THE INTEGRATION OF SAFETY ENGINEERED NEEDLES IN ACUTE CARE HOSPITALS: OPPORTUNITIES AND CHALLENGES OF REGULATED CHANGE

by

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Needlestick injuries have been identified as an important modifiable risk factor associated with the transmission of bloodborne pathogens between patients and healthcare workers. A number of jurisdictions, including the province of Ontario, turned to regulation to accelerate the adoption of safety-engineered needles (SENs) for the prevention of needlestick injuries. Available surveillance data demonstrates that needlestick injuries captured in work-related emergency department records and workers’ compensation claims have not declined substantially in Ontario. Drawing on organizational change and implementation science theory, a qualitative instrumental case study design was used to examine the implementation of SENs in three acute care hospitals in Ontario. Program documents were reviewed and interviews were carried out with staff across the three hospitals. While all three hospitals responded to the regulatory requirements with integrity, there was evidence of inconsistent processes and outcomes, which may have been due to variation in the types of SENs that had been integrated, the organization’s readiness for change, and the implementation practices that were adopted. During the initial implementation phase some front-line workers developed strategies to avoid using the SENs. There was a conflict between the values healthcare workers placed on performance and patient care and the learning curve associated with the initial transition to SENs. Explanations as to why needlestick injuries continue to occur were organized under two themes: the importance of staff compliance and "being more careful" and the inevitability of injury as a consequence of the work environment. While further progress will be challenged by competing health and safety priorities, a renewed interested in this injury issue among front-line workers and health and safety professionals may produce better outcomes as there appear to be a number of opportunities to advance prevention efforts to further reduce ongoing needlestick injuries.
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List of Abbreviations

CUPE  Canadian Union of Public Employees
CDC  Centers for Disease Control and Prevention
CNSSN  Canadian Needlestick Surveillance Network
FTE  Full time equivalent
GTA  Greater Toronto Area
JHSC  Joint Health and Safety Committee
MoHLTC  Ministry of Health and Long-term Care
MOL  Ministry of Labour
NACRS  National Ambulatory Care Reporting System
OHA  Ontario Hospital Association
ONA  Ontario Nurses Association
OPSEU  Ontario Public Service Employees Union
ORC  Organizational Readiness for Change
PSHSA  Public Service Health and Safety Association
SEIU  Service Employees International Union
SENs  Safety engineered needles
SEMS  Safety engineered medical sharps
WHITE  Workplace Health Incident Tracking and Evaluation
WSIB  Workplace Safety and Insurance Board
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CHAPTER 1

Introduction

Regulation is a potentially powerful mechanism to promote the adoption of occupational health and safety policies and practices. However, regulatory success depends on the requirements being adequately supported and implemented. A number of jurisdictions, including the province of Ontario, turned to regulation to accelerate the adoption of safety-engineered needles (SENs) for the prevention of needlestick injuries in healthcare organizations. The successful implementation of evidence-based interventions on a large scale requires support at the systems, organizational and practice level. Rather than follow the lead of previous evaluations that have focused on examining the overall impact of regulatory change on needlestick injuries, this study looks more closely at the implementation experience to better understand organizational challenges associated with the implementation of SENs, compliance issues, why needlestick injuries continue to occur despite the availability of SENs, and where future investments should be made to further reduce injury risk.

1.1 Research Background

Safer needle regulation is designed to promote the uptake of SENs with the objective of reducing the incidence of needlestick injuries among healthcare workers. Needlestick injuries have been identified as an important modifiable risk factor associated with the transmission of bloodborne pathogens between patients and healthcare workers. These injuries are common, have potentially life-long health consequences and are often preventable (1). Needlestick injuries are incidents that involve an accidental puncture of the skin with a needle and can result in the transmission of blood borne pathogens (e.g., hepatitis B, hepatitis C, HIV) between patients and healthcare workers. Despite a low probability of infection and the availability of post-exposure treatments, psychological symptoms often arise following a needlestick injury (2). Affected workers will often follow a post-exposure protocol, which might include additional testing at 6 weeks, 12 weeks and 6 months post-exposure if the infection source is unknown (3). The process of being tested and receiving post-exposure treatments has been found to have a wide range of psychological impacts on healthcare workers including depression, post-traumatic stress disorder, health anxiety, general anxiety, trauma related anger, and impaired work functioning
These injuries can also be costly with estimates for a single injury ranging from $65 to as high as $4,800 (2012 US$) for post-exposure treatment and testing (1).

The potential health impacts that arise from a needlestick injury and the recognition that healthcare work environments are inherently unpredictable put greater emphasis on improved sharps disposal practices and the use of engineering controls to protect workers from injury (13;14). Since safety-engineered medical sharps became available on the market, their uptake has been advocated for the prevention of both needlestick and other sharp-related injuries. In this dissertation ‘SENs’ will pertain to safety engineered needles or any hollow-bore needle with a safety feature or needleless device that replaces a hollow-bore needle. The term ‘SEMS’ will pertain to safety engineered medical sharps (SEMS) referring more collectively to a wider range of medical sharps with safety features (e.g., suture needles, scalpel blades, lancets). Tosini (15) further categorized SENs as active and passive devices. Active devices were further subdivided into safety devices that have a manual design; for example, a device with a protective shield that slides forward or is flipped over the needle. These devices will be referred to here as manual SENs. The other group of active devices has been termed ‘semi-automatic SENs’ referring mostly to those designs where the safety feature is activated with the push of a button. Passive safety devices are fully automatic. This would include devices where the needle will retract automatically once the injection is complete.

As with any new innovation, the adoption of these devices by healthcare organizations was initially slow (16), in part due to the higher costs of SENs relative to conventional devices. Unions and associations in both the United States and Canada came together to advocate for regulation that would stimulate a system wide transition to the use of SENs. At the federal level, the United States adopted the Needlestick Safety and Prevention Act (2000) with new requirements under their bloodborne pathogen standard and over the past decade, several provinces in Canada have followed with similar regulatory requirements. Ontario's regulation on needle safety came into effect under the Occupational Health and Safety Act in September 2008. The regulation requires healthcare facilities to replace conventional hollow-bore needles with SENs.
1.2 Problem Rational

There has been very little information available on whether Ontario’s regulation on needle safety was implemented successfully and what impact it has had on organizations and the intended outcome: a significant reduction in needlestick injuries. There can be a number of challenges for organizations implementing a new innovation under a regulatory standard. Regulatory requirements often define an effective date for compliance that provides a narrow window for organizations to make necessary changes, which can limit the use of more comprehensive implementation strategies. A small number of studies have examined the impact of safer needle regulation in the United States and British Columbia and have found variation in levels of compliance and impact (17-22). These studies have not provided contextual information on reasons for continued issues with the use and implementation of these devices. There are a number of knowledge gaps that remain including how safer needle regulation has influenced investments in safety technology, organizational challenges associated with the implementation of SENs, why needlestick injuries continue to occur despite the availability of SENs, and where future investments should be made to further reduce injury risk.

In resource constrained systems, it is important to ensure that public health interventions are effectively designed, delivered, and implemented to increase the likelihood of successful outcomes. This point was emphasized recently at a conference in Virginia, USA for the tenth anniversary of the Needlestick Safety and Prevention Act (23). The Consensus Statement and Call to Action that was drafted by members of a multi-stakeholder steering committee acknowledged that while substantial progress has been made, preventable sharps injuries and blood exposures continue to occur in U.S. healthcare settings. The committee recognized that one cannot assume that all issues will be resolved following the enactment of regulatory standards to promote the uptake of SEMS and that renewed commitment was needed to achieve further progress.

The decision to focus on Ontario's regulation on needle safety evolved from several stakeholder discussions with representation from employer associations, unions, government and manufacturers. It was learned that the majority of target hospitals in Ontario have taken action to respond to the requirements; however, it was also learned that implementation is an ongoing process and challenges remain.
This thesis partly responds to current knowledge gaps regarding the implementation of Ontario’s regulation on needle safety by examining the implementation experience in acute care hospitals. Further examining how Ontario’s regulation on needle safety has been implemented and the obstacles faced will provide novel information that is both practical and theoretical in nature.

1.3 Justification of Design

While Chapter 5 provides an overview of the research methods for this study, it is important to justify some of the design considerations upfront including the selection of a qualitative case study design and a focus on acute care hospitals.

Acute care hospitals were the first type of healthcare facility targeted by safer needle regulation. Hospitals have had a longer period of time to adapt and respond to the regulatory requirements. This allowed the study to focus on barriers associated with sustained implementation and integration of medical devices, a stage of implementation that is understudied in the implementation science field (24). Focusing specifically on acute care hospitals also provided an opportunity to examine the implementation of SENs in a setting that is inherently complex. In acute care hospitals, different types of SENs must be implemented across clinical units where the types of healthcare workers, procedures and hazards will greatly vary.

While impact evaluations can measure the extent to which injury rates have declined, these designs may not be able to explain unexpected trends or describe why injuries continue to occur. Using qualitative methods to study the implementation of Ontario’s regulation on needle safety provided a means to capture a descriptive account of the implementation experience and a contextualized understanding of remaining issues associated with the use and integration of these devices. Using a survey with specific questions and response options or a very structured interview guide would have limited opportunities to identify unexpected program outcomes or challenges.

Stake (25) identified three types of case study designs. An intrinsic case study is used when the case itself is of primary interest and the focus is on better understanding the uniqueness of the case (25;26). In contrast, an instrumental case study is used when the selected case is meant to provide insight into a particular issue or to facilitate understanding of something else (25;26). In
addition, the term collective case study is used when there is more than one case (25;26). The specific qualitative approach used in this study can be described as a collective and instrumental case study design (25). A collective understanding of how Ontario’s regulation on needle safety was implemented was facilitated by examining how different organizations have responded and been impacted by the regulatory requirements. The organizations that were selected were instrumental to providing a better understanding of the implementation of the regulatory standard in acute care hospitals. Case studies are often used when the unit of analysis focuses on organizational change (27). The unit of analysis in this study represents the organizational changes that were necessary to implement Ontario’s regulation on needle safety (28). Selecting a case study approach to examine issues associated with the integration of SENs is also based upon the assumption that implementation effectiveness will be influenced by both the users of the device, practices in place to support the selection and integration process, and the broader organizational context (29). Another key attribute of the case study design is the ability to obtain multiple perspectives from across the organization (28).

1.4 Significance and Objectives

Ontario’s regulation (474/07) on needle safety was established in order to protect healthcare workers from the physical and psychological consequences of needlestick injuries and to reduce costs associated with the treatment of these injuries. As Ontario currently has the largest number of healthcare workers in Canada, this system level intervention could have the potential to make a substantial impact on the uptake of SENs and the reduction of needlestick injuries in healthcare organizations. It is important to invest more research on the implementation of this regulation to identify remaining issues, help interpret future impact evaluations and ensure that the expected outcomes of the intervention are realized.

This thesis does clearly have a substantive focus. The focus of the study, in addition the methodology, also provides a unique opportunity to contribute to the study of implementation including contextual factors that influence successful implementation. There is a need to better understand implementation from an ecological perspective examining the socio-political and organizational context (30). The study explored implementation experiences under circumstances where regulatory pressures are influencing the organization's change process. Furthermore, the timing of the study provided an opportunity to focus on issues that arise during the later stages of
implementation including some of the barriers associated with the continued investment in more advanced safer needle technology. Previous reviews of the implementation science literature have identified the need for more research that examines later stages of implementation (Fixsen ref). The study also provided the opportunity to examine the relevance of implementation science concepts in the field of occupational health and safety where the adoption of an innovation is designed to enhance the health and safety of workers. Previous work in implementation science has tended to focus on innovations designed to enhance an organization's productivity or competitive advantage. The dissertation thus has both practical and theoretical applications. This study was designed to explore how the implementation of safer needle regulation played out in acute care hospitals in Ontario through a collective and instrumental case study design. The study had the following broad objectives:

I. To describe how acute care hospitals have responded and managed the integration of SENs under Ontario’s regulation on needle safety;

II. To better understand the consequences of integrating SENs under Ontario's regulation on needle safety;

III. To provide a contextualized understanding of remaining issues associated with the use and integration of SENs; and

IV. To examine the utility of existing models of organizational implementation effectiveness under regulatory framework.

In addition to the broad objectives defined above, the study was also framed with the use of foreshadowed issues. Simons (2009) recommends the use of foreshadowed issues in case study research to help narrow the focus of fieldwork (31). The use of foreshadowed issues is based upon the assumption that fieldwork is rarely initiated without having some preliminary ideas about what will require further examination. In this study, a list of foreshadowed issues served as a preliminary guide as to what to explore but was not meant to constrain the research process (31). To guide the development of the foreshadowed issues a conceptual model was defined to organize a number of relevant concepts and issues that were identified through a preliminary review of previous studies, implementation guidelines, anecdotal reports, and concepts from the
implementation science and organizational change literature. Much of this literature also influenced the data analysis and interpretation and will be reviewed in subsequent chapters. The list of foreshadowed issues can be found in Appendix A with references to supporting literature.

1.5 Organization of the Thesis

Following the introduction, Chapter 2 provides a detailed overview of the regulatory standard that is examined in this dissertation. Ontario’s regulation (474/07) on needle safety will be reviewed and contrasted with regulatory standards in other jurisdictions. The ideas, interests and institutions behind the changes that led to the establishment of the regulatory standard in Ontario will be reviewed in Section 2.2 highlighting the values and expectations around the use of SENs. The chapter concludes with an overview of two guidance documents that were prepared by the Centers for Disease Control and Prevention (CDC) and the Public Service Health and Safety Association to support the implementation of SENs. These documents were also used to help frame the topical information about each organization's implementation process.

Chapter 3 examines what is known about the impact and implementation of SEMS and more broadly regulatory standards promoting the uptake of these devices. This chapter will also describe trends in needlestick injuries in Ontario drawing on workers' compensation claims and work-related emergency department records. Chapter 4 presents the conceptual framework; the traditions, assumptions, theories, and concepts that influenced the initial framing of the study in addition to the analysis and interpretation. Chapter 5 provides a detailed overview of the research methods. This chapter also reviews a guiding framework that was used to consider how specific design features should be incorporated to enhance the overall credibility of the research findings.

Chapter 6 presents descriptive case reports for each hospital under study. The following two chapters move into a more in-depth analysis focusing on conditions that challenged and supported the integration of SENs in Chapter 7 and the need for ongoing commitment to advance needlestick injury prevention in Chapter 8.

A discussion of the case study findings will be presented in Chapter 9 with a focus on the knowledge gained about the impact and implementation of Ontario’s regulation on needle safety,
methodological issues encountered, theoretical contributions of the case study findings, and recommendations to enhance current prevention efforts.
CHAPTER 2

A System Transition to Safety Engineered Needles

This chapter will outline Ontario’s regulation on needle safety and how the requirements align with the design of regulations in other jurisdictions. The context and drivers of the policy change will be captured by discussing the underlying ideas, interests and institutions behind the development of the regulation (32). The chapter will conclude with an overview of recommendations for the implementation of SENs from two guidance documents that were available to assist organizations respond to the new regulatory standard in Ontario.

2.1 Ontario’s Regulation on Needle Safety

Before outlining Ontario’s regulation on needle safety and the history of its development, it is important to first understand the structure of Ontario’s prevention system. For companies or sectors that operate across provincial or international borders (e.g., airports, banks, railways), the federal government has jurisdiction over occupational health and safety regulatory standards, inspections and enforcement. This accounts for approximately 10% of the Canadian workforce (33). The Ontario government has responsibility over occupational health and safety for the majority of workplaces in the province. The Ontario prevention system includes the Ministry of Labour (MOL), the Workplace Safety and Insurance Board (WSIB) and health and safety associations which are designated under the Workplace Safety and Insurance Act (34). The MOL sets, communicates and enforces workplace standards. The WSIB is funded by premiums collected from employers in Ontario. At the time of the establishment of Ontario’s regulation on needle safety, the role of the WSIB was to promote prevention through funding the provinces occupational health and safety system, oversee the province's occupational health and safety programs and services, compensate injured workers and the survivors of deceased workers, and assist injured workers return to work (33). The prevention system in Ontario also includes, as of January 1, 2013, 6 health and safety associations (33). The association that services healthcare is the Public Services Health and Safety Association (PSHSA) which was formerly the Ontario Safety Association for Community and Healthcare. PSHSA provides a range of services including workplace audits and information and resources on injury prevention initiatives and changes to legislation, codes and standards. The health and safety associations have a separate
mandate and role in the prevention system. PSHSA does keep employer operations and practices confidential; however, they are obligated to disclose information to the WSIB or MOL if their client fails to address or eliminate “serious, imminent danger[s] to a worker’s or workers’ health and safety” (35).

To reduce rates of needlestick injuries in Ontario, a regulation was established under the *Occupational Health and Safety Act* (36). Ontario’s regulation 474/07 on needle safety was announced officially in 2007. Prior to the development of the regulation, inspectors could order employers to implement safety devices citing general requirements under the *Occupational Health and Safety Act* (37). One of the duties of the employer in the Act is to “take every precaution reasonable in the circumstances for the protection of a worker” (37). Inspectors would cite organizations under this section of the Act in specific cases and areas where needlestick injury rates were elevated and where there was insufficient action being taken to reduce risk. One year before the *Safe Needles Save Lives Act* was introduced in the Ontario provincial legislature, it was reported that inspectors visited over 192 healthcare facilities and 68 orders were given for needlestick injuries (38). A more specific requirement to mandate the use of SENs was believed to be necessary to discourage requests for appeals and to accelerate the uptake of these devices across all healthcare organizations in Ontario (38). The specific requirements for employers are outlined below.

> When a worker is to do work requiring the use of a hollow-bore needle, the employer shall provide the worker with a safety-engineered needle that is appropriate for the work. O. Reg. 474/07, s. 3 (1).

> Subsection (1) does not apply if the employer is unable, despite making efforts that are reasonable in the circumstances, to obtain a safety-engineered needle that is appropriate for the work. O. Reg. 474/07, s. 3 (2).

> The employer shall develop, establish and provide training for workers to assist them in applying subsection (2). O. Reg. 474/07, s. 4 (4).

The term hollow-bore needle is essentially any needle device that is used to administer injections or draw blood (36). The regulation defines a ‘safety engineered needle’ as any device designed to eliminate or minimize the risk of skin puncture injury to the worker that has been licensed as a medical device by Health Canada (36). The definition also incorporates the use of needleless
devices (36). A non-safety device can be used if the potential for harm to the worker or patient is greater when using the safety device.

When the regulation came into effect in 2008, it applied to all hospitals as defined in the Public Hospitals Act (39), every private hospitals as defined in the Private Hospitals Act (40), every institution as defined in the Mental Hospitals Act (41), and Homewood Health Centre Inc. (delivers psychiatric services). Two other effective dates were later announced for other workplaces. In April 2009, long-term care homes, rest homes, labs, and specimen collection centers were required to adopt SENs. Another amendment came into effect in July 2010 impacting all physicians’ offices and practices where hollow-bore needles are being used on patients for therapeutic, preventive, palliative, dentistry, diagnostic or cosmetic purposes.

We do not know to what extent this investment was successful in promoting the uptake of SENs across hospitals in Ontario. We do know that there were a number of hospitals that had not yet transitioned to safety devices when the regulatory requirements were announced in 2007 (42). While there is some variation in cost based on the type of device, costs of SENs are higher than conventional needles. The California Department of Occupational Safety and Health conducted a cost analysis using data from two manufacturers of safety devices (43). The percent increase in the median unit cost for five of the most commonly used sharps ranged from 40%-70% (43).

In March 2005, the Ontario government made a one-time investment of 11.6 million dollars to support 148 hospitals in the province transition to SENs (44). This funding may have been sufficient to cover the initial costs associated with the conversion process including the logistics and training but was not expected to alleviate the annual increased costs associated with the purchase of SENs. The impact of this one-time financial investment was not evaluated and it is unknown whether it was successful in promoting the uptake of SENs across hospitals in Ontario. There was negative feedback following the funding announcement. When the investment was announced, an editorial was circulated in the news that emphasized the limitations of a one-time investment in safer needle technology:

The government should make instruments such as safety-engineered needles mandatory in all hospitals and clinics – and funding for the equipment should be allocated as part of every facility’s annual operating budget rather than a one-time infusion of 11.6 million… (45)
Following the enactment of Ontario's regulation on needle safety, there was no additional financial investment to support the purchase of SENs.

Establishing a regulatory standard for the adoption of SENs was not a simple venture. It involved several years of collaboration, planning, awareness campaigns, and regular meetings with members of the provincial legislature. Shelly Martel, a member of the New Democratic Party, introduced the Safe Needles Save Lives Act as a private members bill on two occasions. The first Bill was debated in Ontario parliament in 2005 and it went to committee (38). The Act was re-introduced as Bill 30 in 2006 but again nothing came to pass after it was sent to committee. When neither bill passed third reading, the Ministry of Health and Long-term Care (MoHLTC) and the MOL worked collaboratively on a regulatory standard, which was established under the Occupational Health and Safety Act (36). Only the US federal government and the Nova Scotia and Manitoba provincial governments have passed separate legislation to promote the uptake of SENs. Ontario (2007) Saskatchewan (2007), British Columbia (2007) and Alberta (2006) have enacted new regulatory standards under their existing occupational health and safety acts or codes. Table B1 in Appendix B summarizes information on the delivery, target population, and regulatory requirements in Canada and the United States. The consecutive adoption of regulation on needle safety across a number of provinces in Canada can be attributed in part to a national campaign led by the Service Employees International Union (46;47).

In 2013, a European Union (EU) directive on sharps safety came into effect (48). The directive on the prevention of sharps injuries in the hospital and healthcare sector did not only focus more broadly on the uptake of SEMS but also provided a more integrated approach to sharps injury prevention incorporating guidance on risk assessment, worker involvement in device selection, considerations for device selection, training, and other measures to reduce exposure. Member states were given three years to adopt the requirements outlined in the framework.

Unlike the EU, United States, British Columbia, and Alberta, Ontario has not yet extended the regulatory standard to apply to all sharp medical devices including suture needles, scalpels, and lancets. Unions involved in supporting the move toward SENs in Ontario workplaces have proposed that the scope of Ontario’s regulation on needle safety be extended (49). In 2009, they requested an amendment to the regulation that would require employers to consider safety
devices for all medical sharps not just hollow-bore needles. This has yet to be adopted and according to external informants, the requirements are unlikely to pass unless physician groups come together to support the proposed changes. The importance of securing physician support was emphasized as this group would be targeted by the product changes. Physicians in particular, were identified as a group that according to external informants, were more resistant to the use of SENs.

There are a number of differences in how the United States (US) and Ontario regulated safer needle use. The U.S. Needlestick Safety and Prevention Act (2001) explicitly states that SEMS are not required for applications that do not involve direct patient care (50). The regulation in Ontario more broadly requires all needles being used to include a safety-engineered component. The needle safety regulation in the US is explicit about the role of worker involvement in the selection of SEMS. In Ontario, the Occupational Health and Safety Act does have specific requirements for worker involvement on the joint health and safety committee (JHSC); however, in some target organizations the implementation of SENs was assigned to an independent committee (37). The involvement of workers in the section of SEMS is thus less explicit. A cross-jurisdictional comparison highlights a number of differences in how the mandatory use of SEMS has been approached (Appendix B). These differences need to be recognized when thinking about the generalizability of evaluation results.

2.2 Regulatory Change in Ontario

A number of historical documents were collected to trace the context and drivers that led to the regulatory changes in Ontario drawing on a policy analysis framework that involves three dimensions: ideas, interests and institutions (32). The information was compiled from multiple sources including key informant interviews with individuals involved in supporting the development and implementation of the regulatory requirements with representation from a union, government agency and product vendor. Two of the three external informants were members of the Alliance for Sharps Safety and Needlestick Prevention. This section was also informed by a number of documents including transcripts of Legislative debates, current regulations, news releases, educational material, union statements, and correspondence. To identify some of the underlying ideas behind the movement towards safer needle regulation in Ontario, transcripts from the two readings of the private members bill were reviewed (38;51). A
qualitative and open content analysis (52) was carried out to identify trends in what was emphasized about the use of SENs and the prevention of needlestick injuries. Three questions helped frame the analysis: what arguments were presented to support the need for safer needle regulation; what were expectations for the impact of the regulation; and what were anticipated challenges or concerns expressed in the debate? The transcripts from the readings of the two bills that introduced the Safe Needles Save Lives Act helped reveal values and expectations about the use of SENs and the importance of a regulatory standard.

2.2.1 Ideas

Examining the ideas or underlying paradigm “specifies not only the goals of policy and the kind of instruments that can be used to attain them, but also the very nature of the problems that are meant to be addressed” (53, p 7). This is especially important when examining the implementation and impact of Ontario’s regulation on needle safety as it can help identify expectations for the impact of this system level transition. To identify some of the underlying ideas behind the movement towards safer needle regulation in Ontario, transcripts from the two readings of the private members bill were reviewed (38;51). The following section examines the arguments that were presented for the need for safer needle regulation; the expectations for the impact of the regulation; and the anticipated challenges or concerns expressed in the debate.

The most prominent trend that was identified in the debate was the frequent use of injury statistics to capture the burden of needlestick injuries in Ontario. The estimate ‘33,000 injured healthcare workers’ (17,000 in the acute care sector) was repeated throughout the debate. These estimates were released by the Alliance for Sharps Injury Prevention. There are limited details available on how these estimates were established. The key informants that were interviewed also emphasized the importance of having information on burden of injury to communicate the importance of establishing regulation on needle safety. It’s important to note that the injury statistics that were widely used were only estimates of the potential burden of needlestick injuries in Ontario. Capturing an accurate estimate of the potential burden of needlestick injuries and changes over time is challenged by limited surveillance sources and uncertainty concerning the reliability and integrity of incident reporting.
The use of safety devices as a cost savings strategy was also an important argument. It was estimated that the move to safety devices in acute care hospitals would result in $10 million dollars in savings based on the expectation that injuries would drop by 82%. The fact that other jurisdictions had already adopted safer needle regulation was also emphasized. The United States had passed the *Safer Needles Saves Lives Act* back in 2001 and at the time of the second debate in 2006, Manitoba, Saskatchewan, and British Columbia had already established regulations mandating the use of SEMS. It was also important to emphasize that a solution existed: safer needle technology was widely available and shown to be effective. There were also a number of references that emphasized the value of healthcare work and the importance of sustaining an active and healthy labour force.

We pay a lot of attention to health care in Ontario, and we want to make sure that all the health workers on the front line are safe and using safe equipment. It’s important for all of us, because those people, the health workers in Ontario, maintain our health, maintain our capacity to go back to work, and we want to give them the chance, the capacity and the tools to continue to work and to serve the great people of Ontario. (51)

It is important to also acknowledge the regulatory context and its influence on underlying ideas behind the movement towards safer needle regulation. Interviews with key informants who championed the development of safer needle regulation in Ontario have identified the SARS outbreak (2002-2003) as a crisis that set the stage for the development of safer needle regulation in Ontario. The SARS crisis raised public awareness of the hazards inherent in the work of healthcare workers. It was also viewed as an event that increased awareness and concern among healthcare workers of the dangers and hazards inherent in their work and a realization that many of these hazards could and should be prevented.

During the legislative debate, some of the more serious implications of exposure were described including the risk of infection and death but also the emotional and psychosocial costs to the worker undergoing treatment and testing following an exposure. The mandatory requirement for organizations to adopt safety devices was argued to have the potential to not only protect healthcare workers but also the broader community. The mandatory use of SENs was also presented as something that healthcare workers wanted. To summarize the argumentation, those supporting the *Safe Needles Save Lives Act* argued that a solution existed to dramatically reduce
the burden of needlestick injuries, it will save lives, save the government money, and provide Ontario workers and the wider community with the same level of protection that is being provided in many other jurisdictions across Canada.

There were a few statements that captured the expectations for the potential of this systems level intervention to impact injuries. The Member of Provincial Parliament that introduced the bill argued that the mandatory use of these devices could eliminate up to 90% of injuries (51). There was reference to an evaluation of the impact of the federal law in the US that found a 51% decline in injuries one year after implementation with only a quarter of facilities in compliance (51). Other estimates of the potential impact were based on a case study at Toronto East General Hospital. They had reported an 80% decline in needlestick injuries following the transition SENs (54).

At both readings of the bill, there were limited arguments made against the mandatory use of SENs; however, there were some concerns expressed about the process. Specific challenges included the potential cost implications for organizations, a need to further consult with organizations that would be impacted, and the need for more reliable data to understand potential costs.

In summary, these underlying ideas suggest that the mandatory use of SENs was expected to have far reaching benefits for both healthcare workers and the wider community. It was anticipated that injury rates could be reduced by 80-90%, as SENs are effective and wanted by healthcare workers. Furthermore, the mandatory use of these devices was also believed to have the potential to save the government money in the long-term through reduced costs associated with testing and treatment.

2.2.2 Interests

There were a number of interests represented in the move towards safer needle technology. Healthcare workers, particularly nurses, were of course at the center of the decision-making arena. Nurses communicated their support by participating in the national campaign and were leading advocates for the Safe Needles Save Lives Act. Their presence in the galleries at the legislative assembly where Bill 30 was introduced was acknowledged by members of provincial
parliament throughout the debate (51). The interests of front-line workers were represented by multiple unions including the Ontario Nurses Association (ONA), Ontario Public Service Employees Union (OPSEU), Canadian Union of Public Employees (CUPE) and Service Employees International Union (SEIU). Supporting this initiative was in line with unions’ mission to proactively participate in initiatives that improve welfare of their members. Persistence was very important as it did take several years to get the regulation in place and there were a number of roadblocks along the way. The unions invested their resources in developing promotional kits that included posters and guidance documents to be used and circulated among their members. They also supported a sharps campaign that served to educate both the government and the public about the importance of safer needle regulation.

2.2.3 Institutions

While nurses in Ontario were the largest interest represented and had the most to gain from the reduced risk of injury, safety device manufactures had the most to gain financially. It was this group that initiated the Alliance for Sharps Safety and Needlestick Prevention. They recruited a government relations consulting group, SAMCI to lead the safety alliance and gather support from multiple unions and associations including the ONA, OHA, CUPE, SEIU and the OPSEU.

Throughout the development and implementation of Ontario’s regulation on needle safety, a number of unions, government organizations, and employer associations were involved. The Ontario Health and Safety Committee appointed under Section 21 of the Occupational Health and Safety Act provided a means to bring together union and employer representation on the issue of needle safety. The committee is responsible for providing advice and information to the MOL on how to make improvements to health and safety in the healthcare sector. This committee prepared a guidance note for workplace parties to help them understand their obligations in responding to Ontario’s regulation on needle safety (55). The Ontario Hospital Association, who participates on the Section 21 committee, also provided links to resources for the selection of SENs and medical devices in their Safety Bulletin (56).

Following the establishment of regulation on needle safety in 2007, the Alliance for Sharps Safety and Needlestick Prevention continued to engage with the premier, the MoHLTC and the MOL to expand the regulation (39). The MOL and the MoHLTC used a consultation process to
seek input from stakeholders on how to implement proposed extensions to Ontario’s regulation on needle safety (57). Four unions including CUPE, ONA, OPSEU and SEIU provided feedback on extending the scope of the regulatory standard (58). There position was that the regulation ought to apply to all workers where there is a risk of exposure and that the regulation be amended further to apply to all medical sharps and all sharps injuries (58). The Ontario Home Care Association also provided feedback on the consultation paper (59). There recommendations were for funding to be provided to support the integration of SENs, for consistent standards to be in place for purchasing methods, and for members of the Ontario Home Care Association to be consulted regarding the use of different types of sharps used in these settings. ONA was actively involved in developing handbooks and pamphlets to raise awareness about the risks of needlestick injuries, prevention, and post-exposure management (60). Having a large group of stakeholders that had an invested interest in the potential outcome of the regulatory change with resources to initiate and support a campaign and the development of implementation supports was clearly a unique facilitator to the process.

There was support for the mandated use of SENs coming from a number of groups; however, at the end of the day it was the regulatory authority that needed to be convinced that the initiative was worthwhile. Originally the National Safer Needle Alliance attempted to gather support from individual Members of Provincial Parliament; however, the private members bill supporting the Safe Needles Save Lives Act was not successfully passed. Representatives from the National Safer Needle Alliance felt that more progress was made when the MOL and the MoHLTC were consulted. One important incentive for the involvement of the MoHLTC was the fact that the costs associated with the treatment and testing following a needlestick injury does not always get absorbed by the WSIB but rather by the Ontario Health Insurance Plan. The Section 21 Committee facilitated negotiations with these two agencies.

It is important to appreciate the complexity and timing of the policy changes that were made. The right political groups had to be targeted at the right time and with persistence. It is important to note that the regulation was adopted in 2007, an election year in Ontario. The way in which SARS played out in Ontario also appeared to have a lasting impact on people’s perceptions of the inherent risks associated with healthcare work. The regulatory requirements also happened to have mutually beneficial outcomes: there was potential cost savings for the government,
improved working conditions for healthcare workers, and financial incentives for safety device manufacturers.

2.3 Implementation Recommendations and Resources

This section reviews resources and recommendations for the implementation of SENs that were available to support organizations respond to the regulatory standard in Ontario. Hospitals in Ontario did have the flexibility to adopt their own implementation strategy; however, all three hospitals under study did use specific implementation processes that were in line with a number of the recommendations. It is important to emphasize that these guidelines foreshadowed what processes might be used in the three cases under study. They therefore had an important role in framing the topical questions that were used to guide the data collection process. The case reports will demonstrate some of the challenges in executing these recommendations in practice and where some recommendations, if adopted, could help enhance the existing sharps injury prevention program.

To support the integration of SENs, four union groups (CUPE, ONA, OPSEIU, SEIU) sent local coordinators, bargaining unit presidents, JHSC members, and health and safety network leads material to support implementation including a step-by-step process to help implement the initiative, a checklist, and samples of written recommendations that could be used by the JHSC to make recommendations to their employer. The checklist (61) that was circulated was based on a checklist developed by the International Healthcare Worker Safety Center, University of Virginia (62). It included best practices for sharps safety and needlestick prevention in the areas of sharps safety devices, exposure control plans, and sharps injury logs. It was recommended that the checklist be used in conjunction with best practices to establish minimum recommendations in writing from the JHSC to the employer. The four union partners (CUPE, ONA, OPSEU, SEIU) later distributed a revised checklist (63) outlining more specifically situations covered by Ontario’s regulation on needle safety (specific to hollow-bore needles) and situations covered more generally by Section 25(2) of the Occupational Health and Safety Act (‘take every precaution reasonable in the circumstances for the protection of a worker’) (37).

More detailed implementation guides were also available to support the integration of SENs. Two of these guidance documents are reviewed in this section. The Workbook for Designing,
Implementation and Evaluating a Sharps Injury Prevention Program was prepared by the CDC (64). As reviewed above, the United States initiated the move towards the mandatory use of SEMS several years before Ontario established needle safety regulation in 2007. To support organizations respond to the new regulatory standard in Ontario, the Public Service Health and Safety Association (PSHSA) and collaborators prepared and distributed their own guidance document: A Planning Guide to the Implementation of Safety Engineered Medical Sharps (65). The two guidance documents share a number of similarities. In fact, the PSHSA guide actually references the CDC document in a number of areas referring readers to a number of tools available in the workbook. The recommendations or “implementation suggestions” defined in the document are supported by relevant literature, regulatory standards, and expert opinion. This section will not attempt to outline the two guidelines in their entirety but rather pull out specific recommendations that informed the data collection and analysis process and are important for contextualizing some of the findings of the case study.

The guidelines provide important recommendations for capacity building, needs assessment, and the development of a sharps injury prevention program with specific recommendations for selecting and implementing SENs, and a final evaluation or monitoring phase. The content of the guidance documents reflects the view that gains in the prevention of injuries from medical sharps will only be accomplished through a multi-component prevention approach that goes beyond the adoption of safety devices to also incorporate other improvements to education, clinical practice, and the work environment.

2.3.1 Organizational capacity

Both guidance documents discuss the importance of getting senior management commitment, support and leadership. This emphasis on senior management support is well aligned with models of implementation effectiveness that will be reviewed in more detail in Section 4.6. Neither guideline makes an explicit reference to the use of organizational change theory or concepts from implementation science; however, a number of the suggestions that are outlined are well aligned with this literature.

Senior management support has been identified in the implementation science literature as essential for supporting the development of comprehensive implementation policies and
practices (24;29;66;67). Much of the work that has established empirical support for the critical role of senior management support for successful implementation has been in the information systems literature (68-70). Specific to the field of occupational health and safety, senior management support has been identified as one of the most important conditions for enhancing compliance and reducing occupational exposures (71). The PSHSA guidance document provides strategies to obtain initial buy-in from senior management assuming that the momentum that is supporting the need for SENs tends to come from the top. To obtain this buy-in from management, the guidance document recommends the use of injury statistics and information to highlight the costs of these injuries to the hospital. Both guidance documents emphasize the importance of having senior management communicate their commitment and support for the transition to SENs via written organizational priorities and revised corporate goals.

In addition to providing sufficient human and financial resources to carry out the implementation process, the guidance document recommends the appointment of a program leader and the development of a multidisciplinary prevention committee to guide the implementation process. Both guidance documents make a number of suggestions for the structure and purpose of this multidisciplinary committee. Rather than identifying specific occupational titles, the PSHSA guidance document identifies areas of expertise that should be represented including occupational health and safety, infection control, staff educators, purchasing, the JHSC, and product evaluation. The importance of front-line user involvement is also emphasized with recommendations to include representation from nurse management, front-line caregivers, clinicians or physicians, and union representatives.

2.3.2 Needs assessment

Both guidance documents provide a comprehensive section on suggestions for different types of activities to review current policies and practices including an assessment of the organization’s safety culture, current injury reporting practices, safety equipment being used, and current training and education. There is an expectation that the organization should devote a significant amount of time to this preliminary planning phase.

The suggestion to examine the safety culture of the organization is more specifically focused on evaluating how sharps injury prevention strategies are valued and the systems in place to
maintain a safe work environment. It is important to point out that throughout both guidance documents the term safety culture is used. The terms safety culture and safety climate are often used interchangeably and are often not well defined (72). Guldenmund (72) integrates previous understandings of safety climate and safety culture in his framework that conceptualizes safety culture as having three layers. At the core are the basic unconscious assumptions held by members of the organization. The next layer focuses on values that are operationalized as attitudes regarding hardware, software, people or risks. The outer layer refers to specific manifestations, which in the health and safety field might include inspections, use of personal protective equipment, accidents, near misses, and different types of safety behavior. This outer layer seems to be what the guidance document is referring to when they recommend organizations look at the systems in place to maintain a safe work environment as part of the assessment of the organization’s safety culture. The recommendation to look at how sharps injury prevention strategies are valued would align with the second layer of the framework.

A few optimal conditions for a strong safety culture are listed in the PSHSA guidance document including a blame free environment for injury and hazard reporting; an environment where staff are encouraged to report near misses and hazards; where communication is delivered on the effectiveness of the sharps injury prevention program; communication tools are used to provide information on findings from investigations and prevention improvements; and where personal accountability measures are in effect. The CDC guidance document specifically advocates an assessment of safety culture when previous implementation initiatives have not been successful. The idea behind collecting this type of information is to identify any problems, barriers and strengths of the workplace culture that can then be used to modify or improve current program components or develop educational materials. The CDC document lists a number of strategies for creating a culture of safety that are related to sharps injury prevention including the development of opportunities for personnel to be involved in planning and implementation activities, encouraging the reporting and elimination of sharps injury hazards, and developing a feedback system to increase safety awareness.

In effect, the assessment of the organization’s safety culture with a specific focus on sharps injury prevention may help to identify the presence and quality of current initiatives. The CDC
guidance document recommends that whether or not the safety culture assessment is carried out, the organization should list current prevention initiatives to create a baseline profile.

Part of the assessment also involves the review of current strategies for sharps injury reporting to ensure that adequate information is being collected to measure progress over time, evaluate interventions, and identify underlying problems that are contributing to ongoing injuries. A number of recommendations are made on what information about an injury should be collected (e.g., procedure, activity, type of device). Emphasis is placed on obtaining sufficient information to monitor sharps injury causation and the effectiveness of interventions. The CDC guidance document not only promotes the collection of comprehensive information about incidents but also measures to ensure that healthcare personnel understand reporting procedures and are motivated to report exposures.

It is also suggested that the pre-planning phase look at current education and training around the prevention of blood and body fluid exposures. The PSHSA recommends an educational program related to blood and body fluid exposure prevention incorporating a comprehensive range of topics including skill development exercises; hospital injury statistics and risk profiles; the hierarchy of control concept, with examples; the role of the SEMS implementation team; reporting expectations and changes; and other safety culture initiatives. The CDC workbook outlines two styles of training to support the implementation of new safety devices. The 'team approach' uses in-house staff and product vendor representatives to offer training to a group of front-line users. The workbook acknowledges the limitations in getting all front-line staff to attend formal group based training sessions and thus also recommends 'catch-up training' for those who can’t attend the group based training. This catch-up training can be facilitated by recruiting and training select staff to serve as product experts on the units. What can be generalized from this recommendation is that the implementation strategies that are used to support the integration of SENs should be adapted to the constraints of the work environment. In this case, the issue is reaching a mix of full-time and part-time staff that work across the 24 hour clock and 7 days a week.
2.3.3 Selecting safety devices and developing a safer needle program

While the PSHSA guidance document focused on the implementation of SENs, they also recommend that the transition be considered as part of a larger program designed to prevent and reduce exposures to blood borne pathogens. This involves establishing or updating written policies for product trials, purchasing products, injury and incident reporting, exposure management, waste management, safe work practices, use of SENs, reporting of hazards, reporting of unsafe or defective devices, staff education, and proper disposal of sharps. The PSHSA guidance document specifically emphasizes the importance of the JHSC’s involvement in monitoring the sharps injury prevention program including the annual review of policies and procedures as required under the Occupational Health and Safety Act (37).

The PSHSA guidance document was written to support organizations respond to the new regulatory requirements in Ontario that are specific to the use of SENs. The guidance document does however take a broader focus suggesting that the organization consider other types SEMS (e.g., suture equipment and operating room equipment). Similarly, the CDC guidance document talks more broadly about the use of SEMS.

Once priorities have been established, the guidance document outlines a number of additional steps that should be taken to review and select from available safety devices. An important theme that is present throughout both guidance documents is the importance of carrying out a needs assessment to inform where the sharps prevention program should be enhanced. The PSHSA document recommends that the organization look at the current use of conventional sharps that are to be replaced. They recommend the use of surveys distributed to impacted areas to gather information on potential compatibility issues, unique clinical needs and expectations for device performance. They recommend that this initial needs assessment be carried out to identify areas that may have specific concerns and where representatives may need to be added to the product selection committee.

When the product selection committee is confronted by a wide range of safety options, the CDC workbook recommends that product selection should be based on both design criteria and performance criteria. Design criteria would include the physical attributes of the device considering safety and clinical needs. Performance criteria would relate to how well the device
functions for its intended safety and patient care purposes. A number of features that might be considered are listed including whether the devices are needleless; passive; if active, can be easily activated with a single hand and where the hand remains behind the exposed sharp; the user can tell if the safety feature has been activated; the device can’t be deactivated through disposal; the device is practical and easy to use; the product comes in a variety of sizes or gauges; and is safe and effective for patients. The guidance document acknowledges that there is variation in the quality of safety devices. It’s recommended that this initial phase should involve some preliminary testing to ensure that safety features are working as intended keeping track of cases where the device fails to activate.

The guidance documents and the regulatory requirements do not prescribe that organizations adopt passive safety devices. There is the belief that organizations should have significant flexibility in the types of SENs that are adopted acknowledging that more advanced safety devices may not always be available or feasible to implement. However, there is empirical evidence that has demonstrated the enhanced ability of passive safety features to prevent needlestick injuries. Tosini et al. (15) studied injury reports from sixty-one hospitals in France to examine the incidence of needlestick injuries among different types of SENs with automatic, semiautomatic and manual safety features (15). They found that passive or fully automatic safety devices were associated with the lowest needlestick injury rate.

It is likely that organizations will consider other factors at this point including the costs associated with different options. The PSHSA guidance document acknowledges that there will be other factors at play in the analysis of the information collected about product options including internal politics, preferences for conventional devices, attitudes, opinions of leaders, perceived need for the new device, and patient concerns. The guidance document does not however provide suggestions for how these factors should be balanced or weighted in the product selection process.

A number of suggestions are made for when the safety devices are rolled out on a larger scale including the need for adequate communication throughout ensuring that everybody involved in the trial receives sufficient information. The PSHSA guidance document recommends that the trial process not only examine the products under consideration but also the training that is
provided to those involved to obtain information, for example, on whether more training might be required. It is interesting to note that the CDC workbook suggests that rather than waiting for the full roll out of new devices, compliance with safety device use should be assessed from the beginning. The guidance document seems to recognize that semi-automatic and manual safety devices are likely to be used and because they require user activation there may be cases where staff chooses not to activate. This further supports the importance of engaging with staff during the transition process to identify any barriers with the use of SENs.

In terms of the implementation phase, the PSHSA guidance document emphasizes the importance of stakeholder communication and staff education. Upon the launch of the program it’s recommended that each area receive comprehensive education on new policies and procedures. The CDC actually defines four opportunities for training on sharps injury prevention: initial orientation; annual bloodborne pathogen training; staff development training on procedures; and upon the introduction of new devices. Through this initial implementation phase there are also a number of recommendations for obtaining feedback on the use of the new devices. The guidance documents seem to anticipate that despite the use of product trials, issues may arise when the devices are implemented more broadly. An ongoing monitoring component is suggested to evaluate whether additional training is required and to also assess the impact of the new devices on patient care.

2.3.4 Evaluating the program

To support the planning and implementation process the CDC guidance document takes a more evaluative approach putting more emphasis during the planning process on establishing a baseline profile and defining indicators of improvement. The PSHSA guidance document also advocates ongoing improvement initiatives recommending that program outcomes be monitored to measure successes and to identify areas for improvement. This includes keeping track of the use of non-safety medical sharps and costs of ongoing needlestick injuries.

The transition to SENs and other sharps prevention initiatives is viewed as an ongoing process requiring ongoing monitoring and adjustment. The organizational capacity building section that is recommended in both guidance documents seems particularly important when considering the comprehensive implementation strategies that are outlined. Without management support, it is
unlikely that sufficient resources would be available to adopt the recommendations outlined in the guidance documents. The adoption of the recommendations for the comprehensive needs assessment and product evaluation phase is likely to be influenced by the timelines the organization is working under which will likely be influenced by whether or not the transition to SENs/SEMS is voluntary. This section has presented a comprehensive portrait on what is considered to be an optimal implementation strategy for the integration of SEMSs. It is recognized that not all organizations will adopt these practices and there will be variation in implementation outcomes. The next chapter examines previous attempts to evaluate the impact and implementation of SEMS including but not limited to SENs.
CHAPTER 3

The Impact and Implementation of Safety Engineered Needles

A number of hospitals have participated in product trials to report on the effectiveness of different types of SEMS. The impact of SEMS has also been more broadly examined in studies that have looked at the impact of a system level transition to SEMS. It is important to note that these two types of studies can provide different types of information. Controlled and site-specific product evaluations can provide information on the potential for specific SEMS to decrease needlestick injuries under optimal implementation conditions. These studies have tended to examine the impact of these devices within organizations that have voluntarily made the decision to transition to SEMS. System level evaluations can look at the impact of investments in the development of regulatory standards on levels of compliance in safer needle use and reductions in needlestick injuries. These types of evaluations are not only examining the impact of transitioning to SEMS but also the influence of various system level supports used to guide implementation and enforce compliance. The first section of this chapter summarizes evidence that has looked at the efficacy of SENs or more broadly SEMS. Section 3.2 moves on to examine previous evaluations of regulatory standards mandating the use of SENs. This section will also examine trends in needlestick injuries in Ontario drawing on two independent data sources. The chapter will conclude with some reflections on limitations of current studies in this area and how this study fills in an important gap in the literature.

3.1 Efficacy of Safety Engineered Medical Sharps

In 2006, a literature review was published looking at efficacy of SEMS incorporating studies published between 1995-2005 (73). In February 2012, this review was updated using the same search terms, databases and exclusion and inclusion criteria (See Appendix C for complete results of the search update). A total of 9 new studies were identified in the review update (74-82). This section will refer to 'percutaneous injuries' rather than 'needlestick injuries' as a number of studies examine the impact of a broad range of SEMS. A percutaneous injury is essentially a puncture of the skin by any sharp medical device.

All studies identified in the review observed reductions in percutaneous injuries following the implementation of SEMS; however, there was a wide range of outcomes. Needlestick injuries
declined by 9.8%-100% across the studies under review. There were studies that reported no statistically significant differences between the experimental and control groups (83-85). These studies also describe having insufficient power needed to detect an effect or where low compliance with safer needle use could have underestimated the potential impact. In some cases, the data source used to measure changes in percutaneous injuries was perceived to have an important influence on the evaluation results. For example, a randomized controlled trial documented an 18% decline in the intervention group when examining data collected from a questionnaire. However, when the same study examined changes in injuries tracked by the hospital register, no statistically significant differences were observed (80).

There were studies that focused on implementing an enhanced safer needle program that incorporated education, training, and the implementation of a wide range of SEMS. These types of studies reported smaller declines in needlestick injuries following the transition to SEMS. Studies that have examined the impact of a wider range of SEMS may reflect more accurately what organizations would face when impacted by a regulatory standard. Collectively, what these studies have shown is that there may be variation in the efficacy of different SENs for the prevention of needlestick injuries.

An important consideration is whether the results of these studies are useful for anticipating what impact a regulatory standard promoting the uptake of SENs could have on rates of needlestick injuries monitored at the systems level. If specific types of SEMS decrease rates of needlestick injuries, can we also expect to see major reductions following safer needle regulation? There may be more variation in levels of compliance within organizations that adopt SEMS due to a regulatory requirement, as the organization may not be as proactive in adopting implementation practices that promote the use of the new medical device. A second consideration is that experimental studies have not been conducted on all types and brands of SEMS, for all procedures and in all settings. However, Ontario's regulation on needle safety requires SENs to be adopted irrespective of whether there is sufficient empirical evidence demonstrating effectiveness.
3.2 Impact and Implementation of Regulation on Needle Safety

This section moves on to examine the implementation and impact of larger scale efforts to promote the adoption of SEMS via a regulatory standard. Evaluations that have been carried out in other jurisdictions have documented significant variation in levels of compliance and impact. Section 3.2.3 will review trends in needlestick injuries in Ontario drawing on two independent data sources.

There appears to be a shared perspective that legislation is a powerful mechanism to promote the health and safety of workers. The Stresa declaration on workers’ health supported by the Global Network of World Health Organization Collaborating Centres for Occupational Health viewed weak legislation as one reason for hazardous workplaces (86;87). International strategies have encouraged the use of regulations to protect and promote the health of workers (88;89). Legislation and its enforcement have been seen as an opportunity to “provide good opportunities for improving the health of workers and [to] promote a culture of health and safety at work” (86, p 2).

Mischke et al. (87) has reviewed some of the evidence that collectively suggests that health and safety legislation has made a less than optimal impact on injury risk. For example, it has been noted that the introduction of the United States Occupational Health and Safety Act in 1970 did not have a notable influence on injury trends that had already been declining for decades (87;90). There continues to be low quality evidence supporting the effectiveness of regulatory enforcement tools meaning that further research is very likely to have an important impact on the current estimates of effect (87;91). Some evidence suggests that inspections as an enforcement tool have inconsistent effects in the short term but they do decrease injury rates after more than three years follow-up (87). These studies have focused on measuring the intervention effects reporting on the level of statistical significance. It is important to start thinking about what would be a successful outcome. How much do injuries need to decline for regulation and its enforcement to be considered worthwhile? Reductions that are statistically significant but do not meet expectations for improvements in health and safety outcomes may not only suggest that there is a flaw in the design of the regulation but rather how the regulatory requirements have been implemented.
There are of course challenges in attempting to isolate the impact of regulatory change. It is important to invest in activities that monitor injury trends following the establishment of regulation to identify whether injury rates have declined. If injury rates have not declined as expected, there may be a need to examine whether there is an underlying flaw in the design of the regulation and whether there have been implementation problems. The following section takes a closer look at studies that have examined more specifically the impact and implementation of regulation on needle safety.

3.2.1 Needlestick injury trends in British Columbia

WorkSafeBC has been monitoring the impact of regulatory changes that have mandated the uptake of SENs (January 2007) and more broadly SEMS (July 2007) (92). An indicator of effectiveness has been set at a 50% reduction in sharps injuries over 3 years. British Columbia’s health authorities now use the Workplace Health Incident Tracking and Evaluation (WHITE) database that collects information on documented incidents routinely reported by workplaces to their respective health authorities. The number of documented incidents has declined by approximately 12% between 2005 and 2009 (92). In 2009, there were approximately 800 needlestick injuries recorded in the WHITE database from six BC health authorities. There were 200 other incidents associated with medical sharps (92). Lost-time claims were described as not being statistically credible to examine trends over time.

Further work has been done in this jurisdiction to examine the implementation of SEMS in acute care hospitals. To explore variation in compliance, six hospitals in the province were recruited to participate in a study that involved audits of sharps disposal bins (20). The audit, which was conducted approximately 1.5 years after safer needle regulation came into effect, found conventional devices still being used and safety devices inactivated (20). This suggests that even if facilities appear to be in compliance (i.e., have made SEMS available), there may be issues within the facility that are interfering with successful implementation.

3.2.2 Needlestick injury trends in the United States

Similar to British Columbia, regulation in the United States requires that both needles and other medical sharps be replaced with SEMS. An impact evaluation, that was carried out with data from 87 hospitals (across 11 states), found that one year after the effective date, the injury rate
decreased by 34% (18). While a decrease in the injury rate was documented, the study also found that needlestick injuries continued to occur (18). A second impact evaluation drawing on the same data and focusing on sharp injuries in the surgical setting found that rates actually increased from 6.3 injuries to 6.9 injuries per 100 occupied beds (17).

There have been some efforts to examine levels of compliance in reference to regulatory standards promoting the uptake of SEMS in the U.S (21;22). Eight years after the effective date of the US Needlestick Safety and Prevention Act, 80% of home healthcare nurses reported limited access to SEMS (21). Three years following the effective date of the same regulatory standard, only 29% of allergists had switched to using safety needles for intradermal testing and only 59% had switched to safety needles for allergy injections (22).

It is important to recognize that injuries won’t necessarily be eliminated after the integration of SEMS. Furthermore, it is possible that needlestick injuries may increase again following initial declines. In 2001, the National Blood Service in the UK implemented needleguards (94). Needlestick injuries decreased by almost 50% a month following the introduction of the needleguards; however, a year later the number of needlestick injuries doubled and two years later increased again by 50%. This was attributed in part to inadequacies in training as well as defects in the design of the new devices.

3.2.3 Needlestick injury trends in Ontario

At this time, there is no routine surveillance of needlestick injuries in Ontario. The Canadian Needlestick Surveillance Network (CNSSN) was established in 2000 by the Public Health Agency of Canada to monitor exposures to blood and body fluids. When Ontario’s regulation on needle safety was established there were 12 hospitals across Canada providing information to the CNSSN. The number of hospitals participating in the network has increased to 16 sites across Canada (95). Unfortunately, data has not been released since 2004 (95). There are limitations in using this data source to examine trends over time. Only a small number of hospitals in Ontario are currently participating which limits opportunities to examine the impact of the regulatory standard in this province. The surveillance system was not designed to obtain information from hospitals consistently over time for the purposes of examining trends. The data has primarily
been used to estimate variation in risk by for example, occupation, type of exposure, and timing of exposure.

Needlestick injuries are partially captured in workers’ compensation claims. A proportion of needlestick injuries that are reported to the employer may lead to a lost-time claim. If the worker experiences lost-time arising from the exposure incident or requires medical treatment (including diagnostic testing or prophylactic treatment), the incidence is to be documented in a Worker’s Report of Injury/Disease (Form 6). Some employers follow a surveillance protocol when a worker is exposed to, or is suspected of having been exposed to, an infectious disease through a needlestick injury. The WSIB’s Program for Exposure Incident Reporting (PEIR) is a voluntary program that provides employers and employees the opportunity to report an unplanned incident in the workplace that results in a leak, spill, explosion or release of a dangerous substance or that results in an unexpected contact with a potentially infectious substance. The purpose of this voluntary reporting program is to obtain information about the exposure incident experienced by the worker should an illness or disease develop in the future. Exposures may be reported either by the employer or the worker by completing the Worker’s Exposure Incident Form (3958A).

Another data source that can be used to examine needlestick injuries across all industries in Ontario is work-related emergency department records. In 2000, Ontario mandated reports of all emergency department visits to the National Ambulatory Care Reporting System (NACRS). When emergency department visits are determined to be work-related, the responsibility for payment code is assigned to the WSIB.

It is important to note that there are currently no administrative records available that can provide comprehensive ascertainment of the burden of needlestick injuries in Ontario. Not all workers will visit the emergency department following a needlestick injury and employers are not obligated to report needlestick injuries to the WSIB if the worker does not experience lost-time arising from the exposure incident or does not seek or require medical care. There is also the issue of under-reporting. Under-reporting of needlestick injuries was first described by Hamory (96) who estimated that 40% of needlestick injuries are not reported by workers. Under-reporting may be even higher for specific occupational groups. There have been a number of studies that
have examined levels of under-reporting that suggest anywhere from 30-90% of needlesticks are not reported (96-103).

While current data sources may not be able to estimate the complete burden of needlestick injuries, workers’ compensation claims and work-related emergency department records can be used to examine rates of needlestick injuries over time assuming that reporting practices have not changed over the period of observation. Rates of needlestick injuries in Ontario were estimated with work-related emergency department records over the period 2006-2011 and with workers compensation claims over the period 2004-2012. A separate ethics approval was obtained from the University of Toronto to examine these records.

Methods

A custom tabulation request from the Ontario WSIB provided counts of needlestick injuries by year (2004-2012) and claim type (lost-time and no-lost-time). Counts were obtained for all rate groups combined and for each of the following rate groups in the health and social services sector: 851, homes for nursing care; 852, homes for residential care; 853, hospitals; 857, nursing services; and 858, group homes. WSIB covered employment estimates were obtained from statistical reports available online (104). Full time equivalents (FTEs) were based on employer reported insurable earnings divided by the average hourly wage for the rate group divided by 2,000 hours, assuming a person works 2,000 hours per year. To calculate rates, the number of claims associated with needlestick injuries was divided by the number of FTEs and multiplied by 10,000.

Work-related emergency department records over the period 2004-2012 were obtained from the Canadian Institute for Health Information who currently maintains NACRS. For each record, a main problem and up to 9 other problem codes have been assigned using the International Classification of Diseases version 10, Canadian edition. Needlestick injuries were defined using an external cause code and a series of main problem codes. Records where the external cause was associated with a ‘contact with a hypodermic needle’ were extracted. The external cause code for a ‘contact with a hypodermic needle’ was only introduced in the fiscal year 2006-2007; therefore, there were no counts of claims associated with contacts with hypodermic needles during the first three months of 2006. The first three months were imputed based on the average
number of needlestick injuries reported monthly for this year of data in order to examine trends over the period 2006-2011. Records were further examined if the main problem was described as a wound, superficial injury or other injury. Records were also further examined if the main problem was described as ‘special screening for infectious and parasitic disease’. This code would correspond to those emergency department visits that were for the purposes of testing and monitoring the worker for the presence of an infectious disease following an injury with a hypodermic needle. It is important to note that emergency department records do not include a coding scheme to identify specific industries or occupations. Therefore, records of needlestick injuries from this data source will include injuries that occur both within and outside the health and social services sector.

To establish the denominator, counts of the number of employed persons in Ontario were obtained from the Labour Force Survey; data that is publically available from the Canadian Socioeconomic Database (CANSIM) maintained by Statistics Canada. To calculate rates, the number of emergency department visits associated with needlestick injuries was divided by the number of employed persons and multiplied by 10,000.

Results

Tables D1-D2 in Appendix D present rates of workers compensation claims by year and by claim type and rate group, respectively. Table D3 in Appendix D presents rates of work-related emergency department records by year and case definition. Figure 1 presents the rate of work-related emergency department records associated with needlestick injuries by year (2006-2011). Between 2006 and 2011 there was a 3% increase in the rate of needlestick injuries captured in work-related emergency department records. This data can be further divided into two groups. First, there are injuries involving a contact with a hypodermic needle where the main problem was identified as a wound, superficial injury or other injury. Rates established with this case definition declined by 30% (Figure 1). The largest year-to-year decline in the needlestick injury rate was between 2008 and 2009 where injuries declined by 12%. It is important to note that this was also the peak of the economic recession in Ontario. There was a large decline in the rate of occupational injuries during this time period and the decline has been estimated as much greater than the reduction in hours of work (105).
The second group of injuries that were further examined had an external cause code assigned to a contact with a hypodermic needle and where the main problem was identified as a special screening for infectious and parasitic disease. These estimates increased by 52% over this time period (Figure 1).

Figure 1: Rate of work-related emergency department records associated with needlestick injuries by year. Note. Special screenings = special screenings for infectious and parasitic disease.

Figure 2 focuses on those records where the main problem was described as ‘special screenings for infectious and parasitic diseases’. Records that were assigned an external cause code ‘contact with a hypodermic needle’ are compared with records that were assigned other external cause codes. This figure emphasizes that an increase in work-related emergency department visits for these special screenings are not only limited to contacts with hypodermic needles.
Figure 2: Counts of work-related emergency department (ED) visits for special screenings by external cause

Figure 3 presents rates of accepted claims by year (2004-2012) and claim type (no-lost-time claims versus lost-time claims) for the health and social services sector (nursing care, residential care, hospitals, nursing services, group homes). Comparing the number of claims in 2004 to 2012, there was a 26% decline in no-lost-time claims associated with needlestick injuries.

Figure 3: Rate of workers compensation claims associated with needlestick injuries per 10,000 FTEs by claims type and year restricted to 5 rate groups in the health and social services sector
The final figure (Figure 4) presents rates of accepted claims by rate group including hospitals, nursing care (long-term care), and nursing services. Nursing services includes for example attendants, nursing aides, registered nurses in nursing care, dental technicians, health care aides and providers, home care aides and workers, home support workers, and sports therapists. The rate group for hospitals includes employers who would have been impacted by the regulatory standard in 2008. The nursing care rate group includes employers that would have been impacted in 2009 and the nursing services rate group includes employers that would have been impacted by the regulatory standard in 2010. Rates of accepted claims have declined by 31% between 2004 and 2012 for hospitals and by 67% for nursing care. Claims from the nursing services did not decline over the period 2004-2012. Low claim counts prevented the inclusion of other rate groups in the analysis.

![Graph showing rates of needlestick injuries per 10,000 FTEs by rate group and year](image)

**Figure 4:** Rate of claims associated with needlestick injuries per 10,000 FTEs by rate group and year

Table 1 presents rates of needlestick injuries for both data sources. The counts of work-related emergency department records associated with needlestick injuries that are presented in this table are estimates based on information obtained from the compensation claims on the proportion of needlestick injuries that are from five rate groups in the health and social services sector. Approximately 63.3% of the accepted workers’ compensation claims over the period 2004-2012 were from five rate groups in the health and social services sector (homes for nursing care,
homes for residential care, hospitals, nursing services, and group homes). The FTE counts established for the 5 rate groups were used to calculate rates for both data sources. The rates of work-related emergency department records presented in Table 1 have not varied substantially over time whereas workers' compensation claims have declined by 31% over the period 2006-2011. As reviewed earlier, this is largely attributed to increases in reporting of needlestick injuries that require special screening for infectious and parasitic disease. It is not clear why reports of special screenings have increased. An important consideration is whether the emergency department records associated with contacts with hypodermic needles involving an injury are independent from those records that are assigned to special screening for infectious and parasitic disease. While the ability to confirm whether these cases are in fact independent could be examined through a data linkage, there were no unique identifiers available to support this analysis. An assessment was carried out to examine the likelihood that these events were related based on age, gender, geographic region, and year and month of the injury. This assessment suggested that it is very unlikely that these events captured in the emergency department records are related.

Another important observation from Table 1 is that the rates of needlestick injuries based on the workers' compensation claim data are higher than the rates based on the work-related emergency department records. We might expect to see higher rates of needlestick injuries captured in workers' compensation claims as typically these injuries would be managed by an occupational health and safety department rather than emergency services. The needlestick injuries that are captured in emergency department records may include incidents that occur among health and social services workers within a community setting or who are employed by organizations that do not have an occupational health and safety department or a staff member available that can provide the necessary medical attention. Injuries that do occur within a hospital setting may also end up being captured in emergency department records when the injury occurs during off-hours when the occupational health and safety department is closed.
Table 1: Rates of needlestick injuries in Ontario restricted to 5 rate groups* in the health and social services sector by data source and year

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<td>WSIB Claims</td>
<td>1,373</td>
<td>1,260</td>
<td>1,249</td>
<td>1,181</td>
<td>1,165</td>
<td>1,159</td>
<td>956</td>
<td>933</td>
<td>1,011</td>
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<td>FTEs x 1000</td>
<td>305.1</td>
<td>310.5</td>
<td>318.2</td>
<td>324.7</td>
<td>334.2</td>
<td>342.2</td>
<td>340.2</td>
<td>344.9</td>
<td>361.0</td>
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<td>Rates per 10,000</td>
<td>45.0</td>
<td>40.6</td>
<td>39.3</td>
<td>36.4</td>
<td>34.9</td>
<td>33.9</td>
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<td>ED records</td>
<td>694</td>
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<td>FTEs x 1000</td>
<td>318.2</td>
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<td>Rates per 10,000</td>
<td>21.8</td>
<td>21.4</td>
<td>21.2</td>
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<td>21.4</td>
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*FTE = full-time equivalent; ED = emergency department.

It is important to reflect on the data relative to some measure of success. As reviewed in Section 2.2.1, some of the arguments supporting the need for safer needle regulation in Ontario were based on the idea that SENs could reduce needlestick injuries by 80-90%. British Columbia defined an indicator of success as a 50% decline in the number of lost-time claims and health care only claims associated with needlestick injuries over a three-year period following regulatory change to promote the uptake of SEMS. This may be a more reasonable goal. The CNSSN has reported that approximately 41% of needlestick injuries occur when the device is being used and 45% after the device is used (106). As SENs are designed to be activated following a procedure, they may have limited potential to reduce risk of injury before or during a procedure. Injuries captured in work-related emergency department records have not reached this measure of effectiveness. Trends in lost-time and no-lost-time claims have also been short of the measure of effectiveness defined by WorkSafeBC which the exception of the nursing care sector where accepted claims have decreased by 60%.

Previous efforts to examine the impact of regulations on needle safety have discussed a number of challenges (18;92). Randomization, control groups, blinding, prospective designs, and the use of placebos all serve to establish causality and reduce confounding; however, it has been proven to be very difficult to integrate these research design features in the evaluation of complex occupational health and safety interventions. Studies that have examined the impact of regulatory standards on needle safety have been challenged by the absence of a clear starting and ending point for the intervention. While Ontario’s regulation on needle safety came into effect in 2008, healthcare organizations in Ontario may have started to integrate SENs as early as 2003-2004.
There has been a gradual decline in the number of compensation claims reported by the hospital rate group. In contrast, needlestick injuries in the nursing care rate group dropped more sharply over the period 2009-2010. This may reflect differences between these two workplaces in the proactive adoption of SENs.

There are a number of other limitations in the data used to examine needlestick injuries. Not having information on occupation or industry in the NACRS data limited the ability to focus the analysis on trends in the health and social services sector. There are a series of codes described in the ICD10 manual that are used to identify the place of occurrence for visits that have an identifiable external cause. Based on the nature of the coding structure, healthcare institutions cannot be distinguished from other settings. For example, injuries that occur in nursing homes are described as ‘residential institutions’ which also include for example, prisons, reform schools, and children’s homes.

A comparison of the trends in claims associated with needlestick injuries within and outside the health care sector emphasizes the important influence of Ontario’s regulatory standard and other supportive initiatives to prevent needlestick injuries among healthcare workers. The data also demonstrates that needlestick injuries may still be occurring with the use of SENs or ongoing injuries may reflect continued use of non-safety needles. When Toronto East General Hospital developed a sharps safety program in 2003-2004 they reported an 80% decline in sharps injuries following the transition to a wide range of SEMS (54). This magnitude of this decline has not been reflected in the system level data available to examine trends over time in Ontario.

### 3.3 Conclusion

Section 3.1 examined studies that have reported on the extent to which needlestick injuries have declined following the transition to SENs based on the results of product trials. Section 3.2 examined the impact of regulation on needlestick injuries and reviewed studies that have quantitatively measured levels of compliance with the regulatory requirements. A review of available data describing trends in needlestick injuries in Ontario suggests that while the regulatory standard has brought injury rates down, there may be additional opportunities to further prevent ongoing needlestick injuries that are being captured in administrative data sources. Trends in needlestick injuries in Ontario following the establishment of a regulatory
standard do parallel findings in other jurisdictions including British Columbia and the United States.

There is a paucity of studies that have been able to examine why the safety features on SENs are not always used and whether ongoing needlestick injuries occur as a result of limitations in the design of SENs or broader contextual influences. A review of the literature identified only one study that provided some insight as to why needlestick injuries continued to occur following the transition to SEMS. This study examined why operating room personnel continued to experience needlestick injuries (107). A focus group identified the following barriers: inadequate horizontal and vertical communication, powerlessness, resistance to change, intimidation, inconsistencies in practice, negative attitudes, inexperience of medical and nursing staff members, and time constraints. It is promising to see studies that attempt to examine implementation using qualitative methods, which can provide more detailed accounts to help understand why there are continued issues with the integration of SEMS. There would be value in obtaining multiple perspectives from across the organization on the source of implementation challenges and to consider both internal and external influences.

While there have been efforts to examine the impact and levels of compliance associated with regulation on needle safety, there have been minimal efforts to describe why needlestick injuries continue to occur, limitations in the design and delivery of the regulatory standard, and the challenges associated with the integration of SENs into practice. The focus of this dissertation is thus filling an important gap by examining the implementation of SENs through a qualitative multi-site case study design.
CHAPTER 4
Building a Conceptual Framework

The purpose of this chapter is to present the conceptual framework that influenced the study design, analysis and interpretation process. There are a number of ways in which a research problem can be approached combining different paradigms, methodologies, data collection strategies, research disciplines, and levels of theory. This study examined a regulatory standard promoting the uptake of SENs drawing on a particular paradigm, evaluation tradition, and body of theory rooted in the implementation science and organizational change literature. The first section reviews the underlying paradigm that guided the research process, which is essential for understanding the specific qualitative approach that was used, and all other aspects of the research process from the data collection phase to the analysis and interpretation of findings. It is important to also acknowledge that the study was examining a specific intervention from an evaluative perspective. Evaluation research is unique in that it can enhance knowledge, decision making and also have practical applications. Section 4.2 will review the origins of the evaluation methods that were used. The final section will examine theories and concepts from the implementation science and organizational change literature that directly influenced the initial framing of the study but also the analysis and interpretation process.

4.1 Paradigm

There are a number of theoretical perspectives that have been traditionally used to inform qualitative inquiry (e.g., ethnography, phenomenology, heuristics, ethnomethodology, symbolic interactionism, ecological psychology, hermeneutics). The dissertation is guided by a particular philosophical orientation: a variety of post-positivism that has an element of critical realism, what Patton has referred to as a ‘reality oriented perspective’ (108). A 'research paradigm' is used here to refer to a set of epistemological beliefs that guide the research process (109). It is important to make these belief systems transparent as they not only influence the design of a study and the research questions but also what becomes considered a methodological issue like generalizability.

A critical realist ontology carries specific assumptions that have implications for the design, fieldwork, and analysis (110-112). The research is carried out recognizing that the acquisition of
knowledge is in part subjective in nature. Layder (113) describes this variation of realism as an “attempt to preserve a “scientific” attitude towards social analysis at the same time as recognizing the importance of actors’ meanings and in some ways incorporating them in the research” (p 16).

Unlike logical positivism, this perspective is not limited to studying phenomena that has to be perceived directly (113). One can obtain information from multiple individuals' past experiences and perceptions to obtain a collective understanding. This perspective is captured in the nature of the research objectives that have been proposed, which bring attention to collective experiences, issues and perspectives towards Ontario’s regulation on needle safety and the integration, and use of SENs.

When following this perspective, there is a tendency to focus on structures, mechanisms and processes in context. The specific unit of analysis is seen as being influenced by multiple levels including institutional forces (e.g., regulation, organizational policies) and individual behavior (action, language, cognitive processes) (110). Theory plays an important interactive role throughout the study framing the initial focus but also allowing for new emerging ideas and theoretical explanations during the analysis and interpretation.

This perspective has direct implications for how the study views the role of the researcher; the role of bias and how it should be managed; and how best to increase the validity or trustworthiness of the study. This perspective does not see the role of the researcher as being completely detached from the research process (114). For example, the qualitative data collection process requires that the researcher serve as the research instrument. The participants are seen as active contributors in the process of generating data for analysis. This perspective also strives for neutrality. From an evaluation perspective, one wants to have a neutral perspective towards the intervention and to develop design strategies that ensure information is not selectively pursued to confirm a preconceived idea. Overall the goal is to produce credible information (defined as an equivalent concept to internal validity) (115). Further details on the criteria used to optimize the trustworthiness or credibility of the case study findings are reviewed in Section 5.5.
4.2 Innovative Approaches to Evaluation

The previous section presented the overriding philosophical orientation of the study. This next section focuses specifically on the evaluation approaches and traditions that guided the focus and objectives of this work. The review of the evaluation literature in Chapter 3 highlighted an important limitation associated with impact evaluations or cross-sectional compliance assessments. There is often no contextual information to explain unexpected results. Due to the complex nature of system level interventions, more innovative approaches to evaluation were explored that would support the examination of the regulation within an organizational context. The evaluation approach was influenced by several authors who have advocated for a more contextual approach to evaluation. Both Stake (116) and MacDonald (117) have been credited as the forerunners of the evaluation case study movement that considered a greater role of looking at context and the implementation process. Stake (118) describes an evaluation model that he labels ‘responsive evaluation’. It emphasizes the importance of making the evaluation process more personal by integrating face-to-face contact with people in the program and identifying concerns among those directly impacted (108). The focus of the dissertation was also guided by Pawson’s approach to examining complex interventions (119). The complexity of Ontario’s regulation on needle safety is evident both in terms of its design and delivery across a wide range of healthcare facilities impacting a wide range of clinical practice environments and healthcare workers. As demonstrated in the review of recommendations for the implementation of SENs, complexity can be found at the organizational level.

Pawson (119) describes his approach as generally being interested in what it is about a program that works (or doesn't work) for whom or what groups, in what circumstances, in what respects, and why. The intent of this type of evaluation can be described as explanatory rather than judgmental in nature. These ideas do also fit with the aims of what has been referred to as illuminative evaluation (120). According to Parlett and Hamilton (120), illuminative evaluation takes into account wider contexts and is primarily concerned with description and interpretation. This approach might focus on how a program operates, how it is influenced by various situations, and its advantages and disadvantages. These influences helped support the development of an evaluation perspective toward Ontario’s regulation on needle safety that went
beyond a traditional impact evaluation strategy to emphasize the importance of more closely examining the implementation of the regulatory standard via a case study design.

4.3 Implementation Science

This section will review theories and concepts that helped frame the data collection, analysis and interpretation process drawing on the implementation science and organizational change literature. The literature that will be reviewed in this section helped conceptualize the implementation process, the barriers and facilitators encountered by the three hospitals under study, and more generally the overall implementation experience. The implementation science literature is vast. Two review papers were particularly helpful for navigating this literature. Fixsen et al. (24) conducted a review to synthesize research on implementation and to determine what is known about core components and conditions of implementation. Damschroder et al. (121) established a consolidated framework based on broad review of theories of implementation effectiveness related to dissemination, innovation, organizational change, implementation, knowledge translation, and research uptake. The concepts and theories found to be most relevant to the case study findings will be reviewed in this section. While these theories and concepts do have different utilities for thinking about implementation they are to some extent related. At the end of this section a conceptual model will be presented to outline how these theories and concepts overlap. The model is meant to be meta-theoretical (121). Efforts are made to demonstrate how the different concepts relate; however, the intent is not to define interrelations or hypotheses between them.

4.4 Stages of Implementation

Implementation has been defined as ‘a specific set of actions designed to put into practice an activity or program of known dimensions’ (24). It is important to first clarify how research on implementation had been distinguished from research on diffusion and dissemination. The National Implementation Research Network views implementation as including diffusion and dissemination but not being defined by it (122). In the diffusion literature or the ‘letting it happen’ literature, the outcome tends to focus on the adoption of an innovation (122-124). In the dissemination literature or the ‘helping it happen’ literature the outcome tends to focus on attempts to use an innovation in practice (122;124). There is a focus on developing forms of
communication that promote understanding and use of an innovation (122;125). One might described the development of a regulatory standard to promote the uptake of SENs as a dissemination strategy. In the implementation literature or the ‘making it happen’ literature there is a greater focus on how to ensure that innovations are used as intended and the outcome is actual use of an innovation with good results in practice (24;122).

While empirical research on diffusion of innovations has tended to focus on whether or not an innovation is adopted, efforts to conceptualize diffusion as a process have extended beyond the outcome of adoption to look at additional stages involved in the spread of an innovation into practice (126). Stages of diffusion have been defined as: innovation development, dissemination, adoption, implementation, maintenance, sustainability, and institutionalization (126). Maintenance refers to the ongoing use of an innovation over time (126). This might refer to a period where front-line staff routinely use SENs and activate the devices as intended. Following maintenance, sustainability follows and has been defined as the degree of which an innovation continues to be supported after initial resources are invested (126). Sustainability might refer to a stage where initial implementation activities have been carried out to ensure that SENs are available where possible; however, there continues to be investments in activities to promote ongoing monitoring and improvements over time.

Institutionalization, the last stage, is defined as a state where the program has been incorporated into the routines of an organization or broader policy and legislation (126). With respect to the implementation of SENs, institutionalization might refer to a stage where SENs are considered the norm and where written policies and practices consider safety in the purchase of all new sharp medical devices.

It would seem that these three stages, maintenance, sustainability and institutionalization, would to some degree overlap. There would eventually be a phase where SENs are routinely used by staff, there are ongoing practices to monitor SEN use and effectiveness in reducing injuries, and the importance of safety is engrained into the practices of the organization. The stages of diffusion might need to be thought of as a cycle. The initial stock of SENs that is selected and implemented might reach a stage of institutionalization; however, there may be the need for ongoing activities to identify opportunities to reduce the need for exceptions or invest in product enhancements when needlestick injuries continue to occur.
Fixsen et al. (24) have defined their own stages of ‘implementation’ including: exploration and adoption, program installation, initial implementation, full operation, innovation, and sustainability. The stages of implementation focus more on the implementation process breaking it down further into program installation and initial implementation. This model does not include stages that precede the adoption phase (i.e., innovation development and dissemination). The first stage, ‘exploration and adoption’ is aligned with the adoption phase in the stages of diffusion. Fixsen (24) makes an important connection between this stage of adoption and later implementation pointing to the importance of receiving early support from political, financial and human service systems as this support can have an important influence on later implementation stages. Program installation is viewed as a stage that involves identifying and allocating resources and establishing a strategy for implementation. This would correspond with the series of planning and assessment activities described in Section 2.3. Initial implementation is characterized as a stage that involves a number of changes in skills, organizational capacity, and culture which may require education, practice and time to mature. As Fixsen describes, this initial implementation stage is where “fear of change, inertia, and investment in the status quo combine with the inherently difficult and complex work of implementing something new” (24). Full operation is described as a stage where new learning is integrated into practices, policies and procedures. The implemented program is fully operational and the innovation is “accepted practice” (24). Full operation seems to combine elements of both the concepts maintenance and institutionalization that were defined in the diffusion of innovations model. The innovation stage would be relevant when there is an evidence-based program that is attempting to be implemented with consistency across different settings. Under these circumstances, the stages of implementation describe a period where there would be opportunities to refine and expand on the evidence-based program. The final stage, sustainability is similar to the concept defined in the diffusion of innovations literature. It involves efforts to ensure that the program is sustained over time. For example, if staff were replaced in the occupational health and safety department, there would be the need to ensure that new staff sustain and build on the plans to, for example, monitor injuries and provide annual training related to sharps injury prevention.

Figure 5 presents a model that adapts and combines relevant steps from the stages of implementation and the stages of diffusion for the purposes of this study. Sustainability was
replaced with ‘ongoing monitoring and improvement’. This stage is seen as taking place concurrently during the initial implementation and full operation phase and may lead to the exploration of new options for SENs and reinforced training. These concepts highlighted in Figure 5 will be used in the summary of findings chapters to refer to different stages in the implementation of SENs.

**Figure 5**: Stages of implementation (24;126)

### 4.5 Levels of Implementation

Chapter one described the use of foreshadowed issues to frame the data collection process. It was anticipated that in some cases while there may be written policies and procedures to promote the use and uptake of SENs, these policies and procedures might not function optimally in practice. This issue was influenced by the concept 'degree of implementation' discussed in the implementation science literature. Fixsen (24) defines three levels of implementation including **paper implementation, process implementation and performance implementation**. Each level has been aligned with a specific theory of change including the recorded theory of change, integrated theory of change and expressed theory of change (24). Paper implementation or the recorded theory of change includes the development of new policies and procedures. A study that focuses on paper implementation would only look at program documents to determine whether certain policies and practices are recorded. It is process
implementation or the integrated theory of change (127) that pertains to actually putting written policies and procedures into place. Performance implementation goes a step further to describe situations where procedures and practices actually function optimally to support users adapt during the change process (24). By having access to program documents and obtaining information from different groups across the organization, one can look at the degree to which written policies and practices are in place and whether they are perceived to adequately support the use of an innovation. This distinction can be applied when obtaining information on an organization’s strategy for implementing SENs. To examine paper implementation one might review what the organization has put in writing around policies and procedures for the use of SENs and other practices to prevent needlestick injuries. This might include a written statement on how the organization will be committed to providing training to support the use of new SENs. Obtaining information on ongoing activities and events that align with the written policies and procedures would get at process implementation. This might involve obtaining information from informants on what type of training is provided, how the training is promoted, and how training completion is monitored. Finally, obtaining input from front-line workers on how these activities support their use of SENs and where there may be gaps would provide a means to assess performance implementation. For example, front-line staff may be aware that training is provided but indicate that they are not always able to attend due to workload demands.

4.6 Implementation Effectiveness

The initial framing of the study drew on an organizational theory of implementation effectiveness, which was originally defined, by Klein and Sorra (29;66) to identify important concepts to consider when identifying processes by which an organization successfully implements an innovation. There are three specific requirements for the application of this model including: a centralized authority over whether or not innovations will be adopted; the implementation process requires specialized training, resource allocation and support; and it is necessary for there to be coordinated innovation use by organizational members to produce benefits for the organization adopting the innovation (29;30;128). While the implementation effectiveness model was originally defined for the implementation of innovations in the manufacturing sector, the model has been used in others areas including the implementation of worksite health promotion programs (30) and the implementation of complex prevention
programs in healthcare (67). The conditions described above suggest that the model is also relevant for the implementation of health and safety interventions in hospitals. First, there is a centralized authority overseeing the adoption of new medical devices in hospitals. Second, the integration of SENs would require coordinating a product selection and evaluation process, communication to affected areas, and the delivery of training and education. Finally, in order for the devices to be effective in reducing needlestick injuries, staff have to be committed to activating the safety features. There were two updates to the implementation effectiveness model in 2007, which were perceived to have enhanced the relevance and utility of the model as an explanatory framework for the purposes of this study. An adapted version of the model that includes the more recent contributions is presented in Figure 6 (30;67).

![Figure 6: Organizational implementation effectiveness model; adapted from Klein and Sorra (29;66), Helfrich et al. (67) and Weiner et al. (30)](image)

Implementation policies and practices have more specifically been described as formal organizational actions to support the development of skills, promote change, and identify and manage barriers encountered during the change process (29;67). Klein and Sorra (66) identified a wide range of policies and procedures that have been identified as influencing implementation effectiveness including the quantity and quality of efforts to train staff, provide user support, reward innovation use, communicate reasons for change, and provide staff with sufficient time to test out and become more familiar with the new innovation (29;129-132). Klein and Sorra (29) emphasize the idea that there can be a number of different combinations of high quality
implementation policies and practices that will achieve the same level of implementation success across different organizations.

Weiner's version of the organizational implementation effectiveness model adds 'innovation efficacy' (30). Comprehensive implementation policies and procedures are needed to ensure that the evidence-based innovation is able to produce its desired effect (30). For example, for organizations to observe reductions in needlestick injuries, it would be necessary to ensure that the staff are skilled at working with the new devices and their safety features. A combination of high quality implementation policies and practices are thought to also influence the overall implementation climate which has been defined as "targeted employees' shared summary perceptions of the extent to which their use of a specific innovation is rewarded, supported, and expected within their organization" (29). There would be a strong implementation climate if "employees perceive that innovation implementation is a major organizational priority, supported, and rewarded by the organization" (66, p 813). When Helfrich (67) adapted the organizational implementation effectiveness model for the health sector 'implementation champion' was added to the model having a direct influence on the implementation climate. To define ‘innovation champion’, Helfrich drew on the work of Rogers who provided the following definition: “[a] charismatic individual who throws his/her weight behind the innovation, thus overcoming the indifference or resistance that a new idea often provides in an organization” (123, p 283). While a strong implementation climate will increase the likelihood that employees will use an innovation, it is also essential that employees are committed to innovation use. Innovation-values fit has also been described as a key influence on implementation effectiveness. It has been defined as the "extent to which targeted users perceive that use of the innovation will foster the fulfillment of their values" (29, p 1063). This could more specifically refer to the perceived fit between the innovation and professional or organizational values, competencies and mission. Implementation effectiveness has been defined as "the consistency and quality of targeted organizational members' use of a specific innovation" (29, p 1058). When thinking about the integration of SENs, implementation effectiveness can be considered a state where conventional sharps have been replaced by safer alternatives and where workers consistently use the devices as intended. This state would be aligned with the full operation stage outlined in Figure 5.
What is unique about the version of the organizational implementation effectiveness model presented by Weiner (30) is that it is extended to consider the ‘aftermath of implementation’ to distinguish between implementation effectiveness and innovation effectiveness. Weiner sees innovation effectiveness as an organizational construct referring to the benefits an organization realizes from an innovation (30). The benefits an organization might receive from the implementation of SENs would include a reduction in needlestick injuries with potential cost savings to the hospital. On the other hand, benefits may not be great enough to justify efforts to sustain the innovation. As outlined in Figure 6, implementation effectiveness is defined as a prerequisite for innovation effectiveness. The addition of innovation efficacy is strategic in the model and meant to emphasize the following “if the program theory itself is faulty or if (during implementation) the program has been adapted in ways that undercut its efficacy, no amount of consistent, high quality and appropriate use will generate the benefits anticipated by program adoption” (30, p 300). Applied to the integration of SENs, an organization might develop a comprehensive implementation program that meets all the recommendations for effective implementation; however, if the organization chooses to integrate a safety device that is not well designed, they are unlikely to observe significant gain in the reduction of needlestick injuries.

Weiner (30) emphasized that while the model focuses on organizational determinants of implementation effectiveness, “the broader social, cultural, economic and regulatory context in which the organization operates will also influence […] implementation …” (p 301). The current model does not capture these external influences. This study provides an opportunity to examine implementation under a regulatory context. There may be a complex interaction at play between the regulatory context, organizational conditions, and the implementation process. Those organizations that implemented SENs in response to Ontario’s regulation on needle safety could be considered externally motivated whereas those organizations that respond voluntarily could be considered intrinsically motivated. **Extrinsic motivation** has been conceptualized as increasing effort by supplying a reward or punishment (133). One acts to increase the probability of rewards and decrease the chances of punishment. With **intrinsic motivation**, there is a focus on the task or activity rather than on consequences of not acting (134). The concepts internal and external motivation have been drawn on to study how the source of individual effort (extrinsic or intrinsic) can influence organizational change. For example, Newby (134) examined how organizational changes will be more likely accepted and maintained when employees are
intrinsically motivated to support an organizational change. Staff may support the change because they are interested in the problem itself. It would be interesting to examine the relevance of these concepts to study how organizational effort (extrinsic or intrinsic) can influence the implementation experience of organizational change efforts. These concepts ‘extrinsic and intrinsic motivation’ were used to describe the source of each hospital’s decision to adopt SENs. Hospitals that adopted SENs in direct response to the regulatory standard or a workplace inspection order were considered ‘extrinsically motivated’. 'Intrinsically motivated' hospitals were those that adopted SEN independent of regulation or an inspection. The decision to adopt SENs was based on the organization’s interest in improving the health and safety of front-line workers.

4.7 Organizational Readiness for Change

The organizational implementation effectiveness model (Figure 6), reviewed in the previous section starts with the concept ‘organizational readiness for change’. Klein and Sorra (29) originally defined readiness for change focusing more on structural influences including management support and financial resources. Weiner (30) defined this stage more broadly as organizational readiness for change (ORC). In later work, Weiner (135) presented a more refined definition of the concept of ORC and a theory of its determinants and outcomes. The concept ORC was not used to frame the study initially. It was drawn on during the analysis and interpretation phase when it was recognized that all three cases under study were at very different levels of readiness when SENs were adopted and this appeared to have an important influence on the implementation process. Furthermore, the theory was also useful for examining whether or not the organizations under study would continue to invest in the enhancement of their safer needle program.

While Weiner’s theory of ORC requires further testing, it was found to be a useful explanatory model for this study. ORC has been conceptually linked to Lewin’s three-step model of change: unfreeze, change and refreeze (136). Lewin’s three-step model does parallel the stages of diffusion and implementation outlined earlier. The unfreeze stage being characterized by the need to create motivation for change convincing organizational members that the current state is undesirable (136). This stage defines a period where the old ways of doing things are changing yet there is not yet a clear understanding of the new processes. New behaviors, attitudes and
values are formed (136). Refreeze would align with the full operation stage and would define a period where there is a sense of stability and familiarity with the organizational change.

Returning to Weiner’s theory of organizational readiness for change (aligned with the unfreeze stage) it theorizes that implementing organizational change requires change commitment and change efficacy (135). **Change commitment** which is based on Bandura’s notion of goal commitment (137) which refers to “organizational members’ shared resolve to pursue the courses of action involved in change implementation” (135, p 2). **Change efficacy**, which is related to Bandura’s notion of collective efficacy (137), refers to “organizational members’ shared beliefs in their collective capabilities to organize and execute the courses of action involved in change implementation” (135) (p 2). Organizational readiness is high when there is a shared interest in wanting to implement change and staff feel confident that this can be accomplished. Weiner also defines conditions that promote organizational readiness for change including **change valence** and **information assessment**. Change valence refers to whether organizational members consider proposed changes to be needed, important, beneficial or worthwhile. What Weiner emphasizes is that it may not be necessary for different organizational members to have the same reasons for supporting a proposed change. Applied to the implementation of SENs, senior management staff may value the transition to SENs because reduced injuries could present cost savings for the hospital whereas front-line staff may value any efforts to create a safer working environment.

**Informational assessment** is identified as another influence on ORC and involves a process of appraisal in three areas including **task demands, resource availability and situational factors**. Situational factors may refer to whether it is believed that there will be sufficient time available to implement the change or whether the proposed change aligns with the internal political environment. Weiner also describes the influence of other broader contextual conditions that influence ORC and postulates that these conditions more directly influence change valence and information assessment. Drawing on previous work in organizational change a number of general influences are described including: organizational culture, policies and procedures, past experience, and organizational resources and structures.
This section has described a number of concepts and theories related to stages of implementation/diffusion, organizational implementation effectiveness, stages of change, and organizational readiness for change. Figure 5 attempts to organize this literature outlining where implementation stages and implementation influences overlap. A number of these concepts will be drawn on in Chapters 7 and 8 when the case study findings are analyzed.

**Figure 7**: Meta-framework of organizational change, implementation effectiveness, and stages of implementation (24;29;30;66;126;136)
CHAPTER 5
Research Methods

Drawing on organizational change and implementation science theory, a qualitative instrumental case study design was used to examine implementation experiences in three acute care hospitals in Ontario. Three acute care hospitals were randomly selected to participate from a list of hospitals in two regions in Ontario. Program documents were reviewed and interviews were carried out with front-line workers, managers and organizational informants to examine how each hospital responded and managed the integration of SENs in relation to the regulatory requirements, described the consequences of integrating SENs, and highlighted remaining issues associated with the use and integration of these devices. Three case summaries were prepared to capture the overall implementation experience, the impact of the transition to SENs, and how each organization is continuing to make advancements to further reduce needlestick injuries and promote related safety practices. A thematic analysis was carried out to identify patterns and themes within and across the three case sites.

This chapter is organized in six sections to provide further details on the study sample (Section 5.1), recruitment process (Section 5.2), fieldwork (Section 5.3) and analysis (Section 5.4). Key considerations and strategies around enhancing the ‘trustworthiness’ of the research are reviewed in Section 5.5. Section 5.6 provides further details on how reflexivity was operationalized during the data collection and analysis process. This chapter will conclude with a discussion of ethical concerns associated with the research process and how they were managed.

5.1 Study Sample

While Ontario’s regulation on needle safety now impacts a number of healthcare organizations, the study focused on acute care hospitals. To gain a more comprehensive understanding of the opportunities and challenges associated with safer needle technology, there was an interest in examining organizations where different types of safety needles would be in use across a number of clinical areas. As acute care hospitals were the first type of healthcare organization to be targeted by Ontario’s safer needle regulation there was also an opportunity to focus on issues that arise during later stages of implementation, a period during the implementation cycle that has been understudied (24).
There is often tension between two objectives: optimizing description and increasing the number of cases to increase the variation in experience and stability of the study findings (138). Increasing transferability is essential for increasing the potential utility of the study findings and therefore, thick description and greater time spent within each organization was considered a priority (139). Focusing on a smaller number of organizations would reserve sufficient resources to enable a descriptive account to be formed for each organization while also allowing the case study findings to be explored in different settings. There was interest in examining the implementation experience in both a large teaching hospital and a smaller community hospital. It was expected that integrating safety devices in these two types of hospitals might present different challenges. Larger teaching hospitals would have a greater number of staff and resources to facilitate the selection and integration of SENs but would also have to manage some of the complications associated with implementing a new medical technology that would greatly impact a large number of employees working across multiple sites. There was also an interest in examining the implementation experience in a hospital outside the Greater Toronto Area (GTA). As a consequence of the number of hospitals in the GTA, the Safe Needles Save Lives campaign had a greater visible presence in this region which may have influenced the extent to which organizations transitioned to safety devices prior to the development of the regulation (54).

After evaluating the time commitment involved in recruiting and collecting information from a single case site, it was determined that available resources could accommodate three hospitals. Three cases would allow input to be obtained from both a community hospital and a large teaching hospital within the GTA and from another hospital outside the GTA.

The website for the Ontario MoHLTC was used to identify 59 potential hospitals or 80 hospital sites in six neighboring local integration health networks in the GTA and in a second region located outside the GTA. First, homogeneous sampling (140) was used to create an initial list of potential organizations that were either general hospitals or teaching hospitals (this process excluded specialist hospitals). Focusing on hospitals with similar structures and departments would facilitate the analysis of similar units across organizations. Convenience sampling was used to further refine the list of potential organizations that would be within 40 kilometers from two available offices (within and outside the GTA). This left 17 hospitals and 23 hospital sites. Convenience sampling was judged to be an ideal sampling approach as organizations in closer proximity could be accessed more frequently and for longer periods of time while demanding
Interviews were carried out with organizational informants, front-line nurses and unit managers. Organizational informants were considered to be staff that had a direct role in the selection and integration of SENs including staff in the occupational health and safety department, representatives from the Joint Health and Safety Committee (JHSC), professional practice nurses, purchasing managers, managers of logistics, and staff on the sharps safety committee. The second group of participants included front-line healthcare workers with or without a direct safety role including unit managers and front-line registered nurses or registered practical nurses.

5.2 Recruitment

The 17 hospitals were listed under three categories representing a) community hospitals in the GTA, b) teaching hospitals in the GTA and c) both teaching and community hospitals in a region outside the GTA. Sites were randomly selected from each category until three agreed to participate. A regional consultant at the Public Service Health and Safety Association (PSHSA) assisted with the recruitment of organizations that had been randomly selected. The consultants contacted the manager or director of occupational health and safety at the selected hospitals by email to introduce the opportunity and provide a brief summary of the project. PSHSA consultants have experience working with healthcare organizations on occupational health and safety initiatives. The director or manager in the occupational health and safety department was asked to contact the researcher directly if they were interested in further information. A phone interview was carried out with this contact to further describe the purpose of the study and ascertain their willingness to be selected as a potential case. Nine hospitals had to be contacted by health and safety consultants during the recruitment process before three hospitals agreed to participate. Reasons for not participating were often attributed to not having retained sufficient information about the transition to SENs or not having a sufficient number of organizational informants that were with the organization during the transition to SENs. Other ongoing research projects involving staff at the hospital were also a barrier for participating.

Ethics approval was obtained from the ethics review board at the University of Toronto in addition to the ethics review boards at the three participating hospitals. The study was also reviewed by the director or manager of occupational health and safety, other senior level employees (e.g., VP Human Resources, Director of Nursing Professional Practice) and the
JHSC. There were different expectations and procedures involved in gaining entry at each site in terms of who within the organization had to approve the research, level of detail required for ethics approval, contractual procedures, and training requirements that were expected before the fieldwork could be initiated (e.g., corporate orientation, ethics tutorials).

The initial contact person who sent out the electronic invitation varied across the three organizations. This included a staff member in the occupational health and safety department, unit managers in select areas, and internal representatives from the Ontario Nurses Association (a provincial nurses union). The email invitation sent to staff introduced the researcher as a doctoral student at the University of Toronto and included a small introduction to the study, what types of topics would be addressed, options for the duration and location of the interview, and the voluntary nature of participation. Nurses were initially recruited from areas of the hospital where SENs would be in frequent use including the emergency department or critical care unit. The emergency department and critical care unit represent two settings with several similarities in the types of SENs used. In both of these settings, different types of SENs would also be used on a regular basis. The original strategy was to initiate the recruitment process through an email distributed centrally by a representative in the occupational health and safety department to a random selection of nurses working in the emergency department and critical care unit. This would be accompanied by a snowball sampling strategy where participants would help identify additional contacts that might be interested in participating. The use of a generic email that was administered to a number of front-line nurses was not successful in attracting participants. During the early recruitment process a number of workers felt that they did not have much to contribute on the topic. There were a number of younger nurses who did not feel they had an adequate reference for comparison as they had received their training when SENs were widely available. Staff that were more keen to participate and had richer accounts of the transition to SENs or were more “information rich” (140) had the following characteristics: they had been working in the field for a number of years; they had been involved in the transition process; and/or had recently experienced or observed a needlestick injury. The second strategy, snowball sampling, proved to be more effective in attracting front-line workers and organizational informants to participate and was particularly useful in attracting staff with unique perspectives and insight on the topic of needlestick injury prevention (140). For example, during the fieldwork, there were a number of needlestick injuries reported to occupational health and safety
at one particular site. The health and safety contact who was participating as a key organizational informant forwarded my contact information to these workers who had recently had a needlestick injury. As they had recently experienced an injury, they were able to provide rich detail about their experience highlighting how needlestick injuries can still occur despite the transition to SENs.

5.3 Fieldwork

The fieldwork consisted of regular visits to each case site over the course of 3-4 months where interviews were carried out with staff and relevant program documents were reviewed. The two main sources of data in this study included documents and interviews. Interviews were particularly important in this project as several of the project objectives focused on informant perceptions and experiences. Furthermore, there was an interest in past organizational activities associated with the selection and integration of SENs. The timing of the research influenced the nature of the information that was obtained. The interpretation of key organizational events has been argued to unfold over a series of stages (141). Studying in-depth interviews with managers, Isabella (141) characterized how perspectives towards change evolve. It is argued that initial views tend to be influenced by rumors and disconnected pieces of information. People tend to form interpretations of the change in reference to past similar events. The final interpretive stage, relevant here, has been described as aftermath. It is defined as a period during which those involved in the change process tend to take an evaluative perspective towards the event. There is a focus on the permanent changes that have been made with a greater focus on consequences of the change (141). The timing of this study was advantageous as there was an interest in obtaining information on the consequences of integrating the technology and what things are like now relative to when SENs were first implemented.

To ensure the study was focused on the most pertinent topics, an external advisory committee was established. The committee included four individuals who had a key role in the development and implementation of Ontario’s regulation on needle safety. The committee members were from regulatory, labour, and not-for-profit health and safety organizations that focused on the healthcare sector. Early consultation with this group helped formalize the initial list of topics that guided the data collection process. This committee was also established to provide recommendations on how the study results could be disseminated.
The development of the interview guides were influenced by the consultations with the external advisory committee and issues raised in the literature around the use of SENs. An interview guide was prepared in advance of each interview that listed relevant topics to be discussed. There were interview topics that were asked at all interviews with organizational informants and front-line healthcare workers. Unique questions were added in order to accommodate the specific roles and experiences of the participants. The interview process was approached with flexibility to freely explore and probe on new insights and directions (142). The interview guides were not circulated in advance to provide some flexibility in the line of questioning and direction of the interview. Quite often information would be shared during the course of the interview that revealed unique experiences or specific roles that would require an adjustment to the planned list of topics to be addressed.

There were a series of interview topics that were asked in all interviews including the status and timing of the transition to SENs, whether needlestick injury prevention was an ongoing priority, the overall implementation experience, barriers and facilitators to the implementation process, and recommendations to improve the delivery and implementation of the regulatory requirements. Organizational informants were asked more detailed questions about implementation policies and procedures related to the implementation process in addition to ongoing implementation activities. Front-line staff were asked more detailed questions about the use of SENs, impact on injury risk, design preferences, employee input and their injury experience. There were a number of topics that were tailored to key informants based on the nature of their expertise. Table E1 in the Appendix E presents a detailed list of topics and corresponding groups of participants that provided information.

Three external informants were also interviewed. This included individuals from the Ontario Nurses Association (a provincial nurses union) and the Ontario MOL. The third informant worked for a product manufacturer who was also a member of the original Alliance for Sharps Safety and Needlestick Prevention that helped gather support for safer needle policy in Ontario. These contacts were identified with the assistance of the thesis committee and the external advisory committee. External informants were contacted directly by email to provide an overview of the study and to describe the nature of the interview questions that would be asked. The questions were aimed at obtaining a better understanding of how external organizations
helped support the development and ongoing implementation of SENs. Contextual factors that were perceived to have influenced the activities of this safety alliance were also of interest. While there were a number of relevant documents available online to capture the development and implementation of the regulation, these interviews provided a contextualized understanding of the process and highlighted specific challenges and facilitators that were not captured in any documentation.

The duration of the interviews were based on the amount of information the informant had to share on the topic. All interviews were conducted on site usually within a private office or conference room. A small number of interviews were also carried out on the unit or the local cafeteria. Interviews that were carried out on the units provided an opportunity to observe firsthand what safety devices were being used. All interviews with organizational informants were conducted during regular office hours. Interviews with front-line staff took place during and outside work hours depending on the preference of the employee and their manager.

Interviews were audio recorded and subsequently transcribed using the services of a transcriptionist. Each completed transcript was reviewed for accuracy by listening to the original audio recording. During this process, names of individuals or organizations were removed. Following each interview, contact summary forms were completed to summarize the information obtained, record general impressions, analytical surprises, and to propose new questions and directions for future interviews (140). A similar summary sheet was used to organize the collection and analysis of documents.

Getting some form of feedback from participants has been recommended in case study research to enhance overall credibility (25). A review of the literature on member checking returns several different perspectives on the utility and contribution of this design strategy (139;140;143;144-147). The position taken in this study was that feedback from participants could improve the depth and accuracy of information about the organization’s implementation strategy. It would provide an opportunity to have interviewees elaborate on the information shared during the interview and an opportunity to summarize and share preliminary findings. Following each interview, the audio recordings were used to prepare a 1-2 page summary of the content discussed during the interview which then was sent to participants for feedback via
email.Interviewees did not receive a copy of their transcripts but rather a descriptive summary of the issues, explanations, and stories that were shared. Participants were asked to review the summary and clarify or elaborate on any of the content. They were also asked to identify any descriptive information that they may have seen as identifiable information. Nine participants responded to the interview summary that was sent. There was often limited feedback returned unless there were specific requests for clarification. Some participants chose to clarify and elaborate on their experience. While no conflicting interpretations were offered by the participants, the position taken was to treat these interpretations as means to challenge initial interpretations or present alternative views of the data that could enhance the overall analysis.

Documentation was an additional source of data that was collected. Informants in the department of occupational health and safety and/or purchasing or procurement department assisted with the collection of supporting documents including: evaluation reports, written policies and procedures, training materials, and administrative documents from the sharps safety committee. Some of the documents that were reviewed were treated as the organization’s ‘paper implementation’ describing the goals of the organization’s approach to needlestick injury prevention and what specific implementation activities were carried out (24).

Information was extracted from each document to address topical questions about the implementation process (Appendix E). The topical questions listed were also addressed in the interviews with key informants. The supplementary material was useful for reducing issues of recall bias in describing how the organization implemented SENs. In addition to the interviews and documents, field notes were taken to describe the setting and other characteristics that would later be used to contextualize the data collection process.

5.4 Analysis

To centralize the storage of information collected and to track the coding and analysis process, a case study database was created using NVivo (QSR International Pty Ltd. Version 9, 2010), a qualitative data management and analysis software. The use of a computer program in the analysis process was not meant to take away from the inherent subjective and interpretative process involved in the analysis of qualitative data (148). This program was used to note changes to the coding structure, facilitate the review of coded data across the three sites, and keep track of
new directions taken in the analysis. Internal memos within NVivo assisted with the analysis process by keeping track of new directions, emerging themes, and propositions.

The case study approach does not prescribe a single analysis strategy. A number of analysis approaches and tools were used to fulfill the requirements of a case study approach and to accommodate the evaluation focus. Coding was used as the main analytical device in the analysis. The first stage used coding as a means to summarize the data collected and to guide the identification of relevant text across interviews, documents and cases. The case study approach recommends that the data be organized around certain topics, themes or central questions (149). Mayring (52) describes this general analytical procedure as the ‘summary stage’. A number of ‘topical codes’ were defined during the proposal stage. For example, there was a topical code defined as ‘implementation facilitator’. This code was applied to data that referred to specific strategies used by the organization that were perceived to have been instrumental to the implementation process. Codes defined at the proposal stage were later expanded on and refined based on new issues and directions that developed during the fieldwork and analysis. This was an open process where new codes were also developed when content did not fit into existing categories (150). During the early analysis phase, new codes were also developed to keep track of preliminary themes. Both document summary forms and interview transcripts were reviewed at this stage. When approximately half of the material was coded, the descriptive codes were organized to start to think through how they might be related and whether two or more codes should be combined (52). Once a more refined list was created, the material was reviewed a second time to identify any relevant documentation or accounts that may have been overlooked (52). A manual was used during this initial stage of coding. It included a definition for each code and explained how its content would apply to the study objectives and/or foreshadowed issues. Table F1 in the Appendix F includes a list of the codes used during the first coding stage. The table indicates whether the codes were considered ‘descriptive codes’ or ‘thematic codes’. The table also organizes the codes in two sections to identify which codes were used to support the within case analysis and which codes ended up supporting a cross-case analysis.

A unique feature of the case study approach is the importance of description to provide a contextualized understanding of the case. During the initial coding process, relevant information pertaining to the topical questions was recorded for each case site to capture the organization’s
implementation history and relevant activities and outcomes (25). This material was later used to inform the case descriptions. Documents were not only reviewed to collect evidence for the organization’s ‘paper implementation’. The content was also reviewed to identify what was missing and what was being emphasized to examine what the organization wanted to convey.

Further guidance on how to synthesize the case study data was drawn from Braun and Clarke’s guidelines for thematic analysis (150;151). Thematic analysis shares many similarities with grounded theory, the key difference is that thematic analysis does not always lead to a theoretical model (151). The process involved reading through the data extracted during the first coding stage to note down initial ideas (150). Initial sub codes were generated and applied to the extracted data. In most cases this also involved grouping of sub codes. These codes were later used to summarize the data collected, assist with pattern identification and interpretation, and guide the identification of relevant text across interviews, documents and cases. In the process of identifying themes the focus was not strictly about prevalence but whether the theme “captured something important about the data in relation to the research question” (150, p 10). Towards the later phases of the analysis, existing theory and concepts from the implementation science literature were drawn in to assist with the interpretation of the findings.

The analysis considered both retrospective reflections of the implementation experience and reflections on current conditions. There was a focus on examining the implementation experience and ongoing conditions and practices related to needlestick injury prevention at each case site. The analysis also went further to ask why organizations approached the implementation process differently and had different experiences. When analyzing interviews with front-line workers, attention was placed on practices, understandings and conditions at the workplace level, to examine not only what they reported about the use of safer needle technology but how they talked about it. The analysis and interpretation process was not limited to a descriptive exercise to summarize the accounts in direct relation to the research questions. There was also an attempt to think through some of the implications of shared views or divergent perspectives and underlying assumptions to better understand the implementation experiences and ongoing challenges.
Coded interview data was compared across different respondents and across groups of respondents. For example accounts from respondents that were identified as organizational informants were compared with accounts from front-line workers. Divergent perspectives were not always seen as contradictions. There was an attempt to understand why there may be divergent perspectives by, for example, looking at the circumstance and focusing on the different positions and experiences between the two groups.

While most of the analysis was at the organizational level, there was also an effort to make a connection between the external regulatory environment and decisions and experiences at the organizational level. Quite often organizational informants were able to articulate in what ways the regulatory requirements supported their decision to integrate SENs. This was examined further by examining both ongoing practices and written goals that touched on their commitment to meet the basic requirements of the regulation or continue to make advances to reduce sharp related injuries.

5.5 Trustworthiness

Lincoln and Guba’s conceptualization of trustworthiness was used as a guiding framework in the design and analysis process (139). This framework was developed through considerations around how the researcher can “persuade his or her audiences (including self) that the findings of an inquiry are worth paying attention to, worth taking account of” (139, p 290). Rather than apply conventional criteria and strategies used to assess the quality of quantitative research, they propose parallel criteria including credibility, transferability, confirmability, and dependability. Credibility (closest to the quantitative concept of internal validity) refers to the ‘truth value’ or establishing confidence in the ‘truth’ of the findings considering the research design, informants, and context (139). Transferability refers to the extent to which sufficient information about the study context is provided to allow the reader to decide whether or not the findings can be transferred to other contexts. Confirmability refers to whether the findings from the study are internally coherent and how well they are supported by informants of the study and by events that are independent of the researcher. In reference to dependability, Lincoln and Guba (139) discuss issues with replicating qualitative work as it assumes that what is being studied cannot change over time, can be controlled and has some stability. Attention is redirected at tracking sources of variability in the research process considering whether the researcher has made errors
in designing the study, collecting data, analyzing the results or reporting the findings. The research thus aims to maintain field notes and reports of the research process.

These values and strategies influenced the design of this study. For example, in the pursuit of more credible findings, the analysis relied on data collected from multiple perspectives and data sources. Providing participants with the opportunity to elaborate and clarify information after their interview was also a means to enhance credibility. To enhance transferability, a descriptive portrait was prepared for each hospital under study to provide information about the organizational context to enable readers to better assess the transferability of the case study results (Chapter 6). To strengthen the confirmability of the study, the findings were examined in relation to other literature and findings of related work (Chapter 9). The process of analyzing and interpreting the data was recorded to establish a form of audit trail that could be used to demonstrate how the findings were grounded in the data. Documenting the data collection and analysis process, the use of a coding guideline, and efforts to review the material more than once during the coding process, were all strategies that were designed to enhance the dependability of the research findings.

5.6 Reflexivity

In Section 4.1, the importance of recognizing the researcher’s influence on the data collection and analysis process was emphasized. Reflexivity has been identified as a means to better understand and describe the role of the researcher in analysis and interpretation. It is based on the assumption that when meanings are attached to data they have been made not found (152). It is the researcher who chooses how to interpret the data and what to extract as evidence (152). The conceptual framework reviewed throughout Chapter 4 served to outline the various theoretical influences that informed this work.

To further help operationalize the reflexive process, elements of the voice-centered relational method of data analysis were used (148;152-154). A component of their analytical approach involves a reading of the interview transcripts for ‘reader-response’. As recommended, the worksheet technique was used where the interview transcripts were laid out in one column and any reactions and interpretations were recorded in the adjacent column (152). In reading the texts a number of influences were considered including background, theoretical perspective and
experiences in relation to the respondent. This was later summarized to examine how early assumptions and views might later impact the interpretation (152). As Mauthner and Doucet (152) explain, “this reading is based on the assumption that locating ourselves socially, emotionally, and intellectually allows us to retain some grasp over the blurred boundary between the respondent’s narrative and our interpretation” (p 419).

During this process I identified a number of assumptions and approaches to the analysis that could be traced back to having a positivist background in epidemiology. I also recognized during this reflexive exercise that by not having a nursing or clinical background I tended to view the participants as experts. This seemed to result in a tendency to examine participant’s perspectives and experiences at face level. Mauthner and Doucet (148) caution that the tendency to view the research as an opportunity to give voice to the participants can mask the role of the researcher in the analysis and writing process. In the process of working to capture and reflect on the experiences of participants, this can prevent the researcher from going beyond the words of participants to examine the context that influences the respondent’s accounts and the significance of their perspectives (148).

This process helped challenge initial ideas about the nature of the data to apply a deeper level of interpretation. For example, rather than providing a purely descriptive analysis that catalogued what people said, I recognized how the analysis could go beyond that to examine underlying assumptions and the implications of what was being shared.

### 5.7 Ethical Issues

#### 5.7.1 Privacy and confidentiality

To preserve anonymity, names of individuals and organizations were not used. There are limitations to establishing complete anonymity when information is obtained from multiple informants within a single organization. Co-workers within the organization may have been aware of interactions between the researcher and the participants. Attempts were made to aggregate responses on particularly sensitive issues. Participants were also asked to review a summary of the content discussed during their interview to identify whether the content may have included any identifiable information. The most important consideration was to ensure that all participants were aware of the limitations to confidentiality and the potential issues that might
arise from this (155). The information and consent forms that all participants were asked to review and sign provided an opportunity to inform staff about the limitations of complete anonymity. All three hospitals had different internal requirements for what was to be included in the consent form distributed to staff. A copy of one of the consent forms used is included in Appendix G.

5.7.2 Compensation

Compensation was offered to participants if the interview took place outside regular work hours. The level of compensation was set at $35/interview. If the interview took place during work hours, participants were given a small token of appreciation which was a $10 gift card to their local coffee shop. When the interview was scheduled outside regular work hours, participants were offered reimbursement for any parking costs. If travel to and from the interview at an off-site location involved public transit, the participant was offered bus or subway tokens.

5.7.3 Risk benefits

Potential harms or risks associated with participating in this study were related to two main factors including 1) the time commitment involved for employees who are currently burdened by heavy workloads and 2) the potential for negative information about individual or organizational practices to be exposed. These risks had to be continually evaluated. Healthcare workers are faced with time constraints and increased workload demands. Attempts were made to be as flexible as possible in the timing, location, and duration of interviews. The other underlying concern was the potential that information related to individual work practices or perceptions of the organization’s performance could be connected to either the name of the participating organization or the names of the individual participants. The risk of disclosure was managed through periodic checks of the data management process to ensure that the steps designed to protect the anonymity of the participants were completed (e.g., the removal of names from transcripts and identification numbers from contact information).

There were a number of benefits for those involved in the study. Healthcare organizations and their employees could benefit if the results identify how the use of SENs could be improved, how the use of SENs could be better supported, how resources could be allocated to better support implementation, and how regulations could be more optimally designed and supported
externally. Organizational resources are needed to carry out internal evaluations. This study provided the organization with the opportunity to receive useful information about the implementation and use of SENs with limited organizational resources. The organization also had the opportunity to share good ideas and exemplary practices related to the implementation of SENs. The organizations that participated recognized the potential value in participating in a project that was focused on improving the health and safety of staff. Front-line staff seemed to value the opportunity to share their experience and to make recommendations on how current practices could be improved. All informants and front-line workers who participated in the study were sent a summary of the results of the study.
CHAPTER 6
The Implementation and Impact of Safety Engineered Needles in Acute Care Hospitals – Three Case Reports

The findings have been organized under three chapters. The first chapter presents three case reports that highlight the overall implementation experience, perceived facilitators, and progress towards sustained integration in the use of SENs. The next two chapters will draw on these case reports and other material from the interviews and documents to carry out a more in-depth analysis. Chapter 7 examines three aspects of the implementation experience that were relevant across the three case reports and that are important for understanding the utility of health and safety regulation, the nature of the challenges that are encountered with large scale implementation, and how these challenges can be overcome. Chapter 8 focuses on the post-implementation phase examining the need for ongoing commitment to needlestick injury prevention and what might be impeding further progress.

6.1 Interviews and Documentation

The case reports reflect what was learned from interviewing both front-line workers and organizational informants and reviewing historical program documents. A total of 30 individual interviews were carried out ranging from 30 minutes to 2 hours in length. The majority of interviews were with registered nurses or registered practical nurses. There was a broad range of clinical areas represented. While the majority of front-line workers and managers were from the emergency department and intensive care unit, input was also received from staff working in labor and delivery, general medicine, long-term care, surgery, cancer care and rehabilitation. A large proportion of the respondents had a role on the JHSC (N=11). Staff on the JHSCs were easily accessible as they could participate in an interview during the time allotted for their JHSC related activities. These informants could talk about their own use of SENs in their practice but also provide information on how the JHSC was involved in the implementation process, current health and safety priorities, and ongoing activities to invest in needlestick injury prevention. Additional details on the respondent characteristics can be found in Table 2.
Table 2: Respondent characteristics

<table>
<thead>
<tr>
<th>Primary Informant Category:</th>
<th># Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered Nurse / Registered Practical Nurse</td>
<td>17</td>
</tr>
<tr>
<td>Organizational Informant</td>
<td>9</td>
</tr>
<tr>
<td>Clinical Manager / Supervisor</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health and Safety Role:</th>
<th># Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupational Health and Safety</td>
<td>4</td>
</tr>
<tr>
<td>JHSC</td>
<td>11</td>
</tr>
<tr>
<td>Safer Needle Task Force</td>
<td>6</td>
</tr>
<tr>
<td>None of the above</td>
<td>9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender:</th>
<th># Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>22</td>
</tr>
<tr>
<td>Male</td>
<td>8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time in Current Organization:</th>
<th># Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5 years</td>
<td>5</td>
</tr>
<tr>
<td>5-10 years</td>
<td>9</td>
</tr>
<tr>
<td>More than 10 years</td>
<td>16</td>
</tr>
</tbody>
</table>

The original intent was to recruit staff who had been working with the organization when the majority of SENs were implemented. A large number of respondents had been with the organization for more than 10 years. A small number of respondents had only been with the organization for less than five years. While they had not all been with the organization during the initial roll out, their input was of significant value as they could speak to ongoing challenges, recent product changes and any recent experiences with a needlestick injury. In terms of the final number of interviews, there was an attempted to obtain input from different groups of informants that would have been directly involved in the implementation process (e.g., representatives from occupational health and safety, employee education, logistics, purchasing, infection control, the safer needle task force). Interest in participating and attrition of employees involved in the implementation process influenced the final sample of organizational informants that were recruited. It was anticipated that perceptions towards the implementation of SENs held by front-line workers might vary across the three hospitals and there would be a need to recruit a number of front-line workers at each site to establish different themes. Across the three hospitals there were more similarities in experiences and perspectives towards the integration of SENs than expected. After interviewing 30 staff, there was sufficient information collected to understand in detail remaining issues associated with the use and integration of SENs. During the last few
interviews with front-line workers there was minimal variation in perspectives towards the organization’s implementation process and ongoing issues with the use of these devices.

At each hospital, any relevant documents that would provide further background on the organization’s implementation process were collected. The three sites varied in the extent to which they had retained relevant documentation associated with the implementation process (Table 3). Across the three sites, 55 individual documents were reviewed for relevant information.

Table 3: Summary of available documentation by case site

<table>
<thead>
<tr>
<th>Case A</th>
<th>Case B</th>
<th>Case C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policies and procedures</td>
<td>Policies and procedures</td>
<td>Policies and procedures</td>
</tr>
<tr>
<td>Injury statistics</td>
<td>Injury statistics</td>
<td>Injury statistics</td>
</tr>
<tr>
<td>Newsletters</td>
<td>Newsletters</td>
<td>Newsletters</td>
</tr>
<tr>
<td>Email correspondence</td>
<td>News reports</td>
<td>Email correspondence</td>
</tr>
<tr>
<td>Terms of reference</td>
<td>Task force meeting minutes</td>
<td>Training notices</td>
</tr>
<tr>
<td>Exemption request forms</td>
<td>Product announcements</td>
<td>Safety posters</td>
</tr>
<tr>
<td>Employee survey results</td>
<td>Safety exception forms</td>
<td>Taskforce meeting minutes</td>
</tr>
<tr>
<td>Ministry of Labour orders</td>
<td>SEN cost comparison</td>
<td></td>
</tr>
</tbody>
</table>

6.2 Case Study Reports

Three case reports are presented for each hospital under study. The reports provide an overview of the strategies and processes used by each organization and reveal perceptions and beliefs shared by both front-line staff and organizational informants about the overall implementation process. Each report ends with a review of how the organization was continuing to ensure that the use of SENs was supported and improved over time, and how the use of these safety devices had become integrated into practice.

During the initial fieldwork, it was recognized that the three hospitals that were selected to participate were very distinct in the timing and motivation for their transition to SENs. To capture these differences, each case was labeled using the terms intrinsic and extrinsic and early or late adopter. This classification was inspired by concepts from the diffusion of innovations literature (123). In this study, early adopters refer to organizations that transitioned to SENs before Ontario's regulation on needle safety was officially announced. Late adopters refer to
organizations that waited to adopt SENs until the regulation was officially announced in 2007. The terms intrinsic and extrinsic were also used to distinguish between organizations that voluntarily transitioned to SENs and organizations that transitioned early but still in response to external pressures (e.g., workplace inspection).

6.3 The Extrinsic Late Adopters

The first hospital, Case A, was a large teaching hospital outside the Greater Toronto Area serving a large urban population. Prior to the transition, there had been a number of structural changes in the health and safety department with the development of new positions and the combining of existing positions. It is important to note that during the fieldwork, there was a public announcement that hundreds of jobs would be cut to manage a large budget shortfall at the hospital. Concerns about workload and staffing were raised during some of the interviews with organizational informants and front-line workers.

6.3.1 The implementation experience

With respect to the timing of the transition to SENs, the organization can be considered an ‘extrinsic late adopter’. Unlike the other two hospitals under study, the move to SENs occurred after the regulation was announced in 2007. An official news release outlining the organization’s response to the regulation and plans for implementation was distributed to staff in January 2008 stating that the devices would be fully transitioned by late summer. According to organizational informants, prior to the regulation being announced, neither staff nor their union representatives were actively pushing for the adoption of SENs. Thus the transition was almost entirely initiated by the regulatory requirements. The timing of the implementation process meant that the organization had less than a year to convert their entire stock of hollow-bore needles. A number of safety devices were implemented over this time period. The most frequently used SEN had a manual safety design; however, semi-automatic SENs were also implemented.

During the initial implementation process, organizational informants involved in leading the change process talked about getting ‘push back’ from key stakeholders groups. A number of organizational informants and front-line workers involved in the implementation process described physicians as being resistant to the use of safety needles. As one worker from the JHSC put it:
I do think the doctors were probably one of the biggest, after the staff got used to them, the doctors were probably the biggest problem. I think they are a little more compliant, there’s still some that aren’t though. I don’t know how you fix that.

Not being able to fix the problem of physician ‘push back’ was also expressed with frustration by another informant:

The rest of them who refused to comply still refuse to comply and to this day probably refuse to comply and are disabling devices left right and center. And I don’t have a mechanism for that.

An organizational informant attributed this initial resistance from physicians to a previous negative implementation experience. Before the transition to SENs was announced, the organization had attempted to switch the type of sutures being used for cost purposes. This resulted in significant internal conflict as physicians did not support the change and felt they were not adequately consulted. The new sutures were never adopted. The health and safety staff attempted to meet with physicians at their division meeting to explain that the transition to SENs was an occupational health and safety initiative that was required under the Occupational Health and Safety Act and not a strategy to lower costs for the hospital. However, a number of physicians did not attend and it was reported that they continued to resist the changes.

This was not the only area of resistance described by organizational informants involved in the implementation process. As the regulation does not specify what types of safety devices should be used, organizational informants found it challenging to get approval from finance to integrate specific types of safety devices that were expected to be more effective but also more expensive. As an organizational informant explained:

The regulation wasn’t written really well because it gives people a big doorway to get out. If the doorway wasn’t there I could force the hospital to change all of their shields... The hospital doesn’t really want to change their shields because of the expense of changing them all. So, if the regulation is written in the right way we can use it actually to get [the safety devices], buy something that’s more expensive.

The quote above does highlight the absence of any wording in the current regulation that specifies what types of SENs should be implemented and how this can sometimes be a disadvantage. Under some circumstances, regulation can be used as a tool to justify investments that are supported by health and safety but resisted by senior management.
The organizational informants described a number of issues with the use of safety devices during the early implementation process. For example, safety caps were being physically removed from the devices or not activated before disposal. One of the informants elaborated on a number of practice issues that were encountered including product ‘hoarding’:

The other issue that does occur and I am sure its occurred in many hospitals is some staff will try to steal, hoard the old needles and we have found here and there stashes of non-safety needles that staff were hiding.

‘Stealing’ needles was later explained in connection to ‘exceptions’. When a safety needle could not be used for a specific procedure, non-safety needles would continue to be made available as an exception. Organizational informants not only found it difficult to approve and keep track of these exceptions, it also provided a means for some staff to avoid using the new safety technology. As a manager explained:

The other issue or difficult issue is keeping people with exemptions right from going beyond the exemptions because we have no way of monitoring and keeping people who don’t have exemptions from taking needles from the carts of people who do have exemptions.

A number of informants and front-line workers referred to a specific safety butterfly needle that when implemented, actually resulted in an increase in needlestick injuries. One of the informants described how this device became a 'non-functional safety'. There were reports that the safety mechanism was no longer being activated. Organizational informants acknowledged that the device did have some design issues describing the safety component as “flimsy” and awkward to activate. The health and safety staff reported that the ongoing review of needlesticks and other incidents every quarter helped reveal that ongoing injuries were being reported with the use of this specific safety device.

The solution taken was to integrate an alternative safety butterfly needle with a semi-automatic safety mechanism: a device that could be activated with the press of a button. Organizational informants emphasized that the roll out of this particular device did not go well. While it took significant effort to convince administration that the added cost for a more advanced safety device would be worthwhile, the device was initially rejected by a large number of front-line staff. Organizational informants described a number of challenges getting it approved. The product vendor supplying the new product ended up having to negotiate with the finance
department: they would reduce needlestick injuries to a certain point or refund the difference in price. The idea was that reduced injuries would present cost savings to the organization and thus would justify the purchase of the more expensive device.

To implement this new safety butterfly needle, the organization followed the process used to integrate other SENs. The review and selection process was facilitated by an existing committee that had representation from clinical areas, infection control, occupational health, purchasing, and finance. Unit managers from impacted areas hand selected experienced staff to participate in product evaluations. Selected staff were then trained and given a personal supply of needles to work with over a 1-2 week period where they were then asked to comment on best practice, patient satisfaction, infection control, and ease of use. The evaluation process was led by a representative from the product vendor who presented the results back to the product selection and evaluation committee. In reference to the semi-automatic safety butterfly needle that was described earlier, one of the organization informants explained that the product was very well accepted in the pilot evaluation but emphasized: “when we rolled it out it became a different issue”. This new device was resisted across the organization. As one organizational informant described, there were a number of issues raised by staff:

It wasn’t sort of one pocket of people that just don’t want change or things like that, it was so universal all over the hospital and the main issue was that they didn’t like the feel of it, they did not get flash back and sometimes it wouldn’t retract, sometimes they’d open the package and it would retract so that’s a waste of product, so things like that. They had quite a long list of I think it was about 10 things they weren’t happy with.

When the fieldwork was carried out, most of the product changes had been in place for three years with the exception of a few devices including the new safety butterfly needle discussed earlier. Despite a number of issues being brought forward during the initial implementation process, organizational informants reported hearing very little from staff three years after the initial rollout. Interviews with front-line staff revealed some indifference about the safety devices that had been implemented:

But now looking at it I talked to a few staff in the last couple of days and it’s like second nature, it’s like they don’t even know the difference anymore. Even the people that kind of use them in the past they go, they don’t dislike them, they don’t like them.
The front-line staff that were interviewed at this site had a lot of positive views towards the transition with particular emphasis on how these devices have served to protect staff from needlestick injuries. For example, one front-line worker emphasized the value in having access to SENs in situations where needles don’t get disposed of after use during rather chaotic situations:

Once you get the intravenous or you poke them you retract the system, the whole needle gets into this little plastic container and you can throw it in the garbage and you won’t get poked or on the ground... I had people step on needles and get poked after really bad trauma in [the] emergency department where everything has to happen right away but you know, it’s all chaotic we’ve had needles here, there, so we have always been mindful when we turn patients, remove any sheets or anything, to check first before you put your hand, now even if you hit something you’re not going to get poked from it... it’s been retracted. So, definitely a very low risk.

6.3.2 Implementation facilitators

Organizational informants were asked to describe what was important for addressing emerging issues and facilitating the implementation process. Front-line staff were also asked what supported them adapt to the new technology. Their reflections centered on the importance of external support, use of existing organizational resources and processes, internal networks and communication, training accommodation and support, and strategies to re-evaluate and improve the integration process.

In terms of external support, organizational informants talked about the important contribution of product vendors. These representatives played a key role in helping the organization select from a variety of safety devices, carry out the product evaluation process, deliver training, and provide ongoing support when issues arose during implementation. One of the organizational informants described how thorough the product vendors were when there were troubles integrating a new safety device:

So we contacted the company and they came back and they provided additional training, they went around to the units, they contacted a hospital in Toronto to see how it went with their implementation...so the company actually followed up with us numerous times...

Follow-up action that addressed ongoing problems helped the organization act on implementation issues. There were strategies that were used to monitor the use of safety devices
that were not perceived to be that useful. The director of occupational health and safety did report that audits of sharps disposal bins were completed for the first two years but hadn't been done since. Auditing of disposal bins was described as a “very questionable practice” and not particularly helpful.

Not all external resources available to support implementation were perceived to be helpful or welcomed. One of the organizational informants described a rather negative experience being offered assistance with the implementation process:

No in fact we found that our community safety association called us up and told us they wanted to come in and tell us how to do it, we were already midway through our roll out and we said no, and they said well look, we have this document that we produced to do this and actually they were almost trying to bully us into coming in. And I found actually they were more of a stressor than anything else so I flatly refused them. You shouldn’t really do that and the reason being they report back to [the WSIB] and the MOL that you’re not being compliant...

This interaction highlighted how important it was for the organization to draw on their existing processes to facilitate the transition. Having an existing system in place to review and evaluate new medical devices was perceived as a facilitator by organizational informants. The organization did not want to start from scratch as they felt they already had a well-functioning product evaluation and selection process. As a representative from logistics pointed out, the organization introduces 75-100 new clinical products each year. The resistance may have also been heightened by the pressures of having to comply with the new regulatory standard by the effective date which gave them less than a year to transition to SENs. What seemed to be helpful were resources that were timely and could in effect transfer some of the workload off the organization. While a formal implementation guide was not utilized, the organization did appear to adopt some strategies that were aligned with some of the core implementation principles outlined in these guidance documents. For example, a sharps safety committee was established with select members from the JHSC to examine ongoing injuries and address any ongoing issues with new safety devices. This committee did not have a direct role in the product selection and evaluation process but played an important role in monitoring ongoing injuries.

Organizational informants, who were committed to transitioning to safer needle technology saw the regulation itself and the enforcement of the regulation as an important facilitator in helping
staff in the occupational health and safety department succeed in getting SENs approved. For example, here is how one organizational informant described his impression of regulation and inspections:

So, it’s moving in the right direction but regulations are helpful. I tell our MOL inspector who can be as much of a friend as a foe that often regulations help us out.

In retrospect, organizational informants talked a lot about the value of engagement and awareness during the early implementation process. One of the first steps in the implementation process was the formation of a steering committee with senior level staff to raise awareness about the regulated changes and to obtain input on how to proceed. However, it was also expressed that more engagement and input throughout the implementation process would have been helpful and could have avoided some of the setbacks encountered along the way. For example, one of the organizational informants identified the need for the health and safety department to better communicate with other departments in order to avoid conflict:

The third very important person is the education coordinator ... I think because if you don’t get the educators on board and control education and they push back to you, you’re in trouble and initially with our initial roll out, we got a push back from them.

Another informant echoed the importance of cross-departmental communication particularly between the purchasing staff and the educators:

I think the biggest thing is good communication within the organization itself...I will maybe get a call from purchasing or I don’t even get a call from purchasing and there’s a new product coming on Monday. I don’t know, educators don’t know, staff doesn’t know, but our purchasing knows for months.

What is raised in the quote above is not only lack of cross-departmental communication but also a need to improve communication with front-line staff. Organizational informants felt that this may have contributed to the problems encountered with the more recent safety butterfly needle that was implemented. Many of the clinical groups affected did not feel they were consulted. The issues encountered with the safety butterfly needle suggests that the initial product review and pilot testing process was not successful at picking up on unintended consequences associated with the new technology. One of the organizational informants emphasized that this process could be improved through better input from front-line users:

I don’t know if that’s necessarily well decided as to who trials or trialed enough but I think that’s such a huge component of it and on occasion you have non-clinicians
making a decision about which clinical product we should use without that proper input and I think that comes back to bite us every now and then.

While internal networks and communication were perceived to be instrumental to a smooth implementation process, they were not identified as a strength but rather something that could be improved.

The final area that was identified as important to the implementation process was training accommodation and support. Informants reported that the organization had recognized from previous experiences that training needs to be adapted to accommodate the constraints involved in reaching such a large number of staff across a multi-site hospital. Face-to-face training sessions delivered by the product vendor were perceived by organizational informants to work better than the ‘train-the-trainer’ approach. The ‘train-the-trainer’ approach was not perceived to be effective in accessing a large number of staff working over a 24 hour shift schedule. However, front-line staff also emphasized some of the limitations with the face-to-face training sessions. One front-line worker described the conflict staff faced balancing work and training demands:

So, for nursing it’s hard to say well okay, let's all go there, all 20 staff let's just leave all of our patients and go in there for half an hour ... and so we kind of just try to get the educator involved to try to get, okay go to your in-service I will kind of take care of your patients while you’re there.

In summary, this organization was confronted with the challenge of introducing SENs within a very short time frame, there was minimal internal push for the transition, and the organization had recently had a negative implementation outcome. The retrospective account of the implementation experience identifies a number of conflicts and challenges that were encountered. This section has revealed that a number of informants were able to identify conditions and supports that would have been helpful in facilitating a smooth implementation experience. What appears to have been important in working through the challenges that were encountered was the ongoing monitoring activities and leadership from the occupational health and safety department to actively pursue solutions when problems were identified.
6.3.3 Reaching full operation

When focusing on the current status of the transition to SENs, it was important to examine whether the organizations under study had reached full operation or a state where SENs have been integrated into practice, whether they had made any efforts to go beyond the requirements of the regulatory standard, and whether there were ongoing processes to monitor and improve upon the existing needlestick prevention program. The organization did have policies and procedures related to medical sharps safety that not only focused on safety device use but more broadly incorporated guidance on safe work practices. General education on needlestick injury prevention and management was part of corporate orientation and the half day training program delivered every 3 years. The organization also had resources on the prevention of needlestick injuries available on their intranet including short training videos on how to activate SENs; the written policy highlighting the organization’s commitment to sharps injury prevention and specific responsibilities; and guidance on how to manage needlestick injuries. Both organizational informants and front-line workers talked about the limitations in reaching and engaging with staff to deliver training and education acknowledging the limitations with electronic forms of communication. Organizational informants seemed to put more emphasis on lack of engagement among staff. From the position of the front-line worker, information overload and workload more generally was the problem.

In terms of ongoing monitoring activities, it was reported that the committee established to oversee the transition to SENs had not been disbanded but was no longer meeting on a regular basis. One of the main mechanisms by which the organization continued to monitor the safer needle program was through regular reviews of injury reports. The organization demonstrated commitment in the past to ensure that safer needle technology was functional. The health and safety staff had to be very persistent to convince administration to adopt more expensive passive safety butterfly needles when there was an increase in needlestick injuries detected with the use of the original safety device. Furthermore, when there was negative feedback with the new safety butterfly needles, there were efforts to meet with staff in different areas and bring the product vendor in to provide additional training.

Front-line staff and organizational informants reported that needlestick injury prevention was not an ongoing priority in relation to other health and safety issues at the hospital. There was also the
impression that the initial problems encountered with the safety devices (e.g., design issues, difficulties with activation) had been resolved or staff had just gotten used to them. However, despite the belief that most of the problems had been worked out, this did not mean that the devices were always used as intended or were able to always protect staff from injury. For example, here is how one of the informants described ongoing ‘misuse’ of safety devices as not only being about the design of the device but also workload demands:

You still find that people don’t use the device correctly ... I don’t know if it’s a matter of education, I think it’s more a matter of they’re so busy at the time that they do something and they just forget to do it. Because workload has increased so much that people are just crazy busy and they don’t always stop to do something that’s correct.

One worker emphasized how important the proper use and timing of the activation is for the ability of these devices to protect staff from injury:

I find that sometimes they don’t retract them early enough and because it’s an accordion thing the plastic is a little tough so if you don’t retract it right away sometimes when you let go it might just swing around a bit just because of the nature of the plastic and what not and that’s where people will get a needle poke because as it swings around they sometimes move their hand and by moving their hand they sometimes will [get a needlestick injury].

There was also a perception that practice issues were ongoing among physicians in particular, who from the initial implementation period were not perceived to be entirely committed to safer needle use. Percutaneous injuries associated with medical sharps other than hollow-bore needles were also considered to be an ongoing problem. One worker identified how sharps disposal practices in the operating room influence risk of injury to workers in other areas of the hospital:

The sharps in the operating room, we have difficulty or problems sometimes with people leaving sharps on trays that go down to cafeterias and so somebody down there will end up cutting themselves because there [has] been a sharp left on a tray.

As described previously the organization was continuing to monitor needlestick injuries. Between 2008 and 2011, needle related injuries declined by 28% across the hospital. There were 99 needlesticks in 2011 down from 137 in 2008 when the organization started their transition to safer needle technology. While the frequency of injury had decreased, the health and safety department had noted that the severity had not gone down meaning that the number of lost-time claims had not declined over the past four years. Thus the impact of the transition had not
benefited the organization in terms of reducing their lost-time claims associated with needlestick injuries. It was reported that there had not been a notable cost decrease associated with the uptake of safety devices despite a 28% decline in overall frequency.

There didn’t seem to be a great deal of concern about the fact that needlestick injuries were continuing to occur. One front-line worker described how having 100 injuries annually may not be considered an important priority considering the size of the hospital:

    When you look at it, I think there’s about 5-6000 nurses across the [hospital sites] and 12,000 employees, when you look at that number that’s pretty small, so it is quite low I think.

While there were some positive views towards the increased use of passive safety devices to further reduce injuries, there was some apprehension about this technology considering existing budget constraints at the hospital. While there was some frustration about the lack of progress with respect to lost-time claims, there were no specific plans in place to further reduce needlestick injuries.

6.4 The Extrinsic Early Adopters

The second hospital, Case B, was a multisite community hospital in the Greater Toronto Area. The hospital was embarking on a large redevelopment project which would result in a number of improvements in the physical work environment. In terms of the structure of the health and safety system, all sites had their own health and safety unit which was led by a director of health and safety and supported by a health and safety analyst and specialist. There was also a centralized JHSC overseeing health and safety related issues across the hospital sites.

6.4.1 Implementation Experience

With respect to the timing of the transition, the organization can be considered as an ‘extrinsic early adopter’. To a large degree, the use of SENs was something that the health and safety department had been looking into for some time. For example, the hospital had already implemented a needleless IV system ten years earlier. The health and safety staff reported having difficulty getting other safety devices passed by administration due to cost constraints. One front-line worker recounted her interactions with the hospital administration before SENs were
adopted. She explained how they attempted to demonstrate how the transition to SENs could result in reduced costs for the organization:

To get the message across to administration here at that time was very, very difficult and I even put together cases, like in California where they had implemented them, how much money it actually saved using them. They were saying they cost too much money but they could save money because of the money that’s spent on each needlestick injury and God forbid somebody gets AIDS or something that would cost the hospital. But it was a fight.

Aligned with the strategy used during the safer needle campaign, the argument for safety needles had to be broken down to dollars saved rather than injuries prevented. One front-line nurse, who at the time was an active member of the JHSC, continued to observe needlestick injuries on her unit and when her recommendations to implement safety devices were ignored she requested support from the MOL. Due to elevated needlestick injuries in select areas, a MOL inspector ordered the organization to transition to SENs in three departments deemed to be high risk. This order was received in 2006. The organization initially resisted the order. A copy of the appeal listed a number of reasons why the organization did not feel the order was appropriate including the fact that there was currently no legal requirement mandating the use of safety needles, the exclusive use of safety devices was not an industry standard, and very few hospitals had made a full conversion. At the time of the inspection, Ontario's regulation on needle safety had not yet been established under the Occupational Health and Safety Act. The decision to appeal the order did receive some negative media attention and as one informant recalled, initiated further internal conflict between union and management. The organization did eventually withdraw their appeal.

In an effort to manage the conflict that arose, the hospital took a different approach and initiated a rather comprehensive safer needle program. In 2007, the hospital formed a ‘Safety Workplace Partnership’ with their health and safety association (the Public Service Health and Safety Association) which was designed to enhance the workplace health and safety culture. As part of this partnership, a health and safety consultant was appointed to serve as an advisor to support the development of a safety engineered medical sharp (SEMS) task force. The PSHSA provided the organization with a guidance document they had prepared to support the implementation of SENs.
The SEMS task force was guided by terms of reference that outlined a number of responsibilities including the evaluation of the existing program, developing strategies to promote safety culture and awareness, making recommendations to senior management, reviewing the education and awareness program, and developing strategies to ensure that staff were using safety devices appropriately. A number of documented activities revealed that this committee was very active during the transition to SENs. The organization adopted a separate committee to oversee the implementation of safety needles rather than facilitate the selection using existing structures and processes to integrate other forms of medical technology.

The organization had to select and implement safety devices within a very tight time frame in the three areas that were cited by the inspector. However, the hospital also chose to transition to SENs in other areas before the regulation took effect which allowed for a more gradual transition process. The health and safety staff did find that most clinical groups were in support of the transition; however, there was some apprehension among physicians. As one organizational informant emphasized “it takes a little bit more persuasion with the doctors” and another “it’s only from the doctors where I get push back”.

While organizational informants reported that front-line staff were generally in support of the adoption of SENs, the product changes were difficult for some to get used to. Issues with SEN use encountered during the initial implementation phase were not attributed to any specific group. Physicians did make requests for specific non-safety needles to be used in areas where SEN options were not perceived to be feasible. Organizational informants described how staff would remove the safety from the device. There were also documented discussions among the SEMS task force members during the initial transition about staff having difficulty seeing around the safety caps. Organizational informants recognized that safety device manipulation seemed to be connected to limitations in the design of the SENs that have been introduced:

A lot of people still do that to this day because it’s difficult for them to see sometimes, I mean the safety device is quite cumbersome on a lot of needles right? It’s the big pink thing but it’s easier for them to rip it off so that they can see as opposed to having it in their way when they are doing their work.

The hospital had transitioned to SENs five years prior to this study. When front-line workers were asked about their views towards the safety devices currently in use there was a lot of
positive feedback. Front-line workers tended to emphasize ways in which safety devices had reduced the potential for exposure during unpredictable situations:

So, like when everything is everywhere because right now this patient’s life is more important than anything that’s happening, so if they are using it at least they’re capped right? So, if they end up on the bed on the floor, somewhere there’s so many people working in that vicinity and there is the risk of getting a needlestick injury from this patient, the [safety] caps really decrease the risk.

There was a sense that SENs had been integrated into practice and something that staff didn't really think about anymore:

I think it was definitely more complicated initially because of the learning but once it was implemented I think it would be hard to find any nurse out there now who doesn’t like them. I haven’t heard any complaints and the new nurses that are coming in are trained on them, that’s how they are being trained you know, they don’t have any other experience with them but yeah, I think right now, I think everybody is okay with them and the devices that we use.

It was particularly interesting to hear from nurses who were new to the field, including staff that had not been trained with the non-safety needles. One front-line nurse, who had just finished her training at the time of the transition, didn’t understand why SENs were initially resisted:

I don’t see the benefits of complaining about something that’s going to eliminate being stuck by a needle... of the things they teach you in school you know, you’ve got to make sure you don’t do this ...I think one of the problems that I remember when I was on the floor is that people were complaining, when it was first rolling out you can’t always have them, sometimes you had them, sometimes you didn’t have them and that’s what they were complaining about more.

6.4.2 Implementation Facilitators

Despite the transition being particularly resource and time intensive, in retrospect, organizational informants felt that the overall process had gone smoothly and identified a number of supports that helped facilitate implementation. The labour inspection order was deemed to be instrumental for the early transition to SENs. While some informants emphasized that the occupational health and safety staff were making some progress with respect to prevention efforts to address needlestick injuries, there was doubt that the organization would have integrated SENs across the hospital before the regulation took effect had the MOL not been involved.
From the perspective of those involved in the implementation process, starting early and introducing SENs in phases was perceived to be an important facilitator. There was an initial focus on priority areas that were high risk. This resulted in mini projects which were found to be logistically more manageable. The initial transition to SENs in three select high risk areas was perceived to be advantageous as the changes could then be used as a model to demonstrate to staff how the new devices had been successfully integrated into practice: a means to obtain buy-in in other areas. The initial transition in response to the MOL orders established a process, generated some lessons learned and helped identify which devices would work in other areas.

What was particularly unique at this site was the use of a needs assessment during the initial planning stage. The needs assessment was facilitated by the main product vendor who visited high risk areas to observe what devices were in use and how they were being used. Based on this initial assessment they made specific recommendations. This early engagement with staff may have also served to increase awareness around the hospital that product changes were pending. Another form of needs assessment was conducted by the SEMS task force after the initial transition in high risk areas was complete. Injury statistics were used to identify the next top priority areas that would be targeted for product changes.

The implementation process seemed to have benefited from having key staff in place that were championing the change process including specific staff that had been selected to lead the transition as well as natural early leaders who were committed to addressing health and safety issues at the hospital. A staff member in the purchasing department was identified by other organizational informants as a committed leader, who was very supportive during the implementation process providing timely access to product information and usage reports. The organization also appointed a lead for the implementation process who was described by a clinical manager as “very positive person who believed in what we did, and was very proactive”. A front-line nurse, who was committed to addressing health and safety issues at the hospital, was also identified by a number of the informants as a natural champion that was able to bring the perspective of the front-line worker to the change process.

There were a number of supports identified that could be more generally related to the importance of having strong internal networks and communication during the implementation
During the early planning stage, getting staff to buy-in to the change process was discussed as a key priority. There were documented discussions among the SEMS task force about strategies that could be used to provide staff with information on the risks associated with needlestick injuries. One initiative led by the task force was the distribution of an organizational wide questionnaire to assess the organization’s culture of safety and to identify strengths and gaps in the current sharps injury prevention program.

Another form of engagement included efforts to work with physicians during the device selection process. When there were concerns about how the transition to SENs would impact specific procedures, the product vendors would meet with doctors to discuss what was working for other hospitals. Having a third party with product expertise involved in the exchange with physicians may have provided a means for physicians to feel like they had more control over the proposed changes.

In addition to engagement with staff it was also recognized that while the transition to SENs was driven by a MOL order, there was sufficient internal support among specific groups within the organization that were willing to invest significant time and effort into the implementation of SENs. One informant explained how the adoption of safety needles was consistent with the values and goals of the OHS department and how the momentum was already there:

They looked at safety [in] previous years but I think it was the cost at that time that they didn’t go forward with it but ... OCC Health I believe pushed for safety. So, some of the ground work in terms of you know, policies and procedures and on the clinical [side] I think there was a bit of a momentum already starting so, it wasn't a brand new discussion.

Possibly as a result of the timing of the transition, the hospital was able to benefit from a number of external supports including a partnership with their health and safety association and the use of an implementation guide that helped the task force evaluate their safer needle program and obtain some feedback from their front-line staff. There was openness to receiving both external guidance and resources to support the transition process. While this was the only hospital that reported working with representatives from a health and safety association during the initial implementation phase, it was actually the support received from the product vendor that was identified as the key external facilitator to the implementation process. The product vendor provided a number of services to support the implementation process including product selection
and evaluation, inventory review, training, and auditing. These resources may have been particularly helpful for a smaller community hospital that had less staff available to facilitate the transition process.

The integration of the new technology was also in part facilitated by measures to ensure that the safety devices were working and being used as intended. In 2008, close to the effective date of the regulation, the SEMS task force brought in the vendor that supplied the majority of SENs to conduct a final audit. At that time, there were non-safety devices found on some units and there were also reports that not all safety devices were being activated. The organization addressed this issue by having unit managers audit their areas to ensure that non-SENs were returned. There were also other activities conducted by the SEMS task force to follow-up on issues. For example, in response to reports that sharps disposal containers were installed too high, the task force initiated a survey to assess the location and height of sharps containers.

In summary, this organization was confronted with the task of introducing SENs when initially there was little management support for the adoption of these devices. The organization was able to overcome this challenge and reach a full operation stage in the use of SENs prior to the regulatory standard coming into effect. There are a number of supports and conditions that were described in this section. What stood out from the retrospective account of the implementation experience was the important influence of external supports including the labour inspection order that initiated the transition, guidance received from the health and safety association during the program installation phase and the resource support from the product vendor during the initial implementation phase. It is also important to acknowledge that initiating the transition well in advance of the regulatory standard gave the organization sufficient time to collaborate with external consultants to develop and implement a comprehensive implementation plan.

6.4.3 Reaching Full Operation

There was an opportunity during the interviews with front-line workers and informants to identify areas where the implementation process could have been improved or how current measures to support needlestick injury prevention could be enhanced. Front-line workers had a lot to share with respect to training. A number of staff recognized the value of comprehensive hands-on training direct from product experts (face-to-face) rather than a 'train-the-trainer'
approach. The ‘train-the-trainer’ approach was the primary training strategy used at this site during the transition to SENs. A representative from the product vendor would come in and provide training to the clinical practice leaders who would then train front-line workers on their unit. A number of front-line staff either described the training provided as very brief or could not remember receiving anything formal. A number of front-line workers reporting learning how to use SENs on their own:

I don’t remember ever you know, having somebody come and say this is what we’re doing, this is how it’s supposed to be used, just kind of figured out how to do it on your own or ask the nurse how to use it

Another worker recalled notifications about information sessions but emphasized “most of us can’t attend”. On one hand, staff appreciated the idea of more comprehensive training that was face-to-face but at the same time acknowledged that they had very little time available to attend these types of training sessions. In terms of ongoing activities in place to ensure that SENs were used as intended, the only formal ongoing practice that was identified was general education on needlestick injury prevention that was provided as part of employee orientation. When discussing ongoing practices to further reduce needlestick injuries, organizational informants had a number of ideas about what could be done next including the review of the exception list, re-training, audits, and collecting more information on why needlestick injuries are still occurring to evaluate whether a move to more advanced SENs would be of value. One of the organizational informants emphasized that they would jump on any new advances in SENs that would reduce the need for exceptions if those options were brought forward by a product vendor.

The organization had primarily integrated manual SENs. A number of staff talked about the advantages of semi-automatic or passive SENs for ease of use and injury prevention. One worker who recently had a needlestick injury using a safety device felt that her injury could have been prevented had a passive safety been available. She emphasized how current safety devices can’t protect all injuries and believed quite strongly, based on her own incident, that a move to passive safety would make a difference:

So even if it has the flip safety it’s still going to poke you right? So, if the patient will move just you know, a little movement or there’s resistance from the patient you will still poke yourself with that one and I talked to my manager there’s one needle that’s really good that is retractable, once you inject it and you pull it out there’s no needle that will be exposed... I think the resistance is because of the budget and the
retractable are really very, very safe, we just push once, there’s no exposure of the needle, so how can you go wrong with that right.... But it’s really, if they are after the safety of the nurses and all the providers, retractables are really the best, you will see dramatic results...

However, health and safety staff had reported that they did not receive requests from staff to integrate more advanced safety devices. They felt there wasn’t sufficient drive to propose this kind of change considering the roadblocks that would be faced from administration due to the significant increases in cost associated with more advanced SENs.

While organizational informants talked about the possibility of re-evaluating safety device exceptions, analyzing injury data to determine the potential value of passive safety devices, and offering re-training, none of these activities had received any momentum. Time constraints were identified as the main reason there was a delay in initiating these activities. While informants emphasized time constraints, not moving forward also seemed to be more about a lack of urgency. This lack of urgency to invest in further activities to integrate these devices may have been influenced by the recent disbandment of the SEMS task force. As the organizational informants explained, the SEMS task force was recently disbanded due to low attendance and reports that no new issues were being brought forward. It may also be in part due to a general sense that the time commitment involved in initiating these activities may not make a difference in the end. One of the organizational informants expressed some doubt about the impact of conducting a regular review of current safety exceptions. Reviewing the need for conventional sharps or exceptions had been on the agenda for a number of months; however, it was believed that revisiting the list of exceptions would be very time consuming and would likely not result in any product changes.

There was also a shared view among front-line staff and organizational informants that practice issues had declined to a large extent and that front-line staff were committed to consistent and quality use of SENs. As one front-line worker put it:

   Everybody has kind of caught on that they have to go with the safety engineered...I haven’t seen much bad practice.

There were select reports from both front-line workers and organizational informants about continued areas of ‘bad practice’. A representative from health and safety who was routinely collecting and analyzing injury data emphasized that while usage had improved over time there
were still issues and injuries. Front-line staff were able to speak to the types of “bad practices” that were ongoing. For example, one front-line worker reported ongoing issues with one specific type of safety device used on her unit:

I’ve noticed that some people, we use TB syringes to give vitamin k to the babies and I notice a lot of people don’t [activate]...

Another front-line worker reported observing more experienced staff continuing to avoid the use of SENs:

I see a lot of the older nurses using the old school techniques on things that I personally would not be comfortable using but they’re used to it, even if it’s like instead of using the butterfly with the guided sleeve, they will use a needle top that doesn’t have the [safety component]

Issues were not only limited to whether or not staff used safety devices; it was also about how these safety devices were being activated. For example, one staff member whose role was to support staff when they encountered difficult intravenous line insertions had not picked up on any ongoing issues with the use of safety devices but observed issues with the timing of activation:

I still see some nurses they just, they will pull [the needle] out and then hit the button which is defeating the whole purpose...

The quote above refers to a safety device that is designed to be activated before the needle is withdrawn from the patient. Removing the device before it’s activated limits the potential for the device to reduce risk of injury when the needle is withdrawn.

Organizational informants reported regularly reviewing injury data with the SEMS task force and at the JHSC. A 'plateau' in needlestick injuries was described. Since 2007-2008, approximately 40 needlestick injuries are reported each year to the occupational health and safety department. There were 41 needlestick injuries reported in 2010-2011. Comparing the number of injuries between 2005-2006 to the average number reported over the period 2009-2012, there has been a 61% decline in needlestick injuries following the transition to SENs.

In terms of whether these ongoing injuries could have been prevented through further advances in safer needle technology, organizational informants explained that time constraints have prevented root-cause analyses from being carried out. Therefore, there was currently no
information to determine whether ongoing injuries could have been reduced through advances in SEN technology or through safer work practices.

6.5 The Intrinsic Early Adopters

The third hospital, case C, was a large teaching hospital in the GTA. The hospital has been awarded for their progress in advancing working conditions and benefits for their employees. In terms of the structure of the health and safety management system, the hospital had a central health and safety department and a central JHSC. They also had a number of smaller safety groups that formed in some areas of the hospital to conduct more detailed and regular inspections. The occupational health and safety staff were about to launch a mandatory online training program on musculoskeletal injuries and violence prevention.

6.5.1 Implementation experience

In terms of the timing of the transition to SENs, the hospital could be considered an ‘intrinsic early adopter’. There were a number of advances in the uptake of safety devices that dated back to 2003, five years before Ontario’s regulation on needle safety took effect. At that time, there was new leadership in the occupational health and safety department. One of the goals of the new director was to address needlestick injuries at the hospital.

The transition to SENs seemed to be very gradual. In 2004, a new vacutainer safety blood collection set and needleless IV system were implemented. Over the next few years the organization implemented a mix of passive, semi-automatic, and manual safety devices. Passive safety devices were implemented specifically in areas deemed to be high risk (e.g., emergency). The hospital also implemented a mix of manual and semi-automatic SENs. While the organization initiated their implementation process back in 2003, they adopted specific implementation strategies that were later recommended in guidance documents to support the implementation of SENs. A Needlestick Task Force was formed in 2004 and was composed of multiple stakeholder representatives from across the organization including purchasing, union representatives, educators, infection prevention and control, occupational health, primary care managers, and physician groups. The task force was guided by a formal administrative manual that laid out specific responsibilities including the ongoing review of injury statistics, prioritizing needs, and making recommendations. While this taskforce had the primary responsibility to
oversee the transition process, the JHSC was also periodically updated on the status of the transition, ongoing needlestick injuries, and the annual review of exceptions.

Organizational informants did not feel that Ontario's regulation on needle safety was an important driver for their decision to transition to SENs. Regulation did however appear to influence the development of some formal aspects of the hospital’s safer needle program. A few months prior to the effective date of the regulatory requirements, the organization finalized written policies that formally stated the hospital’s commitment to only use SENs, outlining specific responsibilities for workers, managers, occupational health and safety staff and the JHSC.

When informants and front-line workers talked retrospectively about the transition to SENs, they emphasized that the rollout was rather seamless. However, there were reports that some staff had difficulty adapting to the new technology. One informant described this early transition experience emphasizing that negative feedback was often limited to specific devices and was only temporary:

   Nobody likes change... they are a little bit more awkward, it’s getting used to it, getting used to the feel of it and there’s been no complains, it was very little push back we had, it was a matter of nurses just took it on and used it. If they were concerned about a device then they fight like crazy and we all go in and we meet with the company and figure out was the problem is.

The organization did act on problems encountered with the use of some SENs. For example; the Needlestick Task Force investigated a particular safety device that staff were not activating. Eventually this specific device was removed as staff found it awkward to work with. The hospital was not always able to select SENs that were perceived to be the most user friendly. For example, the hospital ended up selecting a particular device that was found to be more challenging to activate as the alternative option did not provide the necessary range of syringe sizes.

While front-line staff seemed to express support for the transition to SENs, compliance with device use was an issue that the health and safety department was aware of during the initial transition:
They just weren’t using it, they just would give their injection and not, some of our things like the BD ones they have the thing hanging off the side so you give the injection and then you’re supposed to go like this and it closes over the needle and they weren’t using that, they were just throwing it in a sharps container without putting on the safety device.

Issues with device activation were initially monitored through audits of disposal bins which were carried out by the product vendors. The organization did report using this information to target reminders about SEN use. In some cases, the product vendor would be brought in to address any issues or deliver further training. Issues with SEN use encountered during the initial implementation phase were not attributed to any specific groups.

6.5.2 Implementation facilitators

There were a number of supports in place to help facilitate what organizational informants described as a 'seamless rollout'. These supports were related to the timing of the transition, readiness for change or implementation climate, communication and engagement, external facilitators, and monitoring and acting upon implementation issues.

The organization’s decision to adopt safety needles before regulation took effect was perceived to have benefited the overall implementation process. As one organizational informant explained, starting early allowed the organization to ensure that adequate implementation measures were in place:

A lot of hospitals were rushing at the time of the legislation; they had to change over everything whereas we had already been doing it for 4 years at that point... it was like every 6 months we would do something new and then once we got that one up and running we could move on, what do we need to do next...it was a slow process as we went through it.

Organizational informants emphasized a number of internal conditions in place that provided an environment that was receptive to change. As reviewed earlier, the move to adopt SENs was championed by a new leader in the health and safety department. Senior management support was also perceived to be essential for supporting the early adoption of SENs despite the associated cost increase. Health and safety staff didn’t have to fight for change:

We have a strong senior leadership team and they’re very good. Anything that is going to protect our staff especially from blood and body fluids, with HIV potential and all these things, they do it. We’ve never had an issue with it.
Another informant currently on the JHSC echoed this strong support from senior management emphasizing not only how it has supported the move to SENs but also how it may have provided a strong message to staff about the hospital’s commitment to safety:

I think it has to also come from the top down, front-line staff have to see that this is an expectation of not only their manager, their APN, but the director, see I think if you look at the global organization we have had for a long time senior management safety walk arounds, so the message on safety .. and [that] we don’t want our employees hurt comes from above downward and I think in some organizations if they don’t have that, the staff, they don’t value it so they take the shortcuts, they do all these things because the value of a safe working environment has to be there.

In addition to emphasizing the important role of senior management support, the quote above also addresses the importance of communicating with front-line staff. The organization did initiate some activities to communicate with staff and raise awareness. Sending a clear message to staff about the importance of health and safety seemed to be an important principal shared by health and safety staff. One informant described how even the strategy used by the organization to roll out SENs was designed to convey an important message to staff about the organization’s commitment to safety:

Having the supplies there, like turnover day was turnover day you know, like it wasn’t oh well, we’re getting them to you next week or we ran out so we went back to the old stuff, that hasn’t happened and if people are doing that then you’re not going to, if I say to you this is the new device and it’s safe ... and then I turn around and say, we’re not getting them in for another 6 weeks, I am not giving you the right message...

To ensure that staff were sufficiently prepared and informed about the proposed changes, a 'poster build-up' was initiated prior to the roll out of SENs to notify staff, highlight the purpose of the transition, and to outline key advantages associated with the move to SENs. Training was also identified as an important component of the implementation process. The organization used two training strategies to reach the maximum number of staff. Group based training led by a representative from the product vendor was used to deliver face-to-face training. The organization also used the train-the-trainer approach to ensure there were product experts on the unit for staff who were unable to attend the training sessions. Despite this dual training strategy, reaching staff was emphasized by a number of informants as an important challenge. While the product vendors would provide counts of staff who attended the training sessions, training
coverage was not officially documented with the train-the-trainer approach. One informant described this form of training as a “hit or miss”:

Reaching everyone, it’s not that easy, you only reach a percentage of the full time staff on a regular basis and you have to come in [during] evenings and nights to reach everyone plus the challenges are probably weekend and casual staff, it’s just impossible to reach everyone... I haven’t been that specific, like okay, here’s all the nurses that attended and here whose missed, I didn’t do any of that, it’s just hit or miss you know?

Despite these challenges, the organization did value the training support provided by the product vendors. Front-line workers that were able to attend the training sessions did value the opportunity to get hands-on experience with the SENs before the devices were integrated:

In-services are usually like the company that [is] supplying the product, will come in with one of their specialty agents or whatever you call them, and they would have in-services, so they would have little, I don’t know what you call them, out in the community, like a workshop kind of thing, where they would have all the different devices and they would show you how to use them, and then they would take questions and they would, explain why they were changing to the new devices, the reason for safety and all this stuff, and then actually give you hands on [experience] using them before they actually come into the hospital for use, so that you’re already familiar with the [devices].

Organizational informants also emphasized the importance of engagement with front-line users during the device selection process. The organization had a pre-existing product evaluation committee that was already established to recruit small subgroups with high end users to oversee product changes. In line with recommendations for the selection of SENs, product evaluations were carried out considering multiple product options. Trials were designed to obtain input from end users using a standardized questionnaire. Some of the design features that were evaluated include ease of activation, timing of activation, whether the device can be reused after activation, and whether there were any issues with needlestick injuries or near misses when using the device. There were a number of documented examples of how front-line users provided input into the device evaluation and selection process.

Ongoing surveillance was described as one strategy used to identify and address issues with SENs. The hospital’s health and safety staff were perceived by outsiders as being very active in monitoring and managing occupational health and safety issues:
I think we have an excellent occupational health department that makes a big difference for sure... The safety specialists are fantastic, on the ball, they’re right there, any concerns you have they’re right on them to get them dealt with right away. So, I am sure that, has a big impact ... if your occupational health department is where they should be.

There had been a recent focus on ongoing injuries associated with the disposal of sharps. When health and safety staff investigated these incidents further they attributed the problem to overfilled sharps disposal bins and believed the underlying issue was confusion or lack of ownership over who should be replacing the containers. To address reoccurring problems with sharps disposal practices, there were a number of examples of posters, emails and newsletters that had been distributed. The hospital periodically circulates a newsletter that is specifically focused on the health and safety of employees. The newsletter is often used as a means to communicate with staff about health and safety issues.

In terms of external support, the hospital did not have the opportunity to benefit from the services provided by their health and safety association to support the implementation of SENs as they transitioned to safety needles voluntarily many years before the safety association's guidance document was available. The organization did emphasize the importance of having support from the product vendors to deliver training. It was reported that the product vendors were available 24/7 and were able to come in to provide re-training if there were any issues with the SENs that had been implemented.

This organization can be considered a leader in initiating efforts to prevent needlestick injuries making a voluntary commitment to adopt SENs several years before the regulatory standard was established. The implementation experience was described as a relatively smooth process. While a number of supports were described in the section, what stands out in this retrospective account of the implementation experience is the important influence of internal conditions and supports including a strong safety culture, senior management support, and strong leadership in the occupational health and safety department. These internal supports helped drive efforts to invest in more advanced passive safety needles.
6.5.3 Reaching full operation

There was a shared view among a number of informants and front-line workers that the use of SENs had become integrated into practice and that few, if any, injuries continued to occur. Front-line workers and informants that were interviewed had a lot of very positive things to say about the current use of SENs acknowledging the impact of the change on employee safety. In stark contrast to reports during the early transition process that safety needles were awkward to use and took some time getting used to, one front-line worker emphasized that safety needles can be easier to use:

There’s no risk of you driving yourself or anyone around you, but as to the ease of use ... it’s no different than it was 20 years ago, other than the fact that the safety measures a lot easier than it was before.

Organizational informants did emphasize that all hazards are considered a priority; however, due to the significant decrease in needlestick and other sharp related injuries, there was less focus on this injury issue. Following the transition to SENs, there was evidence that needlestick injury prevention did continue to be a topic reviewed periodically by the JHSC. While existing policies did not make any commitments to annually review new safety technology for better design alternatives, there was evidence that the hospital’s exception list had been reviewed annually. Organizational informants reported that there had been advances in the design of SENs that have decreased the need for exceptions. Other than ongoing reviews of incidents, there were no activities in place to formally monitor the use of SENs beyond the ongoing review of incident reports. As there had not been any recent audits, any issues with SEN use would have only been noticed by the health and safety staff if problems were identified from reported needlestick injuries.

There were a few recent events described by staff that suggested a need for ongoing measures to monitor the use and availability of SENs. One informant reported that recently a member of the JHSC brought a non-safety needle that was found on her unit. It was reported that the needle must have been brought in by another source as the organization was no longer supplying that device. One of the participants brought a non-safety needle to the interview. She had reported talking with a co-worker about it and was going to follow-up to see if there was something more up-to-date. The organization’s written policies and procedures around the use of SENs identified
one of the responsibilities of front-line workers was to report unsafe acts and hazards and to keep and report any defective products. An organizational informant did report that there is a process online that staff can use to report issues with SENs and other medical technology. This process did not seem to be well understood by other staff that were interviewed. One of the organizational informants reported that the organization does not have any ongoing formal activities to collect information from staff who encounter issues with safety devices. There was some confusion expressed by one front-line worker who had an issue with a safety device about how these types of issues should be reported:

I know that there’s an incident report you could fill out but I don’t know whether that’s just for near misses or like something happened and that’s when you have to report because this device failed...

There were few activities described that were more proactive in continuing to ensure that SENs have been integrated into practice. The organization did provide general re-education on needlestick injury prevention during their annual safety day; however, needlestick injury prevention is not part of any mandatory training.

Despite there being recent issues with incidents involving sharps disposal bins, some staff had not heard or seen anything recent about needlestick injury prevention. One informant described the absence of any focus on needlestick injury prevention but also felt that further communication that reminds staff to be cautious may not be necessary:

I think the main huge thing they are pushing for is hand hygiene first... I don’t see the needlestick injury as a huge thing it’s more blood transfusion error now, they want to make sure that’s done properly, so I have seen those in email blasts, not a lot of, to be honest in the years that I have spent here I haven’t heard of ‘oh watch out for a needlestick injury thing’, like posters or signs, or email blasts about it because people know to just watch out as a nurse you need to be cautious like don’t be stupid flying around...

In terms of the progress in reducing needlestick injuries, between 2003 and 2011, needlestick injuries declined by 85%. In 2011, there were 16 needlestick injuries, down from 106 in 2003. Overall lost-time claims had decreased over this time period, not only for needlestick injuries, but for other injuries as well. It is important to note that the organization did not observe immediate gains from the transition to SENs. In fact, injuries occurring during a procedure actually doubled between 2003 and 2006. The organization was periodically observing upward
trends. One of the organizational informants attributed this in part to influxes in new medical residents. The decision to focus on other health and safety priorities seemed to be supported by the substantial reduction in needlestick injuries and positive views shared by front-line staff towards the current use of SENs.

6.6 Conclusion

Despite a number of similarities in the types of safety devices that were implemented and very similar types of challenges faced during implementation, the case reports present three very different experiences in the transition to SENs. Table 4 presents a summary of key findings across the three cases under study including a description of the organizational characteristics; transition to safety needles; types of SENs introduced; use of external resources; perceived challenges and facilitators; outcomes of the transition; and activities in place to support the sustained integration of SENs. It is important to note that there was substantial variation in the outcome of the transition to SENs with declines in needlestick injuries ranging from 28\%-85\%. The next two chapters will reflect further on these three implementation experiences. Chapter 7 focuses on the implementation experience during the program installation and the initial implementation phase examining the conditions that challenge and supported the integration of SENs. Chapter 8 focuses on the full operation stage examining the need for ongoing investment in needlestick injury prevention.
**Table 4**: Summary and comparison of the content from the three case reports

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<thead>
<tr>
<th></th>
<th>The Extrinsic Late Adopter</th>
<th>The Extrinsic Early Adopter</th>
<th>The Intrinsic Early Adopter</th>
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<tbody>
<tr>
<td><strong>Organizational Characteristics</strong></td>
<td>Large teaching hospital</td>
<td>Multi-site community hospital</td>
<td>Large teaching hospital</td>
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<tr>
<td><strong>Transition to Safety Needles</strong></td>
<td>2007, in response to safer needle regulation</td>
<td>2008, in response to a workplace inspection order</td>
<td>2003, voluntary transition</td>
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<tr>
<td><strong>Types of SENs Introduced</strong></td>
<td>Mix of semi-automatic and manual safety needles</td>
<td>Mix of semi-automatic and manual safety needles</td>
<td>Mix of semi-automatic, manual and passive safety needles</td>
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<tr>
<td><strong>Use of Resources from Health and Safety Associations</strong></td>
<td>No</td>
<td>Yes</td>
<td>No (not available)</td>
</tr>
<tr>
<td><strong>Perceived Challenges</strong></td>
<td>Physician resistance</td>
<td>Initial senior management resistance</td>
<td>Safety features not used/removed</td>
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<td></td>
<td>Product hoarding</td>
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<td></td>
<td>Safety features not used/removed</td>
<td>Working out exceptions</td>
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<td>Engagement with staff Implementation champions</td>
<td>Needs assessment</td>
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<td>Internal communication / awareness</td>
<td>Engagement with staff</td>
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<tr>
<td><strong>Relative Decline in NSIs: year transition to 2011</strong></td>
<td>28%</td>
<td>61%</td>
<td>85%</td>
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<tr>
<td><strong>Implementation Policies and Practices to Support Sustained Integration</strong></td>
<td>Written policies and procedures</td>
<td>Written policies and procedures</td>
<td>Written policies and procedures</td>
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<td>Ongoing monitoring of incidents</td>
<td>Ongoing monitoring of incidents</td>
<td>Annual safety day</td>
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<td>Resources available on intranet</td>
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<td>Annual review of exceptions</td>
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<td>Ongoing monitoring of incidents</td>
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CHAPTER 7

A Cross-case Comparison of Conditions that Challenged and Supported the Integration of Safety Engineered Needles

This chapter examines three aspects of the implementation experience that were relevant across the three case reports. The first section will contrast the underlying motives and conditions that influenced the decision to adopt SENs and their implications for how the implementation process played out. The second section will examine how shared values held by front-line staff around the importance of clinical performance influenced the 'push-back' that was described in all case reports. The role of 'change fatigue' and the 'learning curve' on how front-line workers initially responded and adapted to the integration of SENs will also be examined. The final section will look at the role of key implementation supports that were found to influence the transition to SENs across the three cases drawing on implementation effectiveness theory as an explanatory framework.

7.1 Readiness for Change Under a Regulatory Context

This section is based on a cross-case comparison that will contrast the different circumstances and motives that supported or dampened the decision to transition to SENs. As there were different motives that influenced the transition to SENs across the three hospitals, this provided an opportunity to examine the utility and limitations of regulation for both the adoption and integration of an innovation when there is variation in organizational readiness for change. Each organization implemented SENs under very different circumstances. For example, at hospital C 'want to' motives were at play in the change decision whereas the other two sites initiated change because they needed to in response to regulation. Hospital C appeared to have a high readiness for change which may have influenced their persistent approach to the integration of SENs that included a comprehensive training strategy, high profile awareness campaign, ongoing collection of detailed information on needlestick injuries, and the use of root cause analysis to identify underlying problems that could be contributing to upwards trends in needlestick injuries. There were a number of contextual influences at play at hospital C that may have supported the decision to adopt SENs before the regulatory standard was established. There was a history of innovation in advancing employee working conditions and benefits. Those involved in the
selection and implementation phase reported receiving support from senior management throughout the transition process. A number of informants also emphasized how the health and safety staff appeared to be committed to strengthening the safety culture across the organization. Most importantly, needlestick injury prevention was one of the priorities of the newly appointed director of occupational health and safety.

Hospital A represented an interesting case of how implementation can play out when there is regulation influencing the uptake of an innovation but low readiness for change. The organization did not start to transition to SENs until the regulation was announced in 2007 and there had been no internal push for the adoption of SENs. One of the organizational informants explained that while nurses may have thought there could be something out there that would help reduce injury risk, they were not actively looking for safer alternatives:

I think we had a lot of needlestick injuries and it was a big concern, whether people were sitting there saying we need to have something different... So I am not saying, I don’t think that they actually felt there should be something out there, that it should have come quicker, I do think that they thought there was something out there that could be better then what they were doing. But you know, how do I put this, I think nurses go on and do their job you know there should be something better than this but they don’t really push to find something that’s better...

What was particularly interesting about the conditions leading up to the adoption of SENs at hospital A was the negative past implementation experience the organization faced when they attempted to replace their suture needles. As described in the case report, one of the organizational informants believed that this may have contributed to the lack of physician support for the integration of SENs. This failed implementation experience may have also been a deterrent for the health and safety staff to pursue the adoption of SENs without regulatory backing. There may have been sufficient resources to support the transition to SENs but no motivation to do so before the regulation came into effect. It may not be surprising that this organization encountered significant levels of resistance from physicians, poor cross-departmental communication, and a number of problems with safety devices not being used as intended.

At hospital B, both 'want to' and 'have to' motives seemed to be at play. Initially senior management did not support the proposed changes. However, what was emphasized in the case report was that there were a number of other groups within the organization that were motivated
to transition to SENs. Hospital B's decision to comply with the MOL order back in 2006 and proceed to implement SENs in other areas may have been in part influenced by the pending regulatory requirements and also as an attempt to recover from the negative image portrayed by the decision to appeal the MOL order.

Case reports A and B demonstrate the important role of regulation in promoting the uptake of SENs despite there being low readiness for change. The influence of this form of external motivation was demonstrated when senior management at hospital B appealed the order to transition to SENs on the grounds that no specific regulation was in place mandating the organization adopt SENs. What was also influential in having the regulation in place was the level of persistence it initiated to ensure SENs were implemented successfully. When an organization voluntarily implements a new innovation that is widely rejected by employees, not used as intended, or doesn't produce immediate results, an organization can switch back to the old way of doing things. When SENs were not used as intended or did not produce desired impacts on needlestick injuries, the organization could not return to the use of conventional needles as the use of SENs was regulated. To address implementation issues, the organizations had to conduct audits, provide further training, and circulate reminders. Essentially, having the regulation in place provided more pressure to initiate activities that would help ensure consistent and quality use of SENs. Despite a number of differences in the timing and motivation for change, all three hospitals encountered 'push back' during the initial transition phase.

7.2 The Initial Rejection of SENs

7.2.1 Change fatigue

For the hospitals under study, the move to SENs was a very large and costly investment that was specifically designed to protect staff from needlestick injuries. Despite the fact that the integration of SENs was for the health and safety of employees, it did not follow that all the devices were immediately accepted and used by front-line workers. While there were varied levels of verbal complaints made about the move to safety needles across the three cases, device use and activation problems appeared to be an important issue at all three hospitals. Issues with non-safety needles being stored, safety needles not being used, or safety devices not being activated were strategies front-line workers used to avoid the new technology.
When these issues were raised by front-line staff and organizational informants, explanations often centered on the idea that 'nobody likes change':

People usually start panicking because we as a human being, we don’t like changes right, we always think when the changes come it’s always for the worst, never for the better and we have a clinical educator that goes around, teaches us how to use and when to apply them basically and there is a lot of panic going at the time because they say why are we trying to implement something new when the old works...

One organizational informant felt that the initial resistance to SENs might not always be a good reflection of its potential value but rather a general frustration that has arisen from working in an environment that is under constant change:

Hospitals are going through so much change right now universally that people are almost bawking at anything, I mean not just making an argument for the sake of arguing but people are fed [up], in the current state just get a little fed up with change so I think that’s confounding what they really feel about the product or its safety. If it’s something different it’s a change and they don’t want it.

This idea of 'change fatigue' would be particularly relevant to those organizations that transitioned to SENs in response to the regulatory requirements which provided a 12 month period for compliance. As reported by one of the organizational informants at hospital A, in addition to transitioning the entire stock of hollow-bore needles, 75-100 other new products are transitioned in every year. Organizations that were not constrained by the effective date of the regulatory requirements could be more strategic in their roll outs introducing SENs when there were no other conflicting product changes. 'Change fatigue' was also touched on as an explanation for not investing in further activities to address ongoing needlestick injuries:

The company that supplies our needles has offered to come in and assist with training again. We’ve had so many changes in the hospital lately it just hasn’t been, timing hasn’t been good for more training. We switched over to a new computer program for registration of patients; we have a new payroll system coming in so lots and lots of changes going on within the hospital. So, we didn’t feel that it was, it was a good time ... people have too much on their plates right now.

While ‘change fatigue’ is drawn on as an explanation for why additional training hasn’t been implemented, there may also be a lack of urgency for additional initiatives to address needlestick injury prevention. This will be discussed further in Chapter 8.
7.2.2 Performance first

Another important influence on how front-line workers responded to SENs was an apparent conflict between the changes imposed by the new SENs and the values shared by front-line workers towards performance and patient care. While the implementation of SENs was designed to protect staff from needlestick injuries, the initial transition had the unintended consequence of temporarily influencing performance and from the perspective of front-line workers, their ability to get the job done. The following quote is from a front-line worker on the JHSC who believed that physician ‘push back’ had a lot to do with how they believed the use SENs would influence their practice:

“It’s like, it’s a safety device for them, I don’t know. I don’t know why I think it’s more they have their own way of doing things, they are comfortable with how they do it, they don’t want to change, you know, you’re doing your procedure, you’re doing it a certain way, you do it with a certain needle, to them it’s in the way it’s causing them not to be able to do the procedure that they want to do as safely as they think they could do it, they’re not looking at the safety in themselves, they’re looking at how they’re doing the procedure...

The influence of product changes on performance was recognized by a number of staff. One front-line worker explained the performance impact using the analogy of a professional pool player. If you change the design of a pool stick used by an amateur player, they may not notice a difference; however, if you change the pool stick of an advanced player, the different feel and design could make a large impact on their game. What he emphasized was the more fine skill and experience you’ve developed working with a specific device, the more you’re going to be thrown off by even minor changes in equipment. The impact of product changes on performance was also described well by one of the organizational informants:

“You’re taking people who are used to for example holding a wing set in a certain way and applying it and they’re now masters of that and now you’re suddenly asking them to use something in a different way and anybody who draws blood for a living will bawk against it.

The role of health and safety staff is to enhance the health and safety of workers. They had put a lot of effort in to get SENs integrated and were invested in the process. As the role of the front-line worker is to deliver the best care possible to their patients, it may not be surprising that they would be concerned with how the new technology might impact their practice. Despite there being two groups with potentially different positions and interests, health and safety staff did
seem to appreciate and even relate to the concerns raised by staff. One organizational informant, who had previous clinical experience as a front-line worker, explained how product changes can impact performance drawing on his own experience:

I used a technique that wasn’t used in Ontario so initially they allowed me to use it, it wasn’t a problem and I was very good, I was seen as the master I could get anybody with a stick and then all of a sudden the medical director changed and he said nope, not acceptable I don’t want them using that so I had to learn to use it the other way. My success rate dropped like a stone, I was very miserable and I was no longer the expert and the same thing happens with them so I understand why they have problems changing practice.

The performance first prioritization did not only appear to initiate verbal complaints against the transition to SENs, it also led front-line workers to avoid or manipulate the safety devices. Reasons why SENs were not always activated were attributed to critical situations and heavy workloads. As a number of informants and front-line workers revealed, safety caps can be ripped off the devices when they interfere with a procedure.

Being able to carry out a procedure well and with ease is really about providing optimal care to patients. Patent centered practice was also an important related theme identified across the three cases. It not only seemed to influence how front-line workers responded to SENs, patient care considerations were also an important component of the implementation process. For example, product evaluations used by the three hospitals included measures to assess whether or not the new devices negatively impacted patient care. One hospital even incorporated patient interviews in product evaluations. Patient care considerations were also attributed to decisions over the adoption of safety sharps not yet addressed in the regulatory standard (e.g., safety scalpels). As one organizational informant explained, one of the many barriers to moving towards SEMS, specifically blunt tip suture needles, was that these devices would not be accepted by staff as patients may encounter more pain and discomfort.

The importance of patient quality of care was raised in a number of other contexts. When staff were asked if they had any recommendations for other health and safety improvements they would often take the opportunity to comment on how patient care could be improved. One front-line worker directly linked the use of safety needles to the health and safety of patients:
You had to pay attention and look where [the needle] is, ... when you put the cap [on], [you're] perfectly happy because you know what, you're not going to stick yourself. And also you’re not going to stick the patient again.

The importance of patient quality of care was also used as a means to present a case for investments in SENs. It seemed as through two goals, to improve patient care and to improve worker health and safety, were very much connected and thought about collectively. This was reflected in a written statement from hospital C that explained their decision to move to SENs:

The committee felt that in order to support our two corporate initiatives, patient safety and staff safety, this is exactly the type of direction we must take.

7.2.3 Innovation-values fit

The connection between how front-line workers responded to the implementation of SENs and values towards performance and patient quality of care is well aligned with the innovation-values fit concept from the implementation effectiveness model reviewed in Section 4.6. To some extent, the idea of moving to SENs was in line with shared values in protecting the health and safety of workers. As the adoption of SENs was for the health and safety of workers, its implementation was aligned with the priorities of the occupational health and safety staff. As mentioned earlier, Hospital C had made a public statement supporting the transition to SENs as it was consistent with two important missions of the organization: to improve the health and safety of workers and the health and safety of patients. There appeared to be a less than optimal fit initially for front-line workers. When some SENs were difficult to work with, they may have been viewed as being in direct conflict with one's professional competency motivating front-line workers to develop strategies to avoid using the new devices.

7.2.4 Learning curve

Reports of negative feedback about the design of SENs, resistance to the transition, and activation problems were often discussed in retrospect. In all three cases, there was the belief that issues with SENs had either been resolved or staff had learned to adapt to the new technology.

One front-line worker connected this period of adaption to the concept of a ‘learning curve’:

It was a little bit of a different technique so once they got used to that they were okay, but initially there was a bit of a learning curve there....When I first came in there was no safety, it was just you pull the needle out and you get rid of it, so when they brought in the new ones with the button...there was a lot of educating. I know our
calls went up a bit, we could see that in the stats, they went up because the nurses were still getting used to it, I had worked with [them] previously so it wasn’t a big learning curve for me but for a lot of the nurses they struggled with the new device but I mean over time, now I think they’ve adjusted well you know?

The concept of a learning curve often refers to an initial period of poor performance that decreases over time with experience. This notion of a ‘learning curve’ was touched on by other staff when they described how initial challenges with the use of SENs have been resolved over time. For example, one organizational informant emphasized that ‘pushback’ was not because staff didn’t value the protection the new devices provided; it was just a matter of getting used to the new feel of the device:

One of our biggest users was our IV team and they know it’s for their protection and they’d much rather have it, it’s getting used to it, they’re a little bit more awkward it’s getting used to it, getting used to the feel of it and there’s been no complaints, it was very little that pushback we had, it was a matter of the nurses just took it on and used it.

The notion of ‘learning curve’ was also considered formally during the product selection and evaluation phase. For example, there were documented planning notes from hospital B that estimated what impact a specific safety needle would have on practice. The planning committee anticipated a 2-4 month ‘learning curve’ for staff and physicians. Knowledge and awareness of this period of adaption is particularly important for interpreting and managing needlestick injuries associated with SENs. As reported in the case report for hospital C, needlestick injuries actually increased for a period of time after SENs were implemented before overall rates of needlestick injuries declined by 85%. At hospital A, when injuries increased following the implementation of a new safety butterfly needle, the decision was made to transition to a more advanced safety device. Whether to wait for staff to adapt to the use of a new SEN or integrate a new device appears to be largely dependent on whether challenges with the use of a SEN can be attributed to a learning curve or whether there are fundamental issues with the design of the device.

This section examined how front-line workers responded and adapted to SENs over time examining the influence of a learning curve, change fatigue and values towards clinical performance and patient care. Initial challenges with the use of SENs were not only believed to be a consequence of fundamental problems with the design of SENs. As emphasized by one
informant, there can be other things that confound how staff really feel about a new innovation. While increased exposure to SENs was believed to be important for the integration of SENs, there were a number of other important conditions and resources that were emphasized in the case reports that will be reviewed in the next section.

7.3 Conditions that Facilitated and Limited Implementation of SENs

The previous section revealed a number of challenges encountered across all three sites in getting front-line workers to support and use SENs. A number of implementation facilitators were described in each case report. This section is based on a cross-case comparison of the key implementation supports to examine more closely why they were valued and how they were used. The analysis is framed by drawing on the implementation effectiveness theory reviewed in Section 4.6.

7.3.1 External support

As articulated in the three case reports, there was a lot of emphasis on the role of product vendors during the implementation process. They provided a wide range of supports including needs assessments, product suggestions, product evaluations, training, and follow-up consultations to address any product issues. What was characteristic of the supports provided by the product vendors was that they worked with the needs of the organization. For example, to accommodate the size and complexity of Hospital A and the limitations the educators had encountered with the train-the-trainer approach, the product vendors delivered group based face-to-face training. The first case also describes how the product vendors committed to reducing the organization’s ongoing needlestick injuries associated with butterfly needles or they would refund them the difference in price. The services provided by the product vendors came with no cost implications and essentially served to transfer some of the workload off the organization.

The implementation effectiveness model defines financial resource availability as an important condition influencing the comprehensiveness of the implementation policies and practices. This form of external support may be essential for the implementation of large scale innovations under a regulatory framework when there are strained human, financial and informational resources.
7.3.2 Management support

Management support was also an important influence on the implementation process at each hospital. Case reports A and B demonstrated how lack of management support can challenge the implementation process. In the second case report, despite there being strong values supporting the adoption of SENs among health and safety staff and front-line workers, it was reported that senior management was initially resistant to the transition. At this site, the MOL had to be called in to initiate the transition to SENs. Hospital A also encountered challenges during the implementation process in receiving support from senior management to integrate a more expensive semi-automatic butterfly needle to address ongoing needlestick injuries. Hospital C was the only site that emphasized the support they received from management and identified it as a key facilitator to the implementation process. This hospital also reported fewer setbacks in getting specific SENs approved for purchase and use. While strong senior management support may not have been necessary to initiate the transition to SENs under a regulatory framework, this form of support did appear to facilitate a more smooth transition process and provided the opportunity to adopt more advanced SENs that went beyond the minimum requirements for safety.

7.3.3 Implementation champion

The presence of an implementation champion was identified as a key support in the transition to SENs. As SENs are designed to protect the health and safety of healthcare workers, leaders in the occupational health and safety departments would be natural champions. There were a number of examples across the three cases that demonstrated how health and safety staff were committed to ensuring SENs were integrated. For example, the health and safety director at hospital A actively perused measures to address ongoing needlestick injuries associated with the use of SENs by developing strategies to work with product vendors and finance to get a more advanced safety needle approved. What was unique about hospital B was that a front-line worker became a champion of the implementation process, initially requesting support from the MOL to encourage the hospital to move to SENs and later serving as an active participant on their SEMS task force. The championing behaviour present in Case B may have been particularly important to support the transition process as there was very limited senior management support during the initial implementation phase.
7.3.4 Implementation policies and practices

An important limitation associated with the implementation of an innovation under a regulatory framework is that often there is a limited time period available to initiate a comprehensive implementation strategy. Hospital A had less than a year to convert all existing needle technology and develop implementation supports. Organizational informants at hospitals B and C reported that the early transition to SENs was an important facilitator as it provided a means to phase in the new devices more gradually.

Broader organizational conditions and constraints appeared to have an important influence on the execution of implementation activities including training. Training was identified as an important implementation support; however, setting aside time in the workday for staff to attend training was a common problem encountered across all the three cases. The ability to get staff trained seemed to be limited by the nature of the work. One front-line worker emphasized how patient demands can prevent staff from attending group based face-to-face training sessions:

So, for nursing it's hard to say well okay, let's all go there, all 20 staff let's just leave all of our patients and go in there for half an hour and so we kind of just try to get the educator involved, okay go to your in-service, I will kind of take care of your patients while you're there.

Another training strategy that was used at hospital B and C was the 'train-the-trainer' approach where the product vendor trains the clinical practice leaders, educators or other select experienced staff and then those staff provide training to their coworkers. There were a number of issues raised with this approach as well. One organizational informant emphasized how system changes have made this type of training particularly challenging:

One of the problems we have with front-line staff is 5 years ago when they mandated that all schedules have 70% full-time and 30% part-time for nursing. Sounds good, however what it meant in order to make those schedules within a budget you ended up with a lot of weekend workers, so you ended up with a pool of people who only appear Saturday and Sunday, I haven't seen some of my staff in a very long time, email back and forth that kind of thing, they come Saturday and Sunday when the manager isn't here.

As staff hours are distributed across 24 hours and 7 days a week, the 'train-the-trainer' approach can often miss a large proportion of front-line staff. What appeared to be instrumental in managing training challenges was the existing culture of staff interdependency. In all three cases,
front-line staff reported learning how to use SENs from coworkers. While this may have be particularly helpful in managing issues with training coverage, a number of staff recognized limitations in relying entirely on co-worker support. One front-line worker felt that at times this can result in the transfer of bad habits:

I think it would be good of course to have the you know, the rep whoever is selling it come in and say these are what we’re bringing in and this is the proper way of doing it because every nurse has their way of doing something it’s not always the best way, so if you’ve got it straight from the source of course if you know, I am sure they tell you the proper way to use it. So, yeah it would be good to have a representative come in and say this is the proper way to use it, don’t do this or do this, so that would eliminate any risk of possibly doing it wrong and still being poked.

Training challenges stood out as one of the most important issues identified by both organizational informants and front-line workers and across all three cases. While it seemed that comprehensive face-to-face training was valued the most, it was also the most challenging to implement.

7.3.4 Organizational culture and context

There were a number of other supports that could be generally related to the organizational culture and context. It was important to recognize that from a logistical perspective the integration of SENs was not viewed as distinct from other product changes. All three organizations had pre-existing systems in place to evaluate, approve and integrate new products. The importance of having a pre-existing system in place to select and approve medical technology was emphasized at hospital A as they had to facilitate the transition to SENs within a very short time period. They were able to utilize their existing committees and evaluation processes to trial, evaluate and select from different SENs. Another important contextual influence was the organization’s existing occupational health and safety management system. The case report for hospital C presented views shared by a number of informants on how the organization has attempted to demonstrate its commitment to employee safety and how this can influence front-line worker engagement with new health and safety innovations. These supports bring attention to the broader organizational culture and context that influences implementation.
7.4 Conclusion

There were a number of parallel challenges and opportunities that the three hospitals under study encountered during the implementation of SENs. The implementation effectiveness model was well aligned with a number of important influences that were described by organizational informants including the important role of management support, comprehensive policies and practices, and champions of the implementation process. There appear to be important distinctions about the importance of some of these influences defined in the model when thinking about the implementation of an innovation under a regulatory context. The model does appear to be limited in supporting an analysis of the broader organizational context and external influences. Possible extensions to this model are discussed further in Chapter 9.
CHAPTER 8
Examining the Need for Ongoing Commitment to Needlestick Injury Prevention

The previous chapter looked back to examine how the overall implementation process played out. This chapter will focus on the post-implementation phase. All three hospitals under study had completed their implementation of SENs under the regulatory requirements. The first section of this chapter will examine why needlestick injuries continue to occur and will describe how the organizations under study have moved towards sustained integration in the use of SENs. While there were a number of different mechanisms identified that contributed to ongoing needlestick injury risk, how they are all related to two important limitations in the design of SENs is of significance. Despite ongoing injury risk, there were few activities in place to continue to proactively monitor and reinforce the use of SENs. The second section of this chapter will look more in-depth at what might be damping further efforts to advance needlestick injury prevention and support consistent quality use of SENs. The analysis presented in this chapter draws on the three case reports presented in Chapter 6 and additional content from the interviews and program documents.

8.1 Ongoing Needlestick Injuries

At all three hospitals, needlestick injuries declined following the implementation of SENs; however, as emphasized in each case report, needlestick injuries continued to occur. Healthcare workers were asked why they thought needlestick injuries continued to occur despite the availability of SENs. They were asked to think about a recent injury they personally experienced or ones they had observed in practice. The most common explanation centered on injuries that occurred before SENs were activated, during a procedure and as a result of patient action. In these situations, patients were described as being 'aggressive', 'combative', or 'not-cooperative'. A number of front-line workers and organizational informants also linked ongoing injury risk to improper sharps disposal practices including the use of overfilled sharps disposal bins. The examples that were provided emphasized how these practices did not only impose a risk of injury to oneself but also to other nurses and housekeeping staff working in the same area. For example, one front-line worker observed the following:
I have seen people get jabbed from the sharps container, someone puts in a needle like a 60 cc with a great big gauged needle on it that doesn't fit and they jam it in and it sticks out the end of the sharps container and then someone picks up the container...

One of the organizational informants at hospital B listed a number of recent incidents that were all related to improper sharps disposal and more specifically a result of safety needles being left inactivated:

Overfilled sharps containers, a nurse leaving the needle not engaged on a tray, that could be a dietary tray, that could be a nursing tray, that could be a procedural tray, then this device gets to the floor and somebody steps, you know, gets stuck in the foot which has happened, which is weird... Not engaging properly, so that when they are disposing it, the needle is still exposed.

In reference to ongoing needlestick injuries, front-line workers and managers emphasized not only the potential for needlestick injuries to occur before safety devices were activated but also during activation. The most common SEN in use across all three sites had an active design where the safety cap had to be manually flipped over the needle. The potential for injury arises when a healthcare worker attempts to use their finger to flip and lock the safety cap into place rather than using a stable surface such as a bed frame or table to activate the device. There are also safety devices that require the healthcare worker to use their finger to slide forward a safety gauge to lock the safety cap in place.

There were a number of incidents described by front-line workers and informants that emphasized that not all SENs are equally effective, easy to use, or able to eliminate needlestick injuries. As described in the first case report, staff had a number of challenges adapting to the use of particular device that actually resulted in an increase in needlestick injuries. The needlestick injury data collected from hospital C demonstrated that needlestick injuries occurring during a procedure actually doubled following the implementation of SENs but then slowly declined over time. This suggests that some safety devices may not immediately decrease risk of injury. The engineered safety component may need to be mastered before it can be effective.

8.1.1 Individual versus environmental influences

There were a number of explanations as to why needlestick injuries continue to occur and how they could be further prevented. These explanations can be organized under two themes: the
importance of staff compliance and "being more careful" and the inevitability of injury as a consequence of the work environment. The following quote provides an example of how front-line workers attributed ongoing injury risk to individual action. In this case there was an emphasis on the importance of taking control over the situation:

I tell nurses you are the one in control, you have the needle in your hand, make sure they stay still which means either you hold them still or you tie them down, get another nurse to hold them down because if they flinch, it's going in through him and you

Also aligned with this focus on individual practice, another front-line worker described how risk of injury increases when workers rush through a procedure:

There still are some needlestick injuries but they're small and a lot of times it seems like the person you know, have documented that they rushed so time seems to be a factor, so it's more individual kind of slowing down and taking their time to do the process...

While there was a shared view that individual practice does play an important role (one needs to slow down and take control of the situation), there were also a number of accounts that emphasized that some injuries are unpredictable and that environmental influences including workload and limitations in the design of SENs can influence ongoing injury risk. The following quote is from a front-line worker that described the unpredictable nature of some needlestick injuries:

Maybe a patient becomes very anxious or just swats their hand very quickly and catches the nurse completely off guard whereas the needle can end up sticking them instead of a patient, those are things that sometimes you really just don't know what may happen and it may not be preventable in a sense because it just happens so sudden.

One of the front-line workers that had recently been injured attributed her injury to patient action. What was emphasized in her account was the unpredictable nature of interactions with patients and the challenges associated with anticipating how patients will react. Based on her assessment she had determined that her patient was 'compliant' and 'coherent'. Her injury occurred during the second injection; the first injection gave no indication that the patient would resist.
There seemed to also be recognition that safety needles that need to be manually activated are particularly limiting in these types of situations. The following quote highlights how safety needles that need to be manually activated can be less effective in protecting staff from injury:

We have the cap that flips over the needles, the butterflies have a little device that you retract up, not the easiest device to use but if you're in a contained stable environment it's fine but if you have a patient who's not very cooperative, I have been stuck by one of the butterflies before because I couldn't get the sleeve up to cover it...

Some explanations went beyond patient interactions and limitations in the design of safety needles to focus on broader structural problems. One organizational informant described how current budget constraints and subsequent increased workload demands may limit the impact of health and safety interventions:

It’s a big environmental factor. And it’s not something that hospitals really can fix because they don’t have the money to fix it...I am not saying it’s a staff problem or it’s a hospital problem I am just saying that you know, if you can only get so much money to do so many things than the workload still falls on the staff, it’s the frontline workers that are the ones that are having to do all the work, it’s do more with less and do it faster and the faster part is a big problem because when you try to do something faster and you’re trying to move onto something else then people not necessarily even get careless it’s just you try to do it and something happens, that’s when people have accidents. Not even just with the safety engineered devices it’s the slips, trips and falls, it’s everything else.

It is important to capture different perspectives towards the source of ongoing injury risk as it may have important implications for whether or not future health and safety initiatives are supported. For example, staff may not advocate for safety advances when bigger structural problems are left unresolved.

The next section looks across the three cases to reveal a number of similarities in how the three organizations under study reached the full operation stage. Despite ongoing injury risk, there were limited ongoing activities to monitor, reinforce and support the use of SENs. While all three cases had integrated SENs, there was limited availability of more advanced passive SENs.

8.2 Reaching Full Operation

The final stage of implementation has been defined by Lewin as the ‘refreeze’ stage. As reviewed in Section 4.7, this stage has also been referred to as the full operation stage. All three hospitals
under study had transitioned to SENs. There were written policies and procedures in place stating a commitment to make SENs available and outlining specific responsibilities for front-line staff, supervisors, the JHSC, and the occupational health and safety department. As the case reports highlighted, a number of concerns were raised by staff early during the transition process; however, health and safety staff reported that more recently, there have been no specific problems raised with the current stock of SENs. There were a number of accounts from front-line workers that reflected positive views towards the transition to SENs and the impact of these devices on needlestick injury risk.

The final stage of implementation has been characterized by monitoring and adjusting in response to ongoing problems. Relevant activities were described in the case reports. For example, hospital A had implemented a new semi-automatic safety butterfly needle when there were ongoing injuries with the original safety device. Hospital C responded to an increase in sharps injuries by conducting a root cause analysis. When the underlying issue appeared to be due to confusion over who was responsible for emptying overfilled sharps disposal bins, reminders were distributed to problem areas. While hospital B continued to monitor needlestick injuries, there were no reports of any recent efforts to address ongoing needlestick.

Overall, ongoing activities to monitor and reinforce practice appeared to be more reactive in nature; action would be taken only when there was a notable increase in injuries. As the injury reports collected by the occupational health and safety department directly informed actions and priorities that were initiated, it is important to consider how this form of surveillance can adequately capture ongoing issues. There was a shared view among front-line workers that not all injuries get reported. It was learned that reporting in some cases had a lot to do with perceived risk:

> There’s a lot of people who don’t do anything, if they’re like my patient’s low risk of any kind of disease transmission is it worth my time to go down, have my blood drawn, have a consent form done by the patient, have their blood drawn and then you know, like go through all the motions it’s a really, it’s a big procedure...

If injury reporting is related to perceived risk, the injuries reviewed by the health and safety department are unlikely to include potentially valuable information on the types of safety needles, circumstances, and procedures associated with injuries that are perceived to be low risk
including reports of near misses and injuries with sterile needles. The importance of reporting
injuries or near misses was articulated in all written policies and procedures that were reviewed.
Hospital C was the only case to have a policy that explicitly required front-line workers to report
unsafe acts and hazards and to keep and report any defective products. There were however, no
formal procedures in place to provide a system for this information to be obtained or to
encourage staff to report.

As reviewed in the three case reports, there were no ongoing activities to formally integrate
needlestick injury prevention into mandatory annual training. There were recommendations that
supported the use of more comprehensive training; however, these recommendations were to
support training for new products rather than re-training for SENs currently in use. One front-
line worker who had recently experienced an injury herself and had also observed a number of
practice issues on her unit, emphasized the importance of reminders as a means to communicate
with staff about the importance of adhering to safety practices:

Review of the basic principles, it feels like people become, they develop a sense of
redundancy to the basic practices somehow their mind becomes immune so it has to
be reiterated to the staff what is the right thing to do.

What is being emphasized is that over time people do not necessarily forget how the safety
devices work but staff may need to be reminded that needlestick injuries do still occur with the
use of SENs and how these injuries can be prevented.

Organizational informants were asked about whether or not passive safety needles were
considered during the selection process or whether they might be considered in the future. As
reviewed in Section 2.3.3, there is cumulative evidence supporting the added protection provided
by passive SENs. The debate over whether the organization should move to passive safety
devices did come up during the interviews with both front-line workers and organizational
informants. As reviewed in Section 1.1, one way in which safety devices have been classified is
whether the safety component is manual, semi-automatic (activated with the push of a button), or
passive. There were a number of examples where front-line staff expressed a preference for the
use of semi-automatic or passive safety devices over safety needles that require manual
activation. All three sites had adopted semi-automatic safety devices (e.g., the needle retracts
with the push of a button). Hospital C was the only site that had adopted a passive safety device
in select areas. There was hesitancy and some doubt expressed by informants and front-line workers towards the increased use of passive safety needles. The next section will further examine how organizational conditions, external influences and shared beliefs may influence plans to investment in future needlestick prevention initiatives.

8.3 Ongoing Investment in Needlestick Injury Prevention

There were a number of organizational conditions and beliefs that were identified as dampening further motivation to make additional improvements to the needlestick injury prevention program. Relevant themes were organized under existing concepts defined by the organizational readiness for change model previously outlined in Section 4.7 including change valence, informational assessment and contextual influences.

8.3.1 Change valence

It is important to consider whether further advances in needlestick injury prevention are needed, important, beneficial or worthwhile. There were a number of front-line workers that were not aware that needlestick injuries were continuing to occur or were surprised to hear that there were ongoing needlestick injuries. Among those who were aware of ongoing injury risk, there were some alternative perspectives towards whether or not ongoing injury risk was an important problem. The following quote is from one of the organizational informants at hospital A who felt that 100 needlestick injuries each year is low considering the size of the organization:

When you look at it, I think there’s about 5-6000 nurses across the [hospital sites] and 12,000 employees, when you look at that number that’s pretty small, so it is quite low I think.

This perspective was echoed by another informant at the same hospital:

When it comes to needlestick injuries, the incidents that I have looked at, there hasn’t been a lot of needlestick injuries ... there still are some needlestick injuries but they’re small and a lot of times it seems like the person you know, have documented they rushed so time seems to be a factor, so it’s more individual kind of slowing down and taking their time to do the process.

What can also be drawn out of this particular account is the view that the injury problem could potentially be optimally addressed by improvements to individual practice. As revealed in the previous section, there were a number of different drivers that were perceived to be influencing
ongoing injury risk. There was a shared belief that ongoing needlestick injuries were not only influenced by the nature of the safety devices being used but also individual adherence to safety precautions. As one front-line worker emphasized "at the end of the day the issue isn’t what the hospital has, the issue is how the staff uses it". Some staff may have different perspectives towards what is driving ongoing needlestick injuries and thus may also have different perspectives towards the value of investments in more advanced safer needle technology to address ongoing needlestick injuries.

An important force that will influence whether or not change is perceived to be worthwhile is the availability of information on the nature and magnitude of the problem. At hospital B, there was no data available to determine whether or not the plateau in needlestick injuries could be further reduced by investing in passive SENs. The organization was not routinely carrying out a root cause analysis when a needlestick injury was reported to the occupational health and safety department. There was no information to assess whether a different device could have prevented the injury.

There were some instances where staff expressed apprehension about the value of future investments to promote consistent and quality use of SENs and the need to improve the availability of SENs. For example, organizational informants at hospital B felt that the time investment involved in re-examining current exceptions would be unlikely to result in many product changes and thus was not perceived to be worthwhile. Another important consideration that is relevant to the importance of whether or not future change is perceived to be needed or worthwhile, is how front-line staff feel about the current stock of SENs and ongoing injury risk. Across all three cases, there was no collective push for the increased use of passive safety needles. The following quote is from a front-line worker who did express positive views towards the added value of passive SENs but also emphasized that staff are content with the current stock:

I do think that staff are quite happy with their safety engineered devices, I am not saying that, that they wouldn’t be happier if they have had their retractable, I would certainly think in certain cases it would be, it would be better, but I do think that, what we’ve got is certainly helping...
What was explored Section 7.3 was how front-line workers develop a level of comfort using a particular device and how changes can impact performance and perceptions towards the value of change. While staff appeared to have a number of challenges initially adapting to SENs that needed to be manually activated, these devices are now considered the norm. Future changes would again disrupt performance and initiate another learning curve.

Health and safety staff are unlikely to invest significant effort to move to more advanced safety needles if there is no feedback that suggests passive safety devices would be of value. Organizational informants emphasized that front-line staff do not ask for upgrades to the safety devices currently in use. Interviews with front-line workers who had recently been injured did present a very different perspective. A number of front-line staff expressed positive views towards the use of both semi-automatic and passive SENs, both in terms of the ease in which the safety could be activated and their ability to protect staff from injury. One of the nurses brought two safety devices to the interview to visually demonstrate why semi-automatic safety devices are easier to activate. All front-line workers who participated in an interviews and recently reported a needlestick injury expressed strong support for the use of passive SENs. The following quote is from a front-line worker who felt that a semi-automatic SEN could have prevented her injury:

I got one needlestick injury since I’ve been here and it happened so fast, so quick... as I [was] going over with OCC health, I thought I did almost everything right...I think the best thing that I am always for, is to have one of those retractions, like the IV one we have, it goes in and then locks by itself, you don’t have to take it out before you activate.

Another injured worker revealed that she had agreed to the interview because it provided an opportunity for her to demonstrate how needlestick injuries can still happen with some types of SENs. She also felt strongly that semi-automatic and passive SENs could further reduce injury risk. There were a number of workers who preferred using semi-automatic and passive safety devices. They seemed to value the ease and speed of activation. As one worker put it:

You’re 100% sure that you’re not going to stick yourself right? And the other ones that are not retractable, you have to be very careful with them.

Staff tended to focus on the differences between manual safety devices and semi-automatic devices. Few staff at hospitals A and B had the opportunity to work with truly passive SENs. A
theme that helped explain why there may be varied perceptions towards the importance of additional investment in needlestick injury prevention centered on being 'in the know'. Being 'in the know' was defined as having experience or information that a problem exists and the ability to envision how the problem could be addressed. Injured workers could draw on their experiences to reflect on how needlestick injuries could still occur and where improvements could be made to the design of SENs; however, there were a number of front-line staff that were unaware that needlestick injuries continued to be reported.

The following quote is from an organizational informant who recognized that a number of staff may not be aware of safety device alternatives beyond what is currently available at the hospital:

Another thing too a lot of people work at different hospitals so we have this one and it’s a passive device so they like it better so there’s those, if everybody just worked here nobody would know but people work outside the hospital all of a sudden they have different devices somewhere...

It was often difficult for front-line workers to talk about the safety components on the devices they used. Some front-line staff did not have the expertise to envision how current safety needles could be improved:

We do have blunt tip needles for withdrawing liquids from a vial for instance whereas before we used to use a regular needle to withdraw fluids now we have a blunt tip needle which is great, less chance of injury with it, but for any of the injections, suturing you definitely would still need to have a regular sharp needle, you can’t really get away from it, I don’t see how you could.

Blunt tip suture needles have been on the market for a number of years; however, it does not follow that front-line staff would have had the opportunity to work with these devices or know that they even exist. To better facilitate a smooth transition to SENs, a number of informants emphasized the importance of getting "buy-in" from staff. The assumption being that if staff are made aware of the risks associated with needlestick injuries they will be more likely to understand and support the transition to SENs. As a number of front-line staff are not aware that injuries continue to occur and are not informed about different safety alternatives, they are unlikely to perceive the need for change and express support for future improvements in safer needle technology.
The drive to pursue additional activities to support consistent and quality use of SENs (e.g., re-training, reminders, risk communication) and adopt passive SENs was examined in this section considering whether changes are valued, needed or considered worthwhile. There were a number of conditions that suggest why change valence may be low including lack of awareness of ongoing injury risk; different views over whether ongoing needlestick injuries could be further reduced; whether the investment required would be worthwhile; variation in perceptions towards what needs to be changed; and lack of information on whether ongoing injuries could be impacted by those changes. This section demonstrated a number of ways in which different values towards needlestick injury prevention can influence further commitments to ongoing needlestick injury prevention. The next section will examine the role of 'information assessment'.

8.3.2 Informational assessment

There were a number of conditions and perceptions shared by front-line staff and organizational informants that revealed influences on the appraisal of the capacity for further change. **Perceptions of available financial resources** were an important consideration when SENs were initially selected. It also appears to continue to be an important influence on whether organizations move to more advanced safety technology. The most prevalent trade-off associated with the move to SENs was the added cost of these devices relative to conventional non-safety needles and syringes. Hospital B was the only case that had conducted a formal assessment of the cost impact following the implementation of SENs. Overall, costs increased by 52% percent from $351,400 to $735,600. Front-line staff acknowledged the cost implications of moving to passive safety devices or even semi-automatic safety devices. The following quote is from a front-line worker at hospital A, who was doubtful about further investments in more advanced safer needle technology:

> A retractable would be better it’s a much higher cost and right now everybody is cutting so much that I can’t imagine them bringing anything more in...

With knowledge of constrained budgets and the increased costs of more advanced SENs, staff may not advocate for change because they don’t perceive change as feasible. One of the front-line workers was hesitant to even make recommendations:

> There are some concerns I have but I am not sure how they could be, I mean it’s going to cost a lot more money to implement them.
Safer needle regulation did not appear to promote the uptake of the most effective SENs available. Cost dependency in how SENs were selected was an important theme identified across the three cases. How SENs were approved and plans for future investments in safer needle technology were largely dependent on cost considerations. The following quote is from one of the organizational informants at hospital B who believed that the hospital was unlikely to increase the use of semi-automatic and passive safety devices unless there was no difference in cost.

So in order for us to propose something like that we would have to make the justification on why. But if we see that now we’re ... paying 18 cents for eclipse, now the safety glide, if there’s a reduction in price, now the safety glide is 18 cents, so it doesn’t cost the hospital more... [if] it’s feasible in neutral costs [for] better technology then we may get the buy in from senior management to say okay now you can convert.

Decisions to invest in safer needle technology beyond the minimum requirements under the regulation appeared to be influenced in part by the perceived risk and burden of injury. Hospital C had implemented more advanced passive SENs in select areas where there were increased levels of violence including emergency, psychiatry and areas of long-term care. One of the organizational informants at hospital B emphasized that going beyond the minimum requirements of the regulation to consider adopting other SEMS was very much dependent on injury risk:

Other types of safety sharps haven’t been.... I think we have probably a mixed bag of those, I wouldn’t say 50:50 but you have some safety and some non-safety. We don’t because of regulation, we wouldn’t be so stringent in what we use again based on risk, we look at our needles, our sharps injuries and we track them so we were able to determine if there some type of causation

The health and safety staff at hospital A described efforts they had taken to get a semi-automatic safety butterfly needle approved when injuries were continuing to occur with the original manual safety device that had been selected. The challenges they encountered getting approval from finance demonstrated that ongoing injury risk may not be adequate justification to invest in more advanced SENs. As reviewed in this case report, the health and safety staff had to present a cost recovery assessment. They needed to show how much could be saved if these injuries could be avoided. In the end, to get the new safety devices approved, the product vendor had to guarantee
that injuries would be reduced to a certain point or they would refund them the difference in price.

There were also a number of situational influences that had important implications over whether or not further investments in needlestick injury prevention would be made. The influence of other internal priorities was particularly relevant. As outlined in the case reports, needlestick injury prevention did not appear to be an important topic relative to other health and safety issues. The health and safety departments at all three sites were engaged in other activities including violence prevention and musculoskeletal training and the implementation of patient lifting devices. In Section 7.2.1, the theme 'change fatigue' was presented. It also has relevance here. Change fatigue was examined as one potential influence on how front-line workers respond to product changes. It may also influence ongoing investment in needlestick injury prevention.

As reviewed earlier in this chapter, one of the informants at hospital A was reluctant to support re-training on needlestick injury prevention as staff were currently having to complete specific training to support a number of other administrative changes at the hospital.

8.3.3 Contextual influences

It is important to also acknowledge other broader contextual conditions that may influence future investments to advance needlestick injury prevention. Weiner theorized that past experience with change can positively or negatively impact whether or not future changes are valued, worthwhile or even feasible. Organizational informants across the three case sites did describe the complicated logistics involved in the initial transition to SENs and as revealed in the case reports, there were a number of issues in the beginning getting staff to adapt to the use of SENs. These experiences may have an important influence on perceptions towards whether future investments will deliver benefits and be valued by front-line workers. At one of the hospitals, a passive safety device had been implemented in the last year and received lots of negative feedback over the more bulky design. Staff reported that the new device disrupted sightlines and it was more difficult to confirm whether the device was inserted correctly. Some felt that it was more difficult to insert the needle or that it resulted in more discomfort to the patient. While semi-automatic and passive safety devices have been found to be superior in preventing needlestick injuries, these devices can actually be more difficult to get used to due to the more complicated design that is sometimes characteristic of these devices. There were a number of
front-line workers that did identify limitations with the design of these more advanced SENs.
The following quote is from a front-line worker who had encountered a number of issues with semi-automatic retractable safety devices:

Not everything can [be] put into those automatic self retractable [needles] but even those don’t work and, for example, literally for example last week and I was teaching a patient how to do Fragman she clicked it but it never retracted ... you really have to push it really hard ... sometimes even if I clicked it, it’s just stuck in there so you have to walk around with this needle sticking out to the sharps container right away before it hurts anyone. So, even the retractables don’t work sometimes.

Because performance is valued and clearly the feel of the device plays an important role, past challenges with the design of more advanced SENs may influence how staff respond to future product changes.

A final contextual influence worth considering is the external regulatory environment. The three case reports demonstrated the important influence external regulation had in promoting the uptake of SENs when budgetary constraints and other influences were dampening efforts to transition to these devices. While hospital C implemented SENs voluntarily before safer needle regulation came into effect, at that time, other jurisdictions were starting to move towards the mandatory use of SENs. The external political environment does not appear to be motivating further advances in the use of SEMS at this time. As outlined in Section 2.1, when Ontario’s regulation on needle safety was established, unions in Ontario did recommend that the regulatory requirements be extended to mandate the use of safety devices for all medical sharps; however, these recommendations were never adopted and no additional recommendations have been made to extend the requirements.

8.4 Conclusion

This chapter examined ongoing commitment to needlestick injury prevention. The post implementation phase was characterized by increased availability and use of SENs and declines in needlestick injuries. Ongoing implementation activities were described as reactive in nature. There were minimal examples of ongoing reinforcement and support to promote consistent and quality use of SENs and other measures to prevent needlestick injuries. Examining different perspectives shared by front-line workers and organizational informants revealed mixed
perceptions towards whether additional investments in needlestick injury prevention are important or worthwhile. Front-line staff that had recently experienced a needlestick injury showed greater appreciation for the use of passive or even semi-automatic safety devices over manual designs. Weiner's organizational readiness for change model (2009) supported a review of influences that may be dampening further investments in needlestick injury prevention including perceived resource constraints; inherent limitations in the design of more advanced passive safety devices; past implementation experiences; and the absence of any additional external motivation for change.
CHAPTER 9

Discussion

The purpose of this study was to examine how acute care hospitals responded to a regulatory standard promoting the uptake of SENs, to describe the consequences of adopting SENs, and to identify remaining issues associated with the integration of these devices. Available surveillance data for Ontario demonstrated that needlestick injuries captured in work-related emergency department records and workers’ compensation claims have not declined substantially. While all three hospitals under study responded to the regulatory requirements with integrity, there was evidence of inconsistent implementation processes and outcomes across the three cases, which may have been due to variation in the types of SENs that had been integrated, the organization’s readiness for change, and the implementation practices that were adopted. Across all three sites, professional values and organizational constraints challenged the integration of SENs. Ongoing commitment to support safer needle use, to monitor the use and effectiveness of SENs, and to act on product issues helped overcome implementation problems. Ongoing activities to address needlestick injuries were described as reactive in nature and heavily reliant on injury data that is to some extent limited by under-reporting. A number of explanations were identified for the lack of additional investments in needlestick injury prevention including a lack of awareness of ongoing injury risk; different views over whether ongoing needlestick injuries could be further reduced; whether the investment required would be worthwhile; variation in perceptions towards what needs to be changed; and lack of information on whether ongoing injuries could be impacted by those changes. Further progress also seems to be heavily influenced by perceived financial constraints and a number of competing health and safety issues.

The substantive content of this study fills an important gap in the literature by providing a contextualized account of why a regulatory standard may be limited in being able to produce dramatic declines in needlestick injuries and where there is a need for a multi-faceted approach to needlestick injury prevention. By drawing on concepts and theories from implementation science and examining their utility as an explanatory framework, this study has also demonstrated how an existing model of organizational implementation effectiveness could be used to study implementation under a regulatory framework. This final chapter further examines the case study findings drawing on existing theory and previous studies. Section 9.5 draws on the
case study findings to point to strengths and limitations of regulation for promoting the integration of health and safety innovations. Potential contributions to implementation science theory will be explored in Section 9.6. Methodological issues encountered during the study will be reviewed in detail in Section 9.7. The final section provides an overview of a number of practical lessons learned about the implementation of SENs.

9.1 Implementation Conditions

This study observed variation in the outcomes of the transition to SENs across the three hospitals. This drew attention to differences across the three sites in the strategies, structures and support systems. What stood out from the cross-case comparison was the variation in the underlying conditions and motivations for implementing SENs. External motivators appeared to have an important influence on the decision to adopt SENs at hospital A and B. Hospital C voluntarily transitioned to SENs and was considered to be intrinsically motivated. A number of authors have examined the influence of intrinsic and extrinsic motivators on individual behaviour (156-158). Hospital A was described as having a low readiness for change when the organization responded to the regulatory standard. There was little internal motivation for the adoption of SENs, a recent unsuccessful implementation experience, and a short period of time available to transition before the regulation came into effect. It is possible to hypothesize that a regulatory standard may be most effective when there is some level of readiness to support necessary implementation efforts (e.g., implementation champion, available resources) yet additional momentum is needed to get approval from senior management. This was reflected in the implementation experience at hospital B where there were groups within the organization that wanted to transition to SENs and were ready to commit to the implementation process; however, commitment from senior management was lacking. The case studies provided an interesting opportunity to examine variation in organizational readiness for change and implications on the implementation experience. There have been limited opportunities to study organizations that adopt a new innovation while having a low readiness for change.

9.2 Safer Needle Use

The case study reports revealed that while the integration of SENs was for the health and safety of employees, it did not follow that all the devices were immediately accepted and used by front-
line workers. Some front-line staff would either not activate the safety feature or would physically remove it from the device. These practices are consistent with findings from previous studies that have identified inactive safety devices in sharps disposal bins (20;42). There have also been commentaries that have brought attention to this issue previously (159;160).

‘Change resistance’ has been a topic of interest in the organizational change literature. It has been defined as “negative and disruptive behaviors that jeopardize the change process and its desired outcomes” (161, p 1). The accounts of front-line workers not following safety procedures including the activation of SENs, despite the use of training and education, is in line with previous studies that have demonstrated that healthcare workers may recognize safety policies and procedures and understand the rationale behind them, but not always put them into practice (162). There are a number of influences at different levels that can account for the ‘change resistance’ that was observed. At hospital A, where SENs had to be integrated within a very short time period, resistance to change was in part attributed to employees responding more generally to an overload of changes at the hospital. The concept ‘change fatigue’ has been studied in the organizational change literature and recently discussed in relation to nursing practice. It has yet to be integrated into the study of implementation success and failure. Change fatigue has been defined as “overwhelming feelings of stress, exhaustion, and burnout associated with rapid and continuous change in the workplace” (161, p 1) and has been linked to increases in biological stress markers and sick leave days among healthcare workers (163). Hasson et al. (163) describes a number of changes in healthcare that can contribute to ‘change overload’ including changes to nursing scope of practice, human resource allocation, and technology.

Another consideration is the nature of the change process itself. Episodic change in general has been attributed to fatigue, apathy, or resistance to change efforts (164-167). The transition to SENs under a regulatory standard can be described as an episodic change, which has been conceptualized in the organizational change literature as changes that “occur in distinct periods during which shifts are precipitated by external events such as technology change or internal events such as change in key personnel” (168, p 179). This type of change tends to be dramatic and externally driven. In contrast, continuous change is constant, evolving and cumulative (168). A more gradual transition to SENs, which was more characteristic of the transition experience at hospital C, can be considered more of a continuous change. One could argue that every hospital
is undergoing a number of constant changes. The form of continuous change described here can be distinguished by changes that are small and more proactive rather than large scale changes that are more reactive in nature. While regulation initiates an externally driven change process, there is the option to promote a more continuous change process through a longer advanced warning period of 3-5 years. Perhaps one of the weaknesses in Ontario was the abrupt introduction of the regulatory requirements; however, there was a national campaign than ran before the regulation was established to raise awareness about needlestick injury risk and how these types of injuries could be prevented through the increased use of SENs.

This study described the influence of organizational conditions, the nature of the change process and professional or organizational values on safer needle use. Other authors have also looked more generally at why nurses in particular do not always comply with organizational policies and practices and have described a number of other influences. Drach-Zahavy and Somech (162) discuss previous research that has focused on examining structural influences on noncompliance to precautions, policies and safety procedures. Previous research has looked at low staffing levels (169); working conditions (170); rotating shift work, fatigue and sleep disorders (171;172); and heavy workloads (171;173). A number of participants attributed ongoing needlestick injuries to consequences of the work environment including current budget constraints and subsequent increased workload demands. These types of influences are important but the implications of attributing the problem of ongoing injury risk to environmental conditions alone may not lead to timely countermeasures.

Previous research has also examined individual characteristics on risk taking behaviour among nurses (162) including nurses’ knowledge of safety risks and adequate precautions to cope with hazards (171;174); risk perceptions; and work engagement (170). In addition to focusing too heavily on structural influences, Reason (175) also warns against a ‘blame trap’ where focusing on individuals can overestimate personal factors, which can then deter efforts to learn from the incident and to identify areas for improvement (162). While the case studies were able to explore a number of influences on safer needle use, it is recognized that there are a number of other conditions and influences at play. As demonstrated in this section, measures to promote the use of health and safety interventions should consider multiple levels of influences.
9.3 Innovation-values Fit

Chapter 7 described how a number of informants and front-line workers connected patient safety to the integration of SENs and how this served to justify investments in safer needle technology. Displacing the value of occupational health and safety interventions from workers to patients was also described by Myers (176) who examined how work cultures of nurses and physical and occupational therapists were related to the adoption of patient lifting devices. Both nurses and physical and occupational therapists displayed a patient first approach to care-giving. Patient lifting devices were valued for potential patient benefits, not necessarily for staff safety benefits. In this study, explanations for why safer needles were not always used were also linked to patient care considerations. Other researchers have also described this conflict between providing optimal patient care and protecting oneself from exposure (162;162;177). Drach-Zahavy and Somech (162) examined nurses’ implicit rules for when and how to protect themselves. One of the themes they discussed in-depth centered on “continuing to care for patients in as efficient and caring a manner as possible, even at the expense of not protecting oneself” (162, p 1409). They found that nurses would choose to 'cut corners', ignore safety procedures, and continue caring for patients without taking the necessary precautions. Applied to the use of SENs, the possibility of injury and risk of infection is deferred and the importance of treating a patient quickly and effectively is more proximal. It is interesting to note that values toward prioritizing the safety of others before one’s own safety have also been discussed from a gender perspective (178). As nursing has deep historical roots as a gendered profession, there are shared professional values that can be traced to what has been traditionally viewed as feminine qualities of compassion and self-sacrifice (179).

Information on underlying values that guide practice and perspectives towards new innovations, such as the ones reviewed in this section, should be considered when planning how long it will take to integrate a new innovation into practice and what communication strategies should be used to anticipate implementation challenges. The utility of this type of insight has been discussed previously by Rowe et al. (180): “if managers want to promote certain practices, such as those in a guideline, they need to understand the existing and evolving influences that promote desirable and undesirable practices” (p 1027).
A number of influences on safer needle use have been explored. It is important to also acknowledge the positive side to ‘change resistance’. McMillan and Perron (161) reviewed previous literature on change resistance that has focused specifically on limitations of this perspective arguing that it can be used to “dismiss potentially valid employee concerns about proposed changes” (p 784). This is very much relevant to the case study findings where specific SENs were found during product evaluations and upon full implementation to cause a number of problems including increased needlestick injuries. It was important to ensure that employee concerns were investigated.

9.4 Ongoing Needlestick Injuries

Chapter 3 examined trends in needlestick injuries captured by compensation claims and work-related emergency department records. What was emphasized in relation to this data was that despite a system wide transition to SENs, needlestick injuries continue to occur. Ongoing injuries following the transition to SENs have been described in other jurisdictions (18;92) and in the product trials that were reviewed in Chapter 3. The three case studies suggest that there might be considerable variation in the degree to which needlestick injuries are continuing to occur across hospitals in Ontario. Hospital C had dramatically reduced their number of needlestick injuries and was only observing a small number of incidents each year with periodic increases corresponding to influxes in new residents. Organizational informants at Hospital B discussed at length a ‘plateau’ that they had been observing. Hospital A had only observed a 28% decline in the number of needlestick injuries reported annually.

This case study made an important contribution by examining in more detail what might be contributing to ongoing injury risk and also how front-line workers attribute the source of ongoing injury risk. Being able to study an organization in depth enabled the use of multiple data sources to better understand ongoing needlestick injuries. Three sources of data were used to describe why needlestick injuries continue to occur including accounts from front-line workers, accounts from organizational informants who routinely monitor injury data and more directly administrative records of needlestick injuries.

Three pathways for ongoing injury risk were described including injuries that occur during a procedure, often as a result of patient action; injuries that occur after a procedure before the
safety feature is activated or when the safety feature is left inactive; and injuries that occur during disposal when sharps disposal containers are overfilled and when needles have not been activated. While the study was able to describe three pathways where needlestick injuries can still occur despite the transition to SENs, the dissertation did not do a formal accident investigation of needlestick injuries. Therefore the results of this study cannot point to which of these three pathways is most responsible for ongoing injury.

Interviewees did discuss at length the risk of injury arising from patient action. Injuries that are a consequence of interactions with patients were perceived as very difficult to control or anticipate. It is important to examine opportunities for these types of injuries to be avoided. Increased use of co-worker support to administer treatment to patients is an option; however, as one front-line worker emphasized, you cannot always anticipate that an interaction with a patient will require this form of support. There is also the issue of workload demands, which may not always provide opportunities for two nurses to support the delivery of treatment to a single patient. The hierarchy of control model describes measures that remove hazards as preferable over measures that focus on built-in safety features. There would be value in considering opportunities to increase the use of needleless devices including the administration of treatment through other delivery routes.

Ongoing injury risk attributed to inactivate and overfilled sharps disposal bins may be amendable to interventions that promote increased adherence to safety practices and awareness of ongoing injury risk. A number of interviewees emphasized that these types of issues can be impacted by broader structural problems including workload demands. Addressing structural influences may not always be practical, feasible or timely and a sole focus on individual practice may put too much emphasis on the individual. There needs to be a fine balance between developing immediate and effective countermeasures that will further the prevention of needlestick injuries and at the same time, acknowledging the multiple influences on not only needlestick injury risk but other occupational hazards.

There is a need to consider advances in the design of SENs and access to more advanced design options as injuries continue to occur after procedures and during the activation of SENs. All hospitals under study continued to use manual safety devices. Not all SENs are equally effective, easy to use and able to eliminate needlestick injuries. Figure 6 outlined an adapted version of the
implementation effectiveness model. What was emphasized in Chapter 4 and conceptually outlined in Figure 6 was that organizational benefits from an innovation will only be realized if, in addition to being implemented effectively, the innovation was initially efficacious and remained so during implementation. This study provided an interesting opportunity to reflect on this. Organizations are given complete freedom to choose how to implement SENs and what types of devices should be selected. The most effective SEN will not always be selected due to a number of considerations including budgetary constraints. What appeared to be important in addressing ongoing issues with SENs was a commitment to monitor needlestick injuries and the devices associated with these injuries. Hospital A had integrated a SEN that was found to actually increase needlestick injuries. Front-line workers had difficulty adapting to the use of the new device and they developed measures to avoid using the safety feature. What appeared to be important was the use of comprehensive implementation practices to select, test and evaluate safety device options, reinforce training, and to monitor the use of the devices and their impact on needlestick injuries.

9.5 The Use of Regulation to Support the Integration of SENs

A recent systematic review of occupational safety and health enforcement tools concluded that “inspections as an enforcement tool have inconsistent effects in the short term but they do decrease injury rates after more than three years follow-up” (181, p 28). This finding may also be true for organizations responding to a regulatory standard. This conclusion seems to align with the idea that regulation and enforcement tools may require a period of adaption before significant gains in reduced injury rates can be observed. What was apparent across the three cases was that the transition to SENs required time for product selection, evaluation and implementation and there were cases where, as a result of ongoing injuries, there was a need to cycle back and try out different products. The transition from conventional needles to SENs was not smooth for all front-line workers: a period of adaption was required.

This study provided an interesting opportunity to describe how safer needle regulation has influenced organizations in their transition to SENs. Regulation can have an important influence on the uptake of SENs when there is low readiness for change motivating organizations to elevate needlestick injury prevention on their list of priorities. In addition to initiating the adoption of SENs, regulation also appeared to play an important role on the implementation
process. When SENs were adopted by the three hospitals under study, some of the safety devices were found to be awkward to use, the safety features were not always used as intended and injuries continued to occur. However, the organization could not revert back to the old devices. They were motivated to look for solutions and develop comprehensive implementation supports to comply with the regulatory standard. Regulation can support more successful implementation by motivating the use of implementation practices that address implementation barriers to avoid product failure.

There were a number of implementation challenges that can be attributed to organizational change in response to a regulatory standard. There were a number of front-line staff who were not committed to safer needle use during the initial implementation phase. This was attributed to the initial impact of the new devices on clinical practice. When the drive to adopt a new innovation does not originate internally and the innovation is inconsistent with professional values, this can challenge the implementation process. When organizations choose to wait until regulation is formally established this leaves a short time frame for compliance, which can impose a burden on staff that need to adapt to multiple product changes and limit opportunities to invest in comprehensive implementation practices.

There was value in not waiting for the regulation to be formally established. Hospitals that transitioned voluntarily would have been able to stagger the implementation process working around other changes at the hospital. This emphasized a need to ensure that there are a number of efforts to establish lines of communication between stakeholders involved in developing regulation and the organizations that will be impacted by the regulatory requirements to motivate early adoption.

Regulation alone can only encourage organizations to meet the minimum requirements for safety. Only one of the cases under study had implemented a truly passive SEN in high-risk areas. There did not seem to be sufficient internal and external motivation to invest time, human or financial resources to advance prevention efforts to address ongoing needlestick injuries.

9.6 Contributions to Implementation Science

Chapter 4 described an adapted version of the organizational implementation effectiveness model. This model has been used to examine implementation effectiveness within organizations that are voluntarily adopting a new innovation or program. The model was found to be relevant
to the study of implementation effectiveness under a regulatory framework and served as an important explanatory framework in this study. The organizational readiness for change concept was drawn on extensively to examine different conditions that precipitated the transition to SENs and what might be preventing organizations from continuing to invest in needlestick injury prevention. Aligned with the organizational implementation effectiveness model, **implementation champions** were described by informants as being integral to the implementation process. Previously the importance of **comprehensive implementation policies and practices** were also described in reference to activities initiated to address implementation challenges. **Management support** stood out as an important influence on the implementation experience. Two of the hospitals had encountered issues getting senior management approval to support the initial transition to SENs and to invest in more advanced SENs. Senior management support was described as being an important contributor to the smooth transition experience at hospital C. It is important to also consider the impact of physician support. Physicians were described as being most resistant in the transition to SENs. In the healthcare sector, physician support may play an important role in supporting the adoption of new innovations and also influencing the behaviour and perceptions of other workers.

There were a number of organizational constraints that influenced the implementation process. Helfrich (67) described a few limitations with the organizational implementation effectiveness model including the lack of attention given to the organizational context and external environment. This case study has provided an interesting opportunity to examine the influence of the organizational context and external environment and how these elements influence core implementation processes.

The staffing structure characteristic of hospitals and other healthcare institutions can challenge the delivery of training. Organizational informants and front-line workers described the challenges associated with reaching staff that work over the 24-hour clock and 7 days a week. Front-line workers described how they often could not attend training as they felt that there was inadequate support to leave their patients. Broader organizational conditions also seemed to have an important influence on how front-line workers valued the use of SENs. The influence of change fatigue was described where front-line workers’ discontent with the transition to SENs was not understood to be directly related to the value of the safety features but rather a reaction to a number of other concurrent changes happening at the hospital. The concept ‘innovation-
values fit” described by the organizational implementation effectiveness model (29) was integral to understanding the implementation experience and why front-line workers do not always activate the safety features on the devices. A performance first and patient safety focus seemed to be engrained into their practice and the initial learning curve associated with the transition to SENs was incongruent with these values. Figure 4 presents another version of the organizational implementation effectiveness model that was modified to support the findings of this case study.

Figure 8: Modified implementation effectiveness model for organizational change under a regulatory framework (29;30;66;67)

Three additions were made. Regulation was added to the model as it was found to have an important influence on stimulating organizational readiness for change, bypassing the need for traditional readiness criteria. Regulation was also found to have an important influence on motivating organizations to develop strategies to address implementation challenges as opposed to abandoning the innovation when it was not well accepted by staff or did not produce immediate gains for reduced needlestick injuries. The influence of external resources was also added to the model. Product vendors had an important role in supporting the use of comprehensive implementation practices transferring some of the workload off the organization: an important facilitator for organizations with strained human and financial resources. Physician support was also added as a potential influence that will require further research.

The purpose of this case study was not to test the structure of the organizational implementation effectiveness model but rather to examine how it could be used or adapted as an explanatory framework. The core components of the implementation effectiveness model, with some
additions, proved to have a lot of utility as an explanatory framework in studying the implementation of a regulatory standard.

9.7 Methodological Issues

A number of strengths of this study have been described including the ability to obtain input from informants representing a number of different occupational groups, the opportunity to retrospectively study implementation in depth, and to examine implementation effectiveness under a regulatory context. It is important to also acknowledge some of the methodological issues and challenges that were encountered.

9.7.1 Recruitment challenges

There were a number of challenges encountered during the recruitment process. It was difficult to get access to front-line nurses. There was very limited response to the initial recruitment emails that were distributed to a random sample of staff. There are a number of explanations available to account for low levels of engagement. The recruitment email may not have stood out amongst the high volume of emails distributed to staff. Front-line staff that were not working at the hospital when SENs were initially implemented may have felt that they were not able to provide enough information on the topic. It was anticipated that some front-line workers would find it challenging to commit to an interview based on current workload demands. Recruitment was more successful when the snow-ball sampling strategy was used. Early contacts were able to identify coworkers that would be interested in participating, who would have been with the organization during the transition, and who used SENs routinely in their practice. This recruitment strategy was also perceived to be more useful in getting input from staff that had recently experienced an injury.

As outlined in Chapter 5, 11 hospitals were contacted during the recruitment process. A small number of hospitals provided reasons for not participating which included attrition of employees who could speak to the transition process. However, a number of hospitals did not provide a clear explanation for not participating. Participation could have also been linked to the extent to which the organization had initiated the integration of SENs, ongoing implementation challenges, or were overall not pleased with how the transition process played out. It is important to emphasize that hospitals that agree to participate may be different from hospitals that choose
not to participate. What was interesting was that the three hospitals that did choose to participate all revealed a number of implementation challenges and described limited ongoing efforts to advance needlestick injury prevention. None of the hospitals under study were hesitant about describing implementation challenges. There was also substantial variation in the motives for change and outcomes of the transition.

9.7.2 The representation of participants

Table 2 in Chapter 6 described the characteristics of the interviewees that participated. The primary informant category included registered nurses or registered practical nurses, organizational informants and clinical managers or supervisors. An important clinical group missing from the analysis was physicians. Informants at hospital A described this particular clinical group as being resistant to the integration of SENs at all phases of the transition. Interviews with key informants also identified physicians as a group that responded differently to the integration of SENs putting more emphasis on the potential for these devices to disrupt clinical practice rather than provide a safer work environment. A limitation of the study was the absence of representation from this group. A number of contacts and informants emphasized the challenges in recruiting physicians to participate in research would require an interview due to the time commitment involved. Examining the divergent views of physicians towards SENs and SEMS would be a valuable future contribution to this area.

Approximately a third of respondents were currently or were previously a member of the JHSC in addition to their role as a front-line nurse, manager or health and safety professional. It is important to recognize that there was a lot of input from staff who might be more inclined to describe health and safety efforts at the hospital in a more positive light or even to convey a stronger interest in supporting efforts to further advance needlestick injury prevention. It is also worth considering the value in having a number of staff from the JHSC involved in the study as their position provided them with insight on where there might be limitations with current prevention efforts; how the organization continues to support initiatives to prevent needlestick injuries; and trends in needlestick injuries based on regular reviews of incident reports.

It is also important to note that a large proportion of respondents were with the organization for greater than 10 years. This was in part influenced by an interest in obtaining input from front-line workers and organizational informants who were with the organization during the transition to
SENs. Staff may have felt more inclined to participate if they had the opportunity to work with conventional needles prior to the transition. It would have been interesting to be able to contrast perceptions from staff that were new to the profession at the time of the transition with staff who were more experienced.

9.7.3 The timing of the fieldwork

The study was focused on obtaining a retrospective account of the implementation process in addition to ongoing efforts to implement SENs. Chapter 5 discussed the implications of focusing on retrospective accounts of a change process (141). The timing of this study did provide a means to obtain information on the consequences of integrating the technology and what things are like now relative to when SENs were first implemented. However, there are a number of limitations to carrying out a case study with a retrospective focus. The study was unable to examine the complete implementation process to examine how interpretations of organizational change unfold over time. Recall bias can influence the accuracy and completeness of recollections of the implementation process including specific events or what resources were used in the process. Being able to access documentation from the implementation process did help fill information gaps and verify the information obtained from the informant interviews.

9.7.4 Interactions with other researchers

An important component of enhancing credibility to improve the overall trustworthiness of research is the ability to share and challenge observations and early findings in collaboration with other researchers. There were a number of limitations associated with having only one researcher carry out this study. For example, a number of qualitative studies have drawn on multiple project team members to have the data independently coded and then compared for agreement. In thinking about whether to describe the absence of this specific comparative exercise as a limitation, it is helpful to refer to the literature on the value and purpose of inter-rater reliability. First, there doesn’t seem to be a widespread agreement on the value of assessing inter-rater reliability in qualitative research (182). Post-modernist qualitative researchers (183) would be more inclined to recognize that different researchers would be expected to offer very different accounts of reality due to the multiple views of reality that can be present (182;183). Morse identifies the use of ‘external raters’ as more applicable to quantitative research and challenges the notion that different researchers would have similar interpretations or insights to
offer on limited data (184). Others have argued that that some level of correspondence would be expected to support the assessment of consistency to further the quality of arguments supporting an underlying interpretation of data.

The use of inter-rater reliability has been used in applications that have a more quantitative approach or less interpretive or descriptive approach to analysis where, for example, there may be an attempt to identify key factors or apply weights to pre-established variables (185). Reliability checks also seem to be applicable to projects that use coding as the primary analytical device. Armstrong and associates (182) examined the extent to which researchers showed consistency in their accounts and found that there was close agreement on the basic themes but the way in which the analysts packaged the themes varied to a large extent. This seems to support the idea that assessment of inter-rater reliability would be best suited for applications where there is a pre-established coding matrix. It also seems to be best suited for applications where coding is the main analytical device. A significant portion of this study was devoted to description and contextualization and less on data reduction as an analytical device. Coding was used initially as a navigational tool to support the development of the descriptive case study reports that were later condensed into their current form.

The position taken in this study was that being able to report on the level of agreement in an analysis process is less important than being able to obtain different insights on the data. During the conduct of this study, there were opportunities to present early data to classmates in a qualitative analysis course and share the early case study findings with colleagues and the thesis committee. There were also opportunities to share early case study results with study participants. In this study, the descriptive case reports provide an opportunity for others to apply their own lens and to draw out their own reflections on the underlying meaning of the case study findings.

When research is initiated by one researcher rather than a team of researchers, the researcher’s background and conceptual framework can have an important influence on the selection of interview questions, how information is analyzed and what findings are emphasized. It can however be more feasible to identify what literature and concepts guided the study and to describe how the researcher’s background influenced the data collection and analysis process through ongoing reflexivity. The reader can use this information to help understand how the case
study findings were approached and to also consider how different perspectives may have taken a different outlook or direction on the topic under study.

9.7.5 The method of data collection

It may be worthwhile to reflect back on the potential limitations and strengths in carrying out a qualitative case study approach as opposed to a quantitative survey. A survey administered to acute care hospitals in Ontario would have been able to report on the extent to which hospitals perceive themselves to be in compliance with Ontario’s regulation on needle safety, what outcomes have been observed, the extent to which specific resources and supports were perceived to be of value during the transition to SENs, and the types of challenges that were encountered. A qualitative approach enabled the use of open-ended questions to explore unexpected or unintended consequences associated with the implementation experience. Surveys are not typically designed to answer ‘why’ or ‘how’ questions. This study had an explanatory focus with an interest in understanding ongoing implementation challenges. For example, the qualitative approach provided an opportunity to examine how needlestick injuries were continuing to occur and why SENs were not initially accepted by front-line staff. In terms of policies and procedures used to support the implementation process, a survey would have provided a means to report on the extent to which specific processes and activities are in place to support the use of SENs; however, there would be limitations in being able to go further to examine how these processes and activities actually operate in practice. One of the most important contributions of the case study approach was the ability to obtain input from staff across the organization.

9.7.6 Generalizability

Generalizability is often discussed as a limitation of the case study approach. There are specific characteristics common to all research that is qualitative in nature that have been identified as problematic for ‘generalizability’. He identifies generalizability as a as an important barrier for case study research; however, argues that the specific issues that are raised are not applicable to the type of generalizability that is relevant to case study research. The same question regarding whether one can generalize from a single case is related to the question of whether we can generalize from a single experiment (28). Case studies are like experiments in that they are generalizable to theoretical propositions and "not to populations or universes" (28). As Yin (28)
describes, the goal is “to expand and generalize theories (analytical generalization) and not to enumerate frequencies (statistical generalization)” (p 15).

The purpose of this study was to look at how Ontario's regulation on needle safety is being implemented in context by providing three examples of how the regulatory requirements have been implemented in practice. The process does not aim to identify a small number of organizations that are statistically representative of a larger population of organizations targeted by the regulatory requirements. The process is being used to begin to develop theoretical propositions regarding why Ontario's regulation may be challenging to implement, why needlestick injuries continued to occur, and optimal conditions that support the successful implementation of a regulatory standard. It is important to consider 'transferability', a quality criterion specific to qualitative research. The case study design provided an in-depth description of the cases under study allowing others to evaluate the transferability of the findings or apply different perspectives towards the interpretation of the case study reports.

9.8 Lessons Learned

9.8.1 Facilitators and barriers associated with the implementation of SENs

An important strength of this study was the ability to draw pragmatic lessons learned about the implementation of SENs and how to further the prevention of needlestick injuries. There were a number of implementation supports that were perceived to have helped facilitate the integration of SENs including senior management support; starting the transition process early to allow for a phased in approach; obtaining product vendor assistance with the implementation process; developing strategies to increase awareness about the integration of new devices and needlestick injury risk among front-line staff; promoting ongoing communication between departments involved in facilitating the transition; identifying 'implementation champions'; and initiating implementation practices that support the timely identification of product issues. While product vendor support was identified as a key facilitator to the transition process, it is important to also acknowledge the limitations in relying entirely on product vendors during the product selection and evaluate phase considering their invested interest in the organization adopting one of their products. The product evaluation phase appears to be an essential step for identifying products
that will provide optimal levels of safety, identifying any potential limitations or issues with the design of the device, and collecting information that can be integrated into product training.

There appeared to be a lot of value in thinking beyond the use of SENs for needlestick injury prevention. Other safety practices and environmental considerations appeared to play an important role in ongoing injury risk including the use of sharps disposal bins and the placement of the containers. There is a need for ongoing efforts to ensure that safe work practices are reinforced and the workspace is designed to reduce the potential for injury.

An important challenge discussed by informants and front-line workers at all three sites was the delivery of adequate training to support the use of SENs. This appears to be an important issue not specific to the integration of SENs but to other forms of health and safety training. Staff should receive adequate support and encouragement to attend training sessions. There also appears to be the need for greater accountability in training attendance.

Another challenge discussed was reporting practices. Both training and injury or hazard reporting are important issues not only for needlestick injury prevention but for other occupational health and safety issues. There would be value in developing a new process or promoting awareness about current processes to report near misses or issues encountered with the use of SENs. It will be important to communicate with staff why this information is important and how it can be used.

9.8.2 A need for ongoing commitment to needlestick injury prevention

What was apparent across all three hospitals was that sharps injury prevention was not perceived to be a visible priority. While some efforts to address specific issues were discussed, front-line staff rarely were able to recount any recent communications about needlestick injury prevention. Staff may not necessarily forget how the safety devices work but may need to be reminded that needlestick injuries do still occur with the use of SENs and how these injuries can be prevented. One important activity that might help raise awareness would be to use existing communication forums (e.g., newsletters, posters, emails) to describe recent needlestick injuries and to report how many needlestick injuries are reported to the occupational health department on a regular basis. A number of front-line workers were unaware that needlestick injuries continued to occur.
Overall, ongoing activities to monitor and reinforce practice appeared to be more reactive in nature. Organizational informants at hospital B had listed a number of initiatives that could be taken to further reduce the plateau in needlestick injuries including a review of current exceptions; increased use of semi-automatic or passive SENs; root cause analyses of ongoing injuries; and having the product vendor come in to do a follow-up assessment. However, there were doubts that these initiatives would get any traction. Weiner's (135) organizational readiness for change model supported a review of influences that may be dampening further investments in needlestick injury prevention including perceived resource constraints; inherent limitations in the design of more advanced passive safety devices; difficult past implementation experiences; and the absence of any additional external and internal motivation for change.

If injury reporting is related to perceived risk, the injuries reviewed by the health and safety department are unlikely to include potentially valuable information on the types of safety needles, circumstances, and procedures associated with injuries that are perceived to be low risk including reports of near misses and injuries with sterile needles. There may be value in initiating other means to evaluate the burden of occupational exposures and injuries and to evaluate the degree of under-reporting. For example, an annual survey could be used to obtain anonymous data on injuries that occurred but were not reported. There would also be value in increasing the use of root cause analysis to examine the underlying influences on ongoing injury risk to determine what types of safety improvements may have the greatest impact on ongoing injuries.

Ongoing needlestick injuries and a lack of proactive activities to continue to support the prevention of sharps injuries emphasizes the need for a renewed commitment to further prevention efforts. Only one of the three hospitals under study had integrated truly passive safety needles in high-risk areas. Front-line staff that had recently experienced a needlestick injury strongly supported the use of passive or even semi-automatic safety devices over manual designs. Not all front-line workers shared this view and there were mixed perceptions as to whether or not more advanced safety devices could prevent further needlestick injuries. If perceptions towards the value of passive safety needles are linked to a recent injury experience, occupational health and safety staff may not receive a collective push from staff to adopt this technology. The integration of passive safety needles could potentially make an important contribution to further reduce risk of needlestick injuries. In order to evaluate the potential impact passive safety needles could make, it will be important to periodically carry out a root
cause analysis of ongoing needlestick injuries that are reported to the occupational health and safety department.

9.8.3 Enhanced surveillance efforts
There appears to be very limited work to monitor the impact and implementation of health and safety regulations in Ontario. British Columbia has established the WHITE database to centralize information on incidents in the healthcare sector. This database includes needlestick injuries that would not necessarily be captured in workers’ compensation claims. WorkSafeBC has been using on this database to monitor trends in needlestick injuries since the establishment of regulation on needle safety (92). There would be value in identifying opportunities to enhance surveillance prior to establishing regulatory standards in the province of Ontario to effectively monitor the impact of these types of interventions.

9.8.4 Improvements to safer needle technology
The organizations under study continued to document a number of exceptions for the use of SENs for areas where safety devices were not available or where a SEN interfered in some way with a specific procedure. There appears to be a number of opportunities to advance the availability of SEMS to prevent percutaneous injuries. Product vendors will need to continue to engage with organizations to identify specific opportunities to develop safety options for conventional sharps currently in use.

9.9 Conclusion
This dissertation drew on a qualitative case study design to provide insight on the implementation of Ontario’s regulation on needle safety. Berman drew attention to the idea that often there is much uncertainty in how policies will end up being implemented (186). This uncertainty cannot actually be reduced without removing the local flexibility that is necessary to make the policy work. Ontario’s regulation on needle safety was designed to provide local flexibility in the selection and implementation of SENs. The regulation’s success is heavily reliant on the actions and conditions of regulated workplaces. This was demonstrated in the implementation experiences of the three hospitals under study. While all three were in compliance with the regulatory requirements, there was substantial variation in the implementation processes and outcomes of the transition. The case reports revealed a number of
influences on how SENs were accepted and integrated into practice including how the new devices aligned with professional values towards performance and patient care in addition to broader organizational conditions. Implementation challenges required ongoing monitoring to ensure product issues were identified and addressed. As comprehensive implementation practices are integral to the success of regulatory change, there is the need to raise awareness about implementation best practices to support the successful integration of occupational health and safety interventions.

Ongoing monitoring and evaluation of system level interventions provides a mechanism to make improvements and provide evidence to support the use of similar types of interventions to address health problems. Ontario’s regulation was designed without any clear goal set for expected impacts on needlestick injuries and there was no strategy in place to support ongoing surveillance or evaluation. More research focused on identifying opportunities and methods to examine the impact of regulated change in the province could help support opportunities to address implementation problems and ensure that the expected outcomes of these types of investments are realized. As reviewed in Chapter 1, there hasn’t been any data from the CNSSN published since Ontario’s regulation came into effect. There would be value in analyzing this data to examine how the risk profile may have changed since workplaces in Ontario transitioned to SENs.

There are a number of different areas that would benefit from further research. This dissertation took a particular qualitative approach and used theory from the organizational change and implementation science literature to examine the prevention of needlestick injuries through regulated change. Further analysis on the topic drawing on different lenses and bodies of theory to further enrich our understanding of the injury issue is encouraged. A number of themes discussed in this dissertation centered around the important influence of organizational conditions on the implementation of SENs including professional values, workload demands and change fatigue. These influences appear to be important not only for the implementation of SENs but for other occupational health and safety and infection prevention and control issues. Further research to better understand the impact of these conditions on the health and safety of healthcare workers and patients would be of great value.
This study found great utility in drawing on concepts and theories from the implementation science literature. This literature has not been used to a large extent to study implementation problems under a regulatory framework. This study provided some insight on how implementation science theory can be applied to this area of study. Its application has practical utility and could help support the successful integration of occupational health and safety initiatives resulting in more successful evaluation outcomes.

Only one of the hospitals in the study had implemented passive SENs in select areas. More evidence supporting the added value of passive safety needles over semi-automatic or manual designs may be required to support the adoption of these devices. There may be an opportunity to build on the work of Tosini (15) to examine the effectiveness of passive safety features. To make further gains in reducing needlestick injuries, there is the need to examine more closely the preventability of ongoing injury, which could be facilitated by root cause analyses of injuries that continue to be reported despite the transition to SENs.

While further progress will be challenged by other competing health and safety priorities, a renewed interest in this injury issue among front-line workers and health and safety professionals may produce better outcomes as there appear to be a number of opportunities to advance prevention efforts to further reduce ongoing needlestick injuries.
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APPENDIX A

Foreshadowed Issues

The conceptual model in Figure A1 was created prior to initiating the field work to synthesize relevant literature and theory that defined potential influences on the implementation of SENs. The model highlights the stages of the implementation process that were examined and levels of influencing factors on the implementation process. The integration of multi-level influences in Figure A1 was informed by conceptual work by Fixsen (24) who presented a basic model that emphasized the importance of implementation components, organizational components and influencing factors.

Figure A1: Multi-level influences on the implementation of safety engineered needles

Fixsen's review demonstrated that the literature that is available does support the idea that implementation outcomes are influenced by the interaction between core implementation components, organizational components and external influencing factors (24);(187;188;188-192). The inclusion of implementation climate, innovation-values fit, management support, innovation-
champion, and financial resources in Figure A1 was directly informed by the organizational implementation effectiveness model (to be reviewed in Section 4.6) (29;30;66;67). It is important to recognize that the implementation effectiveness model doesn’t refer to the impact of the broader social, cultural, economic, and regulatory context in which the organization is bound (30). The model defined in Figure A1 describes potential internal and external influences on the organization’s implementation process. Table A1 below outlines the rationale for the inclusion of other organizational and external influences defined in Figure A1.

Table A1: Influences on the implementation of SENs

<table>
<thead>
<tr>
<th>Model Concept</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety culture</td>
<td>As the innovation of interest is meant to improve occupational health and safety, it was anticipated that safety culture would have an important influence on the implementation experience (193).</td>
</tr>
<tr>
<td>Design and availability of SENs</td>
<td>A focus group facilitated by the PSHSA was organized prior to the establishment of regulation on needle safety in Ontario (194). One important barrier that was raised pertained to the apparent lack of choice in safety products and the fact that some SEN designs are not user friendly. It has been demonstrated that device design not only influences levels of compliance but also risk of injury (15). Device design does appear to play an important role in terms of ease of use. For example, Michael et al. (195) found that increasing syringe size was associated with undesirable characteristics perceived by physicians specifically related to loss of control.</td>
</tr>
<tr>
<td>Evidence-base for the effectiveness of SENs</td>
<td>Previous studies that have evaluated SENs were anticipated to be of value to organizations as they proceeded to select and evaluate SENs. It was also recognized that this literature may be limited. Not all SENs have been evaluated or examined in different clinical settings.</td>
</tr>
<tr>
<td>Health and safety consulting services</td>
<td>The focus group described earlier identified external occupational health and safety associations/consultants as a useful resource to support implementation of SENs (194).</td>
</tr>
<tr>
<td>Product vendor support</td>
<td>Anecdotal evidence from early informal pilot work on</td>
</tr>
</tbody>
</table>
this topic and descriptive studies in the literature (196) identified the important role of product vendors in supporting the implementation of SENs. Product vendors were also identified as an important stakeholder in the PSHSA focus group study (194).

<table>
<thead>
<tr>
<th>Ministry of Labour inspections</th>
<th>Ontario’s regulation on needle safety is enforced by the Ministry of Labour through workplace inspections. Workplace inspections were anticipated as potentially supporting the implementation process through the identification of gaps and areas for improvement. Lack of enforcement has been identified as an issue in the non-research literature (160).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupational Health and Safety Management System (OHSMS)</td>
<td>In a 2005 systematic review of the effectiveness of occupational health and safety management systems, the review team found evidence that the voluntary adoption of interventions that support the OHSMS generally have a positive effect (197). Some of these outcomes included increased implementation of interventions, improved perception of the organization’s safety climate, increased hazard reporting by employees, more organizational action on occupational and health issues and decreased workers’ compensation premiums.</td>
</tr>
<tr>
<td>Government priorities</td>
<td>It was anticipated that workplace inspections focusing on the use of SENs could be an importance influence on the implementation of SENs (181).</td>
</tr>
<tr>
<td>Media and current events</td>
<td>This factor was based on anecdotal evidence highlighting the influence of published case studies, conferences and other media events that bring attention to the importance of needlestick injuries and available interventions.</td>
</tr>
<tr>
<td>JHSC recommendations</td>
<td>Recommendations from the JHSC were added to highlight the important role this committee might play in overseeing the implementation process. A well functioning JHSC should be making recommendations pertaining to needle/sharp safety and any accident/illness reports.</td>
</tr>
</tbody>
</table>

In addition to the conceptual model describe above, to help narrow the focus of the field work, a preliminary list of questions were developed to further define foreshadowed issues to examine:
1. **Does needlestick injury prevention continue to be a priority for organizations?**

2. **Are organizations continuing to improve the availability and quality of safety devices and monitoring issues with existing devices?**

The first two questions were informed by previous evaluation work that has found that needlestick injuries continue to occur despite the implementation of SENs. This literature is reviewed in detail in Chapter 3. Current guidance documents for the implementation of SENs encourage ongoing monitoring and improvement to address needlestick injuries (64;65). It was anticipated that most organizations would have already implemented a number of different SENs; however, there may have been cases where SENs are not always used as intended or where needlestick injuries continue to occur with the use of these devices (17;18). The focus on examining whether organizations are continuing to improve the quality of safety devices was specifically related to whether there have been attempts to integrate passive SENs which have been shown to be more effective in reducing needlestick injuries; however, these devices are more expensive. Organizations that have integrated these devices would be making an important commitment to address needlestick injury prevention.

3. **Are existing goals to eliminate needlestick injuries through the uptake of SENs realistic considering device availability and utility?**

The third question is based on an assumption that was informed by transcripts from two private member bills supporting the development of regulation on needle safety (38;51). As reviewed in Section 2.2.1, it was anticipated that needlestick injuries could decline by 80-90% following a system wide transition to SENs. Toronto East General Hospital reported an 80% decline in needlestick following the transition to SENs (54). The CNSSN has reported that approximately 41% of needlestick injuries occur when the device is being used and 45% after the device is used (106). As SENs are designed to be activated following a procedure, they may have limited potential to reduce risk of injury before or during a procedure. Opportunities to reduce needlestick injuries by 80-90% across healthcare organizations in Ontario may be limited by the ability of SENs to address injuries that occur when the devices is being used.

4. **How have healthcare workers responded to the transition to SENs? Is there resistance to the use of these devices among specific groups of workers?**

This question was based on previous studies that have audited sharps disposal bins and have found that safety needles are not always activated as intended (20;42).
5. Has the regulation stimulated the uptake of safety engineered devices beyond the regulatory requirements?

There have been other jurisdictions that have established regulation requiring the use of SEMS more generally. There was an interest in examining whether Ontario’s regulation (which only requires hollow-bore needles to be replaced with SENs) may have stimulated organizational changes that integrate a number of interventions to prevent needlestick injuries including the integration of SEMS.

6. Has the transition to SENs negatively impacted patient care in any way?

This question was in part influenced by the diffusion of innovations literature (198) which emphasizes the importance of examining desirable and undesirable consequences of interventions being open to the possibility that interventions can create new problems. For example, increased splatters or spills have been associated with new safer retractable intravenous catheters (199). There is a large body of literature that has discussed issues with needleless IV connectors and the potential for microbial contamination (200-202).
## APPENDIX B

### Cross-Jurisdictional Comparison

**Table B1: Overview of needle safety regulation in Canada and the US**

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Context of Delivery</th>
<th>Target Population</th>
<th>Safety Engineered Component</th>
<th>Exceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ONTARIO:</strong></td>
<td>Regulation under the Occupational Health &amp; Safety Act</td>
<td>Any workplace where needles are being used for therapeutic, preventative, palliative, diagnostic or cosmetic purposes.</td>
<td>Hollow-bore needles need to be replaced with SENs (needleless device or device designed to eliminate or reduce risk of skin puncture injury) where needles are being used for therapeutic, preventative, palliative, diagnostic or cosmetic purposes. Workplaces in the healthcare industry must convert all needles used for all purposes.</td>
<td>If the employer is unable, after making reasonable efforts to obtain a SEN that is appropriate for the work</td>
</tr>
<tr>
<td><strong>Ontario Needle Safety Regulation 474/07 (36)</strong></td>
<td></td>
<td></td>
<td></td>
<td>Worker believes on reasonable grounds that the SEN poses a greater risk of harm than the use of hollow-bore needle</td>
</tr>
<tr>
<td><strong>Effective Sept 1, 2008</strong></td>
<td></td>
<td></td>
<td></td>
<td>Declaration of emergency in Ontario</td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td>Situations that poses serious risk to public health</td>
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<td></td>
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<td>Supplies of SENs exhausted</td>
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<td>Risk of harm from postponing the work</td>
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<td><strong>UNITED STATES:</strong></td>
<td>A separate Act was defined: the Needlestick Safety and Prevention Action with specific requirements under the Bloodborne Pathogen Standard</td>
<td>All employers in the United States where employees are exposed to blood</td>
<td>Engineering &amp; work practice controls shall be used to eliminate or minimize employee exposure. Engineering controls include safer medical devices, such as sharps with engineered sharps injury protections &amp; needleless systems. Devices should be examined &amp; maintained or replaced on a regular schedule ensuring effectiveness.</td>
<td>Not required for applications which do not involve direct patient contact</td>
</tr>
<tr>
<td><strong>Needlestick Safety &amp; Prevention Act and the Bloodborne Pathogen Standard (50)</strong></td>
<td></td>
<td></td>
<td></td>
<td>Appropriate safer medical devices include only devices whose use will not jeopardize patient or employee safety</td>
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<tr>
<td><strong>Effective April 18, 2001</strong></td>
<td></td>
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<td>If a safer device is not available in the marketplace, the employer is not required to develop any such device</td>
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<td></td>
<td>Revised requirements are limited to the safer medical devices that are considered to be effective</td>
</tr>
<tr>
<td>Province</td>
<td>Act Title</td>
<td>Effective Date</td>
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<tr>
<td>MANITOBA:</td>
<td>The Workplace Safety &amp; Health Amendment Act (Needles in Medical Workplaces)</td>
<td>2006</td>
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<tr>
<td></td>
<td>Province passed Bill 23, the Workplace Safety and Health Act –</td>
<td>January 1, 2006</td>
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<td></td>
<td>Hospitals, personal care homes,</td>
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<td>psychiatric facilities, medical clinics, medical laboratories,</td>
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<td>community health centers, CancerCare Manitoba; physician's offices;</td>
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<td></td>
<td>registered dentist's office; ambulance; and any other workplace where</td>
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<td>physical or mental health treatment or care is provided to a person</td>
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<td></td>
<td>When hollow-bore or intravenous needles are used in a medical workplace,</td>
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<td></td>
<td>the employer must ensure that workers use only SENs</td>
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<td></td>
<td>When it is not reasonably practical to use a SEN, the employer must ensure</td>
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<td></td>
<td>that safe work procedures and practices are implemented in the workplace.</td>
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<tr>
<td>NOVA SCOTIA:</td>
<td>Safer Needles in Healthcare Workplaces Act</td>
<td>2007</td>
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<td></td>
<td>A separate Act was passed: the Safer Needles in Healthcare Workplaces Act</td>
<td>January 1, 2007</td>
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<td>Healthcare workplaces - those under the district health authority,</td>
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<td>long-term care homes</td>
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<td></td>
<td>Every employer must ensure that when hollow-bore or intravenous needles</td>
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<td></td>
<td>are used in a healthcare workplace that employee use only SENs.</td>
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</tr>
<tr>
<td></td>
<td>The employer in consultation with the joint health and safety committee</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(JHSC) or health and safety representative can demonstrate that a safety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>engineered needle: 1) poses more risk of harm than another needle to a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>patient, client, resident or employee; 2) may impair the effectiveness of</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>the treatment of a patient, client or resident.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>A needle device is pre-filled with a biological or antibiotic product that</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>is present in the province on the day that this Act comes into force.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>There is a public health emergency</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>A needle is stockpiled for use in an emergency and is present in the</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Province when this Act comes into force</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes: With respect to the enforcement date, the act specifies that every employer will consult with their JHSC or health and safety representative to develop a phased in compliance plan. Development and implementation of the compliance plan should not exceed one year unless an exemption is granted.
<table>
<thead>
<tr>
<th>BRITISH COLUMBIA:</th>
<th>Changes made to the Occupational Health and Safety Regulation</th>
<th>All workplaces, including physicians' offices and clinics, patients' homes, and long-term care facilities, in addition to hospitals</th>
<th>Requires safety-engineered needles for any procedures involving the use of hollow-bore needles</th>
<th>If the required safety-engineered medical sharp is not clinically appropriate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupational Health and Safety Regulation – sec. 6.36 (206)</td>
<td>Effective January 1, 2008</td>
<td></td>
<td>Most recent amendments require the use of safety-engineered devices for any medical procedure and includes non-hollow-bore sharp device categories</td>
<td></td>
</tr>
</tbody>
</table>

Notes: While the first amendment took effect on January 1, 2008, on Oct 1, 2008 broader requirements took effect requiring the use of SENs for any medical procedure including non-hollow borne sharp device categories, such as suture needles, scalpels and lancets.

<table>
<thead>
<tr>
<th>ALBERTA:</th>
<th>New sections added to the Occupational Health and Safety Code in 2009</th>
<th>Healthcare and industries with biological hazards</th>
<th>Employers must eliminate or control a hazard through the use of engineering controls.</th>
<th>If the use of the required SEMS is not clinically appropriate in the particular circumstances, or the required safety-engineered sharp is not available in commercial markets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupational Health and Safety Code, sec. 525.2(2)(3) (207)</td>
<td>Effective July 1, 2010</td>
<td></td>
<td>An employer must provide &amp; ensure that any medical sharp is a SEMS.</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX C

Literature Review Update

In February 2012, Tuma et al.’s (73) review was replicated using the same search terms and exclusion/inclusion criteria. The objective of the original review was to examine studies that evaluated the effectiveness of device implementation on the rate of percutaneous injuries among healthcare workers. The list of inclusion criteria is outlined below.

**Inclusion Criteria:**

- Study examined the introduction of an engineered sharps-injury protection device or needleless system. (criterion A)

- Study measured the percutaneous injury rate among healthcare workers. In this review update, studies that looked at the glove perforation rate were also included. (criterion B)

- The intervention was evaluated in a defined population with clear comparison groups in clinical settings. (criterion C)

- Outcomes and denominators were objectively measured using consistent methods over the duration of the study. (criterion D)

A search of the literature for peer-reviewed studies published from 16 September 2005 through 1 February 2012 was performed using Medline, Embase, and Cochrane Central Register of Controlled Trials. The search terms included “Needlestick Injury”, “needlestick injuries”, “safety needle$”, engineered sharps injury prevention”, “needleless”, “safe$ device”, “safe$ sharp”, or “safe$ needle”.

**Results:**

A total of 1,076 citations were identified through an initial electronic database search and additional hand searches of the literature. Only 9 studies met the inclusion criteria outlined above (75-82;208). Study designs included randomized controlled trials (RCT) (n=2), cluster RCTs (n=1), uncontrolled before-and-after designs (n=3), controlled before-and-after designs (n=1), cohort studies (n=1), and retrospective cross-section studies with control groups (n=1). Table C1 describes the
study characteristics including the design, study period, setting, population, SEMS implemented, outcome, and other notes for those studies that were identified in the most recent update. The original review paper presents a similar table with information on the studies identified prior to the review update (73).
Table C1: Characteristics of studies described in articles reviewed

<table>
<thead>
<tr>
<th>Author(s), year of publication</th>
<th>Study Design</th>
<th>Study period</th>
<th>Study setting</th>
<th>Study population</th>
<th>SEMS</th>
<th>Outcome</th>
<th>Other notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adams 2006 (74)</td>
<td>Uncontrolled before-and-after</td>
<td>4 years (2001-2005) two int. periods, enhanced training in 2002 and safety needles in 2004.</td>
<td>4 clinical areas, University Hospital, (UK)</td>
<td>At-risk HCWs in 4 clinical areas (surgery, medical ward, outpatient department)</td>
<td>Safety needles with flip cap and safety glide and blunt fill needles</td>
<td>65% decrease in the rate of NSIs between 2003 and 2004.</td>
<td>An 18% decrease in injury rate observed following educational program. Injury rate increased 43% when they returned to the standard education program.</td>
</tr>
<tr>
<td>Azar 2007 (75)</td>
<td>Before-and-after, controlled</td>
<td>18 months pre int. and 18 months post int.</td>
<td>Multiple sites at urban medical center (US)</td>
<td>At-risk HCWs</td>
<td>IV catheter with retractable shield</td>
<td>59% decrease in percutaneous injuries from IV catheters (P&lt;0.01).</td>
<td>Training on the new safety devices was provided.</td>
</tr>
<tr>
<td>Lautier 2008 (76)</td>
<td>Cohort study</td>
<td>4 weeks (2006)</td>
<td>52 hospitals (France)</td>
<td>Nurses in diabetes departments</td>
<td>safety needle for insulin pens (passive)</td>
<td>0 injuries reported with safety needle and 1 with regular needles.</td>
<td>Theoretical and practical training provided. Nurses were satisfied with the safety needles (average score of 8.1 out of 10).</td>
</tr>
<tr>
<td>Sossai 2010 (77)</td>
<td>Retrospective, cross-sectional, with control</td>
<td>2 year pre int. and 2 post int.</td>
<td>1 hospital (Italy)</td>
<td>All hospital employees.</td>
<td>safety IV catheter system (passive device)</td>
<td>85% reduction in the rate of incidents with catheters per 100,000 catheters used (2003-2004 compared with 2006-2007).</td>
<td>Transition was accompanied by a sharps awareness campaign (launched in 2003), training, and courses on NSI risk and prevention.</td>
</tr>
<tr>
<td>Sullivan 2009 (78)</td>
<td>RCT</td>
<td>11 months (2005-2006)</td>
<td>1 medical center/teaching university (US)</td>
<td>Physicians</td>
<td>Blunt suture needles</td>
<td>The difference between the proportion of gloves with perforations in int. and control significant. 17.5% of gloves in control group with perforations and 7.2% in int. group.</td>
<td>Physicians reported that they were not as satisfied with blunt needles compared with sharps needles.</td>
</tr>
<tr>
<td>Valls 2007 (79)</td>
<td>Before-and-after controlled</td>
<td>Post int. 6 months (2005-2006), pre int. 6 months (2004-2005)</td>
<td>1 hospital (Spain)</td>
<td>Nurses in emergency department</td>
<td>Vacuum phlebotomy systems with needle sheath, winged hooded needles, and with IV adapters; blood-gas syringes with needle sheath, lancets with retractable, single-use puncture sticks, catheters with safety-engineered introducer needles, needles with sheath for</td>
<td>93% reduction in relative risk of percutaneous injuries (p&lt;0.01).</td>
<td>Education on safety needles, compliance, risk factors plus hands-on training</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Duration</td>
<td>Setting</td>
<td>Population</td>
<td>Interventions</td>
<td>Questionnaires/Outcomes</td>
<td>Additional Information</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------</td>
<td>----------------</td>
<td>---------</td>
<td>------------</td>
<td>--------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>van der Molen 2011 (80)</td>
<td>Cluster RCT</td>
<td>12 months (2007)</td>
<td>1 hospital (Netherlands)</td>
<td>At-risk HCWs</td>
<td>Injection needles with safety device (manual)</td>
<td>Questionnaire showed 2.6% of workers in the intervention group (safety needle plus workshop) had an injury compared to 11.9% in control group (p&lt;0.05). Difference between groups based on hospital register data NS.</td>
<td>Workshop that accompanied intervention groups 1 and 2 included presentation on needlestick injuries and prevention. 65% of participants in intervention group reported attending workshop; 89% reported using safety devices</td>
</tr>
<tr>
<td>Whitby 2008 (81)</td>
<td>Uncontrolled before-and-after</td>
<td>Post int. 2 years (2005-2006), pre int. 5 year pre int. period.</td>
<td>1 hospital (Australia)</td>
<td>At-risk HCWs</td>
<td>Retractable syringes (select applications), safety winged butterfly needles, needle-free IV system</td>
<td>49% reduction in all NSIs; 81% reduction NSIs related to accessing IV lines (p&lt;0.01)</td>
<td>Education program delivered on potential benefits of new devices</td>
</tr>
<tr>
<td>Azar 2007(75)</td>
<td>Before-and-after, controlled</td>
<td>18 months pre int. and 18 months post int.</td>
<td>Multiple sites at urban medical center (US)</td>
<td>At-risk HCWs</td>
<td>IV catheter with retractable shield</td>
<td>59% decrease in percutaneous injuries from IV catheters (P&lt;0.01).</td>
<td>Training on the new safety devices was provided.</td>
</tr>
<tr>
<td>Wilson 2008 (82)</td>
<td>RCT</td>
<td>21 months (2005-2006)</td>
<td>1 medical center/teaching hospital (US)</td>
<td>Physicians</td>
<td>Blunt suture needles</td>
<td>The difference between the proportion of gloves with perforations in int. and control NS.</td>
<td>No training/education described. Only 46% of surgeons perceived the use of blunt needles protected them against sharp injuries.</td>
</tr>
</tbody>
</table>
## APPENDIX D

### Needlestick Injury Data

**Table D1:** Rates of workers’ compensation claims associated with needlestick injuries by year and claim type for 5 rate groups* in the health and social services sector

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>All Claims (n)</td>
<td>1,373</td>
<td>1,260</td>
<td>1,249</td>
<td>1,181</td>
<td>1,165</td>
<td>1,159</td>
<td>956</td>
<td>933</td>
<td>1,011</td>
</tr>
<tr>
<td>FTEs (n)</td>
<td>305,113</td>
<td>310,453</td>
<td>318,192</td>
<td>324,655</td>
<td>334,222</td>
<td>342,223</td>
<td>340,168</td>
<td>344,874</td>
<td>360,998</td>
</tr>
<tr>
<td>Rate per 10,000</td>
<td>45.0</td>
<td>40.6</td>
<td>39.3</td>
<td>36.4</td>
<td>34.9</td>
<td>33.9</td>
<td>28.1</td>
<td>27.1</td>
<td>28.0</td>
</tr>
<tr>
<td>No-lost-time Claims (n)</td>
<td>1,313</td>
<td>1,204</td>
<td>1,188</td>
<td>1,129</td>
<td>1,101</td>
<td>1,107</td>
<td>914</td>
<td>893</td>
<td>968</td>
</tr>
<tr>
<td>FTEs (n)</td>
<td>305,113</td>
<td>310,453</td>
<td>318,192</td>
<td>324,655</td>
<td>334,222</td>
<td>342,223</td>
<td>340,168</td>
<td>344,874</td>
<td>360,998</td>
</tr>
<tr>
<td>Rates per 10,000</td>
<td>43.0</td>
<td>38.8</td>
<td>37.3</td>
<td>34.8</td>
<td>32.9</td>
<td>32.4</td>
<td>26.9</td>
<td>25.9</td>
<td>26.8</td>
</tr>
<tr>
<td>Lost-time Claims (n)</td>
<td>60</td>
<td>56</td>
<td>61</td>
<td>52</td>
<td>64</td>
<td>52</td>
<td>42</td>
<td>40</td>
<td>43</td>
</tr>
<tr>
<td>FTEs (n)</td>
<td>305,113</td>
<td>310,453</td>
<td>318,192</td>
<td>324,655</td>
<td>334,222</td>
<td>342,223</td>
<td>340,168</td>
<td>344,874</td>
<td>360,998</td>
</tr>
<tr>
<td>Rates per 10,000</td>
<td>2.0</td>
<td>1.8</td>
<td>1.9</td>
<td>1.6</td>
<td>1.9</td>
<td>1.5</td>
<td>1.2</td>
<td>1.2</td>
<td>1.2</td>
</tr>
</tbody>
</table>

* Rate groups include 851, homes for nursing care; 852, homes for residential care; 853, hospitals; 857, nursing services; and 858, group homes; FTEs = full-time equivalents
| Table D2: Rates of workers compensation claims (lost-time and no-lost-time) associated with needlestick injuries by year and rate group |
|---|---|---|---|---|---|---|---|---|---|
| Nursing care | | | | | | | | | |
| Claims (n) | 311 | 300 | 291 | 326 | 299 | 236 | 122 | 127 | 126 |
| FTEs (n) | 61,234 | 63,368 | 64,878 | 67,076 | 67,917 | 68,053 | 70,110 | 71,601 | 75,132 |
| Rate per 10,000 | 50.8 | 47.3 | 44.9 | 48.6 | 44 | 34.7 | 17.4 | 17.7 | 16.8 |
| Hospitals | | | | | | | | | |
| Claims (n) | 896 | 795 | 773 | 682 | 700 | 734 | 660 | 616 | 694 |
| FTEs (n) | 183,472 | 182,300 | 187,845 | 190,303 | 195,803 | 200,091 | 196,072 | 198,832 | 205,657 |
| Rate per 10,000 | 48.8 | 43.6 | 41.2 | 35.8 | 35.8 | 36.7 | 33.7 | 31 | 33.7 |
| Nursing services | | | | | | | | | |
| Claims (n) | 114 | 114 | 119 | 112 | 120 | 123 | 121 | 150 | 156 |
| FTEs (n) | 34,710 | 36,638 | 37,224 | 38,789 | 39,428 | 41,631 | 42,105 | 42,805 | 47,109 |
| Rate per 10,000 | 32.8 | 31.1 | 32 | 28.9 | 30.4 | 29.5 | 28.7 | 35 | 33.1 |

* FTEs = full-time equivalents
Table D3: Rates of work-related emergency department records associated with needlestick injuries by year and case definition

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>All needlestick injuries:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ED records (n)</td>
<td>1,081</td>
<td>1,115</td>
<td>1,162</td>
<td>1,194</td>
<td>1,223</td>
<td>1,154</td>
</tr>
<tr>
<td>Employed persons (n)</td>
<td>6,320,300</td>
<td>6,421,400</td>
<td>6,492,400</td>
<td>6,321,700</td>
<td>6,408,800</td>
<td>6,517,100</td>
</tr>
<tr>
<td>Rate per 10,000</td>
<td>1.7</td>
<td>1.7</td>
<td>1.8</td>
<td>1.9</td>
<td>1.9</td>
<td>1.8</td>
</tr>
<tr>
<td>Wound, superficial injury or other injury; hypodermic needle:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ED records (n)</td>
<td>821</td>
<td>806</td>
<td>794</td>
<td>677</td>
<td>633</td>
<td>594</td>
</tr>
<tr>
<td>Employed persons (n)</td>
<td>6,320,300</td>
<td>6,421,400</td>
<td>6,492,400</td>
<td>6,321,700</td>
<td>6,408,800</td>
<td>6,517,100</td>
</tr>
<tr>
<td>Rate per 10,000</td>
<td>1.3</td>
<td>1.3</td>
<td>1.2</td>
<td>1.1</td>
<td>1.0</td>
<td>0.9</td>
</tr>
<tr>
<td>Special screening; hypodermic needle:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ED records (n)</td>
<td>260</td>
<td>309</td>
<td>368</td>
<td>517</td>
<td>590</td>
<td>560</td>
</tr>
<tr>
<td>Employed persons (n)</td>
<td>6,320,300</td>
<td>6,421,400</td>
<td>6,492,400</td>
<td>6,321,700</td>
<td>6,408,800</td>
<td>6,517,100</td>
</tr>
<tr>
<td>Rate per 10,000</td>
<td>0.4</td>
<td>0.5</td>
<td>0.6</td>
<td>0.8</td>
<td>0.9</td>
<td>0.9</td>
</tr>
</tbody>
</table>

* ED = work-related emergency department record
APPENDIX E

Field Work Guidance Documents

Topical Questions

Initial implementation procedures and activities:

- Was a sharps safety committee established?
- Did the process involve inventory review?
- What role did manufacturers have in facilitating the implementation process?
- Were safety devices pilot tested?
- Were workers involved in device selection?
- What kind of training and education on safety device use and needlestick injury prevention was provided?
- Are there written policies and procedures in place?

Ongoing procedures and activities for sustained integration:

- Are there activities in place to increase compliance with the use of safety devices?
- Is the use of safety devices monitored? How are issues addressed?
- Is there continued training and education on the use of safety devices and needlestick injury prevention?
- Does the original sharps committee still meet?
- Are safety devices beyond the regulatory requirements being considered?

Contextual questions about the transition:

- When did the organization start to transition to the use of these devices?
- Are there still exceptions to the use of safety devices?
- What do health and safety inspectors look for with regards to compliance with Ontario’s regulation on needle safety?
- Has the joint health and safety committee had a role in the implementation process?

What are the organization’s ongoing health and safety priorities?
**Table E1: Interview topics by employee category and theme**

<table>
<thead>
<tr>
<th>Background</th>
<th>Informants</th>
<th>Management/ Front-line Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Role</td>
<td>Educator</td>
<td>X</td>
</tr>
<tr>
<td>Duration with Hospital</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Role supporting transition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transition History and Overall Impact</td>
<td>Status of transition to SENs</td>
<td>X</td>
</tr>
<tr>
<td>Impact of regulation on transition</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Types of SENs available</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Overall impact of transition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ongoing injuries with SENs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SENs integrated beyond regulatory requirements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff support of SENs prior to regulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost Impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEN Implementation process</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff / committee involved in transition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of external resources</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Process remove old stock</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Available policies and procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opportunities for staff to support transition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporting practices</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Table E1 Continued:** Interview topics by employee category and theme

<table>
<thead>
<tr>
<th>Training</th>
<th>Informants</th>
<th>Management/ Front-line Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Educator</td>
<td>Logistics/ Purchasing</td>
</tr>
<tr>
<td>Level of training required</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Perception of quality vendor designed training</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Ongoing training</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Training / education received SEN use</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Enterprise learning management system</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Ongoing monitoring of SEN use</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Ongoing SEN committee activities</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Ongoing process integrate SENs</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Needlestick injury prevention as ongoing priority</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Ongoing review of NSI statistics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current process device selection</td>
<td>X</td>
<td></td>
</tr>
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<td>Reasons for ongoing integration of new safety devices</td>
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<td>Feedback from staff re use of SENs</td>
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<td>Impact of SENs on injury risk</td>
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<td>SEN design preferences</td>
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<td>Feedback on SENs</td>
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<td>Importance of employee input</td>
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<td>Injury experience</td>
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## Table E1 Continued: Interview topics by employee category and theme

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<th>Implementation Issues</th>
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<th>Logistics/ Purchasing</th>
<th>Safer Needle Task Force</th>
<th>Joint Health and Safety Committee</th>
<th>Occupational Health and Safety</th>
<th>Unit Manager</th>
<th>Front-line Worker</th>
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<td>Availability of non-safety devices</td>
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<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td></td>
<td>X</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Contractual obligations</td>
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<tr>
<td>Barriers adoption of passive safety devices</td>
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<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Reasons ongoing injuries</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

| Committees                           |          |                       |                         |                                   |                               |              |                   |
| History of committee development     |          |                       |                         |                                   |                               |              |                   |
| Structure and function               |          |                       |                         |                                   |                               |              |                   |
| Current priorities of committee      |          |                       |                         |                                   |                               |              |                   |
| Previous / ongoing issues discussed re SENs |        |                       |                         |                                   |                               |              |                   |
| Recommendations made by the committee|          |                       |                         |                                   |                               |              |                   |

| Other / Misc                          |          |                       |                         |                                   |                               |              |                   |
| Nature of MOL inspections re SEN use |          |                       |                         |                                   |                               |              |                   |
| Improvements in technology           |          |                       |                         |                                   |                               |              |                   |
| External funding support             |          |                       |                         |                                   |                               |              |                   |

| Overall Experience                   |          |                       |                         |                                   |                               |              |                   |
| Overall implementation experience    | X        | X                     | X                       | X                                 | X                             | X            | X                 |
| Barriers and facilitators to integration/training |        |                       |                         |                                   |                               |              |                   |
| Recommendations for improvements in delivery and implementation of regulatory requirements | |                       |                         |                                   |                               |              |                   |
# APPENDIX F

## Coding Guide

**Table F1:** First stage topic and thematic codes for the within case analysis and cross-case analysis

| Topic Code: Organization Implementation Experience | **Definition:** This code is broadly applied to accounts that describe and reflect on the overall implementation experience. This includes elements of the process that ran smoothly (e.g., logistics) and any resistance faced among specific groups within the organization.  
**Relevance:** To describe how the transition to SENs played out, how hospitals managed the integration, and to provide a better understanding of the consequences of the integration of SENs on the organization and staff. |
|---|---|
| Topic Code: Institutionalization | **Definition:** This concept refers to the final stage of implementation, a period of sustained integration. It will be applied to accounts that pertain to ongoing activities (or lack of activity) that addresses needlestick injury prevention and the proper use of safety needles. It will also refer to accounts of how safer needle use has become integrated into practice.  
**Relevance:** To examine how the regulation influenced the uptake of SENs and other interventions not directly included in the regulation (how did the organization go beyond the minimum requirements) and to examine whether there appears to be a need for ongoing investment in activities to ensure that safer needle technology continues to be monitored. |
| Topic Code: SEN Feedback | **Definition:** This code will be applied to accounts of how front-line workers responded to the integration of SENs and current perceptions towards the technology.  
**Relevance:** To examine how workers have responded to SENs; consequences of integrating SENs; and issues associated with the integration of these devices. |
| Topic Code: Safety Use | **Definition:** This code will be applied to all accounts that describe front-line workers use/misuse SENs or other related safety practices.  
**Relevance:** To examine issues with the integration and use of SENs. |
| Topic Code: Implementation Facilitator | Definition: This code was applied to a broad range of experiences that describe individuals, activities, resources, strategies (internal and external) that were perceived to support the implementation of SENs.  

**Relevance:** To describe how hospitals managed the integration of SENs. |
| Topic Code: Implementation Limitations | Definition: This code will be applied to specific limitations associated with the implementation process that are expressed or identified. It will also refer to accounts that describe implementation barriers, road blocks or challenges (not including issues with the design or use of SENs).  

**Relevance:** To understand issues with the integration of SENs and the consequences of the transition. |
| Topic Code: Front-line Voice | Definition: This code as applied to accounts that described how front-line worker were engaged in the implementation process.  

**Relevance:** To examine how the organization managed the transition to SENs. |
| Cross Case Analysis |  |
| Topic Code: Limits SEN Theory | Definition: This code referred to limitations with the idea that SENs will prevent needlestick injuries. It was applied to accounts that describe limitations with the ability of SENs to prevent needlestick injuries.  

**Relevance:** To examine remaining issues associated with the use and integration of SENs. |
| Topic Code: SEN Design | Definition: This code was applied to accounts describing limitations or advantages with the design of SENs compared to conventional needles. This will also include any negative or unexpected issues associated with the use of these devices including impacts on performance, risk of injury etc.  

**Relevance:** To understand ongoing issues with the use and integration of SENs. |
| Thematic Code: Patient Centered Care* | Definition: This code was applied to accounts that touched on the connection between needlestick injury prevention/safer needle use and patient care (quality of care, patient safety). This includes instances where staffs expressed the importance of patient safety; that patient care needs be considered in the design of SENs; that patient care influences the types |
of SENs that are used.

**Relevance:** To better understand the origin of resistance to the use of SENs and what might influence the integration of future health and safety interventions.

**Thematic Code:**
**Performance vs Safety**

**Definition:** This code was applied to accounts that connected performance/skill/ability to carry out a procedure/getting the job done with decisions to use / activate SENs.

**Relevance:** To understand the origin of resistance to the use of SENs and what might influence the integration of future health and safety interventions.

**Topic Code:**
**Regulatory Influence**

**Definition:** This code was applied to content that demonstrates what role the regulation had or didn’t have on organizational changes to reduce needlestick injuries. It will also correspond to accounts describing limitations with the delivery and design of the regulation.

**Relevance:** To describe how hospitals have responded in relation to Ontario’s safer needle regulation – specifically looking at the influences of the regulation on the organization’s decision to uptake SENs.

**Thematic Code:**
**Change Overload**

**Definition:** This code was applied to accounts that describe negative responses to change among front-line staff.

**Relevance:** To understand the consequence of integrating SENs under a regulatory framework and a contextualized understanding of remaining issues associated with the future integration of safer needle technology and other measures to support integration.

**Thematic Code:**
**Cost Dependency**

**Definition:** This code was applied to accounts that describe the influence of the cost of SENs on the selection and implementation process.

**Relevance:** To describe how hospital responded and managed the transition and the consequences of integrating SENs and making future advances.

**Thematic Code:**
**Learning Curve**

**Definition:** This code started out as an ‘in-vivo code’. It was used to describe the situation where workers initially had difficulty using SENs but learn to adapt to the use of the devices over time.

**Relevance:** To describe the consequences of integrating SENs and what might influence the integration of future health and safety interventions.
| Thematic Code: Staff Interdependency * | **Definition:** This code was applied to accounts that emphasized the role of co-workers in the transition to SENs.  
**Relevance:** To describe how workers have managed the integration of SENs. |
| Thematic Code: Vigilance | **Definition:** This code was applied to accounts that emphasized the role of being vigilant/diligent (a commonly used word) or extra cautious when using needles as a means to further reduce injury risk.  
**Relevance:** To provide contextualize understanding of remaining issues associated with the use and integration of SENs – specifically to examine perceptions towards the role of individual performance versus environmental influences on ongoing injury risk. |
| Thematic Code: In the Know* | **Definition:** This code was created to identify accounts that emphasized the importance of being informed about health and safety innovations. Applied to instances where staff demonstrated a lack of knowledge about safety advances and where informants expressed the importance of internal push from staff for more sophisticated safety devices.  
**Relevance:** To provide a contextualized understanding of remaining issues associated with the integration of SENs – specifically examining the relationship between awareness of safety interventions and the push for change. |
APPENDIX G

Information and Consent Form

Title of the project: Ontario’s Safer Needle Regulation: A Qualitative Multiple-case Study of the Implementation Experience in Three Acute Care Hospitals

Principle investigator: Andrea Chambers, 416-927-2027, ext 2291.

Supervisor: Dr. Cameron Mustard, 416-927-2027 ext 2143

Research Funding: Canadian Institute for Health Research

The study is being carried out by a doctoral student at the University of Toronto’s Dalla Lana School of Public Health, in the Health and Behavioral Sciences program. The work is also supported by the Institute for Work & Health, an independent, not-for-profit research organization.

Introduction

You are being invited to participate in this research study as an employee at [Name of Hospital]. [Name of Hospital] was randomly selected to participate in the study from a list of teaching hospitals in the GTA. To be eligible to participate in this study, you must be an employee at [Name of Hospital].

Please read this information sheet and consent form carefully and ask as many questions as you like before deciding whether or not to participate. You are not under any obligation to participate in any research project that has been recommended to you by a colleague.

Background & Purpose of Research

The project is designed to better understand the implementation and impact of Ontario’s safer needle regulation. Four years have passed since Ontario’s safer needle regulation came into effect. The regulation was intended to increase the uptake and use of safety engineered needles (SENs) to reduce needlestick injuries. Over the next year, detailed case studies will be carried out in three Ontario hospitals to better understand how these devices have been integrated into practice, the consequences and trade-offs associated with their adoption, and important facilitators and barriers associated with the implementation process. The majority of interviews will be carried out with front-line healthcare workers; however, information from multiple perspectives across the organization will be obtained to capture how the organization has and continues to support the use of SENs and the perceptions towards the use of these devices in practice.

Procedure for Participation
Information on this study including this consent form and instructions have been sent to you via another employee at your organization who felt you might be able to provide some insight on the topic understudy. As a participant in this study, you will be interviewed by the primary investigator. The interview will be 30 minutes in length. Interviews will be tape recorded and transcribed.

You will be invited to provide feedback following your interview. If you agree to participate in this feedback process you will receive a summary of what was discussed during your interview. You will be asked to elaborate on or clarify any of the content covered. This process will also provide you with the opportunity to point out specific descriptive information that you may see as potentially identifiable information. You will be given two weeks to provide any feedback.

The interview and feedback process will take place in your organization over the next 3 months. Organizational informants (who have been involved in the implementation of safer needles) and front-line healthcare workers are being interviewed. At your site, approximately 10-15 staff will be interviewed.

Please contact me with any questions you may have or for any additional information you need to make your decision about participating in this study.

**Possible Risks**

It is not anticipated that the study will obtain information that poses any risks to you, your co-workers or your employer arising from your participation in this study.

Unlike a structured questionnaire, it is difficult to anticipate the types of responses that will be obtained from participants in this study. If any information that is perceived to be negative including experiences with the use of SENs or organizational activities, caution will be taken in presenting this material in order to preserve anonymity.

**Benefits of the Study**

This study provides employees with the opportunity to share their perceptions on the use of SENs and on how improvements can be made to the implementation and selection of these devices. The underlying goal of this study is to contribute to the improvement of interventions that are designed to prevent needlestick injuries and other blood and body fluid exposures directly impacting the health of care workers. Your organization will have the opportunity to share good ideas and exemplary practices related to the implementation of SENs. Other acute care hospitals and healthcare workers in Ontario may also benefit from the results of this research.

**Rights of Research Participants**

You may withdraw your consent and discontinue participation without penalty. Nobody within your organization will be informed if you decide not to participate or if you chose to withdraw
your information. All participants are able to request that their data be withdrawn from the study. However, information cannot be withdrawn after three weeks following your last interview as the analysis will be underway and your information may no longer be identifiable.

**Potential Reimbursements**

If you wish the interview to take place outside your regular shift you will be compensated at a rate of $35/interview in addition to any parking or public transportation costs.

**Privacy & Confidentiality**

All of the information obtained from you during the interview will be kept confidential. No participant identifiers (e.g., names, initials, DOB) will be used. Information collected from you during the interview will be assigned an identification code (e.g., A01). Raw data from interviews and supporting documents will be kept locked at a central location. Your name will not appear in any final reports or papers produced from this study. Participants from your organization will receive a complete case report; however, information obtained from multiple participants will be aggregated and the use of descriptive characteristics will be avoided. Additional reports and publications will include cross-case findings.

Your permission will be obtained before any direct quotes are taken from your interview and included in the case report. For the single case reports that will be made available to participants in your organization, no names or specific occupational titles (e.g., chief nursing executive, manager of health and safety) will be used to attribute quotations. When information from all three case studies is analyzed collectively to establish cross-case conclusions in the thesis and other publications no names will be used to attribute quotations; however, more specific occupational titles will be used (e.g., RN, OHS professional).

The information you provide in the interview will be used only by researchers associated with the study and only in ways which ensure that you cannot be individually identified. If you wish to participate in providing further information and feedback following the interview, your transcript will include an identification number that will be linked to your contact information. Following the completion of this feedback process, any data linking identification numbers to contact information will be destroyed.

There are limitations to achieving complete anonymity when information is obtained from multiple informants within a single organization. For example, co-workers within your organization may be aware of interactions between the researcher and the participants. There may also be only a few people in your organization with specific knowledge about the issues understudy. Several interviews are being conducted with front-line healthcare workers and similar topics are being explored at other levels and departments within the organization. Attempts will be made to aggregate responses on the issues explored.

Information collected in this study will be centrally located in a password protected computer at the Institute for Work and Health. While audio recordings will be destroyed upon the
completion of this study, other materials that have served as data will be retained and securely archived for five years.

**Voluntary Participation**

Participation in this study is voluntary. While your organization has approved this study, your decision to participate is completely independent. You may decline to participate or decline to answer specific questions during the interview.

This study has been reviewed and has received ethics clearance through the University of Toronto Research Ethics Board. If you have questions regarding your rights as a research participant, you may contact:

University of Toronto  
Office of Research Ethics  
Telephone: (416) 946-3273  
ethics.review@utoronto.ca

**Consent to Study**

I have read this 4 page Patient Information Sheet and Consent Form. All my questions have been answered to my satisfaction. If I decide at a later stage in the study that I would like to withdraw my consent, I may do so at any time.

I voluntarily agree to participate in this study. A copy of the signed Information Sheet and/or Consent Form will be provided to me.

**Signatures**

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<table>
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