE, expert provided key references, and a secondary iterative search of Google Scholar and Scopus. 1123 references were screened for inclusion based on whether they included any information related to successful implementation that could be consistent with the realist definition of context or mechanism (Saul et al., 2013; Willis et al., 2014). The knowledge user group had previously identified key articles that informed the development of their sepsis screening trigger tool, and these were incorporated into the screening. References from a similar knowledge user group in another jurisdiction were also included and underwent the same screening (BC Patient Safety & Quality Council).

Additional literature searches were conducted because the knowledge users' reference lists were deemed to be insufficient in the amount of theory informing data. A rapid search of the

literature from key databases using sepsis specific search terms was conducted (Table 6.1). The titles and abstracts of 621 published articles were screened using a broadly defined set of inclusion criteria aimed at capturing key references (Table 6.2). This resulted in two articles being retained. Two additional articles were identified through chance on social media outside of the initial search and were included using the same criteria as well as two additional articles identified via pearling reference lists. Overall, six articles were included from these searches in the synthesis (Figure 6.1).

Table 6.1. – Rapid search strategy.

Database	Terms
Initial search	
MEDLINE - 1	[sepsis OR shock, septic] AND [mass screening OR (nursing process OR critical pathways OR "health care quality, access, and evaluation") OR clinical protocols] AND English language and humans
EMBASE - 1	[sepsis OR shock, septic] AND [critical pathways OR nursing protocols OR quality of health care OR health screening]
EMBASE - 2	[sepsis OR shock, septic] AND [(nursing process OR critical pathways OR "health care quality, access, and evaluation") OR (mass screening OR clinical protocols)]
Iterative search: 'implementation & clinical guidelines'	
Scopus	"implementation AND clinical guidelines" 2010-2017
Google Scholar	"implementation of acute care clinical interventions" 2010-2017

Table 6.2. – Reference inclusion and exclusion criteria.

Inclusion - First screening
Sepsis program; intervention related to sepsis screening; 'protocol'; 'bundle'; 'pathway'
'Implementation' or factors related to implementation; 'evaluation'; 'performance'
Early goal directed therapy; Clinical Practice Guideline; 'reduced mortality'
Inclusion - Second screening
Descriptions of implementation that are potentially relevant and rigorous (Pawson et al., 2005)
Exclusion
Reference to 'pediatric' or 'neonatal' patient populations as these areas were not subject to the former SHR sepsis trigger tool implementation

The lead researcher deemed the number of articles retained after screening the knowledge user lists and the initial database results was insufficient. Therefore, an expert in clinical pathway development, Adegboyega Lawal, PhD candidate at the University of Saskatchewan was consulted to identify potentially pertinent key additional references. References pertaining to the implementation of clinical pathway guidelines (CPGs) were considered for inclusion because the nature of such interventions serve a similar clinical purpose of streamlining health care interventions and increasing the timeliness of care delivery to patients as specific screening protocols albeit at a different scope. The difference in scope was not deemed problematic because realist syntheses rely on 'families' of interventions to inform a program theory, as opposed to a specific type of intervention. Thirty-two articles were screened from the two knowledge user sources and the expert source resulting in two articles being included in the synthesis. An additional article was included as a result of pearling these reference lists as well as three articles identified by chance by the primary researcher when attending an implementation science conference during the same period (Figure 6.1).
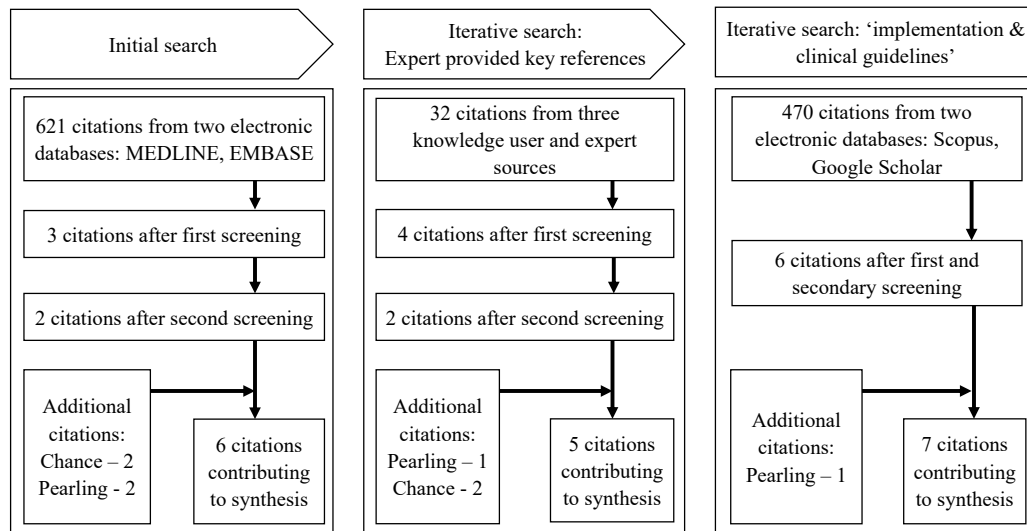
Figure 6.1. – Document search flow diagram for realist synthesis adapted from Wong et al. (2013).

In addition to expert consultation, a third rapid search using Scopus and Google Scholar was done with the intent of discovering additional key references. This search resulted in six articles included in the synthesis plus one identified through pearling these reference lists (Figure 6.1). In total 18 articles were included in the synthesis and are summarized in Appendix E. An additional comprehensive search was not done as it is not a suggested component of a RRR.

6.3 Step 7: Data extraction and program theory synthesis.

The process of data extraction from the literature and creation of a draft program theory occurred over three main iterative steps: EA extraction, CA synthesis and CMO synthesis (Figure 6.2).

RRR Step 7: Data extraction and program theory synthesis
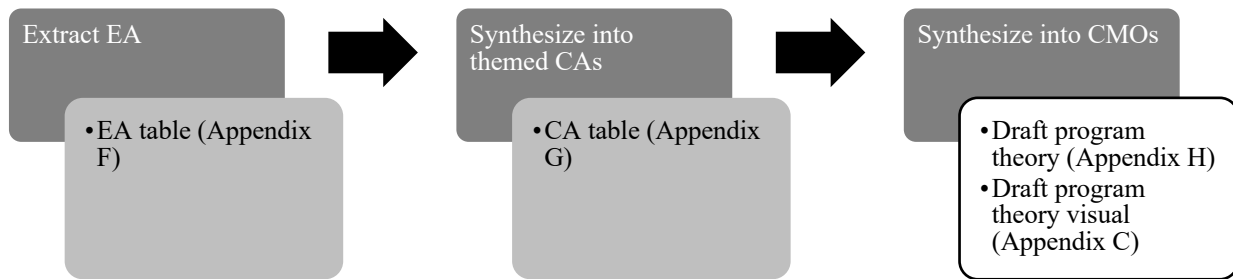
Figure 6.2. Customized RRR process diagram for step 7. Dark grey = actions; light grey = resources used; white = outputs.

Both reviewers appraised the 18 articles independently and together extracted 243 EAs. The EAs included triads and dyads, were collated in a table, and given a unique identification code (Appendix F). The 243 EAs were divided evenly amongst the reviewers and evaluated using abductive reasoning on how logical and consistently they matched the definitions of realist constructs. The reviewers met multiple times to review and eventually agreed on the final list of 65 EAs. Any EA that was identified as being illogical or overly abstract (i.e. not fitting a middle-range description) was excluded. Any discrepancies between the reviewers were discussed and refined until there was agreement on inclusion or exclusion.

Following extraction, the 65 EAs were grouped and synthesized into 41 CAs (Appendix G). The synthesis process involved the reviewers meeting regularly to reduce duplication and redundancy until there was agreement on the final list. A CA was constructed based on the composition of the most theoretically rich EA. Each CA was given a unique identifying number, themed, and labeled as having either a positive or negative impact on implementation success. For example, CA019 was described as 'Confusion or a difference of opinion between professionals about the nature, timing, and course of treatment for an intervention inhibits implementation'. This was derived by synthesizing the following EAs:

- If there is confusion in the nature, timing, and course of treatment then there is a barrier to implementation (EA201).
- If there is a lack of consistency and difference of opinion on what is viewed as correct practice, then there is a barrier to implementation (EA203).

- If there are different beliefs between health professionals on the evidence supporting a guideline then there is a barrier to implementation (EA207).

The list of CAs were grouped based on the similarities in the implementation resources they pertained to following the notion that resources and reasoning are identifiably separate yet connected constructs (Dalkin et al., 2015). The components of the grouped CAs that were judged to best represent contexts and mechanisms were articulated separately and organized into complete CMO propositions. For example, one of the draft propositions was described as an integrated evidence-based practice (resource) introduced into a busy work environment (context), triggers a perception that the intervention is misaligned with everyday practices (reasoning), that results in inhibited acceptability (outcome). This was derived by grouping three CAs, including:

- CA008 – Staff perceptions that an intervention is overly time consuming, or less urgent or essential, than other competing workload demands leads to the judgement that it is contrary to the normal workflow priorities and inhibits achieving the goals of those priorities, which results in unsuccessful implementation.
- CA016 - The perception that an intervention is too simple or superficial relative to professional expertise, or that it threatens the pride and joy in a role, leads to ambiguity as to whether the intervention would support a professional identity and role, which inhibits implementation.
- CA019 - (mentioned above).

At this point additional references identified through chance as previously mentioned, aided in CMO synthesis process by providing descriptions of resources and outcomes (Proctor et al., 2011; Steinmo et al., 2015; Tarrant et al., 2016). Limited details were produced in the initial CMO synthesis process. Therefore, the researchers included more specific terms for successful implementation outlined by Proctor et al. (2011). In this case, implementation outcomes are differentiated separately from service outcomes (e.g. efficiency and safety) and patient outcomes (e.g. health status and satisfaction). Only a subset of implementation outcomes proposed by Proctor et al. (2011) aligned with the emerging contexts and mechanisms and, of these, some were modified to articulate a slightly different phenomenon. The final outcomes included acceptability of the intervention; inhibited acceptability; feasibility to adopt the intervention; adoption of the intervention; and fidelity to the intervention.

At this step in the process a draft of the CMO configuration was shared with the lead researcher's graduate committee for feedback to ensure realist coherence and consistency. This assessment revealed that some constructs labeled as mechanisms more accurately reflected context; that some CMOs were too abstract or disjointed in how they were articulated or how the context and mechanisms were thought to be related; and that there were some residual redundant mechanisms that could be further synthesized and combined. The reviewers then used this input to re-examine the CMOs and further refine the synthesis. Throughout the synthesis process, the reviewers attempted to apply three basic principles to guide their abductive reasoning: keeping the CMO configuration as parsimonious as possible by focusing on identifying 'key' constructs; ensuring the degree of abstraction of a CMO was middle-range; and ensuring the constructs, particularly mechanisms, aligned with the realist definitions.

6.3.1 Substantive theory. The Theoretical Domains Framework (TDF) emerged as the only substantive theory from the literature review (Cane, O'Connor, & Michie, 2012; Steinmo et al., 2015; Steinmo et al., 2016). Iterative synthesis of TDF constructs into the program theory was completed, in addition to the synthesis previously described. Refining the program theory using TDF constructs occurred at the end of step seven. Where applicable, the CAs were reorganized to match the domains and constructs of the TDF. The associated contextual factors were articulated in terms of the intervention activities, in the form of Behaviour Change Techniques (BCT), as previously described by Steinmo et al. (2015) and Steinmo et al. (2016) (Appendix G). The mechanisms were also articulated to match with the intervention content function from Steinmo et al. (2015) and Steinmo et al. (2016), as well as the TDF construct definitions from Cane et al. (2012). The previously synthesized CMOs were then refined to reflect the TDF modifications made with the CAs and to reduce redundancy. The proposed contextual factors and mechanisms were evaluated to determine if there was any overlapping meaning. If redundancy was found,, they were rearticulated or merged to improve clarity. The result was a revision of the draft program theory with embedded TDF definitions and associated resources and contexts (Appendix H). This draft theory departed from the behaviour change techniques by Steinmo et al. (2015) because it was necessary to apply abductive reasoning in order to postulate mechanisms where causal phenomenon were not described by the TDF,

linking mechanisms with context, and relating these dyads to one of the possible implementation outcomes.

Appendix H details the propositions of the draft program theory resulting from step 7 of our RRR. These propositions will not be explained in detail as they represent an intermediate step towards a validated program theory. However, it should be noted that the draft program theory included 25 potential CMO configurations, including four positive and one negative outcome; seven corresponding resources; and thirteen corresponding contextual circumstances. Overall the references used in the RRR did not reveal sufficient detail to explain how and why implementation did or did not work. Despite starting with 243 EAs, the resulting propositions were not sufficiently clear, middle-range, and reflective of a complex reality because they were insufficiently defined and overly linear. This necessitated additional refinement through knowledge user input and validation.

6.4 Step 8: Validation of findings.

Two additional perspectives were added to the validations step (phase 1 and 2) to improve the accurate representation of the complex reality regarding the mechanisms behind the implementation of the sepsis protocol (Figure 6.3). This gap in the draft program theory was addressed by including the knowledge users who had been involved in implementation and the clinician end-users who were expected to use the intervention, but who were not part of the background implementation process.

RRR Step 8: Validation of findings – Phase 1
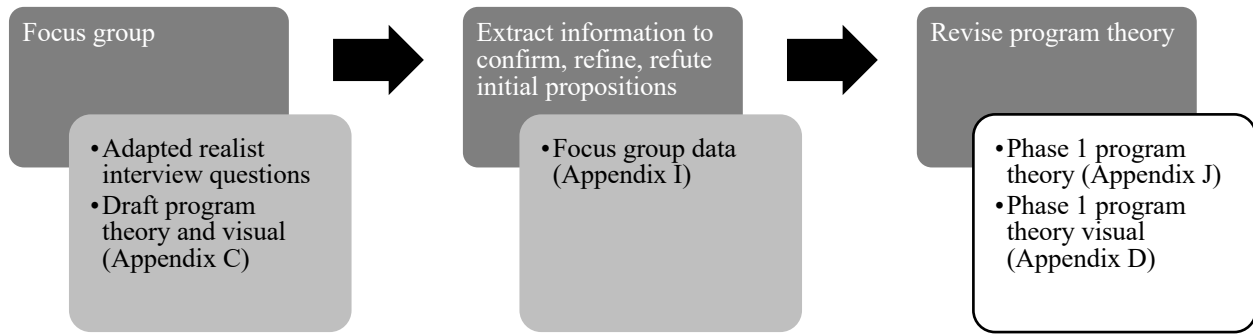
RRR Step 8: Validation of findings - Phase 2
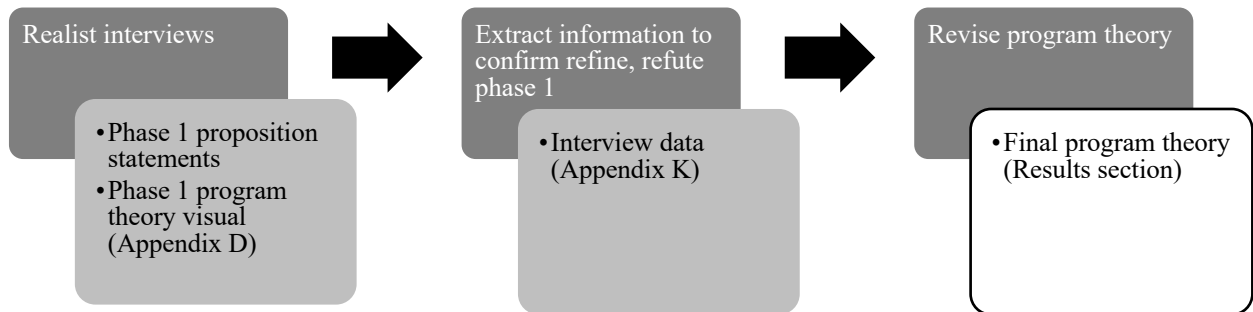
Figure 6.3. Customized RRR process diagram for step 8. Dark grey = actions; light grey = resources used; white = outputs. Phase 1 involved knowledge users from the SHR sepsis working group and phase 2 involved clinician end-users.

6.4.1 Phase 1. The focus group involved four participants and was conducted over an hour facilitated by the lead researcher. Participants included a physician and nurses with a range of experience in their clinical roles, their clinical areas, and educational back ground (Table 6.3). All participants brought forward ideas and actively participated. Several of the participants more frequently led the initial answering of questions or addressing prompts, whereas the others would add to the discussion after the initial comments were made. The prepared questions were used initially to promote discussion (Appendix C). However, in the end these were not followed in sequence and adapted, as it became apparent there were many ideas worth exploring with the participants in greater depth and new considerations that were raised within the discussion. Exploring these ideas meant that not all of the questions ended-up being explored to the same extent because time was limited. The lead researcher (facilitator) was cognizant of the fact that the participants would be unfamiliar with realist terminology therefore some of the questions

were asked about the same phenomenon (i.e. context and mechanism) but reframed to give the facilitator the ability to promote discussion at the level of identifiable mechanisms and context. It was observed that the participants more often referred to each other's comments and the interjections of the facilitator than the printed text and visual resources. This may have been because the resources were organized in CMO sequences and not relatable to the knowledge user's way of thinking.

Analysis of the transcript revealed 22 concepts that pertained to the draft propositions or new ideas introduced about implementation (Appendix I). Each concept was supported by direct quotes or ideas interpreted by the researchers. The concepts were given a unique ID and tabulated based on whether they aligned with a proposed resource, context, mechanism or outcome and whether the discussion confirmed, refined or refuted the proposition. From this information, newly synthesized propositions were produced using the same analytical reasoning and techniques as step 7.

Most of the propositions were refined resulting in 15 propositions and multiple new potential mechanisms that were either introduced directly from the participant's comments or inferred during the analysis (Appendix J). The group of knowledge users identified fidelity to the intervention as being the most important implementation outcome that would indicate success. As stated by one of the focus group participants, "…so, I think the most important outcome… as the absolute end goal, um, is at the apex would be the fidelity." The group also suggested that the other outcomes of acceptability, feasibility and adoption were relevant but intermediate in achieving fidelity. It was also inferred that, in addition to inhibited acceptability there was also an inhibitory outcome related to fidelity that needed to be considered. The outcomes were reorganized such that acceptability and feasibility of the intervention needed to be achieved before adoption, which needed to be achieved before fidelity. The nature of the implementation outcomes being interdependent is reflective of a complex system giving validity to the overall endpoints of the program theory. However, despite having revised propositions, additional validation was required to construct complete CMOs. Certain mechanisms were judged to be too abstract and some of the links between resource, context and mechanism were poorly aligned. For example, results suggested that clinical support resources introduced into a busy work environment triggered a perception that end-users are able to refine their skills, abilities, and independence to form new habits. However, this was not well supported by the knowledge users,

and these resource and context constructs were more representative of characteristics of other constructs such as education and complex work environments respectively. Additionally, although the outcomes were interconnected, the propositions leading to each were still judged to be overly linear.

6.4.2 Phase 2. Individual semi-structured interviews were completed with 11 participants from the clinical areas (emergency department, surgical wards, and medical wards) that trialed the SHR sepsis screening trigger tool. It took six months to recruit and conduct all of the interviews and physician recruitment proved to be the most difficult. Interviews took from 23 to 75 minutes depending on the degree to which a participant would refine a proposition or explain their thoughts. Similar to the participants in phase one, the participants in phase two included physicians and nurses with a range of experience in their clinical roles, their clinical areas, and educational back ground (Table 6.3). Given that focus group participants did not use the reference material, these were revised for the interviews to aid in communicating realist constructs in an understandable form (Appendix D). Instead of detailed descriptions of each proposition, simplified statements were used because it was felt that these would better prompt participants thoughts about the specific constructs that were being validated. The visual references included slightly modified graphics corresponding to mechanisms. However, most interview participants did not refer to the visual references at all. Each statement was read out to the participant and they were asked if it was true, false, or needed to be changed in any way. All of the participants referred to the statements throughout the interview and a few made notes on them throughout. In each interview, the participant was also asked to describe what they had seen work or not work when it came to the implementation of clinical interventions in order to learn about their reasoning and experiences that may not have been captured in the propositions they were asked to confirm, refute or refine. As in the focus group, when new ideas emerged, or it was felt by the researcher that comments needed additional exploration, impromptu questions were asked that deviated from the proposition statements.

Table 6.3. Participant demographics include those from the focus group (FG) and interviews.

	Sex		Mean Age	Current professional role		Mean total years in current professional role	Mean total years at SPH
	M	**F**		**Nurse**	**Physician**		
FG	1	4	53.5	3	1	26.9	17.8
Interview	3	8	37.8	6	5	10.5	8.4

SPH clinical area					Mean total years in clinical area
	Medicine	**Surgery**	**Emergency**	**Medical & Surgical**	
FG	1	1	0	2	12.9
Interview	1	5	3	2	6.7

Highest attained level of education				
	Diploma	**Bachelor's degree**	**Master's degree**	**Medical Doctor**	**Medical Doctor & Master's**
FG	0	2	1	1	0
Interview	1	4	1	3	2

Interview transcripts were analyzed in a similar way to the focus group. For each outcome, responses were tabulated including: whether they confirmed, refuted or refined the proposition; supporting quotes; and the inferred and interpreted modifications to the propositions. In this phase, the majority of the program theory propositions from phase one were confirmed or refined. Refinement involved the same principles and application of abductive reasoning previously described. If one participant refuted a proposition, but most of the other participants confirmed or refined it, then it was kept. The propositions that were pre-judged not to be succinct or potentially abstract from phase one, were either refuted or refined in such a variable way among phase two participants that their coherence was not maintained. In these cases, the propositions were excluded from the program theory. Given that the analysis revealed

that most of the revised propositions appeared to be consistent at a middle-range degree of abstraction, and considering the amount of time it had taken to complete the twelve interviews, it was deemed that no further participants were needed to be recruited.

6.5 Step 9: Synthesizing information.

Multiple steps of synthesis are embedded in the iterative process of any realist review. Synthesis occurred in translating EAs into CAs and CMOs to form the draft program theory. The draft theory was further refined through the synthesis of results from phase one of step seven. The phase one program theory was further refined through the synthesis of results from phase two of step seven into the final program theory. The final synthesis involved two activities. The first was to ensure mechanisms reflected TDF construct definitions (Cane et al., 2012). The second was to describe and explain the propositions, and in particular the mechanisms, in three ways to reflect various levels of familiarity with realism amongst potential knowledge users. These included an overall middle-range mechanism, a summary proposition statement, and a detailed description of the defining characteristics of the salient resources, contexts, reasoning, and how they relate.

6.5.1 Final program theory. The final version of the program theory includes a configuration of five middle-range propositions centred around five main mechanisms, including:

- A sepsis screening intervention is satisfactory and suitable for clinicians when they believe that it benefits their workflow and benefits their patients. This belief is achieved by using standardized evidence-based approaches to clinical practice and implementation in the context of a complex work environment.
- When clinicians have developed individual strategies to cope with complex work environments, standardizing interventions, where clinicians are not accustomed to standardization or adaptation to the extent of large variation in practice, can lead to pessimism about the benefits of the protocol. This leads to the unsuitability of, and dissatisfaction with, a sepsis screening protocol.
- A protocol is adopted when education, that is aligned with a clinical team's need for information sharing, creates a belief that using the protocol is legitimate.

- Strategic implementation with performance feedback used in clinical team problem solving leads clinicians to use a sepsis screening protocol appropriately, thereby reinforcing its sustained use.

- Clinicians are pessimistic about the protocol when they do not feel part of a team and implementation is not strategic. This causes clinicians to use the protocol inappropriately and eventually leading to it being abandoned.

These propositions hypothesize the promoting and inhibitory mechanisms for end-user clinicians that lead to successful and unsuccessful implementation of sepsis screening interventions, the contextual conditions that trigger the mechanisms, and the salient resources that are involved (Figure 6.4). This program theory assumes that an evidence-based practice has already been selected for implementation and that the main actors are end-user clinicians, including physicians and nurses. The final outcome defining successful implementation is achieving fidelity and sustained use. In order to achieve this there are the intermediate outcomes of acceptability and feasibility with the intervention, and adoption of the intervention, that ultimately lead to achieving fidelity and sustained use. There are mechanisms that lead to unsuccessful implementation that occur when there is inhibited acceptancy and feasibility, and inhibited fidelity and abandonment. There are also mechanisms that diverge for the different actors at each stage of successful and unsuccessful implementation. Each proposition maintains a middle-range focus and was constructed backwards from the corresponding outcome.
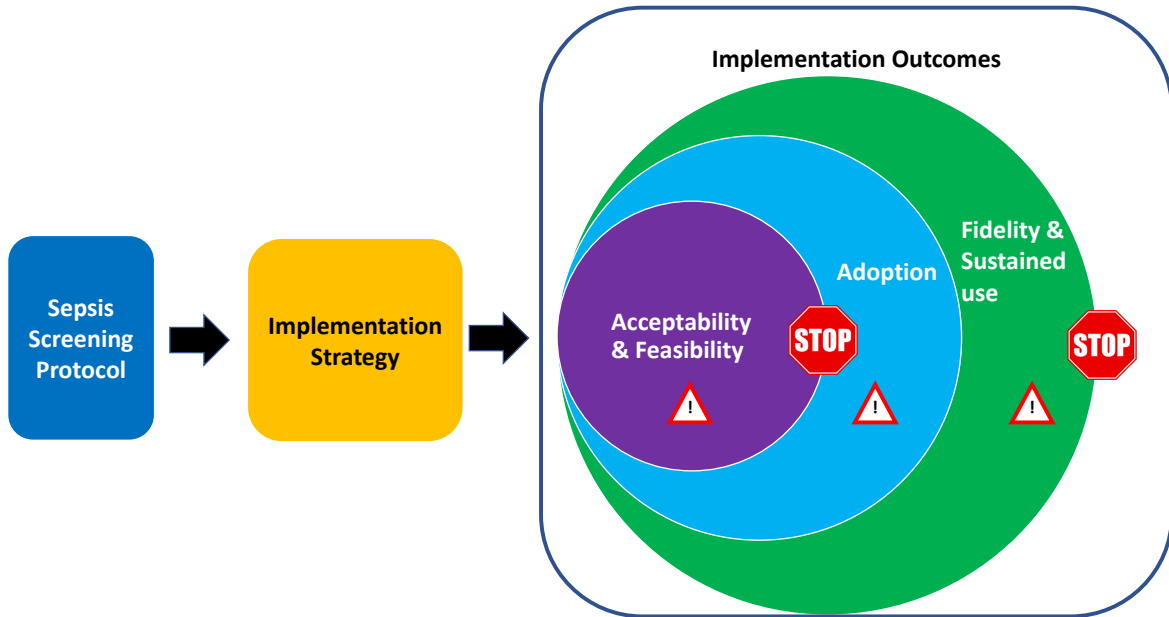
Figure 6.4. Overview of the final program theory for the implementation of a sepsis screening protocol. Stop signs represent inhibitory outcomes. Caution signs represent where mechanism diverge for the different actors at each stage of successful implementation.

6.5.1.1 Mechanism 1: Positive belief about the benefits of the protocol. *A sepsis screening intervention is satisfactory and suitable for clinicians when they believe that it benefits their workflow and benefits their patients. This belief is achieved by using standardized evidence-based approaches to clinical practice and implementation in the context of a complex work environment* (Figure 6.5).
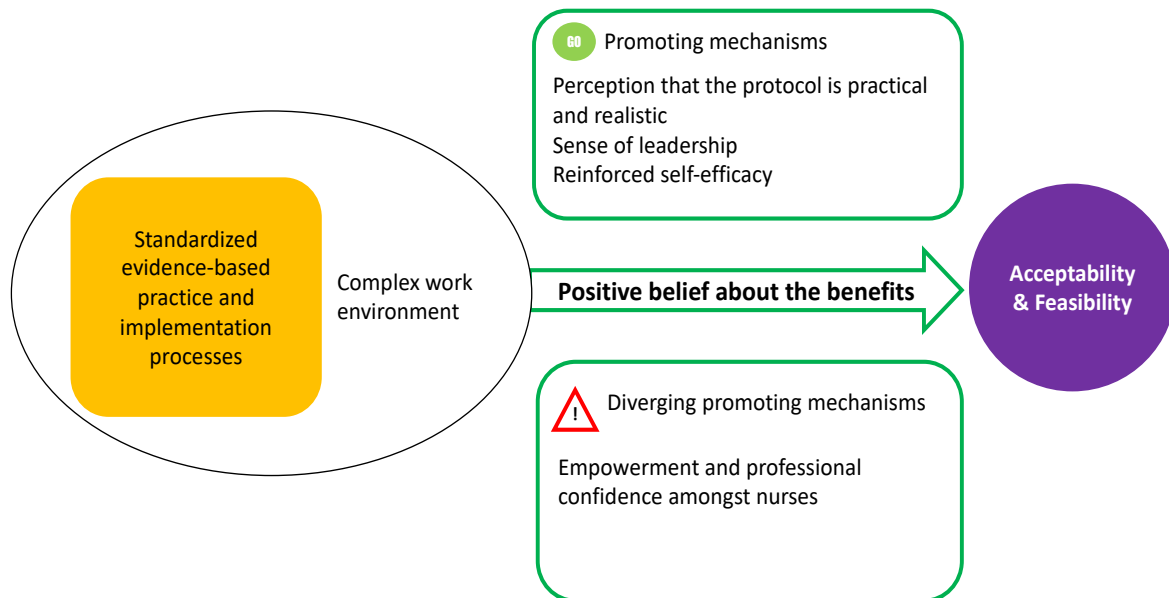
Figure 6.5. Proposition for acceptability and feasibility.

Acceptability and feasibility with the intervention are the intermediate outcomes of this proposition. Acceptability is when clinicians are satisfied with the various aspects of the intervention including content, complexity, comfort, delivery, and credibility (Proctor et al., 2011). Feasibility is when clinicians find the intervention usable, suitable and trailable in a particular setting (Proctor et al., 2011).

A standardized evidence-based practice and implementation process are the main resources that are involved in achieving acceptability and feasibility. A standardized evidence-based practice, such as a SIRS-based sepsis screening tool, simplifies the coordination of resources and task interdependence amongst clinicians to achieve a desired patient care goal. Standardization involves an interdisciplinary team of clinicians who collaboratively adapt the

59

salient functions of an evidence-based practice into an intervention that fits with the reality of the target clinicians' workflows. The process of adaptation considers how a change in practice compares with the current state workflow and includes a function where physicians can modify actions based on their clinical judgement of a patient's condition, comorbidities, preferences, and presentation that overwhelmingly put them outside the reasonable boundaries of the intervention.

Standardized implementation involves a consistent and comprehensive clinician stakeholder engagement process and a systematic theory-based approach. Such an approach examines the root cause necessitating a behaviour change which leads to the design of implementation activities that target a clinician's capacity, opportunity and motivation to change their behaviour (i.e., Behaviour Change Wheel) (Michie et al., 2014; Steinmo et al., 2015).

The salient context in which standardized evidence-based practices and implementation processes operate is a complex work environment. A complex work environment is characterized by the interplay of factors related to the level of patient acuity and clinician workload. Patient acuity includes a patient's physiological state, stability and associated needs; the number of highly acute patients in a clinical area; and the frequency that clinicians work in areas with high numbers of highly acute patients. Clinician workload includes high patient to clinician ratios; the frequency of situations where patient numbers exceed the normal operating capacity of a clinical area, competing demands for clinician time and attention; and the degree and frequency of operational change within clinical areas.

The introduction of standardized evidence-based practices and implementation processes into a complex work environment will trigger a number of multilevel mechanisms and mechanisms that operate within only a subset of actors. Overall, the middle-range mechanism operating is the belief amongst clinicians that there is a problem to solve and that the intervention will bring a benefit to clinicians. This belief motivates a clinician's desire to do the best for the patients in their care. This perceived benefit is further reflected through four lower level mechanisms including a perception that the protocol is practical and realistic, a sense of leadership, reinforced self-efficacy, and empowerment and professional confidence amongst nurses. As a result of the multilevel nature of mechanisms that are triggered in achieving acceptability and feasibility, this proposition is the most complex.

The first lower level mechanism is the triggering of a perception amongst all clinicians that the protocol is practical and realistic. This perception allows for improved action planning

amongst and within clinicians, which results in the formation of an efficient plan to execute the actions indicated by the protocol (Cane et al., 2012). For example, action planning can include pre-selected tasks that allow for less redundant consultation to physicians, a reduction in nurses waiting for direction from physicians, and a reduction in the incidence of nurses anticipating a physician directed action but then being given another.

For nurses, the perception that an intervention (sepsis protocol) is viewed as being practical and realistic also enables consistency in recognizing and responding to sepsis. This involves anticipating appropriate action earlier based on more subtle and earlier changes observed in a patient and avoids them negating other concurrent patient care requirements for the same individual suspected of having probable sepsis, and the others under their care.

For physicians, the perception that the intervention is practical and realistic is contingent on a perception that there is increased efficiency in assessment, ordering tests, receiving test results and decision making. Participation in the development and implementation process ensures efficiency is maintained and creates sense of ownership because it can be seen to align with local factors such as patient population.

The second lower level mechanism is the creation of a sense of leadership amongst clinicians. For both nurses and physicians, leadership comes from motivation inherent in engaging about a change in practice with their clinician peers who are viewed as being an expert in the area. For nurses who are a part of closely-knit teams, peer influence might come from a physician, resident, or nurse whose influence brings a sense of support for the change. This peer function can also be achieved by formally assigning the role of practice change 'champions' to a select group of nurses from the same clinical area. These individuals are purposively given an opportunity to enhance their knowledge and expertise. They apply this enhanced knowledge as a resource and model for other nurses on the unit, reinforcing the change through defined tasks. For physicians, an influential peer is another physician who is viewed to be a clinical expert and for whom an inherent faith and trust in their expertise and judgement exists, which adds credibility and validity to the idea that one should change their practice.

The third lower level mechanism is the creation and reinforcement of self-efficacy. A standardized evidence-based practice can ensure that there are clear instructions for specific and purposeful actions that directly address a suspected threat to a patient, such as sepsis, and that simplifies communication amongst clinicians. For nurses, clear and purposeful actions create the

perception of a smooth process for providing care and escalation to physicians. Nurses feel they are performing to their maximum capacity, fulfilling their responsibility to the patient and they confident to make clinical decisions and act on them. Performing to maximum capacity creates a sense of internal reward, because they are correctly identifying a life-threatening condition and successfully acting on it, which reinforces their perception over time that using the tool creates a benefit for them and their patients.

Amongst physicians, the creation and reinforcement of self-efficacy comes from enabling them to make a clinical decision that is outside of the protocol based on their judgement of the clinical relevance of the protocol in a particular instance. A standardized implementation approach that considers if, when, and how physicians can deviate from the standardized practice enables this self-efficacy. This is important for both screening and treatment protocols but becomes more important for the latter because it involves more outcome directed decision making.

The fourth lower level mechanism is the promotion of empowerment and professional confidence amongst nurses. These mechanisms come from the ability to consistently anticipate the required actions for a septic patient; promote conversations about best practices with peers; creates independence and comfort in decision making; creates consistency in critically thinking about sepsis that leads to consistent practice over time; and creates legitimacy in the inherent differences of the nursing assessment and decision-making process in relation to physician practice. Standardization in these areas also makes sepsis a more real phenomenon for nurses and enables better focused care, encourages knowledge and skill development, and critical thinking about sepsis in line with objective assessment approaches more typical of a physician. This aids in validating the nursing roles in decision making and promotes the authority to act.

6.5.1.2 Mechanism 2: Pessimism about the protocol being beneficial. When clinicians have developed individual strategies to cope with complex work environments, standardizing interventions, where clinicians are not accustomed to standardization or adaptation to the extent of large variation in practice, can lead to pessimism about the benefits of the protocol. This leads to the unsuitability of, and dissatisfaction with, a sepsis screening protocol (Figure 6.6).
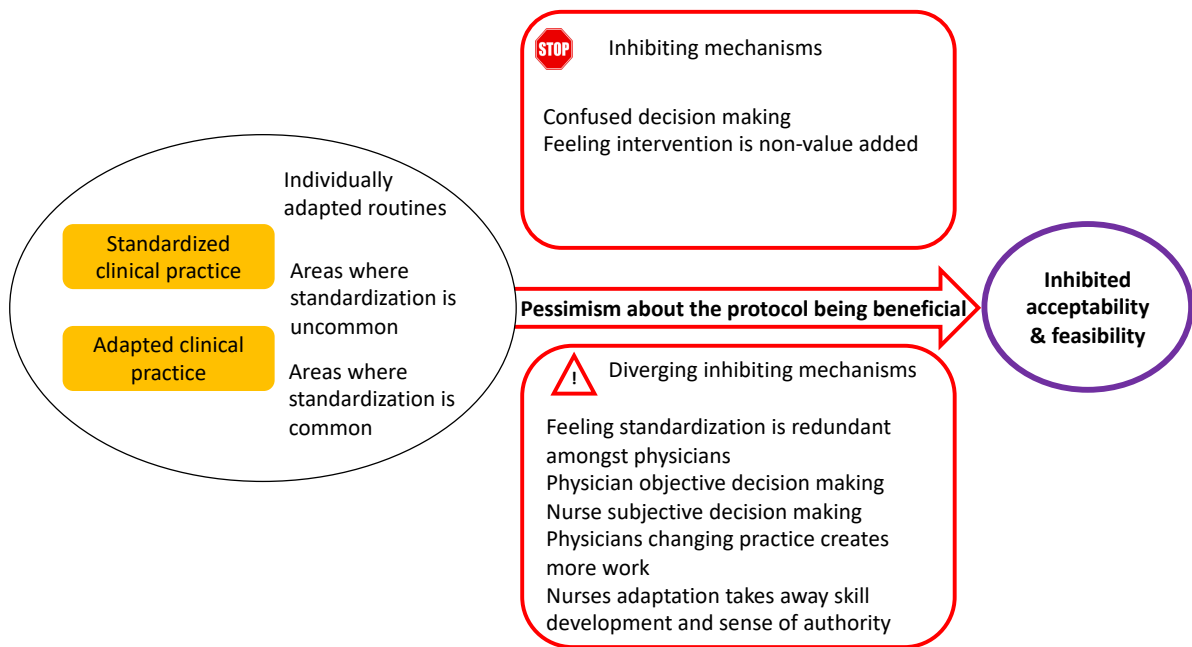
Figure 6.6. Proposition for inhibited acceptability and feasibility.

The outcomes in this proposition are inhibited acceptability and feasibility. They involve the failure to reach satisfaction, utility, suitability and trialability with one or more of the various aspects of the intervention.

There are two theoretical resource and context dyads that can lead to inhibited acceptability and feasibility: standardized clinical process implemented across all areas in the context of individually adapted routines to function with heavy workload where standardization is uncommon; and a clinical process that is adapted for local use across all clinical areas in the context of individually adapted routines to function with heavy workload where standardization is common. A standardized clinical process differs from standardized evidence-based practice in that it may or may not be related to an evidence base. It describes the standardization of operational clinical processes outlining who does what, when, and how.

For physicians, the reasoning that is triggered involves how they view their practice relative to standardization and arrive at clinical decisions that can differ from that of nurses. Individual physicians with highly individualized practice can feel that a standardized sepsis screening protocol is redundant and non-value added. These individuals feel that identifying and responding to suspected sepsis is within their domain of expertise and will be considered in their

critical thinking and clinical decision making regarding a patient presenting with the relevant signs and symptoms. A change that is viewed as being non-value added reflects a threat to professional identity, especially if there is a strong belief that, based on their objective assessment, the necessary actions for a patient should be different from what is prescribed by the protocol. These feelings are amplified if the intervention does not reduce their workload or it is perceived that their workload might actually increase through the generation of unnecessary testing. These feelings are reinforced when the protocol is used inappropriately thereby compounding dissatisfaction.

On the other hand, dissatisfaction with a standardized protocol will also occur if it fails to address or amplifies differences in how physicians and nurses from teams that are geographically separated arrive at and communicate clinical decisions. In these instances, physicians rely on the communication of objective assessment findings to inform their decision making when they cannot directly assess the patient. However, nurses will often use more than just objective findings to inform their clinical decision making and can be reflected in their communication when escalating concerns about suspicions of sepsis. This is because nurses have more frequent contact with a patient and emphasize other factors as being salient in forming a clinical impression. A nurse's clinical impression is often constructed from the accumulation of multiple mini-assessments that occur with every patient interaction and includes the consideration of subtle changes, changes in demeanor and behaviour detected through their interactions. Observations of this nature might introduce seemingly more subjective information than what a physician would expect thus conflicting with the expectation that only objective findings be included in escalation communication. Such innate differences in the way clinical impressions are formed between physicians and nurses, and how they influence decision making are less meaningful when teams have greater connectivity. Connectivity comes from physician-nurse co-location and allows for easier sharing of subtle and subjective observations and perceived as more relevant or less problematic when the physician is considering this type of information in their critical thinking and decision making.

The second case involves the reasoning that is triggered when adapted practices are introduced into areas where standardization is common. Dissatisfaction with interventions adapted for local areas to the extent that they are significantly different in terms of roles, resources, timing and sequence of action leads to confusion in decision making and the feeling of

64

the intervention being non-value added. For clinicians who move between different areas, intervention design differences force them to critically-think, make decisions, and respond differently regarding the same phenomenon. For physicians who move between different clinical areas, overly adapted practices create more work. For nurses, a lack of standardization takes away the reinforcement to develop clinical skills, reduces the sense of authority to follow the requisite actions, and promotes infidelity in using the intervention.

6.5.1.3 Mechanism 3: Belief in the legitimacy of using the protocol. *A protocol is adopted when education, that is aligned with a clinical team's need for information sharing, creates a belief that using the protocol is legitimate* (Figure 6.7)*.*
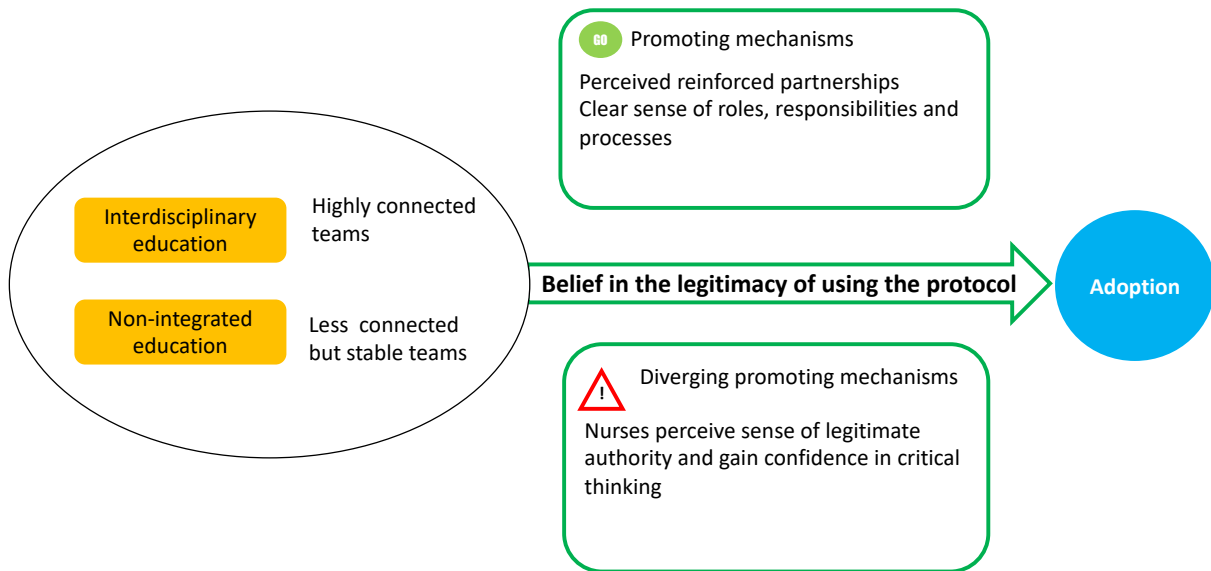
Figure 6.7. Proposition for adoption.

Adoption is the outcome in this proposition and is defined as the clinician uptake and utilization of the intervention (Proctor et al., 2011).

The main resource that leads to adoption is education. Regardless of modality, education must include evidence for a need to change practice expressed in terms of the impact on patients and clinicians; knowledge on who, what, where, when and how the intervention will function; the characteristic of intervention fidelity and what happens if fidelity is not maintained for the

patient. Education must be done during initial implementation of the change, integrated into routine introductory training, and reviewed periodically with clinical team members.

The most suitable method of providing this education depends on the nature of the team; therefore, the context that promotes adoption can be described in two ways. First, there are teams that are highly connected who respond favorably to interdisciplinary education, where clinicians from different disciplines learn about the intervention together. High connectivity can involve teams where clinicians are geographically co-located or minimally separated (e.g. the emergency department) or have purposively constructed function coordination (e.g. accountable care units). However, less connected teams can gain the same functional benefit by receiving non-integrated education (i.e. physicians and nurses are educated separately through different modalities). In this case, the context must also include stability in the clinician groups (i.e. low staff turnover) and a high degree of familiarity with each other through regular exposure to one another.

Amongst highly connected teams, the reasoning that is triggered is that partnerships between clinicians are reinforced when they can learn together because they can learn from each other, share ideas, and discuss issues around understanding, application and operationalization. For less connected stable teams who perceive that they maintain a clear sense of roles, responsibilities, and processes involving each other, the feeling is that they can achieve change adoption with minimal confusion and negative bias if everyone simply receives the same information as opposed to seeing value in interdisciplinary training. In either context, nurses perceive a greater sense of legitimate authority to use a protocol and gain confidence in critical thinking and decision making when consistent education is provided to all groups of clinicians.

6.5.1.4 Mechanism 4: Trust within the clinical team. *Strategic implementation with performance feedback used in clinical team problem solving leads clinicians to use a sepsis screening protocol appropriately, thereby reinforcing its sustained use* (Figure 6.8).
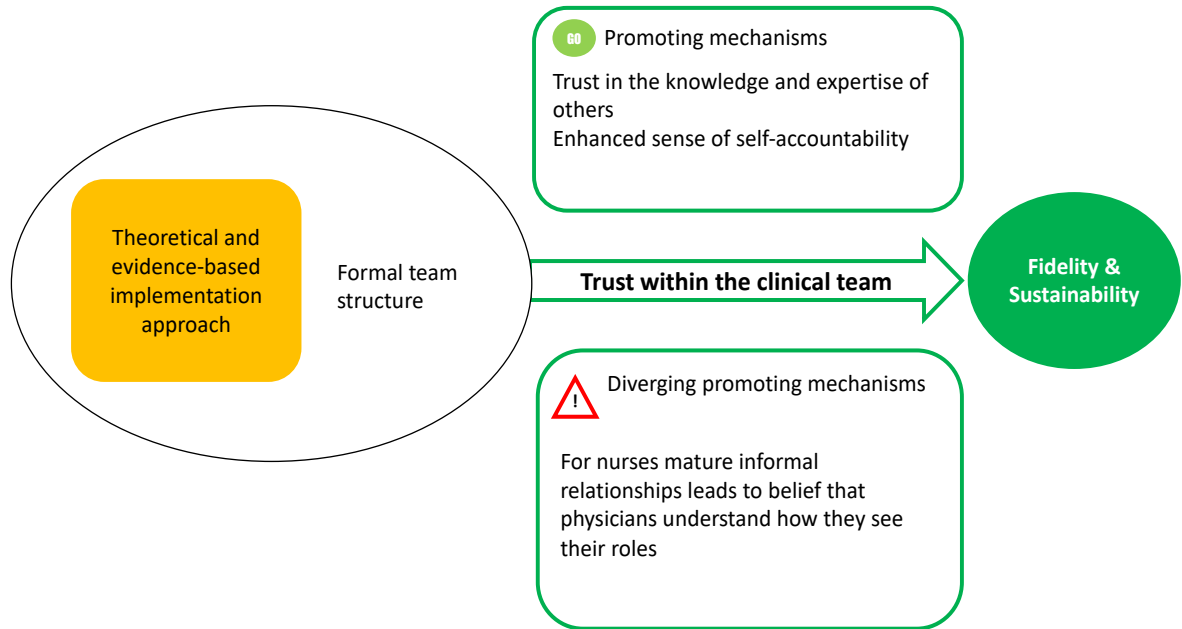
Figure 6.8. Proposition for fidelity and sustained use.

Fidelity and sustainability are the outcomes of this proposition. Fidelity is defined as the adherence to the requirements of an intervention such that the integrity and quality of the intervention is maintained (Proctor et al., 2011). Sustainability involves the incorporation, maintenance, continuation, and durability of the intervention over time (Proctor et al., 2011).

For this outcome to occur, the necessary resource includes a theoretical and evidence-based approach to implementation as opposed to intuitively informed implementation activities and passive dissemination. Supporting resources include dedicated time, human and material resources for all stages of implementation, and expert data collection and analysis of performance data that is routinely fed back to teams.

The context that enables these resources is a formal team structure where clinicians have clear complimentary roles, responsibilities, expectations, and accountabilities, and that there is a formal physician reporting structure. This structure also allows for routine inclusive, team-based iterative problem-solving (i.e. Plan-Do-Study-Act cycles).

Assembling this resource in context triggers an enhanced sense of self-accountability and the development of trust in other clinicians. Teams that can mature within a formal structure, creates the conditions for individual professional honesty, integrity and fallibility thereby

enabling the creation of an enhanced sense of self-accountability. This reinforces the development of trust in the knowledge and expertise of other clinicians.

Trust is dependent on the need for teams to invest in one another and value one another's time, responsibilities, and needs. It reflects a willingness to adapt their practice when they can see the value that their new actions will benefit patients.

As clinicians become familiar with each other over time, they can develop informal relationships that reflect a level of comfort and confidence in one another. Such a relationship allows for mutually beneficial dialogue about patient care with respect to sepsis, which spurs a sense of being valued and a belief that the shared goal in patient care can be quickly achieved. For nurses, the sense of being valued is realized when they believe physicians understand that nurses perceive their roles and responsibilities as an advocate and how their roles and responsibilities translate into their clinical decision making and actions when they are concerned about a patient. For example, if a nurse is concerned about a patient's vital signs but are unfamiliar with an aspect of either the patient's treatment course or comorbid condition, they will perceive that the results of their objective and subjective assessment need to be escalated, even if they do not have all of the objective information a physician might expect. An informal relationship built on trust allows clinicians to have a beneficial dialogue, despite any differences that might exist in expectations for required information in the exchange.

Feedback to clinicians on their performance supports collaborative problem solving within a formal team. This allows for the clear identification of a problem to solve, the contextualization of that problem in relation to the reality of clinical practice, and the reinforcement that in response to the problem there needs to be a change in habit.

6.5.1.5 Mechanism 5: Pessimism about the team. Clinicians are pessimistic about the protocol when they do not feel part of a team and implementation is not strategic. This causes clinicians to use the protocol inappropriately and eventually leading to it being abandoned (Figure 6.9).
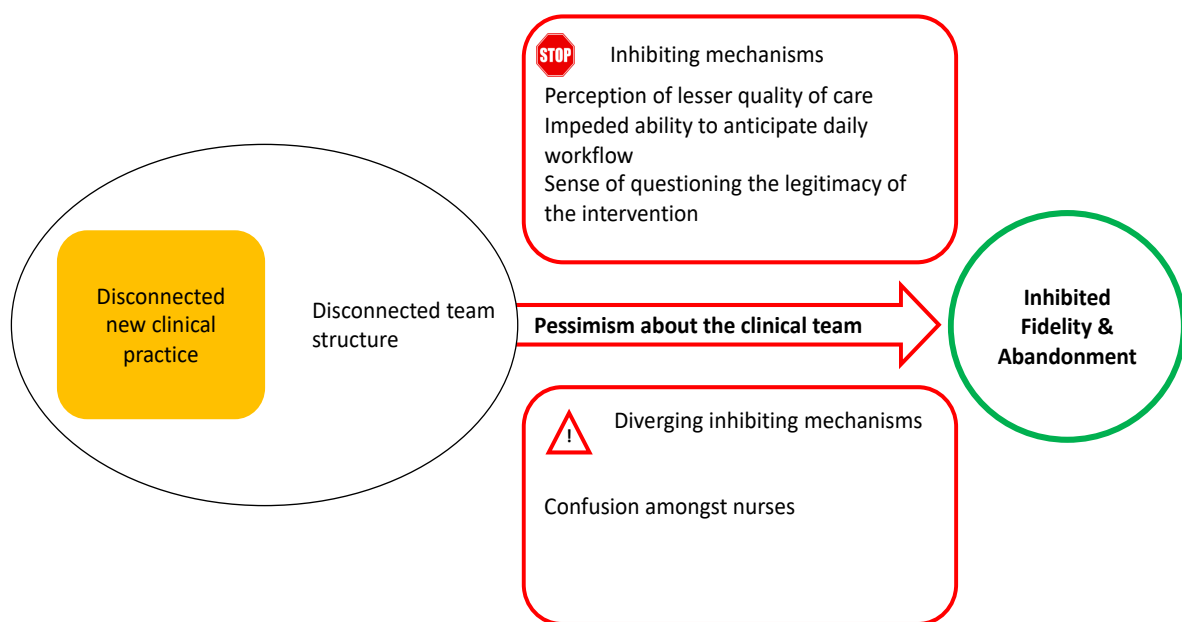
Figure 6.9. Proposition for inhibited fidelity and abandonment.

Inhibited fidelity and abandonment are the outcomes in this proposition. Inhibited fidelity is the failure to adhere to the integrity and quality of the intervention (Proctor et al., 2011) and abandonment is the failure to sustain the use of the intervention.

In this proposition, it is the lack of strategic alignment of a new clinical intervention with existing workflow processes that acts as a resource in leading to inhibited fidelity and abandonment. The lack of an aligned intervention, in the context of a disconnected team structure, triggers the reasoning of team members. A disconnected team is characterized by members who are geographically separated, whose functions and processes are not coordinated, experience significant staffing turnover, and clinicians who are unfamiliar with one another's roles and responsibilities.

Pessimism about the team is defined by a perception amongst clinicians that there is a lesser quality of care, a perception that the clinical environment is chaotic, stressful and unsupportive, and a perception of an inability to anticipate daily workflow. These translate into confusion for nurses, because there is differing physician direction that can include disregarding the prescribed actions of the protocol despite a patient meeting the criteria. They promote

69

behaviours that decrease fidelity, including decisions to escalate care before prescribed actions are completed or completing actions out of sequence. They also promote an inability to implement change which creates feelings of powerlessness amongst clinicians to help their patients. An inability to anticipate daily workflow impedes physicians and nurses from planning and mutual goal-setting resulting in an inefficient protocol. Repeated experience of protocol infidelity creates doubt in the legitimacy of the intervention, devaluing of the intervention, and eventually results in abandonment of the intervention.

6.5.1.6 Program theory summary. The following table is a summary of the program theory for the successful implementation of a sepsis screening intervention. The key resources and functions of an implementation strategy are focused as takeaways for knowledge users.

Table 6.4. Program theory summary.

Middle-range Mechanism	Proposition	Key Features of an Implementation Strategy
Positive belief about the benefits of the protocol	A sepsis screening intervention is satisfactory and suitable for clinicians when they believe that it benefits their workflow and benefits their patients. This belief is achieved by using standardized evidence-based approaches to clinical practice and implementation in the context of a complex work environment.	Resources: • Standardized evidence-based practice • Standardized theory-based implementation process • Interdisciplinary clinical team Functions: • Simplify coordination of resources and task interdependence • Collaborative adaptation of clinical processes while ensuring fidelity of clinical practice • Current vs. future workflow comparison • Consistent physician modification process • Consistent and comprehensive stakeholder engagement process

| Middle-range Mechanism	Proposition	Key Features of an Implementation Strategy
		• Target intervention design and implementation activities to the behaviour being changed and its root cause
Pessimism about the protocol being beneficial	When clinicians have developed individual strategies to cope with complex work environments, standardizing interventions where clinicians are not accustomed to standardization or adaptation to the extent of large variation in practice can lead to pessimism about the benefits of the protocol. This leads to the unsuitability of, and dissatisfaction with, a sepsis screening protocol.	Resources: • Standardized clinical processes • Current vs. future workflow comparison Functions: • Balance degree of standardization of clinical processes with workload between clinical areas • Differentiate standardized clinical practice from standardized clinical processes
Belief in the legitimacy of using the protocol	A protocol is adopted when education that is aligned with a clinical team's need for information sharing creates a belief that using the protocol is legitimate.	Resources: • Education on evidence on the need to change in terms of patient impact; who, what, where, when and how intervention will function; characteristics of intervention fidelity and consequence of infidelity Functions: • Consistent communication reaching all stakeholders regardless of education modality

Middle-range Mechanism	Proposition	Key Features of an Implementation Strategy
		• Education at initial implementation, integrated into routine education, and revisited periodically
Trust within the clinical team	Strategic implementation with performance feedback used in clinical team problem solving leads clinicians to use a sepsis screening protocol appropriately thereby reinforcing its sustained use.	Resources: • Standardized theory-based implementation process • Dedicated time, human and material resources • Expert data collection and analysis Functions: • Team structure with common understanding of roles, responsibilities, expectations, accountabilities • Formal physician reporting structure • Routine performance feedback to clinical teams • Team-based iterative problem solving
Pessimism about the team	Clinicians are pessimistic about the protocol when they do not feel part of a team and implementation is not strategic. This causes clinicians to use the protocol inappropriately and eventually leading to it being abandoned.	Resources: • Current vs. future workflow comparison Functions: • Simplify coordination of resources and task interdependence • Collaborative adaptation of clinical processes while ensuring fidelity of clinical practice • Minimize geographical separation of team members

7.0 Discussion

7.1 Discussion of Results

In this research, a program theory was developed to answer the question, *how, why, for whom, and in what circumstances does successful implementation of an intervention for the early recognition and treatment of probable sepsis occur in medical, surgical and emergency clinical areas?*

A program theory, establishing how local clinical teams can successfully implement a sepsis screening intervention, is valuable for understanding how to bring the evolving evidence base of screening and treating sepsis into consistent practice. It also translates into implementation approaches of similar clinical interventions. T. Greenhalgh (2018) suggested the most important determinant of adoption is a clinician's belief that an intervention is workable in practice. She suggested that a workable intervention simply provides a relative advantage, decreased complexity, and trialability. The final program theory aligns with these basic characteristics to create a parsimonious and purposeful hypothesis for implementation success and suggestions on the resources and functions that could translate it into practice.

The actors in this program theory are the physicians and nurses who are the end-users of a sepsis screening intervention in medical, surgical, and emergency clinical areas. Their beliefs about the positive benefit of an intervention, legitimacy in using the intervention, and trust within the clinical team is how and why successful implementation occurs. These promoting mechanisms are tied to key resources including standardized evidence-based practices and implementation activities, education strategies that match team structure, and theory-based implementation strategies respectively. Conversely, their pessimism about the benefit of the intervention and about the team inhibit implementation. These are tied to atypical standardization and adaptation relative to the norm and disconnected clinical practice amongst actors.

Specific contextual circumstances trigger both promoting and inhibiting mechanism. The actors' beliefs and trust are triggered by a complex work environment, highly connected or stable teams, and formal team structure. Those circumstances that trigger pessimism include individually adapted routines, variation in the use of standardization, and a disconnected team structure.

7.1.1 Reflections on complexity. Although the program theory is parsimonious at the middle-range, there is inherent complexity because the actors, the intervention, and implementation efforts exist in an open system. Complexity of the social system in which implementation occurs is derived from the interdependence of intermediate implementation outcomes and micro-level mechanisms that define the middle-range mechanisms.

Pawson et al. (2005) argued that because health care interventions are often implemented in multiple social settings, the context of one setting can introduce further complexity into another. Simultaneous contextual complexity together with intervention complexity means that an intervention will not always be successfully implemented in the same way in different settings. In the program theory developed in this research, the social setting (i.e. clinical area) an actor practices in and the amount of experience in the clinical area does not appear to play a significant role in determining why successful implementation occurs. In general, actors are motivated by achieving a benefit for their patients, but also require a benefit for themselves, in terms of a more efficient workflow, in order to implement the intervention. When a change adds work and puts greater strain on workflow, there is less time and energy available to meet patient needs. Physicians see this as the paramount factor in deciding to adopt change. The results suggest that to achieve acceptability and feasibility that either change has to make workflow easier or if it cannot, then the complexity of the work environment has to be simplified.

How the actors relate to one another as a clinical team determines the degree of trust in one another, which informs how their communication and decision making is subsequently affected. The results of this research suggest that mature co-located teams have more trust. Teams that are physically disconnected, with more personnel changes, appear to be at risk of greater pessimism about the team. The results also suggest that trust allows for support, engagement with one another, and appreciating differences. These characteristics are reinforced through formal organization and systematic functioning. The sense of team informs how adoption and fidelity can be achieved.

The results found that nurses and physicians differ in their professional relationship. Nurses view their roles and responsibilities as being tied to their relationship with physicians, which impacts their reasoning in adopting change. This suggests that nurses gain confidence in clinical decision making when they work closely with physicians and when they learn with them. This might be related to the tendency of nurses to incorporate more subjectivity in their

assessment and decision making. By physicians and nurses working closely, this characteristic of nursing practice can be better understood and recognized amongst physicians, which promotes confidence amongst nurses. This might also inform why nurses appear to feel more empowered in their decision making and skill development when clinical practice is standardized because many teams are not closely connected, and standardization replaces the function of the relationships.

7.1.2 Reflections on the methodology. Through this process, the researchers identified two characteristics of RRR that make it difficult to distinguish between a stand-alone RRR and a rapid review process in a realist evaluation. Brown, Lhussier, Dalkin, and Eaton (2018) used the RRR as a first step in an evaluation to develop and test program theories through existing literature. The design of the evaluation included a focus group with experts in the field and interviews with health care professionals and patients. This study design closely resembles the approach to the current study; labelling this a customized RRR. However, terminology (i.e. what we call this method or approach) is not as important as ensuring the goal of the process is a theoretical construction usable to knowledge users. As previously described, had the review concluded with the literature review only (i.e. step 7), the resultant program theory would not have been useable. It was necessary to validate the literature-based theory with knowledge users to derive usable theory. Therefore, the modifications made to the approach addressed the identified gaps in existing RRR methods. This highlights the need for further refinement of the methodology in order to build consistency in using RRR methods while understanding the need and appropriateness of method customization.

On the other hand, the act of customization and incorporating multiple phases of knowledge user engagement challenged the notion of the methodology being rapid. Our process took 12 months as opposed to the 3 to 6 month timeline suggested by Saul et al. (2013). Greater experience in realist methods might have decreased the time taken for customization. Adding a second phase of knowledge user engagement took the longest amount of time because of recruitment, interviewing, and analysis. The art of the RRR is balancing the degree to which a program theory is refined with the judgement of how suitably relevant and robust the constructs are. This balance is determined by experience in interpreting and conceptualizing mechanisms such that they are understandable and useable. If the goal of the realist is to generate a pragmatic

understanding of causation, then the definition of a mechanism has to reflect that. Using the definition of a mechanism by Dalkin et al. (2015), we arrived at a family of salient resources linked to hypothetical explanations of causation, the goal of a RRR. Therefore, the definition and the methodology were compatible, but it will require testing of the constructs to determine if the definition and the constructs it informs, are real.

7.1.3 Role of substantive theory. The Theoretical Domains Framework (TDF) guided the interpretation of emerging constructs for this research program theory and was chosen as the most relevant established theory of change and action from the literature. This alignment allowed for the articulation of the mechanisms to be consistent and reflective of the inherent reasoning within actors. This was valuable for not only identifying mechanisms but also synthesizing constructs into those that represent a middle-range phenomenon, such as belief and pessimism. However, in the end the TDF did not provide an overall structure to the pattern of constructs which is a suggested function of incorporating substantive theory into program theory. This is because the TDF is not a systems-based theory where relationships between constructs are defined. Rather, it is more linear because it primarily focuses on facilitators and barriers and cannot capture the dynamic nature of some constructs.

Mechanisms exist on a continuum and are inherently dynamic because, as context changes, so does the presence and power of any one mechanism (Jagosh et al., 2014). The TDF has a limited ability to reflect this because it is a framework produced through synthesis. Frameworks are inherently more appealing for integrating into practice for the very reason they are more linear and thus easy to conceptualize. Substantive theories of change and action can be less practical depending on the degree of abstraction and complexity of their constructs. Therefore, the TDF is limited in the degree of complexity it can reflect when used as substantive theory in RRR. However, it has been shown to be applicable as a theoretical entity used in practice (Debono et al., 2017; Steinmo et al., 2015) by functioning as a useful starting point for informing intervention design and identifying related context. In this, it offers clues to potential mechanisms, such as reinforcement and self-efficacy, but necessitates abduction beyond its defined constructs in order to arrive at a causative proposition. It is possible that using a more appropriate substantive theory could have resulted in a different program theory in this study. However, considering the large range of potential implementation theories to include (Tabak et

al., 2012) and the minimal use of theory in sepsis intervention research (Steinmo et al., 2015), there was little evidence to suggest a more relevant option.

7.1.4 Comparison of findings to current literature. At the outset of this research, the researchers did not find any program theories that aligned with the research questions. However, the final program theory has similarities with a recently published realist review of a clinical intervention (McGaughey, O'Halloran, Porter, & Blackwood, 2017). This review developed a program theory for a hospital-based early warning system that identifies patient deterioration and a rapid response process. An early warning system and rapid response process has the same general purpose as the sepsis screening trigger tool – to facilitate early recognition of the changing patient and direct timely purposeful treatment and care. The difference is that an early warning system captures more potential causes of a patient's status change than sepsis, but can include sepsis. The other difference with this review is that it focused on the use of the interventions from the nursing perspective and nurses' execution of the early warning system and its components. The outcomes were nurses referring earlier to medical staff, nurses' re-evaluation of patients with the early-warning system, and nurses' referral to medical staff or the rapid response team. Our program theory was focused on outcomes related to implementation and included the physician perspective.

Despite these differences, there are key similarities in the identified context and mechanisms that support the robustness of both theories. For the outcome of nurses referring earlier to medical staff, McGaughey et al. (2017) found that empowerment amongst nurses and reduced uncertainty in decision-making were key mechanisms. Positive contextual conditions that would trigger these mechanisms included good relationships in the multidisciplinary team and training. These constructs align the findings of the current study that adoption was more likely among nurses, where a perception of legitimate authority and increased confidence in critical thinking was triggered by highly connected teams as well as mature, less connected teams that received training that aligned with their needs.

Conversely, McGaughey et al. (2017) found that circumstances such as increased workload and a fear of referring to senior medical staff negatively affected nurses referral to medical staff. Although not explicitly stated, one could infer that this means that mechanisms of increased uncertainty in decision-making and disempowerment were triggered. The current

research identified confusion in decision making as a salient mechanism which is similar to certainty in decision making. However, the confusion in decision making was related to inhibited acceptability and feasibility, and triggered by individual and group routines in practice, whether they were related to standardization or individual adaptation. As well, the current research identified workload as an element of a complex work environment, where a standardized best practice had a positive effect on acceptability and feasibility because positive beliefs were triggered.

For the outcome of nurses re-evaluating using the early warning system and referring patients, McGaughey et al. (2017) found that clinical judgement and empowerment of experience nurses were key mechanisms. These positively affected the outcome when triggered by an understanding of professional roles, teamwork and communication, and ongoing multi-professional education. In contrast, the current study found that similar concepts of teamwork and professional roles were manifested as mechanisms rather than context in the form of perceived reinforced partnerships and clear sense of roles and responsibilities triggered by highly connected or mature teams, leading to adoption.

There is greater similarity in the salient negative contexts between program theories developed by McGaughey et al. (2017) and the current study. McGaughey et al. (2017) found that a traditional hierarchical referral system, professional and communication silos, and a lack of role clarity contributed to nurses not re-evaluating and using the early warning system and referring patients. These align with findings of the current study that context of a disconnected team structure ultimately leads to inhibited fidelity and abandonment. As well, McGaughey et al. (2017) found that subjective nursing referral language was a negative contextual factor. Results from the current study found the role of subjectivity was inherent in nursing actions as well. Instead of being a contextual factor, the concept appears as a mechanism in nurses' subjective decision making that leads to inhibited acceptability and feasibility.

The program theories developed in both studies are hypotheses that address similar actors using interventions built on similar functions. Results from both studies suggest that our program theory has a degree of alignment with other findings. However, there are clear differences in how context and mechanism have been interpreted and assigned to similar phenomenon. These are good examples of how similar constructs can be active in response to different conditions, leading to variable outcomes, depending on the actors and the social system in which they

operate. They also reflect outputs of realist inquiry where different understandings of realist phenomenon, approaches to the methodology, and the assumed application of abductive reasoning can result in different program theories for similar clinical interventions.

7.1.5 Reflections on clinical practice and sepsis. The evidence base behind clinical practice including diagnosis, screening, and treatment is continually evolving. The trigger tool used as the focal point of this research is now outdated and does not include latest definition of sepsis (Singer et al., 2016). Such a change in the nature of an intervention is an example of how an intervention adds complexity. Fundamentally changing the definition of a condition on which an intervention is based could be seen to reinforce inhibitory mechanisms for acceptance and feasibility. These changes challenge the notion of standardization as an acceptable practice by reinforcing the belief the standardization is redundant, individual decision making is preferred, and that an intervention for the screening of sepsis increases workload. This reinforces the need for evidence-based implementation strategies that remove such barriers by triggering promoting mechanisms in the context of team-base iterative problem-solving processes and clinical quality improvement. How a program theory can remain relevant with rapidly changing clinical practice is an ongoing challenge. However, despite the problems in adopting potentially imperfect new practices, this does not negate the need for trying novel solutions, such an implementation program theory, for prevalent conditions with severe impacts.

7.1.6 Alignment with quality improvement. Successful implementation is an essential step in clinical quality improvement. Two elements of the program theory in this research reflect important aspects of the quality improvement approach: an emphasis on measuring fidelity (Etchells & Woodcock, 2018; Lavallee et al., 2017) and the use of audit and feedback (Cooke et al., 2018). Fidelity indicates the effectiveness for behaviour change (Lavallee et al., 2017) because it is a measure to which a change is implemented as intended (Etchells & Woodcock, 2018). Fidelity demonstrates both adoption and adherence, which are the defining endpoints in the program theory developed in this research.

Audit and feedback are the means by which information about fidelity is communicated to clinicians. It establishes meaning and credibility of performance data and prompts reflection which stimulates cues for action planning (Cooke et al., 2018). In a study of physicians receiving

feedback with peers, Cooke et al. noted that individuals reach action planning by responding to feedback in a cycle of behaviours that includes reaction to the data, questioning and understanding the data, justifying and contextualizing, sharing and reflecting on the data and the associated guidelines, and planning for change. The fact that the program theory developed in the current study reflects these salient characteristics of quality improvement reinforces its relevance. Useable implementation theory has to be conducive to being integrated with quality improvement (Wandersman et al., 2015).

7.2 Limitations

There are several limitations in this research related to the chosen substantive theory and methodology. The application of realism in implementation science is relatively novel and evolving; with ongoing testing and refinement of methods. The evolving interpretation of what constitutes a mechanism and how that is defined presents a challenge for researchers, especially novices having to understand and apply the theory. We used the definition of a mechanism proposed by Dalkin et al. (2015) who seek to clearly distinguish resources from reasoning that make up the original definition proposed by Pawson and Tilley (1997) to make the concept more useable. However, this interpretation could be seen as deviating from the epistemology of realism in that is can be interpreted such that resources and context are confused. Porter (2015) challenged the very nature of context, mechanism, and outcome by pointing out the ambiguities, inconsistencies, and contradictions in the descriptions of these constructs by Pawson and Tilley (1997). He proposed a different explanation of these phenomenon that he argued is more internally consistent and useable. This modified explanation was articulated as contextual mechanisms + program mechanisms + agency = outcome, although it should be noted that this idea has not been advanced in the realist literature. For a novice researcher, the debate about the very nature of realism, and alternatives to definitions, creates some confusion in how to interpret phenomena in identifying mechanisms.

The rapid nature of a RRR represents another limitation because the focus is on identifying and referring to key sources of information as opposed to a comprehensive approach. This process can easily miss a potentially relevant reference, thereby limiting the relevance and robustness of the final program theory. Although knowledge user involvement is intended to minimize any gaps by relating the evidence to real life, their bias or knowledge deficits might not

only fail to address this gap but introduced other limitations. For example, knowledge users who come from a setting where theory-based implementation strategies have never been used might not relate to or realize the significance of such a critical area of knowledge. The role of the expert in a RRR is to contribute key information to account for that missing critical area of knowledge. Experience in implementation does not necessarily equate to expertise and implementation expertise is not always present within a local team and group of knowledge users. Therefore, ensuring implementation expertise in a rapid review may not always be possible due to limitations such as the expense and availability of involving an external expert.

This RRR did not match the timelines for a RRR suggested by Saul et al. (2013). The need to learn, customize, and apply the methodology meant that extra time was taken pushing the work beyond the 3 to 6-month timeframe. However, with greater experience in realist methods and more resources this ideal timeline could potentially still be realistic. One of the significant challenges that contributed to the timeframe was engaging knowledge users who were not familiar with realist terms, such as mechanism, that were cumbersome to communicate. This meant modifying resources used in the interviews from those used in the focus group, to improve comprehension.

Finally, many realist syntheses and evaluations seek to identify key outcomes within a program theory, whereas this research study used a predetermined outcome based on the nature of the research question. This approach did not appear to be a limitation because the resulting program theory logically aligned realist propositions with implementation outcomes defined in the non-realist implementation literature. However, there is the possibility that a salient feature of the program theory is missing.

7.3 Future Implications for Clinical Screening Interventions

Screening interventions developed to reduce sepsis mortality will inevitably be varied based on what an organization has in terms of finances, technology, human resources, quality improvement capability, and implementation best-practices. Therefore, generalized solutions to implement best practices will not suit many contexts which reinforces the value in developing a realist understanding of causality of what works for whom, in which circumstances and why. Although specific implementation interventions such as education, supports designed using the Behaviour Change Wheel (Michie et al., 2014), and others play a role, it appears that it is the

intrinsic characteristics of actors and their relationships between each other, as well as the social forces, that largely inform how successful implementation occurs.

This study used sepsis screening as the focus and the resulting program theory is intended to inform the implementation of sepsis screening interventions in other similar settings. However, in its final form, the program theory could also apply to other similar interventions in similar contexts with similar actors. In fact, many of the knowledge users drew from their experience with the implementation of the sepsis trigger tool as well as other interventions they had been involved with in their thinking and answers. While this does not mean that the program theory is a generalizable hypothesis for all clinical implementation interventions, it can serve as a starting point for local teams to consider when planning and implementing clinical interventions.

Keeping in mind that this program theory is a hypothesis for what causes successful implementation, the following are several recommendations for knowledge users to consider:

- Clinicians will change their behaviour to adopt a new clinical practice if they perceive that the change will provide a benefit for themselves and for their patients.
- Clinical teams that are highly connected where members can relate to one another, learn together, and jointly reflect on their practice will be more likely to adopt a change in practice.
- The implementation process should be based in theory and planned to clearly achieve acceptability and feasibility, adoption, and fidelity and sustained use.
- To achieve acceptability and feasibility either the practice change has to make workflow easier, or if it cannot, such as if patient safety is put at risk, then consideration should be made to simplify the work environment.
- Implementation activities should be strategic and purposeful and include representative interdisciplinary teams, consistent and complete communication and education, and meaningful performance feedback.
- Physicians and nurses will respond to standardization, modification, and organized structure differently which means that these must be made apparent and actively addressed in intervention design.

7.4 Future Research

This study highlights the need for three areas of future research. The first is to test this program theory for validity to determine if it is a useable theory in practice and if the constructs are reliable. This program theory challenges the conceptual thinking about how interventions are implemented which too often focuses on a package of activities and/or their educational messages (Hawe, Shiell, & Riley, 2009). The program theory illustrates the salient mechanisms and associated resources that leads to successful implementation in dynamic contexts. It reinforces what Hawe et al. (2009) described as necessary for interventions to lead to new structures of interaction, that is, the impact on person-place-time networks, change relationships, displacing existing activities, and redistributing and transforming resources. However, it needs to be tested before it can specifically inform ways to select and tailor implementation strategies. Potential methods to match implementation strategies with promoting or inhibiting mechanisms could be concept mapping, group model building, conjoint analysis, and intervention mapping, as these are processes that can involve the knowledge user (Powell et al., 2017). Bonell, Fletcher, Morton, Lorenc, and Moore (2012) suggested using a realist randomized controlled trial to empirically examine underlying mechanisms hypothesized in a program theory. However, this suggestion is questionable considering it would be extremely difficult to control for a 'hidden' mechanism of reasoning.

The second area of future research should focus on better understanding the specific implementation actions that consistently lead to successful sepsis screening. There is the potential to gain this knowledge from building on the future results of a large-scale quasi-experimental study involving 75 hospitals in Germany (Schwarzkopf, Ruddel, Grundling, Putensen, & Reinhart, 2018). The intervention strategies in this protocol include participatory action amongst collaborators, a centralized resource providing support, and local interdisciplinary quality improvement teams implementing changes. Some of the specific interventions proposed included interdisciplinary case analyses, external peer-reviews, hospital-side staff education, and the implementation of rapid response team as well as a complex risk-model to analyze quarterly data. Comparing and contrasting the characteristics of the program theory of the current research with the results from this study could potentially validate the program theory propositions.

The final area of future research is the continued need to test methods that can lead to an understanding of causality and complexity in meaningful ways in order to advance the use of program theories, especially for local clinical implementation (T. Greenhalgh & Papoutsi, 2018). Although RRR requires more refinement and testing through applied customization, the premise of this methodology filling a real-life operational need in knowledge translation is valuable. T. Greenhalgh and Papoutsi (2018) argued that some of these needs include framing research as understanding open systems characterised by dynamic changing inter-relationships and tensions, including uncertainty, unpredictability, and emergent causality. Realist methods offer a way to get towards this through rich theorizing and generative learning, but the pragmatic adaptation to changing contexts is an area to be advanced.

Advancing the pragmatic use of realist program theory could involve other kinds of systems level theorizing. The Actor-Network theory is described as a framework to address complexity in interventions (Bilodeau & Potvin, 2018). In this theory, systems include human and non-human entities where an understanding of complexity comes from, the interactions between the actions of an intervention, and the context surrounding it. Complexity is made understandable by deriving networks of the various entities and observing how an intervention affects the network.

Another route to understand complexity comes from the use of systems theory (Braithwaite, Churruca, Long, Ellis, & Herkes, 2018). This was a domain of substantive theory not considered at the outset of this research but is intended to address the similar domain of inquiry. Systems theory is applicable at multiple scales and is non-linear in nature. Complex systems include agents and their artifacts, similar to resources and context, and emphasizes the understanding of relationships between components, similar to mechanisms. Agents learn and adapt using different artifacts over time thereby shaping the context around them. These relationships form global patterns of phenomena over time, including feedback loops. This description is synonymous with how reasoning is connected to resources and exists on a continuum while they interact with context as part of an open system. In complexity science this is referred to as a complex adaptive system (Braithwaite et al., 2018).

7.5 Personal Reflections of Lead Researcher

At the end of chapter four, the question was raised as to whether the clinician researcher perspective could also involve that of an expert. After completion of this research, my opinion is that the answer is, yes. As a health care manager with a clinical background, working through this project has enabled an integration of different knowledge that I now see as necessary to answer the real-world questions that I face in practice. The most paramount of these is how to best go about facilitating behaviour change amongst clinicians and adopt new clinical practices. Prior to engaging in this research, I did not have an understanding of the value of implementation theory in guiding practice change nor of the realist perspective on how to understand and explore causation. Combining my new-found academic knowledge with my clinical and managerial experience has prepared me to be more adept at approaching problem solving and engaging in creating and implementing effective solutions.

My background has also reinforced how critical it is to include the knowledge user perspective in research. As a knowledge user in health services, if the products of research cannot be applicable in practice, whether it is because it is too abstract, unrealistic, or complicated, they will likely never be applied. I have tried to maintain this perspective throughout the research process, and my aim is that my peers see my program theory as something that is applicable in their real-world work. Therefore, in response to the other question posed at the end of chapter four, whether the clinician researcher perspective could be considered as a knowledge user perspective, the answer to this is also, yes.

8.0 Conclusions

Describing how to achieve successful implementation of clinical interventions, such as sepsis screening, can be articulated for a particular setting in the form of a program theory. Such a program theory provides a structure to guide clinical teams in developing implementation strategies by focusing on the salient characteristics that can lead to success. These characteristics include the human and environmental factors that complicate implementation. By outlining a theory of causation in a parsimonious way, teams can understand the resources and context to consider that make implementation activities purposeful.

This research developed a program theory that hypothesizes the salient features of the complex reality of implementation for more than just sepsis screening interventions. Mechanisms reflective of trust within teams, beliefs influenced by workload and perceived benefit, and pessimism are not necessarily dependent on the nature of a specific clinical practice change or of only one clinical setting. These constructs could easily exist in the implementation of many other clinical practice changes. Similarly, the salient contexts that were identified are not necessarily unique to one organization or hospital. Therefore, this program theory is potentially applicable to and adaptable for the implementation of multiple types of clinical interventions in other local contexts.

The methods used in this study are valuable outside of the academic sphere. The rapid realist methodology was customized in such a way to facilitate application for other realist research novices seeking solutions to similar questions and methods that are shorter and more timely. The approach integrated the concepts of implementation science and quality improvement science as they pertain to implementation at the local level. As well, it serves as an example demonstrating the value of a realist paradigm to the practice of implementation and implementation science, because the method illuminates the black box of 'human factors' that determine successful implementation of clinical practice changes.

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Appendix A

Figure A.1 SHR trigger tool

Saskatoon Health Region

SASKATOON HEALTH REGION
Saskatoon, Saskatchewan

❑ RUH ❑ SCH ❑ SPH Other _____

File this form in the chart with the PRACTITIONER'S ORDERS

MD-027   ADULT SEPSIS / SEVERE SEPSIS MEDICAL DIRECTIVE- TRIGGER TOOL
(IDENTIFICATION AND INITIAL RESPONSE)

These orders are for all adult patients in SHR Acute Care.
Based on an individual assessment of each patient, RNs and LPNs may order lab tests and initiate IV fluid as indicated. Call the MRP with any concerns.

S E P S I S

1.   Are any TWO of the following present and new to the patient?
❑ Temperature greater than 38°C or less than 36°C
❑ Heart rate greater than 90 bpm
❑ Respiratory rate greater than 20 bpm
❑ WBC greater than 12 x 10⁹/L or less than 4 x 10⁹/L
❑ Altered mental status (from baseline)

YES to BOTH 1 & 2

SUSPECT SEPSIS →

2.   Is there ONE Risk Factor?
❑ Proven or suspected infection   ❑ Diabetes Mellitus
❑ Recent major surgery/trauma/burns   ❑ COPD
❑ Primary disease of liver cirrhosis   ❑ Alcohol abuse
❑ Age greater than 70 years   ❑ Malignancy
❑ Prolonged or recent hospitalization
❑ Immunosuppression (neutropenia, immunosuppressive therapy,
corticosteroid therapy, IV drug abuse, complement deficiencies, absent spleen)
❑ Invasive procedures /devices   (catheters, intravascular devices,
prosthetic devices, hemodialysis / peritoneal catheters, endotracheal tubes)

Obtain STAT:
☒ CBC ☒ INR   ☒ PTT ☒ Alkaline Phosphatase ☒ ALT ☒ AST
☒ Bilirubin Total ☒ Creatinine   ☒ Electrolytes (Na, K, Cl, CO2)
☒ GGT ☒ Glucose Random   ☒ Urea
☒ Venous blood gases (lactate included)   ☒ Blood Cultures x 2
☒ Urinalysis   ☒ Urine culture and sensitivity

Target:
3 hours from time patient is suspected to be septic to the first dose of antibiotic administered
Notify Physician to obtain antibiotic order/other orders for septic workup

Patient suspected to be septic: Date _____ Time _____

Signature (RN/LPN):_____

S E V E R E   S E P S I S

3.   Are ANY of the following present?
❑ SBP less than 90 mmHg or MAP less than 65 mmHg
❑ SBP decrease greater than 40 mmHg from baseline
❑ Venous lactate greater than 4 mmol/L

YES to 1 & 2 & 3

SUSPECT SEVERE SEPSIS →

Obtain STAT: Lab tests as above   (if not already done)
Administer:
500 mL NS infused over 30 minutes maximum
Target:
1 hour from time patient identified with severe sepsis to first dose antibiotic administered and fluid resuscitation strategy in place.
Notify STAT
Physician and request patient be seen within 30 min and activation of Adult Severe Sepsis/Septic Shock Management Order Set (#102864)
Obtain antibiotic order

Patient suspected to be in severe sepsis: Date _____   Time_____

Signature(RN/LPN): _____

S H O C K

Hypotension Unresponsive to Fluid Challenge

ANTICIPATE ICU TRANSFER

This Medical Directive has been approved by the departments of Surgery, Medicine, and Emergency, and complies with the SHR Medical Directive Policy.
Review will occur every year. Next review due December 2017. These orders do not require a prescribing practitioner signature.
Notice of confidentiality: Contains information that is time sensitive or confidential. Use, disclosure, copying or communication of the contents is prohibited. If you have received in error, notify the SHR Pharmacy Manager, Operations (306-655-6695).
Form #104018   12/2016   Category: Medical Directives

SITUATION BACKGROUND ASSESSMENT RECOMMENDATION (SBAR) - SEPSIS

Please fill in the blanks and communicate to physician in this order.
❑ IF SEVERE SEPSIS, CALL STAT

S
Date: _____ Time: _____
Dr. Name: _____ Designation: ❑ Resident ❑ House Officer ❑ MRP
My name is: _____ Title: _____
From Ward: _____
I am calling about (patient name): _____
This patient meets the septic criteria

B
The patient was admitted with: _____ on _____ (date)
Resuscitation Status: _____
Patient's current antibiotics: _____ Allergies: _____

A
This patient has met **sepsis** criteria with the following:
Temperature - _____
BP - _____
HR - _____
RR - _____
Altered Mental Status - _____
O₂ sat _____ on _____
    (room air or supplement O₂)
WBC (if available) - _____

This patient has met **severe sepsis** criteria with the following:
Temperature - _____
BP - _____
HR - _____
RR - _____
Altered Mental Status - _____
O₂ sat _____ on _____
    (room air or supplement O₂)
WBC (if available) - _____
Lactate (if available) - _____

R
SEPSIS:

I have ordered the labs on the sepsis initial response sheet. I need an order from you for IV antibiotics and other appropriate orders to complete this patient's septic workup. We have a target of 3 hours to administer the first dose of IV antibiotic, which will be at _____ (time).

If no response in 10 minutes:
❑ Page MRP   (Time: _____)

Continue to assess patient until call is answered.

SEVERE SEPSIS:

I have ordered the labs and started the initial fluid bolus. I'm asking that you review the patient within the next 30 minutes. We have a target of 1 hour to administer the first dose of IV antibiotic, which will be at _____ (time).

If no response in 10 minutes:
❑ Page MRP stat (Time: _____)
If no response after 5 more minutes:
❑ Page Outreach(**SPH/SCH**) (Time: _____)
❑ Escalate care **STAT** per Unit/Hospital protocol (**RUH/Rural**): (Time: _____)

SUMMARY OF RESPONSE:
❑ Antibiotic orders received
❑ Physician decided not to give antibiotics

Form #104018   12/2016   Category: Medical Directives

Appendix B

Figure B.1 Behavioural Ethics Board exemption and participant consent form

UNIVERSITY OF SASKATCHEWAN

To: Dr. Gary Groot
           Department of Community Health and Epidemiology
           College of Medicine

Student: Jonathan Melville

Date: November 8, 2017

Re: Beh 17-381

Thank you for submitting your project entitled "Understanding the Mechanisms of Protocol Implementation for the Early Recognition and Treatment of Probable Sepsis". The application meets the requirements for exemption status as per **Article 2.5 of the Tri-Council Policy Statement (TCPS): Ethical Conduct for Research Involving Humans, December 2014**, which states "*Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.*"

It should be noted that though your project is exempt of ethics review, your project should be conducted in an ethical manner (i.e. in accordance with the information that you submitted). It should also be noted that any deviation from the original methodology and/or research question should be brought to the attention of the Behavioural Research Ethics Board for further review.

Please revise the consent form to reflect an exemption from the REB or delete the sections regarding REB approval.

Sincerely,

Behavioural Research Ethics Board
University of Saskatchewan

102

You are invited to participate in a research study entitled:
Understanding the mechanisms of protocol implementation for the early recognition and treatment of probable sepsis.

Researcher(s): Jonathan Melville, RN, BSN, Graduate Student, Community Health and Epidemiology, University of Saskatchewan, 306-653-0701, jonathan.melville@usask.ca

Supervisor: Dr. Gary Groot PhD, MD, FRCS(C), FACS, Faculty, Community Health and Epidemiology, 306-966-1670, gary.groot@usask.ca

Co-Investigator: Dr. Tracey Carr PhD, Post-doctoral Fellow, Community Health and Epidemiology, University of Saskatchewan, 306-844-1350, tlc143@mail.usask.ca.

Purpose(s) and Objective(s) of the Research:
- The purpose of this research is to understand the mechanisms for successful implementation of an intervention for the early recognition and treatment of sepsis that are applicable to the local context of the Saskatoon Health Region.
- The objectives of the research are:
  - To construct a general program theory that hypothesizes the mechanisms for successful implementation of an intervention for the early recognition and treatment of probable sepsis.
  - To describe a refined program theory that explains the circumstances and salient mechanisms for the implementation of an intervention for the early recognition and treatment of probable sepsis within the Saskatoon Health Region.

Procedures:
- You are invited to participate in a single focus group or individual in-depth interview. In either case you will be presented will the elements of a hypothesized program theory for the implementation of a sepsis protocol and asked to discuss the elements of the theory.
- The single focus group with up to 12 other individuals will be held at a University or Saskatchewan or Saskatoon Health Region facility. The focus group will take approximately 90 minutes.
- The individual in-depth interview would take approximately 60-90 minutes and be one-on-one with the lead researcher.
- You may be invited to participate in an individual follow-up in-depth interview after either the focus group or initial interview to clarify the analyzed results of the focus group.
- Please feel free to ask any questions regarding the procedures and goals of the study or your role.

Potential Risks:
- There are no known or anticipated risks to you by participating in this research. You will be sharing your opinions in front of other staff and peers; therefore, others will know what you have said.
- The lead researcher is also an out-of-scope manager within the Saskatoon Health Region, however every effort will be made to ensure that the lead researcher maintains a neutral position. Your participation in this study and the information you will provide will have no impact on your employment status, role or professional relationships. Any and all concerns in this regard should be communicated to the research Supervisor identified at the top of page 1 and the University of Saskatchewan Research Ethics Board detailed at the end of page 3.
- Participants will be asked not to share what was said during the focus group with others outside of the focus group.

Potential Benefits:
- The benefits of this research include developing theoretical understanding of how the successful implementation of clinical interventions can occur. It will also contribute to the ongoing evolution of the role of theory in guiding implementation within health care.

Confidentiality:
- Every effort will be made to ensure that the information you provide will be kept confidential; however, there are limits to this confidentiality due to the nature of focus groups. The researchers and other participants will know that you participated and will know what you say.
- Transcripts from the focus group, and interviews if needed, will not contain your name or other identifying information. Your personal identity will not be shared in any presentation or publication of the data.

Storage of Data:
- The focus group will be audio-taped and transcribed for analysis. The written transcripts and audio-recorded interviews will be kept on a password protected computer in the locked office of the Supervisor identified on page 1 for 5 years (2022), after which time they will be deleted or shredded beyond retrieval.
- Notes will be taken during the discussion will be stored in a locked filing cabinet in a locked office for 5 years, after which time this information will be destroyed.

Right to Withdraw:
- Your participation is voluntary. You may refuse to answer any question. You may withdraw from the interview, or leave the discussion for any reason, at any time without explanation or penalty of any sort.
- Should you wish to withdraw, in the case of focus group participation the information you have provided up to that point may not be able to be separated from the data provided by other participants and might be retained for analysis. However, any data that

informs of your participation in the study will be destroyed. In the case of interview participation, any data you provided will be destroyed.

- Employees of the researcher acting as participants in this study will be free from any coercion. The act of participating and the information gained from participation will be considered separate from any formal employment duties. Withdrawal from the study will not impact any aspect of a participant's employment or work environment. Should an employee feel it necessary to withdraw they will be directed to contact the Supervisor listed on the top of page 1.

Follow up:
- Results of the study will be summarized and shared with the Saskatoon Health Region and maintain the anonymity of the participants. Participants will receive a results summary highlighting the outcome of this research.

Questions or Concerns:
- Contact the researcher using the information at the top of page 1;
- This project has been approved for ethical exemption by the University of Saskatchewan Research Ethics Board (U of S BEH 17-381) on November 8, 2017. Any questions regarding your rights as a participant may be addressed to that committee through the Research Ethics Office ethics.office@usask.ca (306) 966-2975. Out of town participants may call toll free (888) 966-2975.

Consent:

Continued or On-going Consent:
- If further participation is required, in the form of an individual interview, the participants will be contacted by email by the researcher. Consent to participate in this research includes being contacted for these interviews and all the rights of the participant listed above will apply.

Your signature below indicates that you have read and understand the description provided; I have had an opportunity to ask questions and my/our questions have been answered. I consent to participate in the research project. A copy of this Consent Form has been given to me for my records.

Name of Participant	*Signature*	*Date*

Researcher's Signature	*Date*

A copy of this consent will be left with you, and a copy will be taken by the researcher.

Appendix C - Focus group questions, graphics and text descriptions

Table C.1 Focus group questions - adapted from Westhorp and Manzano (2017)

After having seen the overview, what do you consider to be the most important outcome(s) for successful implementation of a sepsis screening intervention in SHR? Why?   o What, if any, implementation outcomes are missing that you feel are important?
For the important outcome(s) that you have identified, what implementation activities cause, or help to cause, those outcomes? How do you think these activities cause the outcomes?
In what ways do you think implementation activities change the way end-users think and feel about the sepsis screening intervention? In what circumstances does this happen? Are these different for different end-users?
Based on your experience with the sepsis screening intervention implemented in SHR, what about the implementation made a difference for how it worked? What about the implementation made a difference for how it did not work?
If you could change something about the way in which an intervention such as the sepsis screening protocol is implemented to make it more successful, what would you change and why?
What else do you think we need to know in this case to really understand how implementation of the sepsis screening intervention has worked or not worked?

Figure C.1 Focus group graphics

Figure (top):

Clinical intervention	Implementation resources	Contextual conditions	Mechanisms of reasoning	Implementation outcomes

Sepsis screening → Integrated evidence-based practice

+ Busy work environment → Perceived malalignment with daily practice

+ Intervention standardized → Differing beliefs about treatment / Perceived threat to identity / Belief that skill development is discouraged

+ Collaborative adaptation of the intervention for local use → Confused decision making

= Inhibited acceptability

Figure (bottom):

Clinical intervention	Implementation resources	Contextual conditions	Mechanisms of reasoning	Implementation outcomes

Sepsis screening → Interdisciplinary implementation team

+ Evaluation against current state → Perception intervention is practical and realistic

+ Awareness of implementation strategy → Perception the implementation is not disruptive / Belief in collaboration

Trial implementation + Active stakeholder engagement → Clinician confidence / Perceived ownership

= Feasibility

Table C.2 Focus group text descriptions

Implementation Resources	Contextual Conditions	Implementation Outcomes
Integrated evidence-based practice	**Busy work environment** (A busy work environment is a clinical setting that includes one with a patient population where highly acute patients are frequently encountered, a setting with high degree of patient flow, competing demands for clinician time and attention and regular operational change.)	**Acceptability of the intervention** (Acceptability encompasses the satisfaction with various aspects of the clinical intervention [including content, complexity of use, comfort in the purpose, delivery in the clinical setting, and credibility])
	Collaborative adaptation of the intervention for local use (Collaborative adaptation includes interdisciplinary engagement of clinicians in adaptation [e.g. protocol development] and changing responsibility for initiating and completing care activities to others in order to meet targets [e.g. from physicians to nurses].)	
	Targeted behaviour change (Includes the use of supportive interventions that are designed to change behaviors necessary to support a change in clinical practice [e.g. use of the Behaviour Change Wheel].)	

Implementation Resources	*Contextual Conditions*	*Implementation Outcomes*
Integrated evidence-based practice	**Busy work environment** (A busy work environment is a clinical setting that includes one with a patient population where highly acute patients are frequently encountered, a setting with high degree of patient flow, competing demands for clinician time and attention and regular operational change.)	**Inhibited acceptability of the intervention** (Failure to reach satisfaction with one or more of the various aspects of the intervention.)
	Intervention standardization (Includes the standardization of an intervention across boundaries of practice and local areas within an organization.)	
	Collaborative adaptation of the intervention for local use (Multiple local adaptations of the same intervention within the same organization.)	
Interdisciplinary implementation team **(Includes engaging clinicians, facilitators and experts from across boundaries of practice to participate in implementation.)**	**Evaluation against current state** (Includes evaluating how the intervention might affect clinician current state workflow through activities, such as process mapping, and identifying failures and operational weakness in delivery care; analysis of predetermined performance goals/metrics.)	**Feasibility to adopt the intervention** (Feasibility describes the utility, suitability and trialability of the intervention.)

111

Implementation Resources	Contextual Conditions	Implementation Outcomes
	Awareness of the implementation strategy (Includes dedicated time and resources for all stages of implementation; a theory and evidence-based implementation approach)	
Trial implementation	**Active stakeholder engagement** (Involves inclusion in the evaluation of the outcomes, advantages and disadvantages of the trial.)	
Education on the aims of the clinical intervention **(Includes instruction on how to use the intervention and when to implement, information about health consequences [e.g. the story told of a patient that died from sepsis], severity and susceptibility of sepsis, and evidence for the efficacy of the sepsis intervention for improving patient outcomes.)**	**Broadly accessible information** (Includes such activities as video instruction on intervention steps, intranet resource instruction on implementation, support for implementation and monitoring step completion [e.g. Smartphone app with instructions and timer].)	**Adoption of the intervention** (Adoption describes the uptake and utilization of the intervention.)
	Participatory interdisciplinary training (This includes opportunities for observation and practice in simulation exercises.)	

Implementation Resources	*Contextual Conditions*	*Implementation Outcomes*
Clinical support resources **(Including workplace reminders about the intervention, visual prompts [e.g. poster, flowchart], intervention checklist [e.g. pocket reference card] or electronic practice guideline for completion of each step)**	**Busy work environment** (A busy work environment is a clinical setting that includes one with a patient population where highly acute patients are frequently encountered, a setting with high degree of patient flow, competing demands for clinician time and attention and regular operational change.)	**Fidelity to the intervention** (Fidelity describes the adherence to and, integrity and quality of the intervention.)
Dissemination of performance data and case specific feedback **(Includes daily implementation rates, comparison of current performance with target, patient outcome data, analysis of variation in intervention use, high-performers' characteristics of practice [e.g. Positive Deviance Approach], care case summary, compliments or pointers on how to maintain compliance, follow-up information on the patient's subsequent clinical course)**	**Cooperative PDSA problem solving** (Include problem identification, root cause analysis, planning, implementing revisions and evaluation for change.)	

Table D.1 Interview propositions

Acceptability

An evidence-based sepsis screening protocol is satisfactory when it is introduced into a complex work environment because it creates a perception that coordination of care is simplified.

An evidence-based sepsis screening protocol is satisfactory when clinicians collaboratively adapt it for local use because it creates a:

- belief that it is valid
- belief that it benefits patients and clinicians, and
- a perception that there is improved communication amongst clinicians.

An evidence-based sepsis screening protocol is satisfactory when the implementation activities focus on the clinician's capacity, opportunity and motivation to change behaviour because it creates a belief that there is a problem to solve and that there is a common goal to achieve.

Inhibited Acceptability

An evidence-based sepsis screening protocol is not satisfactory when introduced into a heavy workload because it creates a perception that there is limited capacity to use it and that it is not aligned with the daily workflow.

An evidence-based sepsis screening protocol is not satisfactory when it is standardized across all areas because it creates:

- a perception that it is a threat to professional identity
- differing beliefs about treatment, and
- discourages skill development in identifying and treating sepsis.

An evidence-based sepsis screening protocol is not satisfactory when it is not collaboratively adapted for local use because it causes confusion in decision making when clinicians move between different areas.

An evidence-based sepsis screening protocol is not satisfactory when it is introduced into a context where there is no purposeful support of staff when they commit errors in practice because it causes embarrassed.

Feasibility

A sepsis screening protocol is useable and suitable when it is implemented by an interdisciplinary team who evaluates the protocol against the current state of identifying and treating sepsis because it creates a perception that it is practical and realistic.

A sepsis screening protocol is useable and suitable when it is implemented by an interdisciplinary team that includes hospital administrator participation and investment because it creates a perception that there is sustained support for using and evaluating the protocol.

A sepsis screening protocol is useable and suitable when data collection and analysis expertise is used in a trial implementation because it creates a perception of ownership of the protocol.

Adoption

A sepsis screening protocol is used when there is education and clinical support resources conducted through participatory interdisciplinary training because it creates:

- a belief in the importance of the outcomes when using it
- a perception of legitimate authority to use it, and
- confidence in critical thinking and decision making.

Fidelity

Adherence to the integrity and quality of a sepsis screening protocol occurs when a defined implementation strategy is used in a non-hierarchical clinical team structure because it creates a:

- perception of clear roles amongst clinicians
- a feeling of being valued
- a sense of trust in the knowledge and expertise of other clinicians
- a sense of individual professional honesty, integrity and fallibility, and
- a sense of empowerment to hole peers accountable.

Adherence to the integrity and quality of a sepsis screening protocol occurs when there is disseminated performance data and feedback used by local teams in cooperative PDSA problem solving because it creates:

- a realized need to change habits
- a motivation to perform the requisite behaviours of the protocol, and
- trust that the data reflects reality.

Inhibited Fidelity

Adhering to the integrity and quality of a sepsis screening protocol is prevented when it is implemented without a strategy in the context of uncoordinated clinician practice because it creates a feeling of disempowerment and being unvalued.

Adhering to the integrity and quality of a sepsis screening protocol is prevented when it is implemented without a strategy as part of a rapid change process because it creates a lack of trust and faith in the implementation process and the clinicians involved.

Figure D.1 Interview graphics

Clinical intervention | Implementation resources | Contextual conditions | Mechanisms of reasoning | Implementation outcomes

Sepsis protocol → Evidence-based practice

+ Heavy workload → Perceived limited capacity / Perceived misalignment with daily workflow

+ Intervention standardized → Perceived threat to identity and autonomy / Differing beliefs about treatment / Discouragement to develop clinical skills

+ Non-collaborative adaptation of the intervention for local use → Confused decision making

+ No purposeful engagement when errors occur → Embarrassment in one's performance

= Inhibited Acceptability

Clinical intervention | Implementation resources | Contextual conditions | Mechanisms of reasoning | Implementation outcomes

Sepsis protocol → Interdisciplinary implementation team

+ Evaluation against current state → Perception intervention is practical and realistic

+ Hospital administrator support → Perception of sustained support and importance

Data collection and analysis expertise + Trial implementation → Perceived ownership of the intervention

= Feasibility

117

Clinical intervention | Implementation resources | Contextual conditions | Mechanisms of reasoning | Implementation outcomes

Sepsis protocol → Absent implementation strategy + Uncoordinated clinician practice in silos → Feeling disempowered and unvalued

Rapid change driven implementation process → Lack of trust/faith in process and people

= Inhibited Fidelity

Appendix E

Table E.1 RRR reference characteristics

Citation	Setting	Study Design	Summary of key findings	Use in synthesis
Bahtsevani, C., Willman, A., Stoltz, P., & Östman, M. (2010). Experiences of the implementation of clinical practice guidelines - interviews with nurse managers and nurses in hospital care. *Scandinavian Journal of Caring Sciences, 24*(3), 514-522.	Sweden Multiple clinical areas	Qualitative using questionnaire and interviews with multiple health professions	• Implementation is a continuous process involving all staff members in creating realistic and sustainable routines • Successful implementation comes from guidelines that meet the expectation of better and safer patient care, and that increase knowledge and confidence amongst staff • Compliance comes from involving all staff and following up with feedback • Evaluation demonstrates importance of applying the guideline and to balance priorities	Explanatory accounts
Bjurling-Sjöberg, P., Wadensten, B., Pöder, U., Nordgren, L., & Jansson, I. (2015). Factors affecting the implementation process of clinical pathways: a mixed method study within the context of Swedish intensive care. *Journal of Evaluation in Clinical Practice, 21*(2), 255-261.	Sweden ICU	Exploratory design with sequential mixed methods	• Implementation of pathways should involve a process to realize usefulness and create new habits, and include enthusiasm, support and time • Enablers include bottom-up initiatives, interprofessional groups, and smaller clinical areas	Explanatory accounts

Citation	Setting	Study Design	Summary of key findings	Use in synthesis
Campbell, H., Hotchkiss, R., Bradshaw, N., & Porteous, M. (1998). Integrated care pathways. *British Medical Journal, 316*(7125), 133+.	UK	Discussion paper	• Barriers include inadequate electronic health records, insufficient support and time constraints • Pathways facilitate introduction of guidelines • Improve multidisciplinary communication and care planning • Decrease practice variation • Achieve and exceed quality standards	Explanatory accounts
Damiani, E., Donati, A., Serafini, G., Rinaldi, L., Adrario, E., Pelaia, P., . . . Girardis, M. (2015). Effect of performance improvement programs on compliance with sepsis bundles and mortality: a systematic review and meta-analysis of observational studies. *PLOS One, 10*(5), 1-24.	Italy	Systematic review and meta-analysis	• n = 50 observational studies • high inconsistency in the characteristics of performance improvement programs across studies • programs associated with increased compliance with complete 6-hour bundle, 24-hour bundle, and reduced mortality in patients with sepsis, severe sepsis, and septic shock • Greatest compliance and survival benefit with educational programs and process changes	Consolidated accounts

Citation	Setting	Study Design	Summary of key findings	Use in synthesis
			• The greater the severity of the patient, the greater the compliance	
Dodek, P., Cahill, N. E., & Heyland, D. K. (2010). The relationship between organizational culture and implementation of clinical practice guidelines: A narrative review. *Journal of Parenteral and Enteral Nutrition, 34*(6), 669-674.	Canada Critical care	Narrative review	• Adherence to guideline recommendations comes from leadership support, interprofessional collaboration, shared beliefs about the utility of guidelines • Professional performance and patient outcomes come from the revision of professional roles, interdisciplinary teams, integrated care delivery, computer systems and continuous quality improvement	Explanatory accounts

Citation	Setting	Study Design	Summary of key findings	Use in synthesis
Ishii, L. E. (2013). Closing the clinical gap: Translating best practice knowledge to performance with guidelines implementation. *Otolaryngology - Head and Neck Surgery (United States), 148*(6), 898-901	United States	Discussion paper	• Implementation strategies need to include leadership commitment, education plans, systems plans and alignment of incentives	Explanatory accounts
Jones, A. E., Shapiro, N. I., & Roshon, M. (2007). Implementing Early Goal-directed Therapy in the Emergency Setting: The Challenges and Experiences of Translating Research Innovations into Clinical Reality in Academic and Community Settings. *Academic Emergency Medicine, 14*(11), 1072-1078.	United States Multicenter urban tertiary care – ED, ICU	Discussion paper	• Barriers to implementation of early goal-directed therapy: o Differences in area function and staffing, and need for adaptation o Reluctance to change requiring intensive education and revisiting o The availability of new equipment and training o Time and resources for quality improvement • Enablers: o Implementation team of champions to drive culture change o Organized approach o Upfront training o Ongoing tracking and troubleshooting	Explanatory accounts

Citation	Setting	Study Design	Summary of key findings	Use in synthesis
Kirk, J. W., Sivertsen, D. M., Petersen, J., Nilsen, P., & Petersen, H. V. (2016). Barriers and facilitators for implementing a new screening tool in an emergency department: A qualitative study applying the Theoretical Domains Framework. *Journal of Clinical Nursing, 25*(19-20), 2786-2797.	Denmark ED	Qualitative using interviews and TDF with multiple health professions	• Discovered 2 different cultures in the ED based on professional role and identity, actions and sense making • These cultures effected how a new screening tool was perceived in terms of enablers and barriers for adoption	Explanatory accounts
MacRedmond, R., Hollohan, K., Stenstrom, R., Nebre, R., Jaswal, D., & Dodek, P. (2010). Introduction of a comprehensive management protocol for severe sepsis is associated with sustained improvements in timeliness of care and survival. *Quality and Safety in Health Care, 19*(5), e46.	Canada Tertiary care – ED, ICU	Effectiveness study	• Improvements in average time to early goal-directed therapy and resuscitation goals • Improvements were sustained after 16 months	Explanatory accounts

Citation	Setting	Study Design	Summary of key findings	Use in synthesis
McGoldrick, E. L., Crawford, T., Brown, J. A., Groom, K. M., & Crowther, C. A. (2016). Identifying the barriers and enablers in the implementation of the New Zealand and Australian Antenatal Corticosteroid Clinical Practice Guidelines. *BMC Health Services Research, 16*(1), 1-14.	Australia and New Zealand	Qualitative using semi-structured interviews and TDF	7 perceived enabling TDF domains 5 perceived barrier TDF domains 3 domains differentiating health professional groups 3 domains relating to organization differences - Salient domains suggest ways to enhance implementation and understand how changes are made effective	Explanatory accounts
Michie, S., Stralen, M. M. v., & West, R. (2011). The behaviour change wheel: a new method for characterizing and designing behaviour change interventions. *Implementation Science, 6*(42), 1-11.	n/a	Framework evaluation, development and testing	19 frameworks were identified corresponding to 9 intervention functions - New framework centered around 3-factor behaviour system that informs 9 intervention functions, which in turn informs 7 policy categories to enable the interventions to occur - Reliably used to characterize behaviour change in two applied examples	CMO synthesis

Citation	Setting	Study Design	Summary of key findings	Use in synthesis
Proctor, E., Silmere, H., Raghavan, R., Hovmand, P., Aarons, G., Bunger, A., . . . Hensley, M. (2011). Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health, 38*, 65-76.	United States	Discussion paper	• Proposed a taxonomy of implementation outcomes with definitions • Separated implementation outcomes from service system and clinical treatment outcomes.	CMO construction
Saldana, L. (2014). The stages of implementation completion for evidenced-based practice: protocol for a mixed methods study. *Implementation Science, 9*(43), 1-11.	United States	Protocol	• Intent is to develop a way to measure implementation processes using the Stages of Implementation Completion	CMO construction
Shapiro, N. I., Howell, M. D., Talmor, D., Lahey, D., Ngo, L., Buras, J., . . . Lisbon, A. (2006). Implementation and outcomes of the Multiple Urgent Sepsis Therapies (MUST) protocol. *Critical Care Medicine, 34*(4), 1025-1032.	United States Urban tertiary care – ED, ICU	Prospective, interventional cohort with historical control group	• Protocol patients received earlier antibiotics, more IV fluids, more vasoactive medications in the first 6 hrs.	Explanatory accounts

Citation	Setting	Study Design	Summary of key findings	Use in synthesis
Steinmo, S., Fuller, C., Stone, S., & Michie, S. (2015). Characterizing an implementation intervention in terms of behaviour change techniques and theory: the 'Sepsis Six' clinical care bundle. *Implementation Science, 10*(111).	UK	Qualitative – observation, document analysis, interviews	• 19 behaviour change techniques were identified that made up the intervention • Demonstrated how variety of information sources and tools can be used to determine the content and mechanisms of action of existing behaviour change interventions	Consolidated accounts
Steinmo, S., Michie, S., Fuller, C., Stanley, S., Stapleton, C., & Stone, S. (2016). Bridging the gap between pragmatic intervention design and theory: using behavioural science tools to modify an existing quality improvement programme to implement "Sepsis Six". *Implementation Science, 11*(14).	UK	Qualitative using interviews and Delphi exercise	• Identified 5 themes in line with TDF domains influencing implementation • Modified the intervention of interest to include new behaviour change techniques • Demonstrated compatibility with PDSA quality improvement	Consolidated accounts

Citation	Setting	Study Design	Summary of key findings	Use in synthesis
Tarrant, C., O'Donnell, B., Martin, G., Bion, J., Hunter, A., & Rooney, K. D. (2016). A complex endeavour: an ethnographic study of the implementation of the Sepsis Six clinical care bundle. *Implementation Science, 11*(149), 1-11.	UK	Qualitative ethnography	• Implementation strategies that promote reliable use focused on education, engaging and motivating staff, providing prompts for behaviour • Revealed the complexity inherent within completing the 6 tasks of the intervention which included many more interdependent tasks requiring prioritization and scheduling • The increased complexity resulted in coordination problems and operational failures	Consolidated accounts
Verdu, A., Maestre, A., Lopez, P., Gil, V., Martin-Hidalgo, A., & Castano, J. A. (2009). Clinical pathways as a healthcare tool: design, implementation and assessment of a clinical pathways for lower-extremity deep venous thrombosis. *Qual Saf Health Care, 18*, 314-320.	Spain	Care pathway design and controlled non-randomized cohort	• Multidisciplinary team development of a DVT clinical pathway • Reduction in mean length of stay and stay related hospital costs	Explanatory accounts

Table F.1 EA table

Reference	EA ID	EA	Comments	Reviewer code
01 Verdu et al 2009	001	if there is a clinical pathway then there is the defined optimal sequence, duration, and responsibility degree of interventions of doctors, nurses, and other health professionals		02
01	002	if there is a clinical pathway then there can be minimal delay, improved resource management, and maximal quality of care		02
01	003	if there are multidisciplinary teams made of local staff then a clinical pathway can be developed		02
01	004	if there is a clinical pathway then there is a shorter hospital stay		02
01	005	if there is avoidable variation (lack of ordering diagnostic tests, lack of vital signs monitoring, lack in specific nursing skills) then there is variation in the use of the clinical pathway		02
01	006	if there is a clinical pathway then there is a decreased rate of adverse events		02
01	007	if there is a high degree of implementation then there is guaranteed reliable results about the effects		02
01	008	if there is a large degree of variation in satisfaction survey questions then there is a low degree of reported satisfaction		02

Reference	EA ID	EA	Comments	Reviewer code
01	009	if satisfaction questionnaires are not given to or collected from patients then there is a low response rate		02
01	010	if there is variation in the degree of severity or complexity of a patient, new diagnostic or therapeutic techniques, or organizational changes then the length of hospital stay can be influenced		02
01	011	If there are new technologies and available information in an institution, then the implementation of a clinical pathway needs to be specific to that institution		02
01	012	If clinical pathways are implemented for DVT, then length of stay will decrease		01
01	013	if professionals improve coordination by defining interventions and responsibilities, then the pathway implementation will improve		01
01	014	If the CP is based on best evidence, then the pathway implementation will improve		01
01	015	If the CP is based on an established institutional commitment of care, then pathway implementation will improve		01
01	016	If patient/families are informed about daily expectations, PI will improve		01
01	017	If physicians are provided a powerful educational tool to outline		01

Reference	EA ID	EA	Comments	Reviewer code
		treatment plan and decision-making process, PI will improve		
01	018	If the recording of medical history is simplified and systematized in CP documents, then CI will improve		01
01	019	If there is a lack of teamwork and continuous improvement culture, CI will be reduced		01
01	020	If pathway has not been developed in rigorous and reproducible ways, then CI will be reduced		01
01	021	If there is reluctance to change among professionals, then CI will be reduced		01
01	022	If CP variances exist between the performed and the planned, then problems arise in patient care		01
01	023	If analyses of variances are detected early and their causes assessed, then solutions can be found		01
01	024	If clinicians and policymakers have a philosophy of collaboration, the use of CPs will be advanced		01
02 Bjurling-Sjober et al 2015	025	If clinical pathways are utilized in the context of ICUs then there is improved quality of care, increased adherence to best-practice guidelines, decreased time with mechanical ventilation, decreased length of ICU stay, and reduced hospital costs		02

Reference	EA ID	EA	Comments	Reviewer code
02	026	If there was a wish to improve and assure quality of care, then there were motives for implementing CPs		02
02	027	If there is a wish to facilitate of improve documentation, then there were motives for implementing CPs		02
02	028	If there are enthusiastic staff inspired by previous CP experience or education (bottom up) then there was initiative to implement CPs		02
02	029	If there are local interprofessional project groups made up of active local staff including physicians, then there is successful implementation of CPs		02
02	030	If there is early involvement by clinical staff beyond the project group then there is assured quality and legitimacy of the CPs, successful implementation and strengthened sustainability		02
02	031	If there is capability to search for evidence as well as previous CP experience, then there is facilitated implementation		02
02	032	If there is a lack of knowledge and experience, then there is a complicated implementation process and decreased quality of the CPs		02
02	033	If there are enthusiastic and supportive individuals in the project group, then there is improved implementation		02
02	034	If there is cohesive and regularly allotted time, then there is improved efficiency in developing CPs		02
02	035	If there is allotted time then there is the enabling of structured and		02

Reference	EA ID	EA	Comments	Reviewer code
		pedagogic education of staff, follow-up, evaluation, and renewal of CPs		
02	036	If there is a lack of manager and physician support, then there is undermined legitimacy of the CPs		02
02	037	If there are demonstrated effects of CPs and an interest at a national level, then there is motivation among managers to support		02
02	038	If a targeted patient population has infrequent diagnoses or treatment regimens, then CPs are more utilized		02
02	039	If a CP has daily relevance, then it facilitates its use		02
02	040	If there is a comprehensible and familiar format and terminology, then there is facilitated acceptance		02
02	041	If there is mandatory formal interprofessional training customize to the level of knowledge among staff, then there is a benefit for implementation		02
02	042	If there is brief multifaceted and repeated information in as many forums as possible then there is facilitated implementation		02
02	043	If there is specific timing of CP implementation, then there is less of a burden of excessive information		02
02	044	If there is practical support, enforcement guidelines, quick reference guides and an easily available knowledge base then there is facilitated implementation		02

Reference	EA ID	EA	Comments	Reviewer code
02	045	If there are repeated reminders, then CPs are incorporated in the daily habits of nurses		02
02	046	If there is regular feedback and evaluation, then there is benefit to implementation		02
02	047	If a CP is introduced on a trial basis and evaluated for advantages and disadvantages, then there is less resistance to CP introduction		02
02	048	If staff realize the benefit and aims of CPs, then change in adopting CPs can be achieved		02
02	049	If the steps to be followed of a CP were defined, there was a feeling of safe in the knowledge that the patients' care was quality controlled, help staying abreast through the knowledge base, improved efficiency and easier documentation then there were motivation to use the CPs		02
02	050	If staff are aware of a problem or a need for new knowledge, then there is successful implementation		02
02	051	If implementation of CPs is successful, then future CP implementation is easier		02
02	052	If there are individuals or groups that realize the usefulness of CPs and are enthusiastic enough to initiate implementation then the process continues as project groups, managers and staff also realize the usefulness of CPs and over time the habits of using CPs is created		02
02	053	If those involved realized the usefulness of CPs and managers realized the usefulness of time allotted for the implementation,		02

Reference	EA ID	EA	Comments	Reviewer code
		then enthusiasm and support emerged		
02	054	If CPs are user-friendly and have perceived benefits for staff and patients then staff realize the usefulness of CPs		02
02	055	If an implementation strategy is multifaceted then it is more successful		02
02	056	If there is insufficient EHR, complex patient populations, and large staff then implementation is more complicated		02
02	057	If habits are created, with the aid of enthusiasm, support and time, then successful implementation can occur		01
02	058	If EHRs systems are insufficient, insufficient support and lack of time, barriers to implementation will occur		01
03 Kirk et al 2016	059	If there are insufficient resources, a lack of understanding about the distinction between screening and assessment tools, and perceptions of screening tools as superficial and poorly adapted to the local context then there are barriers to the implementation of screening tools	Theoretical domains framework - Cane 2012 Mazza et al 2013 Murphy et al 2014 Tavender et al 2014 French et al 2012	02
03	060	If there is a local staff culture focused on patient flow, then screening tools that do not support flow are not successfully implemented		02

Reference	EA ID	EA	Comments	Reviewer code
03	061	If there is the belief that the use of a screening tool doesn't benefit daily work, then staff do not view it as being part of their daily routines		02
03	062	If staff perceive that a tool is superficial relative to their expertise in an area, then they can be ambiguous about whether implementation of the tool would support their professional identity and role		02
03	063	If a group of specialized staff feel that they had a reputation in the organization as being loyal, dedicated and enthusiastic in relation to new projects then implementation of the tool would support their professional identity		02
03	064	If staff considered the use of a particular screening task as within their core role (professional boundaries) then they would expect that implementation would be successful		02
03	065	If staff considered a tool to simple or superficial to their roles, then they wouldn't adopt it		02
03	066	If staff believe that using the tool would result in less time for what they perceive is more urgent or essential work, then there would be a barrier to implementation		02
03	067	If a manager assists in the prioritization of tasks including screening, then there would more successful implementation		02
03	068	If staff perceive that a tool would threaten their pride and joy in their role then they would not adopt it		02
03	069	If a tool is agreeable to professional roles and identity, then it		02

		makes sense to staff		
03	070	If a tool is perceived to improve communication, then staff are more open to the idea of using the tool		02
03	071	If there is evidence that a tool adds value, then staff are more included to use it		02
03	072	If a tool can be shown to provide staff with new information on their patients then they are more inclined to view it favourably.		02
03	073	If the tool is identified as a priority by managers, then staff would be more supportive of it if it were to take more time from other tasks		02
03	074	If a screening tools is perceived as complicated, then staff believe additional staffing resources are required for successful implementation		02
03	075	If a screening tool is not perceived as comprehensive and as a support to their professional responsibilities, then there is a barrier to implementation		02
03	076	If a screening tool creates a workflow that is contrary to the normal priorities or inhibits achieving the goals of those priorities, then there is a barrier to implementation		02
03	077	If different groups intended to use the same tool attach different meanings and sense to the tool, then there is the potential barrier to implementation		02
03	078	If is not aligned with groups' culture, autonomy and professional		02

Reference	EA ID	EA	Comments	Reviewer code
		identity then they might perceive their everyday practices be threatened thus they set-up boundaries to secure their work practices		
03	079	If nurses feel instrument use would not be part of their daily routine, then they would not use it		01
03	080	If nurses feel instrument use would not be important, then they would not use it		01
03	081	If instrument use does not fit with professional identity and role, then they would not use it (e.g. too superficial for use as 'expert')		01
03	082	If instrument use fits with self-perception/reputation of loyal, dedicated, enthusiastic, then they would use it		01
03	083	If instrument use does not match perception of competency, then they would not use it		01
03	084	If instrument is perceived as too time consuming, then they will not use it		01
03	085	If the instrument is perceived to facilitate or improve communication, then it was perceived as usable		01
03	086	If resources are dedicated to implementation (staff), then it will occur		01
03	087	If leadership demanded its use and indicated which tasks not to prioritize, then instrument would be implemented		01

Reference	EA ID	EA	Comments	Reviewer code
04 Turi and Von Ah 2013	088	If there is a system for notifying ICU included in the sepsis bundle, then there is an increased likelihood that the more advanced monitoring will be done		02
04	089	If there is collaboration among departments, preplanning and education of ED and ICU nursing staff then there is successful implementation of SSC bundles.		02
04	090	If nursing staff are not educated in the presenting symptoms of sepsis and the individual components of the SSC guidelines, then initiation of the bundle is less likely due to the subtle symptomatology of sepsis		02
04	091	If there is training of nursing staff, SSC guidelines will be followed more thoroughly		01
05 Bahtsevani 2010	092	If CPGs are evidence-based, function to reduce the complexity of decision making, reflect current standards and require few new skills then they are more likely adhered to		02
05	093	If a CPG is produced within a structured program, then they are more frequently of higher quality		02
05	094	If there is concern about the risk of having too many CPGs resulting in the perceived risk of stagnated individual critical thinking, reduced independence and a false sense of security then implementation is less likely	A theoretical conceptual framework to enable the implementation of evidence-based practice, focusing on the complex	02

Reference	EA ID	EA	Comments	Reviewer code
			interplay of elements as evidence, context and facilitation, does exist - reference 14	
05	095	If the prevailing perception is that a particular CPG benefits the patients and is useful in giving support and guidance to staff, then it will contribute to a climate of receptiveness to change		02
05	096	If there is a receptiveness to change then it is expected that use of a CPG will bring about better and safer patient care and staff confidence		02
05	097	If there is an awareness of a need to prevent the forgetting of important tasks and supporting work that is less familiar to providers, then there is motivation to use CPGs and ensure patient safety		02
05	098	If there is concern about unclear routines or external demands, then CPGs can function is an opportunity for a knowledge utilization strategy to keep up-to-date with research and care development		02
05	099	If the need for CPGs originates from a bottom-up identification of problems from providers, then implementation is more straightforward		02
05	100	If there are facilitators and a working team of experts within different professions, then there can be enthusiasm for implementation		02

Reference	EA ID	EA	Comments	Reviewer code
05	101	If there is adjusting CPGs to local conditions, preparing a documentation system, reminders and arrangements for evaluation then preparation and adjustment for implementation can be done		02
05	102	If CPGs are based on research or authoritative sources then there is enhanced willingness to use the guideline, more so for physicians than nurses		02
05	103	If a CPG clearly outline what one is supposed to do, or not do, including visual references then there is the perception that it is easy to understand and follow		02
05	104	If there is a perception that a CPG is useful and beneficial for the patients then a positive attitude is promoted among staff and implementation can progress more independently		02
05	105	If the manager is part of the working team that drives the implementation, then the process is considered to be more important		02
05	106	If there is physician participation, then there is increased willingness of staff to use the CPG		02
05	107	If there are follow up and feedback strategies such as reminders, evaluations and continuous updating of the CPG then CPGs are better promoted, and use ensured.		02
05	108	If staff are united, enthusiastic, and worked together strategically then the changes needed for implementation took place		02
05	109	If there is divergence, even unavoidable, and uncertainty of the application of CPGs (difference recommendations for similar		02

Reference	EA ID	EA	Comments	Reviewer code
		CPGs) then there can be confusion in utilizing CPGs		
05	110	If there is the creation of useful contacts across boundaries of practice, collaborative knowledge development, consensus among staff and support from experts then there is inspired confidence in the implementation of CPGs.		02
05	111	If there is a functional computerized documentation system, then there is constant application of CPGs and increased awareness of the most recent revisions		02
05	112	If there is supervision through informal discussions or structure and rigorous planned evaluations (audits and indicators) then there is greater compliance and demonstrated importance of the application thus motivation to perform		02
05	113	If staff participate in the evaluation, then they become aware and gain insight into the situation and feel that they can influence the quality of care		02
05	114	If there is increased knowledge among staff then patients receive more rapid attention and better information, which strengthens their ability to cope and reduce the risk of complications during their hospital stay		02
05	115	If there are CPGs then staff develop their critical thinking focusing on knowledge based on facts and the possibility of performing care activities based on research		02
05	116	If there is an implemented CPG then staff are reassured that their actions were appropriate		02

Reference	EA ID	EA	Comments	Reviewer code
05	117	If staff are familiar with a CPG then they have a positive attitude towards it and other CPGs, try to act in line with its recommendations, and exhibit a willingness to share the knowledge gained with others		02
05	118	If CPG implementation is continuous with reliable and tenable routines that involve all staff members, then implementation is successful (Figure 1)		01
05	119	If CPG implementation occurs, the proper motives for initiating and using CPGs have been elicited (Figure 1)		01
05	120	If CPG implementation involves the expectation to lead to better and safer patient care	Expectation of better/safer patient care (mechanism)	01
05	121	If CPG are implemented, then knowledge and confidence are increased among staff	Outcome	01
05	122	If staff receive continuous feedback, then CPG implementation is increased		01
05	123	If CPG is evaluated, then nurses can see the importance of the results		01
06 Dodek 2010	124	If there is high quality of evidence to develop guidelines; credibility of the professional group that developed the guidelines; practicality and feasibility of the recommendations; strategies used to assist in implementation; financial implications of implementing or not implementing; and contextual factors including patient, provider and organization characteristics then	Organizational culture - "the invisible force behind the tangibles and observables in any	02

Reference	EA ID	EA	Comments	Reviewer code
		there can be successful implementation	organization, a social energy that moves people to act. Culture is to an organization what personality is to the individual— a hidden, yet unifying theme that provides meaning, direction, and mobilization." reference 6	
06	125	If there is an organizational culture that conveys beliefs, values, and norms suggesting group members are respected and fairly treated then there is greater influence on specific attitudes and behaviours.		02
06	126	If an organization has a questioning culture then it encourages staff and managers to question evidence base for important decisions, encourage participation in research and education, and analyze results of strategic and operational decisions.	Reference 11, 12	02
06	127	If there is the perception that appropriate checkpoints and deadlines are established when major changes are implemented, then there is knowledge of CPG		02
06	128	If there is consistent participation by providers in activities to improve quality of care, then there is adherence to CPGs		02

Reference	EA ID	EA	Comments	Reviewer code
06	129	If there is performance feedback and shared beliefs/attitudes about the role of guidelines amongst leaders, managers, and providers then there is an organizational culture that supports CPG implementation		02
06	130	If there is a shared organizational clinical goal, visible management support to enable a practice, fostering of innovation and flexibility in implementing protocols, uncompromising clinical leaders, collaborative interdisciplinary teams, data feedback to monitor progress, and an organizational culture that fostered persistence then there is an organizational culture that supports CPG implementation		02
06	131	If the organizational culture includes non-blaming approach to identifying problems and a shared vision of the goals of a program, then it supports CPG implementations		02
06	132	If leadership strategies include facilitating staff to use CPGs, creating a positive milieu of best practices, and influencing organizational structures and processes to ensure education, monitor outcomes, and support clinical champions then there is organizational support for CPG implementation		02
06	133	If there is an established interdisciplinary team, leadership support, collaborative decision making, a patient-centered approach, mentorship, group learning, respect for expertise of each team member, a readiness to embrace change, informal, open communication, and a positive work environment then there is successful adherence to CPGs	Framework for understanding guideline adherence in the ICU - reference 40	02
06	134	If there is not a supportive organizational culture for CPGs then a		02

145

Reference	EA ID	EA	Comments	Reviewer code
		revision of professional roles, interdisciplinary teams, integrated care services (e.g., care pathways, protocols), knowledge management (e.g., computer systems), and quality management (e.g., continuous quality improvement, supportive leadership) can lead to a changed culture		
06	135	If there is an established multidisciplinary team, then there is greater adherence to the CPG		01
06	136	If there is support of leadership support, then there is greater adherence to the CPG		01
06	137	If there is collaborative decision making, then there is greater adherence to the CPG		01
06	138	If there is a patient-centered approach, then there is greater adherence to the CPG		01
06	139	If there is formal / informal mentorship, then there is greater adherence to the CPG		01
06	140	If there is group learning, then there is greater adherence to the CPG		01
06	141	If there is respect for expertise of each ICU team member, then there is greater adherence to the CPG		01
06	142	If there is an attitude of innovation: embracing change, then there is greater adherence to the CPG		01
06	143	If there is informal, open communication, then there is greater adherence to the CPG		01

Reference	EA ID	EA	Comments	Reviewer code
06	144	If there is a positive work environment, then there is greater adherence to the CPG		01
07 Ishii 2013	145	If there is leadership commitment to provide resources for guideline planning, education, system participation and incentives then there can be implementation of guidelines		02
07	146	If, for physicians, there is dissemination through multiple approaches (grand-round lectures, peer-to-peer consultation, print and online materials, and physician champions) of guideline information then there is improved implementation		02
07	147	If there are predetermined metrics for effectiveness and adherence, then reliable data governance and management enable ongoing monitoring and feedback		02
07	148	If there is reliable monitoring and feedback, then providers will be able to review their performance on a regular basis		02
07	149	If providers are able to compare their performance with local or national peers, then there can be greater adherence to achieving outcome measures		02
07	150	If there is the empowerment of stakeholders through active engagement in the decision-making processes, then there is greater ownership and a sense of loyalty		02
07	151	If there is an incentive model for recruiting physician champions and provider participation, then this will encourage participation in these activities		02
07	152	If a CPG is to be implemented, then commitment of the leadership		01

Reference	EA ID	EA	Comments	Reviewer code
		needs to occur		
07	153	If a CPG is to be implemented, an education plan for providers must also be implemented		01
07	154	If a CPG is to be implemented, a systems plan must be implemented		01
07	155	If a CPG is to be implemented, an incentive plan must exist		01
07	156	If a CPG is to be implemented, then adequate resources must be allocated to support staff/provider time for planning, education, analytics		01
08 Jiwaji 2014	157	If there are perceptions that protocols cannot be adopted because of competing workload demands, inadequate/unavailable equipment, insufficient number of staff or insufficiently trained staff then aspects of protocol care are not completed, and protocol targets are not met (poor compliance)		02
08	158	If there are inadequate numbers or availability of appropriately trained staff and high staff workload, then barriers to guideline implementation occur		01
09 Jones 2007	159	If in the pre-implementation phase an interdisciplinary team can identify concerns about a protocol, then an action plan can be developed to proactively address the issues	SSC guidelines did not address the ability to translate the protocol use from research driven to operational driven	02

Reference	EA ID	EA	Comments	Reviewer code
09	160	If there is an organized approach pre-implementation then there can be the development of a handbook outlining rationale and approach of the protocol, summary guides, advertising informative summaries, and nursing flow sheet		02
09	161	If there is early and active efforts from a multidisciplinary team then there can be thorough and complete penetration of the protocol into routine practice		02
09	162	If there is specific and agreed upon protocol criteria, then there is less duplication of diagnostic assessments by multiple services (i.e. ED and ICU when admission for severe sepsis will be ICU)		02
09	163	If there is communication about specific cases to the provider (email care case summary, compliments or pointers on how to maintain compliance, follow-up information on the patient's subsequent clinical course) then there is a level of accountability and surveillance established to maintain the protocol in everyday work flow		02
09	164	If there is protocol agreement by all the physicians of the targeted services, then there are less barriers to implementation		02
09	165	If there is targeted separate and shared education on the protocol specifics and the rationale for physicians and nurses, then there are less barriers to implementation		02
09	166	If there is reluctance on the part of physicians to adapt to changes specific to an EGDT protocol, then there is a barrier to the protocol being implemented		02
09	167	If there is intensive education and continued meetings regarding		02

Reference	EA ID	EA	Comments	Reviewer code
		the protocol amongst physicians, then there is less of a barrier to protocol implementation		
09	168	If there is not adequate time and resources for a structure quality improvement approach to EGDT then there is not adoption of a protocol into routine practice	Reference 14 may be useful to include	02
09	169	If there is an implantation team of champions then there can be culture change, an organized approach, upfront training, and ongoing efforts to track and troubleshoot		02
09	170	If the EGDT protocol is adapted to specific institutions, then it is more likely to be implemented	Speaks to the need to consider individual institutional context	01
09	171	If the protocol requires extensive education and continued meetings, then staff may be reluctance to adapt		01
09	172	If new equipment and training is required, then protocol is less likely to be adapted		01
09	173	If time and resources do not exist (especially in community settings) to implement structured QA, then protocol is less likely to be adapted		01
10 MacRedmond 2010	174	If there is mandatory and paid education including theoretical lecture, early recognition, introduction of algorithm, followed by practical instruction and demonstration and buddied in ICU then there is improved identification of septic patients		02

Reference	EA ID	EA	Comments	Reviewer code
10	175	If introduction is done through PDSA cycles and using a pilot study, then EGDT was initiated more promptly and resuscitation goals met more quickly		02
10	176	If a simple algorithm is created and awareness is raised through extensive education, then there is clinically significant improvements in survival from sepsis		02
10	177	If there is positive feedback to staff on the implementation, then there is more enthusiasm for adoption of change		02
10	178	If there is enthusiasm for adoption of change then there is improved compliance with the protocol		02
10	179	If there is a collaborative model for EGDT between ED and ICU teams then the ED staff were empowered in the diagnosis and early management of severe sepsis		02
10	180	If there is a collaborative model developed for EGDT then resistance can be overcome		02
10	181	If nurses are educated, then they will improve in the identification of septic patients		01
10	182	If staff know the time-critical nature of sepsis treatment, then implementation is more likely to occur		01
10	183	If there is a collaborative model, then resistance to the delay in transfer of patients will be less		01
10	184	If invasive haemodynamic monitoring is introduced, then protocol will be followed		01

Reference	EA ID	EA	Comments	Reviewer code
11 McGoldrick 2016	185	If there is a belief that the clinical intervention will ensure optimum care of the patient, then implementation will be enabled (TDF belief and consequences)	References 1-3, 7, 8 worth considering Use of Theoretical Domains Framework (8)	02
11	186	If the administration of the intervention is routine practice and improves outcomes, then implementation will be enabled (TDF belief and consequences)		02
11	187	If the evidence that supports, the intervention is strong then implementation will be enabled (TDF knowledge)		02
11	188	If there is discussion of the intervention with the patient by the interdisciplinary team then administration of the intervention is facilitated (TDF social influences)		02
11	189	If administration of the intervention is a social norm then implementation will be enabled (TDF social influences)		02
11	190	If an intervention is readily available and easy to administer, then implementation is enabled (TDF environmental context and resources)		02
11	191	If adherence and use of clinical practice guidelines is part of the organizational culture, then implementation is enabled (TDF environmental context and resources)		02
11	192	If intervention use is directed by senior health professionals then implementation is enabled (TDF belief about capabilities)		02

Reference	EA ID	EA	Comments	Reviewer code
11	193	If use of clinical practice guidelines helps to standardize practice and ensure consistency, then implementation is enabled (TDF social professional role and identity)		02
11	194	If a new guideline will facilitate decision making, then implementation is facilitated (TDF social professional role and identity)		02
11	195	If the guideline is actively disseminated in a manageable format and include education and implementation resources, then implementation is facilitated (TDF behavioural regulation)		02
11	196	If there is uncertainty around the use of guidelines and practice doesn't necessarily reflect the evidence, then there is a barrier to implementation (TDF belief about consequences)		02
11	197	If the use of an intervention is known to be beneficial but concern exists around potential adverse effects, then there is a barrier to implementation (TDF belief about consequences)		02
11	198	If the knowledge on the evidence related to the guideline is limited, then there is a barrier to implementation (TDF knowledge)		02
11	199	If the evidence that supports, the guideline is conflicting then there is a barrier to implementation (TDF knowledge)		02
11	200	If there is a need to clarify the evidence regarding an guideline in specific populations then there is a barrier to implementation (TDF knowledge)		02
11	201	If there is confusion in the nature, timing, and course of treatment		02

Reference	EA ID	EA	Comments	Reviewer code
		then there is a barrier to implementation (TDF knowledge)		
11	202	If practitioner's understanding of an intervention primarily comes from what they witness in clinical practice, then there is a barrier to implementation (TDF knowledge)		02
11	203	If there is a lack of consistency and difference of opinion on what is viewed as correct practice, then there is a barrier to implementation (TDF social influences)		02
11	204	If there are competing tasks and time constraints, then there is constraint on using the intervention (TDF environment context and resources)		02
11	205	If there is ease of access, readability and implementation tools/education then guideline use is encouraged (TDF environment context and resources)		02
11	206	If clinical judgement supersedes decision making using clinical practice guidelines, then there is a barrier to implementation (TDF social professional role and identity)		02
11	207	If there are different beliefs between health professionals on the evidence supporting a guideline then there is a barrier to implementation (TDF belief about consequences)		02
11	208	If professionals have positive beliefs about the clinical outcomes of the CPG, then implementation will increase		01
11	209	If there is strong evidence for the administration for the use of the CPG, then the CP will be implemented	They also recognize research gaps	01

154

Reference	EA ID	EA	Comments	Reviewer code
11	210	If there is facilitated discussion with the team and patient, then CPG are more likely to occur		01
11	211	If the substance of the CPG is readily available and easy to administer, then implementation is more likely		01
11	212	If adherence/use of CPG is part of organizational culture, then implementation is more likely		01
11			Not sure how to EA "belief about capabilities"	01
11	213	If CPG are perceived to assist standardization and consistency in practice, then they are more likely to be implemented	Part of social professional role and identity	01
11	214	If CPG are perceived to assist decision-making in practice, then they are more likely to be implemented		01
11	215	If CPG are actively disseminated in a manageable format which includes education and implementation resources, then they are more likely to be implemented		01
11	216	If beliefs about consequences of CPG results are equivocal, then there is less likelihood they will be administered		01
11	217	If CPG evidence is limited, conflicting, comes solely from individual clinical practice unclear in specific populations, then implementation is less likely		01
11	218	If opinion on CPG vary or are inconsistent, then implementation		01

Reference	EA ID	EA	Comments	Reviewer code
		is less likely		
11	219	If time and task constraints exist, then implementation is less likely		01
11	220	If CPG access, readability, and implementation tools are high, then implementation is more likely		01
11	221	If CPG access, readability, and implementation tools are low, then implementation is less likely		01
11	222	If CPG is based in good evidence, then my use of it is more likely		01
11	223	If my social professional identity is strong, then my clinical judgement may supersede the CPG		01
12 Shapiro 2006	224	If there is a formalized patient identification program, consistent early provider notification, standardized order set, and systematic check to ensure administration of timely antibiotics then there is more rapid delivery and improved selection of antibiotics and decreased risk of mortality		02
12	225	If there is increased awareness of sepsis by physicians and nurses, then there is greater attention paid to septic patients and increased therapy delivery		02
12	226	If there are differing opinions and ongoing debate regarding ideal, controversial, and scientifically sound treatments then there are influences on protocol adherence and effectiveness		02
12	227	If traditional educational and process-change techniques are used, then a sepsis treatment pathway can be implemented	Test of 'real-world' pathway	01

Reference	EA ID	EA	Comments	Reviewer code
			implementation	
13 Campbell 1998	228	If there is high interest about an important area of practice, then an integrated care pathway can be developed		02
13	229	If there is support for a clinical pathway among local health staff, then an integrated care pathway can be developed		02
13	230	If a multidisciplinary group compare current practice with established clinical guidelines, then an integrated care pathway can be developed		02
13	231	If professionals are reluctant to change, CPG are less likely to be implemented		01
13	232	If there is lack of suitable evidence for CPG, it is less likely to be implemented		01
13	233	If there are obstructive interpersonal politics, then CPG less likely to be implemented		01
13	234	If there is inadequate time to develop CPG locally, then it's less likely to be implemented		01
13	235	If the environment doesn't credit quality improvements, then CPG less likely to be implemented		01
13	236	If there is adequate leadership (well informed and of high standing) coordinating the planning of initiative, then CPG more likely to be implemented		01
14 Mikkelsen 2010	237	If there is physician dissatisfaction with prescribed early goal-directed therapy service, then there is less compliance over time		02

Reference	EA ID	EA	Comments	Reviewer code
14	238	If there is the perception amongst physicians that consultation with specialized services supporting EGDT is not necessary over time, then there is less compliance over time		02
14	239	If there is inertia with historical physician practice, then there is less adherence to EGDT protocols		02
14	240	If there is less disease severity among potentially eligible patients then there can be less timely decision to apply EGDT		02
14	241	If patients are female, have less severe disease, EGDT is less likely to be implemented	Patient level barriers	01
14	242	If physician is female, then EGDT is less likely to be implemented	Physician level barrier	01
14	243	If Severe Sepsis Service is not activated, EGDT is less likely to be implemented	Organizational level barrier	01

Table G.1 CA table

EA ID	CA	CA ID	Mechanism theme	TDF construct	Implementation effect
092	The characteristic of being evidence-based leads to reduce complexity in decision making, increases adherence to practice that reflects current standards and lessens the burden of having to acquire new skills	CA023	Decision making	Reinforcement Skill development	+
214 092 117	Perceptions that an intervention requires few new skills while being evidence-based leads to a willingness to share the knowledge gained with others, which results in successful implementation.	CA024	Willingness to share	Social support	+
124 102 187 014	Inclusion of high-quality evidence in intervention development; credibility of the professional group that developed the guidelines; practicality and feasibility of the recommendations; strategies used to assist in implementation; financial implications of implementing or not implementing; and patient and provider contextual factors leads to an enhanced willingness to use the invention, which benefits implementation	CA025	Willing to use	Stability of intentions	+
117	Familiarity with a type of intervention leads to a positive attitude towards it and other similar interventions, a willingness to try and act in line with recommendations, and a willingness to share the knowledge gained with others, which results in successful implementation.	CA026		Stability of intentions	+

EA ID	CA	CA ID	Mechanism theme	TDF construct	Implementation effect
050 070 097 086 085	Staff perceptions that an intervention addresses the need to improve communication, prevent the forgetting of important tasks, ensure patient safety and support work that is less familiar leads to motivation to use the intervention, which results in successful implementation.	CA007	Motivation	Stages of change	+
050 070 097 085	Staff perceptions that an intervention addresses the need to improve communication, prevent the forgetting of important tasks, ensure patient safety and support work that is less familiar leads to motivation to use the intervention, which results in successful implementation.	CA007	Motivation	Stages of change	+
048 054	Interventions that are seen as user-friendly and that benefit staff and patients leads to an understanding of the aims of the intervention and the realized usefulness, which results in the adoption of the intervention.	CA001	Understanding	Procedural knowledge	+
101 103	A clearly outlined intervention that can be adjusted to local conditions leads to the perception that the intervention is easy to understand and follow, which benefits implementation	CA005	Understanding	Beliefs	+
193 194	Interventions that help to standardize practice and ensure consistency lead to facilitated decision making, which facilitates successful implementation	CA020	Decision making	Decision making	+

EA ID	CA	CA ID	Mechanism theme	TDF construct	Implementation effect
204 066 076 084	Staff perceptions that an intervention is overly time consuming or less urgent or essential than other competing workload demands leads to the judgement that it is contrary to the normal workflow priorities and inhibits achieving the goals of those priorities, which results in unsuccessful implementation.	CA008	Judgement	Goal priority Barriers	-
062 065 068 081 083	The perception that an intervention is too simple or superficial relative to professional expertise or that it threatens the pride and joy in a role leads to ambiguity as to whether the intervention would support a professional identity and role, which inhibits implementation.	CA016	Professional identity	Social/profession al role and identity	-
201 203 207	Confusion or a difference of opinion between professionals about the nature, timing, and course of treatment for an intervention inhibits implementation	CA019	Confusion	Knowledge	-
099 159	Interventions based on bottom-up identification of problems or concerns from interdisciplinary team providers leads to action planning to address the issues, which benefits implementation	CA036	Action plan	Action planning	+
110	The creation of useful contacts across boundaries of practice, collaborative knowledge development, consensus among staff and support from experts leads to inspired confidence in an intervention, which benefits implementation	CA035	Confidence	Optimism	+

EA ID	CA	CA ID	Mechanism theme	TDF construct	Implementation effect
124 102 187 014	Inclusion of high-quality evidence in intervention development; credibility of the professional group that developed the guidelines; practicality and feasibility of the recommendations; strategies used to assist in implementation; financial implications of implementing or not implementing; and patient and provider contextual factors leads to an enhanced willingness to use the invention, which benefits implementation	CA025	Willing to use	Stability of intentions	+
059	A lack of understanding about the purpose of an intervention and perceptions that an intervention is poorly adapted to the local context then implementation is inhibited.	CA002	Understanding	Procedural knowledge	-
168	Adequate time and resources for a structure quality improvement approach to introducing an intervention leads to adoption of the intervention into routine practice	CA032	Adoption	Stages of change	+
123 147	Evaluation using predetermined metrics for effectiveness and adherence, and ongoing monitoring and feedback lead to nurses seeing the importance of the intervention	CA014	Positive belief	Outcome expectancies	+
019 036	A lack of manager and physician support for teamwork and continuous improvement culture leads to undermined legitimacy of an intervention, inhibiting implementation	CA029	Legitimacy	Organizational culture/climate Leadership	-

EA ID	CA	CA ID	Mechanism theme	TDF construct	Implementation effect
078	An intervention is perceived to be maligned with a groups' culture, autonomy and professional identity leads to the perception that everyday practices are threatened and the establishment of boundaries to secure their work practices	CA030	Perceived threat/risk	Organizational culture/climate Leadership	-
094	Concern about the risk of having too many standardized interventions leads to the perception that there is a risk of stagnated individual critical thinking, reduced independence and a false sense of security, which results in inhibited implementation	CA031	Perceived threat/risk	Decision making	-
013	Defining intervention responsibilities leads to improved coordination amongst health care professionals, which benefits implementation	CA038	Collaboration/coordination	Group norms	+
052 053	Individuals or groups that realize the usefulness of an intervention and participate in initiating implementation leads to enthusiasm and support for the intervention amongst other managers and staff, which results in the habit of using the intervention.	CA009	Enthusiasm	Positive/negative effect	+
150 030	Active engagement by stakeholders through early involvement in the decision-making process leads to assured quality, legitimacy, empowerment, greater ownership, and a sense of loyalty, which benefits implementation and strengthened sustainability.	CA041	Users	Professional identity	+
047	Introduction of an intervention on a trial basis and evaluated for advantages and disadvantages leads to less resistance, benefiting implementation	CA040	Resistance	Breaking habit	+

EA ID	CA	CA ID	Mechanism theme	TDF construct	Implementation effect
048 054	Interventions that are seen as user-friendly and that benefit staff and patients leads to an understanding of the aims of the intervention and the realized usefulness, which results in the adoption of the intervention.	CA001	Understanding	Procedural knowledge	+
176 225 115	Extensive education of an intervention leads to greater awareness of the target condition and patient population and the development of fact-based critical thinking and evidence-based practice	CA004	Understanding	Knowledge of task environment Skills development	+
208	Positive beliefs about the clinical outcomes related to an intervention results in successful implementation.	CA012	Positive belief	Outcome expectancies	+
109	Divergence in practice from the outlined intervention leads to confusion amongst others in how to apply the intervention, which inhibits implementation	CA018	Confusion	Barriers	-
196 217 232	Uncertainty around the limitations of the evidence, the applicability of the evidence for a specific population, conflicting evidence, or the role of anecdotal evidence from individual clinical practice and how the intervention reflects the evidence inhibits implementation	CA034	Uncertainty	Procedural knowledge	-
045 057 079	The incorporation of repeated reminders that are a part of an intervention lead to the development of daily habits among staff, which results in successful implementation	CA027	Develop daily habits	Breaking habit	+

EA ID	CA	CA ID	Mechanism theme	TDF construct	Implementation effect
050 070 097 085	Staff perceptions that an intervention addresses the need to improve communication, prevent the forgetting of important tasks, ensure patient safety and support work that is less familiar leads to motivation to use the intervention, which results in successful implementation.	CA006	Motivation	Stages of change	+
130	An organizational culture that includes visible management support and data feedback to monitor progress leads to enabled practice, which benefits implementation	CA028	Enabling	Organizational culture/climate	+
177 178	Positive feedback to staff on the progress of implementation leads to enthusiasm for the adoption of change, which benefits implementation	CA011	Enthusiasm	Positive/negative effect	+
023	Early detection, cause assessment and analyses of variation in intervention use leads to problem solving, benefiting implementation.	CA022	Decision making	Ability	+
163	Communication about specific cases to providers (email care case summary, compliments or pointers on how to maintain compliance, follow-up information on the patient's subsequent clinical course) leads to accountability amongst practitioners and maintained use in everyday work flow, which benefits implementation	CA037	Accountability	Professional role Breaking habit	+

Table H.1 Draft program theory

CA ID	Additional reference	Resource (mechanism)	Context	Reasoning (mechanism)	Outcome
CA001 CA005 CA007 CA020 CA023 CA024 CA025 CA026	Tarrant et al., 2016	Integrated evidence-based practice	Busy work environment (A busy work environment is a clinical setting that includes one with a patient population where highly acute patients are frequently encountered, a setting with high degree of patient flow, competing demands for clinician time and attention and regular operational change.)	Enhanced end-user decision making self-efficacy (Including the perception of reduced complexity and reinforced comfort in decision making; the perception that the intervention provides new patient information to support less familiar work)	Acceptability of the intervention (Acceptability encompasses the satisfaction with various aspects of the clinical intervention [including content, complexity of use, comfort in the purpose, delivery in the clinical setting, and credibility])
			Collaborative adaptation of the intervention for local use (Collaborative adaptation includes interdisciplinary engagement of clinicians in adaptation [e.g. protocol development] and	Belief that the intervention is valid for the setting, easy to understand and easy to use Belief in the purpose and benefit for end-users and patients in using the intervention	

CA ID	Additional reference	Resource (mechanism)	Context	Reasoning (mechanism)	Outcome
			changing responsibility for initiating and completing care activities to others in order to meet targets [e.g. from physicians to nurses].)	Perceived credibility of the local intervention development group Perception of improved communication amongst end-users Perception of decreased coordination complexity and task interdependence in providing patient care	
			Targeted behaviour change (Includes the use of supportive interventions that are designed to change behaviors necessary to support a change in clinical practice [e.g. use of the Behaviour Change Wheel].)	Perception that intractable difficulties in clinical practice become possible to address Belief that an intervention appropriately addresses the need	
CA008 CA016 CA019		Integrated evidence-based practice	Busy work environment (A busy work environment is a clinical setting that includes one with a patient population where highly	Perception that the intervention is misaligned with everyday practices (less urgency than other work, contrary to normal	Inhibited acceptability of the intervention (Failure to reach satisfaction with

CA ID	Additional reference	Resource (mechanism)	Context	Reasoning (mechanism)	Outcome
			acute patients are frequently encountered, a setting with high degree of patient flow, competing demands for clinician time and attention and regular operational change.)	workflow priorities and inhibits achieving the goals of those priorities)	one or more of the various aspects of the intervention.)
			Intervention standardization (Includes the standardization of an intervention across boundaries of practice and local areas within an organization.)	Belief that there are differences about the nature, timing and course of treatment within an intervention Perceived threat to professional culture, identity and autonomy Belief that clinical decision making is made overly simple discouraging the development of skills, abilities and independence	
			Non-collaborative adaptation of the intervention for local use (Multiple local adaptations of the same intervention	Confusion in decision making (consistency in choosing between alternative actions)	

CA ID	Additional reference	Resource (mechanism)	Context	Reasoning (mechanism)	Outcome
			within the same organization.)		
CA002 CA014 CA025 CA032 CA035 CA036	Tarrant et al., 2016	Interdisciplinary implementation team (Includes engaging clinicians, facilitators and experts from across boundaries of practice to participate in implementation.)	Evaluation against current state (Includes evaluating how the intervention might affect clinician current state workflow through activities, such as process mapping, and identifying failures and operational weakness in delivery care; analysis of predetermined performance goals/metrics.)	End-user perception that the intervention recommendations are practical and realistic	Feasibility to adopt the intervention (Feasibility describes the utility, suitability and trialability of the intervention.)
			Awareness of the implementation strategy (Includes dedicated time and resources for all stages	Perception that the introduction of the intervention will not be disruptive	

CA ID	Additional reference	Resource (mechanism)	Context	Reasoning (mechanism)	Outcome
			of implementation; a theory and evidence-based implementation approach)	Belief that there is consensus and collaboration amongst end-users across boundaries of practice	
		Trial implementation (Involves inclusion in the evaluation of the outcomes, advantages and disadvantages of the trial.)	Active stakeholder engagement	Confidence in the intervention Perceived end-user sense of assured quality, legitimacy, empowerment and ownership	
CA001 CA004 CA009 CA012 CA038 CA040 CA041	Steinmo et al., 2015	Education on the aims of the clinical intervention (Includes instruction on how to use the intervention and when to implement, information about health consequences [e.g. the story told of a patient that died from sepsis], severity and susceptibility of sepsis,	Broadly accessible information (Includes such activities as video instruction on intervention steps, intranet resource instruction on implementation, support for implementation and monitoring step completion [e.g. Smartphone app with instructions and timer].)	Perceived clarity in understanding the purpose and the benefit for the end-users and patients Positive belief about the importance of the clinical outcomes	Adoption of the intervention (Adoption describes the uptake and utilization of the intervention.)

CA ID	Additional reference	Resource (mechanism)	Context	Reasoning (mechanism)	Outcome
		and evidence for the efficacy of the sepsis intervention for improving patient outcomes.)	Participatory interdisciplinary training (This includes opportunities for observation and practice in simulation exercises.)	Confidence in critical thinking about the target condition and patient population and how/when to apply the intervention End-user perception of legitimate authority to use clinical discretion in commencing initiation of the intervention	
CA003 CA006 CA011 CA022 CA027 CA028 CA037	Steinmo et al., 2015 Tarrant et al., 2016	Clinical support resources (Including workplace reminders about the intervention, visual prompts [e.g. poster, flowchart], intervention checklist [e.g. pocket reference card] or electronic practice guideline for completion of each step)	Busy work environment (A busy work environment is a clinical setting that includes one with a patient population where highly acute patients are frequently encountered, a setting with high degree of patient flow, competing demands for clinician time and attention and regular operational change.) Cooperative PDSA problem solving	Perception that end-users are enabled to refine skills, abilities and independence to form new habits End-user realization of the need to change habits	Fidelity to the intervention (Fidelity describes the adherence to and, integrity and quality of the intervention.)

CA ID	Additional reference	Resource (mechanism)	Context	Reasoning (mechanism)	Outcome
		Dissemination of performance data and case specific feedback (Includes daily implementation rates, comparison of current performance with target, patient outcome data, analysis of variation in intervention use, high-performers' characteristics of practice [e.g. Positive Deviance Approach], care case summary, compliments or pointers on how to maintain compliance, follow-up information on the patient's subsequent clinical course)	(Include problem identification, root cause analysis, planning, implementing revisions and evaluation for change.)	Motivation to consciously decide to perform the requisite behaviours as outlined in the intervention Persuasion to develop a sense of professional accountability	

Table I.1 Focus group data

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
FGR01	• so, I think the most important outcome as an, as a, as the absolute end goal, um, is at the apex would be the fidelity (FG75)	n/a	Fidelity - priority outcome	Refine – outcome priority	but in order to have a sustained, good outcome, there needs to be reproducibility and repeatability, reliability in our system. And that speaks to that fidelity (FG78) is a measurement of reliability and of success of your process, your process change actually, probably, the process, the process change (FG85) process whereby we can demonstrate that one of two options is, is better than the other (FG104)
FGR02	• using that old tipping point theory, you need, and push, and push, and push, and push until you get enough momentum that it becomes self-sustaining. And, maybe part of this fidelity is, is	n/a	Accessibility, feasibility, adoption - relevant intermediate outcomes	Refine – outcome priority	Pick an interim analysis time (FG600)

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	that we looked at fidelity, or we've contemplated that fidelity as a marker of success, in my mind anyway, yet we looked too quickly. And, we haven't looked at those other markers, (flipping paper) the preceding four, three, three maybe, the acceptability of the model, the feasibility of its continued progress, and then adoption (FG401). • … maybe we did the fidelity testing a little too soon (FG414). • … we're not even sure that the adoption was a significant volume …(FG425). • … but talking to this fidelity, maybe the measure changes over time (FG299).				
FGR03	• we all tend to be data driven (FG100) • if you, if you can't sell me on a data point then I	dissemination of performance data and feedback → cooperative PDSA problem solving → **Belief in the value**	Mechanism – belief in the value of data	Refine – mechanism	

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	believe I am doing good or you believe I'm doing poorly (FG101) • Because we have to see value in what we're doing. And, all disciplines have to see value in what they're doing (FG117)	**of data informed practice →** fidelity	informed practice		
FGR04	• Is the process that's been adopted as a PDSA idea… is that has a change in process brought about positive change, is it a positive change that's come about (FG106) • is the change in process, that we've observed, valuable, and if not or detrimental we have to change the process; if it is valuable then it's a positive feedback loop (FG108)	dissemination of performance data and feedback → cooperative PDSA problem solving → **Belief in the value of PDSA problem solving →** fidelity	Mechanism – belief in the value of PDSA problem solving	Refine - mechanism	
FGR05	we have empathy with these patients. That's our, and that is our accountability. Because of our empathy, our alignment with these patient's outcomes, we don't	dissemination of performance data and feedback → cooperative PDSA problem solving → **empathy with patients →** fidelity	Mechanism – empathy with patients	Refine – new mechanism	

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	do, we don't repeat the harm cycle, potential harm cycle, again (FG344)				
FGR06	if you use sepsis as an example… it's an easy why to ask because it makes everyone uncomfortable. With sepsis you're the worst performer… that's a very easy, an easy question to ask. And it makes everyone feel a little twitchy because it's an embarrassing place to be. (FG149) I mean when you make a misstep clinically you feel awful (FG268). The clinical self-reflection bit (FG270). … So, how did somebody else make it better. Why are we higher than they are? What are we doing right and what are we wrong? And, then we looked at are there wrongs and tried to make them right (FG127)	dissemination of performance data and feedback → cooperative PDSA problem solving → **pride in providing quality care** → fidelity → **clinical self-reflection** → fidelity → **sense of accountability** → fidelity	Mechanism – change persuasion to develop accountability Context – Positive deviance approach	Refine – new mechanisms	

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
FGR07	• it [the clinical problem] has to be significant in the context of something else. So, in the ICU it maybe ventilator associated pneumonias, which is not valuable anywhere else… And that, that's a big contextual why. And to make each of those working groups take ownership or contemplate ownership anyway. (FG157) • the why [the clinical problem] has to have significance and the significance is in the context of where you are and who you're dealing with (FG162) • … we didn't give them the appropriate, the inappropriate care these patients got, and also allows us to go speak with administration to, the resource governors as it were, to lend us a hand. And it gives us that, that power, that ability to go	dissemination of performance data and feedback → **local team cooperative PDSA problem solving** → perceived ownership → fidelity	Context – local team PDSA	Refine - context	A PDSA process that reflects dynamic needs that a specific intervention fits within, triggers ownership

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	and ask elsewhere (FG340) • if you can increase awareness at the patient's bedside, um, you're going to get faster response and improved outcomes (FG725) • so we had matrixes set up and we actually chose sepsis on [the unit] (FG288)				
FGR08	• …when I look at the implementation resources there, dissemination of performance data and feedback, it seems like there should be something almost before that, which is the collection of the appropriate data…(FG360) • … we compared oranges to apples (FG358). • …we've identified that the coding is an issue…(FG364)	Mechanism dissemination of performance data and feedback → cooperative PDSA problem solving → **trust the data reflects reality** → fidelity	Mechanism - trust the data reflects reality	Refine – new mechanism	
FGR09	• You have to look at it from a multidisciplinary approach, right, to see the	Interdisciplinary teams	Context	Confirm - context	

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	why and how, and what do we need to change to make that why better (FG123)				
FGR10	• Time, what I meant by time, is um give the process time, give the tool… time to mature (FG133)	Trial implementation	Context	Confirm - context	
FGR11	• The resources are big, whether it's for data collection or… tangibles that you need… to prove that [the clinical problem] in order to get those things (FG167) • …you would collect data and give me some data (directed at one of the other participants), I would look at charts and then try to find where our problems really did lie, ok. So, we had this delay but really what did it come down to. And, I think it was that because you are putting it into the context of my unit right, that unit and I'm talking to the players, and I'm	Resources data collection and analysis expertise Mechanism • Perception that a clinical problem has been proven • Belief in the significance of the clinical problem	Resources and mechanism	Refine – added resources and mechanism to feasibility	

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	talking to those clinicians and what's the stumbling block…(FG367) • It [the clinical problem] has to be so significant that it appeals to, I don't know appeals is probably a poor term, it, it's disconcerting to all players (FG144)				
FGR12	• And if we can influence those other people in our mix who are non-clinicians but who govern resource allocation for instance say data collection,… to get data from… those other resources that I have no idea how to find, but I can pick up a phone and ask someone for help, and they see the value in me asking for help. (FG175) • it has to be feasible. It has to be doable… So, you can't say I'm going to fix sepsis and not have a plan that is workable and doable within that	Context administration support Mechanism Perception of sustained support and importance	Context	Confirm - awareness of an implementation strategy Refine – added context to interdisciplinary implementation team → feasibility	

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	discipline. Right, so you have to involve all disciplines for the feasibility of it (FG184)				
FGR13	• So, that is bedside nursing and the big why is do you know your patient, and do you know why they might be at risk for sepsis, so that would be my big picture. So, then I think some of this discussion is all around different parts of that, but that is the most important.	Integrated evidence-based practice → Targeted behavior change → **belief that there is a clinical problem to solve**	Mechanism - belief that there is a clinical problem to solve	Refine – new mechanism	
FGR14	• So, the why I think comes right down to where is the patient and who's looking after the patient, and who's responsibility is to, um, bring, ah doctor's attention to that patient… So, where is the patient, what's wrong with the patient, and how do we get attention to the patient. (FG190) • we need to have a common understanding of who is responsible for the patient's care, in terms of	Mechanism • Perception of clear complimentary roles • Feeling valued in their role • Trust between professions in each other's knowledge and expertise • Individual professional honesty, integrity and fallibility • Sense of empowerment to hold peers accountable Context		Refine – new contexts and mechanisms r/t fidelity Refine – new contexts and mechanisms r/t fidelity	Authority to make decisions (formal) – nurses' medical directives (FG507) Authority to hold peers to account (informal) – nurses' role as advocate (FG484) - empowered to be a patient advocate (FG515) Team structure and function that

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	implementation of, of overall care and who is responsible for the daily nursing of the patient. Because those are two different roles. And, on the one hand if you deal with the nursing staff first I think we…, the nursing, the nursing staff at the bedside need to know that they're important, that they're invaluable, not important they're invaluable to the care of the patient and part of that invaluable approach, invaluableness, of their care is recognizing, of knowing their patient. Knowing who they are, what they're at risk for, and how to, how to, how to… appreciate change in clinical condition (FG207) • the team has to work to recognize the players on the team and, you are individuals but you play on a team (FG221)	• Leveled authority structure at the local level – e.g. Accountable Care Unit • Formal system of accountability (e.g. organizational expectations, physician reporting structure)			operationalizes defined roles and responsibilities mechanism = understanding across professions about the advocacy role and perceptions of responsibility and what this means. i.e. when nurses don't feel they know something escalation driven by the perceived need to advocate is the logical course of action. But this might conflict with physician perception of problem-based escalation. Perception for the need and responsibility to advocate being grey for nurses as opposed to black and white for physicians. → perception that in order for timely/fast attention docs perceive a need for black and white, and

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	• the nurse needs to know that they have a role, a sig, usually significant role to play in that. And, and part of it is effective communication with the staff doc who's at arms-length (FG223)				nurses operate in a perception of grey. Why grey → workload, experience, etc. (maybe)
	• We have complimentary roles rather than separate roles. (FG255)				
	• Got to lose the hierarchy (FG6679)				
	• more level system it would get rid of some of those inequities (FG692) What I saw in ACU, Accountable Care Units, was how it's supposed to be. Nurses working with physicians and them both, pharmacy's working with the team to meet the needs of the patients (FG702)				
	• If I don't have authority you can't hold my feet to the fire (FG450)				
	• it's a cultural thing. This is the way we do business				

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	in our organization period. And, and that speaks to a much more formal reporting structure with accountabilities built into it (FG464)				
	• …someone governs your privileging (FG522).				
	• I happen to know a little bit about organ donation, more about sepsis. So, people will tend to pay attention and listen (FG466)				
	• …we are educated to be critical but understand there are people who, you're never going to know it all, and there are people who are always going to be more knowledge about you about slices of medical practice (FG527)				
	• … we've come to realize we're never going to be experts in everything (FG535). I'd say that goes with nursing too (FG540)				

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
FGR15	• And, it's hard to convince all along the way but in the end we all have to think about where's the patient, what's wrong with the patient, how do we get fast attention to the patient. So, if we made errors in the process, um, and that isn't the main goal for everybody involved, that's the problem I think (FG198) • patient care is the goal and the fast response, if and this has been my belief all along not just for sepsis, when you have that working it's gonna impact patient care across, not just sepsis (FG230)	Integrated evidence-based practice → Targeted behavior change → **belief in a common goal amongst clinicians** → Acceptability	Mechanism – belief in a common goal amongst clinicians	Refine – new mechanism	
FGR16	• And then the forth bit is how to communicate that to the responsible physician. And, then, the other side of that equation is the physician who needs to be respectful of the communication that's happened. And, the fact	Integrated evidence-based practice → collaborative adaptation of the intervention for local use → **perception of improved communication** → acceptability	Mechanism – perception of improved communication	Confirm - mechanism	

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	that someone is sensitive enough to draw attention to a patient who's declining and then having an appropriate response in terms of timing and maybe antibiotics or you know whatever that, in the area of sepsis it will be resuscitation and antibiotics, and assessment of the patient (FG214)				
FGR17	• … the need for change then gives the motivation to, to change our behaviours be it review the care that these patients got…(FG339)	Dissemination of performance data and feedback → Cooperative PDSA problem solving → **Realized need to change** → Fidelity	Mechanism – realization of a need to change	Confirm - mechanism	
FGR18	• Right. And part of that screening tool, part of the most important part of that for busy nurses that have 12 patients on their, on their slate and on their load, is to know which ones you would be more worried about based on their medical concurrent conditions, why are they	Integrated evidence-based practice → **heavy workload** → acceptability Integrated evidence-based practice → heavy workload → **perception of limited capacity to change** → inhibited acceptability	Change context from 'busy work environment' to 'heavy workload' Add inhibitory mechanism	Refine – positive context definition and add inhibitory mechanism	Mechanism or context (linked to above) → bedside nurses experience simultaneous constant flow of information about the dynamic needs of multiple patients, and that complexity makes always having the black and white available when concern is raised difficult.

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	in, what medications are they on (FG496)				Hence the tool helps to alleviate this (r/t mechanism about simplifying care coordination complexity).
FGR19	• realize that you can learn from all sorts of people (FG555) • It's every one of us is a learner at some point and everyone is an expert at some point. And the cycles will change (FG562)	Education on the clinical intervention → **participatory interdisciplinary training**	Context	Confirm - context	openness to learn from other professionals and others of the same profession with different experience.
FGR20	• There has to be a sustainability process and I don't think our region has it (FG572) • That's [unsustainable interventions] happened time and time again (FG574) • Yah, I agree with you. Some of it speaks to the planning though (FG586). 　• We, first we went into it pretty naïve; I went into it pretty naïve for sure. Because it seemed	Context Absence of an implementation plan (includes dedicated resources that allow for the work to achieve intermediate outcomes as well as fidelity and having consistent hospital administration actively involved) Mechanism Lack of trust/faith in continuing to get the necessary resources and	Inhibited fidelity	Refine – new inhibitory CMO	Resource is the plan - appropriate scaling, scoping and appreciating/planning the complexity of the work Resource - if we were to re-implement this the group at the table would have included administrators, who real, who, who could hand out funds (FG594) they have access to resources that they can

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	such an easy (FG588). - The other plan, the other problem with our approach is that we looked at, looked at, we looked at it as a short term, quick turn-around fix goal (FG592). - And, I think at each of those stages we have, we have barriers. Those barriers are not just clinicians. Those barriers are administrators, or who, who have… competing interests. They've got a budget to balance, they've got no new resources to give you…(FG406) … recognize that our system is anything but nimble (FG399). - Did we get traction and the accountability? Do	support from hospital administrators (FG582) Belief that systematic change can be achieved over short periods			make available to us. And, that starts with the data side of the house, analytical side of the house, as well as the clinical side of the house (FG596). I would argue if we did this again I would have bigger administrators, powerful administrators at the table, not so they could override us as clinicians but because we could access their influence to give us resources (FG608).

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	docs feel it's important, or nurses? Do we think it's important? In fact, more importantly do administrators think it's important? (FG415)				
FGR21	• And, and, and unfortunately that is an old model of care which is, which is of (unintelligible 22:38) and I think we've slowly moving our culture through this process and this is where it takes time to let the system roll because there have to be iterations and some of those iterations are going to bring… they can embarrass the doc because you make, and, none of us wants to come to work and do a bad job. So, you stumble and go ah jeez I should have	Context Culture that does not support engagement when errors occur Mechanism Embarrassment about practice	Inhibited acceptability (r/t integrated evidence-based practice)	Revised - new inhibitory CMO	

FGR ID	Quote (transcript line number)	Synthesis proposition	R, C, M, O	Confirm, refute, refine	Supporting details
	really dealt with that one sooner. (FG242)				
FGR22	• I think this is historically based, we tend to, we tend to work in our silos. Patients are not in, they're not allowed to voice an opinion or whatever, whatever the cultural context is and the families feel that they're not being listened to or they truly aren't being listened to. Nurses don't feel they're listened to (FG237)	Context Uncoordinated or disconnected clinical practice Mechanism Feeling disempowered and unvalued	Inhibited fidelity	Revised – new inhibitory CMO	

Table J.1 Phase 1 program theory

Resources (mechanism)	Context	Reasoning (mechanism)	Implementation Outcomes	Notes
Evidence-based practice	**Complex work environment FGR18** (A complex work environment is a clinical setting that includes a patient population where highly acute patients are frequently encountered, competing demands for clinician time and attention and regular operational change.)	**Perceived simplified coordination** (Perception of simplified care coordination includes decreased complexity in coordinating the resource and personnel involved in care and task interdependence between clinicians.)	**Acceptability of the intervention** (satisfaction with various aspects of the intervention [including content, complexity, comfort, delivery, and credibility])	
	Collaborative adaptation of the intervention for local use (Collaborative adaptation includes interdisciplinary engagement of clinicians in adaptation [e.g.	**Belief in intervention validity** (Belief by clinicians that the intervention is valid for a particular setting including that it is easy to understand and easy to use.)		

Resources (mechanism)	Context	Reasoning (mechanism)	Implementation Outcomes	Notes
	protocol development] and changing responsibility for initiating and completing care activities to others in order to meet targets [e.g. from physicians to nurses].)	**Belief in patient and clinician benefit** (Belief by clinicians in the intended purpose of the intervention and the benefit for patients in using the intervention.) **Perception of improved communication** (Perception that communication amongst clinicians is improved.) **FGR16**		
	Targeted behaviour change (Includes the use of supportive strategies that are derived through active stakeholder engagement that are designed to change behaviors necessary to support a change in clinical practice focusing on an individual's	**Belief that there is a clinical problem to solve** (Belief amongst clinician stakeholders that there is an deficiency in care and opportunity to improve it.) **FGR13** **Belief in common goal to address the problem**		

Resources (mechanism)	Context	Reasoning (mechanism)	Implementation Outcomes	Notes
	capacity, opportunity and motivation [e.g. use of the Behaviour Change Wheel].)	(A shared belief amongst clinicians from different professions that they are working towards a commonly identified goal pertaining to the clinical problem being addressed.) **FGR15**		
Evidence-based practice	**Heavy workload FGR18** (A heavy workload is a clinical setting that includes highly acute patients are frequently encountered and a setting with high degree of patient flow.)	**Perceived misalignment with daily workflow** (Perception that the intervention is less urgent than other work, contrary to normal workflow priorities and inhibits achieving the goals of those priorities) **Perception of limited capacity** (Perception that workload (competing demands for time and attention [for nurses the nurse to patient ratio] limit the ability to	**Inhibited acceptability of the intervention** (Failure to reach satisfaction with one or more of the various aspects of the intervention.)	

Resources (mechanism)	Context	Reasoning (mechanism)	Implementation Outcomes	Notes
		accept a new clinical practice) **FGR18**		
	Intervention standardization (Includes the standardization of an intervention across boundaries of practice and local areas within an organization.)	**Differing beliefs about practice** (Clinician belied that there are differences about the nature, timing and course of treatment within an intervention) **Perceived threat to professional culture, identity and autonomy** **Discouragement to develop clinical skills** (Clinician belief that their clinical decision making is made overly simple and discouraging the development of skills, abilities and independence.)		*Discouragement to develop clinical skills* change from 'belief in overly simple decision making' because the decision making is too general a reference to clinical skills
	Non-collaborative adaptation of the intervention for local use	**Confused decision making** (Inconsistency in choosing between		

Resources (mechanism)	Context	Reasoning (mechanism)	Implementation Outcomes	Notes
	(Multiple local adaptations of the same intervention within the same organization.) **Lack of support and purposeful engagement with clinicians when clinical errors occur FGR21**	alternative actions when faced with variations of the same type of intervention in different clinical areas.) **Embarrassment in one's own clinical performance FGR21**		
Interdisciplinary implementation team FGR09 **(Includes engaging clinicians, facilitators and experts from across boundaries of practice to participate in implementation.)**	**Evaluation against current state** (Includes evaluating how the intervention might affect clinician current state workflow through activities, such as process mapping, and identifying failures and operational weakness in delivery care [practice-based evidence]; analysis of predetermined performance goals/metrics.)	**Perception that the intervention is practical and realistic** (The intervention realistic for and can be practically applied in the local clinical context.)	**Feasibility to adopt the intervention** (the utility, suitability and trialability of the intervention)	

Resources (mechanism)	Context	Reasoning (mechanism)	Implementation Outcomes	Notes
	Administrator support FGR12 (Includes the support by hospital administration through direct participation and committed investment in the resources clinicians require for implementation.)	**Perception of sustained support and importance FGR12** (Perception that the time and resources for implementation will be viewed and important enough to continue beyond initial implementation.)		
Data collection and analysis expertise FGR11	**Trial implementation FGR10**	**Perceived clinician ownership of the intervention** (Clinician perception of ownership includes the perception that a clinical problem has been proven and belief in the significant of that problem.)		

Resources (mechanism)	Context	Reasoning (mechanism)	Implementation Outcomes	Notes
Education on the aims of the clinical intervention and clinical support resources **(Education includes instruction on how to use the intervention and when to implement, information about health consequences [e.g. the story told of a patient that died from sepsis], severity and susceptibility of sepsis, and evidence for the efficacy of the sepsis intervention for improving patient outcomes.)** **(Support resources includes workplace reminders about the intervention, visual prompts [e.g. poster, flowchart], intervention**	**Participatory interdisciplinary training FGR19** (This includes opportunities for observation and practice in simulation exercises.) **Broadly accessible information** (Includes such activities as video instruction on intervention steps, intranet resource instruction on implementation, support for implementation and monitoring step completion [e.g. Smartphone app with instructions and timer].)	**Belief in outcome importance** (Clinician belief that the intervention results in clinically important outcomes.) **Perception of legitimate authority** (Clinician perception that they are free to use their clinical discretion in commencing initiation of the intervention.) **Self-efficacy in decision making** (Clinician perception of reduced complexity in decision making to support less familiar work and confidence in their clinical thinking about the target condition, patient population and	**Adoption of the intervention** (the uptake and utilization of the intervention)	*Self-efficacy in decision making* comes from combined perceived self-efficacy in decision making (mechanism initially aligned with acceptability) with confidence in critical thinking because both were describing similar phenomenon that were ultimately better aligned with education on the intervention

Resources (mechanism)	Context	Reasoning (mechanism)	Implementation Outcomes	Notes
checklist [e.g. pocket reference card] or electronic practice guideline for completion of each step)		how/when to apply the intervention.)		
Implementation strategy **(dedicated time and resources for all stages of implementation; theoretical and evidence-based implementation approach)**	**Non-hierarchical clinical team structure FGR14** (e.g. Accountable Care Unit) (This includes a team with clear roles and responsibilities, expectations and accountabilities, and physician reporting structure)	**Perception of clear complimentary roles FGR14** (Authority to make decisions (formal) – nurses' medical directives) **Feeling valued in roles FGR14** understanding across professions about the advocacy role and perceptions of responsibility and what this means. i.e. when nurses don't feel they know something escalation driven by the perceived need to	**Fidelity to the intervention** (the adherence, integrity and quality of the intervention)	

Resources (mechanism)	Context	Reasoning (mechanism)	Implementation Outcomes	Notes
		advocate is the logical course of action. But this might conflict with physician perception of problem-based escalation.		
		Trust in professional knowledge and expertise FGR14 Perception for the need and responsibility to advocate being grey for nurses as opposed to black and white for physicians. → perception that in order for timely/fast attention docs perceive a need for black and white, and nurses operate in a perception of grey. Why grey → workload, experience, etc. (maybe)		
		Individual professional honesty, integrity, and fallibility FGR14		

Resources (mechanism)	Context	Reasoning (mechanism)	Implementation Outcomes	Notes
Dissemination of performance data and case specific feedback **(Includes daily implementation rates, comparison of current performance with target, patient outcome data, analysis of variation in intervention use, high-performers' characteristics of practice [e.g. Positive Deviance Approach], care case summary, compliments or pointers on how to maintain compliance, follow-up information on the patient's subsequent clinical course)**	**Local team cooperative PDSA problem solving FGR07** (Include problem identification, root cause analysis, planning, implementing revisions and evaluation for change.) Incorporate → Active stakeholder engagement (Involves inclusion in the evaluation of the outcomes, advantages and disadvantages of the trial.)	**Empowerment to hold peers accountable FGR14** **Realized need to change FGR17** (Clinicians realizing there is a clinical rationale to change their habits.) Clinical self-reflection **FGR06** **Motivation to perform behaviours** (The motivation for clinicians to consciously decide to perform the requisite behaviours as outlined in the intervention.) Sense of accountability FGR06 Empathy with patients FGR05 Pride in providing quality care FGR05		

Resources (mechanism)	Context	Reasoning (mechanism)	Implementation Outcomes	Notes
		Trust that data reflects reality FGR08 (Includes trust in the reliability and validity of the data, value of PDSA problem solving **FGR04** and data informed practice **FGR03**		
Absent implementation strategy FGR20 **(includes dedicated resources that allow for the work to achieve intermediate outcomes as well as fidelity and having consistent hospital administration actively involved)**	**Rapid change driven implementation process FGR20** **Uncoordinated clinical practice in silos FGR22** (practitioners working in silos)	**Lack of trust/faith in process and people FGR22** (Includes not trusting the implementation process or players involved.) **Feeling disempowered and unvalued FGR22** (don't feel you can be listened too)	**Inhibited fidelity**	