EXAMINATION OF THE FEASIBILITY OF THE HOW2TRAK® SURGICAL SITE INFECTION TOOL IN THE ASSESSMENT OF SURGICAL SITE INFECTIONS IN A HOME CARE SETTING

by

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Dedication

I dedicate this work to my three brilliant children who inspire me every day, to my parents who have always encouraged me, and to the patients I serve in the pursuit of better outcomes.

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ABSTRACT

Surgical site infections (SSIs) are the most common of hospital acquired infections, occurring in 2-5% of patients undergoing inpatient surgery. SSIs are expensive for the healthcare system, and cause significant morbidity and mortality among surgical patients. At present, most SSI surveillance is completed in the acute-care setting, and hospital infection control programs do not always include a standardized methodology for post-discharge surveillance (PDS). However, approximately 60% of SSIs occur following discharge and therefore, the true rate of SSI is likely underreported. Moreover, the lack of standardization for post-discharge data collection has resulted in a limited understanding of SSIs in the post-acute and home care areas. This study evaluated the feasibility of a web-based surgical site infection (SSI) tool(how2trak) that used the 1999 United States Centers for Disease Control and Prevention guidelines for the detection of SSIs (Mangram, et al., 1999). Feasibility was evaluated by measuring concordance, a measure of inter-rater reliability, within paired RN assessors and RN assessor feedback regarding the usefulness of the tool. Patient referral and recruitment, RN pair assessments using the how2trak SSI tool, and follow-up visits with the patients occurred from March 2015 through July 2016 at 3 Calea Home Care Clinics in Toronto. Discussion groups were carried out in 2 sessions via teleconference on September 6 and 7, 2016. Overall high concordance within pairs of RN assessors was demonstrated; in many instances, concordance rates were reported above eighty percent. Discussion groups reported that the how2trak tool was a user friendly and useful data collection tool in the clinical setting, and that it made tracking patient outcomes more efficient than the traditional paper-based tool. Using the CDC guidelines for the identification of an SSI, the prevalence of SSIs post-discharge in the Calea Clinic was found to be 34.6 %. Overall, this study demonstrated that the how2trak tool is a feasible data collection tool for RNs in the Calea Clinics. Therefore, the how2trak tool provides a feasible option for standardizing data collection and analysis for the assessment of SSIs post-discharge across clinic settings.

LIST OF ABBREVIATIONS USED

APIC	Association for Professionals in Infection Control and Epidemiology
ASA	American Society of Anesthesiologists Physical Status Classification System
CCAC	Continuing Care Centers
CDC	Centers for Disease Control and Prevention
CHCA	Canadian Home Care Association
CI	Confidence Interval
ECDC	European Centre for Disease Prevention and Control
HAI	Hospital Acquired Infections
HI	Harmful incident
HC	Home Care
ICPS	International Classification for Patient Safety Framework
LHIN	Local Health Integrated Network
NAID	Nurse Assessor Identification
NNIS	National Nosocomial Infections Surveillance
RN	Registered Nurse
SHEA	Society for Healthcare Epidemiology of America
SSI	Surgical Site Infection
SIS	Surgical Infection Society
PDS	Post Discharge Surveillance
WHO	World Health Organization

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CHAPTER 1

INTRODUCTION

Background to the Problem

Globally, surgical care is an integral part of healthcare. The current volume of surgical care exceeds the world's birthrate with an estimated 312.9 million operations performed annually worldwide (an increase of 38.2% compared to data from 2004) (Weiser et al., 2012). However, infections of the incision, or organ space following surgery (Surgical Site Infections or SSIs) are the most common and costly of all hospital acquired infections (HAIs), (Lewis, Moehring, Chen, Sexton & Anderson, 2013) and represent 20% of all HAIs (Ban et al., 2016). In low- to middle-income countries, SSIs affect up to one in three surgical patients (WHO, 2016). Rates are lower in higher income countries, but the European Centre for Disease Prevention and Control (ECDC) surveillance data for 2010-2011 indicate that rates of SSI are as high as 9.5% for colon surgery, 3.5% for coronary artery bypass graft, 2.9% for caesarean section, and approximately 1% for cholecystectomy, hip and knee prosthesis and laminectomy. The estimated annual incidence of SSI in the US is comparable, ranging from 2 to 5% of patients undergoing inpatient surgery (Anderson et al., 2014), although estimates are as high as 33% in patients undergoing abdominal surgery (Sanger et al., 2017). However, the true incidence of SSIs is likely greater than these estimates given that approximately 60.1% of SSIs occur after discharge (Woelber, Schrick, Gessner & Evans, 2016).

The consequences of SSI to both patient and healthcare system are dire. Surgical site infections increase hospital stays by an average of 9.7 days in the US (11 days in Canada CHCA, 2016), are associated with a 2- to 11-fold increase in the risk of mortality (Ban et al., 2016), and are the number one reason for re-admission after discharge in the US (Woelber, et al., 2016). Patients with SSIs are likely to have a reduced quality of life, greater physical limitations, lower

mental health component scores, more outpatient and emergency room visits, and require more radiology services (Perencevich et al., 2003; Whitehouse, Friedman, Kirkland, Richardson, & Sexton, 2002). Although most patients with an SSI recover, the infection is the cause of death in 77% of those who die after re-admission (Anderson et al., 2014). SSIs are the overall costliest heath care associated infection in the US (Sanger et al., 2016), and increase the cost of hospitalization by more than $20,000 per admission, resulting in an additional $700 million USD per year (Ban et al., 2016) ($350,000- $1million CDN in Canada (CHCA, 2016). The healthcare system has recognized SSIs as a pervasive, yet preventable, complication of surgery.

Risk factors for SSI identified in the hospital setting include lack of sterile technique, inappropriate timing/selection of antibiotic prophylaxis, lack of body temperature control, and lack of pre- intra- and post-operative blood sugar control (Ban et al., 2016). A systematic review incorporating data from both high- and low- to middle-income patients also found that a number of factors (high body mass index, diabetes mellitus, prolonged duration of surgery, a 'severe' Nosocomial Infections Surveillance risk index score, and a severe wound class designation) also increased risk of SSI in adjusted analysis (Korol et al., 2013). Studies following patients in the post-discharge period have reported higher rates of SSIs (Oliveira & Carvalho, 2007) than hospital-based surveys, but the specific elements of SSI - rate, severity, timing and contributing factors - during community care remain unclear.

Surgical site infections are most studied in the acute care setting, where they are considered adverse events. Adverse events are unintended injuries or complications that can result in death, disability, or prolonged hospital stay (Baker et al., 2004). For the purposes of my research, I will make a distinction between the term 'adverse events' (referring to unintended injuries or complications in ***acute care***), and the term 'harmful incidents', which will be used to describe these injuries that occur in a ***home care setting***. The reason for this distinction is two-

fold: 1) the nature of care is different in the home care (HC) vs. acute care setting, due to patient factors (age, comorbidities, chronic conditions) and the involvement of family members/other care providers in the home; and 2) the duration of care (which can range from days to years). Wound care (including surgical incision care) in the community setting accounts for approximately 40 to 50% of care delivered on any given day in the country (McIsaac, Sibbald, & Woo, 2009, Hurd, 2009). It is therefore not surprising that early literature on harmful incidents in home care has identified wounds and infections as two of the most common types of events that require more extensive research (Johnson, 2006; Masotti, Green, Shortt, Hunter, & Szala-Meneok, 2007; Sears, Blais, Spinks, Pare & Baker, 2017). A more recent study examining the rate of harmful incidents (HIs) in the home care setting in 3 different regions of Canada found that overall rate of HIs was 4.2% (95% CI 3.0% to 5.4%; also expressed as an adjusted rate per client-year of 10.1%) (Blais et al., 2013). Wound infections were the second most common cause of HIs, accounting for 14% of total incidents (Blais et al., 2013). As a result, funders of home care programs have a keen interest in tracking the incidence and factors contributing to the development of SSIs in this population, to ensure proper utilization of human and fiscal resources (McIsaac, 2010). Although used interchangeably in the ICPS Framework, it is important to clarify and distinguish between harmful events and adverse events when discussing the relevant literature. The ICPS framework categorizes all events that end in patient injury as harmful and adverse. However, SSIs can occur either in the acute care setting when the patient is recovering on the post-op unit, or in the home care setting post-discharge. Therefore, both harmful and adverse events fit well into the ICPS Framework when used to guide research discussion and organization but with the definitions I proposed above, readers will be able to better understand the specific context of the patient event.

Given that up to 60% of SSIs are estimated to be preventable in the acute care setting using evidence-based measures (Anderson et al., 2014), they are now tracked carefully, publicly reported, and have become both the target of quality improvement efforts and a pay-for-performance metric (Ban et al., 2016). Although most surgical site infections are diagnosed following discharge, there is no accepted standardized method for detecting them (Tanner, 2009; Koek, Wille, Isken, Voss, & van Benthem, 2015). The most widely described method of post discharge surveillance is a surgeon questionnaire and this has shown poor sensitivity (Petherick, Dalton, Moor & Cullum, 2006). While there are validated Center for Disease Control and Prevention (CDC) guidelines for the identification of SSIs in acute care, the complexity of the home care environment as well as the resource requirements for completing surveillance have hampered data collection efforts. The solution is three-fold: 1) to develop a reporting system that suits the unique needs of the home care environment, 2) to establish the incidence and causes contributing to SSIs in the community, 3) to improve patient care and prevent the development of SSIs and subsequent complications from SSIs.

Post discharge surveillance of SSI is an onerous task in the community setting, because patients are often ill equipped to recognize the signs of SSI on their own, and home care may not be frequent enough on its own to ensure adequate monitoring. Patients are becoming increasingly empowered when it comes to their health, and many believe that patient-reported health data should be included in their plan of care (Sanger et al., 2014; Sanger et al; 2017). Remote sharing of patient-reported health data already happens in many cases on an informal basis (emailed wound photos, telephone-based check-ins) (Sanger et al., 2016), but technology is catching up to the need for a more formalized mechanism for remote patient health monitoring. In fact, patient reported outcome measures may play a significant role in the development of a comprehensive

patient safety system (Doran et al., 2014) once the conceptual groundwork has been laid and a secure reporting mechanism developed.

Purpose of the Study

The purpose of this study was 1) to evaluate the feasibility of a web-based surgical site infection (SSI) tool that uses the 1999 United States Centers for Disease Control and Prevention guidelines for the detection of SSIs and 2) to determine the SSI prevalence in a home care clinic setting in the Greater Toronto Area.

SSIs as an adverse event are tracked in the acute care setting, but they are not consistently tracked in care settings after hospital discharge where follow-up treatment may be conducted by the family doctor, or by hospital inpatient, or outpatient staff, or by home care professionals. SSIs are therefore difficult to track post-acute discharge.

In Canada, existing evidence related to the prevalence of SSIs in home care is limited. One study documented a significant proportion of clients receiving care for open surgical incisions (McIsaac, 2007). However, documented evidence of the presence of SSIs in the study population was unavailable. A second study implemented a post-discharge surveillance program in the Calgary Health Region Home Care division that documented an increased rate of SSIs in the community (Brandstadt, Armstrong, & Henderson, 2007) compared to measuring SSIs in acute care alone. However, this study focused on bypass surgery patients and strongly recommended that further studies be carried out focusing on other surgery types with similar home care post discharge surveillance programs. A Canada-wide study of adverse events in home care found that wound infections represented the second most common problem in the home care setting (Blais, et al., 2013). Studies conducted in Brazil, the United States, and the United Kingdom also documented increased prevalence of SSIs when post-discharge surveillance programs were implemented in the community (Brandstadt et al., 2007, Koek et al.,

2015, Oliveira, Lima, & de Paula Lima, 2007; Stockley, Allen, Thomlinson, & Constantine, 2001).

Currently, there are no web-based tools used to collect SSI data outside of the hospital setting in Canada. Increased awareness of the feasibility of the how2trakSSI data collection tool may provide insight into assessing SSIs in the home care clinic setting and a valid method that is less onerous to collect data outside of the hospital setting.

Research Questions

There are two inter-related research questions:

1. What is the feasibility of the tool for identifying SSIs?
    a. What is the inter-rater reliability based on concordance within pairs of RNs?
    b. How many SSIs were identified within this study population?
2. What is the usability of the how2trak tool for identifying SSIs?
    a. Is the tool practical for use within a busy clinic?
    b. Do the CDC Guidelines embedded in the tool help the RN to identify SSIs?
    c. Is the tool accepted by RNs in the use of SSI detection?

Feasibility was examined by measuring the concordance within pairs of RNs conducting independent wound assessments using the tool, and by analysis of the feedback from RNs after they had used the tool. The feedback was obtained during two telephone-based group discussions.

CHAPTER 2

THEORETICAL FRAMEWORK

Theoretical Overview

In the course of this research on SSIs in the home care clinic setting, four theoretical frameworks were considered to underpin my study: the Conceptual Model of Effective System Change Strategy (Baker & Norton 2001); the 'Culture of Discovery' Patient Safety Conceptual Framework (Affonso & Doran 2002); the Canadian Root Cause Analysis Framework (2009); and the International Classification for Patient Safety Framework (ICPS) (WHO, 2009). I identified the WHO ICPS framework as the best framework to guide my research.

Conceptual Model of Effective System Change

Baker and Norton (2001) described the development of a conceptual model for understanding the elements of safer healthcare systems. Their model is based on three key elements: 1) measurement, 2) system tools and change strategies, and 3) culture.

The first element in the model is *measurement*, and researchers comment that "this element is critical for understanding the volume of the error and garnering support for action" (p. 13). Measurement is a pressing priority in healthcare. Many healthcare organizations have articulated the need to achieve more positive outcomes, but an increased focus on the practical application of measurement processes is required to achieve their aim. The second element in this conceptual model is *system tools* and change *strategies*. For this element, Baker and Norton (2001) assert that even though adverse events may not be totally eliminated, it is possible to design systems to reduce errors. The third element of the Baker and Norton (2001) conceptual model involves the *underlying culture* and the relationship of culture to the identification of error. Many of the cultural values that exist within the confines of a single work site or an organization may take on a different set of cultural values within the home care setting. Leape,

Berwick, and Bates (2002) discuss the need to create a culture of safety by examining the ways in which healthcare practitioners are taught to engage in such a culture and how they interact with one another in addition to cultural processes. Although this model is grounded in patient safety, it was developed for the acute care environment and not the home care sector; therefore, it would not be an ideal framework to underpin this research.

Culture of Discovery Framework

Affonso and Doran (2002) created a conceptual framework for patient safety. This framework is built on four assumptions: (1) patient safety as a concept and its application in the healthcare environment must always be holistic; (2) transdisciplinary approaches introduce revolutionary ideas in research, practice, and teaching initiatives; (3) it is not appropriate to blame singular entities such as a person, process, system, or event after errors are made in the delivery of healthcare services; and (4) innovative thinking about perpetual issues is achieved by examining the interconnections between social science, medical science, and technological science.

The framework proposed by Affonso and Doran (2002) is constructed around the scientific principles of knowledge, research, practice, and leadership. In order to attain the highest level of patient safety, health professionals must continually pursue new knowledge in all areas of patient safety. This can be achieved by: (1) conducting research; (2) measuring outcomes; (3) providing feedback; and by (4) making adjustments. Based on these scientific principles, there are four primary actions that, when put into practice, will achieve safer healthcare environments for patients. These include: (1) building technological tools; (2) applying human factors to system designs; (3) reforming organizational culture that exists within healthcare institutions; and (4) delivering processes to optimize safe care through critical thinking and decision making (Affonso & Doran, 2002). While the framework provides context for some key concepts in

patient safety research, this current study was aimed at identifying rates of occurrence and factors associated with SSIs in three Canadian home care sites.

The Canadian Root Cause Analysis Framework

Root cause analysis is a method of reviewing patient safety incidents to determine the what, how, and why of these occurrences to prevent re-occurrence (Healy, 2006). The Canadian Patient Safety Institute (2006) describes root cause analysis as an analytical tool for conducting comprehensive system reviews of safety incidents. The process also involves the development of actions plans, measurement criteria, and recommendations for improvement. While this framework offers a critical process for evaluating harmful incidents and increasing knowledge around SSIs as a harmful incident in home care, it was not conceptualized to identify the rate of SSIs in home care.

Conceptual Framework for the International Classification for Patient Safety

After a comprehensive review of the literature, the Conceptual Framework for the International Classification of Patient Safety (ICPS framework), developed by the World Health Organization (WHO, 2009), was chosen to guide this study for three reasons. First, in a well-designed study there is a clear connection between the conceptual framework and the phenomena being investigated (Polit & Beck, 2008). The 10 high classes (primary concepts) of the ICPS framework include: *incident type, patient outcomes, patient characteristics, incident characteristics, contributing factors/hazards, detection, mitigating factors, ameliorating factors, and actions taken to reduce risk* all of which strongly correspond with concepts in SSI research regarding patient safety.

Secondly, the WHO ICPS framework contains definitions of key patient safety concepts that strengthen construct validity and external validity (described below). This definition of concepts allows for comparisons across research studies which makes it easier to compare

findings. Although the field of patient safety has gained widespread attention since the release of the Canadian Adverse Events study in 2004, interpretation and comparisons have been compromised by a lack of common understanding and language (Runciman et al., 2000).

The WHO ICPS framework offers a robust definition of concepts and measures that provided a solid framework from which to conduct my research. Furthermore, it provides a comparative reference point between my research and the research of others in the field. The ICPS Framework identifies 48 secondary concepts (which are subcategories under the ten high classes or primary concepts) and preferred terms, in order to "pave the way for researchers'' to understand each other's work and facilitate the systemic collection, aggregation, and analysis of information" (WHO, 2007). As I began my literature search around SSIs in the home care setting, it became evident that there was a lack of standardization. There was inconsistent use of definitions on how to assess a surgical site infection and there was lack of consistency in how data on SSIs were collected. The ICPS Framework as described by (Runicman et al., 2010) would provide a consistent use of key concepts with agreed definitions and preferred terms, also would allow clear classification, thereby promoting a common language that would facilitate systematic aggregation and analysis of information. in conjunction with a comprehensive but adaptable classification, will promote understanding among researchers and facilitate the systematic collection, aggregation and analysis of relevant information" As researchers use the ICPS Framework to guide their research, they will begin to develop commonality around concepts, measurement methods, and operational definitions that will strengthen the comparability of results as well as generalizations across people, settings, outcomes, and treatments.

Thirdly, face and content validity have been established and this increases the overall validity of the framework. The original conceptual framework and its accompanying concepts

were subjected to a web-based modified Delphi survey administered to technical experts in the fields of safety, systems engineering, health policy, medicine and law, which enabled a congruence of experience and expertise. In addition, its multi-cultural and multi-linguistic appropriateness was evaluated by experts (WHO, 2008).

The results indicated that 93.3% (69 out of 75) of respondents believed the conceptual framework was an adequate model for describing a patient safety event, and 83.1% (59 out of 71) of respondents believed it to be a meaningful and useful tool for translating disparate information into a format conducive to learning and improving patient safety (WHO, 2007). The survey was effective in demonstrating both face and content validity and in improving the overall validity of the framework for researchers.

The WHO ICPS Framework provides a solid context for understanding constructs and this, in turn, strengthens construct validity and generalizability of findings. Furthermore, construct validity indicates that researchers in specialized fields recognize that conceptualizations of variables that are theory-based have a particular meaning (Ferguson, 2004).

The Ten High Classes of the ICPS Framework. The Conceptual Framework for Patient Safety consists of 10 high-level classes: "incident type, patient outcomes, patient characteristics, incident characteristics, contributing factors/hazards, detection, mitigating factors, ameliorating factors, and actions taken to reduce risk. These classes have been identified to facilitate understanding and transfer of information relevant to patient" (WHO, 2009, p. 3), and are further subdivided into standardized categories. Each of the ten high classes will be discussed, in order to illustrate how the key concepts in my study relate to the Conceptual Framework for Patient Safety.

Incident type. The first of the ten high classes is called incident type. It is a descriptive term for a category made up of incidents of a common nature (WHO, 2009). Incident types are broken down into 13 concepts: clinical administration, clinical process/procedure, documentation, healthcare-associated infection, medication/IV fluids, blood/ blood products, nutrition, oxygen/gas/vapour, medical device/equipment, behavior, patient accidents, infrastructure/building/fixtures, and resources/organizational management. Each of these 13 concepts is further broken down into similar categories of patient safety events. Of the 13 concepts comprising incident type, the concept of *healthcare-associated infection* relates most closely with my research.

Healthcare-associated infections are broken down into type of organism and type/site of infection. Surgical site infection (SSI) is one of eight types of infection represented in the Framework. Within my study, SSIs were classified into superficial, deep, and organ/space infections based on CDC Guideline Definitions (CDC, 1999). The WHO ICPS Framework establishes the concept of SSI and defines appropriate methods for its management and classification.

Patient outcomes. The patient outcomes class within the conceptual framework contains the concepts that relate to "the impact upon a patient which is wholly or partially attributable to any incident. Patient outcomes are further classified according to the type of harm, the degree of harm, and any social and/or economic impact" (WHO, 2009, p. 9). Type of harm is divided into pathophysiology, injury, and other. The degree of harm is classified into none, mild, moderate, severe, and death. In this study, the type of harm that is being investigated is a surgical site infection.

In health research, clear definitions are essential to good data collection. The WHO framework provides concise guidance to researchers and allows for the comparison and evaluation of results

across studies. Improving patient outcomes is the impetus for my studying SSIs in the community.

Patient characteristics. Within the Framework, patient characteristics refer to patient demographic information such as age and sex and the initial reason for initiating care, and the primary diagnosis (WHO, 2009). Patient demographics require the collection of data on age and sex. The reason for seeking care is divided into procedure and primary diagnosis. In this study, patient characteristics were captured on all patients.

Incident characteristics. "Incident characteristics classify the information regarding the circumstances surrounding the incident such as where and when the incident occurred in the patient's journey through the healthcare system, who was involved and who reported" (WHO, 2009, p. 10). As previously discussed, SSIs as an adverse event are tracked in the acute care setting, but they are not consistently monitored in the home care setting. Thus, the body of literature lacks information regarding the incident characteristics of patients with an SSI. In this study, the *where* and *when* of the incident were captured but *who* was involved and *who* reported the incident were not captured. Other incident characteristics that were not recorded in this study include surgery type and antibiotic use. Of particular relevance to this study is how family or other caregivers could change the incident characteristics for the development of an SSI. Specifically, if family care-givers, instead of trained health-care professionals, are taking on at-home dressing changes for post-incisional care, this could be a circumstance that potentially increases the risk of incorrect care leading to an increased risk in SSI. For data integrity, all patients in this study only received post-incisional care from nurses at the Calea Clinic.

Origin of incident is divided into: people involved, when the incident occurred, and where. There are 11 categories to define the people involved, specifically: healthcare professional, healthcare worker, emergency service personnel, another patient, relative, volunteer, guardian,

friend/visitor, care/home aid/assistant, interpreter/translator, or pastoral care personnel. In this study, it was difficult to ascertain who was involved at the home/clinic level who had an influence on the SSI; however, a determination of who was involved in the care was recorded. Origin of incident also requires documentation of the stage/phase of care, timing of incident, and date of incident. To specify where the incident occurred requires identifying the care setting (of which there are 11 stages/phases). Each stage of care is broken down into several locations. In the home care location (clinics being one home care location) the stages of care include: assessment, provision of care/medication, treatment, counseling, monitoring of clinical status, management of household routine, follow-up, and transfer of care. The ICPS Framework helps the researcher to determine all of the concepts required to support strong construct validity, which is critically important in a non-experimental design (Polit & Beck, 2008).

In summary, the WHO ICPS Framework has face, content, and construct validity, which strengthens the external validity. Moreover, it solidly supported this research as it has been developed by global experts with strong experience in the field of patient safety and it also clearly describes the concepts, factors, and measurements of surgical site infection required providing consistency, uniformity, and a strong conceptual framework upon which this research was conducted.

Contributing Factors/Hazards. Contributing factors and hazards are defined by the WHO (2009) as the circumstances, actions or influences that are deemed responsible for a patient incident or event. Examples of these factors include both human and organizational or system factors that contribute to the event such as human behaviour, performance, and communication, work environment, and organizational policy. Two contributing factors that are investigated in this study are nurse training and education to determine whether these variables had an effect on agreement of the assessment of surgical site infections.

Detection. This class of the ICPS is defined as the circumstance that results in the discovery of the patient event. There are many methods of detection in the health care setting such as mechanical alarms that sense a change in patient vitals or status and also organizational reviews and audits of the clinical policies and procedures. The tool used for detection in this study is the how2trak tool. It was specifically developed for this study to contain the gold standard for SSI detection: the CDC SSI Guidelines.

Mitigating factors. These factors help moderate the progression of a harmful incident involving a patient. Mitigating factors come into play after the error has occurred and attempt to control the damage that has been done. I did not analyze mitigating factors in this study because the study focused on detection of an SSI using the surveillance tool as the main endpoint of the study, therefore, no data was collected on treatment or procedures that were initiated after the development of an SSI. However, this would be a very important investigation for future studies.

Ameliorating Factors

Actions taken to reduce risk. This is another high class of the ICPS Framework and is guided by prevention of the reoccurrence of the harmful incident. Actions taken to reduce risk attempt to improve patient safety and enhance system resilience. These actions can be taken by patients, the organization, or other health care providers. In this study the actions that were taken to reduce risk were mainly around education and care of the surgical incision. Nurses in the clinic provided this education. As a result of the study and the need to reduce risk, a new mobile SSI surveillance application has been developed whereby the patient uses the application to take a picture of the incision, which is transmitted, securely to the physician or health professional for review. Additionally, the patient is then requested to answer questions related to their incision and then submit the picture and responses via the secure mobile application on their mobile device to the surgeon/infection control team who can review the incision picture and the self-

reported patient data with the aim of identifying an infection earlier, and preventing admission to hospital and better patient outcomes.

CHAPTER 3

LITERATURE REVIEW

The term surgical site infection refers to an infection that occurs in a surgical incision, affecting tissues, organs or cavities manipulated during surgery (Oliveira et al., 2007). The review of literature for this study will contain a discussion of 1) the concept of patient safety, 2) surgical site infections (SSIs), 3) SSI detection and monitoring, and 4) post-discharge surveillance in the context of the home care environment.

SSIs originate in the acute care setting, but their prevalence extends across the continuum of care from acute care to home care. For this reason, the literature begins with a general discussion of patient safety across the continuum, including contributing factors, adverse events in acute care, and harmful events (Lang et al., 2006) in home care, and then focuses on the literature pertaining specifically to SSI detection, patient outcomes, post-discharge surveillance programs, and feasibility studies of electronic collection tools for the collection of SSI data. The following databases were searched on several occasions between October 2010 and October 2017: PubMed, Cochrane Library Database, Science Direct, Wiley Web of Science and Google Scholar with the following search terms: surgical site infection, post-discharge surveillance programs, antibiotic prophylaxis, nosocomial infections, surgical site infection in home care, patient safety and patient safety incidents in home care, harmful incidents, risk factors associated with the development of SSIs, and feasibility of electronic data collection tools to inform the literature review.

Patient Safety

The terms *adverse events*, *patient safety incidents* and *harmful incidents* are used frequently in the patient safety literature. The ICPS framework defines *harmful incident* as "harmful incident (adverse event): an incident which resulted in harm to a patient (WHO, 2009,

p. 23), and uses these two terms interchangeably. A *patient safety incident* is defined as "an event or circumstance, which could have resulted, or did result, in unnecessary harm to a patient" (WHO, 2009, p. 22). For the purposes of this review, I used the term '*adverse event'* to refer to a patient safety incident that occurs in-hospital, and a '*harmful incident'* as one that occurs in home care. It is important to discuss the acute care literature in my home care study because some of these studies are foundational in understanding patient safety.

The publication of the Canadian adverse event study (Baker et al., 2004) and the inauguration of the Canadian Patient Safety Institute represent a recognition of the importance of safety to optimal patient care. These efforts around improving surgical care are concentrated in acute care settings under patient safety initiatives and the Safer Health Care Now campaign and the current focus is safe surgical care. The Canadian Patient Safety Institute (CPSI) and the Canadian Institute for Health Information(CIHI) have been working together since 2011 to develop the Hospital Harm Framework (CPSI, 2016). In 2008, the Safer Healthcare Now (SHN) campaign focused on six targeted interventions to improve patient care, including the implementation of a set of evidence-based interventions for all surgical patients to prevent SSIs.

These interventions have since been expanded upon to include guidelines for the appropriate use of prophylactic antibiotics, antiseptic prophylaxis, appropriate hair removal, maintenance of perioperative glucose control, (Dellinger, 2001) perioperative normothermia which align with the WHO Global Guidelines for the Prevention of SSI (2016) and the importance of nutrition and wound healing (Dixon et al., 2010). Although there is evidence to confirm that the surgical safety recommendations do decrease the rate of SSIs in hospitals, compliance is voluntary and, therefore, not universal (Eckicioglu et al., 2012). The 2016 Canadian Safer Health Care Now report found that SSI prevention protocols are being followed: of the 1,998 patient charts audited, 91% received appropriate antibiotics and 96% received

appropriate hair removal. (Tanner, Norrie & Melen, 2011). No equivalent compliance monitoring mechanism exists for the post-acute setting, which was the impetus for my study.

Harmful Incidents in Home Care: A continuum of care

Home care, defined as a multitude of services provided to the community in the home environment (Canadian Home Care Association (CHCA), 2013) is an essential component of the healthcare system. Home care services may include health promotion and education, treatment intervention, palliative care, rehabilitation, support and maintenance, psychosocial support, and help for the family. Home care differs from the acute care environment in many ways, and there are few parallels in care structure, process, and physical setting between the home care and acute care environments. However, it is critical to understand the continuum of care with respect to adverse events/harmful incidents with respect to SSIs: although the surgery occurs in hospital, SSI occurs both in the hospital and in the post-acute environment such as home, long term care, or other community dwelling. Between 1997 and 2007, the number of home care recipients in Canada rose 51%, with an expected additional increase of 11% in 2011, and 33% by 2017 (CHCA, 2013). Coupled with this increase in demand, home care is experiencing a dire lack of resources, most importantly trained healthcare professionals (CHCA, 2013). Understaffing creates the opportunity for harmful incidents, and recent work suggests that harmful incidents occur in home care at a rate of approximately 10%/patient year (10.1% - 95% CI 8.4% to 11.8%) (Blais et al., 2013). Infected wounds were the second most prevalent harmful incident (accounting for 14% of all incidents), which strongly suggests that a standardized mechanism for tracking and reporting patient wound data at home is urgently needed.

In the home care setting, wound care is a common intervention, accounting for 30 to 50% of care provided (Johnson, 2006, Masotti et al., 2007, McIsaac, 2005, McIsaac, 2007). There are

a variety of wound types that require care, most commonly pressure ulcers (25%), venous leg ulcers (10%), diabetic foot ulcers (15%), arterial leg and foot ulcers (10%), other wounds (15%), and post-surgical wounds that can be open or closed (25%) (McIsaac, Sibbald, & Woo, 2009). In the typical scenario in the home care setting, the client is discharged with a closed surgical incision, and the incision opens at home. The client is then usually referred to home care for incisional care and, most often, is cared for by a general practitioner and not the surgeon. There is clearly a need for standardized post-discharge surveillance of clients with wounds in the home care environment.

Surgical Site Infections

According to the Center for Disease Control and Prevention (CDC), surgical site infection is classified as:

I. Superficial incisional (involving only skin or subcutaneous tissue)

II. Deep incisional (involving fascia and/or muscular layers)

III. Organ/space (involving any part of the body manipulated during surgery, excluding those structures included in the above categories).

Incident type. AN SSI corresponds to healthcare associated infection according to the ICPS Framework. It is diagnosed according to criteria established by the CDC, for example the criteria for a deep surgical site infection include an infection that occurs within 30-90 days of the surgical procedure, and manifests by at least one of the following:

a) Purulent drainage from the incision or from a drain placed into the organ/space.

b) Organisms identified from an aseptically obtained specimen using culture or non-culture-based microbiology testing performed for the purpose of clinical diagnosis or treatment.

c) Incision that spontaneously dehisces or is deliberately opened and the patient has at least one of: pain or tenderness, localized swelling, erythema or heat.

d) An abscess or other evidence of infection involving a deep incision that is detected on gross anatomical or histopathologic exam or imaging test

e) Diagnosis of an SSI by the surgeon or attending physician or other designee.

Patient outcomes. The ICPS framework also includes a classification of patient outcomes, which relates to the impact of the incident on the patient (WHO, 2009). SSI is a possible patient outcome following surgery, which usually occurs within seven to ten days but can occur 30-90 days postoperatively. In the case of implantation surgery, such as a joint replacement in orthopedic surgery, prosthetics, stents, and pacemakers, SSIs are a risk for these patients up to ninety days postoperatively (CDC, 2008). Patient outcomes are described by the degree of harm to the patient within the ICPS framework:

- None – patient outcome is not symptomatic or no symptoms detected and no treatment is required.
- Mild – patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g., extra observation, investigation, review or minor treatment) is required.
- Moderate – patient outcome is symptomatic, requiring intervention (e.g., additional operative procedure; additional therapeutic treatment), an increased length of stay, or causing permanent or long - term harm or loss of function.
- Severe – patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long - term harm or loss of function
- Death – on balance of probabilities, death was caused or brought forward in the short term by the incident. (WHO, 2009, P. 17)

Contributing factors. The ICPS framework calls attention to the contributing factors, which are directly connected to the incident type; the contributing factors inform and influence the strategies for reducing the risk of the incident occurring. A variety of factors contribute to risk for the development of an SSI. Patients often expect the healing of a surgical wound to be an inevitable outcome after surgery; however, this is not always the case. The skin is the body's first line of defense against organisms in the external environment, and surgery can provide a portal of entry for microorganisms whether from the skin itself or from the environment (Barie & Eachempati, 2005). An SSI can develop as a result of the procedure, as an adverse event in hospital, or as a harmful event post hospital discharge (Berrios-Torres et al., 2017).

There are many factors that contribute to the development of an SSI in the acute care setting. The WHO ICPS (2009) classifies these factors into two categories: *human factors* which include behaviour, performance or communication, and *system factors* which include environmental influences and external factors beyond the control of the organization (i.e. physical environment or legislative policy). In addition to the emergence of antibiotic-resistant pathogens (CDC Threat Report 2013) and the increased numbers of surgical patients who are elderly and/or have a variety of chronic, debilitating, or immunocompromising conditions (Kaye et al., 2005) are external factors that increase the risk of SSI across the board. The CDC has put forth many recommendations to minimize the risk of SSI by controlling as many human factors as possible (Berrios-Torres et al., 2017). These recommendations include (among other more specific recommendations):

- having a patient shower or bath with soap (antimicrobial or nonantimicrobial) or an antiseptic on at least the night before the procedure.

- antimicrobial prophylactics should be administered before skin incision, and should be timed such that they reach bactericidal concentration in the serum and tissue when the incision is made.
- skin preparation in the operating room should be performed with an alcohol-based preparation when possible.
- glycemic control should target glucose levels less than 200 mg/dL(11.1 mmol/L) and normothermia should be maintained throughout the procedure.

Unfortunately, even when precautions are followed SSIs do develop. The ICPS framework recognizes that often more than one contributing factor and/or hazard is involved in a single patient safety incident. This study tracked SSIs, a harmful incident, in a home care clinic setting to help understand the continuum of care in those who develop SSIs post-discharge, in order to close gaps in patient care.

Detection and Monitoring of SSIs

The most accurate method for the detection and monitoring of SSIs is the 'direct method', which consists of daily observation of the surgical site by the physician, Registered RN (RN), or infection prevention and control professional starting 24-48 hours postoperatively (Anderson et al., 2014). However, budget/time constraints, early discharge, and the fact that many surgical procedures are performed on an outpatient basis means that few patients are being tracked using this method. Instead, most patients are monitored indirectly by reviewing microbiology and nursing reports, surgeon and/or patient surveys, and review of readmission/antimicrobial prescriptions (Anderson et al., 2014). While these indirect methods are thought to be both reliable and specific in hospital, they are not specific for the home care clinic environment post-discharge.

Predicting Risk of SSI

The CDC has outlined several tools that effectively detect and predict the risk of developing an SSI after a surgical procedure. These include the wound classification system, (Siah & Childs, 2011) the American Society of Anaesthesiologists (ASA) Physical Status Classification System, and the National Nosocomial Infections Surveillance (NNIS) Index (Akin et al., 2011; Mangram et al.,1999; Morales, Escobar, Villegas, Castano & Trujillo 2011). These systems have been chosen by the CDC for SSI risk assessment, based on reliability to evaluate three important variables:

(1) intrinsic degree of microbial contamination of the surgical site,

(2) duration of operation, and

(3) markers for host susceptibility (Society for Healthcare Epidemiology of America [SHEA], Association for Professionals in Infection Control and Epidemiology [APIC], Centers for Disease Control and Prevention [CDC], and the Surgical Infection Society [SIS], 1992).

A set of definitions for classifying the degree of intrinsic microbial contamination of a surgical site was developed by the National Academy of Science (NAS) and the National Research Council (NRC) Cooperative Research Study (1964), and later modified by the CDC (1982) for use in SSI surveillance. It should be noted that although these definitions are widely accepted and utilized globally, the CDC recommends using a combination of risk scales due to their somewhat subjective nature (Mangram et al.,1999).

Using these risk scales, any surgery can be classified into one of four categories (Appendix C). **Class 1 (Clean):** is "an uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract are not entered. In addition, clean wounds are primarily closed, and, if necessary, drained with closed drainage.

Operative incisional wounds that follow non–penetrating, blunt trauma should be included in this category, if they meet the criteria (Mangram et al., 1999). **Class II (Clean/Contaminated):** is "an operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered, under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered" (Mangram et al., 1999). **Class III (Contaminated):** wounds are "open, fresh, accidental wounds. This category also includes incisions from operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, non–purulent inflammation is encountered" (Mangram et al., 1999). **Class 1V (Dirty/Infected):** wounds are "old traumatic wounds with retained, devitalized tissue, and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation" (Mangram et al., 1999).

In addition to classifying the surgery, it can be helpful to categorize the patient according to the American Society of Anesthesiologists Physical Status Classification System (ASA, 2011) when predicting SSI risk. The six classes of this system are:

1) ASA Physical Status 1 - A normal, healthy patient
2) ASA Physical Status 2 - A patient with mild systemic disease
3) ASA Physical Status 3 - A patient with severe systemic disease
4) ASA Physical Status 4 - A patient with severe systemic disease that is a constant threat to life.
5) ASA Physical Status 5 - A moribund patient who is not expected to survive without the operation

6) ASA Physical Status 6 - A declared brain-dead patient whose organs are being removed for donor purposes (ASA, 2011).

Used by surgeons, hospital administrators, clinicians, and researchers, the goal of this system is to assess the physical status of the patient prior to surgical procedures (Davenport, Bowe, Henderson, Khuri, & Mentzer, 2006; Gottrup, Melling & Hollander, 2005). However, studies suggest that the ASA score alone cannot accurately predict SSI risk. Therefore, the CDC has chosen to consider this score, along with the wound classification and the NNIS score, as a more comprehensive set of tools for predicting risk during SSI surveillance.

The CDC's NNIS system also standardized surveillance criteria for defining SSIs once they have developed. By these criteria, SSIs are classified as being either incisional or organ/space. Incisional SSIs are further divided into those involving only skin and subcutaneous tissue (superficial incisional SSI) and those involving deeper soft tissues of the incision (deep incisional SSI). Organ/space SSIs involve any part of the anatomy (e.g., organ or space) other than incised body wall layers, opened or manipulated during an operation. (Appendix A)

Post-Discharge Surveillance Programs

Current standards for post-discharge surveillance (PDS) involve following a patient for 30 days (Mangram et al.,1999), National Healthcare Safety Network (NHSN), 2014 & Koek et al., 2015) after hospital discharge to ascertain whether a surgical site infection develops. At present, most SSI surveillance is done in the acute-care setting, and hospital infection control programs do not always include post-discharge follow-up. According to Dixon et al., (2010):

> "The challenge of determining a surgical site infection rate is great. Most infections become apparent after discharge from hospital, and in all probability, most people with infections do not get readmitted to the hospital where the surgery took place. The sensitivity of reporting from physicians and patients is low. Unless resources are

devoted to the follow up of each patient, infection rates, as determined by standard surveillance, will invariably be an underestimation of the actual rate. (p. 25)"

The literature confirms the assumptions that SSI rates, and the burden of caring for them, are underestimated when relying only on inpatient SSI rates (Baker, Flintoft & Kam, 2008; Daneman et al., 2010; Tanner et al, 2009). Oliveira & Carvalho (2007) estimated that 12 to 84% of SSIs occurred after discharge in studies that included the post-discharge surveillance process. A study conducted by Bryce and colleagues (Bryce, 2013) demonstrated that 86 per cent of patients with SSIs were identified after the 30-day surveillance period. It is evident that postoperative infections can be overlooked unless post-discharge surveillance is undertaken (Koek et al., 2015).

Post Discharge Surveillance (PDS) programs are currently not standardized, and no method for national surveillance has been developed. Some reports estimate that SSI rates are underestimated by as much as 50% (Oliveria, et al., 2007) when there is no PDS program in place; however, the CDC estimates that 19 to 84% of SSIs are diagnosed post-operatively in the post-acute care setting. There is minimal information in the literature on Canadian PDS programs and collaborative efforts between acute care and home care to determine SSI prevalence. The Calgary Health Region initiated a pilot program in collaboration with home care that studied patients over the age of 18 who underwent cardiac bypass graft surgery, valve replacement, or orthopedic hip or knee replacement surgery, between December 2003 and May 2004 (Attrell & Armstrong, 2007; Brandstadt et al., 2007). This study found that fifty percent of all SSIs in this pilot program were identified in the post-acute care setting. The authors also highlighted the need for collaborative communication and dialogue between acute care and home care. The literature confirms that there is a need to examine the rate of occurrence of SSIs and the burden of caring for them in the post-acute care setting (including home care).

Summary of the Literature Review

SSIs increase patient suffering, lengthen of hospital stay, and cause considerable mortality and morbidity in the acute care setting (Ban et al., 2016, Anderson et al., 2014, Koek et al., 2015). The literature and prevalence studies on patient safety in home care have identified wounds and infections as priority areas that require further exploration. The WHO ICPS Framework was used in this review to describe the impact that SSIs have on patient safety incidents in the home care environment, where PDS programs are absent. The Federal Government pledged to contribute $6 Billion CDN to home care over the next 10 years (Budget 2017 Chapter 3 Part 1 http://www.budget.gc.ca/2017/docs/plan/chap-03-en.html), and the provincial government in Nova Scotia subsequently committed to increase healthcare dollar allocation to home care. With the continually increasing demand for home care, the body of research on surgical site infections outside of hospitals will continue to grow.

Feasibility Studies

This study focused on the feasibility of using the how2trak SSI data collection tool in the home care clinic setting. More specifically, the barriers to tool implementation, the rates of concordance between paired RNs, and the rate of SSIs in the three Calea Clinics. The implications of this work are health policy-based, and may support the development of a standardized data collection methodology for post-discharge surveillance of SSIs in the home care clinic environment.

Bowen et al., (2009) identified five scenarios in which feasibility studies are necessary:

1) when community partnerships are initiated or maintained;
2) when there is scant published literature indicating the efficacy of a given intervention;
3) when previous studies did not involve an in-depth exploration, assessing the myriad of complexities in the healthcare environment;

4) the intervention requires specific consideration, in that it differs significantly from other alternatives; or similar interventions have been attempted, with unsuccessful results (Bowen et al. 2009, p. 453).

A feasibility study should focus on acceptability, and look at how the target population and those implementing the intervention react to it. This study was informed by the work of Bowen and colleagues (Bowen et al. 2009), and focused on assessing the feasibility of the how2trak SSI assessment and data collection tool.

The how2trak SSI tool is a web based data collection tool that has been developed to enable effective data collection for the identification of risk of SSI and the clinical identification of an SSI. The how2trak SSI assessment tool was created by combining and integrating (1) validated tools, or gold standard tools, to assess both the risk assessment scales (ASA, NNIS and wound classification); and (2) the clinical surgical incision assessment details recommended by the CDC. It is the most commonly used and most widely accepted tool for the accurate assessment of the surgical incision to determine whether or not an infection is present.

The how2trak SSI tool required a feasibility study before introducing it as a tool in clinical practice. The how2trak tool has been evaluated by Grant Thornton for the assessment of privacy and security protocols and met or exceeded all of the requirements of the privacy impact assessment. The tool has been through a privacy impact assessment as well and meets the requirements for the Personal Information Protection and Electronic Documents Act. There is a privacy officer and a privacy policy for the how2trak SSI system. The how2trak tool was evaluated by a rigorous process to ensure the highest level of patient information protection. This process consisted of a five-day evaluation in which an independent privacy expert visited the Health Outcomes Worldwide (HOW) office and performed a multitude of privacy challenges with the how2trak tool, met and discussed the tool with HOW's Privacy Officer, and assessed

the technical components of how2trak's privacy capabilities. It should be noted that I am the Founder and CEO of HOW and how2trak is HOW's main mobile application. The how2trak tool exceeded requirements for patient information protection. The how2trak tool is compliant with both Health Insurance Portability and Accountability Act (HIPPA) and The Personal Information Protection and Electronic Documents Act (PIPEDA); data from users in the USA are stored in the USA and data from users in Canada are stored in Canada. Amazon is the storage service used by HOW for the how2trak tool.

CHAPTER 4

METHODS

Introduction

In this chapter, the research questions; overall study design, study setting, method of SSI assessment, and statistical analysis are outlined and described. The primary objective of this study was to assess the feasibility of using the web-based how2trak (Health Outcomes Worldwide, New Waterford, Nova Scotia, Canada) surgical site infection (SSI) tool to identify post-acute care SSIs among patients referred to home care clinics in the Greater Toronto Area (GTA) for postoperative incisional care. Feasibility was based primarily on concordance, a measure of inter-rater reliability, of assessments carried out by RN pairs who used the how2trak tool to assess for SSI. The secondary objective of this study was to determine the prevalence of SSIs among this same patient population using the United States (US) Centers for Disease Control and Prevention (CDC) guidelines for determining an SSI (Mangram et al., 1999), which are embedded in the how2trak tool (Appendix A). In addition, the views and feedback of the RN assessors regarding the how2trak SSI tool's relevance and suitability in practice were also used to assess the tool's feasibility.

For the purposes of this study, given that the CDC considers that an SSI may occur up to 30 days postoperative (Mangram et al., 1999), study assessments were conducted on eligible patients who were referred to home health care clinics within 30 days of their surgical procedure. By focusing on the feasibility of an electronic assessment tool and its inclusion of best practice guidelines for infection assessments, the results of this study may guide the design of future research investigating trends in postoperative SSI surveillance development in the home care clinic setting.

Research Questions

There are two inter-related research questions:

1. What is the feasibility of the tool for identifying SSIs?

    a. What is the inter-rater reliability based on concordance within pairs of RNs?

    b. How many SSIs were identified within this study population?

2. What is the usability of the how2trak tool for identifying SSIs?

    a. Is the tool practical for use within a busy clinic?

    b. Do the CDC Guidelines embedded in the tool help the RN to identify SSIs?

    c. Is the tool accepted by RNs in the use of SSI detection?

Study Design

A feasibility study was conducted. It included 1) evaluating the feasibility of using the web-based how2trak SSI tool to identify SSIs in patients referred by the Continuing Care Access Care Centre (CCAC) of Greater Toronto to the Calea Home Care Clinics for postoperative incisional care; 2) determining the proportion of SSIs among patients assessed during the feasibility portion of this study; and 3) obtaining RN assessor appraisals of the tool through discussion groups.

It is important to distinguish between a pilot and a feasibility study. Thabane et al., (2010) present a consolidation of definitions for pilot study. While similar, in that both a pilot study and a feasibility study strive to determine the practicality of a therapy or tool, or to evaluate correlations between patients and risk factors, this study is defined as a feasibility study for its emphasis on evaluating the inter-rater reliability of the how2trak SSI tool. Pilot studies evaluate safety, and adverse events related to the use of the therapy or tool with a clear future plan to complete a larger study with the same design at a later date. The main goal of my study was to

assess the inter-rater reliability of paired RN assessors in the independent use of a standardized tool while performing subjective clinical assessments.

The Dalhousie Research Ethics Board and the Toronto Continuing Care Access Center and the Calea Clinics Ethics Board approved this study. For more information on the ethical considerations of this study, please refer to the section *Protected Health Information and Data Privacy*, p. 39.

Setting. The study was carried out within the home care clinic setting of the greater Toronto area (GTA) in Ontario, Canada. GTA includes the city of Toronto and the regional municipalities of Halton, Peel, York, and Durham. In 2011, these regions had a combined area of 7,126.9 km^2 and a combined population of 6.4 million (Statistics Canada, 2016). The home care clinic setting refers to a specific method of home health care delivery in Canada, in which patients who have been previously hospitalized are referred for follow-up care when complications occur. Patients are referred to these clinics by the CCAC (now referred to as Local Health Integrated Networks (LHIN)), a network of 14 centres located throughout the province of Ontario, which provides assisted-living services and coordinates patient follow-up care, rehabilitation services, and specialized therapy, as needed (Ministry of Health and Long-term Care, 2017). All Ontario residents have access to a CCAC. Within home care, the CCAC provides basic services such as bathing, dressing, meal delivery, wound care, home support, and nursing services. A referral for home care services can be made by anyone on behalf of the patient. A Case Manager determines eligibility for admission to the home care clinic program, completes the initial referral and assessment, and directs the patient to 1 of 10 possible sites. Upon referral from CCAC, patients can receive nursing services at a community clinic for care, or some patients may receive services in their home through home care nursing services.

Among the home health care clinics available in the GTA, Calea Home Care Clinics receive a considerable number of referrals from CCAC for postoperative incisional care. From April 2014 through March 2015, there were 4,017 referrals to the Calea Clinics, 36% (n = 1,446) were patients with postoperative wounds. It is important to note that all patients in the study were referred to the clinic for post-op incisional care, therefore one would expect that within this population there may be a higher rate of surgical site infection. The Calea Home Care Clinics were optimal sites for this feasibility study for the following reasons: (1) the organization was willing to participate because the volume of patient referrals for postoperative incisional care to the home care setting is high (see above); (2) the study focus fit within the strategic goals of the organization; and (3) the Calea Home Care Clinics are geographically accessible, as they are located in a variety of sites within the catchment area of the GTA CCACs. This study took place in 3 of the 5 Calea clinics in downtown Toronto. These three clinics were chosen given their previous experience routinely working with how2trak on-line applications to assess chronic wounds, which resulted in the observation among clinic staff that the lack of a standardized, routine method to assess SSIs was challenging. The clinics' leadership and nursing staff demonstrated willingness to participate in this study and find an optimal method for diagnosing SSIs. The principal investigator (PI), three research assistants (RAs), and fifteen RNs (trained by the PI as RN assessors) carried out this study on-site at the three Calea clinics.

Study Population. In this section, the patient population and RN assessor population who participated in the study are described, with information on how the sample sizes were determined, the recruitment and consent processes, and RN training.

Recruitment and Consent of Patient Sample. The patient sample in this study was recruited from the patient population who had initially been admitted to a hospital in the GTA for a surgical procedure and, after their discharge following surgery, had been referred by the

CCACs to a Calea clinic for postoperative incisional care within a 30-day period from the date of surgery.

Currently, referral to the Calea Clinics most often is made by the patient's family physician or primary care practitioner, who refers the patient based on a postoperative incisional complaint such as redness, dehiscence, irritation, or swelling. While a physician may examine the incision and make a referral, this process is variable. For example, the patients may be referred to the Calea Clinic for follow-up treatment; or for further assessment; or for an assessment and/or treatment of an open surgical wound. Therefore, it is not always clear by the referral as to whether or not the patient has an SSI. Furthermore, referral information provided to the Calea Clinics is usually incomplete, and most times the problem is merely stated as a "wound" or an "open wound" (K. Laforet, personal communication, April 18, 2013).

During this study, upon presenting to the clinic for care, the receptionist and or nursing staff informed patients that a study was occurring on-site and that they may be eligible. Patients were then invited to consent to have their name released to the Principal Investigator (PI) or Research Assistant (RA). Patients who demonstrated interest in participating and who agreed to have their names released were directed immediately to the RA on-site, who explained the purpose of the study, the time commitment, and that the patients would receive the same standard of care regardless of whether they participated. The PI then screened each patient for eligibility. The complete patient inclusion and exclusion criteria are listed below in the following 2 sub-sections.

Inclusion Criteria for Patients

- Patients who had undergone surgery at one of the Toronto area hospitals;

- Patients who were referred to the Calea Home Care Clinics through the CCAC for postoperative incisional care between March 2015 and July 2016; and who were referred to Calea within 30 days of their surgery on the day they were recruited
- Aged ≥ 18 years old
- Signed an informed consent form to participate in the study (Appendix E)
- Patients who were willing to be seen at the Calea Clinic at least once within 30 days of surgery, in addition to the original referral assessment
- Able to converse in English

Exclusion Criteria for Patients

- Patients without a surgical wound
- Patients with a surgical wound who had been discharged for more than 30 days
- Patients on service at Calea Home Care Clinic prior to initiation of study data collection
- Patients who had undergone any surgery in which an implant was left in place
- Inability to understand the study procedure.

Patient Consent

Upon determining eligibility, the PI/RA invited the patient to consent to participate in the study. Regardless of their participation in the study, the PI/RA reiterated that patients would receive the same standard of care in the home care clinic. Patients were informed that at any time they could withdraw from the study and that withdrawal may occur if an unexpected situation arose that would disqualify participation, which could include: a diagnosis of a new condition or disease during the study, hospitalization, and additional surgical treatment. Patients were also allowed to have their data removed up to 1 month following study completion, after which their data would have been analysed. Upon reading the consent form (Appendix E), those who agreed to participate signed the form and were enrolled in the study. The PI/RA collected their

demographic and clinical data in the how2trak tool upon obtaining their consent (for description of data, please refer to the section, **how2trak** SSI Data Collection Tool). The study assessment for each patient was scheduled within 3-7 days of providing informed consent. Signing consent and performing the assessment were not possible on the same day as the extra time necessary for both of these actions was not possible for their busy block schedules. Signed consent forms were scanned and attached to the patient record using the how2trak SSI tool.

The patients also provided consent to have their Calea medical charts reviewed to complete the how2trak SSI tool data collection process. Upon consent an indicator was placed on the front of the patient's chart to indicate study enrolment, which allowed easy identification during follow-up visits. Two records were created in how2trak for each patient to reflect each SSI assessment carried out independently by each member of the pair of RN assessors, and a Patient ID was generated. In addition, those patients who did not have an SSI identified at the initial visit were required to have a follow-up visit at 30 days postoperative. This follow-up visit varied in the time frame from patient to patient, as it directly related to the number of days that had passed between the patient's surgery and the initial assessment. This follow-up visit was scheduled during the initial SSI assessment.

RN Assessors

To ensure that patients were accurately assessed for SSIs using the how2trak tool, a team of fifteen trained RN assessors were recruited from a pool of eighteen RNs who routinely assess postoperative patients at the Calea Clinics. The RN sample worked in rotating pairs. Each patient was assigned to a pair of RNs who performed two independent SSI assessments using the how2trak tool. Each assessment took approximately 3-5 minutes. Having two RNs perform independent assessments, approximately 5-10 minutes apart, enabled the calculation of inter-

rater reliability (a detailed description of the concordance analysis undertaken is provided in the section, Statistical Analysis).

To note, there was neither time nor motive for RN Assessors to compare notes or assessments before submitting to the electronic system. It was clearly explained to RN Assessors the importance of independent assessments. To ensure this was carried out correctly, the PI and RA observed RN Assessments and did not observe any sharing of information between RNs. Additionally, time was extremely limited with having to perform the SSI assessment for this study along with the double documentation in the clinic specific record. These time constraints also helped ensure that there was no sharing of assessments between RN Assessors. With fifteen assessors available to assess patients a measure of inter-rater reliability was achieved, representing a cross section of RNs at the Calea Clinics. Since the more skilled RNs would be more likely to agree than the less skilled RNs, the aim was to involve a representative sample of RNs. A patient sample size was originally set at 300, but based on logistical feasibility the sample size was reduced to 100 (Sample size is discussed in more depth as one of the limitations). Furthermore, Degnen (2013) explains that feasibility studies are not expected to have large sample sizes that are needed to adequately power a full study.

Recruitment and Consent of RN Assessors. RNs working at the Calea Clinics were already familiar with the how2trak application, as it had been in use on-site for several years for the assessment of *chronic wounds*. However, this study was the first one in which the how2trak tool embedded the *surgical site infection* assessment application. Therefore, this was the first time that the RNs used the tool to test for the detection of SSIs. All 18 RNs attended a 60-minute information session provided by the PI on the how2trak SSI tool and the purpose of the study. A PowerPoint presentation was shown that included estimates regarding the amount of time required to conduct a full how2trak SSI assessment and the potential benefits for the patient (e.g.,

standardized method for assessment, potential for earlier diagnosis and treatment, more complete information from referral source,) if an SSI was identified (Appendix A). Following the presentation, RNs interested in participating in the study submitted their names to the PI. RN eligibility to participate in this study was based on their willingness to:

- participate in a 60-minute training session
- carry out the assessment schedule associated with the study using the how2trak SSI tool
- participate in a discussion group with the RA and other RN assessors at the completion of the study to discuss the feasibility of using the how2trak SSI tool as a standardized method
- sign an informed consent form (available in Appendix F).

Participating RNs were informed that they could withdraw from the study at any time without having their employment affected. Withdrawal could also happen if an unexpected situation arose that disqualified their participation, such as if they were no longer employed by Calea Home Care Clinics or were unable to fulfill the duties of a RN assessor.

Fifteen RNs agreed to participate in this study and provided their informed consent to the PI. The signed consent forms were kept in a locked cabinet of the PI. Once enrolled in the study, the following demographic data were collected from the RNs to be used for concordance analysis: age, education, years of experience, years of surgical experience, and years of Calea Clinics experience.

Training of RN Assessors. During this study, participating RNs used the 1999 CDC SSI assessment guidelines (Mangram, et al., 1999, Appendix A) embedded in the how2trak SSI tool as their assessment tool for the determination of whether an SSI was present in the patients. Before SSI assessments began, all fifteen RNs enrolled in the study participated in one of the two 60-minute group training sessions provided by the PI on the use of the how2trak SSI tool to

assess patients for SSI. Ten RNs participated in the first group session, and 5 RNs participated in the second training.

The PI reviewed the PowerPoint presentation and provided a demonstration of the how2trak SSI assessment tool on a desktop computer in the training room. The training covered: (1) the purpose of the study and its importance to nursing practice and patient outcomes; (2) a module on the best practice CDC SSI assessment guidelines and how they differ from the current metrics regarding assessment of infection in place in their clinic; (3) information on the importance of accurate data collection, including methodological considerations; (4) emphasis on the necessary data entry points required in the how2trak SSI tool (which may have differed from current practice); (5) a demonstration of the how2trak SSI platform in terms of data input, maintenance, and security; and (6) feasibility measures (Bowen et al., 2009).

Following training, each RN was assigned a RN Assessor ID (NAID). An administrator gave the PI and the RA the tentative work schedules of the RN assessors. The PI and RA drafted a schedule of when RN assessors were available to be paired so that each pair could assess the same patient on the same day using the how2trak SSI tool. Initially, the intention of the study included a pairing arrangement for RN Assessors that saw each RN paired with a different partner during various days of the study. This was in an effort to randomize factors that might affect assessment such as education level, experience, etc. Ideally, each RN pair would have assessed the same number of patients in the course of the study. The PI attempted to schedule SSI assessments equally across pairs by: (1) having multiple meetings with the Director of Nursing to address the scheduling conflicts; (2) requesting that the Director of Nursing send out 3 reminder memos to nursing staff about scheduling difficulties for this study; (3) having staff meetings to discuss the study and ways to both increase enrolment and assuage scheduling concerns; and (4) hiring three RAs to be on-site for at least three days a week to increase

enrolment and facilitate the assessment process. However, ultimately, pairs did not see the same number of patients due to issues in scheduling, vacation time, Toronto area events, and the logistical challenges of working with three different clinics. Therefore, some assessor pairs assessed more patients than others based on their work schedules. Although some pairs did assess more patients than other pairs, all RNs were paired with multiple different partners for the study.

Scheduling Roles of the RAs and PI. There were three RAs hired as independent contractors by the PI to work on this study, two of whom were RNs, including one part-time RN from the Calea Clinics. The RAs worked closely with the PI to ensure that all of the processes to measure feasibility of the how2trak SSI tool and the prevalence rate of SSIs were closely tracked. The RAs assisted the PI to track the RN pairs and tried to ensure that they were assessing close to the same number of patients, this proved to be difficult for the reasons stated above.

The PI focused on ensuring that all aspects of the study were running as per the design, as well as troubleshooting with the RNs. The PI acted as the conduit between the RAs and the RNs to ensure that RNs understood the processes for pairing and assessment, and that the least possible burden was placed on the RNs.

Study Procedures

In this section, the SSI assessment is described in detail. First, the how2trak data collection tool is described, including its compliance with protected health information and data privacy. Then, the initial study assessment procedure is described (including the role of the PI and RAs); the procedure for the 30-day follow up assessment and its underlying rationale are explained; and the discussion group procedure is described.

how2trak SSI Data Collection Tool. The RN assessors used the how2trak SSI tool to perform the SSI assessment and enter all of the data collected during the initial and follow-up visits. The how2trak SSI assessment tool is a real-time, web-based application for point-of-care documentation that tracks patient care, clinical outcomes, quality of care, and costs. For the purpose of this study, an additional on-line application was created by embedding best practice clinical surgical incision assessment guidelines recommended by the CDC (Mangram, et al., 1999) in the tool to provide an accurate assessment of the surgical incision to determine whether or not an infection was present. During this study, the tool was accessed by password protected URL (https://www.how2trak.com/default.aspx?ReturnUrl=%2f) on desktop computers connected to the internet in each consultation room. It should be noted that since the study assessments took place, the how2trak tool has been made available for use on mobile tablets (iPad, Apple, Cupertino, CA, USA) provided to RNs, the implications of which are discussed in Chapter 6: Discussion.

Prior to the initial SSI assessments, the PI and RAs collected patient data using the how2trak collection tool when the patient consented to participate, so that the RN assessors would already have the patient data at hand when assessing the patients. These data included:

- Date of birth
- Sex
- Patient ID #
- Race/ethnicity
- Diabetes status
- Co-morbidity factors [indication of: cardiovascular disease, chemotherapy treatment, chronic obstructive pulmonary disease, diabetes, dialysis, heart disease, hypertension, hypotension, immunodeficiency, involuntary weight loss, loss of protective sensation,

lymphedema, obesity/Body Mass Index (BMI), patient smokes or lives with a smoker, peripheral vascular disease, polypharmacy, social isolation/lack of support]

- Date of SSI assessment
- Surgery date
- Surgery site/location
- CDC signs and symptoms of SSI

Surgery type was not collected, as previously mentioned, data from the acute care referral sources was extremely difficult to obtain, as the referral forms were not adequately completed and often the surgery type was not provided. For this study, the term *sex* was used instead of *gender* when referring to patient demographic information being male or female. The reason for collecting data about the sex of patients is that it is a risk factor for the development of an SSI. National regulatory bodies have proposed methods to collect data on sex and gender for scientific studies. Clayton and Tannenbaum (2016) note that gender and sex are important in clinical studies and data collection should be guided by the research questions of the study. It is known that biological, cultural, and environmental factors likely play a role as risk factors for any disease or condition and therefore a careful examination of the research question should help guide data collection around sex and gender. Clayton and Tannenbaum (2016) discuss that sex is highly relevant to biologically oriented questions whereas gender is highly relevant to socio-cultural questions. Our study was specifically examining biological/physiological factors associated with the risk of developing an SSI and therefore information about biological sex was collected in this study. Further studies could benefit from examining whether or not gender plays a role in the development of SSIs.

Initially, I had proposed a retrospective chart review from the patient's acute care health record, specifically to collect more details around the surgical classification (Appendix C) and

the ASA risk score (Appendix B); these data would have added to the patient characteristics for analysis. Initially, patients were generally being referred from the University Health Network (UHN) hospitals and, therefore, ethics approval from UHN was sought and granted. However, at the beginning of the study it became clear that patients were being referred to the Calea Clinic from more than 15 different hospitals. Based on the current procedures for ethics approval for health information from the acute care setting, obtaining permission to complete a retrospective chart review would require a unique ethics approval from each hospital. The alternative of excluding patients from all but one hospital would have made recruitment an extremely long process. Given that the most important information for SSI diagnosis and management was incision location, it was decided that I would not complete the retrospective chart review data as it was thought that it would not negatively impact data analysis. It should also be noted that the Calea Clinic chart stored very limited data on other important demographic characteristics, such as socioeconomic status. Therefore, future studies interested in evaluating the relationship of patient demographic information and their risk on SSI should include socioeconomic status.

The how2trak tool was chosen as the tool for this study as it is the first of its kind in Canada. There are other tools being developed in other parts of Canada but they were not ready for use in a post-discharge surveillance capacity in time for the beginning of this study. There was a similar problem with tools in the US; that is, only prototypes were available but no tested or validated tools were ready for use at the beginning of this study. Therefore, the how2trak tool was chosen for this study as it had been tested by key stakeholders (such as surgeons, nurses, nurse practitioners and physicians) for a period of 3-4 years before being used in this study.

Protected Health Information and Data Privacy. All data collected during this study (including the consent forms and discussion group data and information) were uploaded to, and contained in, the how2trak system's triple encrypted software storage base, which is protected by

quality assessment procedures. The how2trak SSI tool is a secure system that has undergone testing and evaluation by independent bodies, has approval from national regulators to hold healthcare information, and has passed all security testing, the testing was completed by Grant Thornton. The tool was determined to be compliant with the Personal Information Protection Electronic Documents Act (http://laws-lois.justice.gc.ca/eng/acts/P-8.6/index.html) and the US Health Insurance Portability and Accountability Act (https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html). The tool has had a Privacy Impact Assessment (PIA) completed by Grant Thornton privacy experts, the results of which are stored in the database. The data are stored and maintained on a data server in Montreal, Canada and backed up on a daily basis on a separate server, as required by the PIA. Any identifying data collected during this study were only accessible to the PI, RAs, and PI's dissertation committee. All data files will be deleted five years after study completion as per ethics requirements.

Initial SSI Assessment Procedure. Study participants presented to the clinic for their scheduled SSI assessment by the assigned RN pair. Each examination room had a desktop computer with on-line access to the how2trak system. The participant met with the first RN, who logged into the how2trak system, entered patient information, and completed a comprehensive wound assessment using the CDC assessment guidelines. The RN measured the length, width, and depth of the wound, determined the wound area, checked for wound characteristics (granulation, exudate levels, periwound characteristics, undermining, and odor), assessed for pain, assessed for general wound infection and antibiotic use, and recorded the number of dressing changes in the how2trak tool. The RN used an iPad provided by the Calea Clinic to take a digital photograph of the surgical incision following the recommendations of Sperring and Baker (2014). The photograph included the patient's name/identification, date of birth, location, and brief clinical history. A white drape was used in the background, and a ruler was placed

alongside the wound to indicate wound size. A close-up photo was taken with the camera body parallel to the subject. The RN uploaded the photograph to the how2trak system.

Next, the RN proceeded with the SSI assessment using the how2trak tool, which took approximately 3-5 minutes. The RN evaluated the wound for the CDC SSI criteria listed in Appendix A and checked off the criteria observed on the how2trak tool. If there was at least one CDC criterion present, then an SSI was determined to be present. The RN assessed the incision sites of the wound as having a superficial, deep or organ space infection. Then the first RN exited the room, and a second RN came in within 5-10 minutes to perform a second SSI assessment using the how2trak tool. The second RN then dressed the wound and provided the patient with care instructions. Patients were then either sent home, or directed for more follow-up tests, or sent to their physician, or sent to the emergency room. It is important to note that the PI and RAs never observed nurse assessors sharing notes or assessments during the research study. During both the processes for consent to participate in the study and the one-hour education session, the importance of objective and independent assessments were emphasised to all nurse assessors. The nurse assessors agreed to adhere to study protocols and procedures when signing consent. Given that the Calea Clinics are very busy clinics, there would not only be no benefit to share assessments, but also not enough time for nurses to share assessments.

The results of the SSI assessments by both RNs were entered into the how2trak system while the RN was in the patient's room and later analysed for concordance between RN pairs to assess whether or not they arrived at the same decision about the incision. Routinely each data field was assessed within the how2trak tool to ensure completeness of the dataset by both the PI and RAs. The PI returned to the study clinics on a regular basis (usually at least twice a month during SSI assessments and data collection; RAs were there 3 days per week) and assessed the how2trak application remotely on a weekly basis to review data collection. If there were portions

of the tool that were not filled in, the PI and/or RA contacted the RN assessor to determine why there were missing data.

Follow-up Visits. For patients who did not have an SSI identified during their initial SSI assessment, follow-up visits were scheduled within 30 days postoperatively. No inter-rater reliability data were collected at the follow-up visits. This was not required at the follow up visit as the inter-rater reliability data were completed during the first visit. Therefore, any of the trained RN assessors could conduct a follow-up visit. Data collected at the 30-day postoperative follow-up visit were solely used to calculate the prevalence rate for the study sample based on whether an SSI occurred (with 30 days postoperative being the standard timeframe used to calculate an SSI). The CDC SSI assessment guidelines were not used at this time. The patients were asked to self-report whether or not they were treated for a surgical site infection.

Some patients were assessed and treated more frequently than others depending on the frequency of the care required for their postoperative incisional wound, but SSI information was only to be collected once at the initial study assessment and/or at the 30-day follow-up visit where applicable. If a patient with a follow-up visit scheduled did not return to the clinic, then the PI and/or RA attempted a follow-up phone call, and the patient self-reported whether or not they had been treated for an SSI by a healthcare professional. Having the patient self-report information about the development of an SSI was a limitation of this study. While it is helpful to know whether patients went to an ER to receive care for their incision or if they received a diagnosis of a surgical site infection, it is a non-standardized, potentially biased form of data collection. This limiting factor of the study prompted further development of the how2trak surgical application, in that, standardized self-reported patient SSI markers were created to ensure a standardized data collection process.

Discussion Groups. Upon completion of the SSI assessments and follow-up visits, RN assessors participated in a discussion group conducted by an RA. Four different groups at different times/dates were offered to RN Assessors to accommodate nurse schedules. However, the PI successfully arranged two separate group discussions via teleconference that incorporated as many nurse assessors as possible. The education session offered to the nurses prior to the wound assessments provided the RN Assessors information regarding the importance of honest feedback about the application. Additionally, during training, it was clearly communicated to the nurse assessors that honest feedback - whether positive or negative - would not benefit or disadvantage them in any way. To prevent bias and alleviate the feeling of obligation for positive feedback from RN Assessors, the PI was purposely absent from any and all group discussions and group discussions were only carried out by independent and objective RA. It should be noted that the Independent RA did not have any connection to the Calea Clinic neither professionally nor socially. Although the PI reviewed techniques of discussion group facilitation with the RA, the RA who conducted the discussion group was not an expert in discussion group facilitation and, therefore, that impacted the data gleaned from those sessions and data did not have sufficient depth to employ sophisticated analysis. In future studies, it would be important to have an expert facilitator lead the discussion groups.

The purpose of the discussion groups was to understand workflow and process issues regarding use of the how2trak SSI tool, with an emphasis on determining the RNs' perspective on the use of the tool compared to the current practice of using non- standardized paper based documentation for the assessment and treatment of SSI. An RA facilitated the discussion and asked the following open-ended questions to facilitate the discussion with the RN assessors:

- How would you describe your overall experience of using the how2trak SSI tool?

- How do you think the how2trak SSI tool compares to the clinic's current method of assessing surgical patients?
- How would you compare the how2trak SSI tool with the clinic's current method of assessing surgical patients in terms of efficiency?
- How would you compare the how2trak SSI tool with the clinic's current method of assessing surgical patients in terms of user-friendliness?
- Overall, what effect, if any, do you think using the how2trak SSI tool had on your delivery of care?

The discussion groups were conducted on September 6th and 7th, 2016, via video teleconference after all of the patient data collection was completed. Each discussion lasted approximately thirty minutes. The data and information collected during the discussion groups were recorded and de - identified to assess RN opinions and RN feedback on the how2trak tool. Full transcripts of the discussions are presented in Appendices I and J. Results from the discussion groups were summarized and presented in the results section. Thematic analysis was not utilized in the evaluation of the discussion group data.

Data Analysis

In this section, the descriptive analysis and the reliability analysis of the data collected using the how2trak SSI tool are described. A compilation of assessor feedback gained from the discussion groups (e.g., the benefits of the how2trak tool, time difference between paper tool and electronic tool, ease in use, whether having more data aided in patient care) are also explained. Finally, the analysis required for calculating the prevalence of SSIs in the patient population enrolled is described.

Descriptive Analysis. Descriptive analysis was used to describe the sample demographic and clinical characteristics of the patient and RN participants. Continuous data

were summarized as a mean or median and standard error of the mean. Frequency data referring to the number of times an SSI was confirmed were summarized as proportions.

Analysis of RN Assessors' SSI Assessments. The data obtained through the SSI assessments by RN assessors were analysed based on RN-related, patient-related, and wound-related parameters. The data for each parameter were grouped by breakpoints. There were no automatic breakpoints for each of the parameters noted in the literature, breakpoint determinations were generally based on the distribution pattern of data and whether there were sufficient data in each category to analyse. For parameters related to the RN experience, the breakpoint decision was also based empirically on the number of years necessary for the RN to be considered experienced. Generally, RNs are considered experienced if they have between five and ten years in a specific area (Benner, 1984; Kanai-Pak, Aiken, Sloane, & Poghosyan, 2008). The fact that there were previously established definitions for RN experience, years of experience was collected as a categorical variable instead of a continuous variable. This facilitated the use of the chi square analysis. To be consistent with the rest of the data, age, BMI, pain, and wound area were collected as categorical variables and were also analyzed using the chi square method. These data were assessed as counts (as the percentage of RNs or patients with data available).

Analysis was conducted for the following RN-related characteristics:

RNs age using a breakpoint of ≥40 years

RNs education using a breakpoint of degree or no degree

RNs experience using a breakpoint of ≥10 years or more

RNs surgical experience using a breakpoint of ≥10 years or more.

RNs Calea Clinic experience using a breakpoint of ≥4 years or more.

Analysis was conducted for the following patient-related parameters:

- Patient's age using a breakpoint of 60 years
- Patient's BMI using a breakpoint of 25 for BMI
- Patient's perceived pain level [Visual Analogue Scale (VAS); 1-10) using a breakpoint of no pain (0) or pain (1-2, and ≥ 2).

One wound-related parameter was analysed:

- Wound area using a breakpoint of 1 cm^2 (area < 1 cm^2 or area ≥ 1 cm^2).

Differences between groups of breakpoint parameters were examined based on the outcome of infection status using chi square for assessments. A 5% significance level (i.e., type 1 error) was used. Concordance was tested later between groups using logistic regression (see below for complete details).

Inter-related Reliability Analysis/Concordance. The assessment of inter-rater reliability provides a way of quantifying the degree of agreement between two or more coders who make independent ratings about the features of a set of subjects (Hallgren, 2012). For this study, simple and exact concordance were determined for the RN pairs based on the 3 possibilities identified by SSI assessment: no infection, superficial infection, and deep infection, as per the CDC standardized criteria. (No organ space infections were identified). For the purposes of concordance analysis, the CDC criteria for superficial infection were coded as 27, 28, 29, and 32, and the CDC criteria for deep infection were coded as 34, 35, 38, and 39. During the SSI assessment, a RN assessor rated the patient's wound according to the 8 SSI criteria (27, 28, 29, 32, 34, 35, 38, and 39) embedded in the how2trak tool by clicking on the relevant criteria applicable to each patient. The criteria clicked determined the RN's decision as being one of the following:

- ***deep infection*** - if one or more of the criteria 34, 35, 38 or 39 was clicked

- ***superficial infection*** - if one or more of the criteria 27, 28, 29 or 32 was clicked but none of 34, 35, 38 or 39 was clicked
- ***no infection*** - if none of the 8 criteria was clicked.

It is noted that a wound with superficial infection criteria (27, 28, 29 or 32) was assessed as a deep infection if any of the deep infection criteria were also present. The wound was considered to have a superficial infection only if it did not have a deep infection (Mangram, et al., 1999).

Simple concordance was defined as the proportion of patients for whom the 2 RNs agreed on the sheer presence or absence of an infection: **either (no, no), or (superficial, superficial), or (deep, deep), or (superficial, deep).** For example, RNs could have had a high simple concordance even if they diagnosed the infection based on different CDC parameters as long as they both agreed that there was an infection present.

Exact concordance was defined as the proportion of patients for whom the 2 RNs agreed exactly: either (no, no), or (superficial, superficial), or (deep, deep). Exact concordance was described as:

[#(no, no) + #(superficial, superficial) + #(deep, deep) + #(superficial, deep)] / N,

When evaluating the feasibility of a tool it is important to measure the reliability of tool as a quality indicator. "Reliability estimates describe the precision of an instrument, its capacity to produce constant, similar results." (Stolarova, Wolf, Rinker & Brielmann, pg 509, 2014). In this study I measured inter- rater reliability as the measure of agreement between raters. Furthermore, I measured both simple and exact concordance

In using the CDC Guidelines as the assessment criteria, it was important to pick up any and all infections regardless of whether or not the assessors used the same criteria to diagnose an infection. It was a good test of the CDC guidelines in determining the ability of the guidelines to diagnose infection. The results of this study support the use of CDC guidelines for infection

detection. It is important to include both simple and exact concordance to gather a comprehensive picture of the SSI rate within this population.

Comparisons between RN, patient, and wound characteristics were analysed for concordance using the same parameters described in the previous section and expressed as a continuous number between 0 and 1, with ≥ 0.7 indicating a strong correlation. Since each RN may not have had the same characteristics as the RN with whom she/he was paired, the unit of observation was the RN, not the patient. Simple and exact concordance were defined as above, but the presence or absence of concordance within the pair was counted once for each of the 2 RN assessors, instead of once per patient. This allowed for each RN to have a value of concordance allocated to the relevant RN variable grouping. When comparing between patient and wound characteristics, the unit of observation was the patient. Concordance was calculated separately within each patient variable grouping.

Concordance Modeling - RN-centric Model. For each RN-pair assessment, both simple and exact concordance were calculated. (1 if both RNs agreed, 0 if they disagreed).

An ordinal variable for RN age was created from actual RN age using a breakpoint of ≥40 years. The RN pairs were then coded thus: 0 = both young (< 40 years); 1 = mixed (1 < 40 years, the other ≥ 40 years); 2 = both old (≥ 40 years); 3 = unknown (ages of 1 or both RNs not known).

A nominal binary variable was initially created for whether the RN had a degree or not (1 = yes; 0 = no). The RN age variable was then coded thus: 0 = neither has degree; 1 = 1 of them has a degree; 2 = both have a degree.

An ordinal variable for years of nursing experience was created from actual years of nursing experience using a breakpoint of ≥ 10 years. The RN pairs were then coded thus: 0 = both inexperienced (< 10 years); 1 = mixed (1 <10 years, the other ≥ 10 years); 2 = both experienced (≥ 10 years); 3 = unknown (experience of 1 or both RNs not known).

An ordinal variable for years of surgical nursing experience was created from actual years of surgical nursing experience using a breakpoint of ≥ 10 years. The RN pairs were then coded thus: 0 = both inexperienced (< 10 years); 1 = mixed (1 < 10 years, the other ≥ 10 years); 2 = both experienced (≥ 10 years); 3 = unknown (experience of 1 or both RNs not known). (In logistic regression, 2 and 3 were combined since the third category was very small.)

An ordinal variable for years at Calea was created from actual years of employment at Calea using a breakpoint of ≥ 5 years. The RN pairs were then coded thus: 0 = both inexperienced (< 5 years); 1 = mixed (1 < 5 years, the other ≥ 5 years); 2 = both experienced (≥ 5 years); 3 = unknown (experience of 1 or both RNs not known).

A wound marker variable was created for each RN-pair assessment of the wound (1 = primary, 0 = secondary). All secondary entries (meaning rows in the statistical database file in which there are duplicate entries for patient- and wound-related and other data for each RN pair) were deleted leaving 1 concordance value for each wound. Correlation between the variables described above were examined based on whether the correlation was ≥ 0.7. All analyses excluded unknown categories.

A univariate logistic regression was conducted for each concordance type, in which each independent variable was entered by itself to determine the rank ordering of each variable by p value. The lowest coded category for each variable was used as the reference (e.g., both young RNs).

Patient- and Wound-centric Models. For the patient-centric model, BMI was categorized as ≤ 25 or > 25, age was categorized as < 60 years or ≥ 60 years, and wound-related pain level was recoded as: (1) 0 (none); 1 (1 or 2); and (3) > 2. For the wound-centric model, wound area was calculated from width x length and categorized as <1 cm^2 or ≥ 1 cm^2.

Logistic Regression with Multiple Independent Variables. Two methods were used to construct logistic regression models with multiple independent variables. For the first method, all variables with marginal p values (< 0.1) were identified from the prior univariate analyses with the most significant variable entered in the first block, followed by the next most significant variable in a second block, until all variables had been added. This process was also done for other orders of the identified variables to ensure other viable model combinations were not accidentally dismissed. Model refinement was then accomplished. Dispersion was calculated as Pearson deviance/df. For the second method, all variables were entered in 1 block and refinement conducted by removing the least significant variables 1-by-1. The odds ratios (OR) and the 95% confidence intervals (CIs) for the model parameters and associated ORs were also calculated.

Other Feasibility Measures. Additional feasibility measures that were identified during the discussion groups s included the benefits of using how2trak tool, its ease in use, its efficiency, its effect on delivery of care, and the overall experience using the tool when compared to paper documentation. The PI documented a summary of the experience of the RN assessors reported during the discussion groups in order to understand the practicality and the workflow strengths and limitations of the how2trak SSI tool in the clinical setting. A basic analysis was completed to identify patterns or themes in the data. The discussion group notes were transcribed by the PI and the key points articulated by the RN assessors were analyzed to understand the feasibility of the tool.

Determining the SSI Prevalence Rate

Study data were used to determine the prevalence of SSIs among the study sites. Diagnosis of SSI (based on the CDC SSI assessment guidelines) was noted if it occurred during the initial SSI assessment or at any point up to, and including, day 30 following the surgery (provided that the patient returned for the day 30 follow-up visit and had data collected for SSIs

that may have occurred after the initial assessment and or was reported by the patient via a phone call follow up visit.

The prevalence of SSI was determined using the data collected by the RN pairs using the how2trak tool during the initial assessments and the infections reported by patients to the PI and RA at follow-up, during a clinic visit or a follow up phone call. For SSIs identified during the initial assessments, each superficial or deep SSI identified by one RN in a RN pair was assigned 0.5 count. Therefore, if both RNs identified an SSI, the count assigned was 1 for that patient. The counts were totaled and then divided by the total number of SSI assessments performed to determine prevalence. For SSIs reported at follow-up, which could be by a clinic visit or by a phone report each infection was counted as 1.

Methodological Implications and Relevance

The Nosocomial Infection National Surveillance Service (NINSS) indicates that the incidence of hospital-acquired infections related to surgical wounds is as high as 10%; these infections complicate illness, increase pain and suffering, and can lead to death (Whitehouse et al., 2002). Patients with SSIs have greater physical limitations, have lower mental health component scores, have more outpatient visits, have more emergency room visits, require more radiology services, have more frequent hospital readmissions, and have a reduced quality of life (Whitehouse et al., 2002; Perencevich et al., 2003; WHO, 2009). The evidence confirms the assumptions that SSI rates, and the burden of caring for them, are underestimated when relying only on inpatient SSI rates (Tanner, et al., 2012). Oliveira et al., (2007) observed that an estimated 12%-84% of SSIs occurred after discharge in studies that included a process for post discharge surveillance.

Although postoperative discharge surveillance increases the detection and thereby improves patient treatment, currently, there is no standardized systematic process identified in

the literature to detect and assess whether or not a patient has an SSI in the home care clinic environment. Prior to this study, participating RNs at the Calea Clinics assessed postoperative incisions for approximation, induration, and signs and symptoms of infection (e.g., redness, pain, and/or pus drainage). Research shows that the assessment and care of patients with a wound infection appear inconsistent, and there can be a variety of different management strategies being utilized by different healthcare practitioners (Collier, 2004).

This study was designed to evaluate the feasibility of a standardized methodology for the detection and treatment of SSIs that has the potential to improve patient outcomes, decrease pain and suffering, and decrease overall costs related to the development of an SSI. During this study, the RN assessors utilized the 1999 CDC SSI assessment guidelines embedded in the how2trak SSI tool as their assessment tool for the determination of whether an SSI was present. After the study was completed, the CDC guidelines were updated in January 2017 (Berríos-Torres et al., 2017); implications for this change are discussed further in Chapter 6.

This study builds understanding regarding the use of a web-based tool instead of paper documentation in a community clinic setting. This is especially important to the home care clinic setting, because home care clinics do not have access to patient medical records and are provided with very limited patient information when patients are referred to their services. The study provides an understanding of whether a more complete set of data from the referral source can aid in earlier identification and treatment of SSIs, thereby improving patient outcomes, decreasing complications, and decreasing admission to hospitals. Additionally, this study supports the critical need for the Calea Clinics to have readily available patient information collected in the acute care setting. Without this information, risk cannot be stratified amongst patients thereby leaving patients at undue risk for developing an SSI. Relevant patient history, current medications, risk profile scores, surgical classification and previous surgical history are

essential in the proper management of SSIs. This study emphasizes the gap in available patient information for those patients receiving post-incisional care at the Calea Clinics.

Until now, there has been no defined prevalence rate of SSIs in the home care clinic setting. The prospective method of data collection undertaken in this study identified the rate of SSIs in a home care clinic setting. This study provides both immediate and long-term benefits to the participating patients. The immediate and direct benefit to patients was that they received a comprehensive standardized surgical incision/wound assessment using the CDC guidelines, which may have resulted in more timely detection and treatment of an SSI. The long-term benefit for the general patient population is an increased understanding of the patient population affected by SSIs in the home care clinic setting, by determining for the first time SSI prevalence in this setting, which will inform future interventional studies for the improvement of care of this patient group.

CHAPTER 5

RESULTS

Introduction

This study evaluated the feasibility of a web-based surgical site infection (SSI) tool that uses the 1999 United States Centers for Disease Control and Prevention guidelines for the detection of SSIs (Mangram, et al., 1999), based on RN assessors' concordance, and determined the SSI prevalence for a patient population in the home care clinic setting in the Greater Toronto Area. Patient referral and recruitment, RN pair assessments using the how2trak SSI tool, and follow-up visits with the patients to place between March 2015 and July 2016 at 3 Calea Home Care Clinics in Toronto. Discussion groups were carried out in 2 sessions via teleconference on September 6 and 7, 2016. Fifteen RNs in various paired combinations assessed 101 patients for SSIs during this study. There were 34 known pair combinations; additionally, 3 patients were assessed by 3 pairs of RNs that did not have the first RN's name recorded. The number of patients assessed by each RN is provided in Table 1. Each RN assessed a mean of 13 patients (SD: 8.1; median: 12; range: 4-28).

In this chapter, the results of the SSI assessments, data collection, and data analyses that were completed as part of the study methodology described in Chapter 4 are provided. First, the patient and RN assessor populations are described. Second, the SSI assessments and concordance by RN-, patient-, and wound-related parameters are provided. Third, the statistical concordance models are given. Fourth, the perspectives identified during the discussion groups are summarized and considered. Fifth and lastly, the analysis for overall prevalence of SSI among patients in this study is provided.

Table 1
Number of Patients Assessed by Each RN Assessor during the Initial Surgical Site Infection Assessments

RN Assessor	No. of Patients Assessed
1	16
2	5
3	22
4	4
5	4
6	12
7	10
8	19
9	17
10	24
11	18
12	28
13	3
14	5
15	12
Unknown	3

Study Populations

Patient Population. There were 1,432 patients with postoperative incisions referred to Calea Clinics during the period of this study; 316 (22.1%) were interested in participating in the study and were screened for study eligibility. One patient was ineligible and excluded due to having a lack of understanding concerning the study procedure. There were 315 patients who were eligible and consented to participate in this study. However, only 109 patients were recorded as presenting for their initial SSI assessment after giving their consent to participate; the rest were lost to follow-up as a result of the RN assessors not being able to carry out the how2trak SSI assessment at the first patient visit due to scheduling issues. These patients were called back, but by the time they returned to be assessed with the how2trak tool, the 30-day period had expired and they were no longer eligible to participate in the study. Three patients were listed twice as duplicates, therefore, 106 were assessed for SSIs. Five patients were not included in the study analysis, because they were only assessed using the how2trak tool by 1 RN. Therefore, in total, 101 patients were assessed for SSIs by a RN pair using the how2trak tool and included in the study analysis. Of the 101 patients assessed by a RN pair, there were three incidents where the RA entered the patient's name in an effort to help the nurse, but the system recorded the RA as the assessor and although two nurses completed those assessments, only one nurse name was recorded. Their demographics and clinical characteristics are provided in Table 2.

The mean age was 46.9 years [standard deviation (SD): 16.8], with 76 (75.2%) of study participants being younger than 60 years and 25 patients (24.8%) aged 60 years or older. Given that the majority of patients were between the age of 40 and 60, it is likely that the majority of patients over the age of sixty did not receive care in the Calea Clinics but may have been referred to other forms of home care for their post-op surgical care. Most participants reported that they

did not smoke or drink alcohol and were not diabetic; 51 (50.5%) had a BMI greater than 25, and 21 (20.8%) were obese (Table 2). The mean wound area was 3.2 cm^2 (SD: 9.9); 73 wounds (72.3%) were less than 1 cm^2, and 28 wounds (27.7%) were at least 1 cm^2.

Figure 1. Patient Flow Diagram

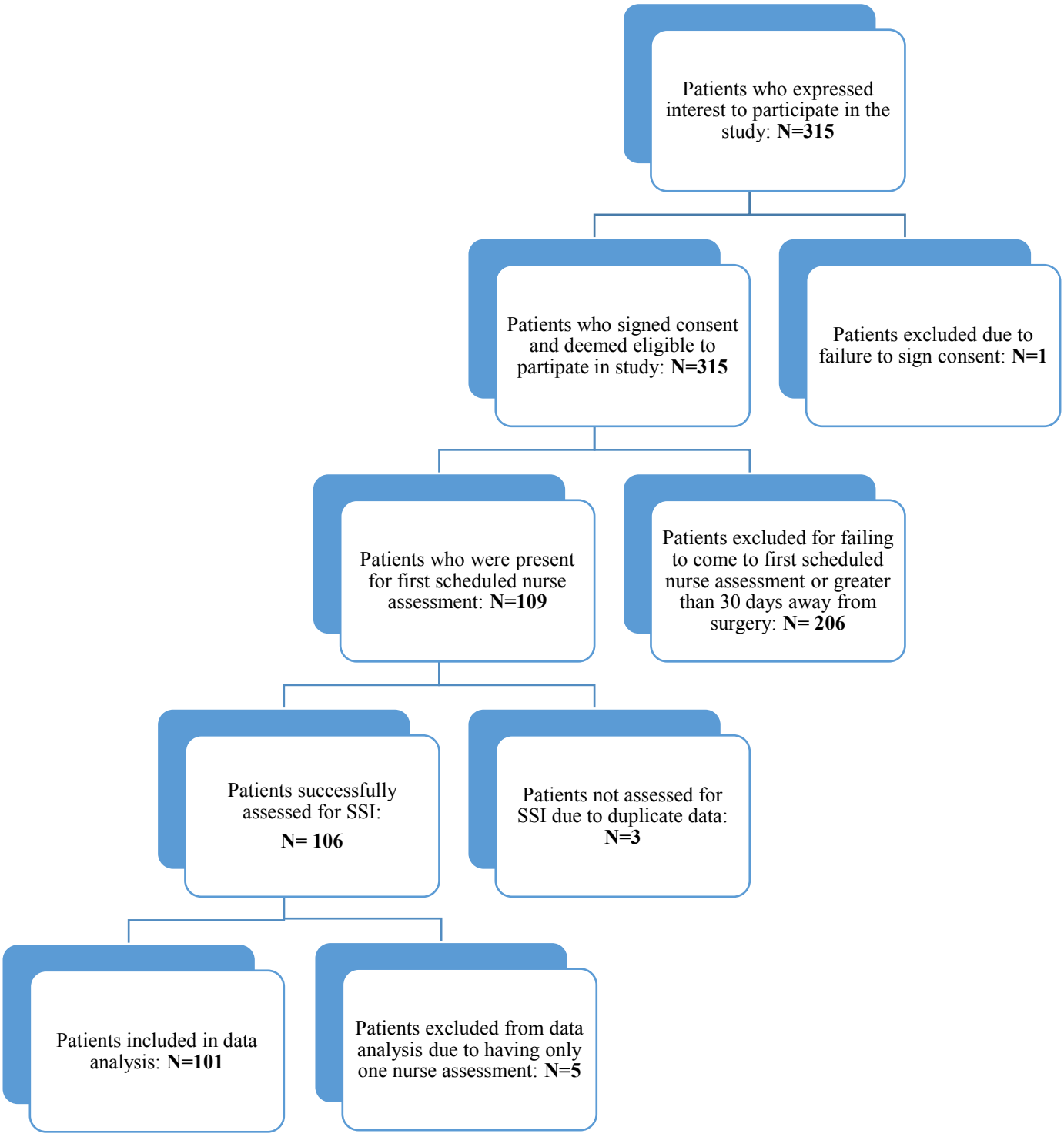

Table 2

Patient Demographics and Clinical Characteristics, n = 101

	n (%)	Mean (SD or Range)
Sex		
Male	55 (54.5%)	
Female	46 (45.5%)	
Race/Ethnicity		
African	3 (3%)	
Asian	7 (6.9%)	
Arab	4 (4%)	
White	38 (37.6%)	
Hispanic/Latino	2 (1.9%)	
Unknown	47 (46.5%)	
Age (years)		46.9 (16.8)
20-49	60 (59.4%)	
50-79	39 (38.6%)	
≥ 80	2 (2%)	
BMI		27.2 (18.9-42.5)
18.5-25.0	29 (28.7%)	
25.1-29.9	29 (28.7%)	
≥ 30	22 (21.8%)	
Unknown	21 (20.8%)	
Smoking		
Yes	16 (15.8%)	
No	77 (76.2%)	
Unknown	8 (7.9%)	
Alcohol		
Yes	26 (25.7%)	
No	60 (59.4%)	
Unknown	15 (15.9%)	
Diabetic		
Yes	8 (7.9%)	
No	93 (92.1%)	

Notes: SD = standard deviation

Forty (39.6%) participants had wounds with at least one sign of SSI observed during the initial SSI assessment; 26 (25.7%) participants had an SSI reported by both RNs and 14 (13.9%) had an SSI reported by only 1 RN. Seven (6.9%) participants had wounds identified as a deep SSI identified by both RNs; 14 (13.9%) had a deep SSI reported by only 1 RN. Twenty-two (21.8%) participants had wounds identified as a superficial SSI reported by both RNs; 15 (14.9%) participants had wounds identified as a superficial SSI by only 1 RN. Sixty-one (60.4%) participants had wounds with no signs of SSI reported by both RNs and were scheduled for a follow-up visit at day 30. The majority of patients did not return to the Calea Clinics for the 30-day follow up visit. Twenty-five (40.9%) patients had some form of follow-up: 6 (24.0%) patients were known to present at the clinic for follow-up, 8 participants had a phone call with the PI or the RA; however, the type of follow-up visit is unknown for 11 (44.0%) patients. Twenty-two (88.0%) participants had no signs of a new SSI infection reported during the follow-up process. Three (12%) participants reported that they had an SSI infection at follow-up. In total, there were 43 (34.6%) participants with an SSI reported during the course of this study.

RN Assessor Population. Fifteen RNs out of 18 Calea nursing staff (83.3%) consented to participate in this study and were trained as RN assessors. Their demographics are provided in Table 3. The mean age was 39.3 years (SD: 11.7), with 7 RNs (46.7%) being at least 40 years old. The majority of RNs had a degree (n = 10, 66.7%). Among the 5 RNs who did not have a degree, they all had a nursing diploma. The majority of RNs were experienced and had worked at least 4 years at Calea Clinic; however, only 3 (20%) had at least 10 years of surgical experience.

Table 3

RN Assessor Demographics, n =15

	n (%)	Mean (SD)
Age, years		39.3 (11.7)
< 40 years	8 (53.3%)	
≥ 40 years	7 (46.7%)	
Degree		
Yes	10 (66.7%)	
No	5 (33.3%)	
Years of Nursing Experience		13.7 (9.1)
< 10 Years	7 (46.7%)	
≥ 10 Years	8 (53.5%)	
Years of Surgical Experience		4.2 (5.5)
< 10 Years	12 (80%)	
≥ 10 Years	3 (20%)	
Years Working at Calea Home Care Clinic		3.9 (3.0)
< 4 Years	5 (33.3%)	
≥ 4 Years	10 (66.7%)	

Notes. SD = standard deviation.

Overall Prevalence and Concordance

The total prevalence of SSIs was 34.2% during this study, 17.8% of the study participants had a superficial infection and 16.3% had a deep infection. The overall simple concordance among RN assessor pairs was 0.822 [83/101; 95% Confidence Interval (CI): 0.73-0.89]. The overall exact concordance was 0.782 (79/101; 95% CI: 0.69-0.86), and deep infection concordance was 0.819 (68/83; 95% CI: 0.72-0.90). The following section analyzes concordances by RN-, patient-, and wound-related parameters.

SSI Assessments and Concordance by RN-, Patient-, and Wound-related Parameters

The results of the SSI assessments and concordance by RN-, patient-, and wound-related parameters are provided in Tables 4-21 and discussed below in further detail. There were 202 SSI assessments performed by RN assessors on 101 patients, but in some instances, RN-related information was missing, so the total number of SSI assessments analysed was smaller at times. Likewise, there should have been 101 wounds available for any kind of concordance between a RN pair (for which the unit of observation is the RN), but missing RN-related data also reduced this number.

RN-related Parameters

Assessments and Concordance by RN's Age. The assessments and concordance by RN's age are provided in Tables 5 and 6, respectively. Younger RNs (< forty years of age), compared to older RNs (> 40 years), reported fewer infections within their SSI assessments (Table 4). Also, Concordance was substantially lower for younger RNs (<40 years) compared to older nurses (>forty years) or RN pairs of mixed age groups (Table 5).

Table 4

Assessment by RN Age Using a Breakpoint of 40 Years, Based on 198 Assessments Performed

Assessment Outcome	Age < 40 years, n (%)[a]	Age ≥ 40 years, n (%)[a]
No Infection	53 (73%)	78 (62%)
Infection	20 (27%)	47 (37%)
Superficial	6 (8%)	28 (22%)
Deep	14 (19%)	19 (15%)

Notes. [a]Number of assessments and associated prevalence (%).

Table 5

Concordance by RN Age, Based on 97 Analyzed Wounds

	Both <40		<40 and ≥ 40		Both ≥ 40	
	Concordance (n/N)	**95% CI**	**Concordance (n/N)**	**95% CI**	**Concordance (n/N)**	**95% CI**
Simple Concordance[a]	0.68 (13/19)	0.43-0.87	0.88 (29/33)	0.72-0.97	0.84 (38/45)	0.71-0.94
Exact Concordance[b]	0.63 (12/19)	0.38-0.84	0.82 (27/33)	0.65-0.93	0.82 (37/45)	0.68-0.92
Deep Infection Concordance[c]	0.71 (12/17)	0.44-0.90	0.83 (24/29)	0.64-0.94	0.86 (30/35)	0.70-095

Notes. [a]Agreement in terms of presence or absence of infection. [b]Agreement in terms of both presence and depth of infection. [c]Agreement in terms of presence or absence of deep infection. CI = confidence interval.

Assessments and Concordance by RN's Education. The assessments and concordance by RN's education are provided in Table 6 and 7, respectively. There were generally a fewer number of assessments coded as *any kind of infection* by RNs with degrees compared to RNs with no degrees (42 vs 89) (Table 6). Concordance showed no pattern by how much education the RN pair had, specifically whether or not the RN had a degree or did not have a degree.

Table 6

Assessment by RN's Degree Using a Breakpoint of Degree or No Degree, Based on 198 Assessments Performed

Assessment Outcome	No Degree, n (%)[a]	Degree, n (%)[a]
No Infection	42 (58%)	89 (71%)
Infection	31 (43%)	36 (29%)
Superficial	18 (25%)	16 (13%)
Deep	13 (18%)	20 (16%)

Notes. [a]Number of assessments and associated prevalence (%).

Table 7
Concordance by RN's Degree, Based on 97 Analysed Wounds

	No Degrees		One Degree		Both Degrees	
	Concordance (n/N)	**95% CI**	**Concordance (n/N)**	**95% CI**	**Concordance (n/N)**	**95% CI**
Simple Concordance[a]	1.0 (9/9)	0.67-1.0	0.80 (43/54)	0.67-0.89	0.82 (28/34)	0.66-0.93
Exact Concordance[b]	0.89 (8/9)	0.52-1.0	0.80 (43/54)	0.67-0.89	0.74 (25/34)	0.56-0.87
Deep Infection Concordance[c]	0.80 (4/5)	0.28-1.0	0.85 (39/46)	0.71-0.94	0.77 (23/30)	0.58-0.90

Notes. [a]Agreement in terms of presence or absence of infection. [b]Agreement in terms of both presence and depth of infection. [c]Agreement in terms of presence or absence of deep infection. CI = confidence interval.

Assessments and Concordance by RN's Experience. The assessments and concordance by RN's experience are provided in Tables 8 and 9, respectively. Assessments were higher for superficial infection among experienced (>10 years) RNs compared to RNs who were less experienced (< 10 years) (Table 8). For these results, experience refers to general work experience, defined by having greater than or less than ten years of general nursing experience. However, concordance did not substantially differ between groups (Table 9).

Table 8

Assessment by RN Experience Using a Breakpoint of 10 Years or More, Based on 198 Assessments Performed

Assessment Outcome	Not Experienced, n (%)[a]	Experienced, n (%)[a]
No Infection	51 (74%)	80 (62%)
Infection	18 (26%)	49 (38%)
Superficial	6 (9%)	28 (22%)
Deep	12 (17%)	21 (16%)

Notes. [a]Number of assessments and associated prevalence (%).

Table 9
Concordance by RN Experience, Based on 97 Analysed Wounds

	Neither Experienced		One Experienced		Both Experienced	
	Concordance (n/N)	**95% CI**	**Concordance (n/N)**	**95% CI**	**Concordance (n/N)**	**95% CI**
Simple Concordance[a]	0.79 (15/19)	0.54-0.94	0.84 (27/32)	0.67-0.95	0.83 (38/46)	0.69-0.92
Exact Concordance[b]	0.79 (15/19)	0.54-0.94	0.78 (25/32)	0.60-0.91	0.78 (36/46)	0.64-0.89
Deep Infection Concordance[c]	0.83 (15/18)	0.59-0.96	0.79 (22/28)	0.59-0.92	0.83 (29/35)	0.66-0.93

Notes. [a]Agreement in terms of presence or absence of infection. [b]Agreement in terms of both presence and depth of infection. [c]Agreement in terms of presence or absence of deep infection. CI = confidence interval.

Assessments and Concordance by RN's Surgical Experience. The assessments and concordance by RN's surgical experience are provided in Tables 10 and 11. Among RNs who were not surgically experienced, the number of assessments were significantly higher for *no infection* (104 vs 27) and lower for *superficial infection* (20 vs 14) (Table 10). All types of concordance were higher when one of the RN pairs was *surgically* experienced (Table 11) compared to *no surgical experience*. However, there were only 3 RN pairs who were both surgically experienced, which makes this concordance more uncertain.

Table 10
Assessment by RN Surgical Experience Using a Breakpoint of 10 Years or More, Based on 198 Assessments Performed

Assessment Outcome	**Not Surgically Experienced, n (%)[a]**	**Surgically Experienced, n (%)[a]**
No Infection	104 (70%)	27 (54%)
Infection	44 (30%)	23 (46%)
Superficial Infection	20 (14%)	14 (28%)
Deep Infection	24 (16%)	9 (18%)

Notes. [a]Number of assessments and associated prevalence (%).

Table 11
Concordance by RN Surgical Experience, Based on 97 Analysed Wounds

	Neither Experienced		One Experienced		Both Experienced	
	Concordance (n/N)	**95% CI**	**Concordance (n/N)**	**95% CI**	**Concordance (n/N)**	**95% CI**
Simple Concordance[a]	0.78 (40/51)	0.65-0.89	0.86 (37/43)	0.72-0.95	1.0 (3/3)	0.29-1.00
Exact Concordance[b]	0.73 (37/51)	0.58-0.84	0.84 (36/43)	0.69-0.93	1.0 (3/3)	0.29-1.00
Deep Infection Concordance[c]	0.77 (34/44)	0.70-0.93	0.87 (32/37)	0.71-0.96	1.0 (2/2)	0.16-1.00

Notes. [a]Agreement in terms of presence or absence of infection. [b]Agreement in terms of both presence and depth of infection. [c]Agreement in terms of presence or absence of deep infection. CI = confidence interval.

Assessments and Concordance by Calea Experience. The assessments and concordance by Calea experience are provided in Tables 12 and 13, respectively. The number of assessments were higher for *deep infection* among RNs who were *not experienced* (< 4 years) at Calea compared to *experienced* (> 4 years) RNs (23 vs 10) (Table 12). However, concordance was consistently higher among RNs who were *more experienced* at Calea compared to RNs who were not experienced at Calea (Table 13).

Table 12
Assessment by RN Experience at Calea Using a Breakpoint of 4 Years or More, Based on 198 Assessments Performed

Assessment Outcome	Not Experienced, n (%)[a]	Experienced, n (%)[a]
No Infection	67 (63%)	64 (70%)
Infection	40 (38%)	27 (30%)
Superficial	17 (16%)	17 (19%)
Deep	23 (22%)	10 (11%)

Notes. [a]Number of assessments and associated prevalence (%).

Table 13
Concordance by RN Experience at Calea, Based on 97 Analysed Wounds

	Neither Experienced		One Experienced		Both Experienced	
	Concordance (n/N)	**95% CI**	**Concordance (n/N)**	**95% CI**	**Concordance (n/N)**	**95% CI**
Simple Concordance[a]	0.79 (23/29)	0.60-0.92	0.83 (40/48)	0.70-0.93	0.85 (17/20)	0.62-0.97
Exact Concordance[b]	0.72 (21/29)	0.53-0.87	0.77 (37/48)	0.63-0.88	0.90 (18/20)	0.68-0.99
Deep Infection Concordance[c]	0.75 (18/24)	0.53-0.90	0.81 (34/42)	0.66-0.91	0.93 (14/15)	0.68-1.00

Notes. [a]Agreement in terms of presence or absence of infection. [b]Agreement in terms of both presence and depth of infection. [c]Agreement in terms of presence or absence of deep infection. CI = confidence interval.

Patient-related Parameters

Assessments and Concordance by Patient's Age. The assessments and concordance by patient's age are provided in Tables 14 and 15, respectively. The number of superficial infection assessments were higher for young patients (<sixty years) compared to older patients (>60 years) (21 vs 15) (Table 14). However, concordance was similar for both groups (Table 15).

Table 14
Assessment by Patient Age Using a Breakpoint of 60 Years, Based on 202 Assessments Performed

Assessment Outcome	Age < 60 years, n (%)[a]	Age ≥ 60 years, n (%)[a]
No Infection	103 (68%)	30 (60%)
Infection	49 (32%)	20 (40%)
Superficial	21 (14%)	15 (30%)
Deep	28 (18%)	5 (10%)

Notes. [a]Number of assessments and associated prevalence (%).

Table 15
Concordance by Patient Age, Based on 101 Analysed Wounds

	Age < 60 Years		Age ≥ 60 Years	
	Concordance (n/N)	**95% CI**	**Concordance (n/N)**	**95% CI**
Simple Concordance[a]	0.82 (62/76)	0.71-0.90	0.84 (21/25)	0.64-0.96
Exact Concordance[b]	0.78 (58/76)	0.65-0.85	0.80 (20/25)	0.59-0.93
Deep Infection Concordance[c]	0.83 (54/65)	0.72-0.91	0.78 (14/18)	0.52-0.94

Notes. [a]Agreement in terms of presence or absence of infection. [b]Agreement in terms of both presence and depth of infection. [c]Agreement in terms of presence or absence of deep infection. CI = confidence interval.

Assessments and Concordance by Patient's Body Mass Index (BMI). The assessments and concordance by patient's BMI are provided in Tables 16 and 17, respectively. Assessments were similar for both groups (Table 16). However, *exact and deep infection* concordance was substantially *lower* for patients with a BMI less than or equal to 25 (0.68 vs 0.87) (Table 17).

Table 16
Assessment by BMI, Based on 160 Assessments Performed

Assessment Outcome	**BMI ≤ 25, n (%)[a]**	**BMI > 25, n (%)[a]**
No Infection	35 (63%)	74 (71%)
Infection		
Superficial	11 (20%)	14 (14%)
Deep	10 (18%)	16 (15%)

Notes. [a]Number of assessments and associated prevalence (%). BMI = body mass index.

Table 17
Concordance by BMI, Based on 80 Analysed Wounds

	BMI ≤ 25		BMI > 25	
	Concordance (n/N)	**95% CI**	**Concordance (n/N)**	**95% CI**
Simple Concordance[a]	0.82 (23/28)	0.63-0.94	0.87 (45/52)	0.74-0.94
Exact Concordance[b]	0.68 (19/28)	0.48-0.84	0.87 (45/52)	0.74-0.94
Deep Infection Concordance[c]	0.67 (16/24)	0.45-0.84	0.91 (45/51)	0.76-0.96

Notes. [a]Agreement in terms of presence or absence of infection. [b]Agreement in terms of both presence and depth of infection. [c]Agreement in terms of presence or absence of deep infection. CI = confidence interval.

Assessments and Concordance by Patient's Perceived Pain Level. The assessments and concordance by patient's perceived pain level are provided in Tables 18 and 19, respectively. Among patients who had *no wound-related pain* compared to those with *wound-related pain*, the number of assessments were higher for no pain in regard to no infection (102 vs 31) and lower in number for superficial infection (16 vs 20) (Table 18). The number of exact concordance and deep level concordance also were very much lower for patients with *wound-related pain* compared to patients with *no wound-related pain* (Table 19). These results are among the most dissimilar in all RN- and patient-related parameters.

Table 18
Assessment by Patient's Perceived Level of Pain Using a Breakpoint of No Pain (VAS = 0) or Pain (VAS ≥ 1), Based on 202 Assessments

Assessment Outcome	**No Pain, n (%)[a]**	**Pain, n (%)[a]**
No Infection	102 (73%)	31 (50%)
Infection	38 (27%)	31 (50%)
Superficial	16 (11%)	20 (32%)
Deep	22 (16%)	11 (18%)

Notes. [a]Number of assessments and associated prevalence (%). VAS = Visual Analogue Scale.

Table 19
Concordance by Patient's Perceived Level of Pain, Based on 101 Analysed Wounds

	No Pain		Pain	
	Concordance (n/N)	**95% CI**	**Concordance (n/N)**	**95% CI**
Simple Concordance[a]	0.85 (61/72)	0.74-0.92	0.76 (22/29)	0.57-0.90
Exact Concordance[b]	0.85 (61/72)	0.74-0.92	0.62 (21/29)	0.53-0.87
Deep Infection Concordance[c]	0.87 (55/63)	0.77-0.94	0.65 (13/20)	0.41-0.85

Notes. [a]Agreement in terms of presence or absence of infection. [b]Agreement in terms of both presence and depth of infection. [c]Agreement in terms of presence or absence of deep infection. CI = confidence interval.

Wound-related Parameters

Assessments and Concordance by Wound Area. The assessments and concordance by wound area are provided in Tables 20 and 21, respectively. Superficial infection assessment numbers were significantly higher for larger wounds compared to smaller wounds (20 vs 16, p = .014) (Table 20). However, concordance was similar for both groups (Table 21).

Table 20
Assessment by Wound Area Using a Breakpoint of 1 cm^2, Based on 202 Assessments

Assessment Outcome	**Area < 1 cm^2, n (%)[a]**	**Area ≥ 1 cm^2, n (%)[a]**
No Infection	88 (70)	45 (59)
Infection	38 (30)	31 (41)
Superficial	16 (13)	20 (26)
Deep	22 (18)	11 (15)

Notes. [a]Number of assessments and associated prevalence (%).

Table 21
Concordance by Wound Area, Based on 101 Wounds

	Area < 1 cm^2, n (%)		Area ≥ 1 cm^2, n (%)	
	Concordance (n/N)	**95% CI**	**Concordance (n/N)**	**95% CI**
Simple Concordance[a]	0.81 (51/63)	0.69-0.90	0.84 (32/38)	0.69-0.94
Exact Concordance[b]	0.78 (49/63)	0.66-0.87	0.79 (30/38)	0.63-0.90
Deep Infection Concordance[c]	0.83 (45/54)	0.71-0.92	0.79 (23/29)	0.60-0.92

Notes. [a]Agreement in terms of presence or absence of infection. [b]Agreement in terms of both presence and depth of infection. [c]Agreement in terms of presence or absence of deep infection. CI = confidence interval.

Concordance Models

The RN-, patient-, and wound-centric models of simple and exact concordance are provided in Tables 22-29 and discussed below in further detail.

Nurse Characteristics. Models for simple concordance (Table 22) and exact concordance (Table 23) were produced with the following RN-centric variables: RN age, RN having degree or not, RN years of experience, and RN surgical experience (Table 22). None of the univariate results were marginally significant for either simple or exact concordance, with the conclusion that the measured RN-pair variables did not explain any kind of concordance.

Table 22
Univariate Analysis of Nurse Characteristics Related to Simple Concordance.

	p	OR[a]	95% CI	
			Lower	Upper
RN Age[b]				
< 40 and ≥ 40	.096	3.35	0.81	13.9
Both ≥ 40	.096	3.00	0.82	10.94
RN with Degree[c]				
Both RNs with Degree	.82	0.88	0.29	2.67
RN Experience[d]				
One RN Experienced	.99	1.01	0.21	4.82
Both RNs Experienced	.88	0.89	0.21	3.80
RN Surgical Experience[e]				
One/Both RNs Surgically Experienced	.163	2.26	0.72	7.08

Notes. a OR: odds ratio; variable reference categories: b Both RNs< forty; c both RNs with no degree or one RN with a degree; d both inexperienced RNs; e both surgically inexperienced RNs. CI = confidence interval.

Table 23
Univariate Analysis of Nurse Characteristics Related to Exact Concordance.

	p	OR[a]	95% CI	
			Lower	Upper
RN Age[b]				
< 40 and ≥ 40	0.14	2.63	0.73	9.49
Both ≥ 40	0.16	2.33	0.71	7.63
RN with Degree[c]				
Both RNs without Degree	0.51	0.72	0.27	1.92
RN Experience[d]				
One RN Experienced	0.72	1.28	0.34	4.78
Both RNs Experienced	0.69	1.29	0.37	4.44
RN Surgical Experience[e]				
One/Both RNs Surgically Experienced	0.24	1.80	0.68	4.78

Notes. [a]OR odds ratio. Variable reference categories: bBoth RNs< 40; cboth RNs having no degree or one RN having degree; [d]both inexperienced RNs; [e]both surgically inexperienced RNs. CI = confidence interval.

Patient Characteristics. Models for simple concordance (Table 24) and exact concordance (Table 25) were produced with the following patient-centric variables: patient age, BMI, and wound-related pain. None of the univariate results were marginally significant with regard to *simple concordance*, leading to the conclusion that none of the patient-centric variables can explain simple concordance. However, for *exact concordance*, BMI was marginally statistically significant (p = .052), and wound-related pain was statistically significant for both VAS pain 1 or 2 (p = .036) and VAS > 2 (p = .020). Higher BMI was associated with increased odds of explaining concordance, and any kind of wound-related pain lowered the odds of predicting concordance.

Table 24
Univariate Analysis of Patient Characteristics Related to Simple Concordance.

	p	OR[a]	95% CI	
			Lower	Upper
Patient Age[b]				
≥ 60 years	0.81	0.86	0.25	2.98
BMI[c]				
> 25	0.30	2.05	0.54	7.81
Wound-related Pain[d]				
VAS Pain 1 or 2	.86	0.5	0.16	4.53
VAS Pain > 2	.39	6	0.15	2.07

Notes. [a]OR reference point = 1.0. Variable reference categories: [b]< 60 years; [c]≤ 25; [d]no pain.
BMI = body mass index. CI = confidence interval. VAS = Visual Analogue Scale.

Table 25
Univariate Analysis of Patient Characteristics Related to Exact Concordance.

	p	OR[a]	95% CI	
			Lower	Upper
Patient Age[b]				
≥ 60 years	1.0	1.0	0.32	3.10
BMI[c]				
> 25	.052	3.07	0.99	9.51
Wound-related Pain[d]				
VAS Pain 1 or 2	.036	0.24	0.064	0.91
VAS Pain > 2	.020	0.25	0.076	0.80

Notes. [a]OR reference point = 1.0. Variable reference categories: [b]< 60 years; [c]≤ 25; [d]no pain.
BMI = body mass index. CI = confidence interval. VAS = Visual Analogue Scale.

Wound Characteristics. One model was produced for simple concordance (Table 26) and exact concordance (Table 27) with *area (size)* as the wound-centric variable. None of the univariate results were even marginally significant for either simple concordance or exact concordance. Therefore, wound area could not explain any kind of concordance.

Table 26
Univariate Analysis of Wound Characteristics Related to Simple Concordance.

	p	OR[a]	95% CI	
			Lower	Upper
Wound Area[2]				
≥ 1 cm^2	0.60	1.36	0.43	4.33

Notes. [a]OR reference point = 1.0. Variable reference categories: [a]< 1 cm^2.
CI = confidence interval.

Table 27
Univariate Analysis of Wound Characteristics Related to Exact Concordance.

	p	OR[a]	95% CI	
			Lower	Upper
Wound Area[b]				
≥ 1 cm^2	0.68	0.82	0.31	2.15

Notes. [a]OR reference point = 1.0. Variable reference categories: [a]< 1 cm^2.
CI = confidence interval.

Logistic Regression with Multiple Independent Variables

Logistic regression models with more than 1 parameter for both simple and exact concordance were made. For simple concordance, there were no marginally significant or significant variables in the model after refinement (see Table 28 for results with all variables entered). Likewise, for exact concordance, no model could improve upon the univariate model for wound-related pain (see Table 29 for results with all variables entered).

Table 28
Logistic Regression Model for Simple Concordance with All Parameters Included and Associated Odds Ratios (ORs)

	p	OR	95% CI	
			Lower	Upper
RN Age[a]				
< 40 and ≥ 40	1.0	2.5×10^{23}	0	—
Both ≥ 40	1.0	3.9×10^{16}	0	—
RN with Degree[b]				
Both RNs with Degree	1.0	7.8×10^{9}	0	—
RN Experience[c]				
One RN Experienced	1.0	0	0	—
Both RNs Experienced	1.0	0	0	—
RN Surgical Experience[d]				
One/Both RNs Surgically Experienced	.12	5.84	0.63	53.86
Wound Area[e]				
≥ 1 cm^2	.87	0.86	0.14	5.22
Patient Age[f]				
≥ 60 years	.35	0.41	0.062	2.72
BMI[g]				
> 25	.042	7.85	1.08	56.97
Wound-related Pain[h]				
VAS Pain 1 or 2	.48	0.37	0.025	5.65
VAS Pain > 2	.16	0.23	0.029	1.77

Notes. Variable reference categories: [a]Both <40 RNs; [b]both RNs without degree or one RN with degree; [c]both inexperienced RNs; [d]both surgically inexperienced RNs; [e]< 1 cm^2; [f]< 60 years; [g]≤ 25; [h]no pain. CI = confidence interval.

Table 29

Logistic Regression model for Exact Concordance with All Parameters Included and Associated Odds Ratios (ORs)

	p	OR	95% CI	
			Lower	Upper
RN Age[a]				
Young and Old	1.0	6.6×10^{10}	0	—
Both Old	.42	4.05	0.14	117.75
RN Having Degree[b]				
Both RNs Have Degree	.033	26.75	1.31	547.86
RN Experience[c]				
One RN Experienced	1.0	0	0	—
Both RNs Experienced	.40	3.63	0.18	72.69
RN Surgical Experience[d]				
One/Both RNs Surgically Experienced	.082	5.31	0.81	34.78
Wound Area[e]				
≥ 1 cm^2	.35	0.52	0.13	2.06
Patient Age[f]				
≥ 60 years	.36	0.43	0.073	2.56
BMI[g]				
> 25	.022	7.45	1.34	42.27
Wound-related Pain[h]				
VAS Pain 1 or 2	.11	0.071	0.009	0.54
VAS Pain > 2	.17	0.11	0.018	0.67

Notes. Variable reference categories: [a]Both young RNs; [b]both RNs having no degree or one RN having degree; [c]both inexperienced RNs; [d]both surgically inexperienced RNs; [e]<1 cm^2; [f]< 60 years; [g]≤ 25; [h]no pain. B = the parameter estimate. CI = confidence interval.

Feedback from RN Assessor Discussion Groups

Eight RNs participated in a group discussion (53.3%): 6 RN assessors participated in the first discussion group and 2 participated in the second discussion group. Seven RNs were unable to participate because of lack of availability (n = 4), being on maternity leave (n = 1), being no longer employed with Calea (n = 1), or having had a change of position (n = 1). The RN assessors provided feedback on their overall experience using the how2trak SSI tool, how it

compares to paper charting (including its efficiency and user-friendliness), and the effect that the how2trak SSI tool may have had on their delivery of care. For the full transcriptions of both group discussions, please refer to Appendices I and J.

Overall Experience Using the how2trak SSI Tool. The key feedback from the group discussions was that the how2trak SSI application is highly user-friendly (Appendices I and J). The RNs overall agreed that the tool was simple and easy to use, with one RN also commenting that "it's fairly easy for patients to use as well" (Appendix I, Line 28, P5)." The RNs thought that because they already had experience using the how2trak tool for general wound care assessment, it was easier for them to use.

How the how2trak SSI Tool Compared to Paper Charting. The RN assessors' major benefit of the how2trak SSI tool was that it houses all of the patient's data and wound photographs in one place, making it easier to track a patient's progress compared with the traditional paper charting method (Appendices I and J). A second strength that emerged from the discussion groups was its photo uploading and storage capabilities. Given the option to choose one method over the other, they agreed that they would prefer to use the how2trak SSI tool over paper charting. However, the RNs commented that for the purposes of this study, using the how2trak SSI tool resulted in a "duplication" of their work, as they were still required to paper chart SSIs *in addition* to using the SSI application (Appendices I and J).

The RN assessors also discussed the feasibility of a potential patient-oriented how2trak application, which was under development but not tested during the study. A patient application would allow patients to sign into the how2trak system, track their wound's progress with regards to SSI, and upload photos of their wounds. One RN expressed concern that patients would not be able to tell the difference between a general wound infection and an SSI (Appendix I). While one RN noted that the SSI criteria they tested via the how2trak tool were appropriate for the clinical setting, the participants also commented on the confusion experienced when

checking off antibiotic use in the past 30 days on the how2trak tool (Appendix I). They noted that many patients spoke of having IV antibiotic therapy that the RNs would never have used for surgical wounds and questioned the value of having to check off general antibiotic use for SSI assessment.

Efficiency of the how2trak SSI Tool Compared to Paper Charting. With regard to efficiency, the RNs again reiterated that because the how2trak SSI tool allows its user to take pictures of the incision at each visit and store those pictures, the user is able to see progress being made. This is something that has not been achieved in the same capacity through the traditional paper charting method (Appendices I and J) and is a major advantage, as one RN explained, "…because there are many RNs working in the clinic, so if…one of the RNs goes and sees a patient for the first time, we can go back to see the pictures taken before and compare how the wound is looking" (Appendix I, Line 48, P1). That same RN also found the usefulness in being able to show the pictures to the patients, "so they can see the difference between the initial appointment and then after the next assessment" (Appendix I, Line 50. P1).

User-friendliness of the how2trak SSI Tool Compared to Paper Charting. With its photo storage capabilities and consolidation of data, the RN assessors agreed that the how2trak SSI application was overall better than the traditional paper charting method (Appendices I and J). That said, participants agreed that there were ways in which this tool could still be optimized to suit the needs of its user(s) and be better tailored to the specific needs of each clinic's experience. For example, the RNs suggested that it would be helpful for the number of dressing change visits to be counted by the application; the dressing product being applying to each patient's incision to be documented; and the application to be mobile (Appendices I and J). Participants also noted that having to upload the digital photographs to the application on the desktop computer in each consultation room was a bit cumbersome; an issue which could be resolved by using a mobile application.

Effect of the how2trak SSI Tool on Delivery of Care. The major theme that emerged regarding delivery of care was that regardless of which method is used to assess for SSIs, RNs must be educated to provide a certain standard of care and that they deliver this standard of care. The RNs agreed that the how2trak SSI tool assisted them in consistently delivering that standard of care. One RN assessor explained, "...if we compare this one [how2trak SSI] to paper, I would say, yes, it would help with the patient outcomes" (Appendix I, Line 91, P1).

SSI Prevalence

During the SSI assessments performed using the how2trak tool, RN assessors identified patients with *no infection*, *deep infection*, and *superficial infection*. While there were no organ space SSIs identified, there were 69 SSIs identified in total, including 33 deep infections and 36 superficial infections. The prevalence of SSIs among patients with postoperative incisions at Calea Home Care Clinic following the initial assessment was 34.2%. The prevalence of deep infection and superficial infection at the time of initial SSI assessment was 16.3% and 17.8%, respectively.

During the follow-up process, 3 additional patients reported that they had an SSI occur after the initial SSI assessment; each infection reported at follow-up was counted as a whole infection (1 SSI reported at follow-up was equivalent to an infection reported by both RN pairs during the initial SSI assessment) and added to the calculation that included infections observed at the time of initial SSI assessment to obtain total prevalence of 34.6%. Specifically, to calculate the total prevalence rate of surgical site infections, the following process was undertaken: 1) the patient/incision was given an initial count of 1 if both nurses rated the wound as infected (deep or superficial), 2) the wound was given a value of ½ if one nurse rated it as infected and the other nurse rated it as not infected, and 3) the wound was given a 0 if neither nurse rated it as infected, 4) if an SSI was reported at a follow-up clinic, visit or if the patient stated that s/he received a diagnosis of an SSI, 1. The data were tallied according to these values and divided by

the total number of patients. This gave a total prevalence rate for any type of SSI during this study as 34.6%.

CHAPTER 6

DISCUSSION

Surgical site infection surveillance post-hospital discharge is currently not standardized, which leads to poor patient care and high costs for the healthcare system. This study evaluated the feasibility of a web-based surgical site infection (SSI) tool that uses the 1999 United States Centers for Disease Control and Prevention guidelines for the detection of SSIs (Mangram, et al., 1999), based on RN assessors' concordance, and determined the SSI prevalence for this patient population in the home care clinic setting in the Greater Toronto Area. A rigorous and standardized mechanism for post-discharge SSI monitoring is urgently needed to prevent the significant morbidity and mortality associated with SSIs.

In this chapter, first I discuss the overall findings from the results section. Second, I discuss the high rate of infection found in the study and its implications in relation to the existing study population and the literature. Third, I explore the concordance rates among RN assessors, pointing to the issues raised particularly in terms of their demographics: age, education, years of surgical experience and Calea experience, patient demographics and wound related demographics. Fourth, I discuss the lack of data regarding the hospital to home transition. Fifth, I discuss the results of the discussion groups, focusing specifically on the perceived feasibility of the tool from the perspective of the RN assessors. Lastly, in the conclusion, I discuss the overall contributions of the of the study. Throughout the discussion chapter, I relate the underlying WHO ICPS framework to issues described herein.

Overall Study Results

There are three sets of results: RN-related, patient-related, and wound-related data. In the RN-related concordance, there were no significant differences between RNs with, or without, a nursing degree. Similarly, there was no significant difference between RNs with more or less nursing experience (>10 years). RNs over the age of forty had higher concordance than younger

RNs, a finding consistent with what one would expect in that older RNs would usually have more experience and, therefore, would have cared for more surgical incisions. Surgical experience and clinic-specific (Calea) experience both resulted in the most significant concordance in the overall group. These findings are congruent with what would be expected, as RNs with more than ten years of surgical experience would have had more exposure to surgical wounds – and, therefore, an increased ability to identify SSI - and more experience handling the care required. Calea Clinic-specific experience as a particularly high concordance data point is also understandable given that the clinic manager has supported continuing education as a part of individual RNs' work experience, and the Calea RNs were already familiar with the how2trak tool. Therefore, Calea RNs could be expected to have an increased ability to identify and care for SSIs.

The WHO (2009) ICPS framework defines clinical performance as one example of a contributing factor/hazard in the development of an adverse event. The results in my study support the idea that high inter-rater reliability is related to Calea Clinic and surgical nursing experience. This is an important finding as surgical nursing experience and Calea Clinic experience could be considered a contributing factor/hazard, a class within the ICPS Framework, for identifying the development of a patient incident – in this case, SSI. The results could help inform nurse managers in scheduling and delivery care for those patients at high risk of SSI. Specifically, as per the ICPS Framework, the high class of 'contributing factors' informs the high class of actions taken to reduce risk. With these findings, Nursing Managers may choose to ensure that patients with a high risk of SSI are seen by nurses with surgical or Calea clinic experience in an effort to identify patients with an SSI.

In terms of patient-related characteristics, there was no evidence that age of patients was associated with affecting concordance. However, there was a lower concordance among patients with a lower BMI (<25). While this seems paradoxical as one would assume that patients with a

higher BMI and, therefore, more adipose tissue, would make it more difficult to identify SSIs, it appears that because patients with a higher BMI have greater risk factors, RNs were more vigilant with these patients than with patients having a lower BMI. Or perhaps, as previously stated, patients with a higher BMI made it physically more challenging for nurses to identify an SSI. Patients who had pain on a visual-analogue scale (VAS) of >2, had a lower concordance than those without pain. If the patient had more pain, it would be difficult to do a thorough physical examination, as the site is so sensitive for the patient. Thus, the inability to do a careful physical examination resulted in lower concordance. Finally, in terms of wound-related concordance, there were no significant differences between large or small wounds. One would expect that there may be a higher concordance difference with larger wounds.

Both pain scale and BMI can be classified into the ICPS framework within the high class of patient characteristics. The framework shows that patient characteristics along with incident type and incident characteristics inform methods of detection within the ICPS Framework. The primary method of detection in this study was the how2trak SSI tool. My study suggests that future methods of detection for the incident of an SSI should further investigate patients with higher pain scores and patients with a higher BMI. It seems that these 'patient characteristics' may influence 'incident characteristics', all of which inform 'detection'. It would be prudent for nursing managers and administrators to use these findings and include them in strategies and 'actions to reduce harm' of developing an SSI.

As mentioned, patients with SSIs have greater physical limitations, have lower mental health component scores, have more outpatient visits, have more emergency room visits, require more radiology services, have more frequent hospital readmissions (Perencevich et al., 2003; Whitehouse et al., 2002; WHO, 2009). These data show the substantial effect that SSIs have on patient quality of life and further prove the critical need for sufficient SSI prevention, timely identification, and successful management. Therefore, future studies should evaluate gold

standard acute management, post-discharge surveillance, management, and the effect on mental health scores, ER visits and hospital readmissions.

High Rate of SSIs identified in the study. The gold standard for SSI identification is the CDC guidelines (Mangram et al., 1999; Berríos-Torres et al., 2017), which were our starting point for the design of the how2traktool. These guidelines classify SSIs as:

1. Superficial incisional (skin and subcutaneous tissue). Diagnosis based on redness, pain, heat or swelling; drainage of pus.
2. Deep incisional (fascia and muscle). Diagnosis based on presence of pus/abscess, fever, tenderness of the wound, separation of the edges of the wound.
3. Organ or space infection (infection of any part of the anatomy manipulated during surgery other than the incision e.g., joint, peritoneum). Diagnosis based on drainage of pus or formation of an abscess detected by histopathological or radiological examination or during re-operation.

The how2trak SSI tool had the CDC SSI assessment guidelines embedded into the tool, the tool served as the method of 'detection' within the guiding ICPS Framework. Having the gold standard of SSI identification guidelines within the tool ensured a standardized, clear and concise method for the detection of an SSI by health care professionals at the Calea Clinic. It should be noted that two prevalence rates were calculated in this study, 34.2 % of patients were identified as having a surgical site infection on the initial assessment; three additional patients were found to have an SSI during the 30 day follow up, this brought the total prevalence rate to 34.6%

Using the above-identified guidelines, we found that 34.6 % of patients in the Calea Home Care clinic developed an SSI in the 30 days following surgery. This is a very significant finding that supports other studies demonstrating that up to 70% of SSIs may occur after the patient is discharged from hospital (National Institute for Health and Clinical Excellence, 2013; Petherick et al., 2006). It is important to note that this group was referred to the Calea Clinic for post-

operative follow up and, therefore, one would expect a higher SSI prevalence rate. Despite this enhanced risk profile of the group, an infection rate of 34.6% is far higher than the World Health Organization's estimate of 3%-22% (2009). This finding may suggest that the hospitals in which these patients had their surgery may require improvement in their infection prevention practices (Davis et al., 2008, Eskicioglu et al., 2012;). Improving infection prevention would be classified into 'actions to reduce harm' within the ICPS Framework. This class encompasses actions which are informed by all 10 high classes. In addition, it supports the findings of Branstadt and colleagues (Branstadt et al., 2007), who concluded that SSI rates are underreported due to the limitations of existing tracking tools and that SSI rates in the home setting could be more than double the SSI rates in the hospital setting as Kent and colleagues (Kent, McDonald, Harris, Mason & Spelman, 2001) found SSI rates of 6.0% (95% CI: 4.7-7.4) in home care vs. 2.7% in hospital (95% CI: 1.9-3.8).

The high rates of post-discharge infection found in this study raises a number of public policy issues. First, these patients are at a higher risk of further morbidity and even death (Kirkland et al., 1999); therefore, from a population health perspective, SSIs affect patients' ability to return to their normal lives including their ability to return to work and contribute to the economy (Sanger et.al., 2016). As mentioned, an 'action to reduce risk' for this population would be more robust post-discharge surveillance as there seems to be a failure of adequate 'detection' for SSIs post-discharge. Tracking 'patient outcomes' can help influence the ways to define the 'actions to reduce risk'.

Secondly, given that many SSIs are preventable, the high rate of infection suggests a need to improve hospital discharge quality standards and protocols and provide more adequate training of physicians and RNs on proper infection prevention techniques (Eskicioglu et al., 2012; Davis et al., 2008). Inadequate education surrounding infection prevention techniques would be classified as a 'contributing factor/hazard' towards developing an SSI. Contributing

factors are directly related to incidents – in this study, an SSI. Therefore, organizations should review all contributing hazards and use them to guide the creation of protocols that include 'actions to reduce risk' for the development of SSIs. Similarly, the high rate of SSIs found in this study could also indicate the need for improved hospital cleaning and equipment reprocessing protocols. Further, it could suggest insufficient education and poor communication with patients on their role in preventing an infection.

Based on the ICPS Framework, both 'patient outcomes' and 'organizational outcomes' should influence the 'actions taken to reduce risk'. Dancer (2014) discussed the current literature on hospital cleaning techniques and found that traditional cleaning techniques were inadequate for infection control and that newer methods, and detergents played a role in improved infection rates. Institutions and organizations should utilize evidence based cleaning techniques as an 'action to reduce harm' in the development of SSIs.

Another factor to consider is whether or not hospitals are following the protocols developed by the Patient Safety Institute surgical safety plan known as the *Safer Healthcare Now!* campaign, which have decreased the rate of SSIs by 60% from 2005-2010 (http://www.patientsafetyinstitute.ca/en/toolsResources/Documents/Interventions/Surgical%20Site%20Infection/SSI%20Getting%20Started%20Kit.pdf). These Guidelines are the gold standard for infection prevention in health care institutions. These guidelines would be a great example of evidence-based 'actions to reduce risk'. If I were to repeat this study, I would recruit patients from acute care, follow them through their post-discharge course and collect information about their acute care hospital course including the safer health care now interventions to determine what 'incident characteristics' from acute care become 'contributing factors/hazards' for the development of SSIs and use these to inform 'actions taken to reduce risk'.

Thirdly, SSIs are the overall costliest type of heath care associated infection in the US (Sanger, et. al., 2016) and increase the cost of hospitalization by more than $20,000 per

admission, amounting to an additional $700 million USD per year (Ban et al.,2016) ($350,000-$1million CDN in Canada (CHCA, 2016). These additional costs are due to the fact that patients with an SSI are more likely to spend time in the ICU, visit the emergency room and/or be readmitted to hospital (Perencevich et al., 2003; Whitehouse et al., 2002), creating additional fiscal pressure for hospitals. This is especially alarming given that many infections are preventable which makes them an avoidable cost. Infections are also costly to the system outside of the hospital given that many of these patients will require home care services (Urban, 2006). These points illustrate the importance of reviewing and tracking 'organizational outcomes' when determining methods to improve patient safety, infection control, patient outcomes and decrease the rate of adverse events. Based on the Framework, 'organizational outcomes' are influenced by mitigating factors, ameliorating actions, and actions taken to reduce risk.

A fourth public policy issue relates to the impact that SSIs have on family caregivers. When a patient's recovery is extended due to an adverse event (AE), such as an infection, family caregivers are affected in a number of ways: they are likely to have to take time off work to care for the patient or to travel with them to appointments; they are likely to take on the extra costs associated with purchasing supplies; and are likely to take on extra tasks at home that impede their health and wellbeing (Dr. M. Dunbar, personal communication, June 15, 2016). This demonstrates that the care delivered by family care-givers can be varied with respect to both duration of time and skill/knowledge level of the family caregiver. Further, caregiver fatigue/stress would be classified as both an incident characteristic as caregivers would be involved in post-op care before the development of the SSI. Similarly, caregiver stress could potentially be a contributing hazard toward the patient developing an SSI. There were no studies found to date that examined the link between caregiver stress and the development of an SSI. Future studies should examine this as a potential contributing factor for those patients receiving post-op care for their incision at home.

Finally, this high rate of infection points to the potential need for improvement in existing post discharge surveillance activities. The most widely described method of post-discharge surveillance is a surgeon questionnaire but this method has shown poor sensitivity (Petherick et al., 2006). Beyond that finding, the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) requires hospitals to hire administrative staff to call a random sample of patients 30-days post discharge to inquire whether the patient has experienced an infection (Berenguer et al., 2010). This method of post discharge surveillance is inadequate in several ways: patients may not know if they have/had an infection, the sampling model likely results in underreporting of infections, and it presumes that patients will be willing to answer a questionnaire. Beyond the ineffectiveness of the call method, this type of surveillance is very costly to administer. 'Detection' is central to the ICPS Framework and similarly robust and evidence based methods of detection should be of central importance in creating protocols for identifying and managing SSIs. It is critical that future research establish methods to accurately identify true rates of post-discharge infection. In future studies, I would ensure robust data collection in the acute care setting by initiating how2trak data collection in the acute care setting following through the post-discharge course. If a tracking system were used across health systems (acute care and home care), this would also improve communication and data availability across the continuum.

In addition to the public policy issues that result from the high rate of infection observed in this study, a detailed review of the data provides additional insight on predictive factors for SSIs. Those who were under 60 years of age, reported pain, or had a wound larger than $1cm^2$ were more likely to have a *superficial* infection. However, these 3 factors were not strong indicators of a *deep* infection. To be able to make some definitive conclusions about the patient and wound related parameters further study and examination is required.

Concordance rates support how2trak's accuracy. Simple and exact concordance, a measure of inter-rater reliability, within the paired RN assessors was evaluated as a feasibility measure of the tool. Each RN assessed a mean of 13 patients (SD: 8.1; median: 12; range: 4-28). Simple and exact concordance for the paired RN assessors was strong and reached higher than 0.80 for many of the paired RN combinations. This indicates that the CDC guidelines embedded into the how2trak tool do provide a standardized methodology for the assessment and identification of SSI post discharge. Indeed, even though RN assessor pairs did not end up assessing the same number of patients, RN assessor pairs were similar in their individual assessments. The factors that improved concordance included: pairs who were over the age of 40 years (simple concordance 0.84, 95% CI 0.71-0.94) and a combination of pairs of over 40 and under 40 years (simple concordance 0.88, 95% CI 0.72-0.97; Table 5). The highest concordance was demonstrated by: both RNs having greater than 10 years nursing experience (simple concordance of 0.83, 95% CI 0.69-0.92; Table 9); RNs having more than 4 years of Calea experience (simple concordance 0.85, 95% CI 0.62-0.97; Table 13); and RNs with more than 10 years surgical experience (simple concordance 1.0, 95% CI 0.29-1.0; Table 11). Based on the author's experience as both a previous surgical RN and a home care manager, these findings would be reasonable to expect; RNs with more years of experience most likely would have assessed more surgical incisions and, therefore, be more skilled in this procedure. The RNs with more Calea Clinic experience is another reasonable finding in that their manager supports continuing education; many of the RNs have gone on to do advanced wound assessment courses, and their manager conducts yearly competency evaluations with respect to wound care. All of these continuing education factors can lead to higher competency in the assessment of SSI.

I thought it was important to include nursing experience and education level within the data collection and data analysis as this study focused on the inter-rater reliability of paired RNs using of the how2trak SSI tool. Nurse Assessors were the primary end-users and therefore, their

demographic and performance related information was crucial in evaluating the utilization of the how2trak SSI tool. These findings show that RN experience could be a 'contributing factor' within the ICPS Framework of the development of an SSI. Similarly, lack of RN Experience could potentially be a 'contributing hazard' to the development of an SSI. As mentioned, Nursing Managers could use this information to provide extra education to less experienced nurses caring for those at increased risk of SSI or ensure that those with high risk for SSI always be seen by an experienced nurse, both representing 'actions to reduce risk' within the ICPS Framework.

Lack of data in the hospital to home transition. The transition from hospital to home is a complex and confusing time for patients (Hesselink, Schoonhoven, Plas, Wollersheim & Vernooij-Dasses, 2013). Uncoordinated discharge planning and inconsistent organization of care can lead to decreased patient satisfaction, harmful incidents(HI) and a higher number of hospital readmissions due to complications (Allaudeen, Vidyarthi, Maselli, & Auerbach, 2011). Studies have shown that up to 20% of medical patients experience an HI within 5 weeks of hospital discharge (Kripalani et al., 2007). A Pan-Canadian study recently found that the second most common AE in the home care setting was wound infections (14% of all AEs) (Blais et al., 2013). There is a clear need for a standardized monitoring program to bridge the care continuum from hospital to home care, and the how2trak tool can be used to meet that need.

The how2trak SSI tool captures patient data and enables the recording wound progression over time through pictures. Home care RNs in this study commented that they often received a referral that stated only that the patient had a surgical wound. All of the other details related to the surgery, including diagnostic tests and the patient's progress were absent. RNs noted that if the how2trak SSI application were used starting in hospital, the information could be stored in the patient record to allow for immediate access to all pertinent information, and ensure a more informed approach to postsurgical care. These findings highlight the importance of proper

documentation of 'incidence characteristics' as they are defined in the ICPS Framework. As per the Framework, both 'patient characteristics' and 'incident characteristics' are integral to the incident type, an SSI in this study, and are used to design methods of detection. It is crucial to have a better understanding of 'incident (SSI) characteristics' starting with data in acute care through the patient's course post-discharge.

The data collected from the RN assessor discussion groups suggest that using an electronic tool to assess and monitor patients for signs of infection is highly feasible. The RNs commented that the tool was highly user-friendly, providing them with an efficient mechanism to collect patient data and easily capture pictures of the wounds. The RNs also indicated that the electronic tool provided a platform superior to paper charts for the review of patient data. These findings show that frontline professionals deemed the how2trak tool a better detection tool versus paper charting. Their reasoning reflects the important aspects connected to 'detection' in the ICPS Framework. Specifically, the how2trak tool likely facilitated the delivery of mitigating actions such as antibiotic dressing use, oral antibiotic use, proper dressing use and overall helped track 'patient outcomes' such as healing rate, wound size, and signs and symptoms of infection.

Implications of Findings from the Discussion Groups. The results of this study demonstrate a clear and immediate need for implementation of a post-discharge surveillance system for SSIs. Towards that end, two discussion groups were conducted with RN assessors to gather their feedback and opinions regarding the use of the CDC guidelines embedded into the how2trak tool for the assessment and identification of an SSI. While the study did show good feasibility between paired RN assessors, it also exposed a significant public policy issue related to the slow implementation of documentation systems in Canada. Given that Calea Clinic uses paper charts as their legal record of the patient's care, the RN had to document the patient's assessment within the how2trak tool and in the paper charts. This is an inefficient use of the RN's time, and it reduces time to deliver patient care.

While the adoption of electronic documentation systems provides an avenue for reducing these inefficiencies, there are significant issues related to interoperability of electronic medical record systems across Canada (Poissant, Pereira, Tamblyn & Kawasumi, 2005). The Healthcare Information and Management Systems Society (HIMSS) defines interoperability as "…the extent to which systems and devices can exchange data, and interpret that shared data" (http://www.himss.org/library/interoperability-standards/what-is-interoperability). In effect, this means that if a patient's SSI assessment was entered into the how2trak tool, their data would be sent directly to the patient's electronic medical record (EMR), thus reducing the duplicated documentation. While federal agencies and provincial governments are working on improving interoperability of EMRs across Canada, there are significant gaps that are hindering the adoption and efficient use of electronic documentation tools across the country http://www.oag-bvg.gc.ca/internet/English/parl_oag_201004_07_e_33720.html#hd3d). This means that archaic systems like fax machines and paper charting continue to persist across Canada.

The feedback received through the RN discussion groups also touched on the feasibility of patients using electronic tools to self-monitor as well as provide reports to clinicians. A natural evolution of the how2trak tool is to have patients, using an app on their phone or tablet, take pictures of their own incision and answer some basic questions that could indicate signs of infection (Sanger et al., 2017). Self-reported data with respect to surgical site infections has been shown to have good reliability and high sensitivity and specificity (Sanger et al., 2017). This type of data is crucial to timely identification of SSIs in the post-discharge period. Giving basic and evidence based signs and symptoms of infection and when patients should seek the care of a professional could potentially help patients get their SSI identified sooner leading to earlier management and possibly better outcomes. Based on the results of this study, the how2trak SSI app was modified to have a patient interface wherein the patient can enter data pertaining to their

post-discharge course. Simple questions such as redness, puss, drainage, fever, and whether or not the patient sought care were included in the app as well as the ability to upload photos.

In the future, I would like to study the effect and SSI rate in a post-discharge setting with the patient application. Self-reported patient data could fall into actions taken to reduce risk wherein it is being sued for a post-op patient before the development of an SSI or could also be classified into a mitigating action for a patient who has already developed an SSI. In both cases, it is advantageous to have close follow-up with the patient with information that includes incision photos and data around signs and symptoms of infection. The RNs commented that some patients may be unable to provide useful reports; for example, a picture may be blurry, or they may not fully understand the assessment questions provided. Furthermore, some elderly patients may be uncomfortable with using an electronic device, or they may not even own a device. Self-reporting through an electronic tool can also prove difficult to use if the wound is on a part of the body that is difficult to access, such as their back (Sanger et al., 2016), as this would require a caregiver to take the picture.

Beyond these practical limitations of using an electronic tool, some patients of certain cultural backgrounds may object to taking pictures of their body and sharing them – albeit in a secure environment – with a medical team. In working with First Nations communities across Canada, it is understood that some people within those communities are highly skeptical of sharing their medical information, or pictures with the government. https://pdfs.semanticscholar.org/a339/5bee5894ac1293bdbe99cb56798d77e5b6b9.pdf .Some conservative cultures, such as those who observe orthodox Muslim, Christian, or Jewish practices, may also be uneasy in taking pictures of incisions located in potentially compromising areas of their bodies. (http://essay.utwente.nl/69112/1/Li_MA_faculty%20of%20behavioral%20management%20and%20social%20sciences.pdf).

Limitations

First, the study had a small sample size. When a power test was conducted for the study protocol, the projected sample size was set for 300 participants. However, in the clinics this proved impossible administratively. Interestingly, the problem was not recruitment of patients: at the end of the study, 316 patients consented to participate, reaching the study's projected target. However, because the assessment could not occur on the same day they were recruited, it was difficult to follow patients after they left the clinic, even though they had consented to participate in the study. After a year of attempting to assess all patients who consented to participate, it was necessary to terminate the study with 101 total participants because the presence of the study was starting to create an undue burden on the clinic environment. While this was not ideal, the results still remain important given the dearth of data whatsoever in the existing literature on SSIs outside of the hospital setting.

Site selection bias was an additional limitation to the study. Because all three clinics had pre-existing knowledge and experience of the how2trak tool, the technology was perhaps used more skillfully than if no prior knowledge or experience pre-dated the study. In this way, use of the tool did not have proper randomization of RN assessor participants, comparing RNs with prior experience with the tool against RNs with no prior experience with the tool to measure feasibility more fully.

Double documentation represents another limitation. That is, the clinic manager required that RNs keep two records of every assessment: in addition to completing the how2trak assessment, they had to document the same values on paper following regimented clinic documentation protocols. Having to input the same values twice in two different platforms could have placed undue burden on the RN assessors.

The definition of an SSI requires monitoring patients for 30 days from the date of surgery. Many previous studies (Oliveria et al., 2006; Petherick et al., 2006) of SSI prevalence

did not complete this 30-day monitoring, producing a gap in determining a more accurate SSI rate. Therefore, a central methodological contribution of the study was to monitor patients for 30 days postoperatively to contribute a more accurate rate to the current literature. However, this proved to be difficult given patients' reluctance to return for the 30-day visit. In the end, only 25 patients completed some form of follow-up, making this a limitation of the study. However, as I discuss in the next section, this also proved to be a strength of the study.

Another limitation of the study was the loss of many of the RN's perspectives. This was an important part of the study in determining the feasibility of the clinical tool. In future studies to glean more RN perspectives I would engage an experienced facilitator and I would offer more opportunities for them to participate in the discussion sessions.

The study methods mandated that RN assessors be paired equally, this proved to be another limitation of the study. That is, measuring feasibility required that RN assessor pairs were distributed equally among the total group of assessors, to account for the possibility that some RN assessors would be more efficient than others at using the how2trak tool. Given the clinic environment, this proved to be not possible for a number of reasons, the most important being scheduling. That is, given the clinic work schedule and vacation time, some RN assessors ended up being paired together more frequently than others, resulting in an overall unequal distribution of pairings. This could have biased the study by either favoring RN assessors who were particularly skilled with the tool, or, on the other hand, those who had particular difficulties with the tool.

Current strategies for post-discharge surveillance (e.g., existing SSI measurement tool questionnaires, retrospective chart reviews and calling a random selection of post-operative patients) have limitations and their suitability is uncertain (Macefield et al., 2017). This study evaluated a standardized post discharge surveillance methodology for the identification of SSIs.

Additional limitations center around our ability to explain why the rates of SSIs were so high in this study. Unfortunately, data was not captured on whether the patient, or their surgical team, followed infection prevention techniques before and during surgery. Originally I had planned to review the patient's hospital chart to be able to ascertain whether or not the safer health care now interventions (Safer Health Care Now, 2007 & 2008) for decreasing surgical site infection were implemented and whether or not the patient was considered as a high risk patient based on their ASA scores. This proved to be difficult as patients came to the Calea Clinics from twelve different hospitals and each of these hospitals required REB approval which proved to logistically impossible. For example, the use of an antibiotic prophylaxis before surgery has been found to decrease the likelihood of infection (Gillespie & Walenkamp, 2010). This lack of data capture meant that further analysis was not possible to determine the likely cause of infection for this patient population. Furthermore, the study did not capture the American Society of Anesthesiologists (ASA) Physical Status Classification score of the surgery, to determine whether or not the patient was at higher risk of developing an SSI due to patient comorbidities. If the vast majority of surgeries were considered high risk, then the higher rate of infection found in this study could be more easily explained. As previously mentioned use of antibiotic prophylaxis and ASA score would be examples of incident characteristics which contribute directly to the risk of the incident – SSI. It is therefore important for future studies to determine the effect of these factors on the development of SSIs in the post-discharge setting.

One plausible explanation for the high rate of SSIs (34.6%) is that the patient population referred to the Calea Clinics were referred for post-operative incisional care and were at a higher risk than normal for the development of SSIs. The high rate of infection in a post-acute clinic setting is not generalizable to other populations but it does raise a number of questions that will need to be further examined in future studies. What is clear is that there are many SSIs occurring post

hospital discharge and a standardized methodology for identification and data collection is warranted.

The study was designed to follow up with patients (that did not have a surgical site infection identified on the initial assessment) at day 30 to ascertain whether or not they were treated for a surgical site infection. Only 40.9% of patients returned for some sort of follow- up, this could have led to either an over-estimation or an underestimation of SSIs. For future studies it would be advised that some sort of electronic follow up be used to make it more easy and accessible for patients to participate in the 30 follow up. In terms of the Framework, the loss of patients would be classified into a failure in 'detection' possibly due to a 'patient characteristic' such as difficulty keeping the appointment, rescheduling the appointment, or other reasons.

Also, the patients that were referred to the clinic may be referred to as a symptomatic population of patients wherein only those patients who showed signs/symptoms of infection at a surgical post-op visit or in hospital may have been referred to the Calea Clinic for incisional care. Therefore, the results can only be generalized to a symptomatic population.

Lastly, detailed information regarding the surgical procedure (for example, whether the physician opened the incision) and completion of diagnostic tests was not always conveyed to home care RNs. Had the RNs at the Calea clinic had access to more patient information from the acute care setting, they may have been able to provide better care post-discharge. Furthermore, this lack of information in some cases impacted their ability to accurately assess the CDC SSI infection guidelines leading to either a higher or lower deep surgical incision infection rate. This finding fits well into the ICPS Framework. The information about surgical procedures and other relevant information that was lacking for the RN Assessors would be classified into incident characteristics and patient characteristics. Both of these are an integral part to the detection of the incident. Therefore, it follows that RN Assessors had difficulty detecting SSIs due to incomplete 'patient and incident characteristics'.

Another set of limitations address logistical issues with the study. Although performing assessments using the how2trak tool did not add a major burden on RNs (approximately 5 additional minutes per patient visit), scheduling RNs to work in pairs was difficult as the RNs' schedules were already fully booked with patients and they traveled between all three clinics. If the how2trak SSI assessment had been part of routine care at Calea, then scheduling the assessments by a single RN would not have been as much of a barrier. Contact and communication with patients was also a limitation, as the majority of patients who consented to participate in the study did not return for subsequent assessment visits. Most patients were contacted by phone by the RA/PI and asked if another health professional had identified an SSI following their initial SSI assessment. As a result, the follow-up phone assessment did not assess for SSIs using the SSI criteria, and did not record whether the infection was deep or superficial. The fact that many patients were followed up over the phone is a limitation as RNs could not confirm whether the patient did indeed have an SSI.

With regard to the Nurse Assessor Groups, only 8/14 Nurses participated potentially leading to an absence of additional valuable feedback. Also, having just over half of the Nurse Assessors participate, the discussions could be less generalizable to all Calea Nurses. In future studies, I would give a longer period for group discussions to try and capture all Nurse Assessors to ensure a more robust representation of opinions and feedback.

Strengths

First, a cornerstone of this study was to use a standardized tool for the identification of SSIs according to the 1999 CDC guidelines. This was a strength for a variety of reasons. First, while the existing literature attempts to measure SSI rate, they are not measured uniformly across different studies. Thus, it is difficult to determine an accurate SSI rate as different studies used different guidelines for SSI identification. By using CDC guidelines, the results of this study can be applied more uniformly with other studies that use the CDC guidelines, in the hope that

standardization of guidelines would provide a more accurate picture of the current burden of SSIs.

Second, ICPS WHO framework anchored the study and provided a robust definition of concepts and measures that provided a solid foundation to underpin this study. Furthermore, the framework provides a comparative reference point between this research in SSIs and the research of others in the field.

Third, while the low occurrence of postoperative patient follow-up was certainly a limitation of this study, it makes a methodological contribution for future studies attempting to measure the SSI rate. In the 25 patients who completed some form of follow up, a total of 3 had an SSI at 30 days postoperative. Therefore, finding ways to ensure patient follow-up at 30 days will be paramount for future studies. I suggest two possible solutions for future studies in this regard. First, patient honorarium may increase the number of clients who return for a 30-day follow-up. Second, and perhaps more advantageous in the long term, would be to integrate an electronic patient-reported data mandate into the study so patients can complete follow-up without being burdened by having to physically return to the clinic postoperatively (Sanger et al., 2016).

CHAPTER 7

CONCLUSION

Post discharge surveillance of surgical site infection has been incomplete, problematic and unstandardized (Kent et al., 2001; Koek et al; 2015) making it very difficult to calculate and understand true SSI rates. This research was the first to assess the feasibility of a web-based tool (how2trak), which uses the CDC guidelines as a standardized methodology for post-operative discharge surveillance of surgical site infection. Overall, it was found that the how2trak software application (with the CDC surgical assessment guidelines embedded) was feasible in assisting RNs to identify post-acute care SSIs among study participants. The first major indicator of feasibility was inter-rater reliability—that is, the likeliness that different nurses using the same tool would yield similar results. The study showed there was good interrater reliability based on concordance, making the tool feasible for inter-rater reliability. The high concordance between paired RN assessors and the positive feedback that nurses reported in the discussion groups demonstrates that the how2trak tool proves feasible in the Calea Clinic clinical setting and thus could be considered as a solution for post-discharge surveillance.

Although the CDC guidelines for assessment of surgical site infection are considered the gold standard, they are not always used in clinical settings. This research also demonstrates that the CDC guidelines could provide a standardized methodology for evaluating surgical site infection in the home care clinic environment.

Currently, as discussed above, the information provided to community nurses, at the point of referral, from acute care to home care, regarding surgical incisions is lacking. If the tool was being used across the continuum of care, it would provide community nurses with the required information needed to care for these surgical patients. Therefore, it could improve the overall transition from hospital to home, which has historically been one of the major gaps in identifying SSIs.

The second major indicator of feasibility addressed in this study was user experience. Based on a discussion groups with nurse assessors, feedback from the nurse participants suggested that the use of an electronic tool was positive. Because the tool is electronic and uses standardized measures, if it were implemented more broadly in a variety of clinical settings, institutions and home care organizations would be able to more accurately track and identify SSIs from hospital to home care clinic. Currently, because different institutions use different information gathering and processing tools for surgical incisions, data collection is not uniform and most times the information is deficient when passed on to home care for patient care. The electronic how2trak tool could fill this gap by standardizing the data collection indicators and the dissemination of the required information across different healthcare settings.

The final major indicator of feasibility was the ability of the tool to help nurses identify SSIs using the embedded CDC guidelines. This result was also positive, with 34.6% surgical site infections identified during the study. Early discharge and increased day surgery has changed the landscape of surgical care in Canada. Post-discharge surveillance of these patients has, historically, been done poorly, if at all, and hasn't monitored patients adequately after discharge (Koek et.al., 2015, Oliveria et al., 2007). Based on the ICPS Framework, my study findings demonstrate that the how2trak SSI tool is a robust method for detection of SSIs. With additional data collection in home care and the addition of self-reported patient data, use of the how2trak SSI tool could be considered an 'action taken to reduce risk' to monitor for the development of SSIs. Given these changing dynamics, this study demonstrates the potential for standardizing patient surveillance for SSI post-discharge using an electronic tool, thereby improving patient care and decreasing both overall healthcare costs and patient burden caused by an unmonitored SSI.

Contributions to Academic Literature

Most studies (Kent et al., 2001; Koek et al., 2015) that have been conducted to assess some form of post-discharge surveillance (PDS) have demonstrated that the rates of SSI increase from 19 to 84% (Berrios-Torres et al., 2017). This study confirms similar findings in that 34.6% of participants were found to have an SSI. There are very few Canadian studies (Attrell & Armstrong, 2007; Brandstadt et al., 2007) that have assessed PDS, this study contributes further evidence that SSI rates increase when PDS is done, thus demonstrating the need for a standardized methodology for the measurement of SSI after hospital discharge. This research evaluated an electronic tool to monitor patients post-discharge, an area that has limited research. Most research related to surgical site infection has been completed in acute care settings; thus this study furthers the understanding of the need for a standardized methodology for post discharge surveillance. Leaper, Tanner & Kiernan, 2013 contend that "surveillance of SSI is often an integral part of organizational infection prevention and control activities, but unless post-discharge surveillance is carried out in a robust manner the data may be inaccurate and misleading." p.83. The positive feasibility of the web based how2trak tool provides a starting point for a robust standardized SSI assessment and data collection process, arming both clinicians and policy makers with a common data set to enable improved patient outcomes.

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APPENDIX A: CRITERIA FOR DEFINING A SURGICAL SITE INFECTION (SSI)

Superficial Incisional SSI

Infection occurs within 30 days after the operation

and

infection involves only skin or subcutaneous tissue of the incision

and at least *one* of the following:

1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative.
4. Diagnosis of superficial incisional SI by the surgeon or attending physician.

Do *not* report the following conditions as SSI:

1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).
2. Infection of an episiotomy or newborn circumcision site.
3. Infected burn wound.
4. Incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).

Note: Specific criteria are used for identifying infected episiotomy and circumcision sites and burn wounds.

Deep Incisional SSI

Infection occurs within 30 days after the operation of no implant[†] is left in place or within 1 year if implant is in place and the infection appears to be related to the operation

and

infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision

and at least *one* of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38° C), localized pain, or tenderness, unless site is culture-negative.
3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

Notes:

1. Report infection that involves both superficial and deep incision sites as deep incisional SSI.
2. Report an organ/space SSI that drains through the incision as a deep incisional SSI.

Organ/Space SSI

Infection occurs within 30 days after the operation if no implant[†] is left in place or within 1 year if implant is in place and the infection appears to be related to the operation

and

infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation *and* at least *one* of the following:

1. Purulent drainage from a drain that is placed through a stab wound[‡] into the organ/space.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of an organ/space SSI by a surgeon or attending physician.

APPENDIX B: ASA PHYSICAL STATUS CLASSIFICATION SYSTEM

ASA Physical Status 1 - A normal, healthy patient

ASA Physical Status 2 - A patient with mild systemic disease

ASA Physical Status 3 - A patient with severe systemic disease

ASA Physical Status 4 - A patient with severe systemic disease that is a constant threat to life

ASA Physical Status 5 - A moribund patient who is not expected to survive without the operation

ASA Physical Status 6 - A declared brain-dead patient whose organs are being removed for donor purposes

American Society of Anesthesiologists (ASA) Physical Status Classification System (2011).

APPENDIX C: NATIONAL HEALTHCARE SAFETY NETWORK (NHSN) DEFINITION OF WOUND CLASSIFICATIONS**

Class I/Clean

An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract are not entered. In addition, clean wounds are primarily closed, and, if necessary, drained with closed drainage. Operative incisional wounds that follow non–penetrating, blunt trauma should be included in this category, if they meet the criteria.

Class II/Clean-Contaminated

An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered, under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.

Class III/Contaminated

Open, fresh, accidental wounds. This category also includes incisions from operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, non–purulent inflammation is encountered.

Class IV/Dirty-Infected

Old traumatic wounds with retained, devitalized tissue, and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

** Mangram et al. (1999). Guideline for prevention of surgical site infection. *Infection Control and Hospital Epidemiology*, *20*(4), 247-278.

APPENDIX D: HOW2TRAK® SSI DATA COLLECTION – RNS WILL USE THIS ELECTRONIC TOOL TO COLLECT DATA TO ASSESS WHETHER OR NOT THE PATIENT HAS AN SSI.

Electronic Fields in the how2trak data collection tool

- Date of birth
- Sex
- Client ID #
- Case load ID # and geographic ID#
- Ethnicity
- Diabetes
- Co-morbidity factors
- Date assessed
- Hospital Admission Date
- Surgery Date
- Surgical Classification
- Surgery Site/Location
- Wound Measurements
- CDC Signs and symptoms of surgical site infection
- Home Care Admission Date

Superficial Surgical Site Infection	
Purulent drainage from the incision	
Organisms isolated from culture of fluid or tissue from incision	
At least one of the following and the superficial incision is deliberately open by the surgeon.	
Pain or tenderness	
Localized swelling	
Redness or heat	
Diagnosis of a surgical site infection by a physician	

Deep Surgical Site Infection	
Purulent drainage from the incision	
A deep incision spontaneously dehisces or is deliberately opened by a surgeon and has at least one of the following:	
Fever present, greater than 38 degrees Celsius	
Localized pain or tenderness	
Abscess or other evidence of infection involving the incision is found by examination or radiological examination	
Diagnosis of a deep incision infection by a physician	

Guidelines for Prevention of Surgical Site Infections. Centers for Disease Control and Prevention, 1999.

APPENDIX E: PATIENT CONSENT FORM

Title: Examination of the feasibility of the how2traksurgical site infection (SSI) tool in the detection of SSIs in a home care clinic setting

Lead Researcher: Corrine McIsaac, PhD candidate, School of Nursing, Dalhousie University, (**corrine.mcisaac@healthoutcomesww.com**, 902-862-8704)

Candidate's Supervisor: Dr. Jean Hughes (jean.hughes@dal.ca, 902-494-2456)

Dalhousie University.

We invite you to take part in a research study being conducted by Corrine McIsaac, a PhD candidate in the Nursing Department at Dalhousie University. Taking part in the research is voluntary and, should you choose to take part, you may leave the study at any time for any reason. The information below outlines what is involved in the research, what you will be asked to do and what risks, inconveniences, and discomforts you might encounter.

PURPOSE AND OUTLINE OF STUDY:
This study is to look at the feasibility of using the how2trakelectronic system in the identification of a surgical site infection as compared to current methods. A surgical site infection (SSI) is an infection in the incision or wound area that has developed as a result of a recent surgical procedure. SSIs can occur up to 30 days following your surgery.

Currently, we do not have the information required to standardize how we assess your incision after you leave the hospital. Researchers have made efforts to track the development of SSIs and have discovered a higher number of infections than previously believed; however, this process is laborious and currently incomplete. I would like to assess whether or not an electronic method using how2trakmakes it easier or more difficult for RNs to identify SSIs.

Note: Calea has been using how2trakfor a few years to assess chronic wounds so your RN is very well acquainted with the system. The use of how2trakin the Calea Clinics has been very successful in giving the RN the correct tools to assess and treat wounds. As a result, patients are healing multiple times faster while receiving the best care possible.

Also, please note that the primary investigator Corrine McIsaac plays a dual role in this study as she is both the primary investigator and also the founder and CEO of Health Outcomes Worldwide, the company that developed the how2traktool.

WHO CAN TAKE PART IN THIS STUDY?
You may participate if you are a:

1) Patient who has had surgery at one of the University Health Network hospitals (Toronto General Hospital, Princess Margaret Cancer Centre, Toronto Western Hospital, and Toronto Rehabilitation Institute).

2) Patient who has been referred to the Calea Clinics through the Toronto Central CCAC for care of your incision after your surgery between DATE and DATE; OR (b) have been referred to Calea within 30 days of your surgery

3) Person over the age of 18

4) Person willing to sign this consent form

5) Patient who is diagnosed with an SSI on your first visit OR a patient who will return 30 days from your surgery date to ensure you don't have an infection.

6) Person who is able to speak English.

HOW MANY PEOPLE WILL BE TAKING PART IN THIS STUDY

150 patients will be recruited to take part in this study.

WHAT WOULD I HAVE TO DO?

To help us understand whether the electronic tool has benefit or not, we will ask you to:

1) Sign consent

2) Agree to an extra assessment of your incision on your initial visit (an extra 5-7 mins)

3) Possibly return to the clinic 30 days after surgery to ensure no infection is present (This visit would not be required should an infection be identified during the first visit)

4) Agree to two assessments on day 30 after surgery (an extra 5-7 mins)

5) Allow the investigators of this study to access your hospital chart to review information about your recent surgery only.

WHAT ARE THE POSSIBLE BENEFITS, RISKS, AND DISCOMFORTS?

There is minimal risk posed to you as a study participant. Minimal risk includes those risks you would encounter in day-to-day life. The role that you, as a patient, will play in this study is to be assessed twice by a RN using our electronic tool. The difference between this and your regular care is the use of a tool that guides RNs through a standard surgical assessment. Since you will receive two assessments instead of one, you will be required to send an extra 5-7 minutes at the clinic.
We know that SSIs can occur up to 30 days after surgery. Currently, it is not required to have a follow-up appointment. As a study participant you will be required to return to the clinic 30 days

after the date of your surgery (if an SSI was not identified during your first Calea appointment). This second visit could potentially mean identifying and treating an infection sooner. This may allow you to avoid complications associated with infection.

DO I HAVE TO PARTICIPATE?

Participation in this study is voluntary and will not negatively impact the care you receive. Whether or not you decide to participate in this study you will receive the standard care given by the Calea health care team. Should you choose to participate in this study and later change your mind, you may withdraw from the study at any time. To withdraw from the study, please contact the primary investigator Corrine McIsaac at (902-578-7994) and your information will not be included in the study analysis. Withdrawal may also happen if an unexpected situation arises where you do not meet the inclusion/exclusion criteria. For example, this could include diagnosis of a new condition or disease (during study), admission to hospital, additional surgical treatment, etc. Up to 1 month following the study you may request to have your data removed. After that time, it will be impossible for us to remove any data because it will have been analyzed.

WHAT ELSE DOES MY PARTICIPATION INVOLVE?

The only requirements of your participation will be the additional time (5-7 minutes) during your initial appointment during which time a second RN will perform an assessment. Should no SSI be identified during this initial appointment, you will be required to return for a second appointment scheduled for 30 days from the date of your surgery during which you will again have two assessments (5-7 minutes each).

In agreeing to participate in this study, you are taking an active role in furthering our understanding of the Ontario health care system and the improvements that may need to be made. You will be contributing to the understanding of an electronic system that may be able to improve care for all future patients. Your participation will lead to results that will help improve the quality of care for future patients who are undergoing what you are enduring right now.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

You will not be paid for your participation in this study. However, we do not want you to incur any costs due to your participation in this study. Should we require you to return to the clinic for an appointment 30 days after surgery, you will be reimbursed for your parking costs.

WILL MY RECORDS BE KEPT PRIVATE?

The only persons who will have access to your personal files are our primary investigator, the research assistant, and the primary investigator's thesis committee. With your consent, the primary investigator and research assistant will retrieve your hospital record related to the surgery for which you were referred to this clinic and collect data necessary for our study. They will assign you a new ID number (that has no connection to your information) for the purposes of the study. No identifying characteristics such as name, phone number, address, health care number, etc. will be collected. During assessments, all data will be collected on iPads or the desktop computer, loaded with the how2trakSSI tool and stored in how2trak®'s triple protected software storage database. The how2traktool has undergone testing and evaluation by

independent bodies and currently has approval from national regulators to hold health-care information and has passed all security testing. . Safeguards of this system include passwords, encryption, firewalls, security scans, redundant systems, back ups, audit trails, and biometrically secured facilities. When we talk about our study data, no names, birth dates, age, sex, or any other type of identifying characteristics will be used. We are obligated to ensure that your personal information is kept private. Data will be kept in a secure locked filing cabinet and in a secure password protected electronic spreadsheet. After data analysis, all files will be permanently deleted (up to 5 years after your participation).

HOW TO OBTAIN RESULTS:

A short description of group results will be mailed the Calea Clinic for distribution to study participants who are interested. No individual results will be given. Please let us know that you are interested in receiving these summary results, as we can indicate this on your chart and provide you with the results the next time you come to the Calea Clinic.

QUESTIONS:

We would be happy to discuss any questions or concerns you might have as a study participant. Please contact the primary investigator (Corrine McIsaac, 902-578-7994) at any time. If necessary, you can contact the primary investigator's supervisor, Dr. Jean Hughes, at jean.hughes@dal.ca. We will inform you of any information that comes up that may affect your decision to participate.

If you have any ethical concerns about your participation in this research, you may also contact the Director, Research Ethics, Dalhousie University at (902) 494-1462, or email: ethics@dal.ca

APPENDIX F: RN CONSENT FORM

Title: Examination of the feasibility of the how2trak®surgical site infection (SSI) tool in the detection of SSIs in a home care clinic setting

Lead Researcher: Corrine McIsaac, PhD candidate, School of Nursing, Dalhousie University,

(**corrine.mcisaac@healthoutcomesww.com**, 902-862-8704)

Supervisor's Name and Department: **Dr. Jean Hughes (**jean.hughes@dal.ca**, 902-494-2456)**

School of Nursing Dalhousie University

We invite you to take part in a research study being conducted by Corrine McIsaac, a PhD candidate in the Nursing Department at Dalhousie University. You are not under any obligation to participate in the study and, should you choose to participate, you have the option to leave the study at any time. The information below outlines what is involved in the research, what you will be asked to do and what risks, inconveniences, and discomforts you might encounter should you participate.

Should you choose to participate in this study, a signed copy of this form will be made available to you.

PURPOSE AND OUTLINE OF THIS STUDY:

The purpose of this study is to examine feasibility of using the how2trakelectronic system for the identification of surgical site infections in the home care setting. A surgical site infection (SSI) is an infection in the incision or wound area that has developed as a result of a recent surgical procedure occurring up to 30 days post-surgery (This does not include any surgical procedures that involved implantation (e.g. breast augmentation, hip/knee replacements, etc.) for which an SSI can develop anywhere from 1-365 days after surgery). SSIs are considered adverse events; an adverse effect is an undesired harmful effect resulting from a medication or other intervention such as surgery. Despite the standard of sterile treatment procedures, a significant number of surgical patients still develop infections. At the moment there is no standardized method for tracking SSIs when patients are discharged from hospital. SSIs are not currently a priority within community care because the lack of standardization in their tracking. At the moment, the rate of SSIs is determined by looking at hospital records. The problem is that there is no standardized, routine method of assessing patients for an SSI.
This study is testing how useful the how2trakelectronic tracking system will be as a standard method in assessing the development of an SSI as opposed to traditional paper-based methods. Additionally, the data collected will be put together to determine the rate of SSIs in the Calea Home Care Clinic.

Note: Calea has been using a different how2trak module for a few years to assess chronic wounds so you may already be well acquainted with the system. The use of how2trakin the Calea Clinics has been very successful in giving the RN the correct tools to assess and treat wounds. Also, please note that the primary investigator Corrine McIsaac plays a dual role in this study as she is both the primary investigator and also the founder and CEO of Health Outcomes

Worldwide, the company that developed the how2traktool.

WHO CAN TAKE PART IN THE STUDY?

You may participate if you are a:

1) RN at the Calea Clinic
2) Person willing to carry out the assessment schedule associated with study
3) Person over the age of 18
4) Person willing to sign this consent form
5) Person who is able to speak English.

HOW MANY PEOPLE WILL BE TAKING PART IN THIS STUDY?

I intend to recruit 10 RN assessors and 150 patient participants for this study.

WHAT WOULD I HAVE TO DO?

To help us understand the rate of SSIs and understand the usability of our electronic tool, we will ask you to:

1) Sign consent
2) Carry out assessments with the how2trakSSI tool
3) Follow the assessment schedule
4) Participate in a discussion group at the completion of the study.

WHAT ARE THE RISKS OF BEING A STUDY PARTICIPANT?

There are no anticipated risks posed to you as a study participant. Minimal risk includes those you would encounter in day-to-day life. The role that you, as a RN assessor, will play in this study is to carry out your assessment of post-op incisions using our electronic health tool.

WHAT ARE THE POSSIBLE BENEFITS, RISKS, AND DISCOMFORTS?

As an assessor, you will be assessing patients as you normally would; the difference is that you will be using the validated Centre for Disease Control guidelines for assessment of the surgical incision. Our tool has been developed to facilitate assessments abiding by these guidelines based on the most recent evidence-based medicine in an attempt to deliver the best care.

DO I HAVE TO PARTICIPATE?

Participation is voluntary. If you decide not to participate in this study your job will not be affected. If you give consent and change your mind, you may withdraw from the study at any time. Should you choose to withdraw, your choice will in no way affect your relationship with either the investigative team behind this study or Calea Clinics. To withdraw from the study, please contact the primary investigator Corrine McIsaac (902-578-7994). Withdrawal may happen if an unexpected situation arises where you do not meet the inclusion/exclusion criteria. For example, if you are no longer employed with Calea or are unable to fulfill the duties of a RN assessor.

WHAT ELSE DOES MY PARTICIPATION INVOLVE?

You will be required to dedicate 3 ½ hours total to study related activities over the 2-month period of data collection. First, you will participate in a **one hour training session** (conducted by the PI) regarding the how2trakSSI tool. Second, you will carry out **30 independent patient assessments** (3 minutes/assessment for a total of 90 minutes) using the how2trak SSI tool. Lastly, following data collection, you will participate in **a one hour discussion group session** with other RN assessors, conducted by a research assistant, to discuss your experience and the feasibility of using the how2trakSSI tool compared with the paper-based assessment tool currently used by the Health Centre. The date, time, and location of this discussion group will be set by the PI in collaboration with participants and will occur shortly following completion of patient assessments During the study, you use the how2trakSSI tool ***only*** for assessments of patients enrolled in the study. You will continue to use the current paper-based tool for all other patient assessments.

Should you agree to participate in this study, you are taking an active role in furthering our understanding of the Ontario health care system and the improvements that may need to be made. Your participation may help us understand if there is value in an electronic assessment for the identification of SSIs and it will help us identify the SSI rate in the Calea Clinic. Your participation will lead to results that may help improve the quality of care for future patients with surgical incisions.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

Should you choose to participate in the study, you will complete all assessments for the study as part of your regular employment through Calea Clinics.

WILL MY RECORDS BE KEPT PRIVATE?

Your name is the only identifying information that will be taken during the study. For analysis, your name will be given an ID. During assessments all data will be collected on iPads or smartphones and stored in how2trak®'s triple encrypted software storage database. The how2traktool has undergone testing and evaluation by independent bodies and currently has approval from national regulators to hold health-care information and has passed all security testing. Safeguards of this system include passwords, encryption, firewalls, security scans, redundant systems, backups, audit trails, and biometrically secured facilities. Identifying information will not be accessible to anyone except the research assistant, the primary investigator and the primary investigator's dissertation committee. When we talk about our study data, no names or any other type of identifying characteristics will be used. Our study team has

obligations to ensure that your personal information is kept private. Data will be kept in a secure locked filing cabinet and in a secure password protected electronic spreadsheet. After data analysis, all files will be permanently deleted (up to 5 years after your participation).
The 60-minute discussion group following the study will be audio recorded. The audio recordings will be transcribed without identifiers (names, places, dates). If you give permission, the researcher may use some of your quotes in reports; however, your name will not be used with any quotes in any reports or presentations.

HOW DO I OBTAIN RESULTS?

If you agree, a short description of group results will be mailed to you at the end of the study. No individual results will be given. Please let us know that you are interested in receiving these summary results by including your contact information with your signature.

QUESTIONS?

We would be happy to discuss any questions or concerns you might have as a study participant. Please contact the primary investigator (Corrine McIsaac, (902) 578-7994) at any time. If necessary, you can contact the primary investigator's supervisor, Dr. Jean Hughes, at jean.hughes@dal.ca.We will inform you of any information that comes up that may affect your decision to participate.

If you have any ethical concerns about your participation in this research, you may also contact the Director, Research Ethics, Dalhousie University at (902) 494-1462, or email: ethics@dal.ca

You may also contact the Joint Research Ethics Board Chair, Dr. Ron Heslegrave, Toronto Grace Health Centre 650 Church Street, Toronto, ON M4Y 2G5 (416) 925-2251 x253.

SIGNATURE PAGE

Project Title: **Examination of the feasibility of the how2traksurgical site infection (SSI) tool in the detection of SSIs in a home care clinic setting**

Lead Researcher: Corrine McIsaac
Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a study subject. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact:

I (Print Participant's Name)_____ have read the explanation about this study. I have been given the opportunity to discuss it and my questions have been answered. I agree to take part in this study. I realize my participation is voluntary and that I am free to leave the study at any time.

Participant's Signature_____ Date:_____
Study Team Signature_____ Date:_____
I give permission for the researcher to use anonymized quotes (no names, identifiers) taken from my during the discussion group in study presentations or reports.

Yes ☐ No ☐

I give permission to have a summary of the study sent to me upon study completion.

Yes No

If yes – e-mail address:

The Dalhousie Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.

APPENDIX G: **SCREENING SCRIPT**

Thank you for your interest in our study. The purpose of the study is to compare two different methods for detecting a surgical site infection. A surgical site infection (SSI) is an infection in the incision or wound area that has developed as a result of a recent surgical procedure. Currently, we do not have a standardized method of monitoring patient incisions after they leave the hospital. Researchers have tried different approaches to track the development of SSIs; however, these methods are take a lot of time and are inefficient. We are assessing whether a computer-based method using how2trakmakes it easier for RNs to identify SSIs.

Participation in the study is voluntary. Should you choose to take part, you may withdraw at any point. Are you interested in learning if you are eligible to participate in this study?

- Before we proceed, I will need to verify your eligibility.
- Are you over the age of 18?
- Have you recently had surgery at one of the following hospitals: Toronto General Hospital, Toronto Western Hospital, Princess Margaret Cancer Centre, or Toronto Rehabilitation Institution?
- What was the date of this surgery?
- During this surgery was an implant left in place?

If you participate in the study, you may be required to return to this clinic for a follow-up appointment scheduled for approximately 30 days from the date of your surgery. Should a follow-up appointment be required, would you be willing to attend a follow-up visit?
If you participate in the study, we will require your consent for us to access information from your hospital chart. Would you give us permission to access your hospital chart for the purpose of gathering this information?

Questions:

- Are you interested in participating in this study?
- You be required to do a 30 day follow up visit are willing to come to the clinic for that visit?
- Do you give us permission to access your hospital chart for the purpose of gathering this information?

Before I continue with the written consent form, do you have any questions?
If you consent to being enrolled in the study, I will ask you to carefully read through and sign this form.

APPENDIX H: DISCUSSION GROUP INTERVIEW GUIDE

Questions

1) How would you describe your overall experience of using the how2trakSSI tool?
2) How do you think the how2trakSSI tool compares to the clinic's current method of assessing surgical patients?
3) How would you compare the two in terms of efficiency?
4) How would you compare the two in terms of user-friendliness?
5) Overall, what effect, if any, do you think using the how2trak SSI tool had on your delivery of care?

SIGNATURE PAGE

Project Title: **Examination of the feasibility of the how2trak®surgical site infection (SSI) tool in the detection of SSIs in a home care clinic setting**

Lead Researcher: Corrine McIsaac
Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a study subject. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact:

I (Print Participant's Name) _____ have read the explanation about this study. I have been given the opportunity to discuss it and my questions have been answered. I agree to take part in this study. I realize my participation is voluntary and that I am free to leave the study at any time.

Participant's Signature_____ Date: _____
Study Team Signature_____Date: _____

The Dalhousie Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.

APPENDIX I: RN ASSESSOR DISCUSSION GROUP TRANSCRIPTION 1

Discussion Group 1

September 6, 2016

12:30 – 1:00pm EST

Teleconference

Interviewer: Julianne Fitzgerald

Participants: 6 RN Assessors

Legend

- I – interviewer
- P – participant

Questions

- How would you describe your overall experience of using the how2trakSSI tool?
- How do you think the how2trakSSI tool compares to the clinic's current method of assessing surgical patients?
- How would you compare the two in terms of efficiency?
- How would you compare the two in terms of user-friendliness?
- Overall, what effect, if any, do you think using the how2trakSSI tool had on your delivery of care?

1. I [Introduction] this will be the final part of the study. I'm happy to stay we completed the study. I got all of the additional info from you guys that I asked for a month ago. We have 111 patients. So that's really great. Most of them did the 30 day follow up, and the ones that we couldn't get in clinic we did over the phone. So now we just have a statistician running some numbers for us. We just want to get your feedback on the app itself and how you all felt while using it so that's why we're doing this. So this is discussion group one, and tomorrow will be number two with the remainder of the RN assessors. So we only have 30 minutes and let me just say that I am so grateful for you guys just taking out the time for me cause' I know the patients are number one and I know you guys are so busy, so. So if you need to leave the call at any time, just interrupt and just tell me that you have to go and I'll make a note. So I said in the email to Alicia, to let you guys know that it will be recorded today, but your names won't be used in any

of the reports. We just want to get some general feedback. So there are only five questions here I don't know if any of you were able to have a read before the call, but if not, it's fine. We'll just get, you know, like I said your general feedback, on the questions. Um and then yeah just don't be afraid either to give us your true and honest feedback [laughter]. It's different here, it's over the phone. I would have preferred to do it in person but we just had a couple obstacles where I just – I couldn't make it so this, ah, is the best that we can do! So I'm going to dive right in and, ah, I'm just going to ask the first question. And anyone can start stalking, you all can hear each other so if you need to, you know, say your name, um, and proceed with your answer, that would be great. It would really help me. Um, so question number one, "how would you describe your overall experience of using the how2trakSSI" – the actual app?

2. P1 [short pause] Hi, this is _____, I would say good.

3. I It was good – okay.

4. P2 I think because we always already were using how2trakit wasn't really too much… there wasn't really too much difficulty with using it. We've had the experience already.

5. I Right. Great. [Short pause] … And so…

6. P3 [Muffled sound]… how do you want us to answer? Do you want us to go into details or just say good, excellent, the same?

7. I No, if you want to go into detail, I'm probably, I'm judging about five minutes per question, so, yeah, you can jump into detail if you'd like.

8. P3 No, I'm thinking for the other questions. So for this one, my answer is "good", but, ah, for the other questions I will -

9. I Elaborate?

10. P3 Specify

11. I Okay, great, great. Um, does anyone else have any feedback about question one? Anything regarding the ease of use, maybe? The physical experience of it, you know, how long it takes you to scroll through things to click through things?

12. P4 [Short pause] It's_____, um, I'd say I'd echo _____'s response. It was pretty much the same as using the regular how2trak®. It was easy.

13. I Okay, great. Okay… alright so let's jump into the next then. So how do you feel the how2trakSSI tool compares to how you guys are currently assessing surgical patients? [Long pause – muffled sound]… and for this I'm kind of looking for information about the detail of information, maybe the relevance of assessment, you know, are the criteria relevant? Are [there] too much criteria [is the criteria] too descriptive? Too general? Um, is the picture aspect of it a good way to provide better care? Anything you want to elaborate on would be really helpful.

14. P1 [long pause] _____ again. So, I will just what they say already. So, um, the current method is not same because we are using the how2trak®. Um, the only difference is that we are entering our treatment twice. We do it in how2trakand then we do it in paper as well.

15. I Right.

16. P3 Um, was this not supposed to be – the purpose of this tool was supposed to be a mobile site, right?

17. I Right.

18. P4 And we never used it really as a mobile site.

19. I Yes, that's right. It wasn't developed at the time of the study, but, yeah, it is now [clears throat] so I'm thinking if it were mobile, and if you were able to access it on your iPads and tablets with the exact same functions as were on the desktop, um, would that be better or worse?

20. P4 Well, I think in our clinic setting it probably wouldn't have made too much difference, but in some settings it probably would've been a lot easier, right?

21. I Okay.

22. P4 If you're doing a lot of walking around, going – I imagine if you're at a hospital setting where you're doing a lot of going around, moving around, doing it at the bedside would've been probably more functional.

23. I Sure.

24. P5 Its _____. Um, I don't know if I misunderstood, but initially, um, I thought that the whole idea was the SSI tool was, to, when patients access it themselves. So if they're doing their own care at home, um, they would log into the SSI on their mobile app and, ah, punch in any of those criteria and then the care provider can see, ah, you know there's one or more criteria that there is a surgical site infection and then we can prompt them to contact the, ah, the physician.

25. I Yes, you're absolutely right. Um, and so that's the part of the mobile app the new developments that we're currently working on. So, [there will be] a physician app which is the one that you – that you've tested, uh, and then [there will be] the patient app. So the patient app and the physician app will communicate with each other. So, you're right _____, the patient can actually sign in and see that criteria, and track their progress as well, so the pictures and everything – the assessment that you've given would be accessible to the patient once they leave the clinic.

26. P5 So, in the regard it's really good because I think it's easy enough for patients to read ad to kind of know what, you know, what criteria they should click on.

27. I [In agreeance] mhm. Great.

28. P5 So, I think in that- it's really easy for us to use since we're all used to how2trakand also I think it's – it's fairly easy enough for patients to use as well.

29. I Okay. And so – yeah no, that's great – I'm just going to kind of elaborate on that point because, um, the some of the criteria – and I have some of it here and I'll read it to you all – I just want to know and get your feedback. Is it relevant criteria? Do you think that it's useful in the setting – not with the patient in mind; just for your own assessments? So I'll read that now. So the "superficial incision SSI, um, infection occurs within 30 days of the operation and infection involves only skin or sub-"oh, I don't even know how to pronounce that, everyone [laughter], "or tissue of the incision in at least one of the following". So, these are the criteria here, and you all are familiar with it, I just want to know, again, if this criteria is useful or if you would change anything. So we have the first one, the drainage: "with or without laboratory confirmation from the superficial incision". We have, "organisms isolated from all [short pause] obtained cultural fluid or tissue from the superficial incision". "At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness or heat and superficial incision is deliberately opened by a surgeon unless incision is culture negative, and diagnosis of superficial incision SSI by the surgeon or attending physician – coded as 32". So I know that's a lot of text, and a lot of things, so what is your initial reaction to those criteria?

30. P1 [long pause] I think a lot of times, the surgical site infections are not- like, we get them, but they're not categorized as surgical site infections. We usually get wound care and then the RNs make an assessment and see if the incision looks like it could potentially be infected. I think for patients at home, it would kind of be maybe tricky for them to know if there is a surgical- like, if there is a [incomprehensible]… they can usually go back and let the patient know.

31. I Okay.

32. P1 Some of the criteria there might not be- applied.

33. I Okay. And I think what we're doing for the patient aspect of the SSI app is to just have it as simplified as possible, so I don't believe that they'll have, um, access to select any criteria. It will simply be the assessment that you give them, that's what they'll see. Um, so, what I'm reading here is that initial page when you go in to assess the patient and I'm just wondering if those criteria that you select – if they're too general for you or if they're no specific enough for you.

34. P6 [long pause] It's _____, from what I remember, I felt that the criteria was alright for our use with the wounds we were seeing in the clinic setting.

35. I Okay. So there's really nothing that jumped out at any of you that we're like, "oh, that's a red flag, that doesn't belong there", or "that criteria doesn't make sense; or it's redundant" or anything like that?

36. P1 Hi Julianne, it's _____, again, if I remember well if- I don't have access again to see the tool, but if I remember something, they were [the application] asking about the use of

antibiotics. I think there was something that didn't make sense most of the time. Um, you see, I, we don't have the tool here, so I cannot take a look again.

37. I Okay, um, let me see.

38. P1 What's the question regarding – the use of antibiotics right now? In the past week or something, no?

39. I Yes, you're right. "Use of any antibiotics or any medications in the past 30 days". And so you felt that, that question wasn't really relevant in some cases, or?

40. P1 I think that most of the time the patients [incomprehensible]… they [the application] were saying something about IV antibiotics and we never, ah, use IV antibiotics for these types of wounds.

41. I Ah, okay, okay. Now I can't think-

42. P1 So we didn't have the information available to see if the patient were treated with antibiotics in the hospital. I think this apply mostly for the patients who have surgical infections in the hospital, you know in the community.

43. I Okay. Okay, I'm just going to make a note of that. I can't think of the criteria right off hand with the IV antibiotics. I do remember reading "antibiotics within the last 30 days" but-

44. P1 -yeah, and the same thing, like, can we access the modules right now just to take a look, because the last time I used it was almost a month or two months ago-

45. I I can't access it right now, unfortunately, but I can look at it again and refer to your notes and what you're saying about that particular question. And with me being able to record this conversation, I can go back and exactly know what you said, so that's great.

46. P1 Okay.

47. I That's great. Thank you so much for that feedback. Um, so we'll move on then, to, so we have question three here, and it's "how would you compare the two in terms of efficiency"? So you all, now I don't know if that question is entirely relevant to you because you all have been using SSIS before. So, I guess, what I would just ask then to kind of, to, elaborate on this question is, did you find that using SSIS for surgical site – to assess your patients – was useful? Did it help you provide the care you wanted to provide [to your] patients? Again, it's a very general question, anything you want to shoot out, you know, if that inspires another kind of response that you want to give go right ahead.

48. P1 [long pause] [incomprehensible] Maybe the pictures are always helpful. The other criteria we always use, even when we answer the questions on paper, we look for signs and symptoms of infection. But because there are many RNs working in the clinic, so if, um, one of the RNs goes and sees a patient for the first time we can go back to see the pictures taken before and compare how the wound is looking.

49. I Right. That's perfect. And so, with the pictures, it's clear that you all can actually see – like you have something tangible that you can see in addition to the criteria that's been filled out on paper and in SSIS. So, do you think that that would be helpful for the patient to see as well?

50. P1 Well, I will say yes. Sometimes, we even show the pictures to the patient so they can see the difference between the initial appointment and then after the next assessment. That's useful.

51. I [In agreeance] mhm, that's perfect, yeah. And so just for my own curiosity too, prior to using SSIS as a part of the study, did you all take pictures? In addition to the way you were assessing surgical site patients?

52. P1 We did with how2trak®, yes.

53. I Okay. Okay. Yep. Okay, so, let's see, so we're actually at eight minutes left which is pretty good. Um, I feel like everyone is kind of chiming in with their thoughts so that's really great. So, we'll just- the fourth question is, "how would you compare the two in terms of user-friendliness?" but I think we've covered that. You all have kind of given a general consensus that it's user friendly and you think the patient would benefit from it and the pictures are very helpful and also that if it were mobile it would be better in some situations where you would have to walk around a lot. So that's really great feedback. So, we'll just dive into the last question then which is, again very general, very basic and again if you all can just describe in your own words, um, how do you think the SSIS tool… or do you think the SSIS tool increased patient outcomes… or would have an effect – a positive effect – on patient outcomes? Meaning, that would the use of this tool help deliver better care?

54. P3 Hi, Julianne, it's _____. So I did get into the how- the SSIS, um, website.

55. I Oh, good!

56. P3 To see all the criteria there and I don't know if you want me just to list what all of these criteria were, but I think that looking at it, it helps you, um, a little bit more recognition when you're looking at it after you've seen a patient wound – maybe to decipher between the superficial and the deeper surgical site infection.

57. I Okay, great. So there's nothing there that you would say is redundant, or that needs to be changed?

58. P3 Well, the, I don't know, _____, is it the "diagnosis of the surgical site infection by a physician", would you want that there?

59. P1 I think there is a confusion, no? Because we use the superficial symptoms and sign of infection for other wounds, for other diagnoses… for Venus Leg Ulcers and this SSI it is more related to surgical infection, no?

60. P3 Yeah. But there's also a criteria here, "organisms isolated from culture-

61. P1 Okay, that's, yeah-

62. P3 -of tissues from the incision". How would we ever be able to determine that?

63. P1 Exactly, I think that's what I was referring to. I remember seeing something that we were… we don't have that information.

64. I Right. Okay. And that was one of the criteria that I read at the beginning, "organisms isolated and obtained of fluid or tissue from the superficial incision". So, yeah, there be no way for you all to have that information at your fingertips, right?

65. P1 and P3 [In agreeance, simultaneously] mhm, right.

66. I Alright. [Mumbling] Go ahead.

67. P3 There's also a… for the deep surgical site infection, um, one of the criteria was, "a deep incision spontaneously [incomprehensible]". Is that really a sign of a deep surgical infection?

68. I Ah, yeah, well these criteria were given to us by surgical site experts, but they've never been tested. You all were the test. [Clinic door-bell rings]

69. P3 Sorry!

70. I That's okay! That's a patient coming in. Um, yeah, so there were just- these were never tested. So in the test environment it was you all using them. So, would you say that that criteria- it's not useful?

71. P3 I'm not sure I've seen that happen [laughter].

72. I [Laughing] okay, so "the infection involves deep soft tissues of the incision in at least one of the following". So, do you see that "the drainage from the deep incision, but not from the organ space component of the surgical site", all of those that fall under that category?

73. P3 Well, they may have already had that happen before they came in to see us. That's the reason why they came to see us.

74. I Right. Okay, let me make a note of that. And so I guess having that there, ah, would you have that information at your fingertips when a new patient was admitted?

75. P3 Sometimes.

76. I Sometimes. Okay.

77. P3 But you would probably get that information from talking to the patient.

78. I Right. Okay. So, that would be a criteria that you could skip over if you didn't have the information, but, okay… that's good to know. Okay, is there anything else, _____, as your reading through that that you're like, just a red flag?

79. P3 Okay, there's one more criteria. Everybody else can listen on this. It says, "abscess or other evidence of infection involving the incision is found by examination or a radiological examination". So, I don't know, _____, what do you think?

80. P1 [Laughing]… yeah it doesn't apply to us.

81. I It doesn't apply? Okay.

82. P1 No, we wouldn't be able to get that information.

83. I Okay [repeating aforementioned criteria] perfect. Is there a situation where you would ever have that information in your setting?

84. P3 It depends on what the referral or the doctor is sending with the patient. You know?

85. I Okay.

86. P3 It doesn't happen too often.

87. I Perfect. Alright, so I've made a note of that. Okay, that's great. Okay and so just again to wrap up, um, right if anyone could kind of chime in – do you think that this app overall would increase patient outcomes, positively?

88. P3 As compared to the one that we're already using, or just by itself.

89. I Um, both. [Short pause] because I think we've kind of established that this is a little bit better, would you agree, than the method that you all have been using?

90. P5 Um, well, the how2trak[clinic door-bell rings] is pretty easy. As for the criteria, like, _____ was saying, superficial vs deep infection does have the – I think it follows [incomprehensible] if we click on the superficial we know there is a superficial infection, if we click on the deep, so, it already has that. But specifically for surgical site it's a good tool. But overall, the other how2trakhas a similar criteria. I would say.

91. P1 Yeah and I think that I would agree with, _____, if we compare that to the other how2trakso, I would say, it is the same. But if we compare this one to paper, I would say, yes, it would help with the patient outcomes.

92. I Okay.

93. P1 But, compared to what we're using right now – that is the how2trak®, that is almost the same.

94. I Right. And correct me if I'm wrong, you're using how2trakfor wound care, correct?

95. P1 Sorry?

96. I The how2trakapplication that you all are using now is specifically, or more generally used for wound care, right?

97. P1 Yes.

98. I Yes. Okay. Um, okay, perfect.

99. P3 Sorry to interrupt, but we have to go, _____ and I. It's _____, okay?

100. I Great! Thank you so much, _____ and _____.

101. P3 Alright. Bye.

102. P5 Yeah, it's one o'clock. [Recorded voice notifying conference call attendees that two attendees have left the call]

103. I That's fine, everybody. So we've gone two minutes over, but I've got some great responses. Thank you all so much. If you have anything else that you want to email me, then you can. I'll send Alicia an email with my email address and anything else you think of you can send that along. But, thanks everybody! Bye!

104. P2 P4 P5 P6 Thank you – bye.

APPENDIX J: RN ASSESSOR DISCUSSION GROUP TRANSCRIPTION 2

Discussion Group 2

September 7, 2016

12:30 – 1:00pm EST

Teleconference

Interviewer: Julianne Fitzgerald

Participants: 2 RN Assessors

Legend

- I – interviewer
- P – participant

Questions

- How would you describe your overall experience of using the how2trakSSI tool?
- How do you think the how2trakSSI tool compares to the clinic's current method of assessing surgical patients?
- How would you compare the two in terms of efficiency?
- How would you compare the two in terms of user-friendliness?
- Overall, what effect, if any, do you think using the how2trakSSI tool had on your delivery of care?

1. I Like I said, it's just because we such a short window and I don't want to go over your time. Okay, so, I don't know if you all received the questions that I sent in Alicia's email.

2. P1 Yeah, we did!

3. I Oh, good. That's perfect. So, you had a chance to kind of look over them?

4. P1 Yes.

5. I Perfect. So, there's only five [questions], um, and so I'll just get your general kind of answers on each of the five questions and then if I feel like we need to dig a little deeper I have a couple of more follow up questions for you. Um, but yeah, but feel free to just

answer completely honestly. We want to know basically how you felt using the SSIS app, um, and how you think that it would help increase patient outcomes. Okay, so we'll go right into the first question. So, number one, "how would you describe your overall experience of using how2trakSSI"?

6. P2 So for me it was similar to the regular module that we are using.

7. I Okay.

8. P2 how2trak®

9. P1 Yeah

10. P2 It's a similar experience.

11. P1 Yeah, same here! I did not find much different; that is what we are doing.

12. P2 Speaking about using the app itself, right?

13. I Yes, exactly. Yep.

14. P2 Yeah.

15. I And so you don't find that there was much difference with using the wound care app?

16. P1 Yeah.

17. I So it was very- was it user friendly? Is it simple to use?

18. P2 Yes, it was, ah, simple tool-

19. P1 Yeah, yeah.

20. P2 we're using the program already, there's really no difference. The only difference was that the data was already… the patient demographics [were] already put in by you or someone else-

21. I Right.

22. P2 -and that was easier for us.

23. I That was easier for you to do, right.
24. P1 Yeah.

25. P2 I think, uh, put the patient's information in there first.

26. I Right. So if you all had to do- if you had to put that info in yourself, um, would that make much of a difference if you had to use it in the clinic in real time?

27. P1 Uh, for me it's same – you know – we don't find much difference. That is what we are doing-

28. I Right.

29. P1 -so it is the same.

30. I Okay, perfect.

31. P2 This is for the surgical app, or?

32. I Yeah, this is just for the surgical one.

33. P2 [In agreeance] mhm, I see, yeah. Um, wouldn't make a difference to me.

34. I Okay.

35. P2 Actually, I wouldn't want- personally I would like to differentiate between two apps. So, um, you can just- you would have to use two modules, two modules I guess. One for, uh, [the] regular patient and the second for the surgical [patient].

36. I Okay.

37. P2 Okay. So that would be something that would be probably extra step rather than keeping it simple.

38. I Right. Right. And I think that the way that we're going to be designing it is that you'll have a separate app for your wound care and then a completely separate app surgical site. Because now what we're doing- we're going to actually take your responses and kind of accommodate our app to kind of suit real life experience and then make the changes that we think are necessary to just make it easier for the RNs and the clinicians that use it. So, that's great.

39. P2 Okay.

40. I Okay, so let's go into question two. So, how do you think the how2trakSSI tool compares to how you currently assess surgical patients? So, and I think you all use the paper, right?

41. P2 Um

43. I Or you had been using paper to assess surgical patients before we gave you the app?

44. P2 Yes. Yes.

45. I Okay. So how has the app, um, how is the app different?

46. P2 Well, the- first of all, it's done by two RNs. The assessment. Versus one on the regular programming. So that makes things, uh, just slightly complicated [Laughter]. Cause' we have to coordinate with the other RN.

47. P1 Yeah.

48. P2 Okay. Um, to that point. Um, [Referring to P1] I don't know about how you feel about it?

49. P1 That's right because another person is running late with a client and [incomprehensible] time issue, you know, sometimes.

50. I Okay, the time issue.

51. P1 Yeah, we are not available on the spot, we are busy.

52. I Right, yeah, definitely. So, now when you- so let's say if you didn't have to do two assessments, that it was just the one, um, do you think it would be easier using the app, or is there no difference in using the app and just assessing the patient with paper?

53. P2 Hm. So, we're talking about the paper. I'm here about four years-

54. I [In agreeance] mhm.

55. P2 -and the how2trakalways been there.

56. P1 Yeah.

57. P2 So, um, not sure, like, for comparison reason, I'm not sure that using- depending- we have to use how2trakand also the paper.

58. I Okay.

59. PI Yeah.

60. P2 Because whatever we put in how2trakis reflected in [the] chart, so we keep the chart copy anyway.

61. I Right, okay.

62. P2 So, it's not like we're using one or the other. We have to use both so far. So, obviously, ah, you know, that's a duplication of work – in my opinion.

63. I [In agreeance] mhm, definitely.

64. P2 At this point. However, ah, you know, there might be benefits to the programming because you can probably, ah, consolidate the data quite quickly and see the other outcomes of the wound healing process quite well. So that's a good plus for using the program. But, um, doing that comparing to the paper itself, it is better for sure. But, like I said we have to use both, so at that point it's a disadvantage.

65. I Right. Okay. And so now, if the option was given to you to just use one. The app or the paper, do you think-

66. P1 Go with the app!

67. P2 I'd go with the app.

68. I Yeah? Yeah. [Audible typing] okay perfect, I'm just making a note of that. Okay, and so that- even though we kind of touched on it in question two, we'll kind of dig a little deeper in question three, and that would be, "how would you compare the two in terms of efficiency? So, and I think we've already said since you have to use paper and the app at the same time, it's a little bit of a time suck.

69. P1 Yeah.

70. I But if you had to use one versus the other and you all had said you would prefer to use the app, do you think it would be more time efficient?

71. P1 Yes.

72. P2 It could be, yeah. One or the other. Of course.

73. I Okay. Is there anything you would change about the app to make it more efficient? Like is there anything that seems a bit redundant or maybe useless?

74. P2 Yeah. Yeah. There [is] repetition.

75. P1 There were some, like, it used to be already the data was entered for the client and if that is already done that would be time saving for us also.

76. I Oh, yeah. That's a good point.

77. P1 Yeah. And then it always counted the number of days the client takes, but it would be nice if it count the number of visit that we are doing the dressing change for the client. How many dressings he already had.

78. I How many dressings, okay.

79. P1 Yeah. The visit- the visit will also be there, so we know in 30 days he already came 10 times or 20 times, so that will give us an idea how much he needs care.

80. I Okay. And so right now, the only way for you all to know that is if you were to see the assessment or if you read your notes? In the file, right?

81. P1 Yeah.

82. P2 Yeah. We actually count at the discharge- we count the number of the visits [the] patient make for stats, right? We have to put that in there.

83. I Right.

84. P2 So, we are- we like to see the how2traktelling us length of stay, okay? And-

85. P1 The number of-

86. P2 how2trakalso could calculate how many visits-

87. P1 visits, yeah.
88. P2 -were there- made, that would be, ah, even better solution for us.

89. I Oh, wow, okay. That's great feedback. [Audible typing] I'm just-

90. P2 For some- we have some chronic patients even for a few years and you can imagine even how thick the chart might get and you try to count those visits at the end of the discharge, um, and it takes- time consuming, and we have, like, overflow charts, and you know, sometimes, you know, [we] can't count the visits correctly because of so many papers.

91. P1 Sometimes the RN forget to sign one of the papers, and-

92. P2 Exactly, the patient goes to a different clinic for a visit, sometimes, and…

93. P1 Yeah.

94. I Okay. And that sort of goes back to your point, _____ about having the ability to consolidate all the data in one application, so yeah, that's really great. Okay. Alright, and so again this is kind of more of the same, but we're just going to dig now just a little bit deeper than question three and we're going to go into question four, and so that is, "how would you compare the two in terms of user-friendliness"? And so for this one I think I just want to change it a little bit. Instead of saying "user-friendliness", I want to kind of get your feelings, do you think that using the application would be better for the patient? That you could kind of see, um, where they're trending? If they're getting better, if they're getting worse. Or would you say that the paper version does the same thing?

95. P2 In my opinion, I think that the program does a good job in tracking the information, yeah, or giving us the graphs. Of course, the chart doesn't have pictures, so that's a main advantage.

96. P1 [incomprehensible] it would definitely help with the percentage of healing and so we know how much we are going in that direction.

97. I Okay, and so the picture aspect of it, is that something that you really like? Would you continue taking pictures?

98. P1 Yeah, def- yeah, definitely. Very important because it's not the same all the time. At least when I am not there, someone else is there, looking at the pictures she knows the wound is really closing or not.

99. I Okay. And now, I'm sorry, cause' I didn't know coming before, but did you take pictures before we gave you the how2trakapp?

100. P1 Yes, yes, yes we were taking pictures

101. I You did.

102. P2 Wait, wait, wait before how2tral®?

103. P1 No, no, no not before how2tral®.

104. I Not before how2trak®. Just with that, okay, that's great [audible typing]. And so do you find that entering the information into how2trakis time consuming?

105. P2 I, ah-

106. P1 Not the information, but the picture, that kind of thing takes time. Not good.

107. I Okay. And so what do you think that we could do or maybe change, if you have any suggestions, to make it more time efficient for you all? Because right now I think you all have the desktop. Um, would having the ability to have it at your fingertips be better? Or maybe less criteria to fill out would be better, or?

108. P2 Okay. Um, I think, uh, not sure if you can do that, how you [are] planning to promote this app, but tailoring the program to the specific needs of the clinic – our clinic – would be beneficial in a way. You have a lot of data and, uh, products that we are not even using so. And I see that the information grows and it's changing as we update the program. For example, you updated admission comorbidities, and now we have maybe 10 or 15 and I think you have 50 different things. Okay. So, um, for the products itself that we are using it's a CCAC based, uh catalogue so sometimes, not sometimes- well from time to time they change those catalogues and the products so I think that there not using anymore they bring in new products which they don't reflect particularly on the program when we select the product. So I'm not sure if that is something that can be reviewed, or tailored to our- to the clinic. So, like, you have the different things on the list and maybe we use just 20 of them now, um, I know there's similar, and I know some product can be substituted – and that's the only thing we are using. But when you are tracking the cost, let's say you have to select, you have to select "Biotine" versus "Mepilex" it will give you a false reading, correct?

109. I Right, that's right. That's such a good point.

110. P2 So, yeah. So, when we are trying to select the dressing, trying to get as close as possible to the product we are using, but, um, you know, that's all we can do right now. We cannot correctly, um, sometimes, quite often, select [the] exact product we are using on the patients. Uh, you know, there's a lot of products I have in mind to say.

111. I Yeah.

112. P2 But, yeah.

113. I Okay. That's great, _____. That's great feedback, really. So, um, actually just jumping off of that point, so, if your, um, if you have a returning patient and you mentioned that their file sometimes- they get so large and you have some papers and everything like that,

so if you have to go back into your files and retrieve patient information is it easy to get that information on how2trakdid you find?

114. P2 Very.

115. I Yeah?

116. P1 Yeah.

117. P2 Yeah.

118. I Perfect [audible typing]. Okay, alright, oh we're making such great time! Okay, so we have eight minutes left-

119. P2 Awesome!

120. I [Laughter] and we'll go right into the fifth question-

121. P1 Yes.

122. I -which is very very general, um, and I'll get just your honest feedback again. So, overall, um, do you think that using the how2trak®, specifically the surgical site portion, um, affected your delivery of care to the patients? [Short pause] either negatively or positively.

123. P2 Um, I think yes and no. From the point of view, I mean, we have a plan of care to follow and whether [we use] how2trakor not we will deliver the plan of care the best we can. Correct?

124. I That's right.

125. P2 Correct. But, then situation where how2trakmight be helpful in providing that care by, um, making, uh, you know, going back to the program and see- the pictures for example what the situation was before, whether the product were used were efficient or not, worked or not, so, you know, in some situations it probably would help, but overall I think-

126. P1 Yeah.

157. P2 I think the care we provide is-

158. P1 [Faintly] is the same

159. P2 -is the standard care.

160. I It's the standard care, yeah. Great. That's a great answer. And so, I guess then – just to kind of dig a little deeper – um, since you provide this standard of care and you mention that how2trakwould kind of help you in certain situations, do you think it would help you more or less than the paper version?

161. P1 It would help more than the paper version for sure.

162. P2 Yeah, I agree.

163. I Okay. And for what reasons?

164. P1 [Short pause] we can easily access and we can, uh, easily read because some peoples handwriting is not so clear it's- everybody has their own way of writing the things. And, I think, yeah.

165. P2 And what we said before, for someone who has been discharged before and for example the terms to the service, it's easy to see what kind of care was delivered before and what products were used. What kind of compression were applying for example. Um, from that point, if you have some background it's easier to make a decision sometimes on the present-

166. P1 Make a- if we are in some other clinic and what to check some patient on the other clinic you can always look and check. Even if I am here and I want to check what she wants for some client, something else I want to check, I can always check.

167. I Oh, yes. And that's a good point too that you haven't mentioned yet, yeah.

168. P1 Yeah.

169. I Okay.

170. P2 Yeah. About [incomprehensible] the wound consultations with our, like say, team leaders, or, they can also see the information easy and look at the wound on the how2trak®-

171. P1 Yeah.

172. P2 -or see the recommendations, or-

173. P1 Yeah. Same thing happens at the office because they also check from time to time how many- if somebody is not getting well they look at the how2trak®, what is going on with the wound, right? This one is here for- and not getting well, you know. They access the data.

174. I Oh, perfect. Great. So you all had a good experience then it seems?

175. P1 Yes. We did.

176. I Excellent. Do you have any questions for me, or any kind of last remarks about the app, or any suggestions that you may have to make it better?

177. P1 Right now, I can't think of, but you can send us an email or some- so that if something comes up later on we can send that information to you.

178. I Yeah! Absolutely. _____, I'm so glad you said that because I was going to say, um, if you or _____, or any of the other RNs that weren't on the call today you can always send me an email.

179. P1 Yes.

180. I And then we can, ah, like I said Corrine is very passionate about this app and so any feedback that comes back is great because we just want to get feedback from people who actively use it and we want to improve patient outcomes, so, this is so great. I thank you guys so much for taking the time to do this with me. And, um, we've actually hit three minutes left, so that's perfect [laughter]. I haven't taken too much of your time, so I hope that I get to see you soon!

181. P1 Yeah, thank you!

182. P2 Yeah! Stop by and say hello.

183. I Yes! Definitely, next time I'm there.

184. P1 Okay.

185. I Alright, bye _____. Bye _____.

186. P1 and P2 Bye.