EXTRA/FORCES

# Intervention Project Final Report

**Planning the Implementation of a Province-wide Patient Safety**

**Reporting and Learning System for British Columbia**

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## 1. KEY MESSAGES

- Patient safety is matter of international concern. In Canada, adverse events occur in approximately 7.5% of hospital admissions and result in 1.1 million added hospital days and $750 million in extra healthcare spending annually.

- Safety event (incident) reporting systems are one means through which healthcare organizations can identify, analyze, learn from and act to prevent adverse events.

- A culture of safety incorporating elements of "just" culture, reporting culture and learning culture, is necessary to the successful adoption of a safety event reporting system.

- Little research has been conducted on the efficacy or effectiveness of safety event reporting systems in a healthcare context or their value in improving patient care or making it safer.

- Little research-based evidence is available to support specific approaches or strategies to facilitate the implementation of safety event reporting systems or their adoption by users.

- Although many studies recommend creating a culture of safety, there is little research-based evidence to demonstrate the effectiveness of safety culture in making healthcare safer.

- Little research-based evidence is available to provide guidance on implementing strategies aimed at creating a culture of safety or to demonstrate their effectiveness.

- Adoption of a safety reporting system by front-line staff requires a multifaceted approach involving change management, safety strategies, user-friendly software, training and support.

- A pilot project offers the opportunity to test strategies for cultural change and system adoption, facilitating an evidence-based approach to sequential system roll-out provincially.

- Engaging the larger organization is critical to successful implementation of the innovation.

- Measuring and comparing indicators pre- and post-implementation is essential to demonstrate cultural change, system adoption and improvements in safety and quality.

- Research in the field of patient safety is needed to prove the value in costly safety strategies to ensure that scarce resources are used to the optimal benefit of patients and the system.

- Working on a large, complex, multi-health authority projects requires leadership and team commitment to collaboration, consensus decision-making and systems thinking.

- Before collaborating on complex projects, organizations should carefully explore differences in cultures, processes, structures and values to ensure sufficient commonality exists to allow them to work together effectively. Explicit readiness criteria should be determined, shared vision and goals developed, and roles and decision-making processes articulated. Project plans, timelines and budgets should reflect the additional effort associated with collaboration.

- A quality improvement model that is flexible, responsive to feedback and iterative is better suited to projects of this nature than a rigid project management approach. Projects should be seen as activities aimed at organizational transformation that evolve over the project life cycle but do not end.

- To grow and sustain the intervention in the long term, it is important to constantly seek opportunities to leverage and build on other projects and initiatives and create partnerships.

## 2. EXECUTIVE SUMMARY

In our complex healthcare system, there are times when care providers, in their efforts to help their patients, inadvertently cause them harm. Over the past decade, reports from around the world have demonstrated high rates of accidental patient injury and death. The financial, human and system costs associated with these events are substantial. Patient safety is a growing international concern, and is receiving significant attention in BC and the Provincial Health Services Authority (PHSA).

Efforts to address the patient safety problem have yielded limited results to date, and surveys in several countries, including Canada, indicate that the public's view of healthcare safety has worsened in recent years. Borrowing from lessons learned in other high-risk industries with impressive safety records, the thinking about patient safety has expanded to include the concept of a *culture of safety*, one where the values of safety and quality are part of the fabric of the organization, as the most effective means to a safer system. A culture of safety requires visible leadership commitment, a non-punitive approach to error management, effective teamwork and a strong desire to learn and improve. These components are critical parts of the solution and support a much-needed systems approach to the problem. Also essential is a safety reporting system to capture information on adverse events, errors and near misses for use as a source of learning and as the basis for preventive action in the future.

In BC, all six Health Authorities are collaborating to establish the BC Patient Safety and Learning System (PSLS) to enable province-wide, electronic adverse event reporting. The initiative is overseen by the BC Patient Safety Task Force (PSTF), established in 2004 by the BC Ministry of Health (MoH) to work with the province's Health Authorities to improve the safety of patients treated by BC's healthcare system. Although the PSLS relies on information technology, the main focus of the implementation project is cultural change to help organizations

across BC move towards safety cultures that embrace reporting and learning.

Prior to provincial roll-out of the PSLS, pilot implementation will provide proof of concept, configure the application and establish a plan for spread. My Intervention Project (IP) focuses primarily on the PHSA pilot in the Neonatal Intensive Care Unit (NICU) at BC Women's Hospital. Because safety reporting systems will not work if front-line care providers do not use them, my IP asks: *What are the conditions or strategies that promote adoption of an electronic adverse event reporting system and encourage reporting and learning behaviour?*

Interest in patient safety has exploded in the past decade and is reflected in the number of publications examining the problem and solutions. However, review of the literature showed that experimental methods, randomized controlled trials, quantitative data and empiricism were rare. Research methodologies varied and local context was an influencing factor, making it difficult to generalize findings. Few systematic reviews and meta-analyses were available.

A literature review was augmented by local evidence, including results of a safety culture survey, focus group interviews and audits. A Comprehensive Unit-based Safety Program (CUSP) provides the project framework and includes stages of assessing culture, educating staff, identifying issues, handling issues, making improvements and sharing stories, and incorporates safety and leadership rounds, all aimed at fostering safety culture. Stakeholder engagement, organizational readiness and communication activities were undertaken through the provincial change management plan; a logic model identified desired outcomes and integrated evaluation.

Working with other Health Authorities provides opportunities for learning and knowledge transfer across organizational boundaries and cultures, but also adds complexity and challenge to the project. Specific criteria should be used to determine organizational readiness to engage in large, collaborative projects, and differences in organizational cultures, structures, processes and values should be explored to confirm that sufficient commonality exists to allow

the groups to work together effectively. Opportunities to develop shared vision and goals should be built into the project plan, and activities, timelines and budgets should take these requirements into account. Roles, accountabilities and decision-making processes should be clearly articulated. Leadership and team commitment to the collaborative model is essential.

A rigid project management approach does not work well with this iterative type of project. Adhering to a pre-determined set of tasks and timelines does not always allow the flexibility to respond to emerging issues, and working through formal change request processes can impede progress. A combination of quality improvement and change management methods offers a more nimble framework. Guidance documents supporting a clear project plan can create an effective "roadmap" and empower team members to enact their roles. Using a multi-modal approach, building "slack" into the plan and allowing top-down and bottom-up interventions to address project challenges may be effective ways to manage large, complex projects.

Integrating pilot site staff into the project team is essential, as their embeddedness in the clinical area allows them to influence practice and create change effectively, they can act as cultural translators in both directions, and their participation ensures the project remains relevant to the clinical program. Engaging physicians by joining them in their efforts to provide quality care and focusing on projects important to them are means of involving them in the pilot project.

Emphasis is now on completing the remainder of the CUSP stages, evaluating the project and preparing for spread across the province. Work done during the pilot phase will provide direction and tools for system implementation and change management.

**INTERVENTION PROGRESS REPORT**

## 3.1 Context

### 3.1.1 Global context

In our complex healthcare system, there are times when care providers, in their efforts to help their patients, inadvertently cause them harm. Over the past decade, studies from around the world have demonstrated high rates of accidental patient injury and death. In 2000, a report by the Institute of Medicine[1] stated that more people die in America as a result of medication errors alone than motor vehicle accidents, breast cancer or AIDS. When combined with deaths due to hospital-acquired infections and adverse drug reactions, deaths in hospital caused by the healthcare system are estimated to be the third leading cause of death in the United States[2]. Researchers from other countries have reported similar findings[3,4,5,6]. In Canada, an estimated 7.5% of patients admitted to hospitals--185,000 people--experience potentially preventable adverse events annually[7]. Patient safety is a growing international concern, and is receiving significant attention in BC and within the Provincial Health Services Authority (PHSA).

The costs of the patient safety problem are substantial, with up to $750 million in extra healthcare spending attributable to adverse events in Canada each year[8]. Patients, of course, pay the highest price in pain and suffering, loss of income, loss of function, loss of limb and, ultimately, loss of life[9]. Families and loved ones suffer by association.

Costs to healthcare providers are also significant. People who choose careers in healthcare genuinely want to help their patients, and certainly don't mean to cause them harm[10,11]. Clinicians are demoralized when patients and their families show a lack of trust in their care, and devastated when they are involved in adverse events that cause harm. Burnout, turnover and absenteeism are all connected to low staff satisfaction with practice environments that do not facilitate safe provision of care. The link between safe care and adequate health

human resources has been made in reports on the nursing shortage[12]. Given the present and predicted future shortages of healthcare professionals, the patient safety issue has important ramifications for staff recruitment and retention[13] and the ability of healthcare organizations to meet the needs of their patients.

Problems with patient safety have other costs, such as the public's loss of faith in the healthcare system's ability to deliver safe, quality care. Romanow noted, "Canadians…expect high standards of quality to be met…Too often, however, those expectations are not being met and, as a result, Canadians' faith in the health care system is undermined" [14].

Efforts to solve the patient safety problem have yielded only small gains to date[15]. In 2004, a US study[16] found that nearly 80% of Americans surveyed believed that healthcare had either stayed the same or worsened since 2000. Recent reports on patient safety in the UK also stated that "the pace of change has been too slow"[17] and that much work remains to be done in this area[18]. In Canada, a 2006 survey of consumers and healthcare workers found a worsening perception of the patient safety compared to results of previous years[19]. A survey of adults in Australia, Canada, Germany, New Zealand, the UK and the US ranking dimensions of healthcare according to the IOM's framework for quality indicated room for improvement in all countries[20].

Other high-risk industries with impressive safety records offer potential solutions. The threat to healthcare consumers is no less than that inherent in industries such as aviation and nuclear power, and is actually greater, as shown by Leape's analogy comparing the number of deaths from iatrogenic injury in the US to "the equivalent of three jumbo-jet crashes every two days" [21]. In reality, air travel is extremely safe, largely due to the aviation industry's unwavering focus on safety over the past few decades. "Practices in [such] 'high reliability' industries may provide models, or at least lessons, for improvement of patient safety in what is clearly a 'low reliability' sector"[22]. Borrowing from these other industries, the thinking about patient safety has

expanded to include the concept of a *culture of safety*, where values of safety and quality are part of the fabric of the organization, as a means to achieving a safer healthcare system[23,24,25].

A culture of safety requires visible leadership commitment, a non-punitive approach to error management, effective teamwork and a strong desire to learn and improve[26]. Leaders must trust that staff will be vigilant and report safety concerns promptly, and staff must trust that leaders will welcome reports and take action[27]. These components are all critical parts of the solution and support a much-needed systems approach to the problem[28].

Additionally, "a major element of programmes to improve patient safety is having the capacity and capability to capture comprehensive information on adverse events, errors and near misses so that it can be used as a source of learning and as the basis for preventive action in the future"[29]. An example of such a reporting system can be found in the UK, where the National Patient Safety Agency (NPSA) implemented the National Reporting and Learning System (NRLS). "Its purpose is to collect incident information so we can learn from it, alert the health system to potential risks, and use the information to design interventions to make care safer"[30].

### 3.1.2 BC context

In BC, all six Health Authorities are collaborating to establish the BC Patient Safety and Learning System (PSLS) to enable province-wide, electronic adverse event reporting. The initiative is overseen by the BC Patient Safety Task Force (PSTF), which was established in 2004 by the BC Ministry of Health (MoH) to work with the province's Health Authorities to improve the safety of patients treated by BC's healthcare system[31]. Although the PSLS relies on information technology, the main focus of the implementation project is cultural change. By introducing or strengthening sustainable patient safety practices, the project will help organizations across BC move towards safety cultures that embrace reporting and learning.

Prior to provincial roll-out, the PSLS will be tested at two pilot sites, one of which is the

Neonatal Intensive Care Unit (NICU) at BC Women's Hospital (BCW), part of Children's &

Women's Health Centre of BC (C&W), an agency of the PHSA. The pilot phase goals are to

provide proof of concept, configure and tailor the software and establish a plan for provincial

implementation. Funded by Canada Health Infoway's (CHI) Innovation and Adoption Program,

the BC MoH and the pilot Health Authorities, the project is being closely observed by the

Canadian Patient Safety Institute (CPSI) and patient safety leaders in other provinces.

Success of the pilot phase is critical to securing support and funding for provincial

implementation and ongoing operations. Although leaders at all levels recognize the importance

of patient safety, the PSLS project--like most projects--must compete with other urgent demands

for funding and resources. Further, the 'business case' for safety has been difficult to make due

to a severe lack of concrete evidence of the benefit of safety interventions[32,33]. However, a link

is emerging between patient safety and other dimensions of quality, such as access to care.

Adverse events result in 1.1 million added days in hospital each year[34]: reducing the incidence

by even 10% would add significant capacity to the system, which could be applied to waitlists.

Preventing adverse events that occur in the community and result in emergency visits[35] could

reduce emergency room crowding. Improving patient safety could demonstrate real business

value by helping solve these and other costly, high-profile problems, and savings realized by

reducing adverse events could be reinvested in improvement initiatives[36].

The BC PSLS project is large and complex, and as co-director of the provincial initiative,

I am involved with most of its components. My Intervention Project (IP) focuses on the PHSA

pilot implementation and touches on aspects of the larger project.

3.1.3  Local context

The PHSA strategic plan[37] emphasizes quality and safety, considering them central to the

work of the Health Authority and its agencies. The PHSA employs approximately 10,000 people.

More than 4,000 of these employees work at C&W, including over 1,500 nurses and 800

physicians. Over 2,000 students and trainees, from a wide range of health professions and

provincial, national, and international academic programs, participate in learning activities at

C&W annually. Nearly 300 people work in the NICU at BCW.

Patient safety problems occur across the healthcare continuum, but some areas pose

higher risks than others. The NICU, a Level IV tertiary neonatal unit for extremely ill and

premature infants, is a very high-risk area. The intensive, often invasive, critical care required by

these babies combined with their profound fragility creates a context where adverse events are

likely to occur, despite the best intentions of highly skilled staff, and consequences are severe.

The NICU is staffed by a large cadre of nurses, a discreet physician group, medical

trainees and respiratory therapists, with support from other clinicians and specialists as required.

In the past few years, several serious adverse events have captured the attention of the NICU

team. A record birth rate at BCW in 2005/06 and limited resources in other parts of the province

have contributed to frequent periods of high census and acuity, with concurrent staff shortages,

high use of nursing overtime and associated fatigue and concerns about retention and safety.

Penetration of technology in the NICU is moderate, and while BCW does not yet use a

Clinical Information System, NICU staff regularly use computers in their daily work.

## 3.2     Problem Statement

Safety reporting systems will not work if front-line care providers do not use them. As

few as 5% of adverse events are formally reported, and near-miss events are seldom brought to

the attention of organizational leaders[38], even though these events offer some of the best

opportunities for learning. Electronic systems tend to increase reporting rates by removing some

of the practical barriers to reporting, but if the only change made is from paper to computer, few

gains are seen in terms of actual learning or benefit to patients. The question I want to answer

though my IP is: *What are the conditions or strategies that promote adoption of an electronic*

*adverse event reporting system and encourage reporting and learning behaviour?*

### 3.3    Evidence Review

3.3.1   Sources

Patient safety is the focus of international reports and an area of growing academic

interest. "The number of studies on patient safety is soaring. Close to a century ago…quality of

care was a relatively rare area of study…By 2003, almost 1% of publications in…PubMed…

dealt with patient safety or medical errors--more than four times the level in 1982" [39].

Literature review involved searches of major databases including Ebsco, PubMed and

Cochrane, and use of search engines such as Google Scholar to examine the topics of patient

safety, healthcare incident reporting, safety culture, leadership and change. Other evidence was

obtained in November 2005, when I visited hospitals in Boston, Massachusetts and London,

England as part of the process of selecting the incident reporting software and spoke with

healthcare leaders who have implemented similar systems about their experiences. I learned how

they had implemented their systems and reviewed some of their documents and tools.

3.3.2   Assessment

Experimental methods, randomized controlled trials, quantitative data and empiricism

were rare in the literature I reviewed, as is often the case in healthcare management research[40].

Methodologies varied and local context was often an influencing factor, making it difficult to

compare results and generalize findings. Few systematic reviews or meta-analyses were

available. The grey literature provided some of the most useful information. Anecdotal reports

and studies describing the process of change and experience of participants and sharing practical

lessons learned were plentiful and indicative of the burgeoning interest in patient safety.

An example of variation in research methodology was found in studies undertaken in

Canada, the US, Britain, Australia, Denmark and New Zealand attempting to quantify the extent

of the patient safety problem. Researchers used similar but not identical methods. The reported

frequency of adverse events ranged from 3.2-12.9%, with 37-51% possibly

preventable[41,42,43,44,45,46,47,48], constituting ample evidence of a serious problem with patient

safety. Even if the actual incidence is on the low end of the estimates, the issue is troubling due

to the large number of people who come into contact with the healthcare system. "In the

aggregate, mistakes add up….Even with a low injury rate, millions of people are getting hurt"[49].

The theme of cultivating a culture of safety as the foundation of a safer system was a

consistent one, with many papers describing the importance of engaging front-line care providers

in identifying, reporting and managing adverse events and promoting communication, teamwork

and learning[50,51]. Although studies in other high-risk industries are available[52,53,54], little

research within a healthcare context exists to guide the execution of strategies to create safety

culture.

A brief review of literature on organizational theory and design focusing on

characteristics of high-reliability and resilience found both research studies and descriptive

papers[55,56,57,58,59]. Themes included recognition of complexity as the enemy of safety,

preoccupation with failure, systematic problem identification, analysis, and learning, efforts to

make sense of people's experiences and data so they could be used to create change, a systems

approach to error management, and trusting relationships between workers and leaders[60]. Studies

drawing on these themes and applying them to healthcare to foster safety culture were

informative[61,62,63,64].

Research-based evidence on incident reporting systems was found in a systematic review

assessing their effectiveness in improving patient safety, clinical outcomes, costs and

operations[65]. The authors concluded that while such systems can provide valuable information

about adverse events, which can form a basis for learning and improvement, their benefits are
not well-established and there is limited evidence of their effectiveness in a healthcare setting.
WHO guidelines[66] represented policy research meant to inform organizations considering
implementing reporting systems, and are consistent with the direction of the BC PSLS.

Problems with safety reporting are not unique to healthcare, and the literature review
offered examples of other industries that faced--and overcame--similar challenges[67,68]. In both
aviation and nuclear power, safety was essential to ensure people were not injured or killed on a
large scale. Safety culture was fostered by systems that afforded reporters anonymity and
protection from punishment, involved expert third parties to analyze, trend and report on lessons
learned, established policies to enable staff to take action to prevent harm, provided education
and feedback and demonstrated visible leadership commitment to safety and improvement.

A barrier to incident reporting was fear of retribution or punishment from leaders or
peers. Fear of litigation was an obstacle for physicians, despite legislation that protects reporting
and investigation of quality issues from disclosure[69]. Poorly designed or inaccessible forms
presented hurdles. Failure to recognize safety problems and the need to report them contributed
to underreporting. Reporting was not always seen as a priority by personnel busy providing
patient care. Lack of feedback discouraged those who reported incidents from doing so again, as
there was no indication that the reports were valued or produced change in the
system[70,71,72,73,74],.

A report to the British Department of Health[75] underscored the importance of ensuring
that reporting results in actionable learning and change. Despite wide-spread use of the NRLS to
identify safety issues (over 60,000 reports per month), there was little evidence of improvements
locally or across the system. Barriers included poor data quality, lack of clinician adoption of the
reporting tool, local inaction and a slow rate of feedback and analysis from the NPSA.

Recommendations to improve the NRLS will inform the long-term direction of the BC PSLS.

User adoption of information technology is critical to the successful implementation of the PSLS. Adoption depends on fit between the attributes of the individuals, technology, tasks and processes, each of which creates a set of potential barriers[76]. Users must perceive the system improves efficiency and eliminates redundancy. Features must facilitate capture of comprehensive information, timely notification and follow-up.

A systematic review examining the leader's role in quality and safety improvement[77] highlighted the significance of leadership in achieving improvement, leadership actions that help or hinder improvement efforts and ways to develop or support leaders in this work. Nembhard and Edmondson[78] emphasized the role of leaders in creating an environment where staff feel safe speaking up about quality concerns in a study set in a NICU, which demonstrated clear benefits associated with leadership in relation to safety reporting and improvement. Pronovost and colleagues described the Comprehensive Unit-based Safety Program (CUSP) developed at Johns Hopkins Hospital[79,80], which offers a staged approach to engaging local staff and senior leaders in creating a culture of safety by conducting a cultural survey, educating staff on the science of safety, identifying and handling safety issues, making improvements and sharing stories. Safety huddles[81] and leadership rounds[82] were strategies used with CUSP to foster safety culture.

I found debate in the literature about how culture should be measured[83,84,85] and whether useful information about safety culture can be obtained by measuring safety climate[86,87]. Most studies agreed that climate and culture overlap, and that measuring safety climate can provide some indication of safety culture. "Recently, instruments have been developed specifically for healthcare...There is now a range of safety culture instruments available to healthcare organizations"[88], although more work on their psychometric factors is needed, especially as they are increasingly being used for large-scale surveys of healthcare organizations[89,90,91]. Several

studies provided a comparison of several tools and their strengths and weaknesses[92,93]. The IHI

suggested the SAQ and the Hospital Survey on Patient Safety Culture (HSOPSC)[94,95].

Review of the change management literature offered a variety of change models and

levels of evidence for consideration[96]. An IHI white paper using a study of initiatives at the

Veterans Administration to demonstrate a framework incorporating change management was

relevant to the provincial roll-out of the PSLS[97]. Berwick's paper on disseminating innovations[98]

drew on change theories by Rogers[99] and others and also offered ideas for future spread.

### 3.3.3   Application

The research base for healthcare management is "loosely defined, methodologically

heterogeneous, widely distributed and hard-to-generalize…[and]…the research methods used,

the importance of local organizational context and culture, and the structural differences between

health organizations and health systems all make research transfer more problematic" [100]. To

effectively select and apply the results of the literature review, I sought local evidence.

In April 2006, safety culture was measured in the NICU using the HSOPSC, with 198 of

272 potential participants responding (73%), representing all disciplines. Results demonstrated

strengths in two dimensions of safety culture: teamwork within the unit, and manager

expectations and actions promoting safety. Room for improvement was found in overall

perception of patient safety, and staffing (a dimension of safety culture). Indicators specific to

adverse event reporting, such as lack of feedback and communication and concerns about

punitive use of reports, were consistent with barriers reported in the literature.

Surveys provide a view of safety climate, but "much more digging behind the façade is

required to determine [culture]" [101]. To develop a deeper understanding of NICU culture[102] and

validate the literature review findings, three focus group interviews were conducted in March

2006 using questions adapted from research studies on barriers to reporting found during the

literature review[103,104,105,106]. Participation was voluntary. Participants were assured that their

input would be reported in summary fashion only and they would not be individually identified.

All disciplines working in the NICU were represented in at least one focus group session.

Analysis of notes taken during the meetings confirmed literature review findings. Fear of

punishment or retribution; confusion about what to report and why, uncertainty about where

reports go and what to expect after reporting, lack of feedback, communication or evidence of

action taken following reporting, referred to as the 'black hole' syndrome, inconvenience

associated with the paper-based reporting system and negative reactions to and connotations

associated with term, 'incident report', were identified as barriers to reporting. The focus groups'

suggestions to promote system adoption were also consistent with the literature and aligned with

strategies described by Kingston, Evans, Smith and Berry[107] and the NPSA[108], which build on

existing reporting habits of nurses and develop reporting habits in others.

The literature suggested a number of indicators that could be measured to assess current

reporting practices and improvement following system implementation. Measures include

reporting volume and severity, reporter characteristics, and quality and completeness of report

data and follow-up information. Using these indicators, a three-month audit began in February

2006 to collect information about pre-implementation incident reporting practices at C&W. The

616 incident reports received by QSRM during that time were reviewed; 91% were incomplete

or contained errors. The average time from event until the form was received by QSRM was 25.6

days, and in some cases, forms took more than a year to arrive. Less than 10% of the forms were

received by QSRM within the expected 48 hour standard. The average time from event until

completion of all follow-up and investigation activities and sign off by managers was 51.1 days;

again, in some cases, this process took well over a year to complete. Most incidents reported

(92%) resulted in no or minor harm to patients. Blaming language was used only 8% of the time.

Repeated follow-up activities by QSRM staff were required related to 83 reports (14%).

Follow-up reports were received for 402 reports and were rated for quality by assigning one point each for evidence of systems thinking, root cause analysis, identification of contributing factors and changes made or suggested to prevent recurrence. Most (67%) received a score of 0 or 1, 19% were rated a 2 and only 14% received a score of 3 or 4.

In summary, the local evidence confirmed that there was room for improvement in NICU safety culture. Staff required education in the area of patient safety and better tools to identify and report issues. They also wanted support to participate in solving problems and making improvements. Leaders needed new processes, structures and skills to follow up on and manage issues. The literature on barriers and promoters to reporting, including technology-related issues, provides effective guidance.

On the basis of the literature review and the local evidence, I was confident that the CUSP model was an appropriate framework for my IP. CUSP supports changes in staff behaviour consistent with event reporting and engages them in practices that foster safety culture. CUSP also requires active participation from leaders to visibly support safety practices, provide positive feedback and use data to enact change, thereby demonstrating the value of reporting. These leadership behaviours are key to changing staff reporting behaviours.

In response to the emphasis in the literature on the thoughtful, deliberate application of change management strategies, the CUSP model was augmented by a logic model and the provincial PSLS change management plan. The evaluation component integrates assessment of online reporting systems[109] and the benefits evaluation approach promoted by CHI[110].

**3.4     Intervention Model and Strategies**

3.4.1   Objectives

The aim of the BC PSLS is to *make healthcare safer.* Although the specific goal of my IP

is to create conditions that encourage adoption of the PSLS by front-line NICU staff and facilitate reporting and learning behaviour, accomplishing the larger objective requires a broad approach "to create an environment that motivates and indeed, inspires [front-line healthcare providers] to insist that all care must be as safe as possible"[111].

Short-term outcomes focus on learning to achieve changes in awareness, attitudes, skills, opinions and motivations of staff and leaders. Medium-term outcomes include observable changes in practices consistent with desired reporting and learning behaviours. Long-term outcomes include a visible culture of safety and learning, better information-sharing among healthcare providers, reduced costs associated with adverse events and increased productivity through efficiencies. Bringing about an organization more receptive to the use of evidence to guide improvement and decision-making is also desired.

The pilot will demonstrate an effective approach to system implementation that can be used to spread the PSLS across the province and increase its chance of adoption by front-line staff. It will show that implementation can serve as an effective vehicle for cultural shift that has a positive impact on patients and staff beyond the reporting system focus, and that implementing changes that foster safety culture promotes adoption of the new system. It will prove that the system provides better information about safety issues, supports analysis, enables learning and leads to actual improvements in patient safety and quality of care, and build support for the provincial implementation, which can then serve as a model to those in other jurisdictions interested in establishing similar systems. Once the PSLS is implemented across BC, it will help clinicians and administrators learn from their own experiences and errors and those of others so they can make changes necessary to enhance safety and improve quality.

### 3.4.2 Models and Methods

Creating conditions to promote adoption of the PSLS by front-line users will help staff

move towards the culture of safety necessary to achieve the ultimate goal of the PSLS, that is, to

*make healthcare safer*, by creating "work environments committed to improving safety…[that

are] are informed, just and flexible; inspire individuals to report incidents and near misses; and

use safety data to learn and reform"[112]. CUSP provides a framework for efforts aimed at

promoting reporting and learning and fostering safety culture.

Front-line staff who report safety events, managers who follow up on reports, QSRM

leaders who investigate serious incidents and executive leaders who receive summary data are

the target audiences participating in this project, although there are many other stakeholders.

During pilot implementation, the system will be installed and tested, users and managers will be

prepared for and begin using the new system, QSRM leaders will be prepared to support and use

the new system and necessary organizational changes will be completed.

Where possible, change initiatives are linked to requirements, such the Canadian Council

on Health Services Accreditation (CCHSA)'s Required Organizational Practices[113], and other

activities in the organization, including work done by clinical quality and safety groups and

committees. Change strategies also link to and leverage other initiatives in the organization, such

as a leadership development series and a quality and safety internship program for front-line

nurse leaders. Change management activities specific to the NICU pilot form part of the larger

provincial project which in turn, shapes the change management activities and strategies used for

my IP. Specific activities relate to stakeholder engagement, organizational readiness,

communications, education and training and evaluation.

Prior to beginning the first stage of CUSP, it was important to begin engaging the larger

organization. The most critical characteristics of successful pilot projects come from their

external orientation, rather than a focus on their internal processes and development[114]. A

number of challenges inherent in pilot site implementation projects can result in them being

isolated from the larger context and seen as either threatening or irrelevant, affecting their long-term survival and impeding their spread. The provincial PSLS change management plan recognizes these risks and provides guidance on activities and strategies aimed at effectively engaging the larger organization, external stakeholders and the pilot site.

Through stakeholder analysis and mapping, the pilot team identified awareness, interest, impact and influence of stakeholder groups and individuals on the project, and the desired level of involvement, and devised a stakeholder engagement plan. Presentations, software demonstrations and briefings were used to inform the larger organization about the project. Existing committee meetings were good forums for sharing information and inviting discussion to promote wide-spread engagement. Regular updates on the status and progress of the pilot site were widely distributed. Wherever possible, the project was linked to organizational priorities and strategic goals, such as our upcoming CCHSA accreditation survey in 2008.

One strategy used to engage front-line leaders from the pilot site in the project was the secondment of clinical nurse leaders to participate in our pilot implementation team. Involving executive leaders in regular, scheduled Leadership Walkrounds™ will also promote engagement and will help foster cultural change[115,116].

The CUSP framework was then used to guide the project activities. In Stage One we assessed safety culture and identified existing safety practices, such as safety rounds, and shared cultural survey results with NICU staff and organization leaders. A post-implementation survey will be conducted to help assess whether cultural shift has occurred. Assessing safety culture was part of a larger process to determine readiness for implementation of the new system. The impact of the planned changes on the NICU and gap between current and desired states were determined. Processes for reporting and investigation, job descriptions, policies and committee terms of reference were reviewed, with revisions made to support the planned changes.

Stage Two focuses on educating staff about safety. A comprehensive education plan was developed, including introduction to the reporting tool, review of related policies and procedures, basic safety education for all staff and more extensive training for managers about event investigation and follow-up. This strategy aims to eliminate barriers to reporting caused by a lack of knowledge about the reasons for reporting, what to report, how to report and what to expect after making a report[117]. Champions from each discipline will support and reinforce learning through one-on-one and informal group discussions and by modeling desired behaviours.

Because developing "competent, conscientious, risk-aware healthcare providers…[is] essential at the 'sharp end'"[118], the focus of education is on patient safety, but teaching staff to use the new system is also critical. The PSLS software was required to meet a number of specifications that will contribute to the system's adoption by front-line users, such as ease of use with minimal training and support and web-based access. Using Ammenworth's approach[119], attention has been paid to the fit between the attributes of the individuals, the technology and the tasks and processes. A survey to assess computer use skills was conducted early in 2006 by NICU educators. Most staff members were competent; support was provided for those who needed help. Offering access to a simulated computer environment within the NICU with one-to-one coaching from educators was found to be an effective way to build competence and confidence. A similar approach will be used.

In Stage Three, staff will begin to use the PSLS to identify issues. Coaching and feedback are critical during this early stage of adoption to ensure known barriers to reporting are addressed and new processes are implemented. Safety rounds and Leadership Walkrounds™ are other ways issues may be identified. Involvement of senior leaders is an important way to demonstrate leader inclusiveness, defined as "words and deeds by a leader…that indicate an *invitation* and *appreciation* for others' contributions"[120]. Leader inclusiveness can help create an environment

where staff feel safe to speak up and identify issues.

In Stage Four, the emphasis is on handling issues effectively. By training and supporting managers in investigating and responding to incidents reported through the PSLS and facilitating problem-solving during safety rounds, we will develop the capacity for pilot site members to analyze, address and learn from safety issues and problems. Handling issues also involves giving feedback to reporters, which will help address the 'black hole' problem. Support for front-line users is needed to promote adoption, so a Help Desk for both computer- and process-related issues will be provided.

In Stage Five, the emphasis shifts to making improvements. The NICU Quality and Safety Committees will begin to review reports produced by the PSLS and formulate plans to address and rectify safety issues. Education on the use of the PDSA process for incremental, rapid cycle change[121] and techniques to examine processes, including Root Cause Analysis and Failure Mode and Effects Analysis, will help Committee members build their skills in managing change and effecting improvement. Several nurse leaders in the pilot site have already received training on the use of these methods. Visible evidence of change and improvement will demonstrate to staff that their reporting activities are valuable.

Stage Six closes the loop by sharing stories and learning. It is a tragedy that adverse events in healthcare repeatedly recur, and that we do not have effective ways to learn from each other about how to prevent them. In 1996, a child died at BC Children's Hospital following the accidental intrathecal administration of vincristine, an intravenous drug that is uniformly fatal if given into the spine. The same error had occurred before elsewhere, and has occurred since. Lessons that organizations that have lived through these painful experiences have learned have not been shared to the degree necessary to create systemic change. This sharing of "stories" and associated evidence-based practice changes is the driver behind systems such as the NRLS, and

will be the real benefit to patients and the system once PSLS is implemented provincially.

By using the report writing capabilities in PSLS to identify "stories" that need to be shared, learning will be better supported and promoted. "Repeatedly telling stories about successful improvements [helps] to introduce and reinforce desired cultured values and behaviours and to build momentum for change"[122]. The PSLS communications plan identifies opportunities to share stories and make successes visible.

Evaluation is a thread throughout all stages. Formative evaluation using the PDSA model to seek feedback on all aspects of the program allows us to continually refine our approach. Summative evaluation at the end of the pilot will include an audit using the indicators measured at the onset of the project, and a re-survey of safety culture. These measures form part of a comprehensive evaluation plan, which also includes a survey to assess user satisfaction with the software and training based on work by Berkowitz[123] and CHI[124]. The project model will also be evaluated so that changes can be made before spread and learning can be shared with others.

3.4.3   Intervention Implementation

The provincial PSLS project has faced several challenges, each of which impacted the progress of the pilot. Staffing the project has been a challenge. Project work develops employees and builds capacity within the Health Authorities. However, to address human resources shortages and the need for specific expertise in change management, large-scale project management, communications and IT, we added external consultants to the team.

Legal and financial issues resulted in several revisions to timelines. Challenges included negotiating a contract with the overseas vendor, assessing privacy impact, developing a governance model, and quantifying and securing ongoing operational funds. Working with CHI and the MoH adds complexity to the project, but also adds value in the form of input from CHI.

Despite these barriers, considerable progress has been made, with emphasis on planning,

design and system configuration. The PSLS will "Go Live" in the NICU in May 2007.

### 3.4.4 Results

At this stage, I am unable to provide outcome or comparative data to show whether or not the strategies I have chosen actually promote adoption of an electronic adverse event reporting system, but do observe shifts in behaviour related to reporting and learning. Results are limited to those we have been able to achieve through the completion of CHI provincial project deliverables. We have completed the first and most of the second stage of CUSP.

One additional important activity is configuring the software to meet the needs of the Health Authorities. The understanding of the NICU and its culture that the pilot team developed during the first stage of CUSP informed configuration decisions, and as educational plans were developed in preparation for the second stage, much attention was paid to ensuring a user-friendly interface. The team used a PDSA approach to test out forms, taxonomy and configuration. The work done in this area will promote user adoption of the system.

Collaborating with other Health Authorities has offered opportunities for learning and knowledge transfer across organizational boundaries and cultures. While sometimes challenging and time-consuming, we are creating a foundation for the provincial implementation that is more likely to be applicable across BC than a single Health Authority perspective would have allowed.

As individuals and as a team, the QSRM staff have benefited from participating in the pilot by developing their project and change management skills, particularly through their association with the expert consultants working on the project. They are now able to apply these skills to other projects and initiatives, resulting in a greater chance of successful change.

Technology is an important component of the project. IT specialists are an integral part of our team and have developed a thorough understanding of the business drivers for the project and its connection to the work that front-line care providers do in caring for patients.

## 4.0    LESSONS LEARNED

Specific criteria should be used to determine organizational readiness to engage in a pilot project, particularly one that involves collaboration at this level, and exploration of differences in cultures, structures, processes and values, should take place before proceeding to confirm that the groups have enough in common to work together and avoid misunderstandings, frustration and delays. Even in the best of circumstances, collaboration takes time and adds complexity. Opportunities for knowledge transfer and developing shared vision, goals and relationships need to be built into the project plan, and activities, timelines and budgets need to take these requirements into account. Roles, accountabilities and decision-making processes should be clearly articulated to avoid confusion and prevent delays. A commitment to evidence-based decision-making is necessary, but presentation of evidence alone is not enough. Decision-making involves persuading people, securing support and consensus-building. In a collaborative project, decisions can be heavily influenced by "organizational or wider system requirement, such as resource availability, pressures in the healthcare marketplace, organizational policies and procedures, and stakeholders' views and interests. These factors may act as limitations, or may even directly conflict with research findings"[125] and add complexity to the process.

A rigid, linear project management approach does not work well with a complex, iterative project. Ironically, a change initiative can come to a grinding halt when it encounters a need to change course that is not easily accommodated by the project plan! Focusing on project control and adhering to a pre-determined set of tasks and timelines does not allow the flexibility to respond easily to emerging issues, and working through formal change request processes can impede progress. Quality improvement project methods and tools combined with thoughtful change management offer a more nimble framework. Guidance documents supporting a project plan can create an effective "roadmap" for implementation team members and empower them to

enact their roles. Ivory and Alderman[126] suggested that "project execution be thought of as a process of constantly adjusting the project system to fit a confounding and emerging reality". A multi-modal approach with built in "slack" to accommodate shifting pace and emerging findings and both top-down and bottom-up interventions is recommended. A quality improvement spread model[127] may be appropriate for provincial roll-out. Comparing the very different approaches taken by the two pilot project teams will offer substantial learning and inform the roll-out plan.

Integrating pilot site staff into the project team is essential. The seconded nurse leaders act as cultural translators in both directions, and are better able to influence practice and effect change in the pilot site than other project team members. This "embeddedness provide[s] a basis for taking action--an opportunity for implementing desired change" and that embedded staff are able to "use…their established networks and intimate knowledge of their work environment to take…purposeful actions designed to change established patterns of work"[128]. Also, pilot site staff members are in the best position to identify both problems and solutions, and are often keen to be part of the project. Giving them opportunities to participate recognizes their important contribution and ensures the project remains relevant to the clinical program.

On a lengthy project, team members can become frustrated with delays and discouraged by apparent lack of progress. Building goals and evaluation activities into the schedule has allowed the team to achieve small successes, which are recognized and celebrated to bolster team spirit and maintain momentum.

We are using specific strategies to engage physicians in the project[129], joining them in their efforts to provide quality care by proposing ways to use the PSLS to support improvement projects that are important to them. Using physician champions to provide peer-to-peer support and coaching within the NICU is another approach we believe will be effective with this group.

## 4.1     Implementation of Change

A major initiative of the BC PSTF, the BC PSLS is positioned for success. The PSTF has a significant role and influence in the province and strong connections with patient safety organizations outside of BC, its chair is the executive sponsor of the PSLS project and a PHSA executive leader. Quality and safety are central to the PHSA and BCW strategic plans; recent restructuring at BCW emphasizes the integration of quality and safety activities at the leadership and clinical program levels. Reorganization underway in the NICU offers opportunities to support staff in new roles through the safety strategies we are implementing during the project. All of these factors facilitate the successful implementation of my IP, but also pose barriers, particularly to timeline, due to the large, complex, high-profile nature of the provincial project.

Inter-Health Authority collaboration will result in better outcomes and learnings than would be possible with a smaller, local project and will contribute to the likelihood the changes we make will be sustained systemically. However, the challenge of working with a large number of people with diverse perspectives and backgrounds and sometimes competing agendas and priorities cannot be underestimated. The collaborative has offered regular forums for review of my approach to the pilot project by the provincial co-directors and representatives from CHI; these discussions have shaped both my IP and the provincial project plan.

A key to sustainability of patient safety and quality initiatives in healthcare is developing capacity for change and improvement at the local level and ensuring resources are dedicated to this work. Helping NICU leaders learn to analyze reports provided by the new system and use evidence-based tools to effect change will enable them to continually improve the quality of care and solve safety problems in their program; these actions will demonstrate leadership commitment to safety, which will encourage staff to sustain reporting behaviours.

Opportunities abound to expand the project and link it with other initiatives, allowing us to weave the changes we are making into the larger system, an approach that will help them be

sustained over time. The question has not been how to gain momentum for the project but how to

contain the scope to minimize and mitigate risk and provide the best conditions for success.

## 5.0    DISSEMINATION

A communications plan for the provincial project identifies regular opportunities to share

progress and results at meetings of BC healthcare leaders. The PSTF website offers a means to

disseminate results and experiences to a healthcare audience and the public. Internally, a

newsletter, brochures and posters ensure stakeholders regularly receive up-to-date information.

Externally, opportunities to present and publish on various aspects of the project will be sought.

The PSLS project team has connected with healthcare leaders in Alberta, Nova Scotia

and Newfoundland who are interested in developing similar systems. We will continue to share

our experiences and invite input from others as we go forward. As a CHI Innovation and

Adoption project, we will share our experiences and lessons learned with other jurisdictions.

## 6.0    IMPLICATIONS

### 6.1    For Other Decision-Makers

At this stage of my IP, implications for other decision-makers considering

implementation of an electronic safety reporting and learning system on a large scale are limited

to the planning and design phases. Literature review findings are important, as they demonstrate

the patient safety problem but do not provide adequate direction for solving it, nor do they offer

evidence of the value of incident reporting systems *per se*. Any approach to implementing a

reporting system should address the barriers to reporting identified in the literature, including the

role of leaders and the application of information technology, confirmed by local evidence. A

model for engaging clinical staff and leaders in activities aimed at shifting them toward a culture

of safety, such as CUSP, could be a useful framework to apply, either as part of system

implementation or separately. Developing capacity for change and improvement can be

facilitated by using in-house resources to staff the project team wherever possible, and engaging

staff from the pilot or target sites in the project is an effective strategy for ensuring the project

approach is relevant and that changes will be sustained.

**6.2     Different Audiences**

Those embarking on large projects involving multiple stakeholders and organizations

should note that while significant benefits can be achieved through a collaborative approach,

careful attention should be paid to initial planning. There are implications for the project plan,

timeline and resources.

The emphasis we have placed on change management as opposed to IT system

implementation has required a different approach than is seen in typical software-related

projects. Given the problems with system adoption faced by many IT project teams, leaders of

such projects might benefit from our experience.

**6.3     Future Activities**

Linking with other projects and organizations with similar or related interests will help

sustain my intervention and the PSLS in the long term. A research project examining adverse

event reporting in BC emergency rooms has been funded by the CPSI, a second research project

engaging patients and families in reporting adverse events is planned, a safety alerts project is in

the early stages at provincial level and a third BC Health Authority is now participating in one

aspect of PSLS pilot project. Activities to map the software taxonomy to other applications are in

the planning stages. Future partnerships across provincial jurisdictions may be facilitated by

CHI. CPSI is interested in a national adverse event reporting system. Connecting with CPSI will

be helpful in sustaining the intervention and expanding its scope.

"While a growing interest in better methods of detecting patient safety problems is

welcomed,…reporting systems must be seen in their wider context. A particular need is to ensure

that developments in systems of reporting are matched by developments in systems of response

to what is reported…[including] expert analysis of reported events and timely feedback of

identified risks and hazards" [130]. In the future, an organization like the Patient Safety

Observatory in the UK[131] is envisioned for BC, providing an arms-length body to apply a

sensemaking lens to aggregate data from all Health Authorities and "turn a flow of

organizational experiences into words and salient categories they can comprehend and then use

them as a springboard for action"[132]. Goals will be to identify trends, disseminate best practice

guidance, share stories and lessons learned broadly and promptly and drive research in the area

of patient safety[133].

### 6.4     Overall Plan

At C&W, the involvement of QSRM staff in the pilot project will position them to be

effective, knowledgeable users and promoters of the PSLS, coaching and supporting front-line

staff and managers to encourage long-term adoption of the system. The secondment approach to

building organizational capacity for quality improvement has proven to be effective, and efforts

are underway to create permanent quality and safety leader positions within the programs. Other

initiatives consistent with the PSLS will help sustain the changes over time.

The PHSA Board of Directors has approved safety policies on safety culture, event

reporting and disclosure, which serve as the foundation for safety activities and approach across

the Health Authority. The Board requires regular reporting on a variety of quality indicators,

including safety events, using tools such as a Balanced Scorecard. New reports derived from data

collected using the PSLS will be provided to the Board to give them a more comprehensive, up-

to-date perspective on quality and safety within the PHSA agencies.

The provincial approach taken to the PSLS project offers the best chance for systemic

change and improvement. Benefits and savings due to economy of scale and a centralized data

centre and greater learning and improvement will be possible through the sharing of experiences.

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## 9.0 APPENDICES

## 9.1 Appendix A - Logic Model

# Program Action – Logic Model

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**Inputs**

What we invest
- Staff
- Time
- Money
- Research base
- Materials
- Equipment
- Technology
- Partners
- Leadership
- Expertise

**Outputs**

**Activities**

What we do
See Intervention Design and Strategies section of IP Report

**Participation**

Who we reach
- Pilot site
- Leaders
- Stakeholders

**Outcomes – Impact**

**Short Term**

Learning
- Awareness
- Knowledge
- Attitudes
- Skills
- Opinions
- Aspirations
- Motivations

See Objectives section of IP report

**Medium Term**

Action
- Behaviour
- Practice
- Decision-making
- Policies

See Objectives section of IP report

**Long Term**

Conditions
- Cultural
- Economic
- Environmental

See Objectives section of IP report

**Situation**
See Context section of IP Report

**Priorities**

**Assumptions**

**External Factors**

**Evaluation**

Focus – Collect Data – Analyze and Interpret - Report