EVALUATION OF THE IMPLEMENTATION OF AN ELECTRONIC OCCURRENCE REPORTING SYSTEM AT EASTERN HEALTH, NEWFOUNDLAND AND LABRADOR (PHASE ONE)

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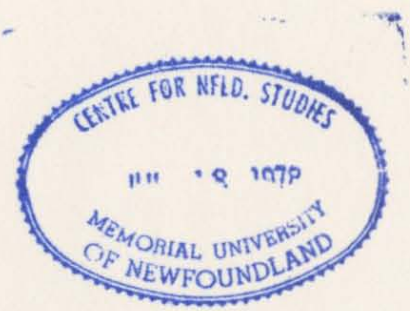
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Evaluation of the Implementation of an Electronic Occurrence Reporting System at Eastern Health, Newfoundland and Labrador (Phase One)

By:
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Abstract

Evaluation of the Implementation of an Electronic Occurrence Reporting System at Eastern Health, Newfoundland and Labrador (Phase One)

In June 2008, Eastern Health completed the implementation of an electronic occurrence reporting system (Phase One). Phase One included a pre-go-live site (an integrated services site in a rural setting) and three go-live sites (acute care, long term care and community health in an urban setting). The evaluation study had a dual purpose: (a) to assess and report on the impact of the implementation of the electronic occurrence reporting system on achieving its stated objectives, particularly those that could be measured within the timelines of the project and (b) to analyze findings to identify contributions to the literature in the recently developing field of implementations of electronic occurrence reporting systems in health care.

The evaluation was guided by the framework outlined in the report, "*Towards an Evaluation Framework for Electronic Health Records Initiatives*" (Neville et al., 2004), which emphasizes stakeholder involvement in evaluation studies, pre/post comparative study design, and triangulation of data where possible. Data were collected from several sources such as project documentation, administrative occurrence reporting records, surveys, focus groups and key informant interviews.

The findings of this study provide evidence that frontline staff and managers support the implementation of the electronic occurrence reporting system, that there is little difference in results between the various sectors of the continuum of health services and the new system had both positive and negative impacts on the role of frontline managers. There were limitations related to some of the findings due to the small sample size, particularly the long term care sector.

Many benefits were realized such as: (a) an increase in the number of occurrences reported, (b) increase in the number of occurrences reported within 48 hours, (c) increase in the number of occurrences reported by staff other than registered nurses, (d) increase in the number of close calls reported, (e) positive changes in the patient safety culture, (f) improved timelines for notification of high alert occurrences to managers, and (g) satisfaction with the electronic tool related to ease of use, accessibility, and consistency.

The implementation process also encountered challenges, such as issues related to customizing the software and development of the classification system for coding occurrences. These issues impacted on the ability of the managers to obtain timely customized reports and to close out files. These challenges are currently being addressed by the Project Implementation Team. Participants noted that resolving these issues will enhance the many positive impacts of the system already realized. Lessons learned during the Phase One implementation process (including the identification of facilitators and barriers) resulted in recommendations that can assist with future implementations.

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There are many people who I would like to thank for their assistance throughout the research process and/or in the preparation of this thesis.

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Gratitude is extended to Canada Health Infoway (CHI) for providing funding for the implementation of electronic occurrence reporting system, which also included funding for the evaluation component. A report of the evaluation was submitted to CHI in March, 2010. Thanks is extended to Eastern Health, the other sponsor of the project, who provided the opportunity for me to use some of my time as part of their in-kind contribution towards the project. Eastern Health was also generous in their financial assistance for the costs associated with participation in a PhD program.

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This thesis is dedicated to my husband, Rick, and my children, Bradford and Jasmine.

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List of Acronyms

AC	Acute Care
BCPSL	British Columbia Patient Safety Learning
CHI	Canada Health Infoway
CCHSA	Canadian Council of Health Services Accreditation
CPSI	Canadian Patient Safety Institute
CSRS	Clinical Safety Reporting System
CH	Community Health
EH	Eastern Health
IT	Information Technology
LTC	Long Term Care
QRM	Quality and Risk Management
QCSL	Quality and Clinical Safety Leaders
RN	Registered Nurse

1 Introduction

1.1 Patient Safety and Occurrence Reporting

Florence Nightingale once wrote "it may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm" (Nightingale, 1859). That was over a hundred and fifty years ago and yet, today that requirement is still identified as an issue in the health system. While the health system has changed since that time, the "doing no harm" to patients is part of the patient safety agenda worldwide in health care. Health care is provided in a high risk environment.

In a report by The National Steering Committee on Patient Safety (2004) which outlines a strategy for improving patient safety in Canadian health care, a brief description of that high risk environment is provided:

> "Health care is provided 24 hours a day, seven days a week. Dramatic advances in the diagnosis and treatment of disease have made care processes more complex; however, many organizations are hampered by outdated modes of communication, record keeping, employee training, and traditional hierarchical authority structures. The aging population, resource limitations, a critical shortage of qualified health professionals in a growing list of locations and specialties, and challenges created by mergers, and restructuring within health care organizations,

are creating unequalled strain on the systems, thus, increasing the likelihood of adverse events, sometimes with lethal consequences" (p.5).

Patient safety has been defined in the Canadian Patient Safety Dictionary as "the reduction and mitigation of unsafe acts within the health care system, as well as through the use of best practices shown to lead to optimal patient outcomes" (Davies, Hebert, & Hoffman, 2003, p.12).

The issue of patient safety has gained an increasing profile in recent years, especially since the publication of *To Err Is Human* by the Institute of Medicine (IOM) in 2000. The report estimated that between 44,000 and 98,000 Americans die each year from adverse events at a cost to the nation of $8.5 to $19 billion annually (Institute of Medicine, 2000). Other countries, including the United Kingdom, Australia and New Zealand have investigated the extent of the problem and clearly shown that adverse events are a global patient safety concern (Baker et al., 2007; Sheps and Cardiff, 2007; White, 2007; Williams and Osborn, 2006; and Vanderheydeen, et al., 2005). Baker et al. (2004) conducted a detailed study of patient safety in Canada and revealed that 7.5% of adult acute care patients in Canadian hospitals in the year 2000 experienced an adverse event and 36.9% of these events were deemed to be preventable. The study estimated that between 9,250 and 13,750 deaths from adverse events could have been prevented. Their study also looked at similar studies in other countries (United Kingdom, Australia, New Zealand, and the United States) and found that adverse event rates ranged from

2.9% to 16.6% of acute care admissions. They point out that one of the key steps in promoting patient safety is to have a reporting system that allows adverse events and near misses/close calls to be recorded so that health care workers can learn from them and implement corrective action plans.

An adverse event can be defined in "one of three ways: (1) an unexpected and undesirable incident directly associated with the care or services provided to the patient, (2) an incident that occurs during the process of providing health care and results in patient injury or death, or (3) an adverse outcome for a patient, including an injury or complication" (Davies, Hebert, & Hoffman, 2003, p.40). Baker et al.(2007) define adverse events as "unintended injuries or complications that are caused by health care management, rather than the patient's underlying disease, and that lead to death, disability or require additional use of hospital or other healthcare organizational resources such as prolonged hospital stay, additional testing, or intervention" (p.3). While both of these definitions are similar, the former is broader and takes into account adverse outcomes for patients not associated with the process of providing care or service. However, it is the latter definition which often reflects the reporting of adverse events referred to in the literature. A near miss/close call is defined as "a situation in which a patient had a narrow escape from a serious complication" (National Steering Committee on Patient Safety, 2004, p. 35).

The development of reporting systems for adverse events in healthcare can be traced back to the late 1970's. Since then, many countries have been implementing reporting systems; however, countries such as the United Kingdom, Australia, Japan, and the United States are ahead of other countries, including Canada, particularly as it relates to national reporting systems (Simon, Lee, Cooke, & Lorenzetti, 2005; White, 2007).

1.2 Eastern Health

Eastern Health (EH) was formed on April 1, 2005 from the merger of seven health organizations and has a mandate related to promoting health and well-being, providing supportive care, healing illness and injury and advancing health care knowledge. Eastern Health is the largest integrated health organization in Atlantic Canada, serving a regional population of more than 290,000 and offering tertiary level and specialty services to a population of about 500,000 across the province of Newfoundland and Labrador. The organization has approximately 12,000 staff and operates 27 institutional health service facilities and community health services in 30 communities. The services provided by Eastern Health cover a wide range of services across the three sectors: acute, long term, and community (Eastern Health, 2008).

1.3 Occurrence Reporting at Eastern Health

Occurrence reporting process is defined by Eastern Health as "a process that facilitates the identification and monitoring of adverse events and incidents that occur during health

care treatment or service and/or within health care facilities" (Eastern Health, 2006, p. 5). Occurrence reporting is often used interchangeably with incident reporting or adverse event reporting, although occurrence reporting is a more inclusive concept, covering a wide variety of circumstances that contain risk or quality issues and close calls. Other terms that also used interchangeably in the practice setting and less commonly in the literature include patient safety learning system and clinical safety reporting system.

The reporting system at EH is used to report on occurrences such as falls, safety/security issues for patients, medication errors, treatment and procedural mishaps, and medical equipment malfunctions. An individual who is involved in an occurrence or witnesses an occurrence completes a report and forwards it to the manager. The manager has the primary responsibility for ensuring communication to appropriate levels of authority and ensuring appropriate follow up action. The form captures information such as patient name, patient record number, diagnosis, location of the incident, type of occurrence, time of occurrence, impact on patient, notification information, assessment information, physician assessment, and follow up actions required. A copy of the paper form and a listing of the fields in the new electronic form can be found in Appendix A.

Early in the newly merged organization, EH recognized the need to improve and standardize its occurrence reporting processes, as each of the legacy organizations involved in the merger had their own occurrence reporting processes, most of which used a paper form. There were issues with the legacy occurrence reporting systems such as

inconsistencies in what was reported as occurrences, different forms in use throughout the region, delays in notification to the Quality and Risk Management department, incomplete forms, and lack of feedback to employees about the numbers and types of occurrences and what was being done to address the issues identified. In an effort to address the issues identified, EH submitted a proposal to Canada Health Infoway seeking funding to implement an electronic occurrence reporting system throughout the region. Canada Health Infoway is a national organization with the mandate for promoting the implementation of electronic records in the health system throughout the country. The proposal entitled "The Regional Occurrence System Enhanced", originally referred to as the ROSE project (Eastern Health, 2006), outlined thirteen specific objectives which are as follows:

1. To enhance the development of a patient safety culture through education and ongoing support initiatives.

2. To explore opportunities for collaboration throughout development, implementation, evaluation and knowledge transfer.

3. To increase the response rate for occurrences within provider sectors and across the continuum of services in Eastern Health.

4. To develop and implement a common dictionary and framework for reporting occurrences across the continuum of services in Eastern Health consistent with the pan-Canadian Patient Safety agenda.

5. To develop and implement a timely electronic mechanism and process for reporting, feedback and appropriate follow-up on occurrences across the continuum of services in Eastern Health.

6. To ensure communication of relevant occurrences among sectors/providers across the continuum of services in Eastern Health.

7. To enable appropriate timely follow-up to mitigate/prevent negative outcomes for patients, residents and clients receiving service in Eastern Health.

8. To trend, analyze and report on occurrences at multiple organizational levels.
9. To facilitate the initiation of corrective quality improvement processes required to address issues identified in the occurrence reports.
10. To facilitate accurate and timely monitoring of the quality of services across the continuum of services in Eastern Health.
11. To enable public and stakeholder reporting of measures of the quality of care and patient safety in Eastern Health.
12. To support external benchmarking of provincial/national quality of care measures.
13. To support related research and evaluation studies.

Approval for the project came in late 2007 with a funding commitment of $1.6 million from Canada Health Infoway, with the remainder to be provided by EH. It was expected that EH would provide at least 25% of the resources required (about $500,000) and that amount could be as in-kind contributions. The approval included funding to evaluate Phase One of the project.

1.3.1 Description of Phase One

Eastern Health changed the name of the project from the ROSE project to the Clinical Safety Reporting System (CSRS) project early in the implementation of the project to better reflect the positive intent of the system. The organization now uses clinical safety reporting and occurrence reporting interchangeably. However, for the purpose of this report, the term occurrence reporting will be used most frequently except when

discussing some of the data collection results (as CSRS was the term used on some of the survey questionnaires).

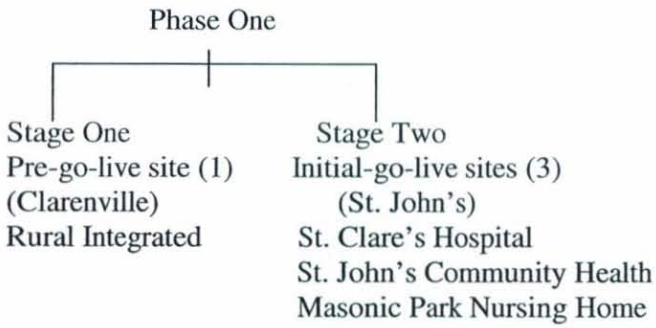
Eastern Health decided to do a staged implementation of the electronic occurrence reporting project due to the large number of employees, the wide range of services it provides, and the large geographic area it serves. The implementation is expected to be completed this year. The implementation aspect of the initiative was a complex project that involved many stakeholders. A project management structure was developed to oversee the implementation component. The structure included a Project Steering Committee, Project Implementation Team, and Site Implementation Teams. A description of the structure can be found in Appendix A.

The Project Steering Committee was formed to have the oversight responsibility for decisions related to implementation and reported into the Regional Quality Council, a committee already in existence as part of the quality structure for the organization. The Project Implementation Team had the primary responsibility for addressing development issues related to executing the implementation plan and they were assisted by Site Implementation Teams for the service level operational issues. The training was lead by the quality and clinical safety leaders. A description of the training plan can be found in Appendix A.

The training plan provided tools and templates to facilitate consistent training for managers, super users, and all staff who would potentially be using the system. The instruction included a combination of formal and informal training (such as small group or individual) in the service area and eLearning tools available on the intranet. As noted in the plan, the training was to be used as a starting point for implementation and referred to the acquisition of knowledge, skills, and competencies required by staff to operate successfully in the new system. One of the main objectives of the project was to use the implementation of the new system as a change management tool to assist with learning processes and concepts related to clinical safety.

Phase One of implementation consisted of two main stages: the pre-go-live stage which was aimed at refining and customizing the software tool itself, developing the change management plan (which included the training and communication plans), and refining the evaluation plan; and stage two, which included implementation at three sites representative of each sector (acute, long term care, and community) in the urban centre. Figure 1 shows the sites of each stage in Phase One.

Figure 1: Phase One Stages



Pre-Go-Live

The site chosen for the pre-go-live stage was Clarenville, a rural setting, which has an acute care unit (50 beds), a long term care unit (21 beds) and provides community health services. The number of employees at this site is approximately 355. Selection of this site was based on considerations such as range of services provided (acute care, long term care, and community health), results of the change readiness assessment conducted by the project implementation team, and support of senior leadership. The pre-go-live stage began November 18, 2008.

Stage Two — Initial Implementation Sites

The sites chosen for the Phase One implementation in St. John's, an urban setting, were St. Clare's Hospital - acute care; the Public Health Nursing and Community Children Services sections - community health, and Masonic Park - long term care. St. Clare's is a 204 bed acute care hospital that provides a range of acute care services (Emergency, Ambulatory Care, Cardiac, Critical Care, Medicine, Surgery, Perioperative, Diagnostic Imaging and Laboratory) and employs approximately 1,240 individuals. The Community Health program offers a variety of community-based adult and children's services in the urban area and employs approximately 225 people in the section being included in Phase One. Masonic Park is a 40 bed long term care facility that provides predominantly level three nursing care (which means that most residents require professional nursing care and are not able to live independently). There are approximately 70 employees working at Masonic Park. Phase One implementation for the three sites in the city began March 25,

2009 at St. Clare's, followed by April 1, 2009 at St. John's Community Health Services and June 23, 2009 at Masonic Park.

1.4 Purpose of the Evaluation Study

The evaluation study focused on Phase One due mainly to the limited resources available and the project timelines. As Phase One included a representation of all sectors of Eastern Health (acute care, long term care, community health, urban and rural), it was decided that data from these four sites would provide sufficient information to be able to address the objectives of the evaluation.

The evaluation study had a dual purpose: (a) to assess and report on the impact of the implementation of the electronic occurrence reporting system on achieving its stated objectives, particularly those that could be measured within the timelines of the project and (b) to analyze findings to identify contributions to the literature in the recently developing field of implementations of electronic occurrence reporting systems in health care.

The report provides information that contributes to the growing body of knowledge of occurrence reporting systems and patient safety as well as identifying recommendations that can be considered by Eastern Health to assist with the rollout and by other health care organizations that may be considering implementing a similar system.

1.5 Key Research Questions

The evaluation plan for this study was based on a framework developed by Neville et al. (2004) and validated by stakeholders in workshops focused on the following research questions, indicators and impacts (Eastern Health, 2006):

1. What were the anticipated benefits of the system?
2. What benefits were achieved and how do they compare with anticipated benefits?
3. What were the projected costs of the system?
4. What were the costs of implementing the system and how do they compare with projected costs?
5. Were the necessary planning and management structures in place to proceed with the project?
6. Did any unforeseen harms and/or disadvantages occur?
7. What were the key facilitators and barriers to successful implementation of the project?

The questions of interest outlined in the evaluation plan included measuring the following indicators and impacts:

1. Patient safety culture.
2. Number of occurrences reported.
3. Reporter characteristics (nurses and non-nurses).
4. Timelines for reporting.
5. User satisfaction.
6. Costs of the implementation.

7. Perceived benefits.
8. Perceived disadvantages/unforeseen harms of the system.
9. Impact on frontline managers' role.
10. Lessons learned from implementation and project management.

1.6 Conflict of Interest Statement

This study was conducted as partial completion of the requirements for a PhD in Medicine and I assumed the role of principal investigator. For part of the study period, I was also employed in the position of Director of Quality and Risk Management at Eastern Health. Some of the employees in the department were involved in the coordination and management of the implementation of the electronic reporting system throughout the organization. There were measures were in place that minimized any potential conflict of interest including: (a) an evaluation planning committee was created to provide feedback on the evaluation plan; (b) a steering committee was overseeing decisions related to the implementation of the project; and (c) a research assistant was employed to assist with data collection, note taking, data entry, and collation.

My responsibilities as the principal investigator included: (a) conducting the literature review, (b) developing the evaluation plan for presentation to key stakeholders, (c) selecting and developing the data collection tools, (d) developing the agenda and leading the stakeholder workshops, (e) conducting the interviews and focus groups,

(f) collecting data, (g) analyzing data, (h) consulting with the stakeholders in the finalization of recommendations, and (i) writing the report and dissemination of findings. As the principal investigator, I did not gain financially from the study or make any decisions related to site selection and implementation. Any time spent working on the study was recorded and identified as part of the required in-kind contribution of Eastern Health.

2 Literature Review

This chapter provides an overview of the literature that informed this study, specifically the approach to evaluation, the development of data collection tools, and the discussion of findings. The literature has been categorized into four primary areas: (a) patient safety culture, including approaches to measuring a safety culture, (b) adverse event /incident/occurrence reporting in the healthcare field, (c) approaches to evaluation of information systems, and (d) evaluations of occurrence reporting systems. The chapter also provides a discussion of the gaps in the literature and how this study can contribute to the literature and practice.

2.1 Patient Safety Culture

Patient safety is on the agenda worldwide in healthcare. In the practice setting, the term patient safety is used interchangeably with resident safety, client safety, and clinical safety. In the literature, patient safety is the term most commonly used and is also used in this report interchangeably. The terms used are often reflective of the how health care providers refer to the people who use the services specific to their setting. In the acute care setting, providers use the term "patients"; in the long term care setting, the providers refer to "residents"; and in the community health setting, providers use the term "clients". The term clinical safety is sometimes used to refer to the provision of services by clinicians regardless of the setting.

There are many initiatives in Canada aimed at improving patient safety. Flynn (2008), on behalf of the Provincial Healthcare Safety Advisory Committee in Prince Edward Island, conducted an environmental scan of patient safety through review of peer reviewed literature and interviews with key contacts in Canada, identifying many initiatives and strategies in progress. These initiatives and strategies were organized into six groups: (a) educational initiatives, (b) analytical initiatives, (c) legislation, (d) policies, (e) communications, and (f) quality initiatives. Specific examples of these initiatives and strategies include such things as patient safety conferences, patient simulators, educational software, the patient safety required organizational practices promoted by Accreditation Canada, staff safety briefings on the unit, prospective analysis, root cause analysis, and implementation of the Safer Healthcare Now bundles and patient safety competencies being promoted by the Canadian Patient Safety Institute. The Safer Healthcare Now bundles include initiatives (e.g. Preventing Surgical Site Infections, Medication Reconciliation, and Preventing Ventilator Associated Pneumonia) that promote evidence-based practices.

There are a multitude of initiatives (above is not an exhaustive list) aimed at improving patient safety and the discussion of each is beyond the scope of this report. Many of the initiatives and strategies are focused on improving a culture of patient safety. It is widely accepted that the desired improvements in patient safety require a change in the culture within healthcare (Canadian Patient Safety Institute, 2004; Institute of Medicine, 2000).

Zboril-Benson and Magee (2005) state that "culture includes the norms, values and rituals that characterize a group organization and culture serves as a social control mechanism that sets expectations about appropriate attitudes and behaviours of group members"(p.26). The importance of cultural factors has been researched in other high reliability industries such as nuclear power and petrochemical processing (Fleming, 2005). The Advisory Committee on the Safety of Nuclear Installations (ACSNI) produced a definition of safety culture that is often cited and is as follows:

> The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competences and patterns of behaviour that determine the commitment to, and the style and proficiency of an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded in mutual trust, by shared perceptions of the importance of safety and by the efficiency of preventative measures (ACSNI, 1993, p.23).

Singer et al. (2003) identify components that are deemed to be essential for an organization to have a culture of safety. These are:

1. Commitment to safety articulated at the highest levels of the organization and translated into shared values, beliefs, and behavioural norms at all levels.
2. Necessary resources, incentives and rewards primed by the organization to allow this commitment to occur.
3. Safety is valued as the primary priority, even at the expense of "productivity" or "efficiency". Personnel are rewarded for erring on the side of safety, even if they turn out to be wrong.

4. Communication between workers and across organizational levels is frequent and candid.

5. Unsafe acts are rare despite high levels of production.

6. There is openness about errors and problems; they are reported when they do occur.

7. Organizational learning is valued; the response to a problem focuses on improving system performance rather than an individual blame.

The Singer study involved a consortium of hospitals with an interest in advancing their performance on patient safety therefore, may not be representative of all hospitals.

To help support a culture of safety, health care organizations need to have an understanding of staff and physician perceptions of the current state of patient safety culture (Murphy, 2006). The term "just culture" has been used when referring to the cultures that health care organizations need to encourage improvements in patient safety. Kaplin and Fastman (2003) describe a just culture as "one that provides a safe haven in which errors may be reported without fear of disciplinary action (in events which do not involve reckless behaviour)" (p.69). They also conclude that the culture of an organization along with the provision of standardized methodologies, classification systems, tools for analysis and feedback to staff are factors in determining the success of an event reporting system.

There are a number of culture survey tools that have been used in the health service field to assess patient safety culture. Fleming (2005) provides an overview of four instruments that have been used extensively in healthcare including:

1. Safety attitudes questionnaire. (Sexton et al., 2004)
2. Stanford Instrument. (Singer et al., 2003)
3. Hospital Survey on Patient Safety Culture. (Sorra and Nievo, 2004)
4. Modified Stanford Instrument. (Ginsberg et al., 2005)

A comparison is made of the patient safety elements measured, questionnaire length, reliability measures, strengths, and weaknesses. The questionnaires range in length from 30 items to 79 items. The reliability indicators were similar (none reported for the Stanford instrument), ranging from .63-.86. He concluded that there is no one best instrument and organizations need to select an instrument that is most appropriate for their purposes (Fleming, 2005).

Nieva and Sorra (2003) reviewed a variety of culture assessment tools being used in the United States, describing the characteristics of the tools, their current uses, and potential uses. A safety culture assessment can have multiple purposes. They identified "four purposes including: (a) diagnosis of safety culture and raising awareness, (b) evaluation of product safety interventions and tracking change over time, (c) internal and external benchmarking, and (d) fulfillment of regulatory or other requirements" (p.19).
They outlined four criteria for determining the suitability of tools to assess patient safety culture which include: "(a) the domains of culture that are assessed, (b) the types of staff who are expected to complete the tool, (c) the settings for which the tool was developed, and (d) the availability of reliability evidence about the tool" (p. 20).

Nievo and Sorro (2003) note that quantitative data has its limitations and should be supplemented with other sources of information about patient safety such as qualitative information from staff interviews and focus groups, or procedural safety checklists used in traditional safety audits. They also offer pointers for future research such as learning how to use assessment data to initiate patient safety culture change.

Ginsburg et al. (2007) completed further research and development with respect to safety culture assessment tools in Canadian hospitals. They conducted a study of four organizations representing six hospitals and health regions from across Canada. The organizations chosen included all sectors such as pre-hospital care, acute care, long term care, community health, and mental health. The study was large, with 22,624 surveys distributed and 6243 returned for a response rate of 28%. The survey tool used had been developed based on previous research and subjected to exploratory factor analysis and reliability analysis yielding reasonably strong outcomes.

Ginsburg et al. (2007) outlines different ways that patient safety culture data can be used, such as looking at high and low performance on individual survey items, focusing on questions that are important to staff, and benchmarking. They point out that it may be more valuable to consider how specific sites or units within a health care organization perform, due to the diversity that might exist between health care organizations. The data from the patient safety culture surveys can be used to guide discussions of safety culture

in different parts of the organization. Their research has resulted in a tool that has been adopted by Accreditation Canada (Langlois, J., 2008; Murphy, 2006).

In the Canadian health care system, a safety culture within an organization is one of Accreditation Canada's primary safety goals and required organizational practices. Accreditation Canada, previously known as the Canadian Council of Health Services Accreditation (CCHSA), represents all sectors in the health care field (acute, community, and long term care). They are a national accrediting body that sets standards for health care delivery and monitors health care organizations through a peer reviewed process. In Canada, virtually all health care organizations are involved and have been reviewed to determine whether they meet or exceed the national standards (Penney, 2010). Accreditation Canada also recognizes the use of the terms (patient, resident, and client) interchangeably but tend to use the term "clients" in many of their standards and documents.

Accreditation Canada promotes the use of a patient safety culture assessment tool. In 2007, they conducted a national pilot project of the tool, a Modified Stanford Instrument, and Eastern Health was one of the pilot sites. Accreditation Canada now promotes the use of an adapted version (CCHSA, 2007). Organizations are only required to administer the tool once every three years; however, they can choose to administer it more frequently. Eventually, organizations will be able to compare their results and evaluate their progress over time (Langlois, 2008). Staff can complete the tool on-line through a dedicated

portal for the organization. A minimum number of responses are required for each organization and Accreditation Canada will provide an analysis and a report to each organization (to be used by each organization). Accreditation Canada does have unpublished aggregate national data related to organizations that have completed the surveys (e.g. over 30,000) that is available to organizations to assist in benchmarking; (such data was used in this study). However, comparisons and benchmarks with other organizations must be made with caution as there are many variables affecting the patient safety culture of an organization (Accreditation Canada, 2009; Ginsburg et al., 2007).

While assessment tools can provide information about various elements of an organization's culture, they give little direction about practical actions to improve the culture. Fleming (2003), in a research forum commentary, has likened safety culture surveys to describing the water to a drowning man -- "They tell you how bad things are but do little to help in solving the problem" (p. 42).

A study in an acute care urban hospital by Sine and Northcutt (2008) examined results of a patient safety culture tool, the Agency for Healthcare Research and Quality's *Hospital Survey on Patient Safety*, looking at 12 dimensions of patient safety and compared them to available benchmarks for that tool.

> They suggest that comparing local results to benchmarks is useful but the comparison leaves several questions unanswered including: (1) If several dimensions are less than the benchmark, how are priorities assigned (in terms of

> which dimensions should be addressed first)? and (2) What will be the effects on the organization as a whole if changes are made to particular aspects of patient safety? They conclude that neither comparisons or internal rankings satisfactorily answer questions related to priorities and that there must be an appreciation for which dimensions of patient safety culture that are identified as upstream drivers rather than as downstream outcomes (Sine & Northcutt, p. 78).

In order for the results of patient safety culture scores to be used effectively in the development of an organizational plan to improve patient safety, the organization must determine which dimensions being measured on the survey are the drivers. Sine & Northcott (2008) provide an example; in their study, the dimension relating to "supervisor expectations and actions" ranked higher (more positive percentages) than the dimension of "response to error", however, they suggested that it would be better to focus on improving supervisor expectations and actions, as that can drive the patient safety outcomes such as "response to error" (p.81). Factors such as communication and feedback about error and management support for patient safety are often considered to be the drivers for improving patient safety culture and thus can be integrated into a plan to improve patient safety culture.

Fleming and Wentzell (2008) developed a Patient Safety Culture Improvement Tool (PSCIT) to help organizations assess a number of important organizational practices that influence patient safety culture. The tool can be used to describe how organizations at

different levels of maturity approach safety culture improvement. The tool was developed based on previous work of other researchers and input from patient safety experts, but they caution that there is currently a lack of reliability and validity data.

Frankel, Gardner, and Bates (2003) in their study suggested that "changing culture" is a new watchword in patient safety. Their findings indicate that many projects aimed at different components of patient safety must occur at the same time for significant change to occur. Some of the initiatives they put forward include executive walkarounds (senior managers visit staff in their clinical setting to ask questions about patient safety), accountability principles related to a non-punitive reporting policy, educational initiatives and safety briefings. There are a wide range of other patient safety initiatives that can be implemented in organizations, and many health service organizations are taking important steps to help enhance patient safety.

Longo, Hewitt, Ge, and Schubert (2005) define patient safety systems as "the various policies, procedures, technologies, services and numerous interactions among them necessary for the proper functioning of hospital care"(p. 2859). They conducted a survey of all acute care hospitals in Missouri and Utah at two points in time (2002 and 2004) to look at development of patient safety systems. Response rates were high (76.8% and 78%). They also included an extensive review of the literature. They indicate that if implemented, these systems influence hospital environment, behaviours and actions; reduce the probability of error; and improve the probability of safety. Their study

concluded that patient safety progress is slow and that efforts for improvement must be accelerated. Limitations of their study include a focus on acute care only and the survey involved self-reports by hospital leaders. Also, reporting and tracking of incidents was only one of many elements of patient safety systems listed and there was little description of what those systems involved.

2.2 Adverse Event/Incident/Occurrence Reporting in Health Care

One of the challenges related to a dialogue on patient safety is the lack of a universal taxonomy which defines terms and promotes consistency in language. Terms such as adverse event reporting, occurrence reporting, incident reporting, and patient safety reporting can be found in the literature and are sometimes used interchangeably. Ginsburg et al. (2009) state that we lack clear and universally accepted definitions of error. In particular, the way front-line providers or managers understand and categorize different types of errors, adverse events and near misses and the kinds of events these groups believe to be valuable for learning are not well understood. Their study involved 10 focus groups with frontline providers and managers (a total of 74 participants) in 5 hospitals in Ontario. They concluded that "confusion surrounding patient safety terminology detracts from (a) the abilities of providers to talk about and reflect on patient safety events and (b) opportunities to enhance learning, reduce event reoccurrence and improve patient safety at the point of care" (p.154). Their study did not include the perspective of other stakeholders such as physicians.

Vincent (2007) points out that local incident reporting systems in hospitals typically use an incident report form that comprises basic clinical details and a brief description of the incident and that to make real sense of an incident the story must be interpreted by someone who knows the work and the context (p.51). Regardless of the name given to the reporting system, there is increasing attention being given to the need for systems to facilitate reporting of adverse events and near misses/close calls. "Near miss" is a term that is used interchangeably with "close call" and refers to "a situation where the adverse event did not reach the patient because of timely intervention or chance" (Baker et al., 2007, p.3). By reporting near misses, there are opportunities to take corrective action and/or educate others to prevent future occurrences that could result in a harmful incident.

In a paper prepared by White (2007) for the Canadian Patient Safety Institute, a review of the literature related to adverse event reporting and learning systems was undertaken. The paper examines many aspects of adverse event reporting, including description of national reporting systems in other countries such as the United Kingdom, Japan, and the United States. Systems may vary in that they may be paper or electronic, mandatory or voluntary, anonymous and/or confidential, use different terminology and classification schemes, and vary in their policies and practices for reporting. The paper supports the view that adverse event reporting and learning systems in health care have the potential to improve safety for all patients through the analysis of reported events, dissemination of recommendations for system improvements, and the local implementation of leading

practices. This is achieved while maintaining a system-based emphasis of seeking and understanding the lessons that can be learned (White, 2007).

Baker et al. (2007) conducted a survey of 340 Canadian hospitals regarding the existence of incident reporting systems. The response rate was 24% (82 hospitals) and 65 of the 82 hospitals responding indicated they have an incident reporting system. Incident reporting represents one of various tracking systems for collecting data on incidents. A review conducted by the Alberta Heritage Foundation (Simon, Cooke, & Lorenzetti, 2005) listed some examples of other methods for tracking incidents such as confidential inquiries, medical audits, retrospective chart review, and litigation databases. They state that the major difference between incident reporting and other tracking methods is that incident reporting relies on the acquisition of real-time data directly related to the incident as reported by the staff and physicians involved in identifying the occurrence. In the practice setting and in the literature, reference to involvement in incident reporting also includes people who witness an incident.

There are many cited barriers to incident reporting by individuals such as lack of knowledge about the process and what constitutes an incident, time constraints, lack of feedback after a report is submitted, fear of reactions of co-workers, fear of litigation, fear of reprisal, loss of job, loss of reputation, code of silence, lack of anonymity, and lack of trust in the organization (Barach & Small, 2000; Kingston et al., 2004; Mekhja et al., 2004; Williams & Osborn, 2006; Wilson et al., 2008). Principal among these is the

idea of a "blame culture", with staff concerned that they will be individually held responsible for errors and disciplined (Wilson et al., 2008; Kaplan & Fastman, 2006). Underreporting of incidents among clinicians is generally acknowledged, although the extent of underreporting is not well known and estimates vary (Hirose et al., 2007; Kingston et al., 2004; Mekhjian et al., 2004; Williams & Osborn, 2006). Reporting is important to improving the health system. Understanding the factors that contribute to errors and harm are fundamental to making changes that are necessary to preventing future occurrences.

Leape and Berwick (2005) in an article published five years after the landmark Institute of Medicine report explored what progress has been made and put forth the position that the conversation around adverse events has changed and that the topic has become a frequent focus for journalists, health care leaders and concerned citizens. They refer to the "mantra in health care" that preventing errors and improving safety for patients require a systems approach in order to modify the conditions that contribute to errors and support the notion that "the problem is not bad people; the problem is that the system needs to be safer" (Leape & Berwick, 2005, p. 2385). Systems factors that can contribute to adverse events include such things as poor job design, inadequate resources (including supplies, a well trained and knowledgeable workforce, and appropriate workloads), equipment malfunctions, complex procedures, outdated technology and policies. Leape and Berwick (2007) point out that there are critics of this view which looks at system

design as the major factor rather than individual clinician incompetence and that public support for improving patient safety often turns instead to fixing blame.

Vanderheyden et al. (2005) conducted a telephone study involving 1500 adults living in Alberta to assess their perceptions of and personal experiences with preventable medical errors. Concerns about medical errors emerged as the second most important factor associated with overall quality in healthcare, second only to accessibility. Results indicate that patients appear to blame individuals, versus the system, for errors and seem to be more concerned with the process by which errors occur versus the errors themselves, thus further supporting the view that the mantra of the systems issue is not shared by all. This possibility of being blamed can be a deterrent in comprehensive and accurate reporting.

The barriers to reporting need to be considered in the development of an incident reporting system. According to Tuttle, Holloway, Baird, Sheehan, and Skelton (2004), the characteristics considered to be important for a successful incident reporting program include a non-punitive or safe environment, simplicity in reporting, and timely and valuable feedback. They state that although the approaches and information collected may differ, the underlying goal to learn from experience remains the same. Their study examined the impact of implementing an electronic reporting system at a large academic medical center in the United States and found that knowledge in the use of the reporting system and the frequency of reported events increased over the first year, which should

be the first goal of an electronic reporting system. This increase in the number of occurrences reported will allow the collection of increasing source of information for analysis and feedback for improvement purposes. They indicate that a component of increased reporting should also include wider representation of all healthcare personnel (as most reports are completed by nurses) to broaden the content of events reported, as well as the perspectives to understanding contributing factors. Besides reviewing the changes in the safety events reported, they also administered a survey to assess knowledge and attitudes of patient care personnel. The majority of respondents reported that they did not have a good understanding of how the electronic system worked. The response rate was low (10.3%) therefore the ability to reach conclusions is limited.

Another study conducted on an electronic reporting system by Mekhjian et al. (2004) found that there were benefits over the paper based system such as user friendliness, efficiency, timely notification of critical events, facilitation of investigation, and feedback responses. They suggested that a full organizational transformation was required and this included simplifying the steps and reducing the time required to report. A fundamental objective of the event-reporting initiative was to assure care givers that the health system could and would respond to reported events and thus encourage a culture of commitment to patient safety. They note that when a provider can observe a response to a reported event within hours or days versus weeks or months, the provider is more likely to report future events.

A qualitative study conducted by Kingston, Evans, Smith, and Barry (2004) involved asking semi-structured questions to five focus groups—one each for consultants, registrars, resident medical officers, senior nurses, and junior nurses. The study recruited medical and nursing staff using purposive sampling from three hospitals in Australia. The main purpose of the study was to examine the attitudes of doctors and nurses towards incident reporting and to identify measure to facilitate incident reporting. The investigators found that common barriers to reporting included time constraints, unsatisfactory processes, and deficiencies in knowledge, cultural norms, inadequate feedback, beliefs about risk, and a perceived lack of value in the process. They concluded that strategies to improve incident reporting must address cultural issues. The authors also point out that the limitations of this study included those related to the use of focus groups (which may favour group dynamics and silence voices of dissent); the study was conducted in public hospitals and the findings may not be representative of the entire system; and the method of achieving participation may result in more motivated and opinionated people attending.

2.3 Approaches to Evaluation of Information Systems

There are differing approaches to evaluation of information systems including various perspectives, models, and frameworks. One of the best known perspective classifications was proposed by Friedman and Wyatt (1997) and compares the objectivist perspective to the subjectivist perspective. They describe the objectivist perspective as one in which

agreement exists regarding the aspects of the system to evaluate, "gold standards" exist in terms of optimal systems performance that can be used for comparison, and the system attributes can be described and measured using quantitative methods which permit precision in analysis of findings and replication of study findings in similar settings. In contrast, with the subjectivist perspective, there are differing views on which aspects of the system are important to measure, no "gold standards" to compare results, and qualitative methods are used to understand different opinions and conclusions reached by different observers in the same setting and may not necessarily be transferable to another setting.

The issues around using an objectivist approach such as randomized controlled trials to evaluating medical informatics was also explored by Moehr (2002) and he argues that "the application of objectivist principles to real information systems may hamper rather than advance insights and progress and that it is difficult to adapt an approach that was designed for laboratory experiments to the evaluation of information systems in a practical real-world environment because such systems tend to be complex, change rapidly over time, and often exist in a variety of variants" (p.113).

The use of quasi-experimental methods, often referred to as nonrandomized, pre-post intervention studies, are often used in the evaluation of medical informatics. In a study by Harris et al. (2006), the authors conducted a systemic review of four years of publications from two informatics journals and reviewed 34 quasi-experimental studies. They

reviewed a total of 11 designs that fell within four broad categories: (1) quasi-experimental designs without control groups, (2) quasi-experimental designs that use a control group but no pre-test, (3) quasi-experimental designs that use control groups and pre-tests, and (4) interrupted time-series design. They examined the nomenclature and the relative hierarchy of these designs with respect to their ability to establish causal associations between an intervention and an outcome. Studies in the first category were used most frequently, particularly, the one group post-test and the pre-test/post-test design. This study design is often used in medical informatics due to time, technical, or cost restraints. As one moves from the category 1 though to the category 4, the level of methodological rigour improves. The limitations of each design are discussed. "One of the main limitations is the difficulty in measuring or controlling for confounding variables, variables that are associated with an exposure of interest and the outcome of interest. Another limitation of these designs is results being explained by the statistical principle of regression to the mean which can result in wrongly concluding that an effect is due to the intervention when in reality it is due to chance"(p.18). They note that it is important to discuss the strengths and limitations of the design when reporting on findings.

One of the most commonly cited models for guiding evaluations of information systems is the Delone and McLean Information Systems (IS) Success Model (Delone & McLean, 1992). Subsequent research using the 1992 model provided critical review and constructive feedback which was factored into a revised model (Delone & McLean,

2003). The tool has been used in many studies and has been supported by psychometric testing. The updated model consists of six interrelated dimensions of information systems success: information, system, service quality, (intention to) use, user satisfaction, and net benefits.

The work of Delone and McLean was used to assist in the development of a benefits evaluation framework for the health information systems currently being implemented across Canada through Canada Health Infoway with its jurisdictional partners and investment programs (Lau, Hagens, & Muttitt, 2007). The Canada Health Infoway framework includes three dimensions of quality (system, information and service), two dimensions of system usage (use and user satisfaction), and three dimensions of net benefits (quality, access and productivity). Each is described briefly below.

System Quality: characteristics related to functionality, performance, and security; includes measures such as response time, ease of use, system downtime, accessibility, reminders, alerts, and views.

Information Quality: characteristics related to content and availability; includes measures such as users' perception of information completeness, accuracy, relevance, timeliness, comprehensiveness, reliability, and consistency.

Service Quality: characteristics related to responsiveness; includes measures related to user training, ongoing technical support, and availability of support.

System Usage: characteristics related to use behaviour and pattern, self-reported use and intention to use; includes measures such as frequency, duration, location, type or nature of actual or perceived usage and factors for current non-users to become users.

User Satisfaction: characteristics related to competency, user satisfaction, and productivity; includes measures such as knowledge, skills, experience, perceived expectations, value, and user friendliness.

Net Benefits: characteristics related to quality, access, and productivity; includes measures such as improvements in patient safety, effectiveness, health outcomes, access to services, and efficiency.

Researchers agree that there is no one framework that will be able to address every issue for every evaluation project. Deciding on the evaluation approach is influenced by a number of factors, including the individual disciplines comprising the research team and the tradeoffs among the options available (Heathfield et al., 1999). Yusof, Papazafeiropoulou, Paul, and Stegroulas (2008) suggest that evaluation should incorporate a combination of several approaches to provide a more thorough evaluation.

Kaplan (1997) put forth a model that is grounded on the interactions between individuals, systems, and organizational characteristics and considers not only the impact of the information system on the organization, but also the impact of the organization on the information system. The framework was developed based on research within medical informatics and other disciplines over a 20 year period. Kaplan (1997) provides five methodological guidelines for creating a detailed plan for the evaluation of health information systems suggesting that the evaluation: (a) focus on a variety of concerns (technical, economic and organizational), (b) use multiple methods, (c) be modifiable, (d) be longitudinal and (e) be formative and summative. The framework emphasizes the importance of an evaluator being sensitive to the 4Cs of evaluation, which are issues of care, communication, control, and context. The proposed guidelines can assist with some of the challenges related to analysis. Collecting data from both qualitative and quantitative methods and from a variety of sources strengthens the robustness of research results through a triangulation process. Given the complexities of the issues (technological, economic, organizational, and behavioural) of the implementation of electronic health information systems, the multiple methods can assist with a more comprehensive evaluation. The multiple methods approach was integrated into this study design.

Heathfield et al. (1999) examined the issues that arise through interaction between information technology and people and described the problems of multi-disciplinary teams working together to understand and evaluate information systems. Their findings

note that "information systems operate in the real world and information systems projects have numerous constraints e.g. limited time and resources, logistics, conflicting cultural, social and political forces etc."(p.272). Heathfield, Pitty and Hanka (1998) point out that "pure methods such as randomized controlled trials cannot address all issues of evaluation in health care and that information technology is not a drug and should not be evaluated as such" (p.60). They support the use of multi-method evaluation and the notion that "evaluation is not just for accountability, but for development and knowledge building in order to improve our understanding of the role of information technology in health care and the ability to deliver high quality systems that offer a wide range of clinical and economic benefits" (p.61).

Recent literature such as Yusof et al., (2008) also supports the belief that evaluations should address not just how well a system works, but also how well a system works with particular users in a particular setting. They reviewed discourses, dimensions and methods of Health Information Services (HIS) evaluation described in the wider health informatics and information systems literature. They defined an information system as a "group of interrelated processes implemented to aid in enhancing efficiency and effectiveness of an organization in performing its function and attaining its objectives" (p. 378). They state that HIS evaluation seeks to answer the *why, who, when, what, and how* questions relating to technological, human, and organizational issues surrounding it. They suggest that different aspects of frameworks available can be combined in a single framework to enable comprehensive evaluation.

One of the best known frameworks for evaluating health information technology is the PROBE (Project Review and Objective Evaluation for Electronic Patient and Health Records Projects) framework. In 2001, a report was prepared for the National Health Service in the United Kingdom, referred to as the PROBE report (PROBE, 2001). The report prepared by the UK Institute of Health Information provides practical support for evaluations of electronic patient records and electronic health records. The key principles emphasized in this report are the need for formative and summative elements, advance planning, close integration into the project lifecycle, clearly defined aims and objectives, the inclusion of a comparative element, and the collection of qualitative and quantitative data. The Probe framework identifies six steps which help focus stakeholders on the expected benefits and barriers of electronic health records and methods of measuring them.

Working closely with stakeholders is also a major component of the benefits evaluation framework (Neville et al., 2004). This framework was informed by the work of Heathfield (1999) and the PROBE project in the United Kingdom (2001) and employs seven steps (building on the six steps identified by the PROBE project) and these are:

> Step 1: Identification of Key Stakeholders in each jurisdiction. This includes several categories of stakeholders such as funders, health system administration, user groups, researchers/academics and other health system – related agencies.

Step 2: Orient key stakeholders to the evaluation framework and reach agreement on why an evaluation is needed. This is usually achieved through the use of pre-evaluation workshops with key stakeholders.

Step 3: Agree on When to evaluate. This should involve longitudinal evaluation usually at three or more points when possible, at baseline (pre-implementation), during implementation, and post-implementation.

Step 4: Agree on What to evaluate. It is recognized that there can be many questions which need to be answered but there needs to be a limit on the questions that get researched, in terms of the funding and availability of expertise to conduct the study.

Step 5: Agree on How to evaluate. The questions being asked will influence the methods used to collect data and the available resources. Mixed methods are encouraged and the framework provides samples of potential core questions and indicators that can be used.

Step 6: Analyze and Report. It is recommended that the findings be shared with the stakeholders to permit fuller discussion of the interpretation and implications of the results.

Step 7: Agree on recommendations and forward them to key stakeholders. The nature of the recommendations may result in disagreements, particularly if the recommendations arising are negative in terms of the continuation of the initiative, however, the involvement of the key stakeholders in the discussion can increase the likelihood of support for the recommendations.

The Neville Framework has been used successfully in the past five years to evaluate electronic health information systems in the province of Newfoundland and Labrador since 2004. Studies have included Evaluation of the Client Registry System (Neville, MacDonald, and Gates, 2005), Evaluation of the Implementation of the Pictorial Archiving Communications System (PACS) which is a digital radiological technology system (MacDonald, 2008), Evaluating the Impact of Enhancing Information and Communication Technology in a Rural, Community-Model Primary Health Care Setting (Collins, 2010) and most recently, the Evaluation of the Provincial Telehealth Program (Newfoundland and Labrador Centre for Health Information, 2010). These studies have included stakeholders in the planning and implementation of evaluation plans and have resulted in comprehensive evaluation studies and reports that can be used to inform practice and add to the literature, providing descriptions of benefits obtained and recommendations for practice.

2.4 Evaluations of Electronic Adverse Event/Incident/Occurrence Reporting Systems

It is only recently that literature related to electronic adverse event/incident/occurrence reporting systems is available. Relevant to this study, there is little literature available on the evaluation of electronic occurrence reporting systems. The evaluation of electronic systems in the healthcare field is a new area of research, as the development and implementation of electronic occurrence reporting systems is a relatively new initiative in health care organizations. Evaluations have tended to rely on tools used in the evaluation of Health Information Systems (HIS) as described in the previous section as there are no frameworks described in the literature that focus solely on occurrence reporting systems. Also, studies conducted to date have focused mostly on the acute care setting (Cochrane et al., 2009; Levtsion-Korach, Alcalai, & Orav, 2009; Tepfers, Louie, & Drouillard, 2007; Walsh & Anthony, 2007).

Tepfers et al. (2007) reported on their experience in developing an electronic report at a multi-site teaching hospital in Toronto. They point out the importance of receiving feedback on the development of the system from all users, not only those that support the system. They used focus groups and meetings with key stakeholders to determine their information and workflow needs. The report focuses on the formative evaluation and provides recommendations for future development of the electronic tool.

The objective of the Walsh and Antony study (2007) was to present the challenges and gaps in using an electronic adverse event reporting system from a commercial supplier to an acute health care setting in the United Kingdom. They used documentation and triangulation and found gaps and challenges such as different terminology and definitions in use across the organization can cause confusion, location of incidents are not always able to be identified, low involvement of physicians in using the system, and reporting being time consuming for the nurses. They point out that there is limited research and knowledge of managers and clinicians views of designing, implementing and evaluating an integrated electronic adverse incident recording and reporting system in order to improve patient care.

In an Australian study conducted by Braithwaite, Westbrook and Travalgia (2008), investigators conducted an on-line, anonymous questionnaire survey of 2,185 health practitioners including nurses, allied health professionals, and physicians who worked in the publicly funded health system. The main objective of their study was to examine the utilization and attitudes toward an electronic incident reporting system a year after its introduction. Their findings indicated issues with the culture, logistics, and software. They also identified three aspects of incident reporting that need to be factored into future research including: measuring attitudes relate to reporting, researching existing electronic systems to provide information on aspects of software that can be improved, and a need for more data on how software is deployed in health settings. The study had limitations in

that the sample of health professionals was largely self-selected and that managerial and allied health staff were over-represented.

The Levtzion-Korach study (2009) focused on an analysis of submitted reports to a commercial web-based reporting system at a tertiary care hospital in the United States for a 31 month period. They looked at the leading incident categories and found them to be labs (30%), medication issues (17%), falls (11%), and blood work (10%). They did identify benefits such as ease of use, increase in use of reporting, and improved timelines for managers receiving reports. Their study did not focus on the qualitative components of evaluation of the implementation.

Milch et al.(2005) conducted a study of the rate and types of errors reported in 26 acute care hospitals throughout the United States that were using an electronic reporting system. The hospitals included in the study had to be using the electronic system for at least three months. They examined 92,547 reports, looking at the type of event reported and the reporter characteristics. Their findings show that rates vary widely across hospitals (9-95 reports per 1,000 in-patient days) and that nurses provide nearly half the reports and physicians only 2%. They point out that the high rates of reporting in an institution may not necessarily represent poor patient care, but rather an institutional culture that encourages reporting. Two limitations of their study include:

(a) underreporting may be affecting the numbers and types, and (b) reporting bias may be present due to the imbalance of reporter characteristics (predominantly RNs) as nurses report different types of events compared to other disciplines.

Cochrane et al. (2009) reported on the pilot project conducted in British Columbia, focused on the evaluation of the implementation of the electronic system on two acute care units, using a variety of evaluation methods. Their results did show benefits such as increased reporting, involvement of other disciplines in reporting, and excellent adoption by frontline workers. The Cochrane study is the study most similar to this study as it involved evaluating the same software system and looked at some of the same indicators and impacts such as user satisfaction, changes in occurrence reporting, lessons learned, and benefits determination. The key differences is that the Cochrane study did not include the community health and long term care sectors nor did it include such a qualitative component exploring the perspectives of managers. The work in British Columbia did reveal a need to evaluate further the impact of implementing such a system on the role of frontline managers (British Columbia Patient Safety and Learning System Evaluation (BCPSL), 2008).

In the long term care sector, Pierson et al. (2007) conducted an evaluation of a large scale web-based error reporting system in 25 nursing homes, after it was in use for four months. They focused on the reporting of medication errors and also included a survey about the evaluation of the new system. Their findings did include the views of staff

regarding the new system where staff indicated the new system was easy to use, would improve the accuracy and completeness of reporting, would help reduce errors, would help identify areas for improvement and training, and improve patient safety. They identified two limitations with their study: (a) it did not show whether or not the system reduced the amount of medications errors and (b) they could not be certain of the accuracy or completeness of reported errors, a problem consistent with spontaneous reporting systems.

A study by Hoffman et al. (2008) describes the development, structure, and initial results of an electronic incident reporting system for general practice in German-speaking countries. They examined 199 reports looking at four domains (error type, impact, contributing factors, and prevention strategies). They compared the reporting rates to other healthcare settings in the National Health Service Reporting System in England and Wales and found that the reporting frequency in general practice remained low, representing only 0.5% of the more than 80,000 reports in the system. One of the reasons given for the lower reporting rates is that they are small organizations with low risk technology. In addition, the fear of being sued and loss of reputation also contributed. Their findings are based only on German speaking clinics and they do not describe the sample such as the numbers of clinics that were included, therefore the findings are limited in making any generalizations.

Highlights of findings from the review of the literature related to evaluations of electronic adverse/incident/ occurrence reporting systems in the health care field are listed below:

1. Implementation results in an increase in reporting and improved timelines for reporting.

2. Health care providers prefer systems that are easy to use, accessible, and do not require excess time to complete.

3. RNs are the highest reporting group. Reporting needs to be encouraged from other disciplines.

4. Reporters want to receive feedback on the reports and see improvements to the system as a result of reporting (more than a tracking activity).

5. There are issues related to inconsistency in terminology.

6. Underreporting and barriers to reporting exist.

7. There is little known about the impact of reporting systems on improving patient safety.

8. Electronic reporting is only one initiative on the journey to improving patient safety- other initiatives are required to change patient safety.

9. Most of the evaluations have focused on the acute care setting.

2.5 Gaps in the Literature

Bates (2008), in a commentary on patient safety research, indicates that "patient safety represents an important issue globally and the amount of research is skyrocketing" and that the "entire discipline of patient safety research is a young one" (p.156). He highlights a number of limitations and gaps in the literature including the point that most of the studies focus on acute care and inpatient services and epidemiological data about the incidence of harm.

In 2007, the Canadian Institute of Health Information (CIHI) published an Analysis in Brief report that provided updated information on what we know and what we do not know about patient safety in Canada. The document outlines questions about the state of patient safety and how to translate findings into improvement initiatives. The report which outlines patient safety findings from several studies, surveys, and databases suggests that there are many examples of information gaps with respect to patient safety and adverse events in Canada.

Some of the questions provided in their report (Canadian Institute of Health Information, 2007) as examples of knowledge gaps include:

> How is reporting and communicating of adverse events changing?
>
> How can it be increased or encouraged?
>
> What does patient safety look like across the continuum of healthcare services?
>
> What are the rates and types of adverse events occurring outside the acute care environment?

Some of the other gaps arising from a review of the literature include: (a) the impact of incident reporting systems on improving patient safety, (b) the impact of implementing incident reporting systems from the perspective of managers, (c) evaluating the effectiveness of different methods of detecting incidents, and (d) evaluation of electronic systems from a Canadian perspective.

2.6 Contribution of this Study to the Literature and Practice

The results of this study will add to the new body of literature that is emerging and is therefore timely in this era of focus on patient safety. The study addresses known gaps in the literature such as: (a) evaluation of implementation of electronic reporting systems, including benefits, barriers, and facilitators, particularly adding to the literature from a Canadian perspective, (b) exploration of the impacts of implementation of occurrence reporting systems across a continuum of health care services (acute, long term care, and community health) including rural and urban settings, rather than focus primarily on the acute care environment in large urban centers where much of the literature has previously focused, and (c) exploration of the impact of the implementation of the new reporting system from the perspective of managers.

The results of this study also provide information and recommendations that can inform healthcare practice such as identifying ways to facilitate the successful implementation of similar systems in other organizations. The study identifies areas of strength and areas for improvement in the patient safety culture and these findings can be used to prioritize patient safety initiatives and refine patient safety plans in the organization. The study provides baseline information that the organization can use in subsequent evaluations to assess impact of patient safety initiatives on the patient safety cultures and the number and type of occurrences.

3 Methods

In this chapter, the approach to and design of the evaluation are described. The methods used in collecting and analyzing data from the surveys, key informant interviews, focus groups, occurrence reporting records, and project related documents review are provided. The evaluation methods outlined contributed to obtaining data that assisted with addressing the gaps in the literature.

3.1 Evaluation Approach

The approach to evaluation was both qualitative and quantitative using several methods of data collection. The approach was informed by previous work in evaluation of electronic systems and patient safety including:

1. The work of Neville et al. (2004) which outlines a framework for evaluating electronic health records initiatives. A key component of the framework is the involvement of stakeholders throughout the process and the use of pre and post study designs.
2. The work of Delone and McLean (2003) on an information system success model which has been incorporated by Canada Health Infoway into a benefits evaluation framework (Lau, Hagens, & Muttitt, 2007). A key component of this work

involves the identification of indicators that can be used in the development of data collection tools to measure various dimensions of information systems success and using tools that have been subjected to psychometric testing.

3. The work conducted by the British Columbia Electronic Incident Reporting Pilot Project (BCPSL, 2008) which was related to evaluating the same occurrence reporting system being implemented at Eastern Health (the B.C. pilot project focused on the acute care urban setting).
4. The work of Ginsburg et al. (2007) and Accreditation Canada (2008) in patient safety culture surveys using tools that have been subject to psychometric testing such as exploratory factor analysis.
5. Pre- evaluation workshops attended by key stakeholders.

3.2 Study Design

The evaluation was designed primarily as a pre/post comparative study, focusing primarily on identifying the benefits realized, facilitators, and barriers to implementation. The design involved measuring patient safety culture and occurrence reporting data before implementation and six months post-implementation. The pre/post comparative design is consistent with the Neville et al. (2004) framework and was chosen to measure the impact of the implementation of a new system on selected indicators.

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This quasi-experimental design is often used in the evaluation of health information systems due to time, cost, and technical restraints (Harris et al., 2006). It also involved a post-test regarding user satisfaction as well as evaluation of training sessions.

3.3 Sampling

All frontline clinical staff and managers working in each of the four sites of Phase One were included in the sampling for the questionnaires. These included staff such as registered nurses, licensed practical nurses, personal care attendants, allied health professionals, ward clerks, diagnostic imaging and laboratory staff. Physicians, research, and non-direct care staff were excluded from the sample. The rationale for the inclusion and exclusions was based on the historical utilization of occurrence reporting and the planned implementation schedule. The individuals identified in the inclusion category were identified by the organization as the target population for the patient safety culture survey for Accreditation Canada. The numbers in the sampling for each tool varied slightly as the tools were administered on different dates due to fluctuating numbers of employees related to vacancies. The numbers sampled for each survey are provided in the relevant section in this chapter.

were sent to the employees by the administrative assistants. The computer training evaluation forms were distributed at the end of the training session by the trainer at most of the sessions. In the acute care setting, trainers sometimes sent the questionnaire to the unit after the session, particularly in situations where the training was done impromptu because the opportunity was there.

The sampling for the interviews included all Directors involved with Phase One. The sampling for the focus groups included all managers and frontline clinical staff in the four sites. They were all provided an opportunity to participate and participation was voluntary.

3.4 Data Collection Instruments

Data were collected using several methods including stakeholder workshops, surveys, focus groups, key informant interviews and review of occurrence reporting records and project documents. Pre-evaluation workshops were held prior to having all tools being finalized, particularly the focus group and key informant interview guides. The multiple methods approach was taken as such an approach is cited in the literature on evaluations of health information systems as contributing to a more robust methodological rigour. Copies of all data collection tools can be found in Appendix B.

3.4.1 Pre - evaluation Stakeholder Workshops

The framework used to guide this evaluation requires significant stakeholder involvement (Neville et al., 2004). Two workshops were held prior to implementation (Friday, June 20, 2008 and Friday, September 12, 2008). Letters of invitation and a summary of the occurrence reporting project were sent to representatives of various stakeholder organizations and groups. The representatives were from various stakeholder groups such as funders, management, unions, professional associations, government, university, other health boards, and research.

At the workshop, participants were given an orientation to the proposed project and the evaluation plan. In the morning session, the participants were divided into small groups with instructions to provide feedback on the proposed evaluation plan. Specifically, the small groups were asked to consider:

1. Are there additional issues related to occurrence reporting that should be considered?
2. Are there questions that should be added?
3. Are there questions that should be eliminated?
4. Are there indicators/data sources that should be added?
5. Are there indicators/data sources that should be eliminated?

Each group was facilitated by a member of the Evaluation Planning Advisory Committee (a committee that advised on the approach and design of the evaluation) and a member of the Project Implementation Team recorded notes of the discussion. Participants were given opportunities to provide input and to raise questions besides those identified in the draft evaluation plan.

In the afternoon, the participants reported back from their group work and this was followed by large group discussion. The agenda and reports for both workshops are provided in Appendix B. Results from the workshops informed the refinement of the study objectives and tools, specifically the key informant interview and focus group guides.

3.4.2 Patient Safety Culture Surveys

The patient safety tool (Appendix B) administered in this study is based on a Modified Stanford Instrument (MSI) which has been validated in Canadian Studies (Ginsburg et al., 2007). Accreditation Canada, formerly known as the Canadian Council of Health Services Accreditation (CCHSA) piloted the tool in a national study in 2007 with Eastern Health being one of the pilot sites (CCHSA, 2007). Accreditation Canada now promotes the use of this tool electronically through its portal in Canadian health care organizations. The paper form of the survey was used in this evaluation, as the Accreditation Canada

portal for the survey and staff education for the portal at Eastern Health was not available at the time for pre-implementation data collection in this study and using a paper copy in both the pre- and post-surveys was more conducive to analysis.

The questionnaire (see Appendix B) includes 46 items and is designed to measure five dimensions:

1. Organizational leadership for safety.
2. Unit leadership for safety.
3. Perceived state of safety.
4. Shame and repercussions of reporting.
5. Safety learning behaviours.

The survey items address the importance of patient safety on the unit and in the organization, perceptions of how safety failures are handled, the state of attitudes and knowledge regarding patient safety issues, and the perceptions of the state of patient safety in the organization. Items assigned to the five dimensions were subjected to exploratory factor analysis and reliability analysis in previous patient safety research yielding reasonably strong outcomes (Ginsburg et al., 2007). This facilitated the grouping of 32 survey questionnaire items into the five dimensions. See Figure 2 for a list of survey items measured within each dimension.

Questions across all five dimensions were answered using a five point agree/disagree Likert scale ranging from 1-strongly disagree to 5–strongly agree. The questionnaire was mailed to all staff (frontline and managers) working directly with clients in each of the four clinical areas (the pre-go-live site and the three sites in the initial implementation in St. John's). The envelopes were personally addressed to each employee with a covering letter signed by a member of the Eastern Health executive team. The stamped returned questionnaires and envelopes did not require the employee's name as it was felt that staff may be reluctant to respond if they knew they may be identified through a coding system. The questionnaires were colour coded for the care setting. The questionnaires were distributed one to two months pre-implementation and again at six months post-implementation. The strengths of this tool are that it could be distributed to a large number of staff in an efficient manner and it allowed for anonymous responses. The weaknesses include that response rates may be low due to the length of the questionnaire and only motivated staff may respond.

Figure 2: Patient Safety Culture Survey

Survey Items in Each of the Five Dimensions

Organizational leadership for safety
Senior management provides a climate that promotes patient safety
Patient safety decisions are made at the proper level by the most qualified people
Good communication flow exists up the chain of command regarding patient safety issues
Senior management has a clear picture of the risk associated with patient care
My organization effectively balances the need for patient safety and the need for productivity
Senior management considers patient safety when program changes are discussed
I work in an environment where patient safety is a high priority
Shame and repercussions of reporting
Reporting a patient safety problem will result in negative repercussions for the person reporting it
Asking for help is a sign of incompetence
If I make a mistake that has significant consequences and nobody notices, I do not tell anyone about it
I will suffer negative consequences if I report a patient safety problem
Safety learning behaviours
Individuals involved in major events have quick and easy way to capture/report what happened
Individuals involved in major events contribute to the understanding and analysis of the event and the generation of possible solutions
A formal process for disclosure of major events to patients/families is followed and this process includes support mechanisms for patients, family, and care/service providers
The patient and family are invited to be *directly* involved in the entire process of understanding: what happened following a major event and generating solutions for reducing re-occurrence of similar events
Things that learned from major events are communicated to staff on our unit using *more than* one method (e.g. communication books, in-services, unit rounds, emails) and/or at *several* times to all staff hear about it
Perceived state of safety
Loss of experienced personnel has negatively affected my ability to provide high quality care
I have enough time to complete patient care tasks safely
In the last year, I have witnessed a co-worker do something that appeared to me to be unsafe for the patient in order to save time
I am provided with adequate resources (personnel, budget, and equipment) to provide safe patient care
I have made significant errors in my work that I attribute to my own fatigue
I believe that health care error constitutes a real and significant risk to the patients that we treat
I believe that health care errors often go unreported
I am less effective at work when I am fatigued
Personal problems can adversely affect my performance
Unit leadership for safety
My supervisor says a good word when he/she sees a job according to established patient safety procedures
My supervisor seriously considers staff suggestions for improving patient safety
My supervisor overlooks patient safety problems that happen over and over
Whenever pressure builds up, my supervisor wants us to work faster, even if it means taking shortcuts
My unit takes the time to identify the assess risks to patients
My unit does a good job managing risks to ensure patient safety
I am rewarded for taking quick action to identify a serious mistake

Source: Ginsburg et al. (2007) Perceptions of Patient Safety Culture in Six Canadian Healthcare Organizations, p.8

3.4.3 Computer Training Evaluation Surveys

Evaluation forms (Appendix B) were distributed to all staff (frontline, roamers, and managers) who participated in training for the occurrence reporting system in Phase One. Roamers are frontline clinical staff members that serve as resource persons/trainers for their peers. Early in the training period, the Project Implementation Team decided to change the name of "roamers" to "super users" to better reflect the nature of the role.

The purpose of the evaluation forms was to seek feedback on the effectiveness of the training session. The feedback was then used to revise training methods and to assist in the evaluation related to user satisfaction and adoption.

The bulk of the initial training was provided by the Quality and Clinical Safety Leaders (QCSLs) who had been previously trained on how the system works and had used training manuals developed by the Project Implementation Team. The trainers were expected to distribute the survey questionnaires at the end of each session and employees could return them through the internal mail system or pass them in at the end of the session. Employee names were not required.

The evaluation forms were specific to each of the three groups (frontline staff, managers, super users) as each group had specific training relevant to their roles. Most of the questions were similar but there were slight variations based on feedback obtained from project leadership staff and stakeholders, and the evaluation conducted in the British

Columbia project. The strengths of this tool are that it was short, anonymous, and easy to administer. The disadvantage is that response rate could be low as employees may not bother to provide feedback, particularly when the surveys were not distributed at the end of the session.

3.4.4 User Satisfaction Surveys

Frontline staff and managers working in the clinical areas at the Phase One sites were mailed the User Satisfaction Survey (adapted from BCPSLS Evaluation Report, 2008 and the Canada Health Infoway tool described by Lau, Hagens, and Muttitt, 2007). The tool draws on earlier work of Delone and Mclean (2003) which has been used in many empirical studies evaluating health information systems and has been subject to confirmatory exploratory analysis enhancing its reliability and validity. The tools have also been used in the evaluation of other electronic health information systems projects such as laboratory, radiology and pharmacy (Canada Health Infoway, 2009). The survey is intended to measure user satisfaction with the electronic occurrence reporting system.

Two versions of the survey were sent out; one was a 12- item questionnaire for Frontline staff while the second was a 17- item questionnaire for Clinical Managers. (Appendix B) The surveys were designed to measure: (a) satisfaction, (b) ease of use, (c) competency, and (d) content. Questions were designed using a five- points strongly agree to strongly disagree Likert scale with 1 being strongly disagree and 5 being strongly agree.

The questionnaires were individually addressed to employees with a covering letter from a member of the EH executive team as a measure to promote the importance of the initiative and potentially increase participation. As with the patient safety culture surveys, the return envelopes and forms did not require the names of the employees. The questionnaires were colour coded for the care setting. As this was an anonymous questionnaire, a weakness is that only motivated employees may choose to respond.

3.4.5 Occurrence Reporting Records

A data extraction form (Appendix B) was developed for the purpose of capturing key indicators from occurrence reporting records so that comparisons could be made pre- and post-implementation. The indicators chosen were linked to the anticipated benefits of the project and included the number and type of occurrences, number of occurrences reported within 48 hours, timelines for responding to occurrence reports (reporting to the Quality and Risk Management Department and sign off of the form by managers), and reporter characteristics (i.e. various health care occupational groups such as Laboratory, Pharmacy, Diagnostic Imaging and Registered Nurses, etc.). A weakness of this tool is that it had to rely on the information as reported on the forms. This is a common problem with spontaneous reporting systems. Such reporting systems are subject to hindsight bias. The review of the occurrence report records did not include a retrospective review of the patient chart and discussion with managers and reporters to determine the accuracy of the information provided in the report. Determination of the validity of the occurrence reported was beyond the scope of this project.

3.4.6 Key Informant Guides (Senior Management)

The guides (Appendix B) were developed based on the evaluation objectives and on previous work carried out in British Columbia. Feedback obtained from the pre-implementation stakeholder workshops and project management staff during the pre-go-live site also contributed to the development of the guide. The key informant interviews were conducted to obtain opinions of senior managers regarding topics such as barriers, facilitators, benefits, unintended consequences, lessons learned, resources required, impact on managers' roles, and suggestions for improvement. The senior managers included the Directors of departments and programs involved in the Phase One implementation. Key informant interviews were conducted one to five months pre-implementation and six months post-implementation (depending on the availability of the senior managers). The interviews were not taped in an effort to facilitate the sharing of opinions on sensitive questions even though some participants may still be reluctant to express all their views. Notes of the interviews were taken by the principal investigator and research assistant and key points/notes were restated to the Director prior to the end of the session to ensure accurate reflection. The limitations of this method are related to the inability to capture all words and relying on recollections of conversations to draw conclusions. Strengths of this tool include the high response rate and an opportunity to explore issues and views in a more in-depth manner.

3.4.7 Focus Group Guides (Frontline Staff and Managers)

The guides (Appendix B) were developed based on the evaluation objectives and on previous research carried out in British Columbia and a focus group tool guide by Kingston et al. (2004). Feedback obtained from the pre-evaluation stakeholder workshops and project management staff also contributed to the development of the guide. The main purpose of the focus groups was to seek opinions from frontline staff and managers on benefits, facilitators, barriers, impact on role, etc. Focus groups were conducted one month pre- and six months post-implementation with notes taken by the principal investigator and research assistant during the small focus groups and audio tape used for the larger session in the acute care setting. As with interviews, one of the limitations of note taking is that not all words can be captured and it is challenging to rely on reflections of conversations for conclusions. Another limitation is that participants may be reluctant to express all their views, especially if the group dynamics silence those who wish to disagree. Key point/notes were restated to participants prior to the end of the session to ensure accurate reflection.

3.4.8 Project Document Review

Project documents such as the change management plan (which includes the implementation plan, the communications plan, and training plans), the Project Charter (which outlines key roles and responsibilities, deliverables, and project and management controls) and the monthly reports to Canada Health Infoway (which included the change requests and identification of problems and issues faced during implementation) were

reviewed by me as the principal investigator. The review included identifying key elements in the documents and noting any changes to the plan identified in the monthly status reports. A list of questions and findings was generated which were then discussed with the Project Steering Committee, the Project Implementation Team, and training staff from the Quality and Risk Management department. The main purpose of the review was to assist with the identification of lessons learned and development of recommendations for other organizations considering implementing a similar occurrence reporting system. Meetings were held with the Project Steering Committee on January 15, 2010, the training staff on January 19, 2010, and the Project Implementation Team on January 27, 2010. The following questions were asked:

1. What barriers and challenges did they encounter during the implementation?
2. What facilitators did they encounter during the implementation?
3. What advantages and/or disadvantages do they perceive?
4. What communication tools did they use?
5. What changes/recommendations would they make in future implementations?
6. What resources do they think are required to sustain the system?

The meetings also provided an opportunity to share the findings and draft recommendations with them as part of a consultation process as described in the Neville et al. (2004) Framework. Participants were encouraged to offer any other comments related to their perceptions of the implementation.

3.4.9 Research Questions and Data Sources Used

Table 1 provides an overview of the research questions and data sources used to answer the research questions.

Table 1: Research Questions and Data Sources Used

Research Questions	Data Sources
1) Anticipated benefits of this system.	• Stakeholder Workshops • Project Documents • Literature Review • Focus Groups • Key Informant Interviews
2) Benefits achieved and comparison with anticipated benefits.	• Surveys • Administrative Records • Focus Groups • Key Informant Interviews
3) Projected costs of this system.	• Project Documents
4) Costs of implementing the system and comparison with projected costs.	• Project Documents and discussion with Implementation Team
5) Necessary planning and management structures in place to proceed with the project.	• Key Informant Interviews • Focus Groups • Discussion with Implementation Team
6) Unforeseen harms and/or disadvantages.	• Key Informant Interviews • Focus Groups
7) Key facilitators and barriers to successful implementation of the project.	• Key Informant Interviews • Focus Groups • Surveys • Project Documents

3.4.10 Data Instruments

Data collection was conducted at various times due to the staged implementation schedule. Table 2 presents the date and tools administered for each of the 4 sites.

Table 2: Dates and Sites of Administration

Sites / Instruments	Pre-Go-Live	Acute (Urban)	Community Health (Urban)	Long Term Care (Urban)
Date of Implementation	November/08	March/09	April/09	June/09
Pre-Patient Safety Culture	October/09	January/09	January/09	May/09
Post- Patient Safety Culture	May/09	October/09	October/09	December/09
Pre-Key Informant Interview	Nil	January/09	January/09	January/09
Post- Key Informant Interview	June/09	November-December/09	November-December/09	December/09
Pre-Focus Group	Nil	March/09	March/09	May/09
Post-Focus Group	June/09	October/09	October/09	December/09
Computer Training	November – December/08	January – March/09	January – March/09	April-May/09
User Satisfaction	May/09	October/09	October/09	December/09
Occurrence Reporting Records (Pre)	August /08	January /09	January /09	May /09
Occurrence Reporting Records (Post)	June /09	January /10	January /10	January /10

3.5 Ethics

The study proposal along with consent forms, survey cover letter, and all data collection forms were approved by the Human Investigation Committee (HIC) at Memorial

University. The proposal was also submitted and approved by the Research Proposals Approval Committee at Eastern Health. Letters of approval are provided in Appendix C.

Consents were obtained for the interviews and key informant interviews. Information about the study was provided to participants before the focus groups and key informant interviews in person by the principal investigator and participants were given an opportunity to ask questions prior to providing consent. Surveys did not require the name of the person responding and were voluntary. Survey data were collected and entered into the computer anonymously and the computer was password protected. Data collected during the interviews and focus groups did not include any personal identifying information. All completed consent forms and data collection documents are stored in a locked cabinet in a room that is locked and is located in the Quality and Risk Management Department at Eastern Health, in accordance with the research guidelines of Memorial University. Access to the confidential information in the cabinet is limited to the principal investigator and research assistant.

3.6 Data Analysis

3.6.1 Survey Questionnaires

Data from the questionnaires (pre and post patient safety culture surveys, user satisfaction surveys and computer training evaluation forms) were entered into SPSS version 17. Analysis consisted mainly of descriptive statistics (e.g. means and

frequencies) and some comparative statistics (e.g. independent t test, one way ANOVA with post hoc test). A p-value (significance level) of $p < 0.05$ was used to assess the strength of the data with respect to the differences between groups. Responses to open-ended questions in the questionnaires were analyzed through content analysis (as described in Section 3.6.3).

3.6.2 Key Informant Interviews and Focus Groups

The broad categories of responses in the focus groups and key informant interviews (e.g. perceived benefits, barriers to implementation) were determined from the questions in the interview and focus group guides and the responses were grouped into main themes in each of the categories.

3.6.3 Open-Ended Questions

The open-ended questions in the questionnaires, focus group guides, and the key informant guides were analyzed using a method of content analysis that determines the number of times certain qualities appear in written text. Content analysis entails inspection of the data for recurrent instances of some kind, irrespective of the types of instance (e.g. words, phrases, sentences). There are four common coding units in content analysis: a word, a set of words, sentence, or a theme (Silverman, 2005; Wilkinson, 2004). During the interviews and focus groups notes were taken by the principal investigator and the research assistant. The questions that had been developed for the

guides (see Appendix B) were consistent with some of the main themes in the literature and further informed by the results of the stakeholder workshops. The questions included broad categories such as barriers to reporting, advantages and disadvantages, facilitators and barriers to implementation.

In this study, mainly words (single and a set) were used to organize the themes emerging from the responses. The themes were identified through repeated review of responses by the principal investigator and research assistant (independently and then jointly) to agree upon the key words. This included identifying the frequency of mentions of key words and going through the process several times. The data analysis involved data reduction, data display, and drawing conclusions about the data as a measure to narrow down the main themes.

3.6.4 Occurrence Reporting Records

Administrative data obtained from the occurrence reporting records were entered into SPSS version 17.0. Analysis consisted mainly of descriptive analysis (e.g. means and frequencies) for indicators such as number and type of occurrences, reporter characteristics, and timelines for reporting.

3.6.5 Review of Project Documents

Key issues and points were extracted from project documents (e.g. project charter, change management plan, and monthly status reports) after review by the principal investigator. Questions and draft recommendations were developed and discussed with members of the Project Steering Committee, the Project Implementation Team, and training staff to facilitate understanding and accuracy of descriptions and findings.

4 Results

The study involved five methods of data collection: survey questionnaires, key informant interviews, focus groups, review of project related documents, and review of occurrence reporting records. This chapter will describe the findings, organized by method and data collection tool, including a description of the results of the pre-implementation stakeholder workshops. The findings from the workshop are summarized as the stakeholder consultation helped refine the study objectives and data collection tools. Stakeholder consultation is a major component of the evaluation framework that guided the study. In the next chapter, some of these results will be discussed in relation to the key research questions.

4.1 Pre-evaluation Stakeholder Workshops

Two workshops were held (June 20, 2008 and September 12, 2008). The workshops were well attended with 31 representatives attending the first workshop and 34 attending the second workshop. The participants in the first workshop included representatives from funders, government, professional associations representing various health provider groups, unions, management, and research. The second workshop was focused on the managers from within the organization as they served a primary role in the implementation. The feedback obtained validated the planned questions and indicators and provided additional suggestions that were subsequently integrated into the focus

group and key informant interview guides. During the workshops, there were also many points and questions related to the implementation plan rather than the evaluation plan and these were shared with the Project Implementation Team, who also participated in the session and were able to hear first hand many of the suggestions, questions, and comments. These points and questions raised can be found in Appendix C.

The two main themes related to the evaluation plan that emerged were as follows:

(1) Stakeholders validated the approach to evaluation outlined in the evaluation plan. They agreed with the types of data collection methods (surveys, focus groups, and interviews) and emphasized the importance of getting the feedback from frontline clinical and management staff, as they are the primary users. They suggested that a strategy to engage physicians be implemented (after the initial implementation) as the main focus for resources should be on the main users of the current paper based system and an implementation plan for engaging physicians may be different. They agreed that the data collection should focus on user satisfaction, adoption, facilitators, barriers, challenges, benefits, training effectiveness and lessons learned. They supported the need to seek feedback regarding Information Technology (IT) capacity and support, including the amount of downtime and access to ongoing IT support.

(2) Stakeholders identified several questions that they would like to see added to the evaluation plan such as seeking input on how to share learnings on an external

and internal basis, how to engage the public, and how to engage physicians. There was also interest in trying to examine the impact of the new electronic system on quality improvement, clinical safety and on patient safety culture. There was recognition by stakeholders that exploring some of these impacts was beyond the planned scope of the evaluation, however, there was an interest to use the proposed data collection methods as an opportunity to consult with internal stakeholders, especially those on the frontlines, to get input that could assist in future planning for patient safety.

4.2 Patient Safety Culture Surveys

4.2.1 Response Rate

The patient safety culture survey was administered to measure the change of patient safety culture prior to implementation of the occurrence reporting system and six months after it was implemented in each of the Phase One sites. The sample for the surveys included all frontline staff that had direct involvement with residents, clients, and/or patients in each of the four sites. The sample included registered nurses (RNs), non-RN nursing staff, allied health, managers, clerical, and others. Responses were received from all groups. A total of 1,153 surveys were administered in the pre-implementation period, 11 were returned as undeliverable and 319 completed surveys were returned for a response of 27.9 % (See Table 3). Table 3 shows response by care setting and staff category.

Table 3: Patient Safety Culture Response Rates (Pre-Implementation)		
	# returned / # sent out (eligible) (n)	Response rate (%)
Across Full Sample	319/1142	27.9%
By Care Setting		
Acute Care (Urban)	180/707	25.5%
Long Term Care (LTC) (Urban)	13/46	28.3%
Community Health (Urban)	80/196	41.0%
Rural Integrated	46/193	23.8%
By Staff Category		
	# returned / 319	Response rate (%)
RN	193	60.5%
Non-RN Nursing Staff	31	9.7%
Allied Health and Technicians	74	23.2%
Clinical Care Managers	14	4.5%
Other (Educators, Ward Clerks etc.)	5	1.5%
Not known	2	0.6%

In the post-implementation period a total of 1,136 surveys were administered, 60 were returned as undeliverable and 195 completed surveys were returned for a response of 18.1%. Table 4 shows response rate by care setting and staff category for the post-implementation surveys.

Table 4: Patient Safety Culture Response Rates (Post-Implementation)		
	# returned / # sent out (eligible) (n)	Response rate (%)
Across Full Sample	195/1076	18.1%
By Care Setting		
Acute Care (Urban)	127/679	18.7%
LTC (Urban)	8/39	20.5%
Community (Urban)	36/170	21.2%
Rural Integrated	24/188	12.8%
By Staff Category		
	# returned / 195	Response rate (%)
RN	91	46.7%
Non-RN Nursing Staff	22	11.3%
Allied Health and Technicians	54	27.7%
Clinical Managers	16	8.2%
Other (Educators, Ward Clerks ,etc.)	11	5.6%
Not known	1	0.5%

4.2.2 Scoring

These results represent pre- and post-implementation scores of each site. The approach used in reporting results is based on Ginsburg et al. (2007). The performance is measured by the percent positive agreement (which reflects the percentage of staff that agreed or strongly agreed with the survey items that were stated positively). The percent positive agreement can also reflect the percentage of staff that disagreed or strongly disagreed with survey items that were stated negatively.

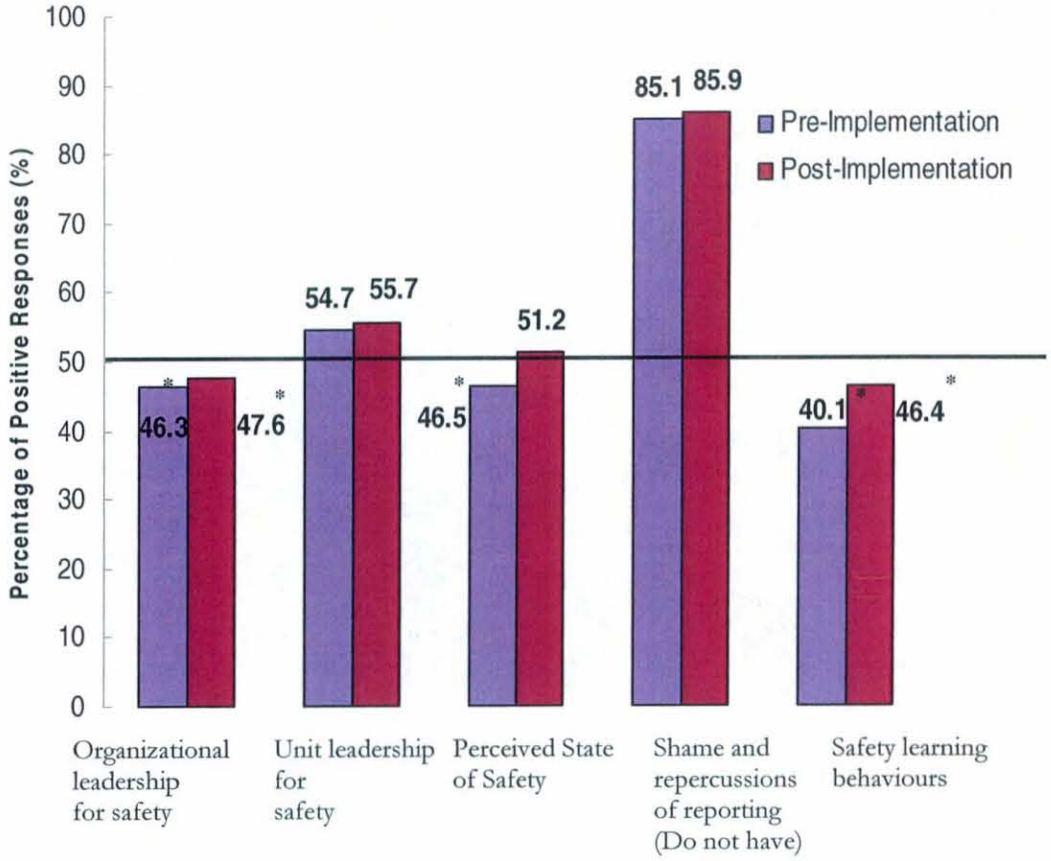
The percentage of positive agreement can be used to examine areas of both low and high performance. Items in which < 50% of the staff gave positive responses represent low performance and are considered to represent areas/opportunities for improvement for the organization. Items in which > 80% of staff responded positively represent areas of high performance reflecting areas of strength for the organization. Figures 3-7 present the means of high and low performances for the five dimensions at each of the four sites.

Further comparative analysis included constructing confidence intervals of the mean generating a lower and upper level for the mean. The interval estimate gives an indication of how much uncertainty there is in the estimate of a true mean with the narrower the interval is, the more precise the estimate. This can also assist in identifying significant differences between care settings and the findings can then be used to help in prioritizing and developing strategies to improve the patient safety culture. Data are presented for groups of questions that were used to measure each of the five dimensions of patient safety culture. Mean scores on each of these dimensions are presented by care setting and for all care settings combined. This analysis was designed to assess differences across care settings and as well as to allow comparisons to available national measures. The national measures used were from a study by Ginsburg et al. (2007) that conducted patient safety culture surveys in six healthcare organizations across Canada and is based on 6243 respondents.

4.2.3 Results of Patient Safety Culture Surveys

The analysis across all care settings (aggregate) for the five dimensions showed little change between pre-survey and post- surveys. In each of the dimensions, from pre- to post- surveys, there was a positive shift. In relation to acceptable and low performance dimensions; in the pre-implementation results, there were 3 dimensions considered to be low (<50 %) and these were organizational leadership for safety, perceived state of safety, and safety learning behaviours. In the post-implementation, there were 2 dimensions in the low (<50%) and these were organizational leadership for safety and safety learning behaviours. The dimension p*erceived state of safety* moved to an acceptable performance post- implementation (from a low performance in the pre-implementation period). The highest performance dimension (> 80%) was s*hame and repercussions of reporting* in both pre- and post- surveys. The lowest performance (<50%) dimension across all the care settings for both pre-and post-implementation surveys was *safety learning behaviours,* although this dimension showed the most positive improvement from pre to post implementation (see Figure 3).

Figure 3: Phase One Sites - Mean Positive Percentage Pre- and Post-Implementation Scores of Five Dimensions. Asterisk (*) indicates dimension with low performance (<50%).



Figures 4-7 show the results for each of the 4 sites on each of the 5 dimensions.

Figure 4: Acute Care (Urban) Mean Positive Percentage Pre- and Post- Implementation Scores of Five Dimensions. Asterisk (*) indicates dimension with low performance (<50%).

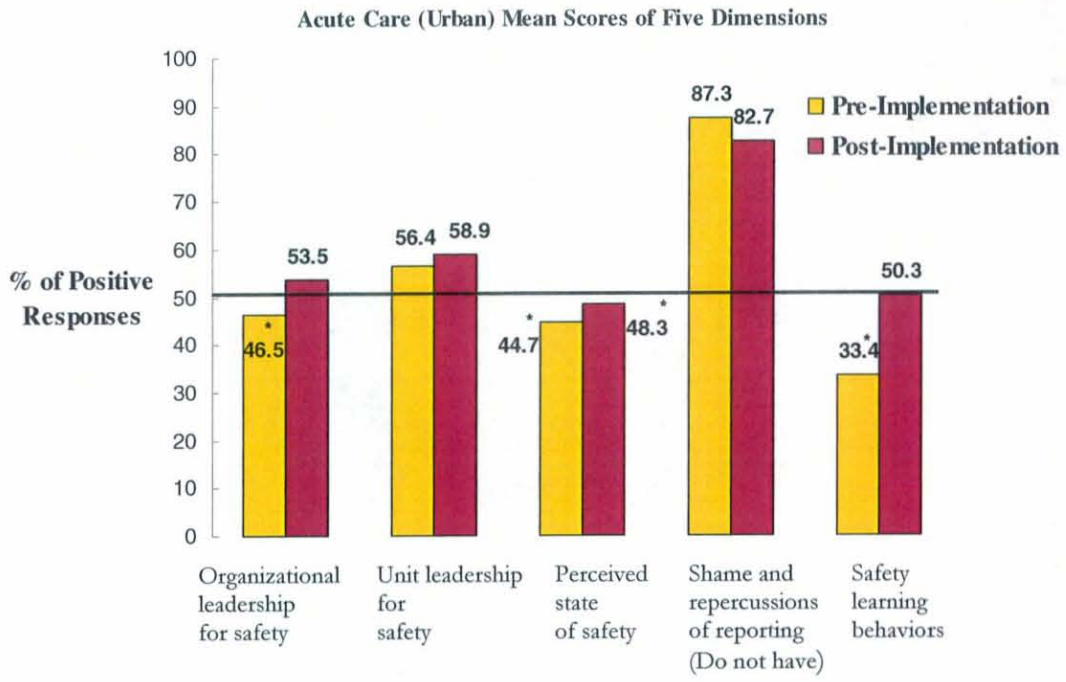


Figure 5: Long Term Care (Urban) Mean Positive Percentage Pre- and Post- Implementation Scores of Five Dimensions. Asterisk (*) indicates dimension with low performance (<50%).

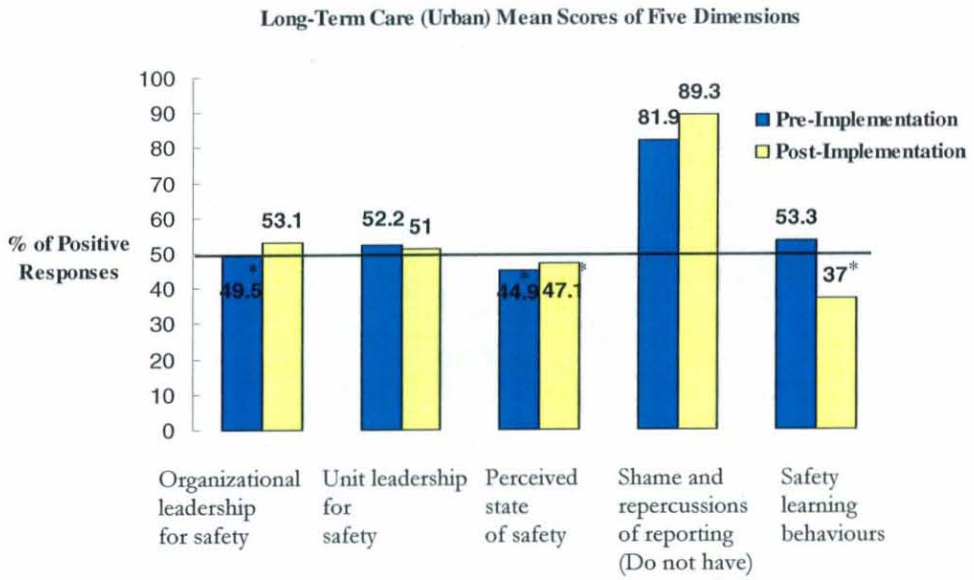


Figure 6: Community Health (Urban) Mean Positive Percentage Pre- and Post- Implementation Scores of Five Dimensions. Asterisk (*) indicates dimension with low performance (<50%).

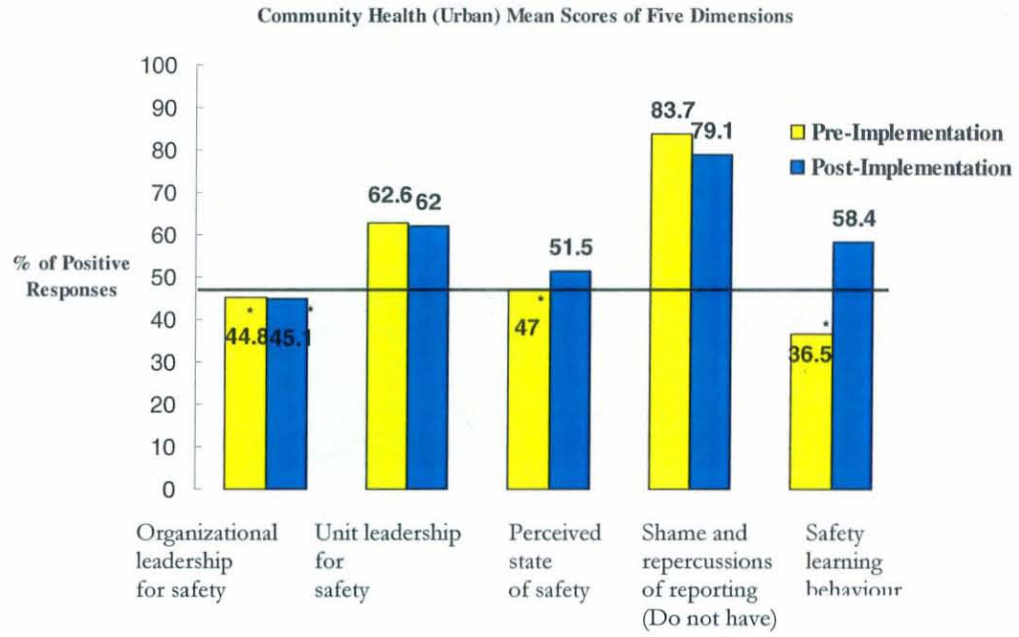
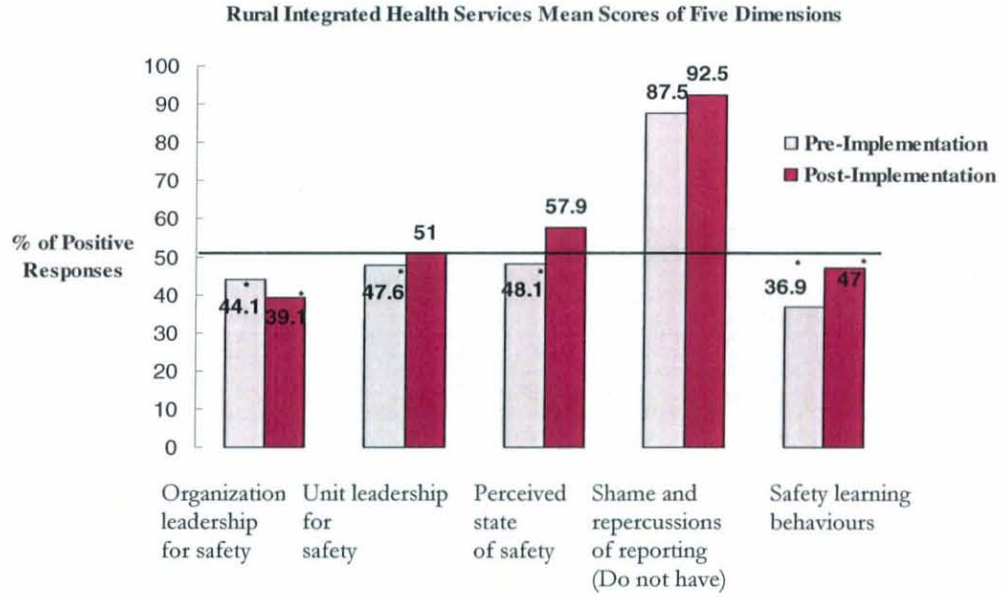


Figure 7: Rural Integrated Mean Positive Percentage Pre- and Post- Implementation Scores of Five Dimensions. Asterisk (*) indicates dimension with low performance (<50%).



The majority (14 out of 20) of the dimensions in all care settings experienced a small but demonstrable positive change, most notably in *safety learning behaviour* within Acute Care (AC) and Community Health (CH) settings. Rural Integrated also showed a positive shift on this dimension but still remained in the <50 % range. However, in Long Term Care (LTC), there was a decrease in *safety learning behaviour* from pre to post implementation. There was a low response rate in Long Term Care (n=8) and 25% (n=2) of the respondents selected "non-applicable" for all questions within this dimension. The p*erceived state of safety* dimension also had a positive result specifically in the CH and Rural Integrated settings, moving from low performance (< 50%) to acceptable performance (>50%).

Another approach to analyzing the dimension scores (both pre and post) include: (a) computing the means of each care setting and comparing them to other care settings and available comparative data and (b) computing 95% confidence interval levels (Appendix E). The 95% confidence interval (CI) was used for the comparison in this study as there were comparative data from a Ginsburg et al. (2007) study that involved six Canadian healthcare organizations. The 95% CI of the mean is provided to help decide if differences between care settings can be considered statistically significant. If the lower and upper bound of the 95% CI for two groups overlap, then differences between the groups cannot be considered statistically significant. For the dimension *organizational leadership for safety* there was a significant post-implementation difference between AC and CH, with CH ranking the item at a lower grade. Another

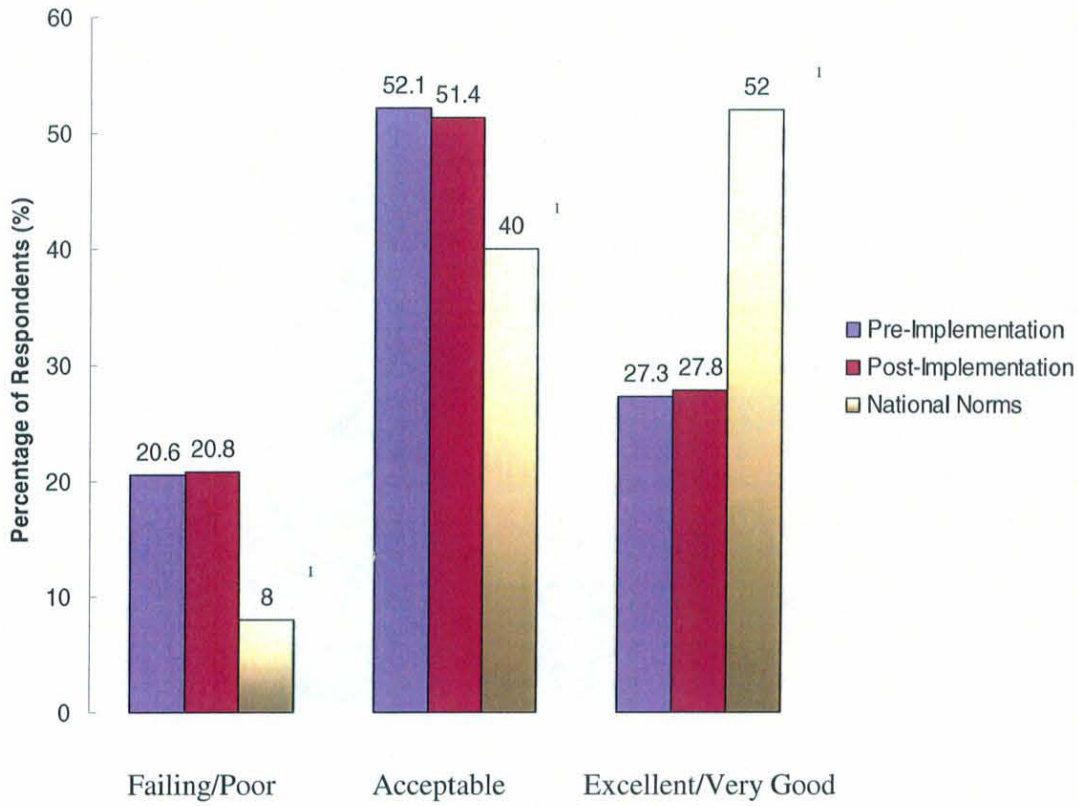
significant difference was that pre and post mean scores on this dimension for all sites were lower than the National data, the national data referring to the six healthcare organizations from other provinces that were included in the Ginsburg et al. (2007) study.

With the dimension *unit leadership for safety*, no significant differences were found pre- versus post- implementation. As well, no significant change occurred between pre- and post- survey mean scores in the dimensions *shame and repercussions of reporting* and *perceived state of safety,* however the scores for both these dimensions revealed a positive significant difference compared to the National data. Lastly, for the dimension *safety learning behaviour,* all Phase One sites showed a positive significant change from pre- to post- survey and the post implementation score was within the National score range for this dimension.

Two key items on the survey were the overall grades for: (a) patient safety for the *organization*; and (b) patient safety on the *unit*, as perceived by respondents. The organizational safety grade showed little difference between pre and post- survey scores for all care settings in response to the question "please give the organization an overall grade on patient safety" (see Figure 8). On these two items, there were national data available from Accreditation Canada that was based on 30,705 respondents (Accreditation Canada, 2008).

Figure 8: Organization Patient Safety Grade – Percentage of Respondents- All Care Settings

Respondents were asked to give their organization an overall grade on patient safety.
Question: **Please give the organization an overall grade on patient safety**



When compared to national data from Accreditation Canada (2008), the organization had higher percentages on Failing/Poor/Acceptable ratings but much lower on Excellent/Very Good ratings. Mean scores across care settings were compared and a significant difference was found for the post- implementation "Excellent/Very Good" rating between community health and long term care (Figure 9C).

[11] Source - Accreditation Canada 2008 – National Normative Data (number of respondents was 30,705)

Overall, little difference existed between care settings in the percentage of positive responses to the item about perceptions of how the organization is doing in relation to patient safety (See Figures 9 A, B and C). Figures show percentages for each of the 3 groups of grading (A) Failing/Poor, (B) Acceptable, and (C) Excellent/Very Good

Figure 9 A: Pre and Post-Implementation Failing/Poor Grade for the Organization by Care Setting

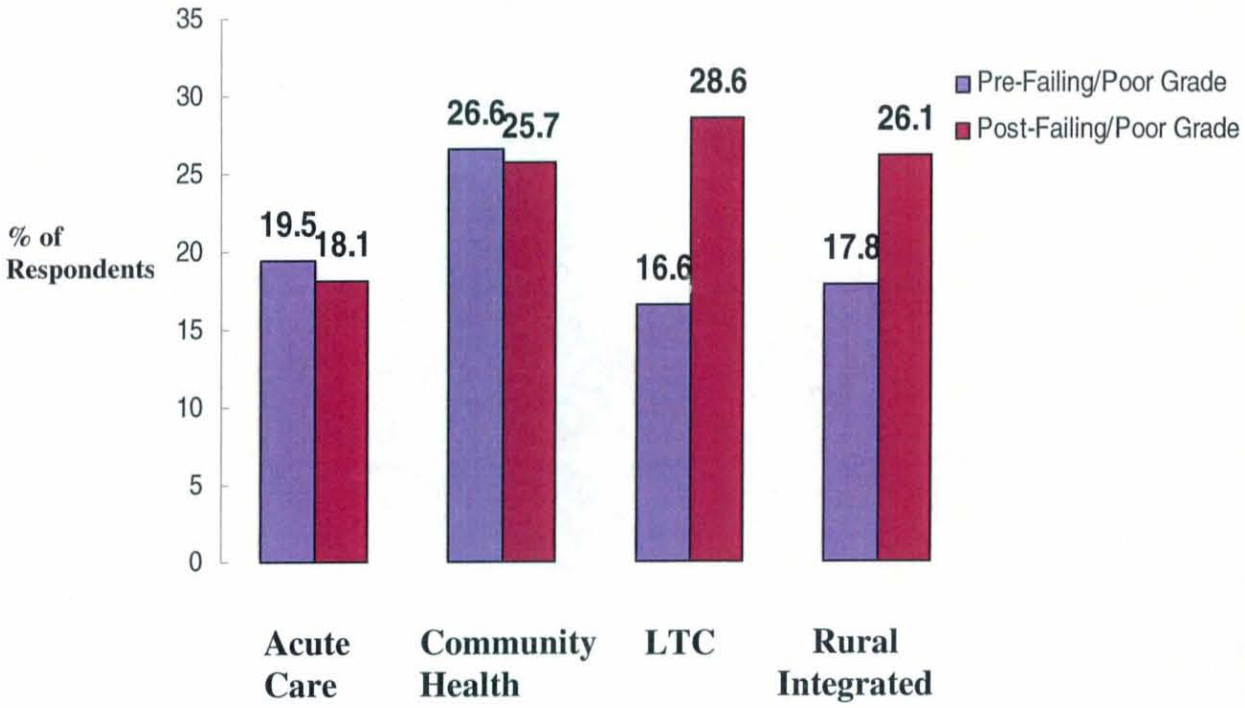


Figure 9 B: Pre and Post-Implementation Acceptable Grade For the Organization by Care Setting

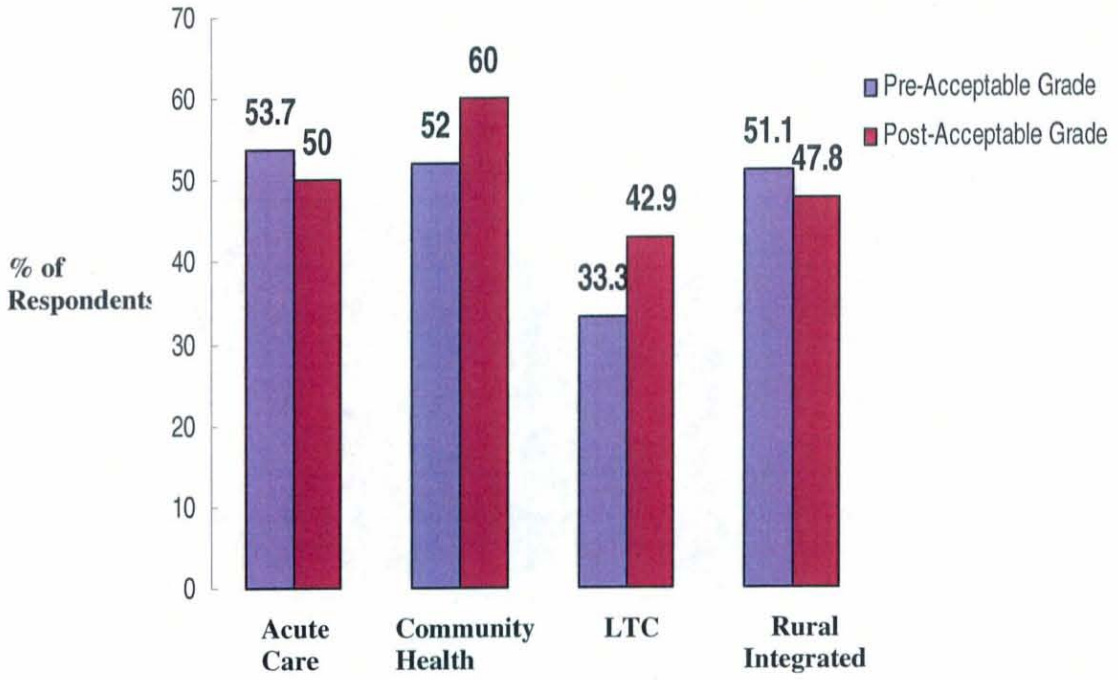
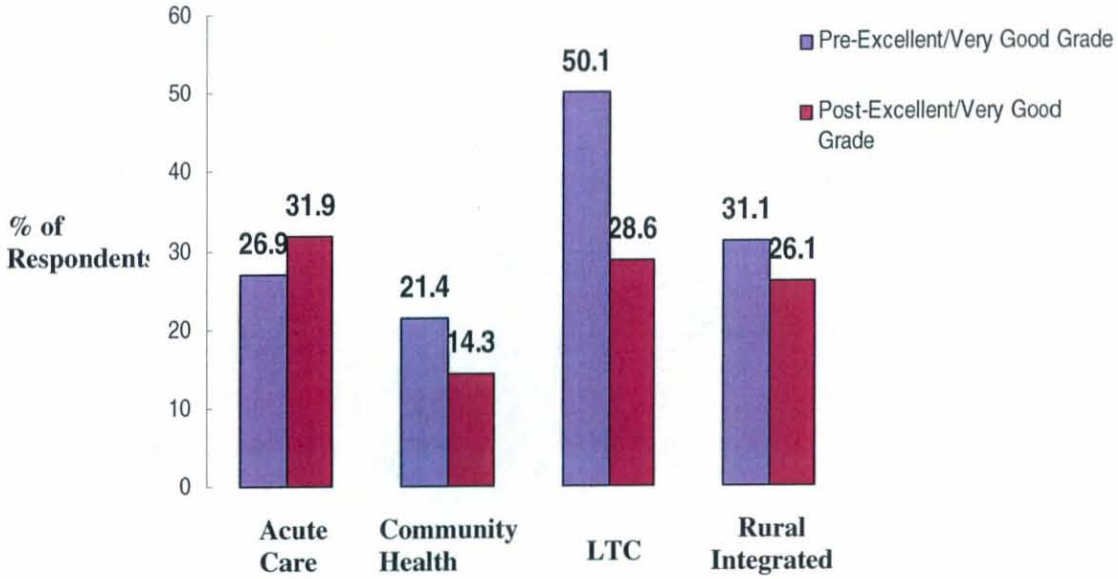
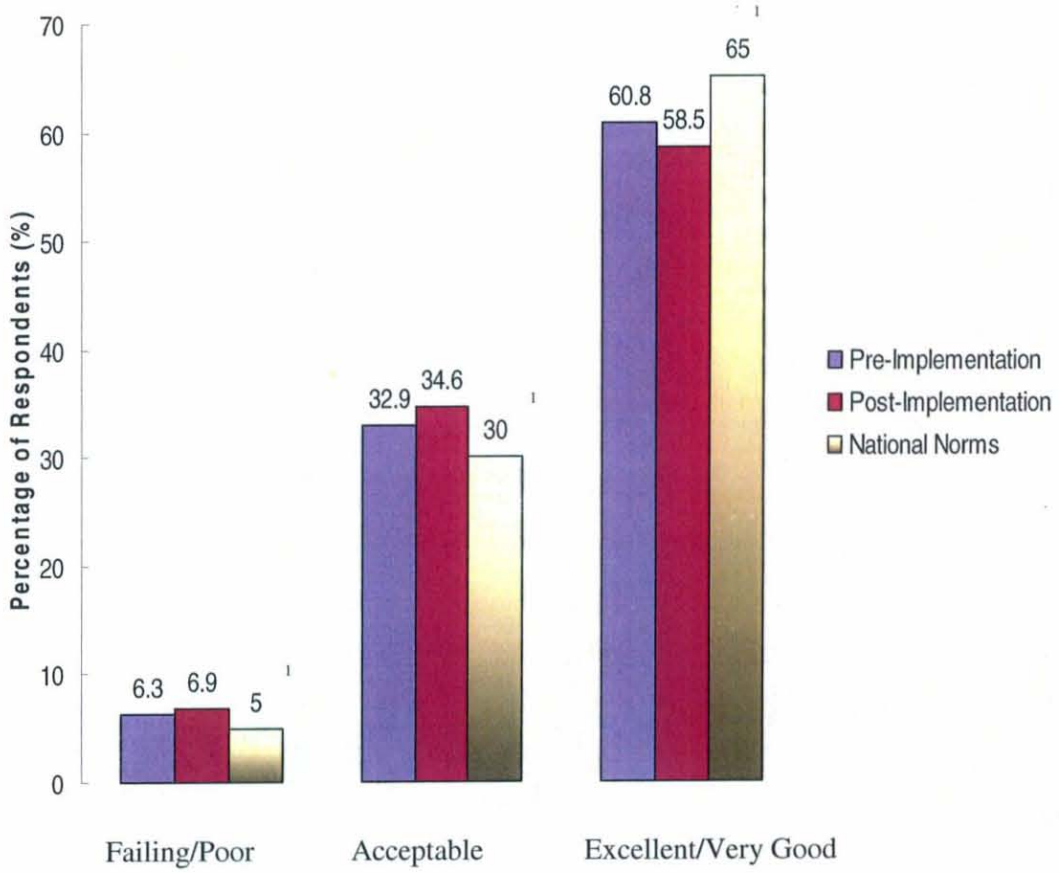


Figure 9 C: Pre and Post-Implementation Excellent/Very Good Grade for the Organization, by Care Setting



When respondents were asked to give a safety grade for their own unit, the unit patient safety grades for all care settings (aggregate) were similar to National scores (See Figure10). Mean scores between care settings were compared and there were no significant differences.

Figure 10 : Unit Patient Safety Grade
Respondents were asked to give their unit an overall grade on patient safety.
Question: **Please give your unit an overall grade on patient safety**



4.3 Computer Training Evaluation Surveys

Evaluation forms were distributed to all staff (frontline, super users, and managers) who participated in training for the electronic system. A total of 255 Computer Training Evaluation forms were returned for a response rate of 33.8%. The response rates for Managers, Super Users, and Frontline Staff for each care setting are presented in Tables 5-7. Managers and super users had a higher response rate than frontline staff as a group; within the frontline staff group, the response rate was much lower for acute care (urban).

The bulk of training was provided by the Quality and Clinical Safety Leaders (QCSLs), who were previously trained by external consultants and used training manuals developed by the Project Implementation Team. The evaluation forms were specific to each of the three groups (frontline, managers, super users) as each group had training tailored to their specific roles. Most of the questions were similar, with slight differences based on feedback obtained from project leadership staff, key stakeholders, and previous evaluation conducted in BC (BCPSL, 2008).

Table 5: Computer Training Evaluation Response Rates: Managers		
	# returned / # sent (n)	Response rate (%)
Full Sample	39/54	72.2%
By Care Setting		
Acute Care (Urban)	23/35	65.7%
LTC (Urban)	3/3	100%
Community Health (Urban)	7/7	100%
Rural Integrated	6/9	66.6%

Table 6: Computer Training Evaluation Response Rates : Super Users		
	# returned / # sent (n)	Response rate (%)
Full Sample	49/60	81.6%
By Care Setting		
Acute Care (Urban)	22/33	66.6%
LTC (Urban)	9/9	100%
Community Health (Urban)	15/15	100%
Rural Integrated	3/3	100%

Table 7: Computer Training Evaluation Response Rates: Frontline Staff		
	# returned / # sent (n)	Response rate (%)
Across Full Sample	167/641	26.1%
By Care Setting		
Acute Care (Urban)	30/336	8.9%
LTC (Urban)	28/35	80%
Community Health (Urban)	88/190	46.3%
Rural Integrated	21/80	26.3%

4.3.1 Computer Training Evaluation Results

The results of the computer training for the electronic occurrence report (also called the clinical safety report) for Frontline Staff are presented in Table 8. The data for the Managers and Super Users are not shown in a table as there were sites surveyed (i.e. rural integrated and long term care) that were small in terms of numbers of individuals in each of these two categories and the number of respondents from the Super User and Manager group was less than five. While the responses were received confidentially and no names provided, as a measure to ensure confidentiality, the results for the Managers and Super Users will be discussed in the narrative section.

Table 8: Frontline Staff (n=167): Results of Computer Evaluation Training Across All Care Settings

	Sites			
Question #1	*Rural Integrated*	*Urban Acute Care*	*Urban Community*	*Urban LTC*
What was the most helpful part of the CSRS computer training session?	1-on-1 instruction; straight forward; user friendly; appears to take as long as the paper system; where to access	The basic info step by step ; computer work; knowing to report close calls; very informative; one-on-one training; easily accessible; user friendly; hands on training with computer; guided assistance	Education on occurrences (OCR), close call, adverse events, why report , attention to all occurrences; training demo; hands on experience with computer; remind importance of OCR; e-training explanation; quick reference card is great	Sample OCR practice with LTC examples , "defining dementia residents"; explanation of process; easy to use; intro to CSRS; trainer guide you through; instructor helpful

Question #2	*Rural Integrated*	*Urban Acute Care*	*Urban Community*	*Urban LTC*
What additional information would have been helpful in the session?	Specifics on the fields, some fields don't have explanation as to required information.	More practice on entering a sample occurrence.	What will happen if the system is down? good that OCR will be monitored; examples of OCR and what to; excellent review	Further review of drop down items is needed – not all inclusive

Question #3	*Rating*	*Rural Integrated*	*Urban Acute Care*	*Urban Community*	*Urban LTC*	*Total*
Now that you have completed your CSRS computer training session, do you feel you could complete an occurrence form?	**Yes**	100%	90%	76.1 %	97.2%	85.1%
	No			2.3 %		1.2%
	No Answer		10%	21.6 %	2.8%	13.7%
	Comments	Only because familiar with computer based programs; easy to follow				

Question #4	*Rural Integrated*	*Urban Acute Care*	*Urban Community*	*Urban LTC*
What would you like more information on?	Some fields not sure what info. is needed; should patient's info. be included on the form when filling out the occurrence		More OCR examples from community in order to know what to report including close calls and adverse events; medications area need to include immunizations	How to write the description section of the form; more explanation on the section where it says minor/moderate/ severe

Most staff members, including managers, were satisfied with the allotted time for the training, the materials used, the hands-on computer exercises, and the ability of the instructor to answer the questions.

The majority of managers and super users indicated that they felt either "very prepared" or "prepared" to use the new system in response to the question "How prepared do you feel using the new system?" The range was 53.8% for managers to 86% for super users. Of note, one manager (14.3%) in the urban community health system felt "prepared" with the majority (85.7%, n=6) in CH indicating that they were "somewhat prepared".

In response to the question "Now that you have completed your computer training session, do you feel you could complete an occurrence form?" 86.3% of frontline staff responded yes, ranging from 76.1% - 100% over all care settings. Key points made by staff included specific items about the occurrence form, for example; "unsure what information is needed in certain fields"; "medication field needed", "need to add immunization"; "further explanation is needed on rating the occurrence (e.g. minor/moderate/severe)". Overall the computer training approach for the electronic occurrence reporting tool was positively received as reported by the three groups.

Each Computer Training Evaluation Form had an "Additional Comments" section which resulted in feedback that was used by the implementation team to assist with planning for rollout including using more specific examples and more customized drop down boxes.

4.4 User Satisfaction Surveys

A total of 358 User Satisfaction surveys from the 1074 administered were returned, for a response rate of 33.3% (See Table 9). All frontline staff and managers in each of the four Phase One sites who have direct contact with patients, clients, and residents were included in the sample. The numbers of responses were broken down into those who reported using the system and those who didn't. Respondents could choose any ranking from 1-5 with 1 being "not satisfied at all" to 5 being "highly satisfied". This survey was administered to measure user satisfaction post-implementation of the occurrence reporting system. Responses for both the Frontline Staff and Managers were positive in all area of measurements. The mean scores of frontline staff in each question ranged from 3.11 to 4.17 (out of five), indicating moderate agreement (see Table 10). Managers' mean scores ranged from 3.48 to 4.72 (out of five), indicating moderate to strong agreement (see Table 11). The standard deviations (S.D.) are included for both groups.

Table 9: User Satisfaction Response Rates

	# returned / # sent (n)		Response rate (%)
Across Full Sample	358/1074		33.3%
"Yes" response(Used the system)	153/358		42.7%
"No" response(Did not use the system)	205/358		57.3%
By Care Setting			**Yes /No** (Use of System- % of Respondents)
Acute Care (Urban)	208/665	31.3%	44.7 % / 55.3%
LTC (Urban)	9/41	21.9%	66.7% / 33.3%
Community Health (Urban)	79/176	44.9%	31.6% / 68.4%
Rural Integrated	62/192	32.3%	46.8% / 53.2%
By Staff Category			
Frontline Staff	330/1032	32.0%	38.8% /61.2%
Managers	28/42	66.7%	89.3% / 10.7%

Table 10 : User Satisfaction Survey Mean Results: Frontline Staff (n=128)

User Satisfaction Survey Questions	Mean Score (S.D.)
How satisfied are you overall with the CSRS?	3.98 (.98)
The CSRS is easy to use.	4.16 (.85)
The CSRS makes it easier to complete occurrence reports.	3.94 (1.15)
I will remember how to use the CSRS next time.	4.13 (.99)
The CSRS is consistent in its performance (behaves the same way each time I use it).	4.17 (.82)
The amount of time to operate the CSRS is acceptable.	3.98 (.96)
The information I am asked to provide is relevant.	4.11 (.89)
I can use the CSRS to report any kind of clinical occurrence that might occur.	3.95 (.94)
I can document a close call using the CSRS.	3.97 (.95)
The CSRS provides feedback in a more timely manner that the paper system.	3.49 (1.16)
The training provided was acceptable.	3.62 (1.08)
The level of ongoing IT support provided is acceptable.	3.11 (1.01)

Table 11 : User Satisfaction Survey Mean Results: Managers (n=25)

User Satisfaction Survey Questions	Mean Score (S.D.)
How satisfied are you overall with the CSRS?	4.04 (1.17)
The CSRS is easy to use.	3.80(1.06)
The CSRS makes it easier to follow up on occurrence reports	3.80 (1.35)
I will remember how to use the CSRS next time.	4.12 (1.13)
The CSRS saves us time.	3.48 (1.66)
The CSRS is consistent in its performance (behaves the same way each time I use it).	4.20 (1.04)
The amount of time to operate the CSRS is acceptable.	4.28 (.79)
I am notified in a timely manner when an occurrence occurs.	4.72 (.46)
I can use the CSRS to manage any kind of clinical occurrence in my area of work.	3.92 (1.18)
I can investigate and manage a close call using CSRS.	4.16 (.99)
I can easily view all occurrence reports assigned to me.	4.64 (.76)
I can easily determine the follow up stage of any occurrence report.	3.96 (1.30)
Occurrence reporting has increased now that we have the CSRS.	3.52 (1.23)
I use information from CSRS to improve clinical safety.	4.16 (.89)
It is easier to provide feedback to reports of occurrences than it was with the paper system.	3.76 (1.01)
The training provided was acceptable.	3.84 (1.18)
The level of ongoing IT support provided is acceptable.	4.00 (.66)

Comparison of Frontline Staff User Satisfaction Survey between care settings found significant differences between CH and LTC on the item ability to "use the CSRS to report any kind of clinical occurrence that might occur"; Community Health rated this item lower than LTC. Also, a significant difference was shown between Acute (urban) and LTC with the item "training provided was acceptable"; Acute Care (urban) rated this lower than LTC (See Table 12). No significant difference existed in Managers' User Satisfaction Survey mean results between care settings (See Table 13). The results for managers LTC urban are not shown in the table as this is a small site and there was only one manager who responded and exclusion from the table is a measure to ensure confidentiality of responses is protected.

Table 12: User Satisfaction Survey Mean Results between Care Settings:
Frontline Staff (n=128) **NS (Non-significant)**

User Satisfaction Survey Questions Mean Score (S.D.) 1-5	Rural Health	Acute Care (Urban)	Community Health (Urban)	LTC (Urban)	Significant difference (p *< 0.05)
How satisfied are you overall with the CSRS?	3.91 (.95)	4.00 (.93)	3.85 (.88)	4.40 (.89)	.663
The CSRS is easy to use.	4.21 (.74)	4.08 (.93)	4.35 (.59)	4.40 (.89)	.513
The CSRS makes it easier to complete occurrence reports.	4.26 (.75)	3.81 (1.22)	4.05 (1.05)	4.00 (1.73)	.399
I will remember how to use the CSRS next time.	4.39 (.78)	4.01 (1.06)	4.15 (.99)	4.80 (.45)	.177
The CSRS is consistent in its performance (behaves the same way each time I use it).	4.43 (.73)	4.09 (.82)	4.05 (.89)	4.80 (.45)	.084
The amount of time to operate the CSRS is acceptable.	3.78 (1.2)	3.96 (.97)	4.20 (.52)	4.40 (.55)	.390
The information I am asked to provide is relevant.	3.95 (1.02)	4.18 (.87)	3.90 (.91)	4.60 (.55)	.294
I can use the CSRS to report any kind of clinical occurrence that might occur	4.04 (.98)	3.97 (,92)	* 3.55 (.95)	* 4.80 (.45)	NS all * except between CH and LTC – .047 *
I can document a close call using the CSRS.	4.09 (.90)	3.97 (.92)	3.65 (1.09)	4.60 (.55)	.186
The CSRS provides feedback in a more timely manner that the paper system.	3.52 (1.12)	3.45 (1.16)	3.55 (1.10)	3.80 (1.79)	.914
The training provided was acceptable.	3.91 (.98)	*3.45 (1.16)	3.75 (.72)	*4.60 (.55)	NS *except Acute and LTC-.028*
The level of ongoing IT support provided is acceptable.	3.26 (.96)	2.96 (1.01)	3.35 (.99)	3.80 (1.09)	.132

Table 13: User Satisfaction Survey Mean Results between Care Settings: Managers (n=24)

User Satisfaction Survey Questions Mean Score (S.D)	Rural Health	Acute Care (Urban)	Community Health (Urban)	Significant difference (p *< 0.05)
How satisfied are you overall with the CSRS?	4.00 (1.18)	3.92 (1.38)	4.20 (.83)	.913
The CSRS is easy to use.	3.80 (.98)	3.84 (1.52)	3.40 (.89)	.798
The CSRS makes it easier to follow up on occurrence reports.	4.17 (1.17)	3.92 (1.26)	2.80 (1.64)	.206
I will remember how to use the CSRS next time.	4.50 (.54)	3.84 (1.71)	4.20 (.84)	.512
The CSRS saves us time.	4.17 (1.6)	3.38 (1.71)	2.80 (1.79)	.419
The CSRS is consistent in its performance (behaves the same way each time I use it).	4.67 (.52)	4.00 (1.22)	4.00 (1.0)	.422
The amount of time to operate the CSRS is acceptable.	4.50 (.55)	4.08 (.95)	4.40 (.55)	.519
I am notified in a timely manner when an occurrence occurs.	4.83 (.41)	4.69 (.48)	4.60 (.55)	.715
I can use the CSRS to manage any kind of clinical occurrence in my area of work.	4.17 (.75)	3.62 (1.39)	4.25 (.95)	.518
I can investigate and manage a close call using CSRS.	4.17 (.75)	4.23 (1.01)	3.80 (1.3)	.724
I can easily view all occurrence reports assigned to me.	4.83 (.41)	4.54 (.88)	4.60 (.89)	.754
I can easily determine the follow up stage of any occurrence report.	4.50 (.84)	3.83 (1.40)	3.40 (1.52)	.383
Occurrence reporting has increased not that we have the CSRS.	4.30 (.52)	3.23 (1.36)	3.20 (1.3)	.172
I use information from CSRS to improve clinical safety.	4.30 (.52)	4.15 (.99)	3.80 (1.10)	.631
It is easier to provide feedback to reports of occurrences than it was with the paper system.	4.30 (.82)	3.84 (1.07)	3.00 (.71)	.890
The training provided was acceptable.	4.50 (.55)	3.69 (1.32)	3.20 (1.10)	.175
The level of ongoing IT support provided is acceptable.	4.17 (.41)	4.00 (.74)	3.80 (.84)	.688

Table 14 also compares the responses of seven questions that were common to each questionnaire (frontline staff and manager). There was a significant difference between managers and frontline clinical staff on how they rated "the level of ongoing IT support provided is acceptable" with managers rating this item higher. For the other survey items there was no statistical significant difference between the groups.

Table 14: User Satisfaction Survey Mean Results: Comparison of Like Questions Managers (n=25) and Frontline Staff (n=128)

User Satisfaction Survey Questions	Mean Score (S.D.) 1-5 Manager	Mean Score (S.D.) 1-5 Staff	Significant difference (p *< 0.05)
How satisfied are you overall with the CSRS?	4.04 (1.17)	3.98 (.92)	.764
The CSRS is easy to use.	3.80 (1.26)	4.16 (.85)	.185
I will remember how to use the CSRS next time.	4.12 (1.13)	4.13 (.99)	.954
The CSRS is consistent in its performance (behaves the same way each time I use it).	4.20 (1.04)	4.17 (.82)	.887
The amount of time to operate the CSRS is acceptable.	4.28 (.79)	3.98 (.96)	.149
The training provided was acceptable.	3.84 (1.18)	3.62 (1.08)	.371
The level of ongoing IT support provided is acceptable.	4.00 (.66)	3.11 (1.01)	* <.001

A key question in both surveys was the "level of satisfaction overall with the CSRS". The staff's responses showed 28.9% were highly satisfied and 49.2% were moderately satisfied whereas the manager's responses showed 40% were highly satisfied and 44% were moderately satisfied (See Figure 11).

Figure 11: Overall Satisfaction with CSRS:
Frontline Staff (n=128) and Managers (n=25) Frequency Results

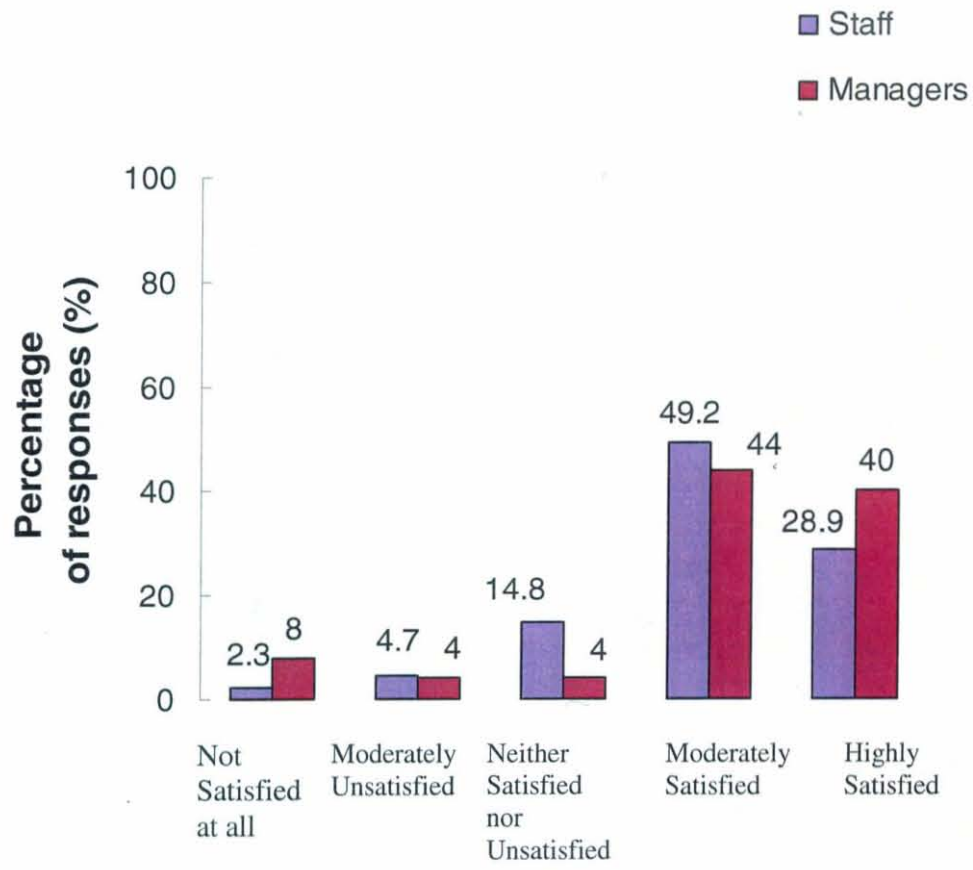
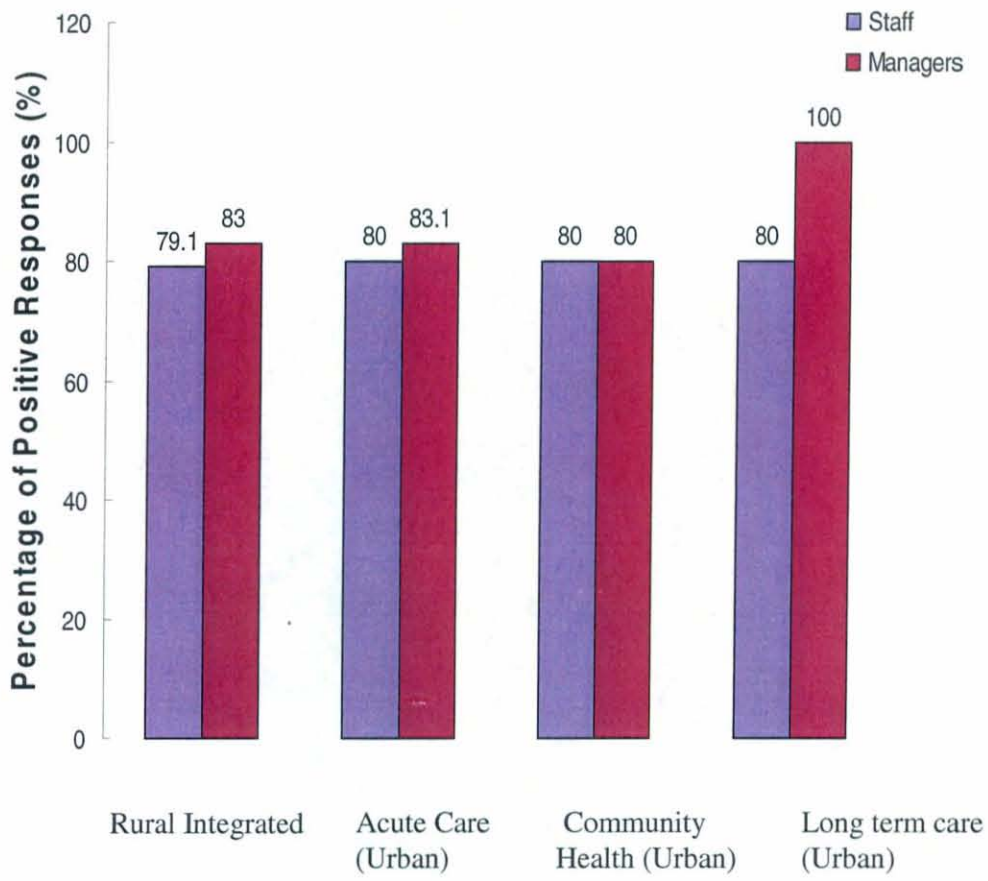


Figure 12 shows a comparison between all care settings for staff and managers responses (highly satisfied and moderately satisfied combined) of "how satisfied are you overall with the CSRS?"

Figure 12: Overall Satisfaction with CSRS:
Frontline Staff (n=128) and Managers (n=25) -- (highly and moderately satisfied combined)



In Figures 13 and 14, the percentages of responses of each group (frontline staff and managers) for two of the questionnaire items are shown, the highest and the lowest scoring item for each group. In figure 13, the percentage of responses for the item with the highest score (A) was "The CSRS is consistent in its performance", and the questionnaire item with the lowest score (B) was, "The level of ongoing IT support provide is acceptable."

Figure 13: Frontline Staff Results (Percentage of responses) of Highest (A) and Lowest (B) Score Questions

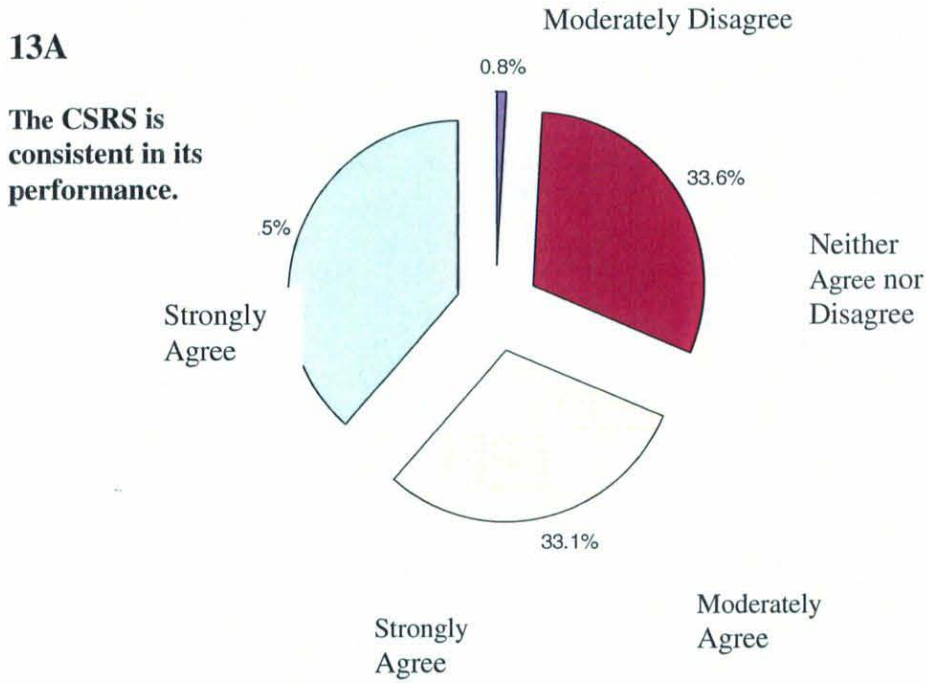


Figure 13B- Lowest Scoring Item – Frontline Staff

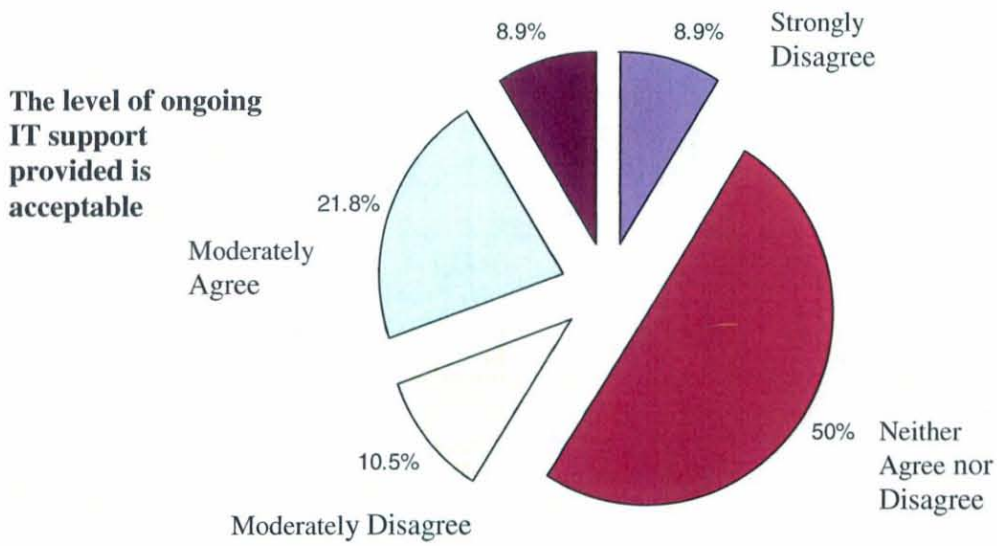
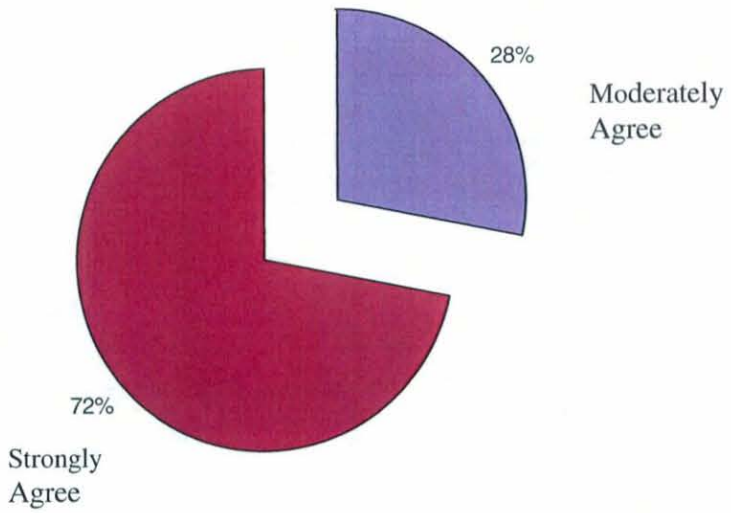


Figure 14: Managers' Results (Percentage of responses) of Highest (A) and Lowest (B) Score Questions

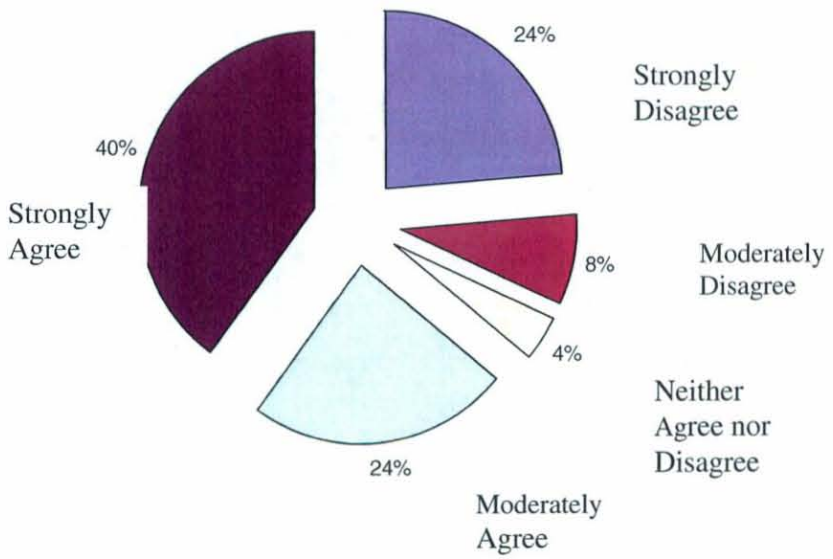
14 A

I am notified in a timely manner when an occurrence occurs



14B

The CSRS saves me [Managers] time



4.5 Occurrence Reporting Records

4.5.1 Post-implementation Results

The purpose of reviewing the occurrence reports in each care setting prior to implementation was to assist in the analysis of the benefits of the electronic occurrence reporting system. The anticipated benefits of the electronic occurrence reporting system included improvement in the following indicators: (1) number and type of occurrences reported, (2) reporter characteristics (by category of health care worker), (3) number of occurrences reported within 48 hours (4) time (reported in days) from reporting the occurrence to sign off by manager, and (5) time (reported in days) from reporting the occurrence to notification of Quality & Risk Management (QRM) Department.

A pre-implementation review of the occurrence reports consisted of manually reviewing paper reports for a six month pre-implementation period of all four sites in Phase One. A post-implementation review of the electronic occurrence reports at these sites was completed for a six month period. As mentioned in the previous chapter, a limitation of this review is that data was collected based on the occurrence reports as recorded by staff and managers. A retrospective review of patient records to determine accuracy of the indicators such as the type of occurrence and timelines was not within the scope of this study.

It is important to note that with the implementation of the electronic system a new classification system of occurrences was also implemented. It was adapted from a draft

taxonomy developed by the World Health Organization (WHO) guidelines (WHO, 2009). The new occurrence classification identifies occurrences into fifteen categories (e.g. treatment, security, medications, a consent, diagnosis, medical device, etc). The complete list (excluding financial) is shown in Table 20 as the financial category did not have any occurrences reported in the pre or post- implementation period. This classification is different from the previous classification, which allowed for seven categories based on types of occurrences (e.g. medications, treatments/tests, blood/blood products , security, assaults, allergic/adverse reactions, and others). When analyzing pre and post-implementation occurrences reported by staff in the care settings, pre-implementation occurrences were re-classified into the new classification system to make comparisons. Tables 15 to 20 present the results of the findings for Phase One overall and in each care setting, for both pre and post-implementation.

The number of occurrences reported by staff six months post-implementation increased by 412 reports (an 83% increase from pre-implementation) for a total of 907 reports. There was a 54% increase in the number of occurrence reports completed within 48 hours.

As shown in Figure 15, reporter characteristics have also shifted. In the pre-implementation period 28% (n=129) of occurrences were reported by non-RN staff and in the post-implementation period 43% (n=391) occurrences were reported by non-RN staff. Diagnostics services staff (included radiology and laboratory staff) represented the

highest reporters of the non-RN reporting group, submitting 147 occurrences (37% of total of non-RN reports). The number of RN reporting did increase from pre-implementation (n=366) to post-implementation (n=516), however, the percentage of reports completed by RNs decreased from 72% to 57%.

There was a decrease in the length of time that lapsed between occurrence report completion and notification of the risk management department from 43 days to immediately (as the new system includes automatic notification to the department).

There was, however, an increase of 5.7 days (50%) in the average time it took for managers to sign off /close out the occurrence report with the electronic reporting system as compared to the time required with the pre-implementation paper based reporting system. Signing off/closing out refers to the closing the file by the manager with no further action required on the occurrence report form. Community Health (urban) was the one care setting that improved in this indicator post-implementation (25 to 18 days) (See Table 18). In the Acute Care (Urban) site it took an average of 36 days to complete follow-up of the reported occurrence, an increase of 21 days (See Table 16).

The types of occurrences reported changed between pre and post- implementation period. The pre-implementation occurrences were re-coded to be consistent with the new classification system that had been adopted. This allowed for comparisons in change of numbers for each category. Most notably, occurrences involving *Clinical Assessment*

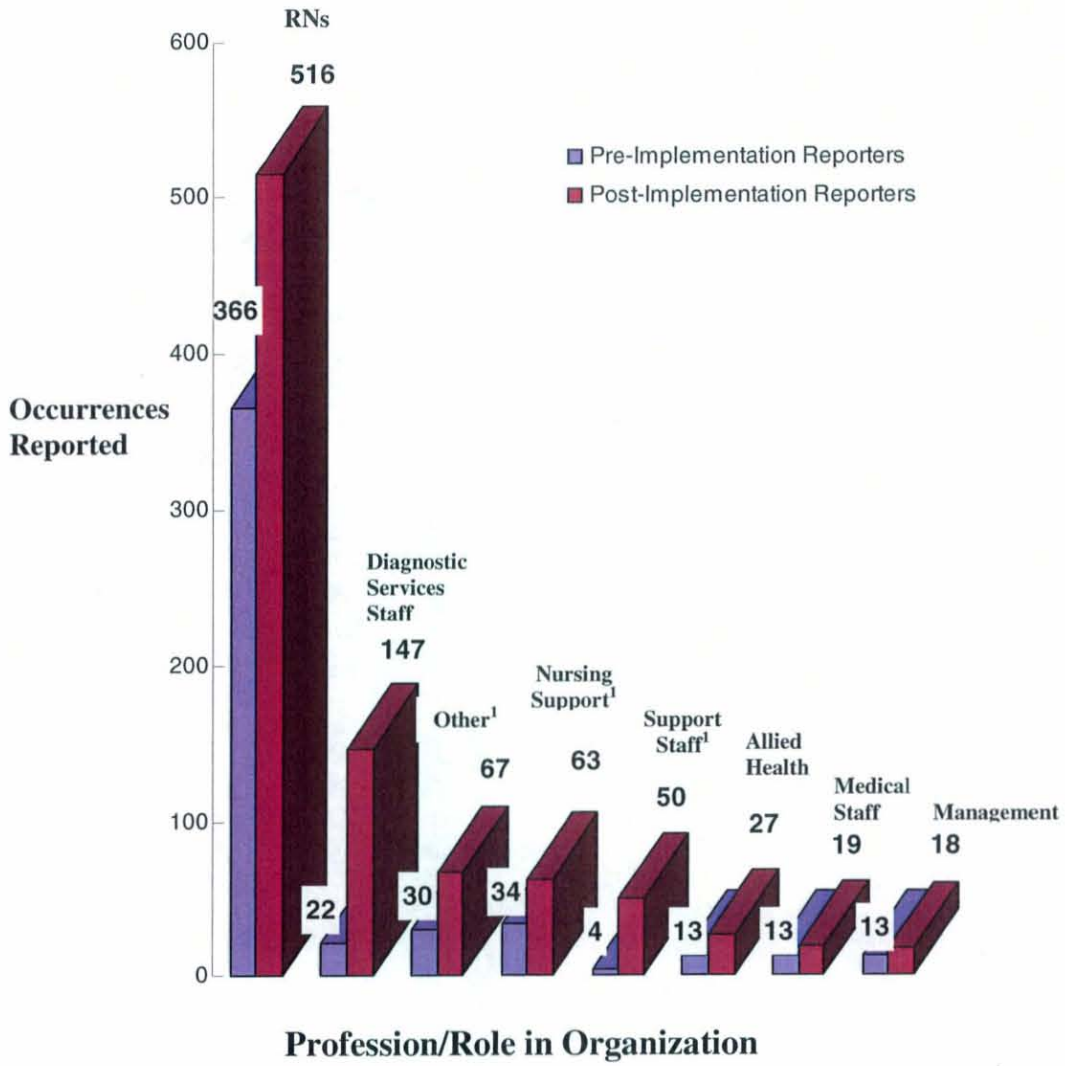
increased by 155 (3100%) reports from pre-implementation and this represented 20.9% of the total occurrences reported in post- implementation period. This category includes occurrences such as incomplete or inaccurate information on requisitions and specimens. Occurrences involving *Medications* increased by 59 (98 %) reports from pre-implementation and this represented 15.5% of the total reported in post- implementation period (See Table 20).

Accidents that may result in personal injury, specifically, *Falls* (n= 195), in this category were the majority of occurrences reported in pre-implementation (39.4 % of total reported) and in post-implementation *Falls* (n = 162) constituted 21.2% of the total reported (See Table 15). There were 97 *Close Calls* reported in the post-implementation period where as in the pre- implementation there were 5 reported (See Table 15). While this represents a 10% increase expressed as a percentage of total reports, it also reflects an increase of 1840% in the reporting of close calls.

Table 15: Comparison of Pre- and Post- Implementation Occurrence Reports

Occurrence Reports INDICATORS	Pre-Implementation (n)	Post-Implementation (n)	Change/Improvement between Pre and Post-Implementation
# of Occurrences Reported	495	907	Increase 412 reports (83%)
Reports Completed	386 (78%)	795 (88%)	Increase 10%
Non-RN Reports	129 (28%)	391 (43%)	Increase 15%
Reported within 48 hours of Occurrence	166 (34%)	799 (88%)	Increase 54%
Average Time between Occurrence and Notification of Manager Sign Off	11.3 days	17 days	Increase 5.7 days (50%)
Average Time between Occurrence and Notification of Quality and Risk Management	43 days	Immediately	Decrease 43 days (100 %)
Close Calls	5 (1%)	97 (11%)	Increase 10%

Figure 15: Comparison of Pre- and Post-Implementation Occurrence: Reporter Characteristic (profession/role) and Number of Occurrences Reported



[1] **Other** –Students – Nursing/Medical, Ward Clerks, Secretaries; **Nursing Support** – Licensed Practical Nurses and Personal Care Attendants ; **Support Staff** – Environmental, Infrastructure and Food Service

Table 16: Comparison of Pre- and Post-Implementation Occurrence Reports in Acute Care (Urban)

Indicators	Pre-Implementation	Post-Implementation	Change
# of Occurrences Reported	(n) 348	(n) 581	Increase 233 reports Increase 67%
Reports Completed	78% (n= 270)	85% (n=491)	Increase 7%
Non-RN Reports	25% (n=86)	35% (n=203)	Increase 10%
Reported within 48 hours of Occurrence	22%(n=76)	91% (n=530)	Increase 69%
Average Time between Occurrence and Notification of Manager Sign Off	15 days	36 days	Increase 21 days 140%
Average Time between Occurrence and Notification of Quality and Risk Management	31 days	Immediately	Decrease 31 days 100%
Close Calls	1% (n=4)	10% (n=59)	Increase 9%

Table 17: Comparison of Pre and Post-Implementation Occurrence Reports in Long Term Care (Urban)

Indicators	Pre-Implementation	Post-Implementation	Change
# of Occurrences Reported	(n) 66	(n) 81	Increase 15 reports Increase 23%
Reports Completed	89% (n=59)	100% (n=81)	Increase 11%
Non-RN Reports	30% (n=20)	65% (n=53)	Increase 35%
Reported within 48 hours of Occurrence	58% (n=38)	98% (n=79)	Increase 40%
Average Time between Occurrence and Notification of Manager Sign Off	4 days	9 days	Increase 5 days 125%
Average Time between Occurrence and Notification of Quality and Risk Management	Not known/ not documented when received	Immediately	Decrease
Close Calls	0% (n=0)	7% (n=6)	Increase7%

Table 18: Comparison of Pre- and Post Occurrence Reports in Community Health

Indicators	Pre-Implementation	Post-Implementation	Change
# of Occurrences Reported	(n) 48	(n) 113	Increase 65 reports Increase 135%
Reports Completed	77% (n=37)	89% (n=101)	Increase 12%
Non-RN Reports	27% (n=13)	33% (n=37)	Increase 6%
Reported within 48 hours of Occurrence	50% (n=24)	62% (n=70)	Increase 12%
Average Time between Occurrence and Notification of Manager Sign Off	25 days	18 days	Decrease 7 days 28%
Average Time between Occurrence and Notification of Quality and Risk Management	90 days	Immediately	Decrease 90 days 100%
Close Calls	2% (n=1)	24% (n=27)	Increase 23%

Table 19: Comparison of Pre- and Post-Implementation Occurrence Reports in Rural Integrated

Indicators	Pre-Implementation	Post-Implementation	Change
# of Occurrences Reported	(n) 33	(n) 132	Increase 99 reports Increase 300%
Reports Completed	61% (n=20)	93% (n=122)	Increase 32%
Non-RN Reports	30% (n=10)	75% (n=98)	Increase 45%
Reported within 48 hours of Occurrence	85% (n=28)	91% (n=120)	Increase 6%
Average Time between Occurrence and Notification of Manager Sign Off	1 days	5 days	Increase 4 days 400%
Average Time between Occurrence and Notification of Quality and Risk Manage	7 days	Immediately	Decrease 7 days 100%
Close Calls	0% (n=0)	4% (n=5)	Increase 4 %

Table 20: Comparison of Pre- and Post- Implementation Type of Occurrence Reports

Types of Occurrence Reports INDICATORS	Pre-Implementation (n)	Post-Implementation (n)	Change between Pre and Post-implementation
# of Reports	495	765 (142 of these reports were yet not classified and are excluded from the rest of this table)	Increase 412 reports (83%) from 907 occurrences reported
Accident that may result in personal injury	205 (195 Falls; 10 other)	193 (162 Falls; 31other)	Decrease 12 reports 6%
Medication	60	119	Increase 59 (98%)
Treatment, procedure	68	27	Decrease 38 (56%)
Security	70	25	Decrease 45 (64%)
Abusive, violent, disruptive or self-harming behaviour	8	33	Increase 25 (313%)
Anesthesia	1	0	Decrease 1 (100%)
Access, Appt., Admission, Transfer, Discharge	20	41	Increase 21 (105%)
Consent, Confidentiality or Communication	7	30	Increase 27 (386%)
Client Information (records, documents, test results, scans)	30	48	Increase 18 (93%)
Clinical Assessment (investigation, images and lab tests)	5	160	Increase 155 (3100%)
Diagnosis, failed or delayed	0	4	Increase 4 (400%)
Implementation of care or ongoing monitoring/review	3	33	Increase 30 (1000%)
Infrastructure or resources (staffing, facilities, environment)	3	10	Increase 7 (233%)
Medical device/equipment/ product	15	42	Increase 27 (180%)

4.6 Key Informant Interviews and Focus Groups

4.6.1 Pre-Implementation

Key Informant Interviews and focus groups were conducted in the pre-implementation period to obtain opinions about the current occurrence reporting system and anticipated benefits, disadvantages, barriers, and facilitators related to the upcoming implementation of the new electronic system.

Key informant interviews were conducted with Senior Management, those in the position of Program Directors for urban sites involved in Phase One. The timelines did not allow for interviewing the two Directors in the Pre-go-live stage, however the Project Implementation Team and leadership at the pre-go-live site were asked for their input into refining the interview tool which was also previously informed by the stakeholder workshop. Eleven Directors were contacted and ten agreed to be interviewed. The interviews were held in the Directors' offices and lasted about 40-60 minutes. The interviews took place from January 2009, depending on the scheduled start of implementation for the site and the availability of the Director.

There were five pre-implementation focus groups conducted, two with managers (n=7) and three with frontline staff (n=19). The focus groups were conducted between March and May, 2009, depending on the staged implementation schedule for each site. The focus groups for frontline staff were held separately from the managers as a measure to facilitate open discussion about the issues surrounding occurrence reporting

for each group. The participants included staff from Nursing, Allied Health, Pharmacy, Laboratory, and Diagnostic Imaging. The focus groups for frontline staff were held in each care setting as a measure to facilitate participation as staff would not have to leave their work site and also to identify any obvious differences in themes emerging by care setting. The separation of the groups also provided opportunity to explore with managers their views about their roles and experience with occurrence reporting, one of the key purposes in the study.

The findings from the key informant interviews and focus groups are presented together as there was overlap in the questions posed in the key informant interviews and groups and the themes that emerged were remarkably similar. It will be noted when themes are specific to a group (senior managers, frontline managers, and frontline staff). The findings were grouped into three broad themes and are summarized below. These included: (a) barriers to reporting, (b) anticipated benefits, and (c) anticipated facilitators and barriers to implementation.

4.6.1.1 Barriers to reporting

There were six sub-themes of barriers to reporting identified ranging from macro-systems level issues such as a perceived culture of blame to micro-level issues such as individual fear and concern. These six sub-themes included: a perception that a blame culture still exists, time constraints, lack of feedback and action taken, issues with the paper forms, lack of clear definition about what an occurrence is, and the need for access

to managers and resources for assistance with completing forms. Each is described briefly below.

Culture of blame: Some of the participants indicated that a culture of blame still exists and that this acts as a deterrent for some people to report. Employees worry about being disciplined, embarrassed, and/or how they are perceived by their colleagues, especially if they are reporting an occurrence that involves someone else. Examples of comments are:

> "If you're filling it out against a co-worker, and then you feel a little bit apprehensive you're going to get them in trouble".
>
> "The culture of reporting is not at the forefront. It is seen as a negative process as opposed to a proactive process".
>
> "Occurrence reporting is still perceived as individual fault and mistake, not a systems issue".
>
> "Occurrence reporting is tied in and confused with professional disciplinary action".

Time constraints: The workload pressures and time demands were a very common theme for both managers and frontline staff. Anecdotally, participants said they are aware that reports do not always get completed or there are delays in getting the form completed in a timely manner. This is often related to the fact that health care providers are involved in other activities they regard as having a higher priority, such as direct patient care. Managers indicated that many units are extremely busy, meaning it is often a challenge for staff to stop what they are doing in the clinical setting where there are many immediate demands on their time and so much required paperwork. As noted by

several participants, "Staff members are really busy and they are less likely to take the time to ask for a form and complete it," "Workloads are high and thus there will be less reporting. It takes a lot of time to stop your work...call the doctor's office and do the report." Taking time to complete forms was seen as an additional task.

Lack of feedback and action taken: Managers recognized that feedback to staff on what has happened with a report and what corrective action has been taken is a deficiency. They believe that it is important to improve in this area in order to encourage staff to continue reporting. The lack of feedback was described by comments such as: "there is no consistent follow-up", "we don't track the number of follow-ups and results", and "there is no feedback and shared learnings". This view was shared by frontline staff too. Staff said they would like to have feedback and know that something was done based on what they reported. They are less inclined to report if they know nothing gets done. Reporting is seen as just more paperwork with no benefit.

Issues with forms: Participants identified several issues with the current paper forms as described; "no standardization across services and regions", " hard to compile data for specific programs", " reports get lost or misplaced", "forms are too broad and descriptive," there is duplication of effort", and " forms are not applicable to some areas".

Lack of clear definition: Participants indicated that there is inconsistency on what gets reported and staffs have different views on what constitutes an occurrence. There is uncertainty about who needs to complete a form and when. As one participant described, "Staff are unable to determine what is an occurrence and adverse event...they need education." Managers said they heard anecdotes that staff did not complete forms on certain occurrences, especially if there was no harm to a patient or they heard about a close call but no report had been completed.

Access to managers and resources: Frontline staff reported that a disadvantage was the lack of quick access to managers and resources for assistance in completing forms. The senior managers indicated that frontline managers have a heavy workload and may not be available on a timely basis to assist staff with completing the report. Managers are often responsible for several units and are challenged to be present on the units as they often are required to attend many meetings and off unit activities. Frontline staff said they would like to have a resource person available when they have questions.

4.6.1.2 Anticipated Benefits

Participants identified many anticipated benefits with the management participants identifying the greater number of anticipated benefits, which are described in four sub-themes including: efficiency and effectiveness, consistency, increased reporting and compliance, and improved management of occurrences.

Efficiency and effectiveness: There were many anticipated benefits identified that would contribute to efficiency and effectiveness such as; increased reporting of close calls, increased feedback to staff, quicker reports to managers and the QRM department, improved notification times for high alert occurrences, easier accessibility, and less delays in getting forms completed (don't have to wait for the physician assessment).

Consistency: Many managers identified consistency in the terminology and form as a welcomed feature of the electronic system. The current paper-based system had different reporting forms in use throughout the region which was associated with inconsistencies in categorizing occurrences. Frontline staff also indicated that "a clear definition of what an occurrence is" would be a desired change.

Increased reporting and compliance: Managers predicted that staff would be more inclined to complete the electronic form if they (the staff) found it easier and less time-consuming to complete.

Improved management of occurrences: Several managers anticipated that the electronic system would improve their ability to manage the occurrence reporting system with respect to tracking and trending reports, providing more timely feedback to staff, and identifying accountability for follow-up actions. As one manager commented, "we will have readily available data; we will be able to make comparisons with national norms and databases."

4.6.1.3 Anticipated Facilitators and Barriers to Implementation

Facilitators: Two anticipated facilitator sub-themes emerged and they were the extra education sessions planned and previous experience with the electronic system and are described briefly as follows.

Education: The most frequently mentioned anticipated facilitator was that of the education planned for the implementation. There was a comprehensive education plan that covered both training on using the electronic tool and the broader issue of patient safety and the importance of occurrence reporting in improving patient safety. There were key messages about patient safety that were delivered throughout the region. The plan also involved hiring additional personnel for this project to assist with the education, rather than rely on existing resources, and this was seen to be a very positive step.

Previous experience with electronic systems: The current use of electronic charts in some areas and other electronic information systems such as order entry was seen as making the learning curve easier. As one participant commented, "Some settings such as long term care and community health already have electronic documentation so it should be easier for them".

Barriers: Three anticipated barriers were identified including; issues with computers, competing demands, and resistance to change and are described briefly below.

Issues with computers: Several participants raised concerns about computers, specifically about accessibility to computers and amount of downtime. A couple of managers pointed out that it will be seen as a negative if the system is down frequently when staff take the time to complete a form. Further, some units have many users trying to access the computers for a variety of reasons such as order entry and looking up patient reports.

Competing demands: This was a commonly cited concern across many of the interviews and focus groups with managers. Managers identified several competing demands including concern about the pending job action by nurses, implementation of other electronic systems, and the Public Commission of Inquiry on (Estrogen/Progesterone) ER/PR Hormone Receptor Testing (requiring some managers to have extra responsibilities for gathering information for the Inquiry). The Public Commission of Inquiry on ER/PR Hormone Receptor Testing was established by the Government of Newfoundland and Labrador (NL) in July 2007. It was an investigation into the ER/PR testing performed in NL from 1997- 2005 to inquire into why the ER/PR tests resulted in a high rate of conversion when re-tested, why the problem was not detected until 2005, and the communications with the people affected. The Commission was presided over by the Honourable Margaret Cameron. While the focus of the Inquiry was not to find fault, it had the mandate to make recommendations on related matters of public concern. The Inquiry involved 93 witnesses, heard over 128 days of testimony (Honourable

Margaret Cameron, 2009). The proceedings were televised and there was regular media coverage. The publicity around Eastern Health was quite negative.

Resistance to change: Several managers identified resistance to change as a barrier to successful implementation. They claimed that the implementation plan will require good communication strategies and messaging to get the buy-in from the staff. The communications about the new system will need to promote the value of the reporting process for patient safety and not just another from to complete. As one manager commented, "People are resistant to any change in process...this (the electronic system) has to be seen more than a task of completing a form....staff need to understand how it will benefit the patient."

4.6.2 Post-Implementation (Key Informant Interviews and Focus Groups)

Post-implementation interviews were conducted at approximately the six month post – implementation period. Timelines for interviews varied depending on the availability of Directors. Thirteen Directors were contacted for an interview and eleven agreed to be interviewed. One interview was conducted by telephone and the other ten were conducted in person in the Director's office and were approximately 45-60 minutes in duration. The interviews took place between June and December, 2009, depending on the site as the project involved a staged implementation.

There were six post-implementation focus groups conducted, two with managers (n=12) and four with frontline staff (n=13). The focus groups for frontline staff were held in each of the four sites in Phase One and also took place between June – December, 2009, depending on the staged implementation schedule. The sessions were approximately 30 minutes in duration. At one site, only one frontline staff member participated and at another site two participated. There were challenges in encouraging participation overall at all sites even though there were posters, e-mails, and reminder notices sent out and lunch was provided. As in the pre-implementation period, the focus groups for frontline staff were held separately from the managers as a measure to facilitate open discussion about the issues surrounding occurrence reporting as well as to allow opportunity for managers to discuss the impacts on their role as managers. Two focus groups for managers were held with 12 managers in total participating. Managers participating included representation from Nursing, Pharmacy, Laboratory, and Diagnostic Imaging.

The main purpose of the key informant interviews and focus groups was to seek feedback about the benefits, disadvantages, barriers, and facilitators and lessons learned to gather input into recommendations for future implementations. The themes quickly emerged and there was little difference of opinions expressed within groups (frontline staff and managers) or settings (AC, LTC, Rural Integrated and CH). The low participation of frontline staff in Rural Integrated and CH is a limitation. The findings are presented together as there was much duplication in the comments and themes

arising in both the interviews and focus groups. Any difference between groups (senior managers, frontline managers, and frontline staff) on the themes will be noted. The results from the post-implementation interviews and focus groups are presented by the following seven broad themes: (a) perceived benefits, (b) unintended consequences/disadvantages, (c) perceived barriers to implementation, (d) perceived facilitators to implementation, (e) suggestions for improvement, (f) resources to sustain the system, and (g) the role of the manager. The findings are more reflective of the managers' views as more managers than frontline staff participated and there were more opinions expressed by managers. Also, the last two themes (resources to sustain the system and role of the manager) were explored only in the management interviews and focus groups.

4.6.2.1 Perceived Benefits

Participants were very positive about the benefits realized in the six months ranging from the micro level of benefits of the form itself to the macro level of improved capacity to manage. There were eight sub-themes of benefits identified such as ease of use, improved reporting, accessibility, consistency, improved confidentiality, increased education, improved timeliness for reports, and improved capacity to manage. Each of these is briefly described below.

Ease of use: Both managers and frontline staff cited ease of use and user friendliness of the new system as a key benefit. Participants commented that the "drop down boxes make it easier to complete the form."

Improved reporting: Participants identified many positive aspects of the electronic system such as: more user friendly forms, less time to complete and review reports, easier to search and track a report, decreased paper, reports are not lost, and increase in the number of reports.

Accessibility: The frontline staff commented that the forms are "so much more accessible… you don't have to go look for one." With the paper forms, someone had to see that the forms were always available whereas, with the electronic forms, participants commented that "any staff member can click on the icon on the computer and pull up a form to complete."

Consistency: Participants reported that they liked having "consistent, up-to-date forms". The form is designed such that the type of information required, definitions used, and the mandatory fields are consistent across settings. The form has also been designed to reflect current issues and definitions in the practice setting.

Confidentiality of reports: The confidentiality aspect was not identified prior to implementation as an issue but during the focus groups, there was acknowledgement

that the new system is more conducive to confidentiality as only the employees involved in reporting and addressing the occurrence have access to the report. As one of the frontline staff commented on the confidentiality improvement noting that "before, the paper form was lying around on the desk and others could see it or it could get misplaced or lost."

Education: The extensive education component provided as part of the implementation was perceived to be a significant benefit by the managers, particularly given that the training was delivered by frontline staff who served in the role of super users and the QRM department staff.

Timelines for reporting: The timeliness of the notification of occurrences was identified as a key benefit in the management group. The new system is designed to provide immediate notification to the manager as opposed to the paper-based system where often, the form would be left on the manager's desk or in the internal mail. As one manager commented, "We receive instant reports now...it was quite delayed before" and another commented "level 4, 5, and 6 reports go immediately to the Director."

Improved capacity to manage: Managers identified several benefits that impacted positively on the ability of managers to manage the occurrence reporting system as described by the following comments, "helps organize occurrence reporting with the manager", "the system is set up to notify when the manager is off and another manager

will receive the report", "I can review what types of occurrences are being received by managers". There was a common view that the new system enhances management accountability and improves the organization with respect to the handling of occurrences.

4.6.2.2 Unintended Consequences/Disadvantages

Participants were asked about unintended consequences or disadvantages experienced Only a couple of sub-themes emerged as an unintended consequence and they were the confusion which resulted initially with respect to the close out/sign off reporting function for managers and issues with the forms themselves. Both are described below.

Confusion for managers: This was mentioned by several managers as described in the following comments, "there was confusion on which manager was signing off when the area manager was off", "we need to sort out the manager's role when two departments are involved with one staff", and "Some reports still show in Review but they are Actioned - not sure if I am signing off correctly or using the system".

The system is designed so that managers can cover for other managers who may be on vacation or away for extended periods. When a report was changing handlers (a term used to describe the person following up on the report), managers were unsure as to what was happening with the report, as there was no confirmation that the handler received and acted upon the report. There was confusion experienced by some

managers, in the initial period, as to how the handoff to another handler worked, particularly the aspect of follow-up actions and knowing what was being done. Confusion was not mentioned in the frontline staff group.

Issues with the forms: There were frequent comments made by both frontline staff and managers with the frontline staff expressing more issues and complaints about the forms than managers including comments such as, forms are too long, fields have to be completed to be sent, judging the level of harm is difficult, there's no place on form for person who attends to the resident and physician section, the locator function is not specific (e.g. room number), it takes too long to scroll down the locator function to find the area of the occurrence, and there's no follow up section for the prevention piece to come back from the manager.

Frontline staff stated that they sometimes found it difficult to assess the level of harm (levels 1-5) using the ranking scale in the new system. The new system requires a different way of describing the level of harm to the patient with a scale of 0-6 with 0 being no impact and 6 being death. Some employees could not fill in certain information. An example provided was "a utility worker is not able to fill in the sections related to cognitive ability in the case of a resident fall." It is important to note that there were also positive comments about the forms, as noted in the previous section on benefits.

4.6.2.3 Perceived Barriers to Successful Implementation

Barriers to implementation that were identified by managers were grouped into three sub-themes including the challenge to provide sufficient time for training staff, competing demands, and lack of summary reports. Each is described briefly below.

Insufficient time for training: Concerns about making time available for training for frontline staff on the new system was noted by several managers as a significant challenge. It was often difficult to release staff from busy clinical areas to attend training sessions and some training had to be done on the unit either in small groups or individually. It was also noted that the learning curve was steeper for some managers as they had a more detailed role with the electronic system compared to the paper-based system and therefore would have liked to have had follow-up sessions.

Competing demands: Other competing demands that were described by the managers were similar to those outlined in the pre-implementation interviews as anticipated barriers. One that particularly impacted implementation was dealing with the H1N1 pandemic issue. As noted by one manager, "We had to set up temporary H1N1 clinics and use paper forms and then enter into the electronic system after the clinics were over."

Lack of summary reports: Not receiving summary reports as anticipated was viewed by many as one of the dissatisfactions with the new system. They were hoping to get timely reports to help with monitoring occurrences in their area and providing data and

information that could help with prioritization of patient safety initiatives. Several managers commented that they "did not get the reports they were promised", and "the system could lose momentum and buy-in if summary reports are not created". The managers did acknowledge that the Project Implementation Team was working on the issue and they were looking forward to the issue being addressed and being able to get the summary reports in a timely manner.

4.6.2.4 Perceived Facilitators to Implementation

Several key facilitators to implementation were identified by managers including good communications, the use of the super user concept, employee attitudes, the staged implementation approach, and computer access and staff skill level with computers.

Good communications: Good communications were noted by many managers to be a key facilitator in the process. Many communication tools were in place and this was noted by many to be a key facilitator to the process. Communication occurred frequently. As one manager noted, "even when there were glitches in the system, we were kept informed" and another commented, "we knew the system was coming… the communications were great."

Super user concept: The super user concept was noted by several managers to have worked well as it was a frontline staff member resource that was readily available to other frontline staff for training and education. The managers were appreciative that they didn't have to do the training which sometimes happened with other initiatives.

Employee attitudes: In some areas managers indicated that employees were eager and wanted to be involved which really helped make the implementation easier.

Staged approach to implementation: The staged implementation was identified by several managers to be positive and as one manager commented, "we could sort out issues before spread (of the electronic system) across sites." Besides being able to work on the technical aspects relevant to a selected area, another advantage identified was being able to manage the time requirements for training and education. Staff could be assigned to attend training sessions in a timely manner linked to the implementation time. There were a limited number of trainers in a large organization so staged implementation facilitated the scheduling of training.

Computer access and skill level with computers: The majority of managers indicated that computer access and skills was a facilitator and there was no problems as originally anticipated in some areas in the pre-implementation interviews. Participants noted that most staff members are comfortable with computers, most systems are already electronic, and there are sufficient numbers of computer terminals available.

4.6.2.5 Suggestions for Improvement

In keeping with the evaluation framework that encourages stakeholder involvement throughout the process, questions were posed to participants regarding ways to improve

the implementation and the system itself. Stakeholders indicated that they wanted to use the evaluation process to get input and suggestions related to improvements even if it was not directly measuring some of the indicators. For example, they wanted to explore ideas on sharing lessons learned from occurrences reported, how to engage physicians, and public, and identifying indicators that may be used to measure long term outcomes for patient safety. This study did not include assessing the impact of the new system on improving patient safety as that is a long term impact, beyond the timelines of this study period.

The consultation helped contribute to the identification of lessons learned and recommendations for future implementations. There were eight suggestions made, with the first five (three linked to education) being identified by both frontline staff and managers and the remaining three arising only in the discussions with the management group. First, they wanted more education about what an occurrence is and about patient safety in general. It was also recommended that the education sessions include department specific examples in the training, such as the Laboratory and Community Health. The third suggestion, still related to education, included sharing learnings internally through such mechanisms as the shared learning bulletins, regular occurrence report summaries for each department and overall, sharing information about close calls. There was strong support for the fourth suggestions which was ensuring that action plans are implemented to prevent re-occurrences and as many pointed out, "There is no point in reporting if corrective action is not taken." The fifth suggestion heard from both

groups were related to improving the form itself such as include more specific drop downs, boxes, specific locator fields, and more text space.

There were three suggestions for improvement raised exclusively by managers and they included: the micro level of improving the electronic tool itself by improving the changing handler function when sending to other departments; the mesa level related to more education for managers in the follow-up process, about producing occurrence reporting tracking and trending reports, and about how the system works; and the macro level of improving the culture of the organization to a "just culture" where employees are comfortable about reporting and that occurrences are viewed from a "systems perspective" while at the same time promoting professional accountability.

4.6.2.6 Resources to Sustain the System

The stakeholders involved in the planning for the evaluation wanted the evaluation process to explore what resources would be required for sustainability of the system. Funding obtained for this initiative was a onetime only allotment and it was not known what impact the new system would have on the need for resources. The questions around the resources required were explored with the managers as they are central to how occurrence reporting gets managed. While the managers did not bring forth ideas on how many personnel or financial resources would be required, they did comment on needs. The suggestions presented by the managers included, "need resources to implement the action plans that arise from occurrence reports", "need a key resource "go

to" person for questions and answers", "need support to learn about the system and to help identify trends and act on them".

4.6.2.7 Role of Manager

The question related to the role of the frontline manager in the occurrence reporting system was posed in the focus groups for managers. Also, in the interviews with senior managers, comments about the role and impacts on frontline managers were also made. The role of the manager was described by participants as managing the occurrence reporting process and they further described the managing of occurrences as gathering information, taking corrective action, conducting follow-up in a timely fashion, contacting other departments and providing informal training. Participants also described their role as "providing support and encouragement to employees completing an occurrence reporting form".

When asked about the impact of the implementation of the electronic system on their role, managers noted both positive and negative impacts on their role, with the positive impacts being more frequently cited and they are described briefly below.

Positive impacts: The positive impacts were associated with efficiencies and the benefits of the system itself, as reflected in the following comments, "the system is user friendly", "there is increased reporting", "more efficient with less back tracking for more

complete information', and as one noted, "I spend less time spent checking to see if the Quality and Risk Management department received the report".

Negative impacts: Negative impacts noted by some managers included the increased demands on time required for some managers, particularly in the areas where there was a significant increase in reporting, such as acute care. As one manager commented, "I have become inundated with occurrences... it takes a long time to do all the follow-up." Also, there was an increase in time required with the level of follow-up detail required.

The managers expressed dissatisfaction with the inability of the system to produce summary reports as anticipated. There were configuration issues and classification coding issues that had not yet been sorted out with the new system and thus customized summary reports were not available to managers and as one described, "I don't feel on top of occurrence reports with this system... with the paper system I felt I knew the process and got quarterly reports...this may change when the sign off/close out function is complete.".

4.7 Document Review

There were several planning documents available to assist the Project Implementation Team with implementation as well as project scoping and budget documents.

4.7.1 Implementation and Deliverable Schedule

The project related documents such as budget, Project Charter, and monthly status reports to Canada Health Infoway, were reviewed by me as the principal investigator and questions/notes related to changes in planned activities and a list compiled, then discussed with the Project Steering Committee and Project Implementation Team. The review of the documents and subsequent discussion revealed that there were several components of the plan that did not proceed as anticipated, such as: (a) the implementation (including timelines and sites selected), (b) the method of training at particular sites, (c) the development of the location taxonomy, (d) the engagement and understanding of all levels of management, (e) the assignment of staff to the Project Management and Site Implementation Teams, and (f) adherence to the schedule for deliverables.

Findings from the review of project related documents and discussion with the Project Steering Committee and Project Implementation Team indicate they were not able to follow the original planning documents exactly as prepared due to several factors which can be grouped as follows: (a) staffing assignments (there were unanticipated changes in staff assignments for leading various components of the plans (e.g. project manager and content lead), there was lack of dedicated resources for planning and training early in the project due to recruitment lags (staff who were assigned to the project still attended to some other priorities in the organization), (b) there were changes in executive leadership and lack of championship at all management levels, (c) there were competing priorities

in the organization (e.g. H1N1 pandemic, implementation of new electronic systems in other areas, nursing job action, public Commission of Inquiry on ER/PR Hormone Receptor Testing), (d) there was a lack of resources to hire full time external project management consultants for the full implementation period throughout the region (the external project management consultants were only available for Phase One) and lack of sufficient IT support resources for development of tools and dedicated Help Desk (the frequent revisions and/or upgrades to the software sometimes resulted in unanticipated changes that required extra time in addition to updating forms, training plans and new implementation), (e) there was a site change for initial implementation as the program leadership in long term care changed sites after initial site selection discussions and planning had occurred, and (f) there was unavailability of in-depth training and project related information for quality and clinical safety leaders across the region in a timely manner consistent with the implementation schedule.

4.7.2. Communications

The Project Implementation Team had developed a comprehensive communication plan and several communication tools to promote the awareness of the new system in the period immediately preceding the implementation, as well as tools that were used during implementation and post-implementation and were positively noted by staff in focus groups and interviews. These included communication tools such as:

1. Standard logo design to help with the branding.

2. Standard design templates that could be used in posters, brochures, e-mail templates, power point presentations, and intranet tools.

3. "Ask me" buttons that were worn by trainers, including the super-users, designed to provide on-the-spot education to end users.

4. An information kiosk placed in a prominent location at the site, although Project Implementation Team members indicated that this was not used frequently.

5. Standard presentations including key messages about client safety and sessions that were interactive.

6. Meetings with key influencers prior to implementation to encourage feedback and direction.

7. A manager's discussion kit to facilitate discussions about client safety at staff meetings and informal discussions.

8. Dedicated section in the Eastern Health intranet to include updates, contests, general information on client safety, links to the reporting tools, fact sheet, and self-directed training tools.

9. Posters.

10. Articles in "The Loop," which is an organization wide newsletter.

11. Tent cards for the cafeteria tables and meeting rooms in the initial period.

12. Orientation packages which contained information about client safety, the reporting systems, fact sheets, and how to access training sessions. The packages were given to new employees.

4.7.3 Costs

4.7.3.1 Projected Costs

The discussion around costs was informed by a review of program related documents and discussion with Project Implementation Team.

In the funding proposal submitted in 2006, the costs related to the implementation of the system were projected to be approximately $2.8 million which included funding to support software and human resources. The costs were associated with budget items such as software acquisition, project management, staff education, staff replacement, communications, and evaluation. (See Appendix A for listing). Eastern Health was required to contribute 25% of the costs which was consistent with Infoway criteria and included acquisition of computer hardware and the server.

When approval for funding was received in late 2007, the projected budget had to be reduced to fit within the amount of funding available. Canada Health Infoway approved $1.6 million dollars for the project and Eastern Health was expected to contribute at least 25% ($530,000) which brought the total budget of the project to approximately 2.1 million dollars. Eastern Health's contribution was mainly in-kind human resources.

4.7.3.2 Actual Costs

It is difficult to identify how much the project actually cost, as Eastern Health's contribution consisted mostly of in-kind human resource contributions and there were challenges in attempting to capture the time spent by all the employees involved. Although employees involved in planning, implementation, and evaluation were expected to keep records of time spent on the project, the records often did not reflect all time spent. Employees would submit monthly reports but they acknowledged that for a variety of reasons they did not capture all their time.

Another challenge related to time keeping is identifying what is solely related to the implementation of the new system versus what would be considered part of the job of QRM staff had they still been using the paper-based system. For example, with the paper based system, the QRM staff had similar responsibilities for reviewing and coding occurrences and conducting education sessions.

As of January 15, 2010, the project implementation team reported that it was within budget. While a detailed breakdown of the budget was not provided, the team did indicate that they were within budget as outlined in the approved deliverable and re-imbursement schedule (see Appendix A) which provides an overview of the deliverables to Canada Health Infoway and the associated reimbursement. The budget for the implementation phase of this system requires more funding than the ongoing operational phase, due to the time required for planning, consultation, and development of the system and the resources needed to provide intense training for end users.

4.7.3.3 Projected Future Annual Costs

It is projected that on a go forward basis, annual funding will be required for the software license, IT support, and QRM Support and is outlined in Table 21:

Table 21: Projected Future Annual Costs

Funding Requirement	Annual Funding
1) Annual software licensing and updates.	• $65,000
2) IT support (I.0 FTE) systems analyst, as there are regular upgrades and smaller revisions to the system which need to be installed, training provided and ongoing IT support for matters such as re-setting passwords.	• $75,000
3) Coordinator in Quality and Risk Management (1.0 FTE) who is knowledgeable about the purpose and content of the system and can be a resource for the organization.	• $90,000
Total	• $230,000

After the system is fully implemented (currently scheduled for this year) the annual costs are estimated to be approximately $230,000. Considering that Quality and Risk Management staff currently have occurrence reporting management as part of their current responsibilities, an assessment would need to be done after the project is fully implemented to determine if there could be some re-assignment of duties rather than creation of a new position, which would reduce the additional operating costs to $140,000.

5 Discussion

This chapter presents a discussion of the study results, organized around the key research questions and purposes of the study (outlined in the introduction), linking to previous relevant research where available. The discussion focuses on the benefits and challenges related to the electronic occurrence reporting system, the barriers and facilitators related to the implementation of the system, the role of the manager and the limitations and challenges experienced in carrying out this evaluation. The costs are covered in the previous section.

5.1 Anticipated Benefits of the System

The proposal submitted to Canada Health Infoway by Eastern Health projected several benefits which included benefits identified in a limited literature review conducted by EH when developing the proposal (Eastern Health, 2006). The anticipated benefits of the electronic reporting system were further explored in this study through a more comprehensive literature review examining the grey literature and databases such as PubMed (Medline), CINAHL, and the Cochrane Library. The findings from the pre-implementation key informant interviews with senior managers and the focus groups with frontline managers and staff also identified anticipated benefits. Table 22 presents a summary (all the benefits listed were not identified in each of the sources) of the anticipated benefits of the occurrence reporting system identified in the literature, key informant interviews, and focus groups.

Table 22: Anticipated Benefits

Anticipated Benefits	Sources
Enhanced culture of safety; Consistent and standardized reporting; Increased reporting, including more non-RN reporting; Enhanced sharing of information; Improved follow-up on occurrences Improved timelines for reporting; Improved tracking, trending, and reporting; Easy system to use	Interviews with senior managers and focus groups with frontline managers and staff BCPSLS, 2008; Braithwaite, Westbrook, & Travaglia,2008 Eastern Health, 2006; Frankel, Gardner, & Bates, 2003; Hoffman et al., 2008; Kingston et al., 2004; Mekhjian et al., 2004; Milch et al., 2006; Pierson et al., 2007 Tepfers, Louie, and Drouilliard, 2007; Tuttle et al., 2004; White, 2007; and Zboril-Benson & McGee, 2005

5.2 Benefits realized and how they compare with anticipated benefits

The discussion for the identification of benefits realized arises from the analysis of the surveys, focus groups, and key informant interviews and is organized along the key

indicators identified in the evaluation plan developed for the project (Eastern Health, 2008). The key indicators included: (a) change in patient safety culture, (b) user satisfaction, (c) change in number of occurrences reported, (d) change in reporter characteristics, and (e) changes in timelines for reporting.

5.2.1 Patient Safety Culture

Changes in patient safety culture were studied primarily through administration of the Patient Safety Culture Survey (Appendix B) pre- and post- implementation of the electronic reporting system. Results of the survey show a positive shift in all five dimensions (perceived state of safety, do not have shame and repercussions of reporting, safety learning behaviours, organizational leadership for safety, and unit leadership for safety) post- implementation of the new occurrence reporting system. On one dimension, *perceived state of safety*, the shift moved from low performance (<50%) to acceptable performance (>50%) post-implementation. The dimension "*do not have shame and repercussions of reporting*" remained an area of strength (>85%). This would suggest that staff who responded to the survey do not have concerns about the repercussions of reporting occurrences. This is in contrast to the literature and feedback provided in focus groups and key informant interviews, where fear of repercussions and being blamed was identified as a barrier to reporting (Barach & Small, 2000; Braithwaite, Westbrook, & Travalgia, 2008; Frankel, Gandhi, & Bates, 2003;Kingston et al., 2004; Mekhjian et al., 2004; Wilson, Bakken, & Fylan, 2008;Williams & Osborn, 2006).

The positive changes post-implementation may be reflective of the increased communication around occurrence reporting that was introduced during the implementation process and of the training provided to staff. It also may be related to the experience of respondents who may not have been involved in an occurrence that involved serious impact on a patient and therefore, do not fear reporting. For example, one participant when responding to questions around "how do people feel when completing an occurrence report", said "why would they worry...it's a fall, it's not their fault?" The participant was working in an area where the majority of occurrences reported were falls.

A study by Castle and Sonon (2006) involved the administration of a patient safety culture survey tool, a similar tool to the one used in this study, in nursing homes in the United States and they found that there was a significant difference between the patient safety culture scores in nursing homes and acute inpatient hospital settings with nursing homes scoring significantly lower. The finding in this study differs from that found in this study where there was no significant difference found between acute care and long term care on the patient safety culture survey. The site chosen for Long Term Care (LTC) in this study were small and had a low response rate (therefore caution must be exercised about any conclusions between LTC and Acute Care). Nonetheless, the lack of significant difference between LTC and Acute Care may be due to the inclusion of the long term care sites (urban and rural) in this study in an integrated organization that

provides regional education programs and quality and risk management policies and procedures consistently across all sectors. The rural integrated setting has employees that work in both long term care and acute care and the findings there were similar too.

One of the initial objectives of the project was to use the implementation of the new tool as a change management strategy to improve the patient safety culture (Eastern Health, 2006). While there is little empirical research evaluating the effectiveness of training interventions on patient safety culture, Ginsburg et al. (2006) studied a group of nurses who attended patient safety workshops and compared them to a group of nurses who did not and found that there was a significant improvement in safety culture perceptions among nurses who received the training. The training provided during implementation at Eastern Health may have contributed to the improvement in patient safety culture. However, caution is required in the interpretation of the results as it is not known whether or not the post-implementation respondents all received training, or if the same respondents participated in the survey pre and post implementation. In addition, there were other patient safety initiatives ongoing during the implementation that may have also contributed to the positive change such as the Safer Healthcare Now initiatives and implementation of the Accreditation Canada required organizational patient safety practices. The possibility of competing explanations for changes in indicators post-implementation is a recognized weakness of the pre/post design (Harris et al., 2006).

One of the lessons identified from the Williams and Osborn (2006) study of the implementation of a patient safety reporting system in England and Wales was that safety culture and information dissemination must be addressed at the same time that a new reporting system is implemented. The implementation at Eastern Health included many communication and education measures which were identified as facilitators and are discussed in section 5.3 and these may have contributed to the shift.

The items in the questionnaire related to the "grading of the unit and of the organization" showed an interesting result concerning how well employees perceive their *unit* and *organization* to be doing in patient safety. The perception of employees on how well their *unit* is doing on patient safety is consistent with national benchmarks. However, the perception of employees of how well the *organization* is doing is significantly lower than the national benchmark for the excellent/very good category (Accreditation Canada, 2008). It appears that employees perceive their individual units to be doing much better with patient safety than the organization as a whole. This may be attributed to the frequent negative media attention EH received during the time of the study. As mentioned in the previous chapter, the provincial Commission of Inquiry on ER/PR Hormone Receptor Testing received significant attention in the media and the organization was profiled in a negative light. The publicity was present both provincially and nationally, during the study period. The newspapers and television had regular coverage of the Inquiry. The leaders of the organization were sometimes portrayed negatively in the media. There were other adverse events during the study period that

also received public attention and consequently, Eastern Health received little positive media representation. The frequent criticism of the organization in the public domain may have influenced employees' perception of how well the organization was doing.

5.2.2 User Satisfaction

The results of the user satisfaction survey, along with the results from the key informant interviews and focus groups, show that employees across all care settings seem to be satisfied with the new electronic reporting system. They report that the system is easy to use and consistent in performance, and that the training is acceptable. The feedback obtained from the computer training evaluation forms also supported this latter point. This was consistent with the findings of the BC project where a similar approach was used to train staff (Cochrane, 2009). With respect to computer training, it is important to point out that early in the implementation at Eastern Health, at the pre-go-live site, it was identified that, small group training on the unit was the preferred method compared to the classroom group settings. Sometimes staff members were challenged to attend group classroom sessions due to workload on the unit. The drawback of the small group training is that staff did not get the "full clinical safety" education session; however, there were still high rates of satisfaction expressed with the training.

Other benefits of the electronic reporting system identified in the focus groups and key informant interviews included: (a) easy access to computers and forms, (b) improved legibility, (c) timely notification of high alert occurrences to the appropriate

management level, (d) increased awareness of what constitutes an occurrence and close call, (e) less time required to complete reports, (f) availability of information about the status of individual managers' occurrences, (g) easy to complete forms, (h) less paper shuffling, (i) fewer misplaced occurrence reports, (j) improved confidentiality (occurrence reports not lying around at nursing station for others to see), (k) easier to track follow-up actions, and (l) more detailed information on reports.

Many of the benefits identified are consistent with those identified in other studies. Ease of use is the most frequently cited benefit (Braithwaite et al., 2008;Cochrane, 2009; Frankel et al., 2003; Mekhjian et al., 2004; Keistinen & Kinnunen, 2008; Levtzion-Korach et al., 2009; Tepfers et al., 2007; Tuttle et al., 2004). Other benefits such as those found in this study are less cited and also include ones not identified in the literature reviewed, such as the availability of information about the status of individual manager's occurrences and fewer misplaced occurrence reports.

Even though many benefits were identified, there were a couple of points of dissatisfaction raised both in the focus groups and key informant interviews by end users. For the management group, the inability to close out files and uncertainty about whether or not the file was closed were viewed as undesirable. When a report was changing handlers (a term used to describe the person following up on the report), they were unsure as to what happened with the report, as there was no confirmation if the handler received or acted on the report. There was also confusion at times with respect

to management responsibility for a particular report when an occurrence involved two departments and one employee. This inability to "close the gap" was a concern because managers felt that despite the fact that they had taken appropriate follow-up action, it was not showing in the electronic system in a timely fashion. There was also recognition that the system implementation had not yet been completed (with respect to the coding classification of occurrences for the organization) and consequently, managers were not able to get timely customized reports. At the time of this writing, work on this issue had been undertaken by the Project Implementation Team and managers indicated that addressing the closing out/signing off function and getting the reports will enhance their view of the system. Although this point of dissatisfaction was raised in the management focus groups and interviews, it did not show on the user satisfaction survey where managers who responded to the survey expressed a high degree of satisfaction with the tool.

Even though there were positive comments about the form and most employees said they liked it, several disadvantages with the form that were mentioned by frontline staff. These included: (a) no place on the form for the person who attends to the client, the intervention or a physician section so that notes can be made, (b) form is too long, (c) locator drop down box does not lend itself to identifying the exact location of the occurrence (for example, "the room number") and (d) the "locator function takes too long to scroll down to find the area of the occurrence." The issue of locator function was

similar to a finding from a study on the same system by Antony and Walsh (2007) where the location of incidents was identified as a concern.

There is no place on the form for employees to receive the feedback from their managers regarding the follow up action and prevention measures taken. Other studies (Clarke et al., 2007, Keisteinen & Kinnunen, 2008; Levtzion-Korach et al., 2009; Mekhjian et al., 2004; Sari et al., 2007) point to the importance of feedback to staff and that staff want to see that by taking the time to report that there will be corrective action taken and that quality will improve. It is well recognized that "you cannot fix what you cannot measure." However, Clarke et al. (2007) point out that it is important to be aware of the types of problems that need to be fixed rather than focus on all the instances of problems that need to be counted (p.314). The counting can be used in tracking but must be accompanied by action. The importance of receiving feedback on occurrences and ensuring that corrective action is taken was a common theme for both managers and frontline staff in this study.

Another issue with the electronic occurrence reporting system identified in the interviews and focus groups was the lack of customized "drop down boxes" for specialized areas such as laboratory and pharmacy services. Staff from the nursing areas, however, indicated satisfaction with the drop down boxes. The Project Implementation Team reported that there is a plan to customize the drop down boxes for the clinical

support areas (e.g. Diagnostic Imaging, Laboratory and Pharmacy) to assist in making them more user friendly for all end users.

The results of the user satisfaction surveys among the various care settings showed little difference except for two items. One item was on the frontline clinical staff survey. On the item "I can use the CSRS to report any kind of clinical occurrence", Community Health scored this item significantly lower than long term care. This may be explained by the feedback received in focus groups about the types of occurrences in their respective areas. Community Health staff indicated that there was "too much focus on acute care" in the examples used in training and not enough on examples relevant to their community health experiences. In long term care, staff viewed occurrences as predominantly resident falls, with few other types of occurrences being reported. However, in Community Health, they viewed occurrences in their area as being different from the institutional services. They recommended that more community health examples (e.g. issues in a client's homes) should be used in the training program as this would make the new system more relevant to them.

On the item "The training provided was acceptable", AC (urban) ranked the item lower than LTC (urban). This finding could be partially due to the differences in training between the sites. The training in long term care was done mostly in a group setting with more detailed education sessions by the trainer. In the acute care setting, there were several different trainers and they had to frequently conduct shorter sessions on the unit

(sometimes one on one), whenever the opportunity arose for the frontline clinical staff to participate. The shortened training session and number of different trainers may have impacted on the staff's perception of the training acceptability.

In comparing the user satisfaction survey responses between frontline staff and managers for the seven common items, there was only one item that showed a significant difference and that was in the item related to "The level of ongoing IT support provided is acceptable". Managers rated this item higher than frontline staff. This is not consistent with feedback provided in focus groups and interviews, where managers expressed concern that they were unable to close out files or were uncertain if they were using the system correctly. The electronic system required more steps for the manager compared to the paper system. Some managers indicated that refresher sessions or technical assistance and guidance on using the electronic system for compiling reports and/or ensuring follow-up was completed would be helpful.

5.2.3 Number of Occurrences Reported, Reporter Characteristics and Timelines for Reporting

The findings from a review of the selected indicators from the occurrence reporting records revealed that post-implementation of the electronic system there were changes in the number of occurrences reported, the characteristics of the reporters (health care professional grouping), and timelines related to notification about the occurrences to various manager groups. The changes in these three indicators are discussed below.

Number of Occurrences Reported

There were notable increases in the numbers of occurrences reported in all settings following the introduction of the electronic occurrence reporting system, which is consistent with the findings from other studies (Braithwaite et al., 2008; Cochrane et al., 2009; Levtzion-Korach et al., 2009). While the number of occurrences increased across all sectors, it is difficult to analyze data about the types of occurrences across sectors. A review paper by Boxwala et al. (2004) examined various approaches to identifying errors and adverse events (of which incident reporting is one) and cautions about making any comparisons across sectors on the numbers and types of incidents, as there are factors such as inconsistent patient safety terminology, the clinical context including the roles of various personnel in the incident, the location, and other contributing factors. The analysis in this study focused on the change in the number of occurrences from pre-implementation to post-implementation, even though data was collected on the change in types of occurrences reported for each sector.

A detailed breakdown of the types of occurrences reported by providers was not conducted. However, a high level review showed that there was a large increase (3100%) in the number of occurrences reported in the Clinical Assessment category. This category includes incomplete information on a requisition and/or specimen. This is consistent with the increase in reporting by Diagnostic Services staff (radiology and laboratory) and was also mentioned in the focus groups and interviews. As in the pre-

implementation period, nurses were the highest reporters for the *Falls* and *Medications* categories. The information on types of occurrences is available to each sector so that it can be used by them to make their own comparisons.

The increases in incident reporting observed in this study may have resulted from the training and education provided about what constitutes an occurrence and the importance of occurrence reporting, including the importance of reporting close calls. In a study by Zboril-Benson and Magee (2005), there was an improvement in the types of incidents reported in a pilot project after cultural and educational changes were made. Pre-pilot reports at their study site indicated that only serious errors in healthcare were likely to be reported (i.e. when a patient has been injured; when wilful violation of established protocol has been violated, etc). After the delivery of education sessions, they found an increase in the reporting of both close calls and occurrences with no harm.

One of the explanations given by a manager in this study for an increase in reporting was that even though all workers in the paper-based system were expected to report occurrences, they did not and often they just dealt with the issue. One of the examples provided was that of a missing armband, "the staff would just do another armband for the patient and not write up the report".

Another contributing factor to the increase in reporting may be the high degree of satisfaction expressed by employees with the ease of use and accessibility of the

electronic tool. As was noted in the focus groups, if staff members are busy, they may not bother to take the time from their day to find a paper report form and write up the occurrence, especially if no harm resulted to the patient.

Reporter Characteristics

This study found a notable change in reporter characteristics post implementation of the electronic system, moving beyond the traditional RN reporter (moving from 28% to 43% of occurrences reported). This finding is consistent with those of previous researchers (Cochrane et al., 2009; Hirose et al., 2007; Levtizion-Korach et al., Milch et. al., 2005). Blais, Bruno, Bartlett, and Tamblyn (2008) point out that because "nurses are often the professionals who fill out the incident report forms, the adverse events they report on are generally limited to the problems relevant to their work" (p.11). This observation would be consistent with the findings of this study, where nurses are the most frequent reporters and the most frequent types of occurrences are related to falls, medication administration, and safety/security issues in the patient care settings.

A study by Hirose et al. (2007), looking at lag time in incident reporting at a university hospital in Japan, found nurses reported 93.3 % of the reports and they offer possible explanations for differences in participation in reporting between nurses and physicians (they did not break it down by other disciplines) including the greater number of patients and greater variety of direct patient care tasks attributed to nursing, and the historical involvement of nurses in incident reporting.

In the study by Milch et al. (2005), looking at voluntary electronic reporting in 26 acute care hospitals, nurses represented the greater percentage of reporters (47%), much less than the 93.3% in the Hirose (2007) study. The Milch (2005) study broke it down with by other disciplines, including physicians. Their explanation for the variation included "different perceptions or definitions of what constitute an error or adverse event, and different training and attitudes toward reporting adverse events" (p. 168).

Timelines for Reporting

There were improvements related to the timing of the notification of the occurrence to the QRM department and to the various management levels. The tool is designed to produce immediate notification of the occurrence to the manager and the QRM department and can be customized for notification alerts to different managers depending on the needs of the area. For example, levels 4, 5, and 6 occurrences (which reflect a higher level harm to the patient) are also immediately sent to the senior manager of the area in which the occurrence took place. This immediate notification function was identified by managers as one of the key benefits of the electronic system as it improves the efficiency of the communication channels in the organization with respect to notification about occurrences. This finding is consistent with the Cochrane et al. (2009) study. The improved notification features also contributed to the increased number of occurrences reported within 48 hours of the occurrence. The increase in this study was 54% compared to the Cochrane study which was 82%, the difference in the

magnitude being related to the difference in pre-implementation baseline timelines where the Cochrane study was much lower on this indicator. The post-implementation timeline was similar for both studies with 88% being the result in this study and 84% being the result in the Cochrane study.

Post- implementation, there was an increase in the average time (5.7 days) for the manager to sign off the occurrence compared to the previous predominantly paper based reporting system, going from 11.3 to 17 days. Managers, quality and safety leaders and project leadership indicated this is related to the increase in the number of the occurrences reported, as well as to the learning curve of managers using the system. This new system resulted in an increase demand for follow-up activity, especially in areas where the number of occurrences had increased significantly, mostly the acute care environment, and managers reported getting behind in completing files. Managers reported difficulties in understanding how to sign off the occurrence (follow-up completion) and they were not sure if they were completing this function correctly. As a result, the occurrence reports follow-up process and closing out the file was longer to complete overall. Hence, the system did not improve efficiency on this indicator during the 6 month post-implementation period. This is in contrast to the study by Cochrane et al. (2009), where the average time between event and completion of investigation decreased by 6 days going from 39 days to 33 days. The researchers in that study felt their result to be "only a slight improvement due to two factors: (a) the setting where the study took place was a busy unit where the manager had to support clinical work with

limited opportunity to perform non-clinical, non-urgent work which included doing follow-up work related to occurrence reports, and (b) the change in practice required of the manager was greater than anticipated" (p.151). This was consistent with some of the feedback reported in the focus groups in this study. Managers reported that they were used to saving up the occurrence reports to complete them on "paper days" when they could have uninterrupted time. The new system provides immediate notification and obtaining uninterrupted time in a busy clinical setting to focus on the follow up actions is a challenge.

5.3 Key Facilitators and Barriers to Successful Implementation

The barriers and facilitators to the implementation process were explored in the interviews and focus groups, as well as through the review of project related documents. The planning and management documents such as the change management plan included a comprehensive plan for communications and training. While the plans were not executed exactly as originally planned due to factors outlined in section 4.7.1, the Project Implementation Team said the plans provided valuable guidance and were modified as the process unfolded to facilitate implementation. There is little research available on the topic of facilitators and barriers related to the implementation of electronic occurrence reporting systems thus this discussion is limited in its ability to draw on previous research in this area. The key facilitators included communications,

education and training, the staged implementation, the computer skills of staff, and the support from the QRM staff. The key facilitators are described briefly below.

5.3.1 Facilitators

Communications: There were many favourable comments made about the communications aspects of the project. As one participant noted, "everyone knew it was coming". The many communication tools in place (as noted in section 4.7.2) promoted consistent messages about the electronic system and patient safety and increased the awareness of the initiative throughout the region. In other studies (Cochrane et al., 2009; Zboril- Benson & McGee, 2005), the findings also reflected that the communication strategies were effective in facilitating change.

Education and training: Both group and individual sessions were frequently available to assist with the training for the new system. The quality and clinical safety leaders were the primary trainers and they were assisted by the frontline employees who were designated as super users. The super users assisted colleagues in their area who were learning about the new system and helped others to complete the occurrence reports. While the majority of the staff (frontline, managers, super-users) indicated that they felt either "very prepared" or "prepared" to use the new systems, the response of the managers was lower than the other two groups. Most managers indicated that they felt "somewhat prepared". This may have to do with the fact that frontline managers have a more detailed role in dealing with occurrence reports. Frontline employees are responsible for reporting the occurrence and completing the report, whereas managers

have to review the report, identify others who need to be involved, develop action plans, take corrective action where necessary, monitor progress and compile regular summary reports.

A number of participants noted that the standardized approach to education and training was positive and "having resources to do the training rather than having it fall to the manager" to do was seen as contributing to the success. It was also noticed that in one area, the responsible executive leader gave thank-you notes to managers and super users, which was appreciated and gave the message to staff that this is an important initiative and that the managers and super user roles were valued.

Staged implementation: Many of the managers indicated that the site by site rollout was a preferred method, as feedback about the system was integrated prior to expanding. In a study by Tepfers et al. (2007) on the development of an electronic incident reporting system, they indicate that consultation with key stakeholders to determine their information and workflow is critical as the feedback received assists with making the forms more user friendly and facilitating buy-in. The timelines for the implementation in selected areas were adhered to once the date of implementation was known and this facilitated the planning for staff training.

Computer Skills: While lack of computer skills was identified as an anticipated barrier in the pre-implementation findings, the post- implementation findings revealed mixed

opinions. The majority of participants viewed the level of existing computer skills as a facilitator. It was mentioned by many that "staff are comfortable with computer use". While only a few commented on the concern that computer skills were a barrier, it does reflect a factor that needs to be considered in the implementation of any electronic system. It was also noted that the IT Help icon on the screen was a useful tool providing quick and easy access to technical assistance.

Support from Quality and Risk Management Department: Staff of QRM Department provided the bulk of the training to employees and assumed the lead role for key components of the project, including the education, taxonomy development, communications, and content leadership. It was reported by managers and frontline staff that the Quality and Clinical Safety Leaders were an excellent resource, provided timely feedback, and were available for questions and very supportive.

5.3.2 Barriers

The discussion around barriers has implications for identifying lessons learned and making recommendations for future implementations. The barriers that were identified included the organizational climate, competing demands, software configuration issues, re-assignment of project resources, and lack of ownership at different levels in the organization. The barriers were presented in the results chapter, however, are mentioned here also as they have implications for the development of the recommendations and were part of the key research questions. They are described briefly as follows:

Organization climate: As mentioned previously, during the Phase One implementation period there were several major issues facing the organization, including job action by nurses in the fall of 2008, planning for the H1N1 pandemic and dealing with the pandemic when it came to the region and the negative stories in the local media about Eastern Health. The Provincial Commission of Inquiry on ER/PR Hormone receptor testing was in process at the start of the project. While the Commission of Inquiry did support the direction of Eastern Health related to the implementation of electronic occurrence reporting initiative, there were also many negative points raised. The Inquiry also raised the awareness that documents once thought to be internal documents (e.g. reports related to the investigation of adverse events) can become public knowledge. Several participants indicated that providers may be wary of documentation related to reporting of adverse events. The impact that this may have on underreporting is not known.

Competing Demands: In addition to these issues, there were also numerous competing operational demands on employees, especially the managers. As mentioned in the previous chapter, the managers were dealing with issues related to other new initiatives being implemented such as the required organizational practices, payroll consolidation, and changes in policies and procedures as part of the ongoing effort to bring standardization and consistency related to the merger of the legacy organizations. This created challenges for them in being able to commit a lot of time to this initiative.

Challenges were also experienced at times in allowing staff to attend the education sessions due to workload pressures. This was similar to a study by Antony and Walsh (2007) where staff reported difficulties in undertaking training in an environment of constant conflicting pressures.

Software Configuration Experience: One of the anticipated benefits of the new electronic system was the ability to customize the software to meet the needs of individual organizations. This, however, created challenges as there were no vendor representatives permanently located in the Eastern Health region (the vendor is based in the United Kingdom). The vendor was linked with a management firm in Canada for project management and the firm did have personnel living in the region but these personnel had no previous experience with the system. There was expertise available in Alberta and British Columbia and representatives did visit Eastern Health on a couple of occasions to assist with customizing the software. Also, employees of the QRM department and the IT department visited the British Columbia site to see how the system worked and to consult with those who had experience. While this was helpful, there were challenges related to the differences in how the system worked in British Columbia compared to Eastern Health. As one staff member said. "We didn't know what to ask – we didn't know about the investigator function". No one locally had previous experience with the system and most of the consultation and development had to be done via long distance (e.g. email, conference call, webinar). Also, there were frequent upgrades and/or slight modifications to the system which required additional

training and communications. It was noted by many participants that significant amounts of time are required by stakeholders in developing taxonomies that have relevance to all sites and services.

Re-assignment of Project Resources: The funding obtained from Canada Health Infoway provided funding for the hiring of two staff to assist with project planning and implementation. There were delays in getting the positions filled (related to the human resources recruitment process and delays in the release of successful candidates in a timely manner from their previous positions). Consequently, existing employees in the QRM department had to take on some of the planning and training responsibilities in addition to their regular job responsibilities. As one leader said, "It was off the corner of our desks". There were employees assigned to the roles of internal project leader and content leader. Sometimes, they had to attend to other priorities in the department. There were re-assignments of project management both internally and externally, contributing to a lack of continuity, delays and steep learning curves for various components of the project.

Lack of ownership at different levels: The project was being driven and lead by the QRM department. As one project management member stated, "It was seen as the Quality and Risk Management departments' project rather than as an initiative of Eastern Health and buy-in from all managers would have helped with the change management issues". It was noted in some of the interviews and focus groups that many

managers were dealing with numerous demands and other new initiatives and thus were limited in the time and support they could give to this project. There were several changes in executive leadership assignment during the period of the study, including the executive sponsor who was also a member of the Steering Committee and had many other responsibilities. While status reports of the initiative were provided on a regular basis to various committees, there was lack of championship for the initiative at other management levels, beyond the QRM department.

5.4 Impact on Frontline Managers' Role

Frontline managers play a key role in the occurrence reporting system as they are expected to review all reports, identity corrective actions that need to be taken, monitor the progress of the action plan, track and trend reports. They also serve a role in educating and supporting staff on the importance of reporting occurrences. These roles are required regardless if the occurrence reporting system being used is paper – based or electronic. Antony and Walsh (2007), note that "there is limited research and knowledge of managers and clinicians views of designing, implementing, and evaluating integrated electronic incident and reporting systems in order to improve patient care and that it is important to seek their opinions" (p.108).

In this study, the results of the user satisfaction survey, focus groups and key informant interviews with managers indicated that the introduction of the electronic system had

both negative and positive impacts on how the managers were able to perform in their roles. While the overall role has not changed with the implementation of the new system, there have been mixed impacts on how they are able to perform in their roles, particularly the impacts on workload and efficiency. As identified in previous sections, there were efficiencies such as less time required to backtrack and get employees to fill in information and more timely notifications of reports, however, inefficiencies such as increase in workload and getting the follow up completed. Also, the managers had mixed opinions on the overall effectiveness of the implementation of the new system.

A study by Braithwaite et al. (2008), on an evaluation of the implementation of an electronic incident reporting system included evaluation by staff with managerial responsibilities as part of the study. Their findings indicate that managers have a broader view of the system as many of them have the responsibility of receiving and dealing with incident reports. They were the ones most likely to request reports of system data and the majority agreed that the system provided incident data in a timely fashion and that it had increased knowledge of quality and risk measures. This was consistent with the findings in this study where managers indicated that they have a more comprehensive role with occurrence reporting than the frontline staff and that they are more likely to request reports of system data (i.e. summary reports for their area of responsibility). However, regarding the timely fashion of incident data and increased knowledge of risk and quality issues, managers in this study did not share the same

views with respect to timely reports as the electronic system was not functioning in a way to provide timely reports to help them with their tracking and trending.

As reported in the previous chapter, the lack of timely reports was frequently mentioned in interviews and focus groups as a source of dissatisfaction as timely summary reports for their area was a benefit they were anticipating but did not happen. There was acknowledgement that when the software configuration and classification issues are sorted (which at the time of this report were being addressed), they will be happy to receive summary reports that can help them with their quality and risk management planning. It was evident that this was an important matter to managers. They acknowledged that had this been sorted out early in the process, their view of the system would have been enhanced. It was also suggested that if trending reports or customized reports were produced early in the implementation process it could create "quick successes" and lead to more satisfaction with the system.

The majority of managers in the study agreed that the reporting of individual occurrences with the electronic system does happen in a timely fashion and is an improvement over the paper–based system. This finding of improved timeliness in receiving reports was consistent with the findings of the Braithwaite et al. (2008) study. A finding that differed from the Braithwaite study was the management perspective about the level of relevant details on the incident report. The majority of the managers in the Braithwaite study disagreed that reports from staff contained all relevant details,

whereas, in this study the majority of managers viewed the reports as more comprehensive, providing more details than the previous paper forms. While the technical and operational aspects of system used in the Braithwaite study may be different than the type of system used in this study, the form in this study had many more mandatory fields than the previous paper-based form.

Managers indicated that the level of detail was better; therefore, they did not have to spend as much time backtracking to get additional information from employees, which improved efficiencies. However, there were managers, particularly those working in the acute care sector, who described this increased level of detail as impacting on their workload by increasing the amount of time required to follow-up on more details. Some managers indicated that it increased their workload, especially those managers in the clinical areas where there was a greater increase in the number of occurrences reported. The amount of time managers spend on addressing occurrence reports is not tracked in any workload measurement system thus the perceived increase on workload is a subjective measure. Consequently, while the majority of managers (64%) who responded to the user satisfaction survey did indicate that the new system saved them time, 32% of managers who responded disagreed.

One of the quantifiable measures that were tracked was the time it took for the manager to sign off/close off the file. There was an overall decrease in efficiency (11.3 to 17 days) on this measure showing in the acute care, long term care and rural settings, but an

improvement in efficiency in the community health sector. The 5.7 day (50%) decrease in efficiency was described by the managers as resulting from an increase in the number of occurrences, increase in the amount of detail requiring follow-up action, and their uncertainty about their whether or not they were using the close-out/ sign-off function properly. While the majority of managers did respond positively to the effectiveness of their initial computer training session through the evaluation survey, it was mentioned in focus groups and interviews that refresher sessions and ongoing IT support would be helpful to ensure that they are using the systems properly.

The decrease in efficiency found in this study differs from the finding in the Cochrane et al. (2009) study which showed a slight improvement in efficiency as described earlier in this chapter. The majority of managers did indicate in the post-implementation focus groups that the electronic reporting system had a positive impact in terms of allowing them to work more efficiently in some ways. In the focus groups and interviews, they reported benefits such as less time checking to see if the QRM department and the senior manager received the report as the new system has automatic notification of high alert occurrences to higher levels of management and the QRM staff, in addition to the less time spent backtracking to get more complete information as mentioned above.

Overall, the managers indicated that there were more benefits than disadvantages and that the system had the potential to positively impact on their role by improving notifications, increasing efficiency in submitting and monitoring reports and getting

more meaningful summary reports (when the latter issue is resolved) which can then be used to help with the development of quality improvement initiatives.

5.5 Recommendations Regarding Future Implementations of Occurrence Reporting Systems

Consultation with stakeholders is a key element of the Neville et al. (2004) framework that was used to guide this study. It requires consultation at several steps throughout the process from pre-implementation through to the development of recommendations. Discussion of findings and recommendations is identified as one of the seven steps. The recommendations presented below were compiled based on the review of the study findings from the stakeholder forums, focus groups, key informant interviews, and surveys. Discussions were also held with the Project Steering Committee and the Project Implementation Team on both the key findings and proposed recommendations of the study to ensure that their interpretation of the findings was consistent with that being reported in the study and that the recommendations flowed logically from the study findings. The following 26 recommendations can assist Eastern Health with the rollout and follow-up of their electronic system and assist other healthcare organizations considering implementing a similar system. The recommendations have been grouped into five categories: Software/Technology Development, Change Management, Communications, Resources, and Training:

Software/Technology Development

1. Ensure software configuration has been finalized and verified prior to training and implementation. Having location and classification taxonomies developed prior to the implementation can facilitate end user satisfaction, especially for subsequent coding of occurrences and compiling customized reports.

2. Compile customized summary/trending reports early in the implementation process so that end users get to see some of the anticipated benefits quickly.

3. Engage stakeholders, such as managers, in the customization of the software tool, including verification before the tool is finalized as this can assist with developing tools that are more specific to the area (e.g. Laboratory).

4. Keep reporting forms short and simple, with limited fields that require subjective judgments from the reporters. Staff indicated that they are very busy in the clinical setting and that reducing the amount of time to complete forms will facilitate compliance with reporting. Drop down boxes related to describing the event take less time to complete.

5. Ensure there is timely technical support when employees require assistance.

6. Consult early in the process with representatives of the vendor, external project management team and other organizations using the system to explore in detail the

capabilities of the system as it relates to organization specific policies and procedures, such as the investigator and handling functions.

7. Engage stakeholders early in the development of taxonomies, including the classification scheme as this can facilitate the development of customized trending reports.

Change Management

8. Ensure that there is buy-in at all levels of management, from the top down. Having champions in positions of authority can assist the Project Implementation Team staff with the change management issues, especially resistance to change. For example, having managers as champions can facilitate the attendance of employees at the education sessions, promote a culture change that is conducive to reporting, provide feedback to employees so they see the value of reporting and help keep the project on track.

9. Engage stakeholders such as managers frequently, especially prior to the site implementation. This will allow opportunity to engage them in a discussion of specific operational details in their setting that can help inform/revise the implementation plan to facilitate successful implementation. It will also provide opportunities for discussion and direction regarding their role in the new system.

10. Include a mandatory session on clinical safety for all managers, emphasizing the importance of reporting adverse events. Managers play a pivotal role in occurrence reporting and are in key position to emphasize key messages about patient safety and promote culture change.

11. Develop a strategy to include physicians in the electronic occurrence reporting system, including the identification of a physician champion. The stakeholder workshops and key informant interviews supported a need to develop a plan for training and education that would factor in the needs of the physicians in terms of their scheduling and practices.

12. Use the "Super User" concept to facilitate adoption as this will increase the level of resources at the service level, increasing the efficiency of training and decreasing the responsibility for training on the managers who are often not readily available on the units.

13. Repeat a review of administrative data in one year to determine whether or not the gains achieved in the first six months have been sustained or improved.

14. Ensure that there are feedback mechanisms in place (besides the acknowledgement of the occurrence report received) so that employees can see the value of taking the time to report an occurrence and see improvements resulting from the reporting

system. If employees see changes in policies, procedures, staffing, or equipment that contribute to improved patient safety, they will be more willing to be compliant reporting and not view the exercise as a waste of time. Also, sharing information about the occurrences and lessons learned can contribute to overall awareness of the importance of improving the patient safety culture.

15. Spend time upfront to develop resources and tools such as change management, training, and communications plans. While there may be adjustments or revisions required as the project unfolds, these plans can be helpful in promoting consistency and continuity.

16. Use information obtained from the patient safety culture surveys to prioritize areas for improvement and develop appropriate strategies and plans to address these areas.

Communications

17. Ensure frequent and timely communication using a variety of tactics and tools to assist with change management. This proved to be quite beneficial especially in the pre-implementation period.

18. Use existing group meetings (such as staff meetings and change of shift gatherings), and committees (such as quality improvement committees), to share information about the types of occurrences and measures for preventing their re-occurrence.

19. Ensure that all users of the system are notified in a consistent and timely manner when there are issues with or changes/upgrades to the system.

20. Continue the monthly publication "Shared Learning Bulletins" based on actual occurrences reported. Participants in focus groups reported that they were quick and easy to read and can be used as a mechanism to share lessons learned and increase awareness with the ultimate aim of preventing re-occurrence.

21. Promote the participation of frontline staff and managers in the evaluation processes, such as responding to surveys and focus groups. While healthcare workers are often busy, there are ways to engage them such as scheduling focus groups at lunch time or bringing them together in small groups in the work setting to provide input.

Resources

22. Assign sufficient dedicated human resources to plan details related to the implementation and training rather than having the duties as add-ons to existing responsibilities.

23. Assign a dedicated resource to coordinate the management of the system, especially in a large organization. This will assist with training on upgrades to the system, orientation of new employees, and ongoing support/resource to employees.

Training

24. Provide in-depth training on the new system and the change management plan to the trainers in a timely manner. In a large organization that requires many trainers, it is important that they all deliver a consistent message and that they feel knowledgeable and equally qualified on providing training

25. Repeat training sessions, especially after upgrades or slight revisions to the system. Also, offer refresher sessions for employees if it has been a long time since they received their initial training as they may not have used the system.

26. Distribute training evaluation forms at the end of the session rather than at a later date as a means to increase numbers responding. The feedback can assist with developing training plans to better meet the needs of employees in different settings.

5.6 Limitations and Challenges of the Study

There were several limitations and challenges to this study including:

1) The low response rate for the post – implementation patient safety culture surveys. Although a response rate of 27.9% was achieved for the pre-implementation patient safety culture survey (which is consistent with a similar national survey), the response rate for the post-implementation patient safety survey dropped to 18.1 %. Managers indicated that this may be attributed to: (a) the fact that there were other surveys being administered in the organization during the same period, (b) the length of the questionnaire, and (c) the workload of those being surveyed. Managers indicated that during the fall of 2009, they were dealing with the H1N1 pandemic issue and there were some operational issues and competing priorities that were impacting on staff at the sites.

2) The site chosen for long term care in the urban setting was a small site, thus impacting on the sample size and number of responses to surveys. The rural integrated site also had employees that provided long term care service in the same setting as the acute care, however, the level of analysis and ability to make conclusions about the findings related to the long term care sector was limited.

3) In an effort to increase participation, the pre and post- patient safety culture surveys were not individually coded (due to the sensitive nature of some of the questions). This limited the level of comparative analysis possible for pre and post responses as it could

not be determined if the same employees responded (only the care setting was identified).

4) There were challenges related to data collection, particularly from the occurrence reporting records, as it required relying on staff at EH who had competing responsibilities. The collection of the data involved quality and clinical risk management staff having to recode pre-implementation paper-based occurrence reports for the new classification system and coding the post-implementation electronic records in time for the data collection period. There was no process to determine the accuracy of the records reviewed as this was beyond the scope of this study. Such spontaneous reporting systems are subject to hindsight bias and the logistics of reviewing retrospective records for accuracy have limitations (e.g. some reports were on occurrences that had been reported on busy units months previously) and can be resource intense to match with patient records.

There were also challenges related to collecting information about actual costs as QRM staff acknowledged that they did not capture all time spent working on the project and there were overlaps with what was time related to the electronic system and what was required for their involvement in the paper based system.

5) The participation rates for the frontline staff focus groups were low. Even though the focus groups were held during the lunch break and lunch was provided, the response

was low, impacting on the level of comparative analysis between care settings for the qualitative component.

6) The post-implementation data were collected at the 6 month post-implementation period and therefore, the many benefits realized during this period can only reflect this time period. It is not known whether or not the benefits realized will be sustained or improved at other intervals such as one or two years.

6 Summary, Implications of Findings and Conclusion

6.1 Summary of Research

An evaluation was undertaken to determine the impact of the implementation of an electronic occurrence reporting system at Eastern Health. The evaluation was carried out on Phase One of the implementation schedule, which included a pre-go-live site in a rural setting that provided integrated services (acute care, long term care and community based health services), and three urban sites (acute care, long term care and community based health services) as part of the initial go-live implementation. The evaluation commenced in June 2008 with a pre-implementation workshop involving internal and external stakeholders and was completed in February 2010.

The evaluation study had a dual purpose: (a) to assess and report on the impact of the implementation of the electronic occurrence reporting system on achieving its stated objectives, particularly those that can be measured within the timelines of the project, and (b) to analyze findings to identify contributions to the literature in the recently developing field of implementations of electronic occurrence reporting systems in health care.

The report provides information that contributes to the growing body of knowledge of occurrence reporting systems and patient safety as well as identifying recommendations

that can be considered by Eastern Health to assist with the rollout and by other health care organizations that may be considering implementing a similar system. Specifically, the study examined factors and impacts such as: (a) benefits realized from the implementation of the electronic occurrence system, focusing on the short term objectives of the project, (b) key facilitators and barriers to the successful implementation of the system, (c) impact of the new system on the frontline manager's role, (d) recommendations for future implementations, and (e) challenges encountered in carrying out the evaluation. The findings of the study also contribute to the recently developing body of literature related to the implementation of electronic occurrence reporting systems in the health care field. The contributions also included reporting on impacts and indicators related to long term care and community health sectors, areas not well represented in the literature.

The evaluation approach was guided by the report "Towards an Evaluation Framework for Electronic Health Records Initiatives" (Neville et al., 2004), which emphasizes significant stakeholder involvement at each step of the evaluation, use of multiple methods and triangulating data wherever possible. The data collection tools were informed by previous research related to the evaluation of electronic health information systems (British Columbia Patient Safety and Learning System, 2008; Canada Health Infoway, 2007; Delone and McLean, 2003) and previously validated patient safety culture survey tools. (Accreditation Canada, 2008; Ginsburg at al., 2007) Feedback

obtained from two pre-implementation workshops with key stakeholders further informed the study.

The evaluation was designed as a pre/post comparative study using surveys, focus groups, key informant interviews, administrative occurrence reporting data, and project documentation as the primary data collection sources. Data was collected pre-implementation at different intervals depending on the tool being administered, ranging from one month to nine months for pre-implementation and at six months for post-implementation. Data collection involved frontline clinical staff and managers in each care setting for both surveys and focus groups. The key informant interviews involved the program and departmental Directors in Phase One.

There were many benefits realized including: an increase in occurrence reporting, increase in the number of non-registered nurse (RN) reporters, increase in the number of occurrences reported within 48 hours of the occurrence, positive changes in the patient safety culture within each of the care settings (acute care, long term care, and community health), improved timelines for notification of high alert occurrences to the managers, and satisfaction with the electronic tool including ease of use, accessibility and consistency. Low participation of frontline staff in focus groups and the small sample size from the long term care setting limited the conclusions that could be drawn from the data on user satisfaction and patient safety culture.

The findings in relation to the role of the manager revealed that there were both positive and negative impacts. The positive included such things as easier to track occurrences, improved notifications of other managers, and less time spent backtracking to get more detailed information. The negative impacts included such things as increased time required for follow up action and signing off/closing files.

The study was unique in that it examined the introduction of electronic occurrence reporting systems across the continuum of care (acute care, long term care, community health) as opposed to only acute care settings in urban areas. However, the findings indicate that the issues and perceptions of staff related to occurrence reporting systems vary little across the different care settings. While there are differences such as numbers and types of occurrences, there is little difference related to barriers to reporting and benefits realized.

The facilitators and barriers identified during the implementation process resulted in recommendations that can assist other health care organizations considering implementing a similar system. Challenges were experienced related to software configuration development and the development of the classification system for coding occurrences (which impacted on the ability of the manager to close out files and obtain timely customized reports). At the time of this report, these issues are currently being addressed by the Project Implementation Team and managers indicated that resolving these issues will enhance the many positive impacts of the system already realized.

6.2 Future Implementations of the Electronic Occurrence Reporting System

In Eastern Health, the implementation of the electronic occurrence reporting system throughout the region is in progress. The Project Implementation Team learned from the Phase One implementation and they are integrating the learnings to facilitate the implementation process. Also, in my role as the principal investigator, as I became aware of issues of concern (e.g. the close out/sign off and report generation issues), I brought these to the attention of the Project Implementation Team for their consideration, as part of the formative evaluation process. This provided additional feedback that they could use in the rollout.

The implementation of electronic occurrence reporting systems is a timely initiative from both a provincial and national perspective. A Provincial Task Force on Adverse Health Events published a report in December 2008 that recommended the implementation of a province-wide electronic occurrence reporting system. The Task Force was appointed in May 2007 by the Government of Newfoundland and Labrador. The scope of the Task Force was to examine and evaluate how the health system identifies, evaluates, responds and communicates in regard to adverse events within the health system; to examine relevant best practices in other jurisdictions; to propose a mandate, structure and budget for the establishment of a health quality council in the province, and to make recommendations as may be appropriate. The Task Force report references the electronic system being implemented at Eastern Health and points out that it will involve a change management process including training and awareness, and is an

opportunity to set the culture on a new course (Government of Newfoundland and Labrador, 2008).

A report in the following year from the Commission of Inquiry on ER/PR Hormone Receptor Testing that was commissioned by the Government of Newfoundland and Labrador (Honourable Margaret Cameron, 2009) also referenced the implementation of the electronic occurrence reporting system at Eastern Health. The report recommended that all regional health authorities in the province should implement a similar system, with co-operation and coordination among all four regional health authorities to ensure the system is utilized to its full potential and that information gained within each health authority can be shared and used to prevent the repeating of similar adverse events. The Government of Newfoundland and Labrador accepted her report and has started implementation of the recommendations.

Recently, in March 2010, the Provincial Government provided funding to the Newfoundland and Labrador Centre for Health Information (NLCHI) to oversee the implementation of the electronic system province wide. This study will be useful to those leading and managing the implementation process. The summary of findings from this study and recommendations has been provided to the NLCHI to assist with the provincial rollout which is now being planned for implementation later this year. They have approached me as the principal investigator in this study about leading the

evaluation of the provincial system which is planned to start implementation later this year.

The provincial direction is consistent with similar discussions ongoing in the country. A consultation paper published by the Canadian Patient Safety Institute (CPSI) in 2008 discusses the need for development of a pan-Canadian reporting and learning system that will support the gathering of information about adverse events so that data can be sorted, integrated, evaluated and acted upon in a highly coordinated and timely manner. This approach has been a key priority for CPSI since its establishment in 2004 (CPSI, July 2008). The paper identifies one of CPSI's key goals as being "the creation of a national reporting system and a store house of patient safety information so that knowledge of the types of adverse events occurring in Canadian health care, and strategies for reducing their incidence can be shared among organizations across the country."

Given the provincial and national attention being paid to the implementation of electronic systems for reporting adverse events, the evaluation conducted at Eastern Health is timely. The findings and recommendations have the potential to provide valuable guidance to other organizations interested in implementing a similar system. The lessons learned can help to reduce costs and facilitate successes in similar organizations. The fact that Eastern Health is a large integrated health care organization that provides the full range of services (acute, long term, and community) across a wide

geographic area that includes both urban and rural health service settings permits the sharing of learnings that may be applicable to many health care organizations.

Opportunities to share the findings of this study will be pursued through submission of articles to health care journals for publication, submission of abstracts for presentation at conferences, and presentations to key stakeholders. The key findings of this study were presented as a poster presentation at a National Patient Safety Conference in Toronto, Canada, April, 2010. Canada Health Infoway, a major funder of this project, plans to include the results of this study in promotion activities related to Benefits Evaluation of electronic health systems in Canada and has developed a "Spotlight of Results" summary sheet to share on their web forums and at conferences.

6.3 Future Research of Electronic Occurrence Reporting Systems

There are no future comprehensive evaluations of the Electronic Occurrence Reporting System currently planned for Eastern Health. Phase One covered all settings (acute, long term care, community, urban and rural). The findings of Phase One, including the suggestions solicited from internal stakeholders are considered to be applicable across the organization. The patient safety culture will continue to be monitored as a part of the required organizational practices for Accreditation Canada. It may also be beneficial to monitor the number and types of occurrence reports and reporter characteristics at subsequent intervals (e.g. one year and two years) to see if the gains achieved in the first six months post-implementation period are sustained.

As this study period only covered a period of sixteen months (the pre and post-implementation periods for the four sites), the focus of the evaluation was on the short term objectives of the project. Future evaluations may want to focus more on the achievement of the longer term objectives (e.g. did the implementation of the system improve clinical safety?). Such evaluations may need to be considered at least five years into the project to allow time for reporting to increase initially, trends to be identified, and safety improvement plans to be implemented and safety culture changes. The data provided in this study can help to serve as baseline data for future comparisons. In addition, findings from this study suggest that future evaluations should utilize some type of incentive to enhance response rates among the end users of the system.

Other areas for future related research opportunities include identification of strategies for increasing the involvement of physicians in occurrence reporting, use of electronic occurrence reporting systems in the primary care setting, long term impact of electronic occurrence reporting systems on reducing adverse events and improving patient care, and strategies to increase the awareness of the public about adverse events in health care and their role in preventing them.

6.4 Conclusion

The findings of this study provide evidence that frontline clinical staff and managers, regardless of the setting (acute care, long term care, community health) at Eastern Health support the electronic occurrence reporting system. The implementation was successful due to factors such as: the education and training that was provided, the communications that promoted the initiative, and the many benefits that were quickly realized.

The implementation has not occurred without its challenges. There were many competing demands in the organization that affected the implementation plan and there were issues that impacted on the ability of managers to close out files and obtain meaningful summary reports in a timely manner. The system impacted positively and negatively on the role of the manager. There were many facilitators and barriers identified which can inform future implementations.

Most of the findings are consistent with the small body of literature on this topic, particularly the barriers to reporting and the benefits of electronic systems in the acute care setting. This study adds to the existing literature by also providing information about electronic occurrence reporting systems in the long term care and community health settings in health care (settings that have not yet been well represented in the literature) and to the Canadian health care perspective. The findings show that there is little difference between settings on indicators such as barriers to reporting and patient safety culture. The study is limited by the low participation of frontline workers. The

triangulation of data from surveys, focus groups, interviews, and occurrence reporting records, however, provide evidence that there were benefits realized and employees support the system. This study also includes the perspectives of managers who play a key role in the implementation and ongoing maintenance of electronic occurrence reporting systems. Their participation in the evaluation was high and revealed that there were positive and negative impacts on their work. The findings also show little difference between managers and frontline staff on overall satisfaction with the training, perceptions of barriers to reporting, and benefits. The findings can serve as a baseline for the organization in their internal discussions and planning for patient safety initiatives and for future evaluations with the ultimate aim of working towards making health care safer for the people they serve.

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Appendix A

Occurrence Reporting Project at Eastern Health (excerpts/scanned EH documents)

- Project Committee Structure
- Paper Form – Occurrence Report
- Electronic Forms – Occurrence Report
- Former Occurrence Reporting Process
- New Occurrence Reporting Process
- Proposed Budget
- Deliverable and Re-imbursement Schedule
- Training Plan

Eastern Health – CSRS Project

Project Committee Structure

Role of Project Steering Committee:

- review and monitor progress
- provide project direction and guidance
- address implementation issues raised by site implementation teams
- renew financial reports related to project and discuss measures to ensure project stays on budget

Role of Project Implementation Team:

- execute the implementation plan
- work with stakeholders for problem-solving
- ensure deliverables outlined in the Project Charter are met

Role of Site Implementation Team:

- assist with implementation at the service level
- champion the initiative at the service level
- act as liaison with project implementation team

Eastern Health

OCCURRENCE REPORTING FORM

This form is to be completed by the individual who identifies an occurence (not employee injury). Complete all parts of the form stating facts only. This form is used for tracking purposes in the monitoring of Quality. Follow-up of occurences will be done by the Program/Department leaders.

2. Date of Occurrence: y____/m____/d____ Hr. [ ][ ][ ][ ]

3. Where Occurred: _____ *(Area/Room #)*

4. Unit / Division: _____

Program/Dept: _____ Site: _____

Reported By: _____ *Name(please print)* *Job title*

1. Name:

Address:

Phone:

Attending Physician

Addressograph

5. Person involved in occurence ☐ Not applicable ☐ Employee(not employee injury) ☐ Outpatient ☐ Inpatient ☐ Visitor ☐ Volunteer ☐ Other (specify) _____

6. Brief Statement of Facts: _____

Witness (Name, Address, Phone, Position) 1. _____ 2. _____

Type of Occurrence (Please ☑ the most applicable one)

☐ 7. Medication

Administration Issue
- ☐ Incorrect patient
- ☐ Incorrect drug
- ☐ Incorrect dose
- ☐ Incorrect route/site
- ☐ Incorrect time
- ☐ Incorrect I.V. Rate
- ☐ Significant Extravasation
- ☐ Incorrect I.V. solution
- ☐ Ommission
- ☐ Unordered drug given
- ☐ Outdated drug/sol. given

Discrepancy Issue
- ☐ Narcotic count
- ☐ Incorrect drug delivered
- ☐ Transcription
- ☐ Other (specify) _____

☐ 8. Treatment/Test

Test
- ☐ Incorrect patient
- ☐ Incorrect procedure/therapy
- ☐ Consent Issue
- ☐ Contamination
- ☐ Count discrepancy (specify Item) _____
- ☐ Foreign body in patient
- ☐ Complication
- ☐ Ommission

RESULTS
- ☐ delay in report affecting care or treatment
- ☐ not reported
- ☐ incorrect result
- ☐ other (specify) _____

☐ 9. Blood/Blood Products
- ☐ Consent
- ☐ Incorrect patient
- ☐ Incorrect blood products
- ☐ Delay in administration
- ☐ Contamination
- ☐ Omission
- ☐ Transfusion card discrepancy
- ☐ Transfusion card not returned
- ☐ Other (specify) _____

SPECIMEN
- ☐ analysis not done
- ☐ analysis compromised
- ☐ incorrect patient
- ☐ lost specimen
- ☐ mislabeled specimen
- ☐ other (specify) _____

☐ 10. Fall

Was Fall Observed? ☐ Y ☐ N

☐ 11. Adverse/Allergic Reactions
- ☐ Drug
- ☐ Contrast media
- ☐ Latex/tape/product
- ☐ Blood/blood products
- ☐ Environmental
- ☐ Food
- ☐ Other _____

☐ 12. Safety/Security
- ☐ Personal/Property Loss
- ☐ Fire
- ☐ Property damage
- ☐ Assault/Abuse
- ☐ Confidentiality breach
- ☐ Other _____

☐ 13. Other Occurences
- ☐ Unplanned return to ER with related diagnosis
- ☐ Unplanned return to ICU
- ☐ Unplanned return to OR
- ☐ Cardiac Arrest
- ☐ Attempted Suicide
- ☐ Unauthorized smoking
- ☐ Burn/Skin alteration
- ☐ Self Inflicted Injury
- ☐ Serious complaint
- ☐ Discharge against medical advise
- ☐ AWOL
- ☐ Patient/Visitor Injury
- ☐ Order entry Issue
- ☐ Non-attendance at Orientation
- ☐ Incomplete Orientation
- ☐ Discovery of illicit drugs/weapons
- ☐ Equipment Issue
- ☐ Other _____

14. Physician Examination - when appropriate

Person refused medical examination ☐

TO BE COMPLETED BY A PHYSICIAN

Date of medical examination: y____/m____/d____ Hr. [ ][ ][ ][ ]

Will length of stay increase: ☐ Yes ☐ No

Describe injury/effect: _____

Name of examining physician (please print) _____ Signature _____

15. Outcome - Clinical ☐

Injury ☐ Yes ☐ No
- ☐ No Intervention
- ☐ Minor Intervention
- ☐ Major Intervention
- ☐ Death

Outcome - Non Clinical ☐

16. Notification - as appropriate

1. _____ Name Date
2. _____ Name Date
3. _____ Name Date

17. To be completed by a Manager / Designate _____

Signature _____ Title / Program _____ Date _____

18. For Office use only:

Reviewed by: _____ Date: _____ Entered by _____ Date: _____

Case Number: _____

COMPLETED ORIGINAL TO BE FORWARDED TO THE QUALITY INITIATIVES OFFICE WITHIN 48 HOURS

Do not place on Health Record. Destruction of form via confidential shredding

White Copy: Quality Initiatives Office Yellow Copy: Program/Department 2006/02 ch-0002

Electronic Form Fields.

Original Field Label	Revised Field Label
Details of person reporting the occurrence	
Full Name	
Your e-mail address	
Job role/grade	
Occurrence details	
Occurrence date	
Time of occurrence	
Region	
Area	
Site/Dept/Prog	
Location (exact)	
Description of occurrence	
Occurrence Classification	
Type of Occurrence	
Detail	
Additional Information	
Was any person involved in the occurrence?	
Was any other contact involved in the occurrence	
Was this a medication occurrence?	
Was any equipment involved in the occurrence?	
Client Information	
Client(s) affected	
First names	
Surname	
Unique ID	
Was the person injured in the occurrence?	
Injury details	
Injuries	
Treatment received	
Other	
Other	
First names	
Surname	
Telephone no. 1	
Medication occurrence details	
Drug administered	
Dose and strength administered	
Equipment details	
Products type	
Serial no.	
Short description of equipment	
What was done with it?	

Original Field Label	Revised Field Label	Extra Text
MAIN FORM		
Name and reference		
Name		
DATIX ID		
Approval status		
Form Reference		
Reported date		
Opened date		
Handler		
Occurrence Details		
Occurrence date		
Time of occurrence		
Region		
Care Type		
Area		
Site/Dept/Prog		
Location (exact)		
Description of occurrence		
Immediate action taken		
Cause analysis required?		
Immediate Actions		
Closed date		
Severity and Result at time of occurrence		
Result		
Severity		
MEDICATION FORM		
Medication		
Medication error		
Drug Administered		
Correct drug		
Form administered		
Correct form		
Dose and strength administered		
Correct dose and strength		
EQUIPMENT FORM		
Equipment		
Product type		
Brand name		
Serial no.		
Manufacturer		
Description of device		
Supplier		
Service records held by		
Model/size		
Current location		
Quantity defective		
Date of manufacture		

Last serviced
Date put in use
Batch/lot no.
CE marking
Outcome code
Description of defect

INVESTIGATION FORM
Investigation
Investigator
Date investigation started
Date investigation completed
outcome of investigation
Further inquiry?

FEEDBACK FORM
Feedback
Recipients
Additional recipients
Subject of message
Body of message

Exhibit One - Current Occurrence Reporting Systems
Seven Different Variations Exist Simultaneously in EH

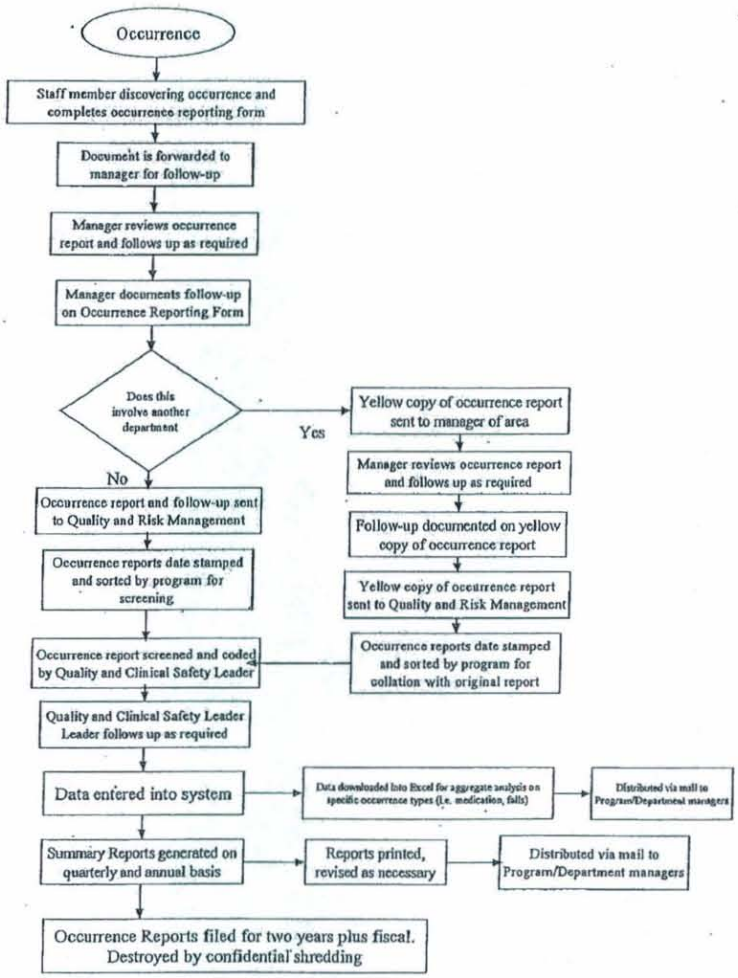
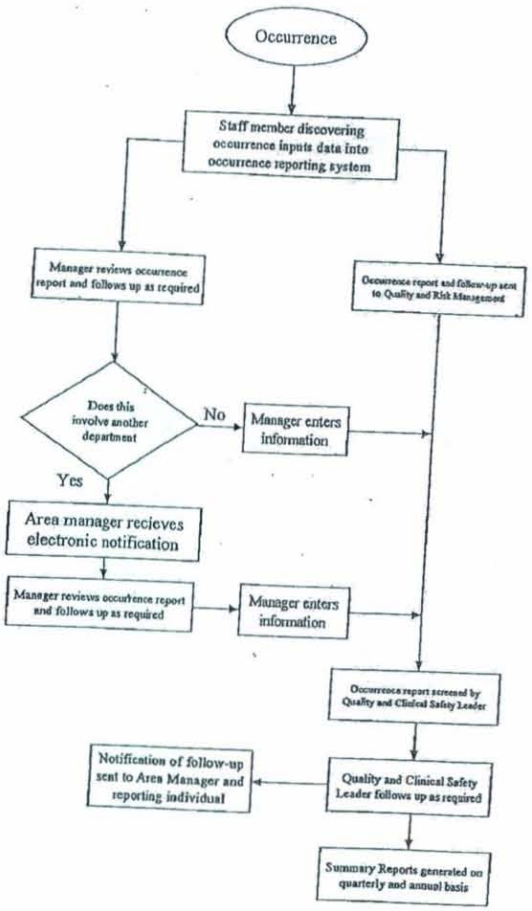


Exhibit Two - Proposed Occurrence Reporting System
Single Integrated System for EH



f) Budget Estimates

ROSE Project Budget ($ 000's)	
Software Acquisition (estimated)	400
Software Maintenance-Support (estimated)	120
Software Interfaces to Existing Systems	100
Project Leader IMAT (See Note 1)	90
Project Leader QRM (See Note 2)	90
IMAT Project Resources (See Note 1)	135
QRM Project Resources (See Note 2)	180
Staff Education (12000 X 2 hrs)	720
Staff Replacement (4500 X 2 hrs)	270
Communications (EH) – See Communication Plan	50
Communications (NLCHI)	20
Travel	80
Benefits Determination and Evaluation	260
Total Innovation and Adoption Project Budget	2515
Costs To Be Absorbed by EH	
Computer hardware (250 units @$1200)	300
Server	25

Note 1 – It is recognized that Eastern Health will be expected to cost-share this proposal, including direct staffing. IMAT Department staff are identified as key project resources. A project leader will be in place for the eighteen months with the equivalent of 1.5 FTE IMAT staff involved throughout the project. The staff will be engaged in software testing, interface/hardware installation and technical support.

Note 2 – QRM Assistant Director will be the overall Project Lead. QRM staff will provide the system development, training to the 12,000 staff and 600 physicians, support, and analysis of the results from the ROSE implementation. Since the original proposal was submitted, EH has approved the addition of four positions to the Quality and Risk Management Department, including a full time claims manager, to assist in addressing issues related to clinical safety.

Eastern Health CSRS Project

Canada Health Infoway Deliverable Schedule and Reimbursement Schedule

Number	Description	Original Target Date	Revised Target Date	Eligible Costs for Work Project	Sponsors Portion of Eligible Costs(25%)	Infoways Portion of Eligible Costs (75%)	Percentage	Completed Date	CHI Acceptance
Phase 1 - Requirements Finalization and Implementation Planning									
				201,736		201,736			
P1-A	Draft Version of Occurrence Taxonomy	29-Feb-08	15-Aug-08	69,066	**19,066**	50,000	**72.39**	15-Aug-08	
P1-B	Phase 1 Project Implementation Plan	29-Feb-08	29-Feb-08	138,132	**38,132**	100,000	**72.39**	29-Feb-08	
P1-C	Privacy Impact Assessment Checkpoint	31-Mar-08	31-Mar-08	69,066	**19,066**	50,000	**72.39**	31-Mar-08	
P1-D	Communication Plan	30-Apr-08	1-Nov-08	207,197	**57,197**	150,000	**72.39**		
P1-E	Change Management Plan	30-Apr-08	1-Nov-08	207,197	**57,197**	150,000	**72.39**		
P1-F	Training Plan	30-Apr-08	1-Nov-08	207,197	**57,197**	150,000	**72.39**		
	Subtotal Phase I			**1,099,592**	**247,856**	**851,736**			
Phase 2 - Staged Implementation and Testing									
P2-A	Phase 2 Implementation Plan	30-Jun-08	15-Nov-08	138,132	**38,132**	100,000	**72.39**		
P2-B	Solution Architecture	30-Jun-08	30-Aug-08	207,197	**57,197**	150,000	**72.39**		
P2-D	Privacy and Security Architecture	30-Jun-08	30-Sep-08	207,197	**57,197**	150,000	**72.39**		
P2-E	Privacy Impact Assessment	30-Jun-08	30-Sep-08	110,505	**30,505**	80,000	**72.39**		
P2-F	PIA Confirmation Letter	30-Jun-08	30-Sep-08	6,907	**1,907**	5,000	**72.39**		
P2-G	Risk Management Plan	(monthly)							
P2-H	Functional ROSE system and Finalized Occurrence Taxonomy	31-Jan-09	15-Sep-09	34,533	**9,533**	25,000	**72.39**		
P2-I	System Test Plan and Results Report	30-Jun-08	31-Oct-08	151,945	**41,945**	110,000	**72.39**		
P2-J	Trained Users	30-Apr-09	30-Dec-09	6,907	**1,907**	5,000	**72.39**		
P2-K	Support Documentation	31-Jul-09	30-Dec-09	6,907	**1,907**	5,000	**72.39**		
P2-L	Analysis/Trending Results and Baseline Occurrence Measurements and Rate	30-Apr-09	30-Dec-09	6,907	**1,907**	5,000	**72.39**		
	Subtotal Phase II			**877,136**	**242,136**	**635,000**			
Phase 3 - Benefits Determination / Evaluation									
E-1	Status Reports	29-Feb-08	(monthly)						
E-2	Evaluation Plan	30-Apr-08	30-Apr-08	138,132	**38,132**	100,000	**72.39**	30-Apr-08	
E-3	Initial Implemenation Evaluation	30-Apr-09	30-Jun-09	15,776	**4,355**	11,421	**72.39**		
E-4	Evaluation Results and Report	31-Jul-09	30-Dec-09	6,907	**1,907**	5,000	**72.39**		
	Subtotal Phase III			**160,814**	**44,393**	**116,421**			
				2,137,542	**534,385**	**1,603,157**		1,603,157	
RACI Legend	RACI Legend			2,137,542		-201,736		0	
R	R - Responsible - person responsible for performance of the task			0		1,401,421			
A	A - Accountable - person accountable for completion of deliverable - only one person to be accountable								
C	C - Consulted - person whose opinions are sought, 2 way communication								
I	I - Informed - person who is kept up to date on progress, 1 way communication								

Scanned Excerpts from EH plan

7.0 Training Plan

7.1 Introduction

Given the cultural shift that is required within our health system to support the effective management of client occurrences, the CSRS is primarily a change initiative supported by technology. This Training Plan constitutes the tactical plan that must be used as the starting point for the CSRS implementations within EH.

The implementation and training delivered for CSRS will be an important step in this journey of cultural change and the CSRS will be a key culture carrier. However other ongoing initiatives and activities will need to reinforce and further ingrain this culture of clinical safety beyond the training program identified herein.

For the purposes of this plan, training refers to the acquisition of knowledge, skills, and competencies required by stakeholders to operate successfully in the new clinical safety work environment. Training is therefore not limited to CSRS system usage skills, but will include learning on process and concepts related to clinical safety.

The Training Plan can be re-visited periodically to ensure ongoing alignment and reflect the realities, including successes and lessons learned, of the CSRS program as it rolls out across the region.

The intended audience for this plan is:

- All CSRS Project resources at the regional and local levels
- All stakeholders participating in the project
- *Project Sponsors at all levels (see section 3, Stakeholder management)*
- Local change management teams
- Local training teams

7.2 Training Objectives

The objective of the training plan is to develop and implement a training program that supports the CSRS project objectives and delivers competent stakeholders with the skills required to complete their roles within the CSRS cultural and work environments.

The purpose of the CSRS Training Plan is:

- Explain the strategy and plan for training CSRS stakeholders to operate successfully in the new CSRS work environment
- Clarify the baseline education that should be considered by the local training teams

- Equip local implementation team with a foundational training plan that should be adapted to local conditions and stakeholder requirements

7.4 Training Guiding Principles

The following principles should guide the development and delivery of all CSRS Training activities. They provide a high-level checklist against which training programs should be assessed.

- Training will always be tailored to the site needs and understanding of the stakeholders.
- The CSRS training effort will be aligned with the learning philosophy of the local sites.
- Existing clinical safety training programs within the sites will be re-used wherever possible.
- The CSRS training team will work with the existing site training groups for support with facilities, technical support, communications, scheduling and all other training-related process, when necessary.
- Training activities will be formally recognized within implementation project plans.
- Training activities at the local level will be planned such that training outcomes can be measured.
- The training program will align strategies and tactics with the local change management programs wherever possible.
- The training program will share the analysis, approach, design, development and materials of all CSRS training interventions across CSRS sites to support the continuous improvement of the regional CSRS roll-out.
- The training will be delivered *just-in-time* - end-users will not receive system training more than 6 weeks prior to CSRS going live at their site. However, the education related to the culture of safety (focused on the attitudes regarding clinical safety) should be addressed well in advance of the system training.
- Assessments using an appropriate sample size could be used to help ensure training effectiveness and ensure readiness of the site to make the transition to the CSRS environment.
- No application training will be delivered in isolation of the context-setting safety culture sessions.
- CSRS training will be delivered in a professional, thorough, accurate, sensitive and culturally acceptable way.

7.5 Roles and Responsibilities

Successful training at any CSRS site will be the result of the collective effort of a number of stakeholders. These stakeholders may encompass multiple roles. The primary responsibility for the delivery of training activities will be the local training level, however a global outlook on stakeholder roles will include as below.

In addition, the safety practices described in the Site Readiness section of the Change Management Plan are supporting processes that can contribute

substantially to the successful implementation and adoption of the EH CSRS. Where possible, consideration should be given to establishing roles, responsibilities and processes to support these safety practices as part of the EH CSRS program.

7.6 Approach

The training approach will reflect the outcome of the above assessments and will be modified by the Site Lead if needed to suit the specific culture and needs of the site. The cultural change is a long term change program and the various classroom and web-based sessions that are delivered as part of the CSRS program will support this cultural change. Other activities outside of this training that will serve to reinforce and support this cultural change include: management practices within the healthcare organization, communication activities, and site facilities setup and preparedness.

7.6.1 CSRS Audience

The Change Management Plan section identifies an approach to conduct a site readiness assessment including an impact assessment to identify the roles and processes that will be impacted by the implementation of CSRS and extent of the change required. A change readiness assessment gauges the preparedness of the stakeholders to successfully operate in the new environment. This assessment will assist site leads in determining training needs of stakeholders within a specific site. (Note: Refer to the Change Management section for more details on the site readiness assessment.)

Based on the assessment, the Site Implementation team should create an Audience Analysis, as part of their implementation plan, which addresses the needs of the audience (I.e. stakeholders) at their site.

7.6.2 CSRS Training Characteristics

The following design approaches characterize the CSRS training program:

- **Role-Based:** Training will be customized and delivered to user groups (i.e. QCSL,
- Manager and Front-Line users).
- **Need-to-know:** Training will be geared to the needs of the end-users based on their roles.
- **Just in time:** Training will be provided as close as possible to the time when it will be applied by the site staff.
- **Occurrence-based:** Training will be organized around clinical safety occurrences. This includes coaching to achieve richer, more analytical reports and investigations, effecting change to encourage reporting as a learning process, working with peers, clients and other departments, etc
- **Realistic:** Training will replicate the CSRS work environment as closely as possible by using near real data, real forms and realistic scenarios and will be delivered to front line staff during their shifts at their worksites. As applicable, there will be extra relief for in- service staff, while they are participating in training.
- **Minimalistic:** Training will cover only those topics related to the CSRS

culture and work environment.

- **Based on adult learning principles**: Training delivery is designed to provide variety, focus on tasks that the participants need to know, to involve the participants and to draw on their own experience
- **Based on learning theory:** Training is designed bearing in mind that we remember 90% of what we say and do, but only 50% of what we see and hear, and thus makes use of hands- on exercises and interactive learning environments
- **Train-the-Trainer:** Use subject matter expert peers to provide support coaching and education services for their staff.
- **Training evaluations:** Users attending training will be asked to evaluate training to determine if the method and content of education has been effective at transferring knowledge and skill.

7.6.3 Training Resources

The following training resource needs have been identified:

- Training space within stakeholder departments to conduct training, if available.
- Workstations and / or kiosks with network and internet access.
- Educators and coaches (I.e. QCSLs, Managers, Roamers).
- Within CSRS portal, a test environment (i.e. "sandbox") for testing and training.

7.6.4 Training Tools

Various training tools have been created by the project team and are being implemented within the pre-go live site. Following site implementation, these tools will be assessment by the Site Lead and project team to determine the benefits and identify any improvements.

Going forward (i.e. post pre-go live implementation), site leads should select training tools, one tool or a combination of training tools, based on audience needs and the availability of site resources. Site implementation teams may need to customize the tools and material to the specific needs of the site.

The following is a list of training tools which have been developed or are in the process of being developed by the CSRS project training team.

- CSRS Project Introduction Power Point Presentation
- CSRS Clinical Safety Power Point Presentation
- Hard Copy training/technical notes relating to CSRS applications
- Training Reference Manual/Guide
- eLearning Tool

Appendix B

Data Collection Tools (13)

Patient Safety Culture Survey

Computer Training Evaluations
- Managers
- Frontline Clinical Staff
- Roamers "Super Users"

User Satisfaction Survey
- Manager
- Frontline Clinical Staff

Key Informant Interview Guides
- Pre
- Post

Focus Group Guides
- Pre (Manager)
- Pre (Frontline Clinical Staff)
- Post (Manager)
- Post (Frontline Clinical Staff)

Data Extraction Form

Patient Safety Culture Survey Respondent Profile

What is your role in the organization? (choose one)

- ○ Nurse
- ○ Licensed Practical Nurse
- ○ Personal Care Attendant
- ○ Allied Health Professional
- ○ Technologist (lab, radiology, etc.)
- ○ Doctor
- ○ Supervisor/Manager
- ○ Other (please specify): _____ What is your role in the organization? (choose one)

What is your gender? (choose one)

- ○ Male
- ○ Female

In which setting do you work? (choose one)

- ○ Administration
- ○ Acute Care
- ○ Long Term Care/Continuing Care/ Rehabilitation
- ○ Community/ Home Care
- ○ Diagnostics and Labs
- ○ Mental Health
- ○ Other (please specify): _____

How long have you worked with the organization? (choose one)

○ ○ ○ ○ ○

< 1 yr **1-2 yrs** **3-5 yrs** **6-10 yrs** **> 10 yrs**

Do you work full-time or part-time with this organization?

○ ○

Full-time **Part-time**

Does your work involve shift work? (choose one)

○ ○ ○

Never **Occasionally** **Frequently**

Instructions:
1. The survey is seeking your perceptions and opinions of these safety issues in your unit. Indicate the extent to which you agree or disagree with each of the following statements. If you are unsure whether you agree or disagree, mark "neutral". If the question does not apply to your role or your work setting, mark "not applicable".
2. Think of unit as the area where you do most of your work–whether that is a patient care unit / ward, clinic, dept., the community, EMS, etc. Think of the patient as the client, resident, etc., depending on where you work.

Patient Safety: *Activities to avoid, prevent, or correct adverse outcomes which may result from the delivery of health care.*

	Strongly Disagree		Disagree	Neutral	Agree	Strongly Agree	N/A
1. Patient safety decisions are made at the proper level by the most qualified people	○	○	○	○	○	○	○
2. Good communication flow exists up the chain of command regarding patient safety issues	○	○	○	○	○	○	○
3. Reporting a patient safety problem will result in negative repercussions for the person reporting it	○	○	○	○	○	○	○
4. Senior management has a clear picture of the risk associated with patient care	○	○	○	○	○	○	○
5. My unit takes the time to identify and assess risks to patients	○	○	○	○	○	○	○
6. My unit does a good job managing risks to ensure patient safety	○	○	○	○	○	○	○
7. Senior management provides a climate that promotes patient safety	○	○	○	○	○	○	○
8. Asking for help is a sign of incompetence	○	○	○	○	○	○	○
9. If I make a mistake that has significant consequences and nobody notices, I do not tell anyone about it	○	○	○	○	○	○	○
10. Telling others about my mistakes is embarrassing	○	○	○	○	○	○	○
11. I am less effective at work when I am fatigued	○	○	○	○	○	○	○
12. Senior management considers patient safety when program changes are discussed	○	○	○	○	○	○	○

13. Personal problems can adversely affect my performance	○	○	○	○	○	○
14. I will suffer negative consequences if I report a patient safety problem	○	○	○	○	○	○
15. If people find out that I made a mistake, I will be disciplined	○	○	○	○	○	○
16. I am rewarded for taking quick action to identify a serious mistake	○	○	○	○	○	○
17. Loss of experienced personnel has negatively affected my ability to provide high quality patient care	○	○	○	○	○	○
18. I have enough time to complete patient care tasks safely	○	○	○	○	○	○
19. Clinicians who make serious mistakes are usually punished	○	○	○	○	○	○
20. In the last year, I have witnessed a co-worker do something that appeared to me to be unsafe for the patient in order to save time	○	○	○	○	○	○
21. I am provided with adequate resources (personnel, budget, and equipment) to provide safe patient care	○	○	○	○	○	○
22. I have made significant errors in my work that I attribute to my own fatigue	○	○	○	○	○	○
23. I believe that health care error constitutes a real and significant risk to the patients that we treat	○	○	○	○	○	○
24. I believe health care errors often go unreported	○	○	○	○	○	○
25. My organization effectively balances the need for patient safety and the need for productivity	○	○	○	○	○	○
26. I work in an environment where patient safety is a high priority	○	○	○	○	○	○
27. I believe that most serious occurrences happen as a result of multiple small failures, and are not attributable to one individual's actions	○	○	○	○	○	○
28. My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures	○	○	○	○	○	○

29. My supervisor/manager seriously considers staff suggestions for improving patient safety	○	○	○	○	○	○
30. Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts	○	○	○	○	○	○
31. My supervisor/manager overlooks patient safety problems that happen over and over	○	○	○	○	○	○

B. These questions are about your perceptions of overall patient safety	Excellent	Very Good	Acceptable	Poor	Falling
32. Please give your unit an overall grade on patient safety	○	○	○	○	○
33. Please give the organization an overall grade on patient safety	○	○	○	○	○

C. These questions are about what happens after a Major Event	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	N/A
Major Events: *Incidents causing fairly serious harm to patients that result from the delivery of health care.*						
34. Individuals involved in major events have a quick and easy way to capture/report what happened	○	○	○	○	○	○
35. Individuals involved in major events contribute to the understanding and analysis of the event and the generation of possible solutions	○	○	○	○	○	○
36. A formal process for disclosure of major events to patients/families is followed and this process includes support mechanisms for patients, family, and care/service providers.	○	○	○	○	○	○
37. Discussion around major events focuses mainly on system-related issues, rather than focusing on the individual(s) most responsible for the event	○	○	○	○	○	○
38. The patient and family are invited to be *directly* involved in the entire process of understanding: what happened following a major event and generating solutions for reducing re-occurrence of similar events	○	○	○	○	○	○

39. Things that are learned from major events are communicated to staff on our unit using *more* than one method (e.g. communication book, in services, unit rounds, emails) and / or at *several* times so all staff hear about it	○	○	○	○	○	○
40. There is a pharmacist who is a full member of the patient care team on the unit (e.g. they participate in rounds and are accessible to people on the unit)	○	○	○	○	○	○

D. These questions ask about some of your own actions	Never	Seldom	Occasional	Often	Always	N/A
41. If I see someone engaging in unsafe care practice, I confront them	○	○	○	○	○	○
42. I take shortcuts which involve little or no risk to patient safety	○	○	○	○	○	○
43. I talk about patient safety issues with fellow workers	○	○	○	○	○	○
44. I engage in unsafe care practice in order to get the job done	○	○	○	○	○	○
45. I report the errors I make	○	○	○	○	○	○
46. I learn from errors made by my colleagues	○	○	○	○	○	○

Clinical Safety Reporting System (CSRS)

Computer Training Evaluation Form – Managers

In which setting do you work? (choose one)

○ Acute Care

○ Long Term Care/Continuing Care/ Rehabilitation

○ Community/ Home Care

○ Diagnostics and Labs

○ Mental Health

○ Other (please specify): _____

1. How prepared to you feel about using the new CSRS?

☐ **Very prepared**
☐ **Prepared**
☐ **Somewhat prepared**
☐ **Not prepared**
☐ **Not very prepared**

Please indicate areas in which you think you require further education:

_____

_____

_____

2. Were the training materials used and distributed in class helpful in your understanding of the CSRS?

- ☐ **Very helpful**
- ☐ **Helpful**
- ☐ **Somewhat helpful**
- ☐ **Not helpful**
- ☐ **Not very helpful**

Please write any suggestions for improving the training materials:

_____
_____
_____

3. Was the training class a sufficient length to cover the material?

- ☐ **Too long**
- ☐ **About right**
- ☐ **Too short**

If you checked Too long or Too short, please explain why:

_____
_____
_____

4. Were the hands-on exercises that you performed in class a useful method of learning the CSRS?

- ☐ **Very useful**
- ☐ **Useful**
- ☐ **Somewhat useful**
- ☐ **Not useful**
- ☐ **Not very useful**

Please write any suggestions for improving the exercises:

_____
_____
_____

5. Did the class instructor answer your questions satisfactorily?

☐ **Yes**
☐ **No**
☐ **N/A**

Please provide any details:

_____
_____
_____

6. Did you feel you had sufficient prior computer skills to allow you to participate in the computer training?

☐ **Yes**
☐ **No**

List the computer skills that you feel would be helpful in future education:

_____
_____
_____

7. Write any comments about your instructor's classroom presentation that may help the instructor provide more clarity in future training sessions:

_____
_____
_____

8. Additional Comments:

_____

_____

_____

Thank you for your time!

Clinical Safety Reporting System (CSRS)

Computer Training Evaluation Form - Frontline Staff

In which setting do you predominantly work? (choose one)

○ Acute Care

○ Long Term Care/Continuing Care/ Rehabilitation

○ Community/ Home Care

○ Diagnostics and Labs

○ Other (please specify): _____

1. What was the most helpful part of the CSRS computer training session?

_____
_____
_____

2. What additional information would have been helpful in the session?

_____
_____
_____

3. Now that you have completed your CSRS computer training session do you feel you could complete an occurrence form?

☐ **Yes**
☐ **No**

If No, please explain why:

_____
_____
_____

4. What would you like more information on?

_____
_____
_____

Additional Comments:

_____
_____
_____

Thank you for your time!

Clinical Safety Reporting System (CSRS)

Computer Training Evaluation Form - Roamers

In which setting do you predominantly work? (choose one)

○ Administration

○ Acute Care

○ Long Term Care/Continuing Care/ Rehabilitation

○ Community/ Home Care

○ Diagnostics and Labs

○ Mental Health

○ Other (please specify): _____

1. How prepared to you feel about using the new CSRS?

☐ **Very prepared**
☐ **Prepared**
☐ **Somewhat prepared**
☐ **Not prepared**
☐ **Not very prepared**

Please indicate areas in which you think you require further education:

_____

_____

_____

2. **How prepared to you feel helping staff with questions about completing an occurrence report?**

- ☐ **Very prepared**
- ☐ **Prepared**
- ☐ **Somewhat prepared**
- ☐ **Not prepared**
- ☐ **Not very prepared**

If you checked No or Unsure, please explain why:

_____
_____
_____

3. **Were the training materials used and distributed in class helpful in your understanding of the CSRS and the Roamer's role?**

- ☐ **Very helpful**
- ☐ **Helpful**
- ☐ **Somewhat helpful**
- ☐ **Not helpful**
- ☐ **Not very helpful**

Please write any suggestions for improving the training materials:

_____
_____
_____

4. **Was the training class a sufficient length to cover the material?**

- ☐ **Too long**
- ☐ **About right**
- ☐ **Too short**

If you checked Too long or Too short, please explain why:

_____

_____

_____

5. Were the hands-on exercises that you performed in class a useful method of learning the CSRS?

- ☐ **Very useful**
- ☐ **Useful**
- ☐ **Somewhat useful**
- ☐ **Not useful**
- ☐ **Not very useful**

Please write any suggestions for improving the exercises:

_____

_____

_____

6. Did the class instructor answer your questions satisfactorily?

- ☐ **Yes**
- ☐ **No**
- ☐ **N/A**

Please provide any details:

_____

_____

_____

7. Did you feel you had sufficient prior computer skills to allow you to participate in the computer training?

- ☐ **Yes**
- ☐ **No**

List the computer skills that you feel would be helpful in future education:

_____

_____

_____

8. **Write any comments about your instructor's classroom presentation that may help the instructor provide more clarity in future training sessions:**

_____
_____
_____

9. **Additional Comments:**

_____
_____
_____

Thank you for your time!

User Satisfaction Survey – Managers

Have you used the Clinical Safety Reporting System (CSRS), the *on-line occurrence reporting tool,* in the past six months?

○ Yes ○ No

If Yes, please answer the following survey and return it in the provided envelope.

If No, please return the survey in the provided envelope.

Survey Respondent Profile - Management

In which setting do you work? (choose one)

○ Acute Care
○ Long Term Care/Continuing Care/ Rehabilitation
○ Community/ Home Care
○ Diagnostics and Labs
○ Mental Health
○ Other (please specify): _____

What is your title?

○ Manager ○ Supervisor

Do you have a Nursing background?

○ Yes ○ No

Do you manage in a setting where the workers are predominately Nursing staff?

○ Yes ○ No

What form of CSRS training did you complete?
(more than one can be chosen)

○ e-Training (on-line self training)
○ Roamers (co-workers on the unit)
○ In-Class (CSRS instructor)
○ None completed

Clinical Safety Reporting System (CSRS)
On-line occurrence reporting tool

User Satisfaction Survey – Managers

1. How satisfied are you overall with the CSRS?

○	○	○	○	○
Highly satisfied	Moderately satisfied	Neither satisfied or unsatisfied	Moderately unsatisfied	Not satisfied at all

2. The CSRS is easy to use.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

3. The CSRS makes it easier to follow up on occurrence reports.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

4. I will remember how to use the CSRS next time.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

5. The CSRS saves me time.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

6. The CSRS is consistent in its performance (behaves the same way each time I use it).

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

7. The amount of time to operate the CSRS is acceptable (time it takes for the form to appear when I click on the CSRS Report Occurrence icon, amount of time it takes drop-down lists to appear when I select them, etc.).

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

8. I am notified in a timely manner (consistent with policy) when an occurrence occurs.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

9. I can use the CSRS to manage any kind of clinical occurrence in my area of work.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

10. I can investigate and manage a close call using the CSRS.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

11. I can easily view the entire occurrence reports assigned to me.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

12. I can easily determine the follow up stage of any occurrence report.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

13. Occurrence reporting has increased now that we have the CSRS.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

14. I use information from the CSRS to improve clinical safety.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

15. It is easier for me to provide feedback to reporters of occurrences than it was with the paper system.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

16. The training provided was acceptable.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

17. The level of ongoing IT support provided is acceptable.

○	○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Not applicable

Thank you for your time!

User Satisfaction Survey – Front Line Staff

Have you used the Clinical Safety Reporting System (CSRS), the *on-line occurrence reporting tool,* in the past six months?

○ Yes ○ No

If Yes, please answer the following survey and return it in the provided envelope.

If No, please return the survey in the provided envelope.

Survey Respondent Profile – Front Line Staff

What is your role in the organization? (choose one)

- ○ Nurse
- ○ Licensed Practical Nurse
- ○ Personal Care Attendant
- ○ Allied Health Professional
- ○ Technologist (lab, radiology, etc.)
- ○ Doctor
- ○ Other (please specify): _____

In which setting do you work? (choose one)

- ○ Administration
- ○ Acute Care
- ○ Long Term Care/Continuing Care/ Rehabilitation
- ○ Community/ Home Care
- ○ Diagnostics and Labs
- ○ Mental Health
- ○ Other (please specify): _____

What form of CSRS training did you complete? (more than one be chosen)

- ○ e-Training (on-line self training)
- ○ Roamers (co-workers on the unit)
- ○ In-Class (CSRS instructor)
- ○ None completed

Clinical Safety Reporting System (CSRS)
On-line occurrence reporting tool

User Satisfaction Survey –Front Line Staff

1. How satisfied are you overall with the CSRS?

○	○	○	○	○
Highly satisfied	Moderately satisfied	Neither satisfied or unsatisfied	Moderately unsatisfied	Not satisfied at all

2. The CSRS is easy to use.

○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree

3. The CSRS makes it easier to complete occurrence reports

○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree

4. I will remember how to use the CSRS next time.

○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree

5. The CSRS is consistent in its performance (behaves the same way each time I use it).

○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree

6. The amount of time to operate the CSRS is acceptable (time it takes for the form to appear when I click on the CSRS Report Occurrence icon, amount of time it takes drop-down lists to appear when I select them, etc.).

○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree

7. The information I am asked to provide is relevant.

○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree

8. I can use the CSRS to report any kind of clinical occurrence that might occur.

○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree

9. I can document a close call using the CSRS.

○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree

10. The CSRS provides feedback in a more timely manner that the paper system.

○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree

11. The training provided was acceptable.

○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree

12. The level of ongoing IT support provided is acceptable.

○	○	○	○	○
Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree

Thank you for your time!

Clinical Safety Reporting System (CSRS) Evaluation
Key Informant Interview Guide – Pre-Implementation
(Senior Management)

---

1. Do you use the current occurrence reporting system?
2. What advantages do you see with the current system?
3. What disadvantages do you see with the current system?
4. What barriers currently exist to reporting?
5. What barriers or facilitators, if any, do you anticipate in the implementation phase?
6. What benefits do you anticipate with the electronic system?
7. What disadvantages do you anticipate with the electronic system?
8. Would you like to make any other comments?

CLINICAL SAFETY REPORTING SYSTEM (CSRS) EVALUATION
Key Informant Interview Guide – Post-Implementation
(Senior Management)

---

1. Have you used the electronic occurrence reporting system?
2. What benefits, if any, have you noticed or heard about?
3. Are you aware of any unintended consequences? If yes, what were they?
4. What were the barriers and facilitators during implementation?
5. Are there ways we can improve implementation for the roll-out plan?
6. Do you have any concerns or compliments about how the project was managed?
7. How can we increase the involvement of other groups (eg. Physicians)?
8. Is there a way to use the CSRS to engage patients/public?
9. What resources do we need to sustain the system?
10. Do you think this will contribute to improved clinical safety in the long term? If so, how? If not, why not?
11. What indicators can we use to help measure and monitor long term outcomes?
12. Would you like to make any other comments?

CLINICAL SAFETY REPORTING SYSTEM (CSRS) EVALUATION
Pre-Implementation
Focus Group Question Guide - (Managers)

---

1. What are some of the perceived barriers to reporting (occurrences and close calls)?

2. Can you think of any positive things that have occurred as a result of occurrence reports? Can you think of any negative things?

3. What is your role in relation to the current occurrence reporting system?

4. What are advantages/disadvantages of the current system from your perspective?

5. What barriers or facilitators do you anticipate in the implementation process?

6. If you were in charge of the occurrence reporting system, what changes, if any, would you make?

7. Would you like to make any other comments?

CLINICAL SAFETY REPORTING SYSTEM (CSRS) EVALUATION
Pre-Implementation
Focus Group Question Guide - (Frontline)

---

1. What comes to mind when you hear the word "occurrence reporting"?

2. Can you think of any positive things that have occurred as a result of completing an occurrence report? Can you think of any negative things?

3. If you were in charge of the occurrence reporting system, what changes, if any, would you make?

4. Why do people decide to complete an occurrence report?

5. How do you think people feel when they complete an occurrence report?

6. What are some of the perceived barriers to reporting (occurrences and close calls)?

7. Does the seriousness of the situation have any bearing on whether or not an occurrence report is made?

8. Would you like to make any other comments?

CLINICAL SAFETY REPORTING SYSTEM (CSRS) EVALUATION
Post-Implementation
Focus Group Question Guide (Managers)

---

1. What benefits, if any, were realized by the implementation of the CSRS?
2. Were any disadvantages or harms noted as a result of implementation?
3. What are some of the perceived barriers to reporting (occurrences and close calls)?
4. Were there any concerns reported about access to computers?
5. How can we provide feedback/shared learnings internally?
6. How can we promote shared learnings on an external basis?
7. Do you think the system has helped to improve clinical safety? Can you provide any examples?
8. Are there ways we can improve the CSRS system?
9. Are there ways we can improve the implementation process?
10. What impact, if any, did this have on your role as it relates to managing occurrence reporting?
11. Would you like to make any other comments?

CLINICAL SAFETY REPORTING SYSTEM (CSRS) EVALUATION
Focus Group Question Guide – Post-Implementation
(Frontline)

---

1. What are the benefits, if any, realized by the implementation of the CSRS?
2. Were any disadvantages or harms noted as a result of implementation?
3. Were there any concerns reported about access to computers?
4. What are some of the perceived barriers to reporting (occurrences and close calls)?
5. How can we provide feedback/shared learnings internally?
6. How can we promote shared learnings on an external basis?
7. Do you think the system has helped to improve clinical safety? Can you provide any examples?
8. Are there ways we can improve the CSRS system?
9. Are there ways we can improve the implementation process?
10. Would you like to make any other comments?

DATA EXTRACTION FORM

OCCURRENCE REPORTS (Clinical Safety Reporting System)

Occurrence Report Form Number	AREA of OCCURENCE {Unit, Site}	REPORTER CHARACTERISTICS {RN, LPN, PCA AAHP, OTHER}	TYPE OF OCCURRENCE {Medication, Treatment/Test; Blood/Blood Products; Fall: Adverse/Allergic Reaction; Safety/Security; Other	TIME {in days} FROM OCCURRENCE TO SIGN OFF BY MANAGER	TIME {in days} FROM OCCURRENCE TO NOTIFICATION OF QUALITY AND RISK MANAGEMENT

Completed Report will indicate:

Number of Occurrences Reported

Reports Completed {%}

Occurrences Reported within 48 Hours of Occurrence

Non-RN Reports {%}

Near Miss or Hazard {%}

Appendix C

Pre- Evaluation Stakeholder Workshops

- Agenda
- Summary of findings

Stakeholder Workshops

EH-Regional Occurrence Screening Enhancement (ROSE) Project

Agenda

ROSE Evaluation Framework Workshop
Eastern Health
Waterford Hospital Auditorium
Friday, June 20, 2008

0830	Coffee, Tea and Muffins
0900	Welcome and Introductions – *Pam Elliott*
0915	Overview of ROSE Project *(Carla Williams)*
1000	Preliminary Evaluation Plan *(Pam Elliott)*
1030	Coffee Break
1100	Break – Out Session - Identify Other Key Possible Issues/Research Questions - Identify Other Key Indicators and/or Data Sources to Address Research Questions
1215	Lunch
1300	Reporting Back on Breakout Session and Large Group Discussion
1400	Wrap Up and Next Steps

Evaluation Workshop (June 20, 2008) Summary

Introduction

Eastern Health received approval of $1.6 million from Canada Health Infoway to implement a regional electronic occurrence reporting system. As part of its proposal to Canada Health Infoway, Eastern Health submitted an Evaluation Framework which included a plan to host a workshop inviting representatives of various stakeholders. The workshop was held June 20, 2008 at the Waterford Hospital Auditorium.

Purpose

The purpose of the workshop was to engage various stakeholders in dialogue about a draft evaluation plan, seeking their input into how the evaluation plan can be improved.

Attendance

There were 31 participants, representing a variety of stakeholder groups (funders, government, university, research, professional practice groups, unions and select internal groups).

Format

The agenda for the workshop is attached. It consisted of presentations, small group discussion and large group discussion. The questions posed to the group included:

Are there questions that we should add?
Are there questions that we should eliminate?
Are the indicators/data sources that we should add?
Are there indicators/data sources that we should delete?

The participants were divided into three groups with each group having a facilitator and recorder who were members of the Evaluation Committee and/or project team.

Results

The day resulted in both suggestions for improving the draft evaluation plan as well as validation of the planned questions and indicators. Some of the points made can be used to guide implementation issues, rather than evaluation components. Following is a listing of the key questions/suggestions/feedback from the discussions:

- Important to do surveys, focus groups, key informant interviews and document reviews.
- In designing the survey questionnaire, it is important to take out questions that are not usable and to include information related to the experience and type of experience of providers.
- Important to include impact of implementation on all front line managers. (non nurses as well as nurses)
- Important to do focus groups with frontline workers about the benefits.
- Important to get feedback on the implementation process.
- Expand literature review to include reporting compliance and high risk events.
- Is there a way to measure the impact of the implementation on team?
- Important to focus evaluation due to tight timelines. (e.g. limit sampling of numbers of focus groups)
- Is there a way to measure cross continuum perspectives related to reporting? (long term ,acute, community)
- Is there a way to link employee safety to patient safety?
- Has there been an improvement in reporting?
- How do we understand the causes/critical factors of adverse events and can the determinants be measured?
- What is the technological preparedness of staff?
- What are the attitudes and comfort levels with the new system?
- Would a training video help?
- Is there physician engagement?
- Is there sufficient access to the system and database?
- Is interdisciplinary reporting a concern, particularly in relation to good catches/near misses?
- Does completing a report assume liability?
- Will the Evidence Act protect the reporter?
- What are the barriers to reporting good catches/near misses?
- Does the report receive a timely response?
- Is the staff involved in the follow up process?
- Do the staff receive feedback in reports submitted?
- Are front line employees knowledgeable about how to complete reports?
- Is the technology user friendly?
- What role does the system play in improving outcomes?
- How does an employee respond/handle situations in which their own manager is part of the problem
- Is there buy-in from the top down? (Department of Health and Community Services and Chief Executive Officer/President of Eastern Health)
- What can the tool realistically achieve?
- Can the system identify/validate when an event has occurred? (e.g. misread x-ray report)
- How do we provide feedback/shared learnings to staff on a regional basis?
- Can the system allow multiple reporters on the same event?

- Are there sufficient human resources to support implementation?
- What percentage of nurse managers' time is spent processing occurrence reports and is there a way to compare pre and post?
- What external linkages exist? (e.g. Institute for Safe Medication Practices)
- Are there opportunities for sharing information externally?
- Is there space for confidential and private discussions?
- Are people aware if their name is in a report?
- What is the level of end user adoption?
- Did adoption improve patient safety?
- Can the evaluation link reporting to outcomes? (e.g. reduction in morbidity, reduction in events)
- Is the training appropriate to different users?
- Has feedback to the reporter improved?
- Are there standard definitions for reporting?
- Is there any cost savings? (e.g. decreased claims or decreased insurance costs)
- Has the implementation facilitated Quality Improvement and Research activities related to occurrence reporting?
- Are there new guidelines and/or policies in place?
- Is IM&T involved in helping to determine other data sources? (administrative or clinical)
- What are the barriers to reporting?
- How does the link of a morbidity and mortality committee link to occurrence reporting?
- Is the impact of the implementation different for different provider groups? (professional groups and service areas)
- Is there potential harm to providers or the organization?
- Is the current climate (e.g. Commission of Inquiry) impacting on reporting?
- Does misdiagnosis constitute an Occurrence Report?
- Is the system perceived as secure?
- What are the consequences for employees who report? (e.g. discipline, peer pressure, working relationships)

Conclusion and Next Steps

The day resulted in significant feedback from various stakeholder groups. The questions and points raised will be reviewed and integrated into the Evaluation Plan and Implementation Plan where possible. Another stakeholder evaluation workshop will be scheduled for early September with a focus on including more of the internal stakeholder groups who will be involved in the implementation process. The feedback from that workshop will also be reviewed and integrated into the final evaluation plan.

The final evaluation plan will be completed by the end of October and submitted to Canada Health Infoway and a copy of the evaluation plan can be provided to any

participant upon request. The final evaluation report will also be made available to stakeholder groups.

Based on observations and participant feedback, the next stakeholder forum should be scheduled in a different forum due to the high temperature and noisy fans of the auditorium.

EH-Regional Clinical Safety Reporting System (CSRS) Project
(Formerly known as Regional Occurrence System Enhanced – ROSE)

Agenda

Clinical Safety Reporting System (CSRS) Evaluation Framework Workshop

Eastern Health
Salon "F" – Holiday Inn, Portugal Cove Road, St. John's
Friday, September 12, 2008

0815	Registration
0830	*Continental Breakfast / Networking*
0900	Welcome/Introductions and Session Overview – *Pam Elliott*
0915	Overview of CSRS Project & Project Update *(Carla Williams)*
1030	*Nutrition Break*
1100	Preliminary Evaluation Plan *(Pam Elliott)*
1115	Break – Out Session - Identify Other Key Possible Issues/Research Questions - Identify Other Key Indicators and/or Data Sources to Address Research Questions
1215	*Lunch*
1300	Reporting Back on Breakout Session and Large Group Discussion
1400	Wrap Up and Next Steps

Evaluation Workshop (September 12, 2008) Summary

Introduction

Eastern Health received approval of $1.6 million from Canada Health Infoway to implement a regional electronic occurrence reporting system. As part of its proposal to Canada Health Infoway, Eastern Health submitted an Evaluation Framework which included a plan to host a workshop inviting representatives of various stakeholders. The workshop was held September 12, 2008 at the Holiday Inn, St. John's.

Purpose

The purpose of the workshop was to engage various stakeholders in dialogue about a draft evaluation plan, seeking their input into how the evaluation plan can be improved.

Attendance

There were 34 manager participants, representing a variety of internal stakeholders.

Format

The agenda for the workshop is attached. It consisted of presentations, small group discussion and large group discussion. The questions posed to the group included:

Are there questions that we should add?
Are there questions that we should eliminate?
Are the indicators/data sources that we should add?
Are there indicators/data sources that we should delete?

The participants were divided into three groups with each group having a facilitator and recorder who were members of the Evaluation Committee and/or project team.

Results

The day resulted in both suggestions for improving the draft evaluation plan as well as validation of the planned questions and indicators. Some of the points made can be used to guide implementation issues, rather than evaluation components. Following is a listing of the key questions/suggestions/feedback from the discussions:

- Are there personal computers available?
- What staff are we training?

- Will physicians be a part of this process?
- Do employees know how to use computers?
- Can data be rolled up for each unit/department/program?
- Will the IT infrastructure support the system (e.g. Downtime, locked, replacements, etc)?
- Timelines of reporting
- Ensure that the system is confidential
- What will be the uptake in the use of the tool?
- Where is the information going once form is filled in (concern of staff)?
- Need proper education and training
- Is it an anonymous system?
- Are there timelines for managers to adhere to for follow-up action?
- When occurrence overlaps, how will we ensure follow-up and by which manager?
- What is the format of the report?
- How do systems talk to each other (eg. Medications)?
- Will CYFS and PHN be involved?
- What will be the return on investment?
- Do we have a safer system because of it?
- What are some of the unintended consequences (e.g. More communication among providers/programs)?
- Is there duplication in filling out complaints and occurrences?
- Is there IT implementation and ongoing support?
- Need to have access to a real person for problems, not the HELP desk
- Need training for super users
- Need to pick champions
- The impact of other interventions on the culture change (compounding variables)
- Impact on certain healthcare providers
- Maybe have focus groups with physicians
- Do nurses report that physicians were notified?
- Research questions – no change
- Need for dedicated resources to audit the system
- Does the tool improve practices on change policies (? Track the number of changes)?
- How should we use this tool to enhance involvement with clients to increase public trust and patient safety?
- How long will occurrences remain in the system?
- How to foster reporting?
- In getting "buy-in", how will this impact on staff workload (? reduce workload)?
- Definition of occurrence will need to be relevant to all areas
- Good catch vs. near miss vs. close call
- Staff may be reluctant to report colleagues
- Source of occurrence may come from a complaint (will they be linked?)
- Need positive feedback for those who demonstrate positive support to others

- Manager follow-up up on occurrence may be perceived more negatively than if colleague follows up
- Are there timelines and mechanisms for providing feedback to staff on their report?
- How does this link to staff safety?
- Is there capacity to share information across programs?
- Is there ability to print occurrence reports or save as another document?
- Will the timelines be calendar days or work days?
- How will we know if we made improvements?
- Important to use examples, to include text, as some staff don't give out details
- Will there be a place to indicate disclosure?
- Will the forms include places to put physician name, date, time and family notified?

General Comments:

- Staff need to receive follow-up from occurrences entered into system.
- Staff need to see and know current work process versus new work process with new system.
- Need to be aware of past failed implementations from a change standpoint. Collect lessons learned from these prior initiatives.
- Post-implementation follow-up, training and reinforcement are critical to success and buy-in.
- More feasible to implement by program rather than by site.
- Various ongoing competing priorities (e.g. ER/PR)
- Regional Services/Programs expecting Director turn over due to retirement within the next few months (i.e. September to December 2008). Expecting at least three retirements.
- Regional Services (e.g. Diagnostic Imaging) are more ready for occurrence reporting.
- There are pockets of resistance (e.g. units) based on experience with other roll-outs (e.g. Medical Reconciliation).
- Need to consider characteristics and status of the profession (e.g. Nursing – bargaining process).
- Training in community setting needs to focus on specific and real examples.
- CYFS are undergoing several reviews therefore timing for implementation must be considered.
- All Community Programs should be implemented by program and not by location – program based implementation.
- Differential readiness across programs. Varying programs need to increase readiness for change.
- Engagement and education is critical.
- Must address unique delivery environments in implementation.

- Communications should provide definitions of key system terms such as: client and patient, incident and occurrence.
- From a management perspective it is easier to combine programs for reasons such as management of processes and reports.
- Awareness needed for political issues within Peninsulas.
- Need to address challenges of smaller facilities.
- Various ongoing competing priorities (e.g. MDS in long term care facilities).
- Combine all long term care for Carbonear.

Conclusion and Next Steps

The day resulted in significant feedback from a variety of internal stakeholders. The questions and points raised will be reviewed and integrated into the Evaluation Plan and Implementation Plan where possible. The final evaluation plan will be submitted to Canada Health Infoway and a copy of the evaluation plan can be provided to any participant upon request. The final evaluation report will also be made available to stakeholder groups.

Appendix D

- RPAC Approval letter
- HIC Approval letter
- Consent Forms

Eastern Health

Department of Research
Corporate Strategy and Research
P.O. Box 13122
Rutter Building, 22 Pearl Place
St. John's, NL A1B 4A5
Tel: (709) 752-4636 Fax #: (709) 752-4733

RECEIVED
FEB 0 9 2009
Quality & Risk Management

February 3, 2009

Ms. Pam Elliott
Quality & Risk Management
Room 1229, Southcott Hall
The Leonard A. Miller Centre
Forest Rd.
St. John's, NL A1A 1E5

Dear Ms. Elliott:

Your research proposal "*HIC # 09.003 –* " Evaluation of implementation of an electronic occurrence reporting system at Eastern Health – (Phase One)", was reviewed by the Research Proposals Approval Committee (RPAC) of Eastern Health at its meeting on February 3, 2009 and we are pleased to inform you that the proposal has been approved.

The approval of this project is subject to the following conditions:

- The project is conducted as outlined in the HIC approved protocol;
- Adequate funding is secured to support the project;
- In the case of Health Records, efforts will be made to accommodate requests based upon available resources. If you require access to records that cannot be accommodated, then additional fees may be levied to cover the cost;
- A progress report being provided upon request.

If you have any questions or comments, please contact Donna Bruce, Manager of the Patient Research Centre at 777-7283.

Sincerely,

Mike Doyle, PhD
Director of Research
Corporate Strategy & Research
Chair, RPAC

cc: Ms. Donna Bruce, Manager Patient Research Centre

Faculty of Medicine

January 7, 2009

Reference #09.03

Ms. Pamela Elliott
Quality & Risk Management
Southcott Hall

Dear Ms. Elliott:

This will acknowledge your correspondence dated January 5, 2009 wherein you provide two revised consent forms for your research study entitled "**Evaluation of the implementation of an electronic occurrence reporting system at Eastern Health (Phase One)**".

This correspondence has been reviewed by the co-chair and **full approval** of this research study has been granted for one year effective January 7, 2009.

Full approval has been granted for one year. You will be contacted to complete the annual form update approximately 8 weeks before the approval will lapse on **January 7, 2010**. It is your responsibility to ensure that the renewal form is forwarded to the HIC office not less than 30 days prior to the renewal date for review and approval to continue the study. The annual renewal form can be downloaded from the HIC website http://www.med.mun.ca/hic/downloads/Annual%20Update%20Form.doc.

For a hospital-based study, it is **your responsibility to seek the necessary approval from the Health Care Corporation of St. John's and/or other hospital boards as appropriate**.

This Research Ethics Board (the HIC) has reviewed and approved the application for the study which is to be conducted by you as the qualified investigator named above at the specified study site. This approval and the views of this Research Ethics Board have been documented in writing. In addition, please be advised that the Human Investigation Committee currently operates according to the Tri-Council Policy Statement and applicable laws and regulations.

Notwithstanding the approval of the HIC, the primary responsibility for the ethical conduct of the investigation remains with you.

We wish you success with your study.

Sincerely,

John D. Harnett, MD, FRCPC
Co-Chair
Human Investigation Committee

Fern Brunger, PhD
Co-Chair
Human Investigation Committee

C Dr. C. Loomis, Vice-President (Research), MUN
Mr. W. Miller, Director of Planning & Research, Eastern Health
Meeting date: January 22, 2009

Consent to Take Part in Research
Focus Group

Title: Evaluating the Implementation of an Electronic Occurrence Reporting System in Eastern Health – Phase One

Principal Investigator:Pam Elliott, PhD Student

Sponsor: Canada Health Infoway and Eastern Health

You have been invited to be part of a research evaluation study by participating in a focus group. You participation is voluntary and this form will explain about the focus group.

Introduction

This study will evaluate the implementation of an electronic occurrence reporting system at Eastern Health.

Purpose

The purpose of the focus group is to seek input from people who are involved in occurrence reporting to assist in the evaluation of the implementation of the electronic reporting system.

Description of the Study Procedures

During the focus group, the research team will ask questions related to the occurrence reporting system. The session will be taped to facilitate report writing and the tape will be destroyed after the report is written. No names will be attached to comments.

Length of Time

You will be asked to participate in a group discussion that is scheduled for a maximum of 1 hour.

Possible Risks and Discomforts

There are no anticipated risks or discomforts associated with this study. However, participants will be asked to give freely of their time and will be asked to participate in discussions.

Initials _____

Benefits

It is not known whether this study will benefit you personally.

Liability Statement

Signing this form gives us your consent to participate in this phase (the focus groups) of the study. It tells us that you understand the information about the research study. When you sign this form, you do not give up your legal rights. Researchers or agencies involved in this research study still have their legal and professional responsibilities.

Confidentiality

Your name will not appear in any report or article published as a result of this study. Any comments provided by you during the group will not have your name attached to it.

Questions

If you have any questions about taking part in this phase of the study research, you can meet with the Principal Investigator.

That person is:

Pam Elliott, (709) 777-8846,

Pam.Elliott@easternhealth.ca

Or, you can talk to someone who is not involved with the study at all, but can advise you on your rights as a participant.

This person can be reached through:

Office of the Human Investigation Committee (HIC), (709) 777-6974, hic@mun.ca

Initials _____

Signature Page

Study Title: Evaluating the Implementation of an Electronic Occurrence Reporting System

Name of Principal Investigator: Pam Elliott

To be filled out and signed by the participant:

Please check as appropriate.

I have read the information sheet	Yes ☐	No ☐
I have had the opportunity to ask questions/to discuss this study	Yes ☐	No ☐
I have received satisfactory answers to all of my questions	Yes ☐	No ☐
I have spoken with a qualified member of the study team	Yes ☐	No ☐
I understand that I am free to withdraw from the study at any time	Yes ☐	No ☐
I agree to take part in this focus group	Yes ☐	No ☐

_____ _____

Signature of participant Date

_____ _____

Signature of witness Date

To be signed by the investigator:

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the participant fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study.

_____ _____

Signature of investigator Date

Consent to Take Part in Research
Key Informant Interview

Title: Evaluating the Implementation of an Electronic Occurrence Reporting System in Eastern Health – Phase One

Principal Investigator: Pam Elliott, PhD Student

Sponsor: Canada Health Infoway and Eastern Health

You have been invited to be part of a research evaluation study by participating in a Key Informant Interview. You participation is voluntary and this form will explain about the key informant interview.

Introduction

This study will evaluate the implementation of an electronic occurrence reporting system at Eastern Health.

Purpose

The purpose of the key informant interview is to seek input from senior managers who are involved in occurrence reporting to assist in the evaluation of the implementation of the electronic occurrence reporting system.

Description of the Study Procedures

During the key informant interview, the research team will ask questions related to the occurrence reporting system. Notes will be taken based on the discussion. No names will be attached to comments.

Length of Time

You will be asked to participate in an interview that is expected to be a maximum of one hour.

Possible Risks and Discomforts

There are no anticipated risks or discomforts associated with this study. However, participants will be asked to give freely of their time and will be asked to provide their opinions.

Initials _____

Benefits

It is not known whether this study will benefit you personally.

Liability Statement

Signing this form gives us your consent to participate in this phase (the key informant interview) of the study. It tells us that you understand the information about the research study. When you sign this form, you do not give up your legal rights. Researchers or agencies involved in this research study still have their legal and professional responsibilities.

Confidentiality

Your name will not appear in any report or article published as a result of this study. Any comments provided by you during the group will not have your name attached to it.

Questions

If you have any questions about taking part in this phase of the study research, you can meet with the Principal Investigator.

That person is:

Pam Elliott, (709) 777-8846,

Pam.Elliott@easternhealth.ca

Or, you can talk to someone who is not involved with the study at all, but can advise you on your rights as a participant.

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Initials _____

Signature Page

Study Title: Evaluating the Implementation of an Electronic Occurrence Reporting System

Name of Principal Investigator: Pam Elliott

To be filled out and signed by the participant:

Please check as appropriate.

I have read the information sheet	Yes ☐	No ☐
I have had the opportunity to ask questions/to discuss this study	Yes ☐	No ☐
I have received satisfactory answers to all of my questions	Yes ☐	No ☐
I have spoken with a qualified member of the study team	Yes ☐	No ☐
I understand that I am free to withdraw from the study at any time	Yes ☐	No ☐
I agree to take part in this informant interview	Yes ☐	No ☐

_____ _____

Signature of participant Date

_____ _____

Signature of witness Date

To be signed by the investigator:

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the participant fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study.

_____ _____

Signature of investigator Date

Appendix E

- Patient Safety Culture Dimension Means - Confidence Intervals

Patient Safety Culture Dimension Means - Confidence Intervals *significant

	Mean	Std. Deviation	Lower Bound (95% CI)	Upper Bound (95% CI)
Organizational Leadership for Safety				
Pre- Rural Integrated Health Services	3.16	1.22	3.03	3.30
Post - Rural Integrated Health Services	**3.25**	**1.14**	**3.07**	**3.43**
Pre - Acute Care (Urban)	3.30	1.21	3.23	3.36
Post- Acute Care (Urban)	**3.44**	**1.20**	**3.37**	**3.53***
Pre- Community Health (Urban)	3.19	1.17	3.09	3.29
Post - Community Health (Urban)	**3.19**	**1.18**	**3.04**	**3.34***
Pre- Long -Term Care (Urban)	3.28	1.48	2.97	3.58
Post- Long -Term Care (Urban)	**3.14**	**1.43**	**2.73**	**3.55**
Pre All Care Settings	3.25	1.21	3.20	3.31*
Post All Care Settings	**3.36**	**1.20**	**3.30**	**3.43***
National Results	**3.47**	**.78**	**3.45**	**3.49***

Patient Safety Culture Dimension Means - Confidence Intervals

	Mean	Std. Deviation	Lower Bound (95% CI)	Upper Bound (95% CI)
Unit Leadership for Safety				
Pre- Rural Integrated Health Services	3.38	1.35	3.23	3.53
Post - Rural Integrated Health Services	**3.48**	**1.01**	**3.27**	**3.69**
Pre - Acute Care (Urban)	3.50	1.29	3.42	3.57
Post- Acute Care (Urban)	**3.57**	**1.35**	**3.48**	**3.66**
Pre- Community Health (Urban)	3.58	1.24	3.47	3.69
Post- Community Health (Urban)	**3.59**	**1.22**	**3.44**	**3.75**
Pre- Long -Term Care (Urban)	3.35	1.49	3.03	3.66
Post- Long -Term Care (Urban)	**3.41**	**1.38**	**3.01**	**3.82**
Pre All Care Settings	3.49	1.30	3.44	3.55
Post All Care Settings	**3.57**	**1.32**	**3.48**	**3.63**
National Results	**3.54**	**.70**	**3.52**	**3.56**

Patient Safety Culture Dimension Means - Confidence Intervals * significant

	Mean	Std. Deviation	Lower Bound (95% CI)	Upper Bound (95% CI)
Shame and Repercussions of Reporting				
Pre - Rural Integrated Health Services	4.43	.89	4.29	4.56
Post - Rural Integrated Health Services	**4.47**	**1.01**	**4.25**	**4.68**
Pre - Acute Care (Urban)	4.42	94	4.35	4.49
Post- Acute Care (Urban)	**4.33**	**1.06**	**4.24**	**4.42**
Pre- Community Health (Urban)	4.29	.99	4.18	4.40
Post- Community Health (Urban)	**4.09**	**1.21**	**3.90**	**4.30**
Pre- Long -Term Care (Urban)	4.33	1.21	3.99	4.67
Post- Long -Term Care (Urban)	**4.36**	**1.19**	**3.90**	**4.82**
Pre All Care Settings	4.38	.96	4.33	4.44*
Post All Care Settings	**4.30**	**1.09**	**4.22**	**4.38***
National Results	**4.14**	**.62**	**4.13**	**4.16***

Patient Safety Culture Dimension Means - Confidence Intervals *significant

	Mean	Std. Deviation	Lower Bound (95% CI)	Upper Bound (95% CI)
Perceived State of Safety				
Pre- Rural Integrated Health Services	3.18	1.44	3.03	3.33
Post - Rural Integrated Health Services	**3.25**	**1.44**	**3.04**	**3.45**
Pre - Acute Care (Urban)	3.10	1.47	3.03	3.33
Post- Acute Care (Urban)	**3.19**	**1.42**	**3.11**	**3.28**
Pre- Community Health (Urban)	3.12	1.47	3.02	3.24
Post- Community Health (Urban)	**3.25**	**1.40**	**3.08**	**3.40**
Pre- Long -Term Care (Urban)	2.83	1.67	2.52	3.13
Post- Long -Term Care (Urban)	**2.92**	**1.55**	**2.52**	**3.32**
Pre All Care Settings	3.11	1.47	3.05	3.16*
Post All Care Settings	**3.20**	**1.43**	**3.13**	**3.27***
National Results	**2.81**	**.57**	**2.79**	**2.82***

Patient Safety Culture Dimension Means - Confidence Intervals *significant

	Mean	Std. Deviation	Lower Bound (95% CI)	Upper Bound (95% CI)
Safety Learned Behaviours				
Pre - Rural Integrated Health Services	3.28	1.04	3.14	3.42
Post - Rural Integrated Health Services	**3.21**	**1.14**	**2.98**	**3.43**
Pre - Acute Care (Urban)	3.17	1.13	3.09	3.24
Post- Acute Care (Urban)	**3.49**	**1.10**	**3.40**	**3.58**
Pre- Community Health (Urban)	3.08	1.18	2.96	3.20
Post- Community Health (Urban)	**3.32**	**1.19**	**3.13**	**3.50**
Pre- Long -Term Care (Urban)	3.20	1.30	2.86	3.53
Post- Long -Term Care (Urban)	**3.13**	**.82**	**2.83**	**3.44**
Pre All Care Settings	3.16	1.13	3.11	3.22*
Post All Care Settings	**3.42**	**1.10**	**3.34**	**3.49***
National Results	**3.40**	**.70**	**3.38**	**3.42**

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